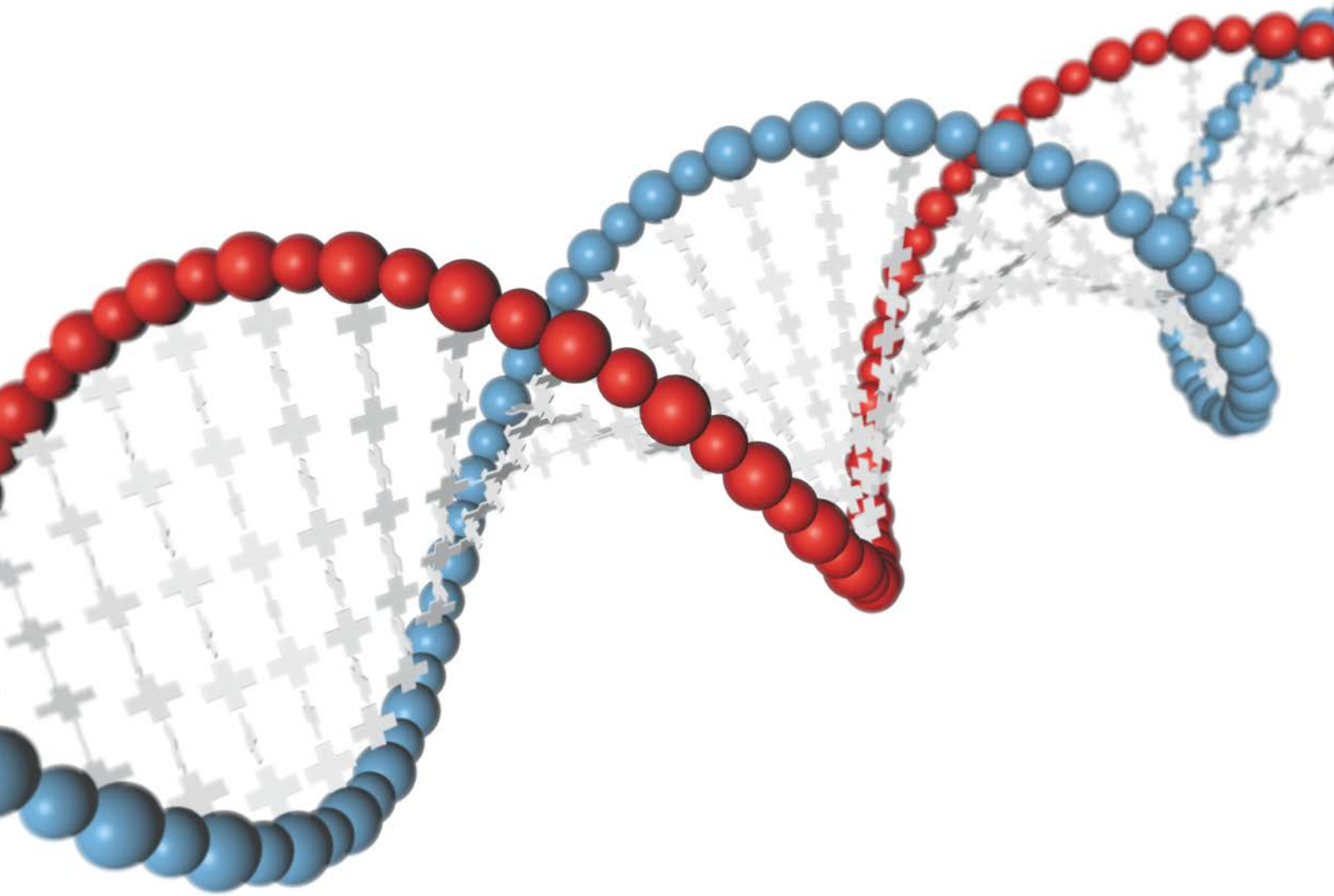
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA

Federal measures for the promotion of biomedical research and technology

18 December 2013



CONTENTS

I SUMMARY

As a business location, Switzerland is highly rated. Among the factors contributing to its success are political stability, the rule of law, an attractive tax regime, flexible employment regulations, a high quality of life and a high level of innovation.

The Federal Council assumes that international competitive pressures will become even more intense over the next 10 to 15 years. There is a need to respond in a timely and flexible manner to changes in the global business environment. Continued efforts are required to maintain competitiveness.

Biomedical research and technology are among the most important sectors in Switzerland: in 2010, the nominal gross value added of the pharmaceutical and medtech industries came to around CHF 21.4 billion, accounting for 3.8% of gross domestic product. This puts the biomedical industry in 7th place among private-sector industries. Between 2000 and 2010, nominal gross value added more than doubled for the pharmaceutical industry, while growth rates in other sectors such as wholesale trade, watches and clocks, or construction ranged from 40% to 65%. A decline of 5% was seen in the financial services sector.

Against the background of the recession in major foreign markets, the depreciation of the euro against the Swiss franc and restructuring in the pharmaceutical industry, the Swiss Parliament requested the Federal Council to prepare a Master plan including measures designed to maintain and reinforce Switzerland's position as a centre of research, development and production for the biomedical industry.

Biomedical research and technology are also growth drivers in countries such as the US, Singapore, Germany and the UK. In the biomedical industry in particular, innovation is the key to commercial success.

As conventionally understood, an idea only becomes an innovation when it is turned into a marketable product or service. Accordingly, great importance attaches not only to product market regulation but also to intellectual property protection and education and research policy. For biomedical research and technology, product market regulation involves, above all, a health policy based on the "Health2020" agenda approved by the Federal Council in January 2013. In the present document, the Federal Council – as requested by Parliament – provides information for policymakers and the public on the current overall framework for biomedical research and technology in Switzerland. In addition, the Federal Council indicates where, in its judgement, action is required, what goals are to be pursued under its long-term strategy, and what measures are to be adopted to achieve these goals.

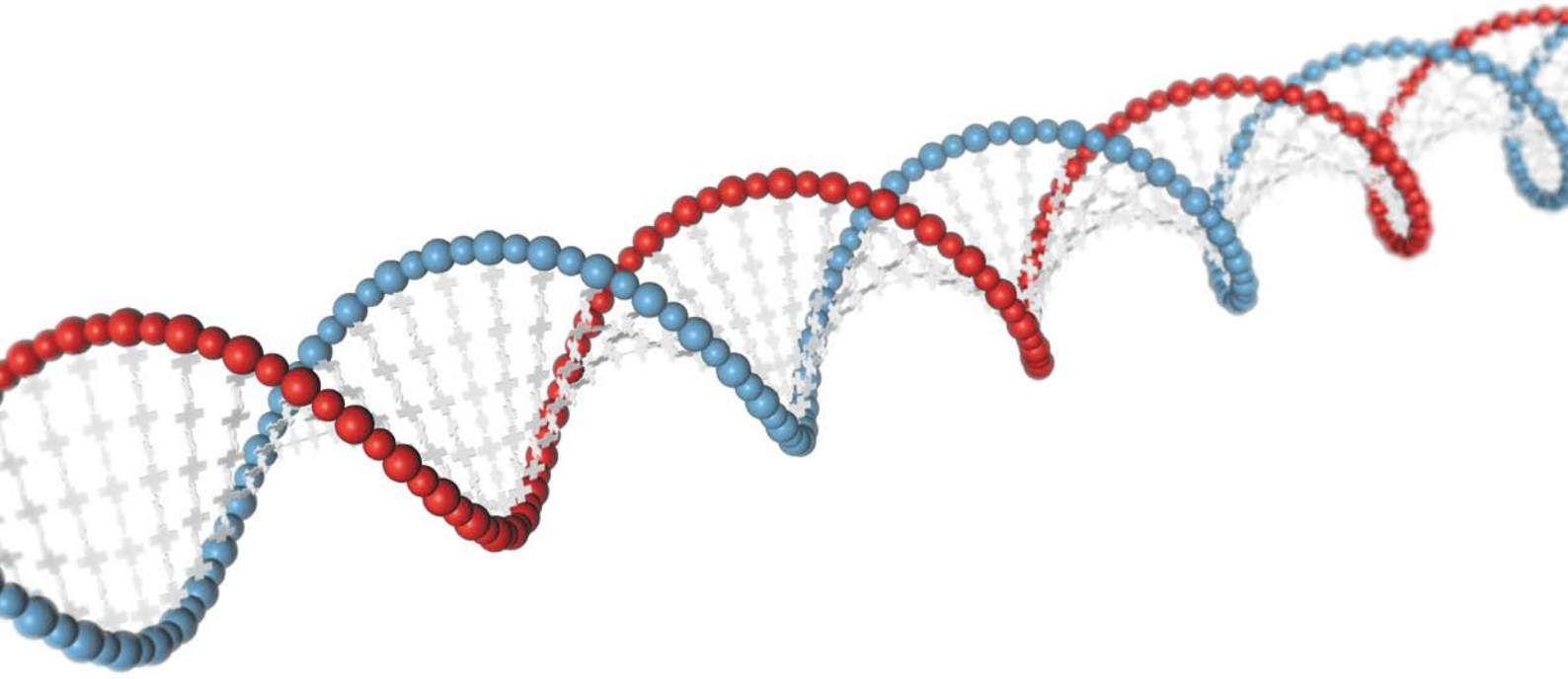
Attention is focused, in particular, on legislative measures in the areas of research promotion, market access, reimbursement, intellectual property and orphan diseases, as well as the acceleration of approval, authorisation and reimbursement procedures. The Federal Council will report regularly on the status of implementation.

General economic policy instruments such as the tax regime – explicitly referred to, for example, in the parliamentary motion "Safeguarding jobs by ensuring a world-leading location for research, development and production of medical products" (11.3923, Forster/Gutzwiller) – have a demonstrable impact on companies' choice of location. However, as these are of relevance to all business activities in Switzerland, they are not dealt with in this master plan.

The Federal Council is aware of the limitations of the present "snapshot". As the effects of certain measures will only become apparent after some time, another report will be published five years from now, assessing the efforts undertaken and, if necessary, proposing the continuation of measures already adopted or the introduction of new measures.

1 BACKGROUND

The Federal Council is pursuing a long-term strategy to establish and maintain a favourable overall framework for biomedical research and technology. This chapter first discusses the various global developments that form the backdrop to this strategy. It then explains the factors that led Parliament to request the Federal Council to prepare a master plan. Finally, it outlines the Federal Council's position and describes the procedure adopted.



1.1 Switzerland's attractiveness as a business location in the context of global pressures

From an international perspective, Switzerland's position as a business location is good to excellent[1]. Among the factors contributing to its success are political stability, security and the rule of law, an attractive tax regime with moderate rates of taxation, flexible employment regulations and a high quality of life. Also crucial in maintaining its attractiveness as a business location is an infrastructure which is effective, secure, environmentally sound and continuously available. A strong foreign economic policy is also vital in ensuring that Switzerland remains a highly attractive location.

The Federal Council assumes that, over the next 10 to 15 years, international competitive pressures will become even more intense. The ability to respond in a timely and flexible manner to changes in the global environment remains crucial for Switzerland's economic prosperity.

It is difficult to estimate to what extent the current significant slowdown in economic growth in key foreign markets will affect Switzerland over the long term. In these countries, ongoing economic uncertainty and declining demand are expected to lead to delays in the introduction of new products, tending to depress exports of Swiss goods to these markets. At the same time, the experience of the 1990s shows that economic crises placed countries such as Finland and South Korea on a new growth path,[2] leading to higher demand for innovative products.

Continued efforts are required to maintain and increase the competitiveness of Swiss companies, to make Switzerland even more attractive to foreign companies as a business location, and finally, to safeguard vital economic functions over the long term, such as the stability of the Swiss financial sector. As the country is too small to cover all industrial and scientific fields, a focused economic strategy is required, concentrating on existing core competencies and significant future potentials.[3]

These include biomedical research and technology,[4] where the capacity for innovation depends largely on efforts in the education sector.

At the same time, global competition for young scientists and top teachers and researchers will become increasingly intense.

The health care market – a key market for biomedical research and technology – is undergoing major changes, triggered and driven by growing international demand for health services and the rapid pace of medical and technological advances.

---

1 Cf. the discussion in the Dispatch of the Federal Council of 25 January 2012 on Legislature Planning for 2011–2015, BBl 2012 534

2 Cf. the discussion in World Intellectual Property Organization (WIPO) / INSEAD, The Global Innovation Index 2012 (www.globalinnovationindex.org)

3 Outlook 2025: Analysis of the situation, context and challenges facing federal policy, Federal Chancellery, 2011, p. 41

4 A widely used definition of biomedical research is that of the OECD:
"Biomedical research comprises:
the study of specific diseases and conditions (mental or physical), including detection, cause, prophylaxis, treatment and rehabilitation of persons;
the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions;
the scientific investigation required to understand the underlying life processes which affect disease and human well-being, including such areas as cellular and molecular bases of diseases, genetics, immunology.
A full list of such activities includes clinical trials and laboratory investigations, the study of exposure to environmental agents and various behavioural hazards." (Source: OECD Glossary of Statistical Terms)
In accordance with the above definition, biomedical technologies are defined as follows:
"Biomedical technologies are tools and techniques to be applied for the purpose of relieving abnormal body functioning, at the molecular, cellular, organ system and whole body levels. Research on biomedical technologies goes up to the point where these tools and techniques are tested on human subjects; it also includes the development of novel medical devices that improve health or quality of life of individuals." (Source: European Commission, DG Research, Health Directorate, Priorities for Cutting Edge Research in the field of Biomedical Technologies, Brussels, 2010).

The health of the Swiss population is better than ever before. On the other hand, chronic diseases are becoming more prevalent, not least as a result of the ageing population. The demands placed on the health system and health services are growing; health is increasingly perceived as a consumer good.[5] At the same time, developments in the life sciences, such as techniques associated with the sequencing of the human genome, are raising new questions relating to disease prevention and societal acceptance.

For Switzerland, the main challenge is to reach a consensus within society concerning the opportunities and risks – and the economic impacts – of biomedical research and technology. Rising costs throughout the health sector and in health insurance necessitate important decisions for a system based on community solidarity. At the same time, increased health awareness and the globalisation of health markets are also creating economic opportunities for the industry.

[5] Legislature Planning for 2011–2015, BBl 2012 532

1.2 Long-term orientation of federal business location policy

These are just some of the pressures shaping the global context within which Switzerland must act in the coming years. From 2011 to 2015, the Federal Council intends to address the various challenges with a strategy based on seven guiding principles.[6] Three of these principles are of particular relevance for biomedical research and technology:

- As a location, Switzerland is attractive, competitive and characterised by a sound federal budget, with efficient state institutions (Guiding Principle 1).
- Switzerland's social cohesion is strengthened, and the demographic challenges are effectively addressed (Guiding Principle 4).
- Switzerland has a leading position in education, research and innovation (Guiding Principle 6).

Seven of the strategic goals defined by the Federal Council relate directly to biomedical research and technology. These specify that:

- the best possible framework is to be established for Switzerland's economic growth (Goal 2);
- the attractiveness and credibility of Switzerland's fiscal system is to be strengthened (Goal 6),
- the opportunities offered by ICT and other modern technologies are to be exploited (Goal 7);
- Switzerland's relations with the EU are to be strengthened (Goal 9) and its foreign economic strategy is to be further developed (Goal 10);
- the growth of health system costs is to be contained, and the quality of health care and patient safety enhanced (Goal 18); and
- the high quality and international reputation of Switzerland's higher education system and research are to be assured (Goal 24).

These guiding principles and goals are in accordance with the strategy of previous legislatures.[7] They demonstrate the government's determination to strengthen Switzerland as a business location over the long term and at the same time to address social policy challenges.

Given the variety of questions to be tackled, there will inevitably be conflicts among the strategic goals defined. Particularly in the area of biomedical research and technology, the benefits of public access to innovative, safe and in some cases extremely expensive treatment methods need to be weighed up against the financial costs arising for the community – and also the economic importance of these sectors as employers and taxpayers.

With the implementation of over 20 measures,[8] the Federal Council intends to address these issues while also improving the overall framework for biomedical research and technology. Certain measures will be beneficial for the economy as a whole, e.g. Corporate Tax Reform III. Other measures will provide specific benefits for biomedical research and industry.

These measures include the promotion of education, research and innovation (ERI) in the years 2013–2016, the introduction of the new Federal Act on Research involving Human Beings and the ratification of the Council of Europe Medicrime Convention.[9], [10] The progress made in the attainment of goals is to be assessed with the aid of indicators and annual reporting by the Federal Council.

---

6 Altogether 28 goals are to be achieved. Cf. the Federal Decree on Legislature Planning for 2011–2015, BBl 2012 7155

7 Cf. "Assessment of Legislature Planning for 2007–2011" in Legislature Planning for 2011–2015, BBl 2012 492

8 The measures specified in the Federal Decree range from reduction of the administrative burden for enterprises (Measure no. 5 of 116), adoption of the business-location support strategy for 2016–2019 (no. 7), adoption of the Dispatch on the Revision of the National Economic Supply Act (no. 8), adoption of the Dispatch on Corporate Tax Reform III (no. 19) and conclusion of agreements with the EU on product safety and public health (no. 36) to more health policy-oriented topics such as adoption of the Dispatch on a new Federal Act on the Electronic Patient Record (no. 21) and adoption of the Dispatch on the Revision of the Therapeutic Products Act (2nd stage) (no. 72). Cf. also the discussion in Chapters 7–9.

9 Council of Europe Convention of 28 October 2011 on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention); Measure no. 55

10 These are Measures no. 102, no. 78 and no. 55.

1.3 Parliament's view of the need for action in the area of biomedicine

Given the deterioration of the economic outlook in major foreign markets, the depreciation of the euro against the Swiss franc, and restructuring measures and site closures in the pharmaceutical industry, the Swiss Parliament requested the Federal Council[11] to prepare a master plan including concrete measures designed to maintain and reinforce Switzerland's position as a centre of research, development and production for the biomedical industry (medtech, biotech, pharma).

Underlying the parliamentary motions was the view that Switzerland's population wished to benefit from medical advances and could do so thanks to the leading position of Swiss industry in the medtech and pharma sectors and in research. It was argued that this was also essential in order to safeguard jobs, especially during an economic crisis. The pharma industry alone accounted for a third of all Swiss exports, and the number of employees rose by 3% in 2010. However, there was no guarantee that this success would be sustained in the future. Harmonisation of framework conditions with those existing in the EU would undermine the country's competitive advantages as a business location. What was required instead was an independent location policy aimed at ensuring superiority over competing locations.

The master plan was to outline the following measures: improvements to the regulatory framework for studies of the efficacy and cost-effectiveness of treatments, reduced bureaucracy for clinical trials, more rapid access to new drugs and treatments for patients, and the strengthening of Switzerland's position as a research centre.

– Firstly, research and development was to be strengthened under a general reform of taxation. Important factors in the competition between R&D locations were not only access to highly skilled researchers, good infrastructure and openness to research, but also tax rates. Here, it was essential to improve the tax regime for research, which should continue to be financed mainly by the private sector in Switzerland.
– Secondly, intellectual property protection was to be improved for orphan drugs.

[11] 11.3923 Motion (Mo.) Forster/Gutzwiller, "Safeguarding jobs by ensuring a world-leading location for research, development and production of medical products"; 11.3844 Mo. SVP parliamentary group, "Revitalisation of Switzerland as a research and pharma location"; 11.3910 Mo. Barthassat, "Strengthening of Switzerland as a research centre and pharma location" (www.parlament.ch/d/Suche/Seiten/Curia-Vista.aspx)

1.4 The Federal Council's position

The Federal Council is aware of the significance of biomedical research and the biomedical industry for the health system and the economy.[12] In its response to the parliamentary motions, it notes that the favourable framework is to be preserved and enhanced with a variety of targeted measures. The Federal Council intends to further strengthen education, research and innovation in the 2011–2015 legislature period. The measures alluded to in the motions are already part of ongoing projects such as the complete revision of the Federal Act on the Promotion of Research and Innovation (FIFG), the new Federal Act on Research involving Human Beings, the ordinary revision of the Federal Act on Medicinal Products and Medical Devices, or the Orphan Diseases Plan.

In the Federal Council's view, a master plan will make it possible to coordinate those measures which have already been adopted with others which are under review or may additionally be necessary so as to ensure the most coherent possible framework for reinforcing Switzerland's position as a centre of biomedical research, development and production – bearing in mind that the quality of the business location needs to be addressed not just for a specific sector, but on a cross-sectoral basis.

1.5 Procedure adopted by the Federal Council

Biomedical research and technology encompasses a variety of activities potentially important for the Swiss location, such as the use of therapeutic products, the transplantation of organs, cells and tissues, research involving human beings and stem cells, and human genetic testing. In view of the parliamentary motions, this report focuses on medicinal products and medical devices, i.e. therapeutic products. Ultimately, this reflects both the frequency of their use and their economic significance.

On behalf of the Federal Council, the Federal Department of Home Affairs organised two round-table events for stakeholders in the latter half of 2012,[13] to discuss the areas where action is required, the goals to be pursued and the measures proposed for the biomedical research and technology sector. Stakeholders were also invited to comment on an analysis of the situation prepared by the Administration, together with proposals for concrete measures, and also to submit their own proposals.

What emerged clearly from the discussions and analyses was that:

- Switzerland's attractive framework can only be preserved and improved by considering the entire value chain – from education/training and market entry for new technologies to the reimbursement and use of products and techniques (thus going beyond the issues raised in the parliamentary brief);
- the various activities involved in value creation (research, development, sales) are often based in different countries, where they are subject to local regulations;
- innovation and location quality are the result of a large number of factors, such as the design of private and public institutions, the development and use of human capital for research purposes, the translation of ideas into innovations, the design of incentives for innovation and their impact on output and, lastly, the capacity of sectors and markets to absorb innovations;
- the individual components of value creation are interrelated in highly complex ways, which

[12] Cf. the response of the Federal Council to 09.4266 Interpellation (Ip.) Humbel, "Strategy for strengthening the health system and Switzerland as a pharma location", and to 11.3923 Mo. Forster/Gutzwiller, 11.3844 Mo. SVP parliamentary group and 11.3910 Mo. Barthassat

[13] Cf. Annex

means that private and public actors in research and industry share a high degree of responsibility for the success of measures;
– the division of responsibilities between federal and cantonal authorities, especially in the areas of education and health, can pose challenges for governance.

Based on a comprehensive assessment and comparisons with the situation in other countries, the Federal Council – in accordance with its long-term strategy – has decided on a series of measures. In the present document, it indicates to policymakers and the public where, in its judgement, action is required to strengthen biomedical research and technology, what goals are to be pursued, and what measures are to be adopted to achieve these goals. The Federal Council will inform the public regularly on the status of implementation.

The Federal Council is aware that the present report can only be a "snapshot", given the breadth and depth of the subject matter and the resultant need for simplification, as well as the rapid pace of scientific and technological developments in this field and global efforts to improve the attractiveness of business locations.

As the effects of certain measures will only become apparent after some time, another report will be published five years from now, assessing the efforts undertaken and, if necessary, proposing the continuation of measures already adopted or the introduction of new measures.

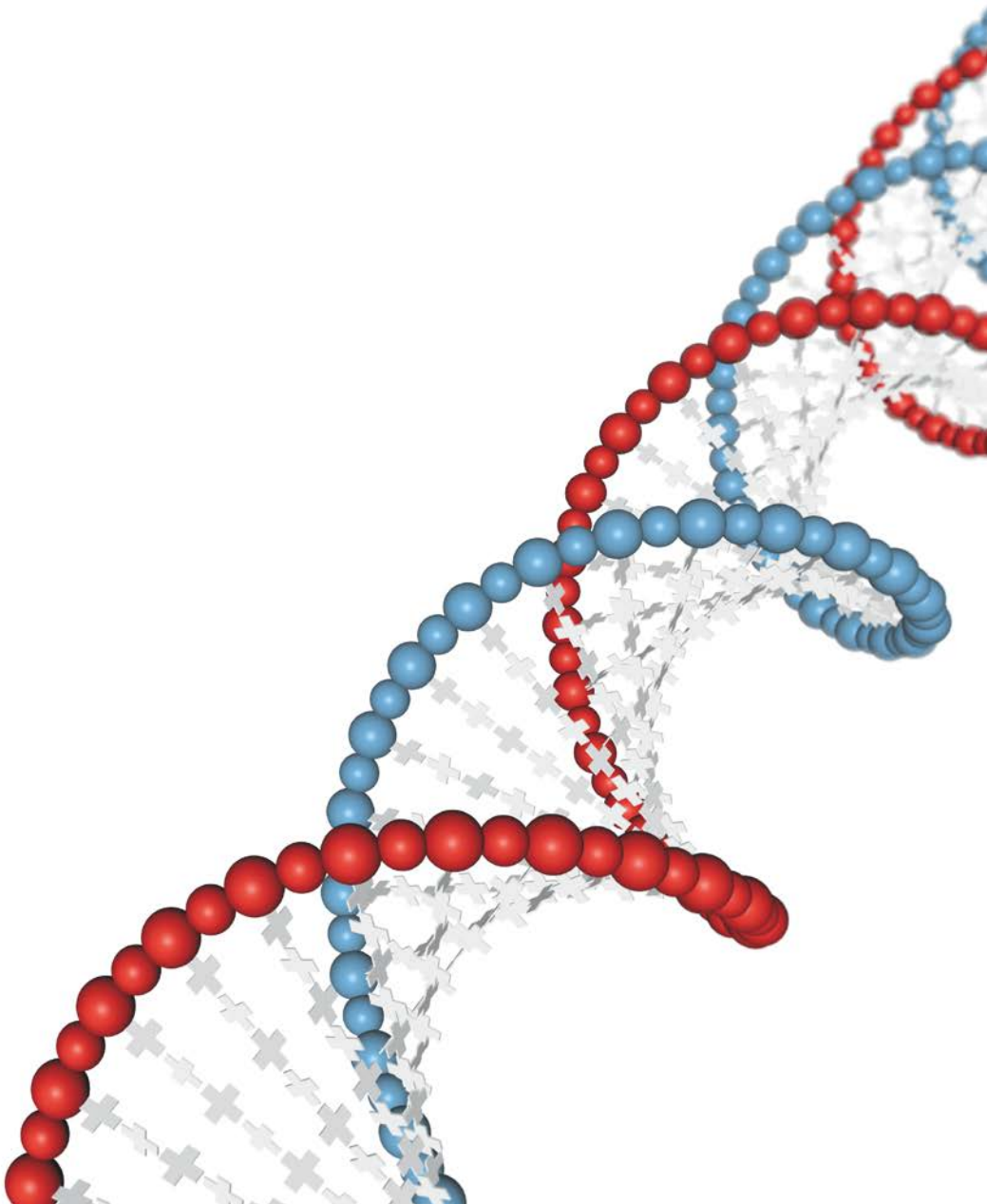
1.6 Structure of the report

After a discussion of the economic importance of biomedical research and technology for Switzerland (Chapter 2), the key concepts of innovation and product market regulation are analysed (Chapter 3). An understanding of these concepts makes it possible to show to what extent the state can establish an overall framework that promotes innovation and enables Switzerland to remain, as far as possible, an attractive location for skilled professionals, entrepreneurs, research institutions and industrial enterprises (Chapter 4). Here, particular importance attaches to health policy as well as to education and research policy.

In Chapter 5, a comparison with other countries indicates not only Switzerland's relative position but also the scope for improving its attractiveness as a location. In Chapter 6, an explanation is given – with more details in Chapters 7–9 – of the goals that have been set by the federal government in the various areas of action, and of the measures adopted in the form of regulations, platforms and projects. At the end of each chapter, an account is given of how the Federal Council intends to assess the attainment of goals.

2 IMPORTANCE OF BIOMEDICAL RESEARCH AND TECHNOLOGY IN SWITZERLAND

In this chapter, the importance of biomedical research and technology for Switzerland is considered in relation to other sectors.



2.1 Comparison with other sectors

A comparison with other sectors for 2010 indicates the relative importance of the biomedical technology.

	Nominal gross value added[14] (in CHF bn)	Growth rate (2000 / 2010;in per cent)	Share of gross domestic product (in per cent)
Wholesale trade	57,4	+63,0	10,0
Financial services	35,8	-5,3	6,3
Construction	29,5	+39,6	5,2
Retail trade	26,3	+21,0	4,6
Insurance	23,2	+64,0	4,1
Health care	20,2	+41,5	3,5
Electronic products, watches and clocks	18,5	+54,6	3,2
Pharmaceutical products	18,1	+127,0	3,2
IT and information services	11,0	+45,4	1,9
Machinery and equipment	10,6	+10,8	1,9
R&D	4,2	+68,0	0,7
Medical technology	3,3	n.a.	0,6

Table 1: Comparison of various sectors, 2010[15]

In 2010, nominal gross value added for the pharmaceutical and medtech industries combined came to around CHF 21.4 billion, putting the biomedical industry in 7th place among private-sector industries – significantly ahead of the traditionally very important machinery and equipment sector (14th) or IT and information services (13th). Together, the pharmaceutical and medtech sectors generated greater value added than health care, which came in 8th place with CHF 20.2 billion. The largest sectors in terms of gross value added are wholesale (1st) and retail trade (6th), financial services (2nd) and insurance (7th). Between 2000 and 2010, nominal gross value added more than doubled for the pharmaceutical industry, while growth rates in other sectors ranged from 40% to 65%. Growth rates were below average in the retail sector (+21%) and in machinery and equipment (+10.8%), and growth was negative in the financial services sector (–5.3%).

[14] This value is obtained by subtracting intermediate consumption from nominal gross output.

[15] At current prices and growth rate (figures rounded); source: Swiss Federal Statistical Office, except for the data for medical technology, which is taken from: Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects.

2.2 Biomedical research

2.2.1 Expenditures on R&D in Switzerland

In Switzerland's federalist system of education, research and innovation (ERI), numerous actors participate. In the delivery and financing of services, as well as in regulatory and control functions, both public and private actors are involved, with differing responsibilities.

In 2008, total intramural expenditures[16] on R&D[17] in Switzerland came to CHF 16.3 billion, which is equivalent to approx. 3% of gross domestic product (GDP).[18] Expenditures by sector were as follows:

	1996	2000	2004	2008	Growth 1996/2000	Growth 2000/2004	Growth 2004/2008
Private sector	7060	7890	9660	11 980	11,8%	22,4%	24,0%
Federal government (departmental research)	250	140	140	120	-44,0%	0,0%	-14,3%
Higher education	2430	2440	3000	3940	0,4%	23,0%	31,3%
Non-profit institutions serving households	250	205	300	260	-18,0%	46,3%	-13,3%
Total	**9990**	**10 675**	**13 100**	**16 300**	**6,9%**	**22,7%**	**24,4%**

Table 2: Intramural expenditures (CHF m) on R&D by sector, 1996–2008[19]

Responsibilities at the federal level include the management and financing of the institutions of the ETH domain (the Swiss Federal Institutes of Technology in Lausanne and Zurich and the four research institutes PSI, Eawag, Empa and WSL), the regulation and co-financing of the cantonal universities of applied sciences (UAS), vocational/professional education and training, and provision of support for cantonal universities (via basic contributions). The federal government is also responsible for competitive research funding (via the Swiss National Science Foundation, SNSF) and innovation promotion (via the Commission for Technology and Innovation, CTI), and for international cooperation in education, research and innovation. With regard to scholarships, the cantons receive federal support. In the management of the Swiss Education Area, the federal and cantonal authorities coordinate their efforts and undertake joint projects.

The bulk of R&D and innovation in Switzerland is carried out and financed by the private sector, with the pharmaceutical industry accounting for the largest share of investments in research.

Innovations are generated primarily by private enterprises, which are the most important actors and provide the majority of funding. Thus, in 2008, 87% of the roughly CHF 12 billion invested by the private sector in intramural R&D was internally financed. For the innovation process, knowledge generated and disseminated via (publicly funded) education and research plays a decisive role in both the short and long term.

Of the CHF 11.98 billion invested by the private sector in intramural R&D, the pharmaceutical sector accounted for CHF 4.628 billion (39%).[20] According to a study of R&D in Switzerland

[16] Intramural expenditures on R&D are the most commonly used indicator of R&D expenditures within an economy. They are defined as all expenditures for R&D performed within a statistical unit of the economy (e.g. an enterprise, university).

[17] According to the OECD Frascati Manual, three types of R&D can be distinguished – basic research, applied research and experimental development (OECD, Frascati Manual – Proposed Standard Practice for Surveys on Research and Experimental Development, 2002, pp. 77–79).

[18] Swiss Federal Statistical Office, F+E der Schweiz 2008. Fortgesetzte Anstrengungen der Privatunternehmen und Hochschulen, 2010

[19] At current prices and growth rate (figures rounded)

[20] Forschung und Entwicklung in der schweizerischen Privatwirtschaft 2008. Swiss Federal Statistical Office and economiesuisse, June 2010.

published by the Swiss Federal Statistical Office (SFSO) and economiesuisse, companies are according increasing priority to applied research and experimental development; these two types of activity showed significant growth. Various sectors are contributing to this trend, most notably the pharmaceutical industry, which devotes half of its budget to experimental development.[21] In 2008, half of all private-sector R&D funding was invested in the research goal "Health" (defined as the protection, promotion and restoration of human health in a broad sense, including questions of nutrition), with the pharmaceutical industry accounting for 77% of these investments.[22]

Unfavourable economic conditions abroad also affect the relative attractiveness of Switzerland in the area of R&D: while gross expenditures in the EU rose by 3% between 2008 and 2011, this was mainly attributable to countries such as France and Germany, with growth of 4%. In the UK, expenditures remained virtually unchanged, while in Sweden and Spain they declined by 1%. Varying trends were also seen in other OECD countries, such as the US (+1%) and Japan (-3%). Growth was due either to private expenditures or to public investments in education and research, depending on the particular country: for example, in 2008 and 2009, private expenditures on R&D declined in Sweden, Canada, Israel, the UK and the Netherlands, while in the US higher investments in education compensated for lower spending by private and public organisations[23]. However, realising that innovations are a result of multi-year investments, most countries avoid cutting or actually increase expenditures in this area.

2.2.2 Benefits of biomedical research

Research is fundamental to innovative, cost-effective and efficient modern health care. In addition, it is an important component of direct health service provision, with considerable numbers of patients receiving medical care – in the form of cutting-edge interventions and technologies – as a result of their participation in research. For example, in the case of patients with rare diseases, participation in a research project is often the only way of gaining access to effective treatment.

The economic importance of investments in clinical research and the returns for public health have frequently been investigated in empirical studies. A UK study, for example, found that, on average, privately/charitably or publicly funded research produces returns of 20% for the investing organisation and 50% for society.[24] Research thus not only generates fundamental knowledge for health care but also permits the targeted application of treatments empirically demonstrated to be effective (evidence-based medicine). This generally leads to significant cost efficiencies.[25]

[21] Ibid., p. 14.

[22] Ibid., pp. 15–16.

[23] OECD Main Science and Technology Indicators, 2013

[24] Health Economics Research Group (Brunel University), Office of Health Economics, Rand Europe, Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK; for the Medical Research Council, the Wellcome Trust and the Academy of Medical Sciences, November 2008.

[25] Cf. also World Health Organization, Knowledge for better health – a conceptual framework and foundation for health research systems. Bulletin WHO, 2003;81:815–820

2.2.3 Biomedical research – a component of comprehensive health research

Core fields of the molecular life sciences such as human genome and proteome research, systems biology and bioinformatics provide a detailed understanding of complex, dynamic biological processes down to the molecular level and make available new methods permitting targeted analysis and representation of these processes. This opens up a wide variety of possible applications in biomedical research.[26] Knowledge of molecular processes in the cell or organism paves the way for research on human diseases and the development of therapeutic and preventive interventions. In this master plan, biomedical and clinical research is seen as a component of comprehensive health research.

Often, the platform technologies and infrastructure required for health research – e.g. high-throughput technologies, reliable disease models, cohorts and biobanks, or competence centres for the planning and conduct of clinical trials – can only be established, maintained and effectively used via the collaboration of various partners.

Cross-institutional collaboration and networks are therefore becoming increasingly important for health research where any kind of medical treatment or practical/clinical intervention is to be carried out on the basis of empirical evidence of efficacy (evidence-based medicine). Clinical trials are a driver of innovation in health research and health care, but each phase of such trials involves high levels of scientific and logistical effort and financial expense, primarily in the interests of patient safety.

[26] Cf. for this section: Federal Ministry of Education and Research, Impulsgeber Lebenswissenschaften: Forschung für die Innovationen der Zukunft. Bonn, Berlin, 2009.

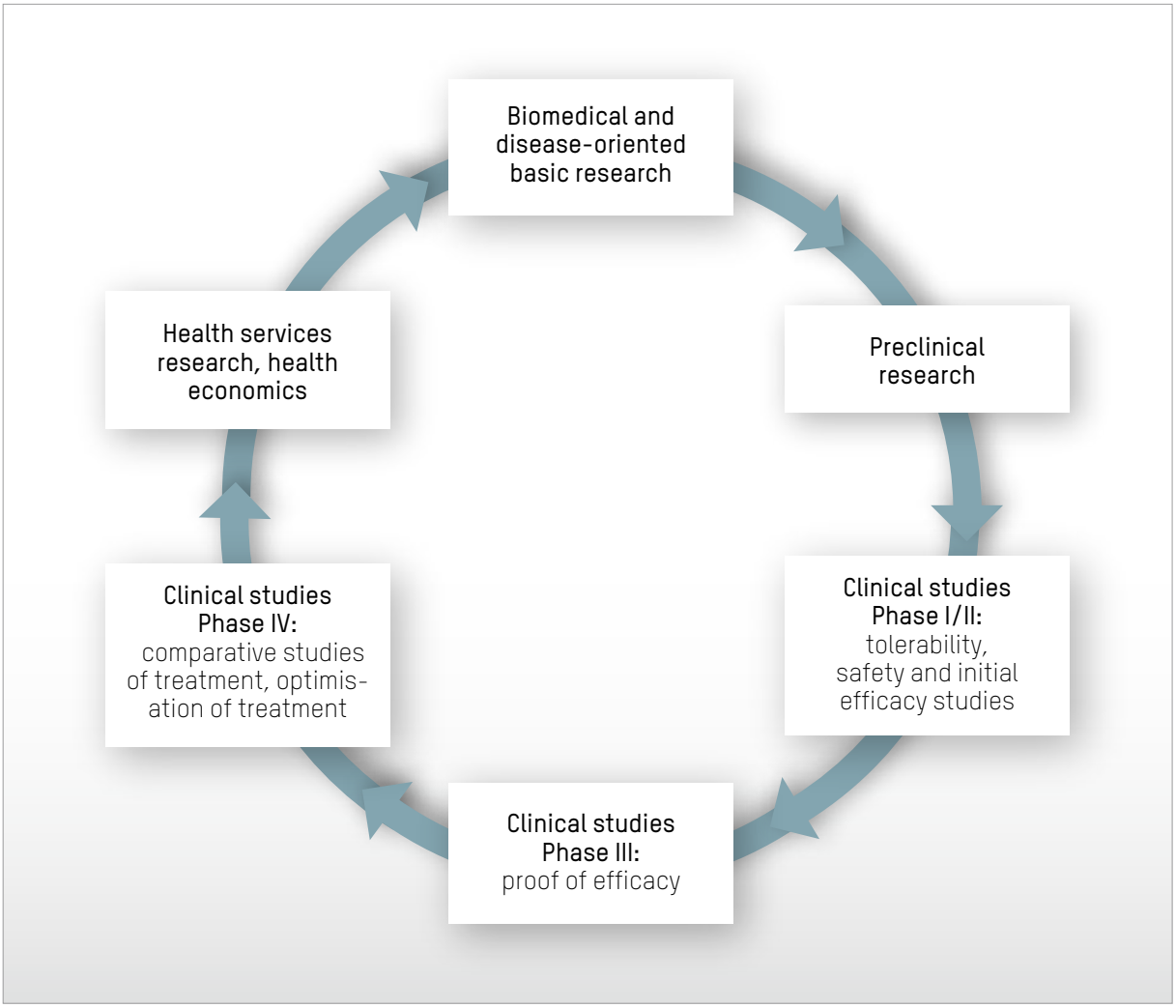


Figure 1: Research cycle

In summary, it can be said that biomedical and clinical research comprises the following distinct but closely linked areas of activity:

basic research,
seeking a deeper knowledge of biological systems (molecular biology, genetics, biochemistry, immunology, physiology, etc.), which then contributes to disease-related research;

applied/disease-related basic research,
which, with the aid of models (e.g. in animal experiments or in vitro systems), uses modern biological methods to obtain insights into the pathophysiology and genetic causes of diseases and to test possible therapeutic approaches; while disease-related research aims to understand the pathogenesis and treatment of diseases, it does not involve direct contact with patients;

applied/patient-focused research,
clinical research in a narrower sense, directly involving patients or trial subjects. In the Federal Act on Research involving Human Beings (Human Research Act, HRA), a clinical trial is understood as a research project involving patients or healthy volunteers, which is carried out in order to assess the efficacy and safety of health-related interventions such as drugs or other forms of treatment. The purpose of clinical trials is to answer scientific questions and to improve medical treatment for future patients. Patient-focused research covers all phases of clinical trials, as well as epidemiological and case-control studies and large parts of health services research. It requires direct contacts between investigators and patients/subjects.

The challenge lies in ensuring that the flow of information "from bench to bedside and back again" is as efficient and effective as possible. The aim is to coordinate basic, disease-related and patient-focused research in accordance with the principle of translational medicine – i.e. effective interaction between research and clinical practice. Translational research seeks to transfer as many findings as possible from basic research via appropriate animal models to therapeutic applications; in the course of clinical testing, questions and ideas frequently arise which can then be fed back into upstream research.[27] Health services research, lastly, seeks to bridge the gap between biomedical and clinical research on the one hand and day-to-day medical practice on the other; it focuses, as it were, on the "last mile" to the patient.[28]

[27] Medicine as a science. Position paper of the Swiss Academy of Medical Sciences (SAMS), 2009.

[28] Cf. the SAMS Health Services Research funding programme: www.samw.ch/en/Research/Health-Services.html, 1 February 2013.

2.3 Biomedical technology

2.3.1 Pharmaceutical industry

In 2012, the pharmaceutical industry achieved sales of CHF 5.1 billion in Switzerland. The total number of packs sold was 207.6 million units. Worldwide, the two largest Swiss pharmaceutical groups, Novartis and Roche, had sales of USD 50.8 billion and USD 34.8 billion respectively, with market shares of 5.9% (ranking in first place) and 4.1% (fifth place).[29]

In 2006, pharmaceutical companies employed around 34,000 people in Switzerland – 50% more than in 1990.[30] Four years later, the number of direct employees had risen to 36,700, while the indirect employment effects for Switzerland in 2010 were estimated at 98,600 jobs.[31] Between 1990 and 2010, pharmaceutical industry employees as a proportion of the total workforce rose from 0.5% to 0.8%. Taking indirect employment effects into account, the proportion was 3.0%, according to a study by Polynomics / BAK Basel Economics.

In 2010, hours worked in the pharmaceutical industry (63.5 million hours) accounted for 0.9% of the total for Switzerland – higher than the share of employees. If indirect employment is also taken into account (166.2 million hours worked), this proportion rises to 3.1%. According to the study, this is attributable to the fact that part-time work (for both men and women) is not as widespread in the pharmaceutical industry as in the rest of the economy; the number of hours worked per employee is therefore higher. As well as a high proportion of full-time positions, the pharmaceutical industry's workforce is characterised by an above-average percentage of non-Swiss employees. Almost two thirds of employees are of foreign nationality, although the majority of these are cross-border commuters from Germany, France and Italy.[32]

Apart from the well-known large corporations, almost half of the other companies are micro-enterprises with fewer than ten employees, which are key sources of innovation.[33] According to the Polynomics / BAK Basel Economics study, the nominal gross value added of the pharmaceutical industry grew by a factor of almost six between 1990 and 2010 (from CHF 2.7 billion to CHF 14.8 billion), while the nominal gross domestic product grew by only 63%. Between 2000 and 2010, the nominal value added of the pharmaceutical industry increased markedly, with total growth of 150% or an average of 10% per year. With the exception of 2010, the growth rate was always higher than for the overall economy.

According to Polynomics / BAK Basel Economics, pressure on prices (also due to changes in exchange rates) reduced the annual rate of growth in nominal value added to 1% in 2010, while for the overall economy the figure was 2%. In real terms, however, the pharmaceutical industry reported higher growth (4.3%) than the overall economy (2.5%). The indirect effect of the pharmaceutical industry on Switzerland's nominal gross domestic product in 2010 was about CHF 14.4 billion. The total direct and indirect importance of the pharmaceutical industry is, therefore, about CHF 29.2 billion, equivalent to a 5.7% share of GDP.

---

29 In 2012, the consolidated data from IMS Health covered around 70% of the total market for prescription drugs at ex-factory prices (whether sales to hospitals are included varies from country to country). It may therefore differ from the data reported by companies. The global market is estimated to be worth USD 856.4 billion. More detailed information is available from Interpharma (www.interpharma.ch).

30 Plaut Economics, Bedeutung der Pharmaindustrie für die Schweiz, study commissioned by Interpharma, September 2007

31 Polynomics / BAK Basel Economics, The importance of the pharmaceutical industry for Switzerland (a study undertaken on behalf of Interpharma), September 2011

32 Ibid., pp. 28ff.

33 Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects, 2013, Zurich, p. 17

In 2010, according to Polynomics / BAK Basel Economics, value added was over CHF 400,000 per employee, or CHF 232 per hour worked, meaning that productivity in the pharmaceutical industry was three times as high as the overall Swiss average.

The vast majority of goods manufactured in the Swiss pharmaceutical industry are exported. From 1990 to 2010, pharmaceutical exports as a proportion of total Swiss exports increased from 10% to 31%. In 2006, the value of goods exported by the Swiss pharmaceutical industry was CHF 46.6 billion; in 2010, it was CHF 60.6 billion.

The data reported by the Swiss Federal Statistical Office or the Swiss Customs Administration for 2000, 2010 and 2011[34] differs to a certain extent from the figures given above:

	2000	2010	2011 (prov.)
Nominal gross output (in CHF bn)	31,0	64,4	63,1
Nominal gross value added[35] (in CHF bn)	7,9	18,1	17,5
Share of nominal gross value added in total nominal GDP (in per cent)	1,8	3,2	3,0
Jobs (in full-time equivalents)	25 690	35 850*	n.a.
Workforce productivity (in CHF)	309 622	503 596*	n.a.
Exports (in CHF bn)	22,1	60,7	60,2
Imports (in CHF bn)	10,4	25,2	25,1
Net exports (in CHF bn)	11,7	35,5	35,1

Table 3: Economic significance of the pharmaceutical industry (*provisional value for 2010)

[34] Sources: Swiss Federal Statistical Office (www.bfs.admin.ch) and Swiss Customs Administration; since June 2012, data for the pharmaceutical industry has been reported separately.

[35] This value is obtained by subtracting intermediate consumption from nominal gross output.

2.3.2 Biotech industry

Biotechnology[36] is used in a wide variety of sectors, such as agro, chemicals, medtech, food and pharmaceuticals.

The industry comprises numerous small and medium-sized enterprises: according to the Swiss Biotech Report 2013,[37] the number of biotech companies (developers) in Switzerland increased from 138 in 2003 to 173 in 2010, and 193 in 2012.[38] Over the same period, the number of biotech suppliers declined from 88 to 63 in 2010 and 57 in 2012. In 2010, the country's 237 biotech companies were mostly located in the Lake Geneva region and the Zurich and Basel regions.[39]

Between 2010 and 2012, private biotech companies employed around 7000 people, while about 6700 people were employed by public-sector organisations.

Over the same period, total revenues decreased from CHF 5.1 billion to CHF 4.6 billion, while R&D expenditures declined slightly, averaging CHF 1.3 billion per year. In 2012, profits totalled CHF 165 million, and profits of CHF 480 million in 2010. For comparison, publicly traded biotech companies reported global sales of USD 89.8 billion in 2012,[40] with US-based companies accounting for 70% of this total.

Often, biotech firms serve as suppliers of global pharmaceutical companies, researching and developing active substances produced by biotechnological methods in genetically modified organisms. In contrast to chemical active substances, these are generally high-molecular-weight and large proteins. The products are mainly used to treat serious or life-threatening conditions, such as multiple sclerosis, cancer, diabetes or blood disorders.

Biotech companies are thus also benefiting from the growing demand for new drug treatments: according to Interpharma, around 30% more biotech drugs were supplied in Switzerland in 2012 than in 2007, with sales totalling CHF 884 million.[41]

Despite this trend, the development of the biotech industry over the past few years has been affected by the upheavals on the global financial markets: for smaller biotech enterprises, it remains relatively difficult to raise capital; they are therefore increasingly seeking investors who are prepared to make longer-term commitments as entrepreneurs. Since 2009, Switzerland's biotech sector has been marked by cost-cutting programmes at Actelion and Lonza and the closure of Merck Serono's Geneva site, with the loss of hundreds of jobs. More positive signals came from the five start-ups spun off from Merck Serono.

---

36 Biotechnology is defined by the OECD as follows:
"The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."
As this definition is very broad, the OECD adds a list-based definition, with different categories of biotechnology techniques (source: OECD Factbook 2011–2012: Economic, Environmental and Social Statistics).
Also found in the literature is a classification into the following types: "green biotechnology" (used in the production of food and feedstuffs), "red biotechnology" (used in the pharmaceutical industry) and "white biotechnology" (application of biotechnological methods e.g. to optimise industrial processes or to reduce energy and waste disposal costs).

37 Swiss Biotech Association, Scienceindustries, CTI, IPI, SNSF, SIX Swiss Exchange AG and Ernst & Young AG, Swiss Biotech Report 2013 (www.swissbiotechreport.ch)

38 Cf. the data from Ernst & Young AG included in the Swiss Biotech Report 2013, pp. 29ff., and the associated notes

39 Polynomics/BAK Basel Economics, The importance of the pharmaceutical industry for Switzerland (a study undertaken on behalf of Interpharma), September 2011, p. 17

40 Ernst & Young, Beyond Borders: Biotechnology Industry Report 2013, pp. 23ff.

41 At ex-factory prices; source: Interpharma

2.3.3 Medical technology

In 2011, Switzerland's medtech industry comprised around 1600 companies employing a total of 51,000 people. 850 companies were suppliers or manufacturers; 750 were service providers, traders or distributors. The medtech industry's total sales in 2011 were around CHF 12.5 billion, with the domestic market being worth around CHF 7.2 billion. Net exports amounted to roughly CHF 5.3 billion. Medtech manufacturers invested 13% of turnover in R&D, while for suppliers the figure was 8%; total annual R&D expenditures amount to CHF 1.4 billion.[42] According to economists at Credit Suisse, the Swiss medtech sector's gross value added for 2011 was CHF 3.8 billion. Apart from two dozen large corporations (some of them dominated by foreign interests), the sector consists mainly of SMEs. With a total of 23,800 employees, labour productivity amounted to CHF 155,000.[43]

[42] Medical Cluster, Medtech Switzerland, IMS Consulting Group, CTI, The Swiss Medical Technology Industry 2012 – "In the Wake of the Storm"; further information is available e.g. in Rütter und Partner, Sozioökonomische Forschung + Beratung, Wirtschaftliche Bedeutung der Medizintechnik in der Schweiz, 2010.

[43] Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects, 2013, Zurich, p. 26.

2.3.4 Importance of sectors for individual regions

The pharma, biotech and medtech sectors are of major importance not only for Switzerland as a whole but also for individual regions:

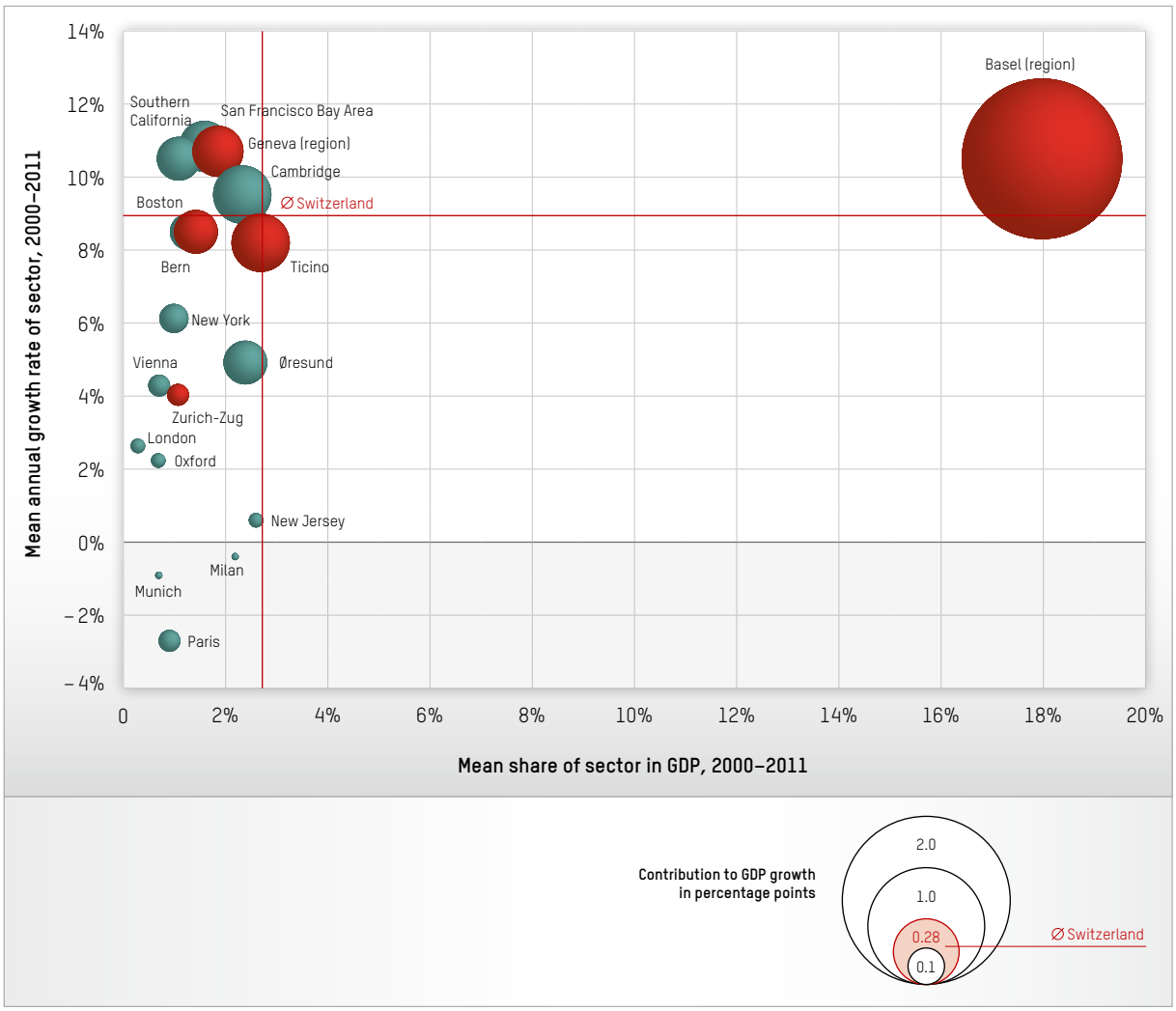


Figure 2: Influence of location on regional economic development[44]

For Basel, in contrast to Geneva or Zurich-Zug, it is apparent that the sector has a relatively large influence on regional economic development. Declines in (previously high) growth rates – due to general economic or structural factors – will thus affect different regions to different extents.

From the perspective of business-location policy, the question arises to what extent promoting the establishment of a high-value-added industry may involve an undue concentration of risk.

[44] BAK Basel; produced on behalf of the Federal Office of Public Health

2.3.5 Outlook for the sector in the short to medium term

The data presented above demonstrates the economic importance of the biomedical industry for Switzerland. However, this reflects past developments. Looking ahead to the near future, therefore, we now consider how professional observers rate the prospects for growth of the three sectors, providing an indication of their economic dynamics.

A. GLOBAL TRENDS

Between 2007 and 2011, the biomedical industry's global revenues grew at a compound annual rate of 6.7% to USD 1.1 trillion. According to Deloitte, the industry will continue to grow in the future as a result of the ageing population, the rising incidence of chronic diseases (due to changes in lifestyle and eating habits) and opportunities in emerging markets, together with increased demand for health services, product innovation and broader insurance coverage, particularly in the US.[45]

However, after years of growth in sales and profits, the industry now finds itself in a challenging environment: a changing health care landscape, expiring patents and generic competition, pricing pressures, heightened regulatory scrutiny, increasing alliances and acquisitions, and expansion into emerging markets are prompting companies to adopt new business models designed to deliver better patient outcomes at lower cost.

While global sales are predicted to rise to USD 1.4 trillion, growth rates will vary from region to region: annual growth is expected to be 6.5% in the US and 8.4% in Asia, with growth of over 10% forecast for emerging countries.[46]

Many companies are increasingly investing in drugs for use in rare diseases (orphan drugs). To date, an estimated 6000–8000 rare diseases have been described, affecting on average 5 in 10,000 people. Such conditions are frequently caused by a gene defect, although they also include rare infectious diseases and autoimmune disorders. Around five new rare diseases are described in the medical literature each week.[47] Treatment costs can amount to hundreds of thousands of Swiss francs per patient per year.

In the past, mainly smaller companies were active in this area, but corporations such as Aventis, GlaxoSmithKline or Novartis are now also involved. Countries around the world are seeking to promote the research and development of orphan drugs by various means – fast-track authorisation procedures, reduced processing fees, market exclusivity and tax breaks. According to market observers, because rare diseases often occur in children or are life-threatening, the cost of treatment is a secondary consideration in the price-setting process.

Among the factors taken into account when prices are set are the extension of survival, improvement of quality of life and shortening of hospital stays. It has been argued that providers behave as monopolists, exploiting their market power to maximise profits.[48]

[45] Deloitte, 2013 Global life sciences outlook – Optimism tempered by reality in a "new normal", 2013

[46] EIU Global Forecasting Service, Economic Forecast, 2012

[47] Cf. the discussion in Section 9.1

[48] Werner Grundlehner, Zukunftsmarkt der Pharmaindustrie – Stete Gewinne mit seltenen Krankheiten, Neue Zürcher Zeitung, 8 August 2013

B. DEVELOPMENTS IN SWITZERLAND

Professional observers rate the medium-term outlook for both the pharmaceutical and the medtech sector as good, given the steady growth in demand for health care services. This demand is driven by the ageing population, the ongoing spread of chronic conditions (e.g. diabetes, cardiovascular disorders, cancer) in industrialised nations and the high standing of health care. Demand for health care is also increasing in emerging countries on account of the higher standard of living, and the export-oriented Swiss pharma and medtech sectors are expected to benefit as a result.[49]

In spite of the difficult environment, the importance of Switzerland's biotech sector continues to increase. While around 1000 biotech products are currently in the pipeline in the US, the total is over 300 in Switzerland.[50] Switzerland, Germany (also around 300) and the UK (the European leader, with over 400) account for about 40% of the total European biotech pipeline.

According to economists at Credit Suisse, the Swiss pharmaceutical industry will continue to grow thanks to rising national and international demand. In 2012, the industry's turnover increased substantially again because prices stabilised. This turnaround was due in no small measure to stabilisation of the exchange rate. Volumes exported continued to decline. Price pressure will continue in the future, and growth momentum will be critically dependent on successful research and approval activity. The entry rate is well above the average for all sectors, and the bankruptcy rate is low. Personalised medicine (tailored to patients with the aid of biomarkers) engenders high expectations.[51]

According to BAK Basel,[52] growth can be expected to accelerate in 2014, both for the chemical/pharmaceutical industry and for the Swiss economy as a whole. However, ongoing uncertainties in Europe will have an impact on the chemical industry in particular. Growing momentum in the global economy and in Switzerland is likely to lead to an increase of 3.6% in the real gross value added of the chemical/pharmaceutical industry. On the labour market, a solid increase of 1.4% in the number of people in employment is also to be expected.

In the medtech sector, turnover progressed only moderately in 2012. According to Credit Suisse, real demand proved relatively dynamic, but nominal growth was limited as prices trended downwards. In 2013, general pressure on prices will continue to prevail, but should be offset by growth in real demand. However, the era of double-digit growth rates as seen in the early 2000s now appears to be over.[53]

[49] Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects, 2013, Zurich, p. 9

[50] Ernst & Young, Beyond Borders: Biotechnology Industry Report 2013, pp. 69ff; a relatively high proportion of these products are in early stages of development (Phases I and II).

[51] Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects, 2013, Zurich, p. 17

[52] BAK Basel, Branchenmonitor Chemie/Pharma, April 2013

[53] Credit Suisse, Swiss Issues Industries – Sector Handbook 2013 – Structures and Prospects, 2013, Zurich, p. 26

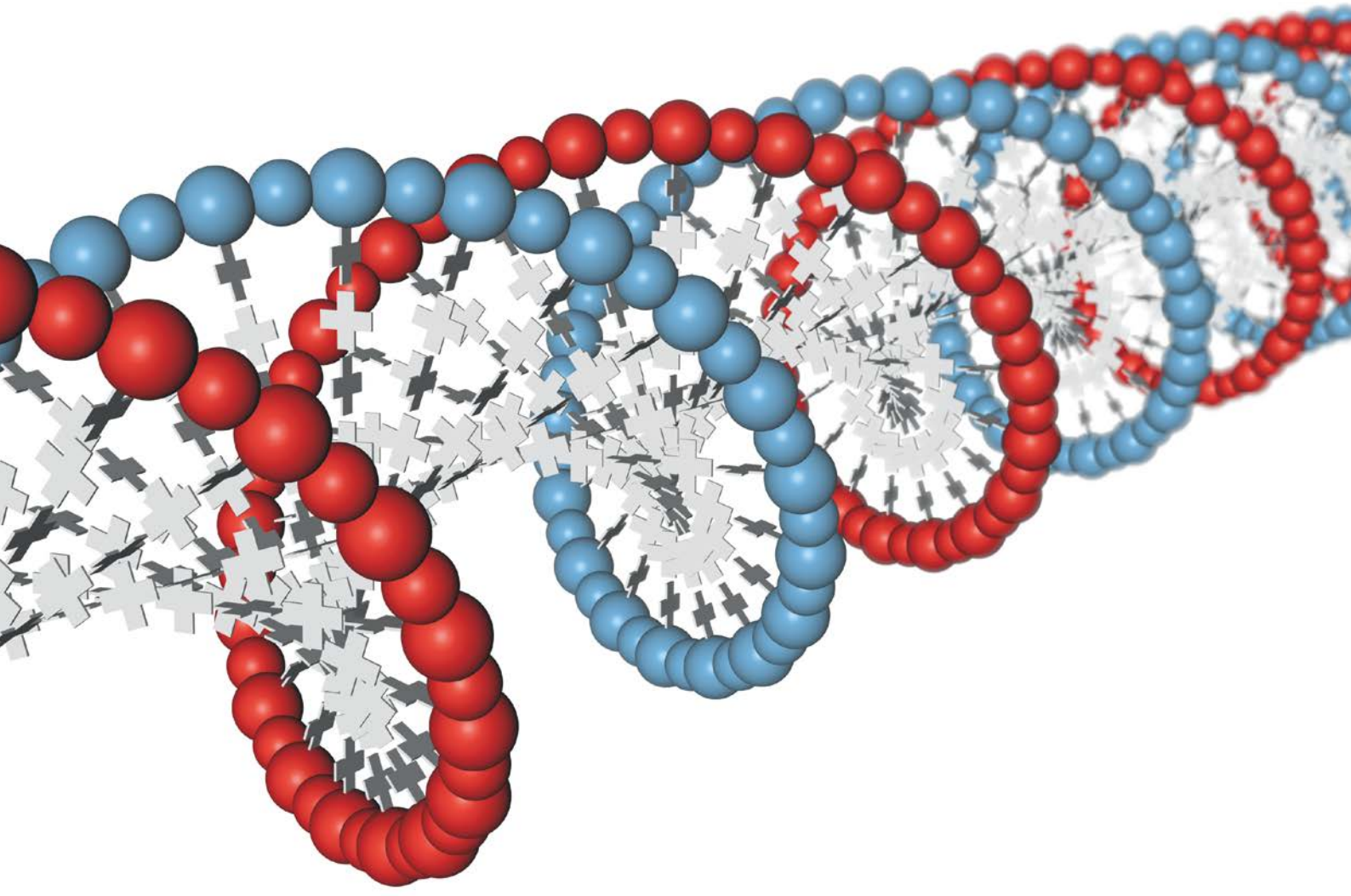
2.4 Conclusions

Biomedical research and technology is of major importance for Switzerland, both directly and indirectly: not only do these sectors exhibit high levels of innovation and value added with above-average growth potential,[54] they also contribute significantly to the provision of high-quality health goods.

[54] The economic significance of Switzerland's health system is shown, for example, by the Infras study: Wertschöpfung und Beschäftigung im Gesundheitssektor Schweiz (Zurich, 2006).

3 ROLE OF INNOVATION IN BIOMEDICAL RESEARCH AND TECHNOLOGY

Given the economic importance of biomedical research and technology for Switzerland, the question arises of how the country's attractiveness as a location for research and industry can be maintained. Here, innovation and product market regulation are key concepts.



3.1 Innovation: a key concept

In today's competitive global environment, successful economies such as Switzerland should rely on innovation, quality and differentiated products rather than seeking to compete with emerging economies on costs or efficiency.[55]

In the context of biomedical research and technology, innovation is of crucial importance. This key concept is defined by the OECD and the EU as follows:

> *An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations.*[56]

Our understanding of the mechanisms of innovation remains incomplete. However, a broad consensus exists in the literature with regard to the following points.

Innovation involves a dynamic and complex process of developing, applying and disseminating new knowledge, which is used in a company, a sector or worldwide – with the deployment of labour and capital – to improve products and services, processes, organisations, or the marketing of products and services. In a knowledge economy, this is only possible by means of intensive exchanges of knowledge within an organisation and with its environment. A key role is played by research and development, codified knowledge in the form of technology standards, for example, skilled workers, and close collaboration with other companies and public research institutions.[57] As a result of their specialisation, SMEs in particular are often heavily dependent on exchanges of knowledge with other companies.[58]

The environment within which companies seek to produce innovations is determined by factors such as the education and training system, the higher education landscape, the quality of science and research, the infrastructure of a region or country, access to product markets and sources of financing, cooperation with suppliers, and the regulatory framework (e.g. patent and tax law).

An essential feature of the innovation process is the uncertainty as to whether R&D efforts will in fact fulfil hopes or produce the desired innovation output. How long this uncertainty lasts will depend on the particular sector and the associated product life cycles. In the biomedical sector, industry representatives assume a period of around 20 years for a new drug, including about 12 years devoted to research, development and preparation for marketing. On average, the costs for the development of a new drug are reported to have increased from USD 802 million in 2001 to USD 1318 million in 2006.[59]

Only a tenth of all products which are clinically tested ultimately reach the market.[60] In the case of treatments for cardiovascular disease, studies suggest that, on average, 17 years elapse between the start of research and application in clinical practice.[61]

---

55 OECD, Moving Up the Value Chain: Staying Competitive in the Global Economy, 2007

56 OECD and Eurostat, Oslo Manual – Guidelines for collecting and interpreting innovation data, third edition, 2005, p. 46

57 Further discussion of the role, origins and theoretical foundations of innovation is to be found in the OECD/Eurostat Oslo Manual and in the relevant literature.

58 Cf. also the experience with knowledge disclosures in a field experiment in bioinformatics reported by Kevin J. Boudreau and Karim R. Lakhani: Innovation & Open Disclosure of Intermediate Results: Evidence from a Policy Experiment in Bioinformatics, Harvard Business School Technology & Operations Mgt. Unit Working Paper, No. 14-002, 2013 (http://ssrn.com/abstract=2288746 or http://dx.doi.org/10.2139/ssrn.2288746)

59 Tufts CSDD, Boston, 2007, cited in: Interpharma, Entwicklungskosten eines Medikamentes, 2013, (www.interpharma.ch)

60 Source: Interpharma 2013, Basel (www.interpharma.ch)

61 Health Economics Research Group (Brunel University), Office of Health Economics, Rand Europe, Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK; for the Medical Research Council, the Wellcome Trust and the Academy of Medical Sciences, November 2008, pp. 20ff.; the mean lag between research and impact is between 10 and 25 years.

Once an innovation has become public, it cannot be protected against imitation without specific measures. Protection of intellectual property rights is thus of vital importance. Such protection is considered to provide a system of incentives whereby private companies are motivated to invest substantial resources in the research and development of new therapeutic products and forms of medical treatment.

Successful innovations not only have positive effects on the sales, market share and profits of an individual company, but may also increase the productivity of entire sectors, benefit other sectors via knowledge transfer in the form of externalities (also known as spillovers[62]), strengthen economic growth and improve an economy's overall competitiveness.

The importance attached to innovation within companies, sectors or economies is apparent from frequently used indicators such as expenditure on R&D and the number of patent applications or scientific publications. Patents are, however, only one indicator: many innovations are not patented, while others are protected by several patents. Some patents have no technical or economic value, while others are highly valuable.[63]

Today, efforts are made to assess the innovativeness of sectors or countries using innovation indices, which comprise numerous input and output indicators and employ a very broad data base.[64]

62 Ibid., cf. the discussion in Chapter 6, pp. 33ff.

63 Cf., for example, the discussion in the OECD Patent Statistics Manual, Paris, 2009

64 Cf. the discussion in Chapter 5

3.2 Radical, incremental and pseudo-innovation

Innovations do not necessarily take the form of a major breakthrough – often, they may also occur in small steps. Efforts to promote biomedical research and technology should not only create a favourable framework for breakthroughs or radical innovations. Cumulatively, a large number of small innovations – e.g. within a class of therapeutic agents – may represent a quantum leap in pharmacotherapy.[65] Slight modifications can significantly alter the pharmacological properties of a drug, thus markedly increasing the therapeutic benefits for users.[66]

While radical innovations exhibit a greater degree of novelty than incremental innovations, they may still have weaknesses which affect their risk profile. Certain findings concerning product safety – such as rare, but serious adverse events – only become apparent when drugs are used in larger patient populations, i.e. after marketing authorisation has been granted. With incremental innovations, it may be possible for the properties of a drug to be gradually optimised, yielding clinically relevant improvements.

Not always readily distinguishable from incremental innovations are pseudo-innovations – "me-too" products where the actual degree of novelty is often very limited[67] and which are introduced in order to gain a share of the market. However, according to the German Pharmaceutical Society (DPhG), most of today's best-known drugs arose through incremental innovations.[68]

In the case of medicinal products and medical devices, radical innovations are frequently only recognisable as such in retrospect – on the basis of broader therapeutic evidence and experience in daily practice. This poses challenges for the scientific assessment of the degree of innovation of new products prior to marketing.

This is significant because the assessment of the degree of innovation is linked to the setting of prices for medicinal products and medical devices, or reimbursement under a social insurance system.[69] How the various types of innovation are to be assessed is a frequent topic of political and scientific debate both in Switzerland and abroad.[70]

---

65 Deutsche Pharmazeutische Gesellschaft, Kriterien für die Beurteilung von Arzneimittelinnovationen (position paper), 2005, p. 11

66 Ibid., pp. 13ff.

67 Springer Gabler Verlag (Herausgeber), Gabler Wirtschaftslexikon, "Innovationswettbewerb", available online at: http://wirtschaftslexikon.gabler.de/Archiv/54722/innovationswettbewerb-v5.html

68 Deutsche Pharmazeutische Gesellschaft, Kriterien für die Beurteilung von Arzneimittelinnovationen (position paper), 2005, p. 15

69 Under the Health Insurance Ordinance (KVV, SR 832.102), an innovation premium may be granted when maximum reimbursement prices are set for drugs. The therapeutic advance or added value is to be justified on the basis of clinical trials. In general, an innovation premium of no more than 20% is granted.

70 Cf. Deutsche Ärzte Zeitung, "Was als Innovation gilt, wird zur politischen Frage: Sprung-, Schritt oder Scheininnovation – was als medizinischer Fortschritt beim Patienten ankommt, wird nicht mehr nur in Labors entschieden", no. 111, 19 June 2008; or Albert Wertheimer, Richard Levy and Thomas O'Connor, Too many drugs? The clinical and economic value of incremental innovations, in: Irina Farquhar, Kent Summers, Alan Sorkin (ed.) Investing in Health: The Social and Economic Benefits of Health Care Innovation, Vol. 14, pp. 77–118, 2001, Elsevier Science Limited

3.3 From idea to innovation – the importance of the demand side

However important intellectual property protection may be in stimulating R&D activities, patents are granted for inventions, the precursors of innovations. One can only speak of an innovation when, for example, a product is mass-produced and becomes well established on the market. This explains the importance of product market regulation in relation to the promotion of innovation. With regard to biomedical research and technology, two types of regulation apply.

Firstly, there are the legal provisions designed to protect the health and dignity of humans and animals – in particular, the Therapeutic Products Act, the Human Research Act, the Transplantation Act, the Human Genetic Testing Act and the Stem Cell Research Act. These regulate, in one way or another, market access for new products and techniques, i.e. the supply side.[71]

At the same time, regulations are in place to ensure that patients can cope with the financial consequences of using medical services. Among the demand-side regulations is the Health Insurance Act.[72]

The Federal Council has defined its health policy priorities for 2013–2020 in the "Health2020" agenda.[73] To meet the challenges of the coming years, action is to be taken in the following areas: "Ensuring quality of life", "Reinforcing equality of opportunity and individual responsibility", "Safeguarding and increasing the quality of health care provision" and "Creating transparency, improving control and coordination"(cf. the discussion in Chapter 6).

[71] The Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA, SR 812.21) is intended to protect human and animal health by ensuring that only high-quality, safe and effective therapeutic products are placed on the market.
The Federal Act on Research Involving Human Beings (Human Research Act) is intended to protect the dignity, privacy and health of human beings involved in research. It is also designed to create favourable conditions for research involving human beings, help to ensure the quality of such research and ensure the transparency of such research. It comes into effect on 1 January 2014.
The Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Transplantation Act, SR 810.21) specifies the conditions under which it is permissible for organs, tissues or cells to be used for transplantation purposes.
The Federal Act of 8 October 2004 on Human Genetic Testing (HGTA, SR 810.12) is designed to protect human dignity and personality; to prevent improper genetic testing and the improper use of genetic data; and to ensure the quality of genetic tests and the way their results are interpreted.
The Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA, SR 810.31) specifies the conditions under which it is permissible for human embryonic stem cells to be derived from surplus embryos and used for research purposes.

[72] Federal Act of 18 March 1994 on Health Insurance (KVG, SR 832.10)

[73] Health2020 is an overview of the priorities which have been set in the field of health policy in Switzerland. The Federal Council's report describes 36 measures in four priority areas for health-policy action which will be gradually implemented. They are directed at achieving a total of twelve objectives and are intended to align the proven Swiss health system optimally with current and future challenges. The Health2020 report was approved by the Federal Council on 23 January 2013 (www.bag.admin.ch/gesundheit2020/index.html?lang=en).

3.4 Conflicting goals between innovation promotion and product market regulation

The specific form taken by property rights and product market regulation has a direct influence on the development of innovations. Economists assume that the more extensively property rights are protected, and the less product and process markets are regulated, the more innovation activity will be stimulated.[74] It should, however, be noted that intellectual property protection and product market regulation serve different goals. Effective regulation will thus depend on a careful weighing-up of the goals in question.

With regard to patent protection, for example, an optimum exists between lengthy, comprehensive protection, emphasising the long-term growth effects of innovation, and very limited protection, aimed at promoting intense competition and low prices. The currently applicable 20-year period, together with the possibility of a supplementary protection certificate, appears to be an internationally accepted solution which is good for the economy as a whole.[75]

As regards product market regulation, all countries regulate market entry for biomedical products and techniques, e.g. for medicinal products and medical devices. These regulations are based on the ICH Guidelines,[76] taking national circumstances into account. For patients, an effective and efficient authorisation and market surveillance system ensures that products and techniques coming onto the market are of high quality, safe and effective. Suppliers benefit in two ways: firstly, this represents an official quality label and, secondly, national recognition also contributes to the exportability of new products.

The goal of maintaining or establishing the best possible framework for biomedical research and technology is thus subject to tensions between, on the one hand, supporting innovation activity via input- (e.g. public funding for research) and output-oriented incentives (e.g. patent protection) and, on the other, protecting the demand side through regulation of the products supplied,[77] while also ensuring willingness to pay on the part of social insurance organisations. In general, the aim of product market regulation is to secure affordable public supplies of high-quality, safe and effective biomedical products and techniques – in particular, therapeutic products.

In the literature, with regard to conflicting goals, reference is also made to the different weighting of short- and long-term effects: relatively rigid patent protection emphasises innovation effects and thus long-term growth effects (so-called dynamic efficiency), while more limited patent protection attaches greater weight to short-term price effects (static efficiency). The greater the emphasis on short-term price effects, the more rapidly consumers will benefit from innovations. It is argued that, from a politico-economic perspective, efforts in recent years to loosen patent protection can be attributed to the desire to achieve short-term price effects.[78]

According to an alternative explanation, society is now less prepared – on the basis of a monopoly granted to a patent holder for a limited period by the state – to pay substantially higher prices for drugs whose innovativeness cannot be immediately assessed and is sometimes a matter of scientific dispute. The risk-benefit ratio (or risk-cost ratio) only becomes apparent – and hence the degree of innovation can only be determined – on the basis of broader therapeutic evidence

[74] Cf. also the discussion in Plaut Economics, Innovation und der Einfluss der Regulierung (study commissioned by Interpharma), 2007, p. 5

[75] Ibid., p. 46; cf. the discussion in Section 9.2

[76] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (http://www.ich.org/)

[77] For example, medicinal products and medical devices must be clinically tested before – on the basis of specific manufacturing requirements – they can be approved by the drug regulatory authorities or receive a certificate of conformity from an assessment body.

[78] Plaut Economics, Innovation und der Einfluss der Regulierung (study commissioned by Interpharma), 2007, p. 8. Cf. also the literature cited therein.

and experience in daily practice – i.e. after marketing authorisation and the decision on reimbursement under mandatory health insurance.[79]

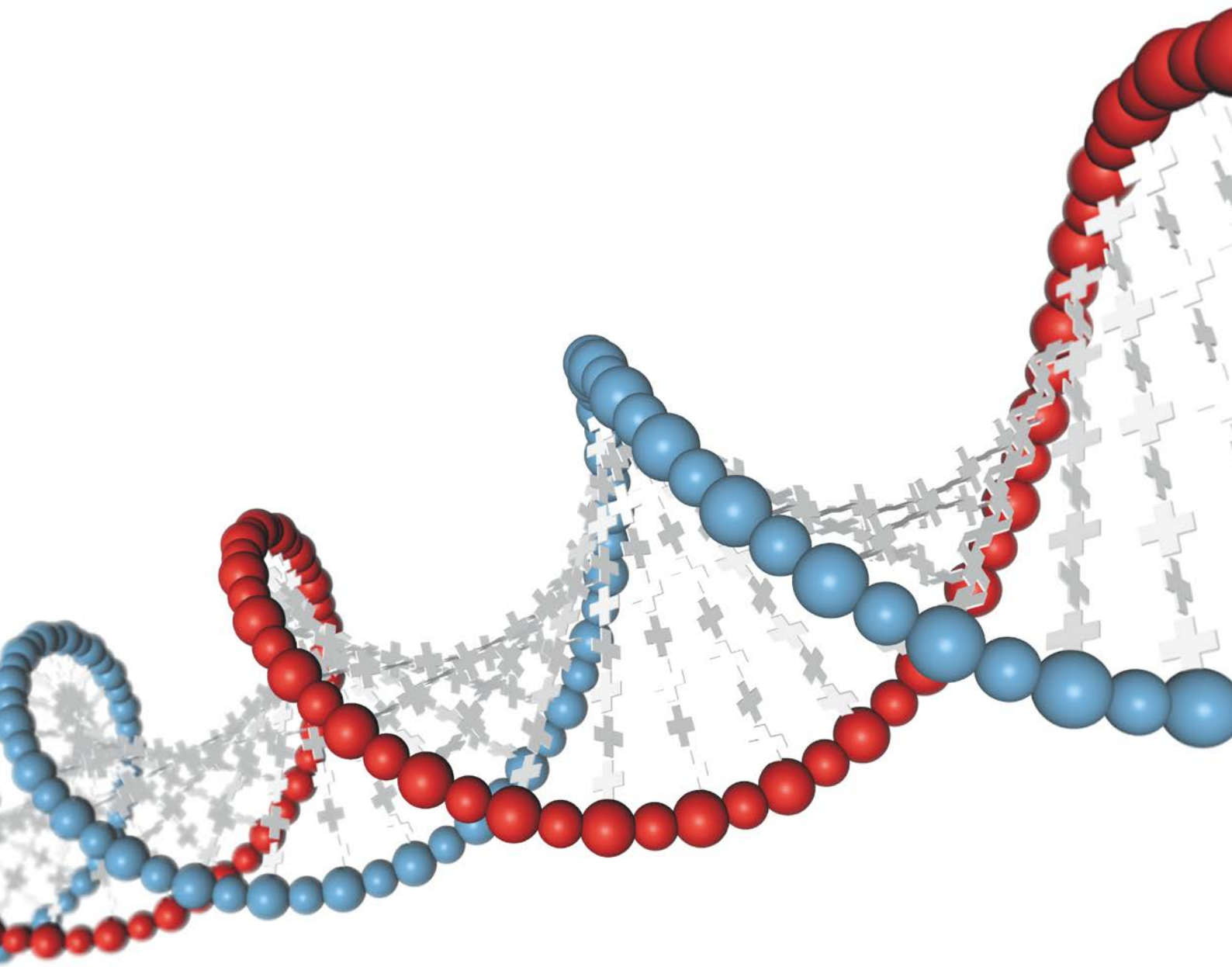
In this situation, as mentioned above, most countries ensure the protection of intellectual property by granting patent protection for a number of years, although the scope and duration of this protection is limited. At the same time, the state intervenes by setting reimbursement prices (in the form of fixed amounts or maximum prices, combined with repayment obligations and periodic reviews) and requiring patients to share costs (e.g. in the form of different co-payment levels).[80]

[79] A case in point is the active substance tolcapone. In 1997, it was introduced by Hoffmann-La Roche (as Tasmar) on the European market for the treatment of Parkinson's disease. A year later, the marketing authorisation was suspended by the European regulatory authority (EMEA) following the occurrence of severe liver toxicity. Since 2004, Tasmar (Meda AB) has been authorised again subject to strict conditions (regular liver function tests).

[80] Cf. the discussion in Section 8.2

4 THE INFLUENCE OF THE FEDERAL GOVERNMENT ON CHOICE OF LOCATION

This chapter examines how the state can influence the promotion of innovation and the choice of location, focusing in particular on the role of the federal government.



4.1 Company-related factors

The decision to maintain or abandon a location may be influenced by operational considerations, such as a company's intention to enter new markets or restructure distribution networks, differences in cost structures, mergers with other companies, acquisitions, and organisational or procedural adjustments. In the biomedical research and technology sector, functional mobility is frequently encountered in companies with international operations – production in China, IT management in India, research activities in the US and corporate headquarters in Switzerland.[81]

4.2 Local, regional and national location factors[82]

For biomedical research and technology, in addition to company-specific considerations, the following location factors are relevant:

Local and regional factors[83]	Supraregional or national factors
• General living conditions • Educational facilities • Clusters and technology parks • Funding opportunities (e.g. provision of venture capital)[84] • Research institutions • Research-focused industries and technology companies • Geographical situation • Public infrastructure • Skilled workforce • Knowledge transfer (e.g. from basic to applied research) • Suppliers	• General economic polic (e.g. employment, foreign economic, fiscal policy) • Education and research policy • Health policy (product market regulation) • Political stability and effective institutions • Intellectual property protection

Table 4: Selection of local, regional and national location factors

81 Cf. also the discussion of choice of location with reference to German companies in: Jens Deuster, Internationale Standortverlagerungen deutscher Unternehmen – Systematisierung – Bestimmungsfaktoren – Auswirkungen, Deutscher Universitätsverlag, Gabler Verlag, Springer, 1996

82 Accounts of cantonal efforts are to be found in reports by the relevant authorities, e.g. Cluster report 2009–2010 – Sector diversity for a strong business location – Activities of the Office for Economic Development of the City of Zurich and of the Division of Business and Economic Development of the Canton of Zurich, 2011.

83 The BAK Basel Life Sciences Report (www.BAKBasel.ch) assesses the impact of these factors on various regional locations of the life sciences industry, which comprises the pharmaceutical, agrochemical and medtech sectors (including R&D in each case). For Switzerland, the major regional centres in question are Basel, Zurich and the Geneva region. The attractiveness of locations is assessed in terms of performance capabilities and framework conditions. According to the authors, the performance capabilities have a substantial influence on the prosperity and attractiveness of a region and on the affluence of the population. The (local) framework conditions for a given industry are crucial for the establishment and development of companies in the region. They are largely determined by political decisions.

84 Various studies have examined the importance of venture capital. They conclude that venture capital backing for start-ups has a positive influence on innovativeness, speed of product launches and professionalisation of management. As well as funding, the involvement of venture capital companies provides start-ups with valuable management and industry expertise and access to networks. In addition, it has been shown that the implementation of innovations in products is improved by the availability of venture capital, which in turn also promotes growth in economic productivity and the transmission of innovations. Cf. the discussion in: Pascal Gantenbein, Nils Herold and Simon Zaby, Die KTI-Start-up-Förderung für innovative Schweizer Jungunternehmen – ein empirischer Vergleich gelabelter und nichtgelabelter Unternehmen (study commissioned by the CTI), Basel University, 2011.

4.3 Effects of federal measures

Here, the effects of federal measures on innovation activity and choice of location are to be examined.

Political stability, effective institutions and general economic policy (e.g. competition or tax policy) are acknowledged to have a major influence on business activity, and in particular on choice of location. These factors are not considered in detail here, as they are generally beneficial for the economy as a whole.

With regard to the other factors, the framework established by the federal government in the following policy areas can have a positive (+) or negative (–) influence on innovation in biomedical research and technology, and possibly also on choice of location:

Policy area…	influences…		Selection of federal instruments
	Innovation	Choice of location	
Education and research policy			
Education and training, continuing education	+	+	Health Care Professions Act[85]; FIT Act[86] UAS Act[87]
Legality of research	+/–	+/–	Human Research Act; Gene Technology Act[88] Stem Cell Research Act, Animal Protection Act[89]
Structural framework	+	+	Research and Innovation Promotion Act[90]
Health policy			
Market entry	+/–	+/–	Therapeutic Products Act, Transplantation Act Human Genetic Testing Act
Reimbursement system	+/–	+/–	Health Insurance Act
Intellectual property protection	+	?	Patents Act[91], data exclusivity[92]

Table 5: Influence of various policy areas on innovation and choice of location

85 The Federal Act of 23 June 2006 on University-Level Health care Professions (Health Care Professions Act, SR 811.11), in the interests of public health, promotes the quality of university education, professional training and continuing education and of professional practice in the fields of medicine, dentistry, chiropractic, pharmacy and veterinary medicine, and ensures freedom of movement throughout Switzerland for health care professionals.

86 The Federal Act of 4 October 1991 on the Federal Institutes of Technology (FIT Act, SR 414.110) specifies, inter alia, that the FIT and the affiliated research institutes are to educate students and specialists in scientific and technical fields and ensure continuing education and training, to expand scientific knowledge through research, to foster junior scientific staff, and to provide scientific and technical services.

87 The Federal Act of 6 October 1995 on Universities of Applied Sciences (UAS Act, SR 414.71) promotes the establishment and development of universities of applied sciences, e.g. in the life sciences field.

88 The Federal Act of 21 March 2003 on Non-Human Gene Technology (Gene Technology Act, GTA, SR 814.91) is designed to protect human beings, animals and the environment from abuses of gene technology and to serve the welfare of human beings, animals and the environment in the application of gene technology.

89 SR 455

90 With the Federal Act of 7 October 1983 on the Promotion of Research and Innovation (Research and Innovation Promotion Act, SR 420.1), the federal government seeks to promote scientific research and science-based innovation and to support the evaluation and exploitation of research findings; to monitor and, if necessary, regulate the cooperation of research bodies; and to ensure the efficient use of federal funds for research and innovation (cf. the discussion in Section 7.3).

91 Federal Act of 25 June 1954 on Patents for Inventions (Patents Act, PatA, SR 232.14).

92 Cf. also the discussion in Section 9.2

Underlying the potential influence are the following considerations:

4.3.1 Education and research policy

Education and research play a crucial role in the generation, dissemination and use of knowledge, providing a basis for innovation at all levels. At the same time – as discussed in Chapter 2 – research is of central importance not only for individual and public health, but also for the economy, and for education and training in the health system. In view of this significance, particular attention is to be paid to the potential influence of the federal government.

Education policy

Education policy has a sustained positive influence on innovation and growth[93] via its effects on the education and training of the people involved in the innovation process. At the same time, there has been a marked increase in the (international) mobility of specialists; consequently, while a sound education policy is a prerequisite for innovation, it cannot guarantee that skilled workers will not move abroad. It must be combined with a research policy which helps to attract and retain the best researchers. Given these considerations, most governments of OECD countries rate education, research and innovation as a priority policy area.

Responsibility for Switzerland's education system is divided between the federal government and the cantons.[94] Since 2006, on the basis of a new constitutional article, these partners, within the scope of their powers, have jointly sought to ensure the high quality and accessibility of the Swiss Education Area.[95]

Legal framework for research

A major influence is also exerted by the legal framework for research. A ban on research prevents innovation activity in the area concerned. The laws in question steer a course between research friendliness on the one hand and protecting the health and dignity of humans and animals in research on the other.

Essentially, the freedom of scientific teaching and research is guaranteed under Article 20 of the Federal Constitution. Activities in key areas of biomedical research and technology are regulated at the federal level in Switzerland – research involving human beings in Article 118b of the Federal Constitution, reproductive medicine and gene technology involving human beings in Article 119, transplantation medicine in Article 119a, non-human gene technology in Article 120, and animal research in Articles 80 and 120. Medically oriented research enjoys broad public acceptance in Switzerland: accordingly, the constitutional article on human research was approved by 77.2% of voters in 2010, the constitutional article on transplantation medicine by 87.8% in 1999, and the Stem Cell Research Act by 66.4% in 2004. This generally positive attitude towards biomedical research and technology is an important requirement for the establishment of an attractive research location.

The extent to which research is regulated varies. The Human Research Act, for example, recognising the increasingly international nature of research, is based on international guidelines and exhibits a degree of regulation comparable to that in other countries.[96] By contrast, the regulation of research involving embryonic stem cells has a strong national orientation: while China, Scandinavia, Anglo-Saxon countries (e.g. Australia, the UK and the US), and Belgium and the

[93] Cf., for example, J. L. Furman, M.E. Porter and S. Stern, The determinants of national innovative capacity, Research Policy 31, pp. 899–933, 2002

[94] Cf. Federal Council Dispatch of 22 February 2012 on the Promotion of Education, Research and Innovation for the period 2013–2016, BBl 2012 3099

[95] Art. 61a of the Federal Constitution, SR 101; cf. also the discussion in Section 7.4

[96] Cf. also the discussion in Section 7.2

Netherlands have a liberal research regime, Switzerland, together with Denmark, France, Israel and India, occupies an intermediate position. The regulations existing in Germany and Italy are perceived as restrictive.[97]

Structural framework
As regards the structural framework for research, the federal government is responsible for the financing of the ETH domain and the promotion of research and innovation by the SNSF and the CTI. If necessary, it can also provide support for non-university-based research institutions and infrastructure and technology competence centres. The cantons contribute primarily by supporting the universities. However, the majority of R&D and innovation is carried out and financed by the private sector, with the pharma and biotech industries predominating in Switzerland. Equally important are the efforts undertaken abroad by Swiss-based multinational corporations.[98]

4.3.2 Health and social policy

With regard to both market entry and the reimbursement system, federal measures have effects at two different levels.

Specification and implementation of requirements for market entry and reimbursement
The more stringent the regulatory requirements that have to be met to secure marketing authorisation for a product or technique, the safer the products will be. This amounts to an official quality label with positive implications for health professionals and patients; at the same time, however, the costs involved in demonstrating quality, safety and efficacy may deter (smaller) companies from commercialising innovations. Depending on their extent, regulations concerning authorisation will tend either to promote or to inhibit innovation. This is essentially also true of decisions concerning reimbursement: the higher the reimbursement price for the company and the greater the degree of coverage, the more attractive the market for (potential) innovations.

As regards the requirements for the authorisation of medicinal products, Swiss regulations are based on the ICH guidelines applicable in major OECD countries. In the case of medical devices, uniform requirements apply for marketing in Switzerland and in other European countries. Legislation for product market regulation is thus designed to establish product safety requirements comparable to those existing in other countries.[99] Reimbursement systems are generally in line with the social policy of the country concerned, although international price benchmarking often forms part of the price-setting process.[100]

Efficient and effective implementation of requirements has a positive influence on innovation: there is thus a need for marketing authorisation and reimbursement systems which deliver coherent, transparent and consistent decisions as rapidly as possible. Accordingly, an important role is played by the quality and duration of procedures.

Health and social policy also have an influence on choice of location: if a company decides to place a product on the market in Switzerland, approval must be granted by the authorities. This requires that the manufacturer, or a distributor appointed by the manufacturer, be domiciled in Switzerland, which may in turn have a positive effect on companies' choice of location. Since medicinal products and medical devices are only eligible for reimbursement by health insurers if they are marketable in Switzerland, social insurance legislation also indirectly influences compa-

97 Landert + Partner, Stammzellenforschungsgesetz (StFG) – Externe Evaluation, 2011 (www.bag.admin.ch)

98 Federal Council Dispatch of 22 February 2012 on the Promotion of Education, Research and Innovation for the period 2013–2016, p. 3317; cf. the discussion of the structural framework for publicly funded research in Section 7.3

99 Cf. the discussion in Section 8.1

100 Cf. the discussion in Section 8.2

nies' choice of location, particularly since products have to be promoted to health professionals.

In practice, however, the decision to market an innovation in the country provides no guarantee that the products will actually be manufactured in Switzerland. As already discussed, the choice of location for production will be mainly based on local and regional factors, such as suppliers, communication infrastructure, availability of staff and logistical considerations concerning the region to be supplied.

Effects of regulation in Switzerland and abroad

A country's product regulation is generally concerned with the domestic market, as it can only be enforced there. The smaller the country, the smaller the market, and the more likely it is that companies' business decisions will be influenced by product market regulations. Both the companies concerned and regulators will seek to increase the size of the potential market.

Companies will do so by seeking to persuade other countries to recognise Swiss marketing authorisations or reimbursement prices – in one form or another – as a benchmark. For example, Switzerland serves as a reference country for numerous African, Latin American, Eastern European, East and Southeast Asian countries. These countries use a simplified registration procedure if authorisation has already been granted by one or more reference countries. Since October 2012, Mexico has unilaterally recognised Swissmedic authorisations for innovative medicinal products.[101]

Swiss regulators, for their part, will take into account the results of tests carried out in a country with a comparable regulatory system if a medicinal product submitted for registration is already authorised in that country.[102] In addition, under bilateral agreements, information is exchanged between the Swiss Agency for Therapeutic Products and the regulatory authorities in Australia, Brazil, Ireland, Japan, Canada, New Zealand, Singapore and the US. A similar agreement exists with the Paul-Ehrlich-Institut in Germany.

[101] As evidence of regulatory approval in the country of origin, third-country authorities request a so-called Certificate of a Pharmaceutical Product (CPP). Since 2010, Swissmedic has issued such certificates for around 120 countries.

[102] Article 13, Therapeutic Products Act

In the setting of reimbursement prices for medicinal products, comparisons are also frequently made with other countries. The case of Europe is illustrated in the following Figure:

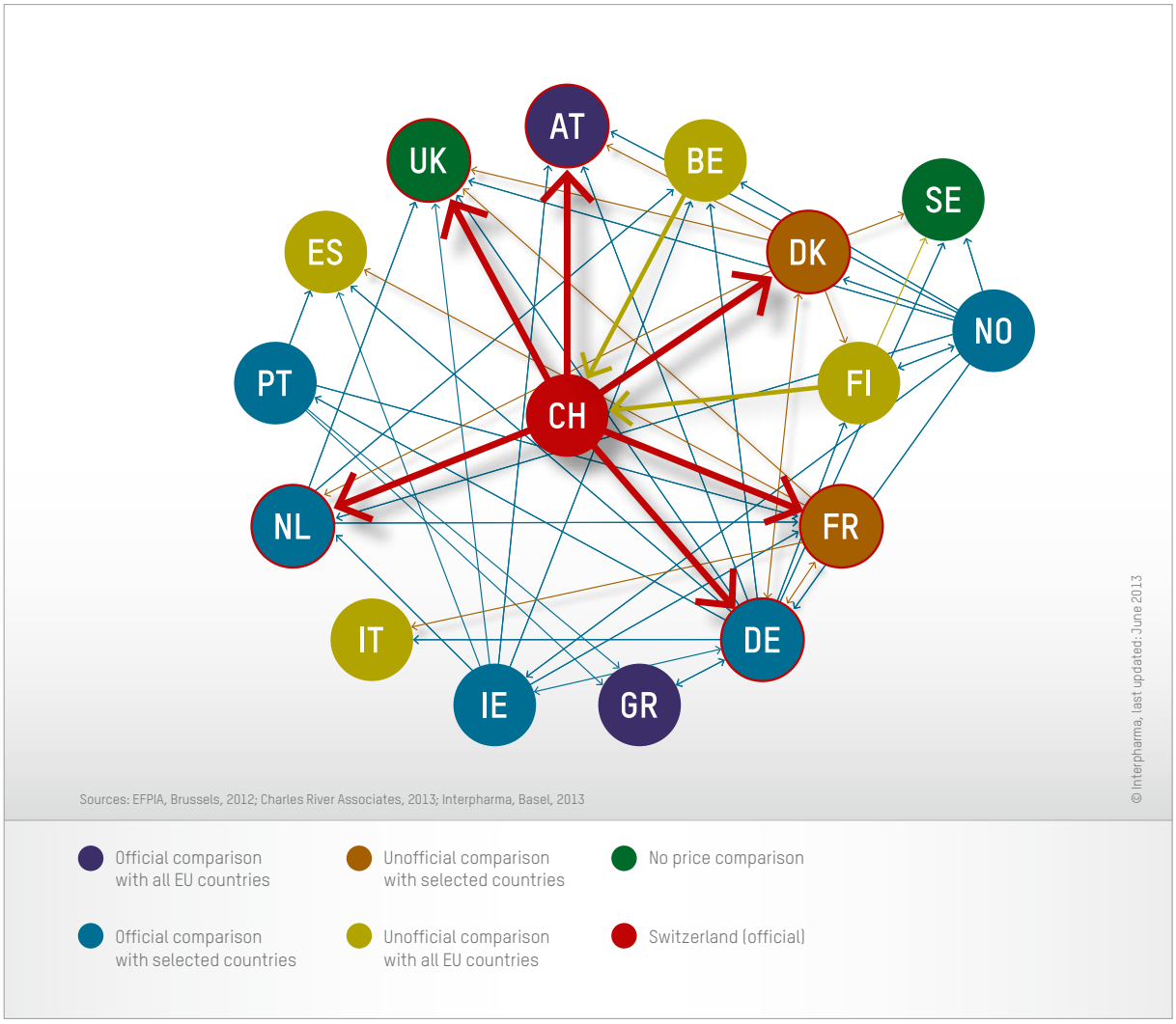


Figure 3: Price comparison systems in Europe[103]

Consequently, national price setting has an international impact, as shown in a study commissioned by Interpharma and Novartis,[104] which takes Switzerland as an example. According to this study, a 10% price reduction in Switzerland would reduce global industry revenues by CHF 1.1 billion, with Switzerland accounting for around half of this total (CHF 515 million), industrialised countries a third (CHF 394 million) and emerging economies about a tenth (CHF 123 million).

As regards medical devices, Switzerland is fully integrated into the European market entry and market surveillance system for medical devices[105] – and thus an internal market with 510 million consumers.[106]

[103] EFPIA, 2012; Charles River, 2013; Interpharma, 2013 (www.interpharma.ch)

[104] Tim Wilsdon, Eva Fiz and Hugh Kirkpatrick, The international impact of Swiss drug regulation (study on behalf of Interpharma and Novartis), Charles River Associates, 2013

[105] Agreement of 21 June 1999 between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (Mutual Recognition Agreement, MRA)

[106] Source: Eurostat, 2013; reference date: 1 January 2012

4.3.3 Intellectual property protection

The importance of intellectual property protection in the promotion and marketing of innovation has already been discussed.[107] Less clear, however, are its effects on the choice of location for research.[108] In Italy, according to the literature, the strengthening of patent protection in 1978 did not lead to an increase in research activity.[109] Positive effects on innovation activity were however observed in Japan[110] and Canada, although in Canada the impact is also attributable to the public commitment of pharmaceutical manufacturers to raise the ratio of R&D spending to sales.[111]

4.4 Summary and conclusions

In the context of biomedical research and technology, innovation is a key concept.

As conventionally understood, an invention only becomes an innovation when it is successfully marketed as a product or service. Product market regulation – as well as intellectual property protection and education and research policy – is therefore of major importance in the promotion of innovation.

In education and research policy, which has a substantial positive influence on innovation and on the attractiveness of a location, management responsibilities are shared between the federal government and cantons, with higher education institutions enjoying extensive autonomy in research and teaching. But improvements in the general framework can only be achieved if the federal government, cantons and higher education institutions pursue a coordinated policy.

The federal government largely regulates the supply and the demand side of biomedical product markets, although primary responsibility for health care rests with the cantons. State intervention – depending on its nature and extent – can have positive or negative effects on innovation and hence on growth. Accordingly, a long-term health strategy based on clearly defined goals – such as the Federal Council's "Health2020" agenda – is of crucial importance, providing clarity and guidance for private-sector investment decisions.

The federal government can exert the most direct influence on intellectual property protection, as it has sole responsibility for regulation in this area. With appropriate protection in place, suppliers of innovative products can be induced to enter the market. To what extent this is associated with decisions in favour of a research location remains unclear on the basis of international experience.

[107] Cf. also Furman et al., The determinants of national innovative capacity, Research Policy 31, 2002

[108] For a comparison of 177 policy changes across 60 countries over a 150-year period, see: J. Lerner, Patent protection and innovation over 150 years, NBER Working Paper, 2002

[109] S. Weisburst and F. M. Scherer, Economic effects of strengthening pharmaceutical patent protection in Italy, International Review of Industrial Property and Copyright Law 26, pp. 1009–1024, 1995

[110] A. Kawaura and S. La Croix, Japan's shift from process to product patents in the pharmaceutical industry: an event study of the impact of Japanese firms, Economic Inquiry 33(1), pp. 88–103, 1995; L. Branstetter and M. Sakakibara, Do stronger patents induce more innovation? Evidence from the 1988 Japanese patent law reforms, Department of Social and Decision Sciences. Paper 45, 2001

[111] B. Pazderka, Patent protection and pharmaceutical R&D spending in Canada, Canadian Public Policy 25(1), 1999

In the light of the above, the following conclusions can be drawn:

Education, research and health policy – as well as general economic policy – influence the framework for biomedical research and technology. They are therefore to be viewed in the context of overall efforts to improve the country's attractiveness as a location.

– These policies – and health policy in particular – are not only aimed at establishing and maintaining the best possible framework for biomedical research and technology but also serve other goals, such as security of supplies, distributional equity, or protection of the health and dignity of humans and animals. This gives rise to conflicting goals, which have to be resolved through the political process.
– The goal of establishing and maintaining the best possible framework for biomedical research and technology can only be achieved by a package of measures, rather than by individual measures. These measures must be undertaken not only at the federal but also at the cantonal and communal level.
– One key prerequisite for innovation is the exchange of knowledge between private and public institutions in research and industry. Without such endeavours to promote closer collaboration among educational institutions, research groups, industry and investors, federal efforts to improve the country's attractiveness as a location will not be effective.[112]

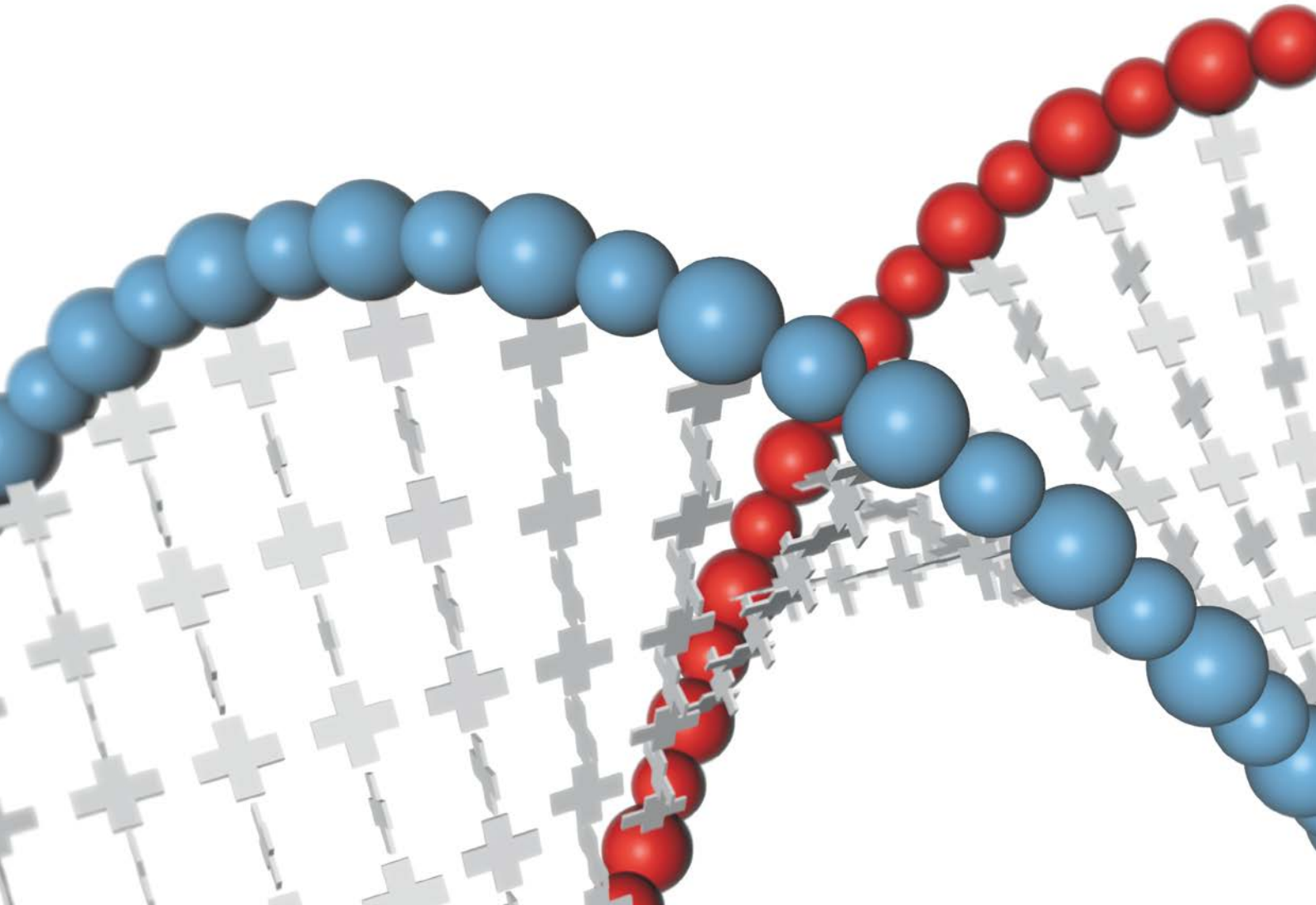
[112] The importance of such exchanges is emphasised by a wide variety of authors; see, for example, the discussions in: Medical Research: What's it worth? Estimating the economic benefits from medical research in the UK; for the Medical Research Council, the Wellcome Trust and the Academy of Medical Sciences, November 2008; or in: World Intellectual Property Organization (WIPO) / INSEAD, The Global Innovation Index 2013.

5 COMPETITION BETWEEN BIOMEDICAL RESEARCH AND TECHNOLOGY LOCATIONS

To assess Switzerland's previous efforts in this area, the country's attractiveness as a location for biomedical research and technology is to be subjected to an international comparison.

Particularly useful in this regard are studies which recognise the complexity of innovation and location quality. This involves taking numerous aspects into account, such as the design of private and public institutions, the development and use of human capital for research purposes, the translation of ideas into innovations, the design of incentives for innovation and their impact on output and, lastly, the capacity of sectors and markets to absorb innovations.

The following discussion focuses in particular on countries such as Germany, Singapore, the UK and the US, which are among Switzerland's main competitors, with their own pharmaceutical industry. As the various reports cited use different methods and criteria, the countries are compared with each other within the framework of each report. Conclusions are presented at the end of this chapter.



5.1 Global comparisons[113]

5.1.1 Global Innovation Index of WIPO/INSEAD

The Global Innovation Index (GII)[114] shows the relative position of 142 countries for five "input pillars" – Institutions, Human capital and research, Infrastructure, Market sophistication and Business sophistication – and for two "output pillars" – Creative outputs and Knowledge and technology outputs – on a scale of 0 to 100, comprising a total of 84 individual indicators.

In 2013, the top-ranked country was Switzerland, followed by Sweden, the UK, the Netherlands and the US. Singapore, a major competitor in biomedical research and technology, was in 8th place (having come 3rd in the previous year's rankings).

The following Figure shows how Switzerland compares with Germany, Singapore, the UK and the US for 2013:

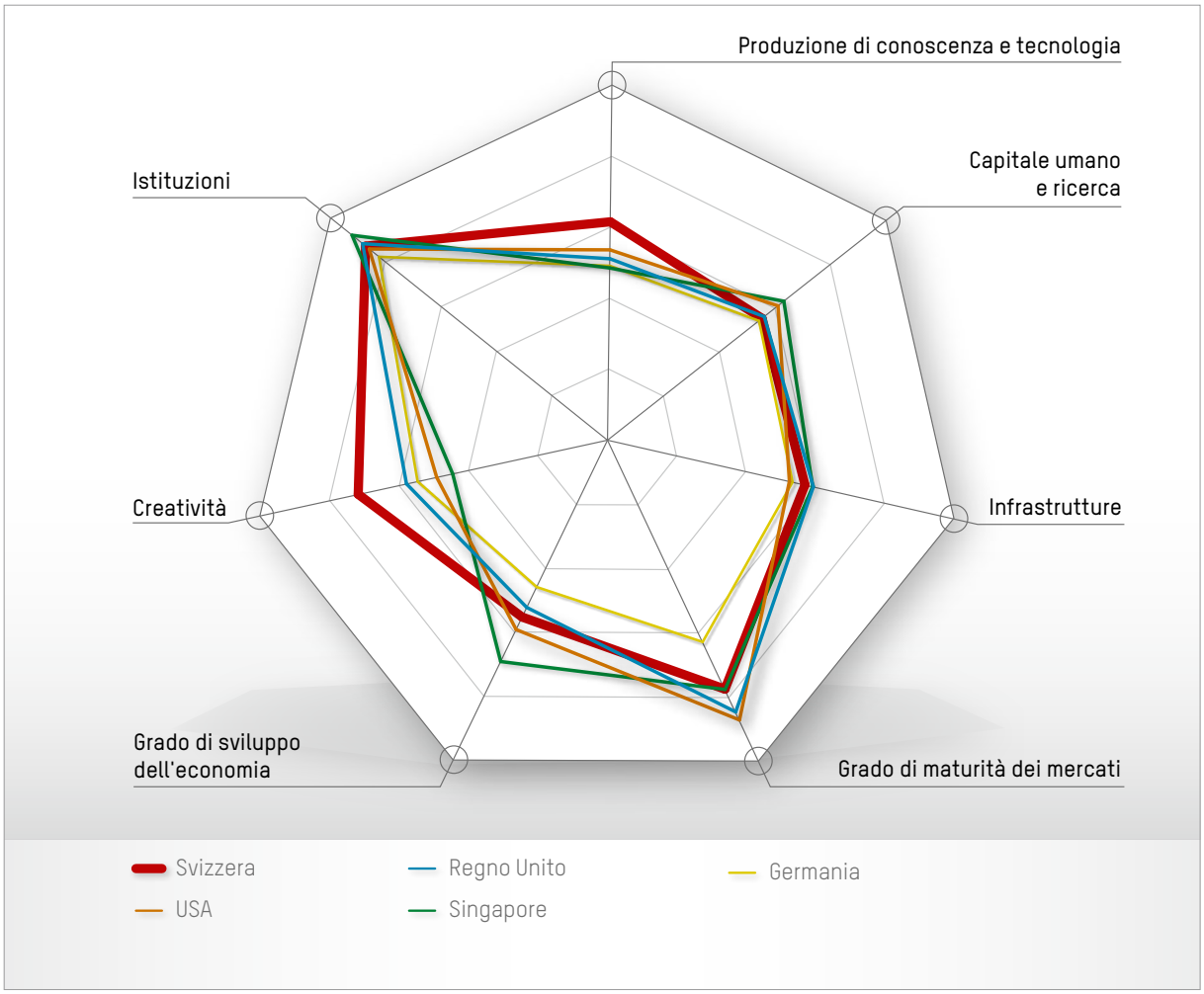


Figure 4: Comparison of five locations based on the Global Innovation Index 2013[115]

[113] The indices are subject to regular adjustments to the composition of the indicators, which can lead in the short run to changes in the rankings of individual countries for methodological reasons.

[114] World Intellectual Property Organization (WIPO) / INSEAD, The Global Innovation Index 2013 (http://www.globalinnovationindex.org/content.aspx?page=gii-full-report-2013)

[115] On a scale from 0 to 100

A. SWITZERLAND

Switzerland has managed to improve considerably its position among the leaders since 2009 – when it was in 9th place – and to maintain its top ranking since 2011. It shows a high level of achievement on the two sub-indices Innovation Input (7th worldwide) and Innovation Output (1st).

According to the authors of the study, Switzerland exhibits a very high Innovation-Efficiency Ratio (12th worldwide, 3rd among high-income economies[116]) and – measured by GDP per capita – it is among the world's leading efficient innovators, along with Sweden, Finland, the Netherlands and the UK. [117] Also among the innovation leaders are countries such as Singapore and the US, which, however, have a lower Innovation Efficiency Ratio. Innovation leaders are said to have "succeeded in creating well-linked innovation ecosystems where investments in human capital thrive in fertile and stable innovation infrastructures to create impressive levels of innovation outputs". For countries at this stage of innovation development, innovation capabilities and results stabilise at a high level in an equilibrium that is more the result of demographics, market size, and comparative advantages (services, trade, etc.) than of planned strategies; the challenge is to avoid the risk of an ever-shrinking scientific and creative community that could imperil future growth.

Switzerland's top ranking is attributable to factors such as the political (6th worldwide) and regulatory environment (2th), R&D efforts (9th), the quality of scientific institutions[118] (6th), the availability of knowledge workers (2nd), and knowledge creation (1st), impact (10th) and diffusion (5th). Switzerland is also the top-ranked country for university/industry research collaboration, which is important for the application of knowledge in practice. Among the key output indicators underlying the top ranking are the number of international patent applications (3rd worldwide) and scientific & technical articles (3rd), computer software spending (4th) and high-tech exports (7th).

Among the indicators where Switzerland achieves lower rankings are the ease of starting a business[119] (61st), the number of graduates in science & engineering (50th) and the ease of protecting investors (133rd). These indicators are also relevant for the biomedical research and technology sector – especially the number of graduates. Tertiary-level qualifications in the so-called MINT disciplines (mathematics, IT, natural sciences and technology) are considered important for the competitiveness of national economies, as they are prerequisites for the effective functioning of a research and innovation location.

Up until 2003, the percentage of degrees/diplomas awarded in natural sciences and engineering (higher education and higher vocational training) showed a slight downward trend. Since 2003, there has been an increase in qualifications in the MINT disciplines; since 2008, however, decreases have again been seen in individual subjects (IT, engineering and construction). At present – and according to forecasts – the number of MINT students is growing again, so that the number of degrees/diplomas awarded can be expected to increase within a few years.[120]

116 Behind Malta in 1st and Kuwait in 2nd place among high-income economies.

117 WIPO/INSEAD, The Global Innovation Index 2013, p. 24

118 Average score of the top 3 universities in the QS world university ranking

119 This is measured by the number of procedures required, the time required and the associated costs, based on the World Bank's Doing Business 2013 report (http://www.doingbusiness.org/data/exploreeconomies/switzerland). For example, the amount that an entrepreneur needs to deposit in a bank or with a notary before registration – recorded as a percentage of the economy's income per capita – is twice as high as in other OECD countries. This – together with the longer duration of the procedure – has an influence on the indicator.

120 Legislature Planning for 2011–2015, BBl 2012 524

B. GERMANY

Germany's strengths (the country is ranked 15th worldwide) lie – as is the case for Switzerland – more in Innovation Output (10th) than in Innovation Input (20th). Its strengths include not only knowledge creation (6th) and diffusion (20th) and creative outputs (14th) but also gross expenditure on R&D as a percentage of GDP (8th) and access to information & communication technologies (ICT, 5th). The country's weaknesses, according to the authors of the study, include innovation linkages (26th), gross capital formation as a percentage of GDP (112th) and the difficulty of starting a new business (53rd), although this indicator is correlated with economic and business cycles. As regards the Innovation Efficiency Ratio, Germany is ranked 9th among high-income economies.

C. SINGAPORE

Singapore (overall ranking: 8th) performs particularly well on the Innovation Input indicators (1st worldwide): compared with the other four locations under review (Germany, Switzerland, UK and US), the city-state is highly rated for the indicators "Business sophistication" (1st), "Human capital & research" (3rd) and "Institutions" (7th). Its strengths include not only tertiary education (1st) and a relatively high researcher headcount (7th) but also broad use of ICT (2nd), especially in dealings with official bodies. Singapore has an effective government (3rd) and offers an attractive regulatory environment (4th).

However, the favourable input indicators are not matched by the Innovation Output indicators (18th): deficiencies not so much in knowledge & technology outputs (11th) as in creative outputs (40th) mean that Singapore is ranked 121st worldwide for its Innovation Efficiency Ratio.

D. UK

The UK presents a balanced picture, ranking in 4th place for both Innovation Inputs and Outputs, and 3rd worldwide. Striking features include the quality of its top universities (1st), university/industry research collaboration (2nd), the citable documents H index (1st) and ICT & organisational model creation (1st). Conditions for companies are favourable as regards credit (2nd) and investment (3rd). The weaknesses identified include the growth of its labour productivity (127nd) and gross capital formation as a percentage of GDP (127th), as well as the conditions for access to foreign markets for non-agricultural products (102nd, common to all EU economies). Despite the balanced rankings for inputs and outputs, the UK is ranked 60th for its Innovation Efficiency Ratio.

E. US

The US is ranked 5th overall (86th for its Innovation Efficiency Ratio). Despite low per capita expenditure on education (48th) and a relatively low proportion of tertiary graduates in MINT disciplines (77th), the research landscape and associated availability of human capital are key to the innovative capacity of the US: like the UK, it offers a research-friendly climate (1st for R&D, 2nd for the quality of its top universities), which is reflected, for example, in knowledge creation (7th), the citable documents H index (1st), patent applications (13th) and university/industry research collaboration (3rd). Access to financial resources (4th for credit, 2nd for investment) ensures the realisation of new business models, leading in turn to payments of royalties and licence fees (13th). The high level of market and business sophistication (2nd for both) facilitate the application of knowledge in practice ("Knowledge & technology outputs": 7th).

5.1.2 Global Competitiveness Report of the World Economic Forum

Similar findings are contained in the Global Competitiveness Report 2013–2014[121] of the World Economic Forum (WEF), which compares 148 countries.

The 114 individual indicators are grouped into 12 "pillars of competitiveness": a solid institutional framework, a robust infrastructure, a favourable macroeconomic environment and a system ensuring good health and primary education are regarded as "basic requirements" for successful economies. Among the "efficiency enhancers"[122] are higher education and training, labour and goods market efficiency, financial market development, technological readiness and market size. The third subindex comprises the factors of business sophistication and innovation, to which a weight of 30% is attributed in the overall index.

The country profiles for Switzerland, Germany, Singapore, the US and the UK are as follows:

[121] The Global Competitiveness Report 2013–2014 (www.weforum.org/reports/global-competitiveness-report-2013-2014)

[122] In the overall index, a relative weight of 20% is attributed to the basic requirements subindex, and 50% to the efficiency enhancers subindex.

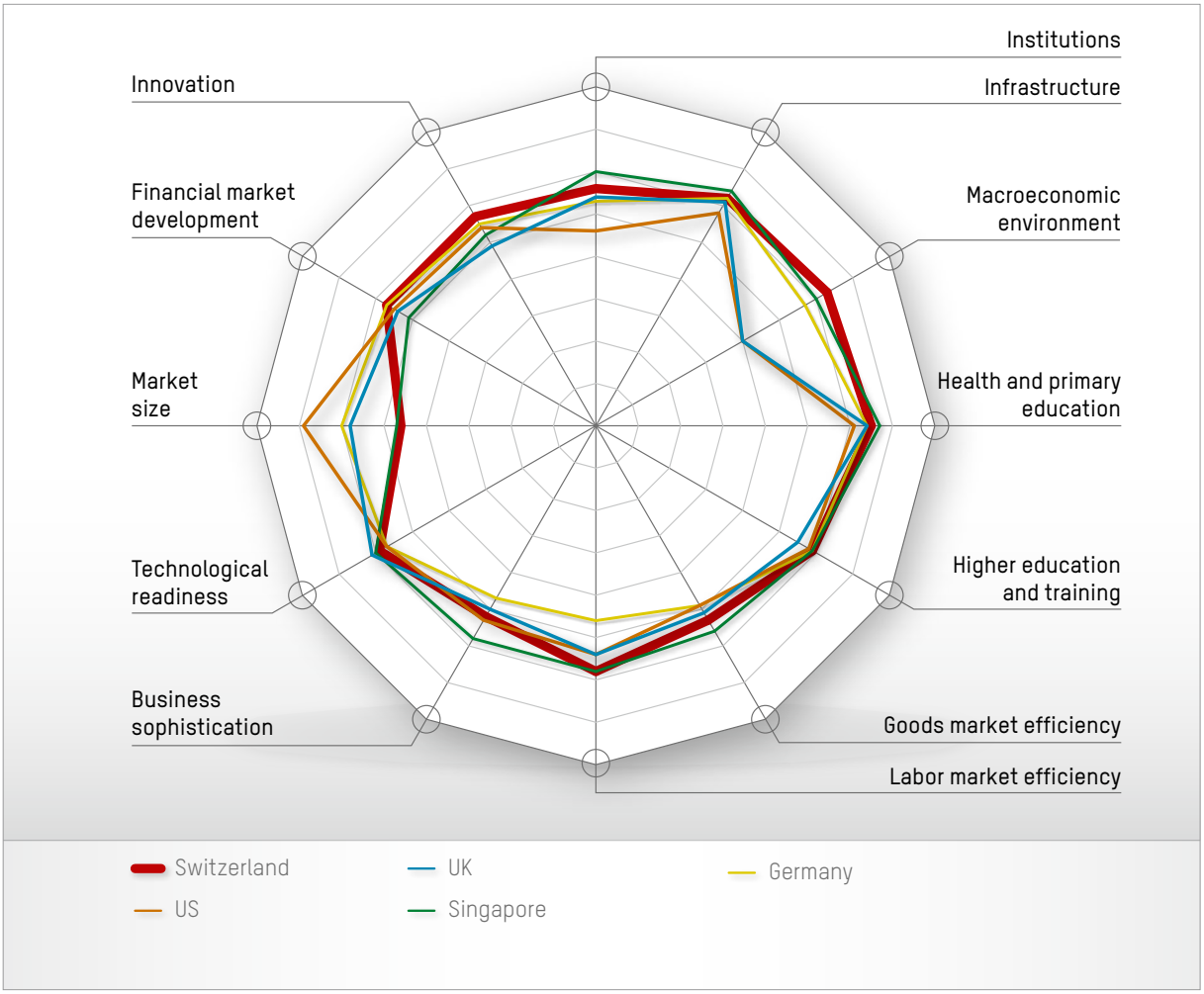


Figure 5: Comparison of five locations based on the Global Competitiveness Report 2013–2014[123]

A. SWITZERLAND

In this report, too, Switzerland is ranked in 1st place, on the basis of leading positions in innovation (1st worldwide), labour market efficiency (2nd), business sophistication (2nd) and higher education and training (4th). For market size, it is ranked 40th (of 148). With world-renowned scientific research institutions, close collaboration between the academic and business sectors, relatively high company spending on R&D and strong intellectual property protection, Switzerland successfully translates its research output into marketable products and processes. According to the authors of the report, the country's public institutions are among the most effective and transparent in the world (5th). Switzerland's competitiveness has been strengthened by the stability of the macroeconomic environment (11th) – benefiting from the early implementation of the "debt brake", with wide popular support – and also by its highly developed financial markets (11th). According to the authors, the country's innovative capacity needs to be maintained by enhancing the talent pool, which will require boosting the university enrolment rate and increasing the participation of women in the economy.

In addition, the authors conducted a survey involving around 15,000 business leaders (almost 100 per country). In the case of Switzerland, respondents expressed concerns over an "inade-

[123] Rated on a scale from 1 to 7

quately educated workforce" (15.4%), "inefficient government bureaucracy" (14.8%) and "tax regulations" (13.0%). The last two points are surprising, since in international comparisons they tend to be counted among Switzerland's strengths.

In a separate section,[124] the authors explore the question of how Switzerland has managed to maintain its extraordinary competitiveness levels for several years. The reasons cited are the robust innovative capacity, the business-friendly environment and the functioning of its institutions and political system (the involvement of stakeholders in political decision-making is mentioned as an example). Switzerland is described as a magnet for global talent, with an excellent education system and a flexible labour market. However, in view of the structural changes which the banking sector, for example, is undergoing, the report warns against complacency and against overregulation and protectionism.

B. Germany

Apart from higher education and training (5th), Germany's strengths include a relatively efficient goods market (21st), high-quality infrastructure (3rd) and a sophisticated business sector (3rd), especially in terms of production processes and distribution channels. Germany is ranked 4th worldwide and can benefit from a relatively large domestic market (5th). The country is ranked 4th for innovation, thanks to high private-sector spending on R&D and companies' ability to absorb the latest technologies (16th). The main weakness identified is the relatively rigid labour market (41st), where job creation is hindered by a lack of flexibility in wage determination and the high cost of firing. The authors see a need for further improvement in the quality of primary education (23th).

The business leaders surveyed saw room for improvement in tax regulations (19.0% of responses), restrictive labour regulations (15.6%) and tax rates (12.7%).

C. SINGAPORE

In this report, Singapore ranks 2nd worldwide for the third consecutive year and features in the top 3 countries for 7 of the 12 pillars. This is the result of leading positions firstly for "Basic requirements" (1st), where the quality of infrastructure (2nd), health and primary education (2nd), and public and private institutions (3rd) is consistently highly rated. Secondly, the city-state is among the leaders for "Efficiency enhancers" (2nd), such as higher education and training (2nd) and labour and goods market efficiency (1st). Clouding the picture is below-average (though improving) business sophistication (17th), as well as the capacity for innovation (9th), where 13.9% of the business leaders surveyed also saw a need for action. The only issues arousing greater concern were macroeconomic stability (inflation, 22.4% of responses) and restrictive labour regulations (22.8%).

[124] Switzerland: Five years at the top of the competitiveness rankings, in: WEF, The Global Competitiveness Report 2013–2014, pp. 13ff.

D. UK

According to the WEF report 2012–2013, an efficient labour market (5th worldwide) – contrasting with those of many other European countries – innovative (10th) and sophisticated businesses (8th) and a large domestic market (6th) have helped the UK (8th worldwide) to make up lost ground in the rankings. This is reflected by the recovery of the financial sector (13th). In view of the fiscal deficit in 2011 (9% of GDP), a high level of public debt (82.5% of GDP) and a comparatively low national savings rate (12.9% of GDP), the macroeconomic environment is said to represent the greatest drag on the country's competitiveness.

At the top of the list of business leaders' concerns are tax issues (tax rates for 15.3% of respondents and tax regulations for 10.2%).

E. US

Ranking in 5th place overall, the US has reversed the downward trend seen over the past few years. The WEF report acknowledges the quality of the country's scientific research institutions (5th), good university-industry collaboration (3rd), high availability of scientists and engineers (6th) and the productive and sophisticated private sector (6th), benefiting from a flexible and efficient labour market (4th) and a huge domestic market (1st). Less favourable, however, is the assessment of the institutional framework (35th) and the macroeconomic environment (117th), with uncertainties arising from the federal budget dispute and a perception of wasteful government spending (76th). Improvements are detected by the authors in the stability and efficiency of the financial markets (10th) and in the performance of the economy.

According to the business leaders surveyed, action is required on tax regulations (16.3% of responses) and tax rates (15.4%), as well as the "inefficient government bureaucracy" (14.0%).

5.2 Comparison of highly innovative European countries

5.2.1 Introduction

In an age of tight budgets, demographic change and increasingly intense global competition, the European Union has recognised that creating a more innovation-friendly environment makes it easier to turn ideas into products, services and processes, thus creating new jobs and safeguarding standards of living. For this reason, innovation was placed at the heart of the Europe 2020 strategy.

Under the Innovation Union initiative, investments in education, R&D, innovation and ICT are to be increased, and EU and national research and innovation systems are to be better linked up with each other. Education systems are to be modernised at all levels, and collaboration between researchers and innovators is to be improved. Further goals include affordable intellectual property rights, smarter and more ambitious regulation and targets, faster setting of interoperable standards and strategic use of the EU's massive procurement budgets.

Thus, by 2020, 3% of the EU's GDP is to be invested in R&D so as to create 3.7 million new jobs and increase GDP by EUR 800 billion by 2025.

Progress is monitored, e.g., by the production of country reports[125] and the publication of the Innovation Union Scoreboard.[126]

[125] The country reports are part of the European Trend Chart on Innovation, established in 1999, which regularly analyses the innovation policy and management of the EU and its member countries.

[126] The Innovation Union Scoreboard contains a total of 25 indicators, divided into three different types: the first type, known as Enablers, capture innovation drivers external to the firm, which include "Human resources", "Open, excellent, attractive research systems" and "Finance and support" (in the form of R&D expenditures and venture capital investments). The second type, Firm activities, concern innovation efforts, including "Firm investments", "Intellectual assets" and "Linkages and entrepreneurship". Outputs, the third type, cover the effects of innovation activities in two dimensions – "Innovators" and "Economic effects" (http://ec.europa.eu/enterprise/policies/innovation/files/ius-2013_en.pdf).

5.2.2 Innovation Union Scoreboard of the European Commission

In 2012, compared to the 27 EU member states, Switzerland showed above-average innovation performance, ranking in first place. This leading position has been documented by the Innovation Union Scoreboard since 2008.

The following Figure compares Switzerland's performance with that of the EU's innovation leaders – Sweden (1st), Germany (2nd), Denmark (3rd) and Finland (4th) – as well as Belgium (7th) and two other major economies – the UK (8th) and France (12th).

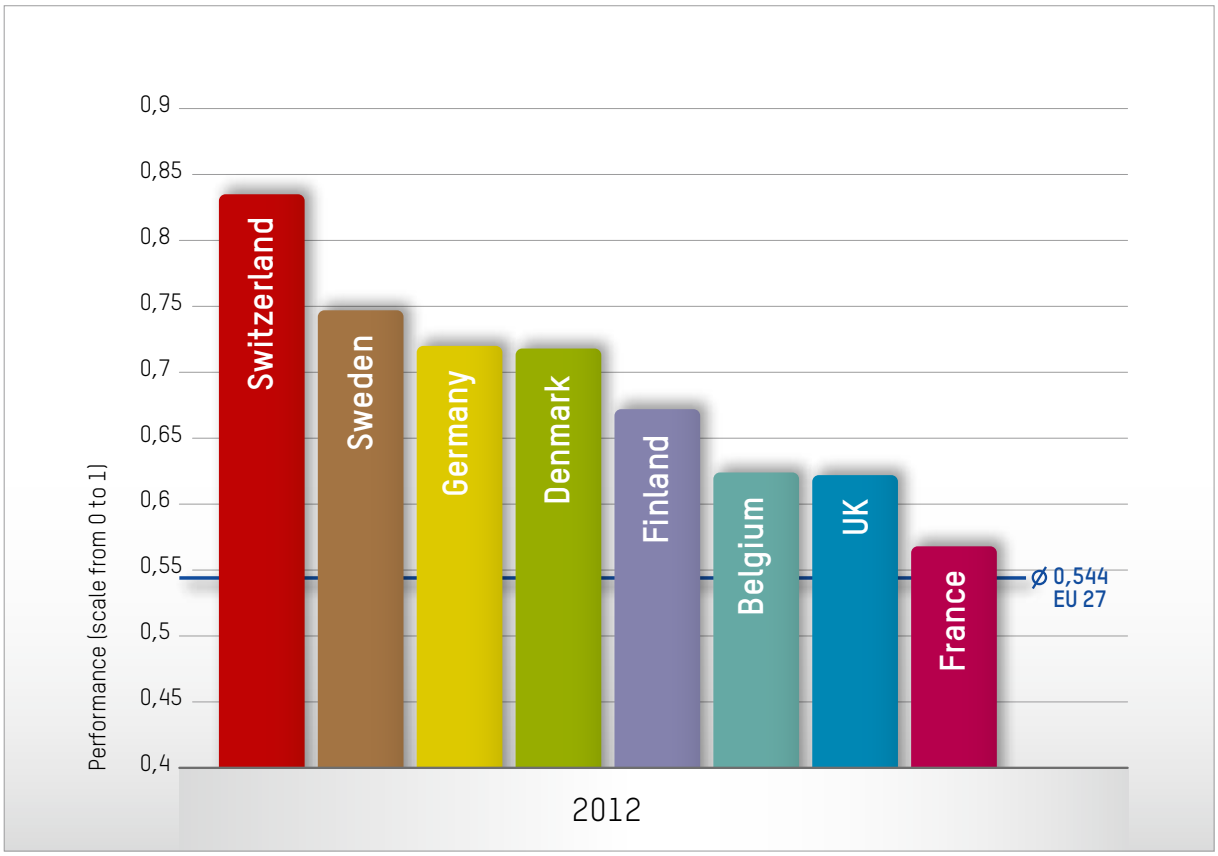


Figure 6: Comparison of locations based on the Innovation Union Scoreboard

Except for Denmark, which overtook Finland, and the UK, which twice changed places with Belgium, the positions of these countries remained unchanged between 2008 and 2012.

5.2.3 Review of selected countries

The situation of Germany and the UK has already been considered in detail in the global comparisons. Here, attention will be focused on countries which are either also among Europe's innovation leaders or – in the case of Belgium and Israel – well-known as pharma and medtech locations. Comparisons will also be made with Switzerland.

For an initial overview, the various countries' expenditure on R&D and the resultant patent applications are compared, with the figures for biotechnology – an important driver of biomedical innovation – being given separately.

Two other indicators are included in the Table – firstly, the intensity of venture capital investment, a key element in the innovation process for start-ups[127] and, secondly, the index of relative specialisation in biotechnology, which shows the relative importance of this field in the country concerned.[128]

National economy*	Switzerland	Sweden	Denmark	Finland	Belgium	Israel
Gross domestic expenditure on R&D (overall)						
in absolute terms (USD bn, PPP)	10,5	13,2	6,7	7,6	6,7	8,6
as a percentage of GDP	2,9	3,8	3,1	3,7	1,9	4,9
percentage financed by industry	68	58	62	67	61	39
percentage financed by government	24	28	26	25	22	15
Share of patent applications (2008–2010)	1,35	1,83	0,72	0,96	0,74	1,09
Venture capital intensity (percentage of GDP)**	0,13	0,21	0,16	0,24	0,10	n.a.

Biotechnology***	Switzerland	Sweden	Denmark	Finland	Belgium	Israel
Gross domestic expenditure on R&D (biotechnology)						
in absolute terms (USD m, PPP)	922,3	534,7	463,7	110,4	574,0	430,8
percentage of total business expenditure on R&D	12,6	6,2	11,0	2,1	12,6	5,6
percentage of industry value added	0,37	0,23	0,39	0,09	0,26	0,32
Share of biotechnology patent applications (2008–2010)	1,50	1,21	1,6	0,57	1,29	1,49
Index of relative specialisation in biotechnology****	1,11	0,66	2,22	0,59	1,74	1,37

* Source: OECD.Stat (accessed 2013). Data for 2011, apart from B (2006), CH (2008), DK/ISR (2009)
** Source: OECD Science, Technology and Industry Outlook 2010; figures for 2008
*** Source: OECD Key Biotech Indicators (accessed 2013). Data for B (2006), CH (2008), DK (2009), ISR (2010), S/SF (2011)
**** Share of patent applications in biotechnology divided by the share of patent applications in all fields (source: OECD)

Table 6: Comparison of selected input and output variables for various countries

[127] Cf. the discussion in Footnote 84 (Section 4.2)

[128] A value over 1 thus indicates an above-average weighting of this field.

A. SWITZERLAND

According to the EU Commission's Innovation Union Scoreboard, the relative strengths of Switzerland are in "Open, excellent and attractive research systems" (the indicator measuring the competitiveness of the science base), "Intellectual assets" and "Innovators", and in the resultant "Economic effects". Relative weaknesses are identified in the collaboration of innovative SMEs with other actors and in the availability of venture capital.[129] In recent years, Swiss higher education institutions have increasingly sought – through partnerships, advice and training – to make it easier for former students to start their own companies: between 2006 and 2011, an average of 40 spin-offs per year were established on the basis of licensing of intellectual property.[130] In numerous cases, lasting results were achieved: 50% of all the companies newly incorporated in Switzerland between 2000 and 2004 were still operating five years later, while the survival rate for ETH Zurich spin-offs was over 90%. In the biotech/pharmaceutical sector, the proportion of ETH Zurich spin-offs surviving was over 85%.[131]

B. SWEDEN

Sweden has one of the strongest science and innovation profiles of any EU or OECD country, as regards expenditure on R&D, the number of patent applications and education indicators.[132] Sweden ranks in first place among the 27 EU countries, with its innovation performance growing at an annual rate of 1.9% between 2008 and 2012 according to the Innovation Union Scoreboard. The strengths identified by the EU Commission are in "Human resources" and in the growth performance of "Open, excellent and attractive research systems"; weaknesses are seen in the "Economic effects" of innovation activity.

In 2008, the government presented a Bill under which, by 2013, research and innovation were to be boosted, dependence on a small number of large companies was to be reduced and, at the same time, SMEs were to be strengthened. At the end of 2012, the Swedish Innovation Strategy[133] was adopted, with the aim of maintaining the country's position as a global leader up to 2020. For the life science and nanotechnology sector, particular emphasis is placed on the protection of intellectual property rights and the development of standards, which facilitate the growth of new markets, driving innovation and promoting the dissemination of new solutions. In the biotech, nano technology and information technology sectors, leading research is to be conducted and incentives are to be developed for collaboration between universities and the surrounding society. Between 2007 and 2013, EUR 5 million was invested in R&D cooperation between public and private institutions in industrial biotechnology, and another EUR 10 million was invested in biomedical engineering.[134]

[129] This assessment is not shared by all domestic observers (cf. Christoph Schmutz, Die Universität ist keine Bank – Spin-offs müssen am Markt bestehen, Neue Zürcher Zeitung, 10 October 2013).

[130] In 2011, the licence income of higher education institutions amounted to CHF 7.7 million. (Source: Swiss Technology Transfer Association, swiTTreport 2007/2012)

[131] Ingvi Oskarsson and Alexander Schläpfer, The performance of spin-off companies at the Swiss Federal Institute of Technology Zurich, thesis for the Masters in Finance Program (MSc Finance), September 2008

[132] Cf. the section on Sweden in the OECD Science, Technology and Industry Outlook 2010, 2011, and the Science and Innovation Outlook 2012, 2012

[133] Swedish government, The Swedish Innovation Strategy, October 2012 (http://www.government.se/sb/d/16569)

[134] PRO INNO Europe, Mini Country Report/Sweden 2011–2012, 2011 (including an overview of measures in the Appendix)

C. DENMARK

On a number of science and innovation indicators, Denmark is also among the leading OECD countries.[135] It is an open market economy with a sophisticated manufacturing industry, e.g. in the pharmaceutical and biotechnology sectors. In the Innovation Union Scoreboard, it ranks in 3rd place among the 27 EU countries; between 2008 and 2012, its innovation performance grew at an annual rate of 2.9%. According to the EU Commission, the marked improvement in Denmark's position is due to the "Open, excellent and attractive research systems", collaboration between private and public research institutions, and the successful introduction of innovations.

The 2008/2009 financial crisis hit Denmark fairly hard, revealing its relatively weak productivity and innovativeness. In response, the Danish government presented a report entitled "Strengthened innovation in business".[136] Comprising 37 policy initiatives, it aims, for example, to strengthen the framework conditions for SMEs, to improve access to international knowledge and technology for enterprises and to strengthen the growth potential of the welfare sector.

Specifically, efforts are to be made to improve the framework conditions for clinical research, to exploit business potentials in hospital investments, to increase exports of health and welfare solutions, and to attract foreign investments in this area.

At the end of 2012, the Danish government launched its innovation strategy Denmark – a nation of solutions. Enhanced cooperation and improved frameworks for innovation in enterprises,[137] focusing on three areas: innovation is to be increasingly driven by societal challenges; more knowledge is to be translated into value; and there is to be a greater focus on innovation in education.

This strategy – which includes 27 measures in the areas of research, innovation and education – aims, for example, to strengthen the exchange of knowledge between private and public institutions, industry and academia.

In addition, Denmark announced in 2013 that it intended to intensify cooperation with innovation centres in Brazil, India and South Korea, which would also benefit the life science sector.

D. FINLAND

Finland's innovation investment and performance are among the strongest in the OECD area. Collaboration with other countries is at a high level, and a large proportion of the labour force has a tertiary qualification.[138] In the Innovation Union Scoreboard, Finland ranks in 4th place among EU countries, and its innovation performance grew at an annual rate of 0.9% between 2008 and 2012. Its innovative strength is export-driven and based on the services sector. Weaknesses are identified in research systems and in collaboration among innovative SMEs.

The country's relatively high private expenditure on R&D, as a percentage of GDP, is largely attributable to the efforts of the Nokia Group. At the end of 2007, Tekes, the Finnish Funding Agency for Technology and Innovation, published a report analysing early-stage business development activities and comparing the ecosystem with Israel and the US.[139] The authors concluded that the current system was based on an export-driven approach to corporate development with

[135] Cf. the section on Denmark in the OECD Science, Technology and Industry Outlook 2010 and the Science and Innovation Outlook 2012, 2012

[136] Danish Government, Styrket innovation i virksomhederne, Copenhagen, 2010; cited in PRO INNO Europe, Mini Country Review/Denmark 2011–2012, 2011 (including an overview of measures in an Appendix to the Report)

[137] Danish Government, Denmark – a nation of solutions. Enhanced cooperation and improved frameworks for innovation in enterprises, 2012 (http://fivu.dk/en/publications/2012/denmark-a-nation-of-solutions)

[138] Cf. the section on Finland in the OECD Science, Technology and Industry Outlook 2010, 2011

[139] Juha Ruohonen and Arvoketju Oy, VICTA – Virtual ICT Accelerator, Tekes, 2007

heavy public-sector involvement. However, companies with growth potential lacked funding ownership (in the form of venture capital) and management talent. It was recommended that Finland should implement a growth-oriented system including strategic targets and strategy-driven key performance indicators. Immediate actions proposed were new rules for public-sector funding, a restart for the venture capital industry, and the introduction of an "incubator 2.0 model", with incubators providing greater support for early-stage technology companies with high growth potential.

In March 2009, the Finnish government presented to Parliament its National Innovation Strategy,[140] comprising measures to promote innovation in the service sector and more user-oriented R&D; in addition, under a new Universities Act, passed in June 2009, the higher education system was reformed, with various institutions being merged.

From 2010, to build a competitive edge, Tekes provided funding for measures supporting R&D cooperation in the pharmaceutical (EUR 9 million) and industrial biotechnology sector (EUR 4.7 million).[141]

The biomedical industry appears to suffer from structural weaknesses[142] – weak local networks, the small size of firms, a poor public image and limited commercial experience hinder the exploitation of the knowledge developed. Policymakers are called on to promote knowledge sharing among the relevant actors and to implement technology-specific policy measures.

E. BELGIUM

"Open, excellent and attractive research systems", "Linkages & entrepreneurship" and "Innovators" are identified as the relative strengths of Belgium, which ranks in 7th place among EU countries in the Innovation Union Scoreboard; its innovation performance grew at an annual rate of 2.9% between 2008 and 2012. According to the EU Commission, Belgium shows above-average performance, but a relative weakness is seen in R&D expenditures, which amounted to 1.3% of GDP in 2006. This applies in particular to private R&D investments, with Belgium relying heavily on a small number of large foreign-owned companies.[143] In addition, the Belgian economy is characterised by a large proportion of SMEs, posing a challenge for the absorption of innovations.

Belgium's innovation policy is controlled not centrally, but by the three regional governments: Wallonia's Marshall Plan 2.Green aims to improve the competitiveness of companies by prioritising the goal of sustainable development. For example, investment in basic research has been increased, a centre of excellence in sustainable development has been created and subsidies have been provided for patent registration (EUR 2.3 million in 2010).

With its Flanders in Action Plan,[144] Flanders aims to rank among the top five European regions by 2020. The programme includes efforts by the regional government to support the procurement of innovation, e.g. by establishing platforms for joint development of innovations by government agencies, private companies and research institutes. In 2010, a budget of EUR 5.7 million was made available in this region for applied biomedical research.

[140] Finnish Government, National Innovation Strategy, 2009 (www.tem.fi/en/innovations/innovation_policy)

[141] PRO INNO Europe, Mini Country Report/Finland 2011–2012, 2011

[142] Matti Pihlajamaa, Anne-Sisko Patana, Kirsi Polvinen and Laura Kanto, Requirements for innovation policy in emerging high-tech industries: the cases of life sciences and solar energy innovation systems in Finland, Aalto University, Oct. 2012

[143] PRO INNO Europe, Mini Country Report/Belgium 2011–2012, 2011 (including an overview of measures in the Appendix to the Report)

[144] www.eutrio.be

The innovation policy of the Brussels-Capital Region is the Regional Innovation Plan[145] for 2007–2013 (updated in 2012). With 14 axes relating to education policy, research funding, identification of potential niches, innovation governance and cooperation with other Belgian regions, a favourable environment is to be created for innovative companies, Brussels is to be positioned as a knowledge hub, smart specialisation is to be used to drive the economy, Brussels' participation in European projects is to be increased, and the governance of innovation is to be strengthened. For the biotechnology sector, the Eurobiotec incubator has already been established; further measures concern the development of ICT applications for health care.

F. ISRAEL

Israel has a technologically advanced and open market economy, with a highly developed industrial sector. According to the OECD experts, its science and innovation profile shows strong performance:[146] the private sector accounts for a high proportion of expenditure on R&D, and Israel performs strongly in the registration of patents, especially in medical technology, and has a high level of educational attainment. While only a small proportion of expenditure on R&D is financed from abroad, scientists cooperate closely with the US in particular.

To improve efficiency, the Ministry of Finance coordinates the budgeting process for all science, technology and innovation budgets. Increased government support became necessary in response to cuts in private R&D budgets after the 2008/2009 financial crisis. By 2010, innovation support budgets were 70% higher than in 2007. The Office of the Chief Scientist (OCS) in the Ministry of Industry and Trade and Labour – the predominant innovation agency – is seeking to diversify the heavily ICT-dependent innovation base and to spread the benefits of innovation to other industries. Bio- and nanotechnology are also receiving greater support:[147] since 2005, biotech incubators have provided funding for projects approved by the OCS. In 2011, the government decided to invest EUR 28 million over a period of 15 years in a Biotech Venture Capital Fund, with an additional EUR 112 million being provided by the investment firm OrbiMed.

[145] www.innovativebrussels.irisnet.be

[146] Cf. the section on Israel in the OECD Science, Technology and Industry Outlook 2010, 2011

[147] PRO INNO Europe, Mini Country Report/Israel 2011–2012, 2011 (including an overview of measures in the Appendix to the Report)

5.3 Regulatory environment in countries with their own biomedical industry

5.3.1 Introduction

Here, the regulations relevant to biomedical research and technology applicable in various countries are to be compared. Once again, attention will be focused on Germany, Switzerland, the UK, the US and Singapore (an important Asian location for pharmaceutical companies).

In reviewing the changes that have occurred in recent years, reference will be made to a study by metrobasel[148] which investigates the development of supply- and demand-side regulation between 2008 and 2011 – and the associated incentives for pharmaceutical research.

Although regulation of the pharmaceutical industry differs from that of medical technology in areas such as price setting, approval and reimbursement, the analysis is still of interest from the Federal Council's perspective, as it may indicate a need for action beyond the pharmaceutical sector.

5.3.2 Summary of the international comparison undertaken by metrobasel

Supply- and demand-side regulation in the five countries concerned was assessed with regard to the goal of safeguarding research activities, and thus in terms of "research-friendliness". Other (competing) health policy goals, such as regulatory quality requirements, were not taken into account.

A total of 25 individual indicators are used to assess the regulation of price setting, authorisation, research and intellectual property protection, on the one hand, and of reimbursement, service providers and patients, on the other, in terms of the effects on incentives to conduct research on new drugs.[149]

For 2011, the authors give the following results (the absolute change compared with the scores for 2008 is shown in parentheses):[150]

[148] metrobasel, Pharmaregulierungen im internationalen Vergleich, Basel, 2012; this study was prepared by Polynomics, with the support of a steering group comprising representatives of Cantons Basel-Stadt, Basel-Land and Zurich, Novartis, Actelion, interpharma, Ernst & Young and metrobasel.

[149] The assessment of price setting covers procedures (the longer, the less research-friendly), frequency of price reviews (research-friendly if none are carried out), existence of reference prices and profit regulation (both inimical to research).
Product approval covers market size (the bigger the market, the greater the incentives for research) and the simplification and duration of procedures (the shorter, the more research-friendly).
The assessment of research regulation considers any restrictions, especially concerning stem cell research.
The assessment of intellectual property protection covers aspects such as the exhaustion regime, patent term and patent linkage (no approval of drugs which could infringe an existing patent), data exclusivity and supplementary protection certificates (all research-friendly).
The assessment of reimbursement includes drug lists, health economic evaluations and the length of procedures (all tend to be inimical to research), as well as compulsory insurance (tends to create incentives for research).
Under the heading of regulation of service providers, prescribing budgets, mandatory generic substitution, control of marketing activities, incentive-based compensation (e.g. capitation / flat rate per case) and clinical guidelines tend to be rated as impediments to research.
Regulation of patients is concerned with co-payments, support for generics and regulation of advertising, all of which are associated with reduced incentives for research.

[150] For the methods used, cf. metrobasel, Pharmaregulierungen im internationalen Vergleich, Basel, 2012, pp. 10ff.; as the authors point out, the analysis is complicated by the fact that the importance of sectoral regulations is barely discussed in the literature.

Regulatory areas	Switzerland	Germany	Singapore	UK	US
Price regulation	0,53 (-0,11)	0,47 (-0,22)	1,00 (n.c.)	0,61 (-0.06)	0,89 (-0.11)
Authorisation regulation	0,44 (+0,06)	0,50 (n.c.)	0,56 (n.c.)	0,50 (n.c.)	0,56 (n.c.)
Research regulation	0,63 (-0,12)	0,50 (n.c.)	0,88 (n.c.)	0,88 (n.c.)	0,63 (n.c.)
Intellectual property protection	0,70 (n.c.)	0,65 (n.c.)	0,75 (n.c.)	0,65 (n.c.)	0,80 (n.c.)
Supply-side regulation (Weighting: 70%)	**0,57 (-0,05)**	**0,53 (-0,06)**	**0,80 (n.c.)**	**0,66 (-0.01)**	**0,72 (-0.03)**
Reimbursement regulation	0,69 (n.c.)	0,69 (-0.06)	0,81 (n.c.)	0,69 (n.c.)	0,78 (+0,03)
Regulation of service providers	0,80 (n.c.)	0,55 (n.c.)	0,60 (n.c.)	0,35 (n.c.)	0,80 (n.c.)
Regulation of patients	0,25 (-0,08)	0,42 (n.c.)	0,33 (n.c.)	0,58 (n.c.)	0,75 (-0,08)
Subindex Demand-side regulation (Weighting: 30%)	**0,58 (-0,03)**	**0,58 (-0.02)**	**0,58 (n.c.)**	**0,54 (n.c.)**	**0,78 (-0,01)**
Overall index	**0,57 (-0,04)**	**0,54 (-0,04)**	**0,73 (n.c.)**	**0,62 (-0,01)**	**0,74 (-0,02)**

Table 7: Research-friendliness of regulations in five countries (source: Polynomics)[151]

According to this assessment, Singapore – which pursues an active industrial policy – and the US are the most research-friendly locations, ahead of the UK, Switzerland and Germany. This is due to the scores achieved in the supply-side regulation subindex, which has a high weighting (70%). Compared with 2008, Switzerland lost 0.04 points (or 6%) in the overall index. With the exception of Singapore, the other countries' scores also decreased.

In these five countries, regulation of authorisation and reimbursement is fairly similar; the main differences lie in the regulation of patients, service providers and prices. The differences between the countries thus arise largely (but not exclusively) from these regulatory areas. According to the authors, price regulation in particular has been tightened in recent years. Well placed overall are the US (in both supply- and demand-side regulation) and Singapore (especially on the supply side). The scores achieved by Switzerland are comparatively low in the areas of prices and patients.

For these areas, the authors' conception of regulations inimical to research could be summed up as follows: the more rigid the criteria for price setting, and the greater the frequency of reviews, the less research-friendly the regulations will be; the same applies for binding comparisons with reference product prices. According to the authors, regulation of patients is inimical to research if co-payments are required, generics are promoted and direct-to-consumer advertising of therapeutic products is prohibited.

[151] n.c.: no change

5.3.3 Placing the results in a broader context

Here, the results of the metrobasel study are placed in a broader context: the findings are evaluated or reference is made to ongoing debates in the countries concerned.

Generally speaking, the study can be said to make an important contribution to the debate on Switzerland's attractiveness as a location for biomedical research and technology, firstly, because it makes it possible to compare key pharmaceutical business locations – despite major differences in these countries' health systems. Secondly, it assesses various supply- and demand-side regulations in terms of their research-friendliness, which is certainly an essential requirement for fuelling the innovation process.

It should be borne in mind, however, that inventions will only become innovations if the demand side of the product market is capable of absorbing them – in other words, if new drug treatments are used by service providers and the public can afford them thanks to the availability of funding (public contributions, insurance coverage or private means). Policymakers must therefore – unlike the authors of the study – consider a number of different health policy goals at the same time and weigh them up against each other. Often, local circumstances will also be taken into account in such decision-making.

A. SWITZERLAND

Reasons given for the assessment

In the metrobasel study, the authors' assessment of Switzerland – on the supply side – is based on the comparatively strict regulation of the prices of products included on the List of Pharmaceutical Specialties and reimbursed under mandatory health insurance. These account for 80% of the total Swiss market volume.[152] While the regulation of authorisation has improved as a result of changes made to the Swissmedic review procedure, Switzerland is the lowest ranked of the five countries on account of its lengthy authorisation procedures.[153] In contrast, the country's intellectual property protection is considered to be relatively research-friendly. On the demand side, the regulation of reimbursement and service providers is rated as research-friendly, while the score for regulation of patients is very low. The reason given for this is the intensification of differential co-payments to further promote the use of generic drugs.

The authors conclude that policymakers in Switzerland attach greater weight to health policy goals other than research-friendliness in regulating the health system and the pharma market. They have the impression that strict regulation is used to reduce expenditures on drugs for the Swiss public, while benefiting from research conducted in other countries; this, however, could lead to delays in innovative drugs reaching the Swiss market, with adverse impacts on health care.

[152] At ex-factory prices (source: Interpharma)

[153] The median duration is reported to be 486 days for a standard authorisation procedure in Switzerland, and 215 days for a fast-track procedure. The federal government has responded by introducing measures to reduce the length of authorisation procedures (cf. Section 8.1)

Broader context

The worse score obtained for regulation of research (0.63 versus 0.75 in 2008) is attributed by the authors to the new constitutional article regulating research involving human beings, and to the new Human Research Act. This assessment is surprising for several reasons: the new regulations adopted at the federal level address key demands of research and industry, such as the introduction of lead ethics committees and parallel procedures within Swissmedic and the cantonal ethics committees; at the same time, they seek – through a national coordination centre – to harmonise cantonal differences in interpretation of the law, which had previously been subject to severe criticism. In addition, the requirements specified for approval are now dependent on the risks associated with a clinical trial – another change in accordance with researchers' wishes. One therefore cannot agree with the authors' view that the regulation of research has worsened overall.

The comparatively high score obtained for the regulation of intellectual property protection in Switzerland is attributed to the principle of national exhaustion in patent law and to the long period of exclusivity for data submitted for regulatory review. The exclusivity period is currently 10 years and is thus similar to that applicable in the European Union.[154]

The assessment of reimbursement regulation is adversely affected by the definitive list of reimbursable drugs (i.e. the Specialties List) and by the average period of 140 days required for authorisation of reimbursement for a medicinal product. Under the present master plan, the Federal Council has addressed the desire for acceleration of the procedure and adopted appropriate measures.[155] Also striking is the authors' view that regulation in Switzerland is likely to become tighter in the future, with a resultant decrease in research-friendliness. Cited as an example is the increased use of Health Technology Assessment (HTA) in the medium term. But HTA in particular can lead to more effective evaluation and more appropriate reimbursement of innovative biomedical technologies, thus stimulating research activities.

[154] Cf. also the discussion in Section 9.2

[155] Cf. the discussion in Chapter 8

B. GERMANY

Reasons given for the assessment

The Medicinal Product Market Reform Act (AMNOG) was largely responsible for Germany's loss of 0.04 points (or 7%) in the overall index. Since 1 January 2011, pricing for innovative new drugs – for the duration of patent protection – has been subject to a strictly regulated negotiation procedure, which is preceded by a benefit assessment conducted by the Federal Joint Committee (G-BA). If the G-BA concludes that the drug offers an additional benefit over a comparator treatment, a higher price can be requested. Otherwise, a maximum reimbursement level is set for the drug. Together with mandatory rebates and price freezes, the introduction of the AMNOG explains the worsening of the score obtained for supply-side regulation.

Points of interest in comparison with Switzerland are, firstly, the protection of intellectual property, which is shaped by EU requirements concerning regional exhaustion in patent law and the regulations on data exclusivity. Secondly, the authors note that marketing authorisation – particularly for innovative new drugs – is organised on an EU-wide basis via the European Medicines Agency (EMA). With a median duration of 417 days, the procedure is said to be more rapid than in Switzerland.

Research regulation is considered not to be particularly research-friendly, especially in the area of stem cell research, where import and use are only permitted subject to stringent conditions.

With regard to demand-side regulation, high co-payments, measures encouraging the use of generics and drug budgets for physicians are regarded as disincentives to research. On the other hand, Germany's regulation of reimbursement is considered to be research-friendly since – in contrast to Switzerland, for example – there is merely a list of drugs which are not reimbursed ("negative list").

Broader context

In Germany, concerns about the location have been expressed for some time: an analysis conducted as part of the federal government's High-Tech Strategy concluded that the biotech sector's innovation drivers were more likely to be found in the US, the UK or in Switzerland, despite the existence of a sizeable German-based industry. According to the Federal Ministry of Education and Research (BMBF), Germany has more biotech companies than any other European country – over 500 – most of which are seeking to develop novel therapies; progress with commercialisation is, however, slow as a result of long development times.

From the ministry's viewpoint, there was an urgent need for new strategic approaches to link up all the relevant players in the biopharmaceutical value chain. In mid-2007, the BMBF launched a new Pharmaceuticals Initiative for Germany,[156] aimed at restructuring funding policy in the area of innovative pharmaceutical development. Under this overarching initiative, existing and new BMBF measures in health research and biotechnology were to be reorganised so as to close gaps in the value chain and strengthen R&D work on new drugs in Germany. Between 2007 and 2011, the overall budget for the Pharmaceuticals Initiative – available for basic and applied health and biotechnology research – amounted to around EUR 800 million.

A key element of the initiative was the BioPharma competition, which encouraged business consortiums to submit their best strategic concepts for the efficient design of the biopharmaceutical value chain. These self-organising groups were to be capable of developing and implementing concepts for economically relevant biopharmaceutical innovations, from research to application. The focus of these partnerships was to be a joint strategy based on a detailed development plan, allowing the process to be realised as efficiently as possible over a period of several years.

[156] Federal Ministry of Education and Research (BMBF), 2013 (www.bmbf.de)

The consortium-led research projects were to involve biopharmaceuticals at an early stage of development but approaching clinical trials. BMBF funding would not be provided for clinical trials required for registration. From 37 applications, 3 consortiums[157] were selected.

In 2011, to promote the development of a coherent innovation policy for medical technology, the national strategy process known as Innovations in Medical Technology was launched by the BMBF, the Federal Ministry for Economic Affairs and Technology (BMWi) and the Federal Ministry of Health (BMG). The aim was to identify challenges facing medical technology and develop recommendations for policymakers. The final report, prepared by a steering group comprising representatives of academia, clinical practice, industry and health insurers, was submitted at the end of 2012.[158]

The authors concluded that there was a need to increase the effectiveness of research and development, shorten development times, step up investment activities in Germany, and ensure rapid access to a regulated market for innovative medical devices which would benefit patients.

To improve the industry's competitiveness, interaction between the medical technology sector and other sectors was to be promoted, new business models were to be established involving several companies, providers and funders, and the framework conditions were to be improved in order to make clinical trials both effective and affordable. In addition, efforts were to be made to secure the standardised application of EU-wide regulations and promote the harmonisation of regulations at the international level.

The efficiency of the health care system could be strengthened, e.g. by shifting the focus of quality evaluation in health care from the analysis of structures and processes to patient-related, outcome-oriented criteria, and by studying the use of medical devices not only in clinical studies but also increasingly in everyday care situations. In addition, greater attention should be paid to the potential of medical registries for health care and innovations.

The innovative strength of research could be enhanced by clearly defining concrete health care needs as a starting point for research funding, initiating exchanges between industry and health services research as partners, and overcoming interdisciplinary boundaries in education and training. In the light of these recommendations, the BMBF intends to focus its efforts in a new medical technology funding programme.

[157] The research topics included new treatments for neurological conditions, focusing initially on multiple sclerosis, and the development of small molecules for the treatment of diseases such as Alzheimer's, cancer and diabetes.

[158] Lenkungskreis für den Nationalen Strategieprozess "Innovationen in der Medizintechnik", Schlussbericht, November 2012 [Abridged English version: Medical technology in transition – Innovation as the key to sustainable success]

C. SINGAPORE

Reasons given for the assessment

The financing of health services in Singapore contrasts sharply with European approaches. As well as the usual co-payments, it involves the compulsory medical savings account Medisave,[159] the voluntary MediShield insurance plan to cover high health care costs, the state-funded Medifund scheme for needy citizens and the private disability insurance scheme ElderShield. The high level of co-payments[160] is one reason why the authors of the metrobasel study rate the regulation of patients and demand-side legislation as less research-friendly overall than the supply-side regulation. According to the authors, Switzerland is the only country where the regulation of patients is even less research-friendly, e.g. as a result of differential co-payment rates for generics.

The city-state is top-ranked for supply-side regulation, with no restrictions on pricing for registered products and no systematic mandatory price review procedures or regulation of profits. Equally research-friendly is the regulation of research itself: the framework is set by the Human Cloning and Other Prohibited Practices Act, and since 2008 stem cell research has been actively promoted by the Stem Cell Society.

Measures for the protection of intellectual property appear to be a mixture of carrot and stick: as soon as drugs are authorised in Singapore, international exhaustion applies: however, the industry can reduce what it regards as the undesirable effects of parallel imports via vertical distribution systems. The 5-year data exclusivity period is also less research-friendly than the corresponding regulations in the EU or Switzerland. On the other hand, Singapore has a patent linkage system and protects patent holders against "premature introduction of generics".

Regulation of authorisation obtains a comparatively poor score, but one which is considerably better than that of Switzerland, even though the two markets are similar in size (population of Singapore: 5.1 million). This is probably attributable mainly to the duration of the authorisation process (400 days for a standard procedure in Singapore; 486 days in Switzerland, according to metrobasel) since Switzerland also has procedures similar to the abridged evaluation of drugs already approved overseas and the simplified procedure for drugs already authorised for marketing in the US, the UK, Australia, the EU or Canada.

As well as the high co-payments for patients, research-friendliness is adversely affected on the demand side by the regulation of service providers: prescribing budgets and Ministry of Health treatment guidelines are disincentives to research, but the lack of a health economic evaluation is favourably rated.

Broader context

Following the international financial crisis of 1997 and 1998, Singapore decided to pursue greater economic diversification and, from 2000, made considerable efforts to promote biomedical research and technology alongside traditional sectors such as electronics, engineering and chemicals: as well as attracting foreign direct investment,[161] the domestic industry was to be strengthened. In competing as a business location with other (Southeast) Asian nations, the aim was to position Singapore as a country with high-value-added sectors. Singapore's long-term Biomedical Sciences Initiative[162] comprises three phases. Between 2000 and 2005, the founda-

[159] All employees are required to pay into this account to cover future expenses for themselves and their family.

[160] These are dependent on income, the drugs concerned and the insurance scheme and amount to up to 50%. Certain treatments included on a "positive list" are subsidised by the state.

[161] Foreign direct investment involves the transfer of assets such as capital, knowledge and technology.

[162] This initiative is supported by an International Advisory Council, whose members include, for example, Professor Patrick Aebischer (President of the EPF Lausanne) and Rolf Zinkernagel (Professor Emeritus, University of Zurich). Cf. also the information on www.a-star.edu.sg

tions for biomedical research[163] were established. From 2006 to 2010, translational and clinical research capabilities were strengthened.[164] The aim of the third phase (2011–2015) is to capture opportunities for greater economic and health impact: research is to focus on mission-oriented programmes with high growth potential in areas such as biologics, medtech, and nutraceuticals/cosmeceuticals. There is evidently a need to promote collaboration between researchers and other professionals (engineers, etc.) so as to provide multi-disciplinary solutions to problems of interest to industry.

The initiative is being implemented by three agencies: the Biomedical Sciences Group (BMSG); the Agency for Science, Technology and Research (A*STAR), which oversees a total of 14 research institutes and 5 consortia, supports university and clinical researchers, and organises educational programmes (also for foreign students); and Bio*One Capital, with assets of USD 700 million under management, which makes strategic investments in biotech firms and start-ups, aiming to attract expertise and technology to Singapore.

To date, Singapore has invested over USD 2 billion in its Biomedical Sciences Initiative alone. From 2006, around USD 1 billion was invested in strengthening translational and clinical research capabilities. A major hub is the Biopolis facility,[165] where thousands of researchers work in private and publicly funded R&D.

Academics have assessed the effectiveness of Singapore's efforts to support the biomedical industry by offering tax allowances and incentives,[166] establishing appropriate infrastructure and attracting and training experts. According to a report published in 2010,[167] employment in the biomedical sector increased from 5,880 to 11,500 between 2000 and 2007, with investment in 2007 alone contributing 1,700 jobs. However, this did not entirely compensate for the decline in employment in the (more labour-intensive) electronics sector. The development of Singapore's public research capabilities led to closer collaboration with multinationals such as Novartis, Johnson & Johnson and GlaxoSmithKline. All the major pharmaceutical companies now have a presence in Singapore. Foreign direct investment in the area of biomedical research and technology rose from around USD 10 billion in 2001 to more than USD 35 billion in 2011,[168] accounting for 6.6% of all foreign investment. Among the success factors cited are a strong government and effective public administration, a good physical infrastructure, well-educated and skilled human capital, well-enforced intellectual property rights, liberal legislation governing research, a single regulatory agency in the form of the Health Sciences Authority, a substantial venture capital sector, attractive fiscal incentives and clustering.[169]

These factors are also mentioned in other studies.[170] In the global comparisons, Singapore outperforms Western European countries such as Switzerland on industrial policy with regard to support for research. However, broader studies indicate that, on innovation efficiency, Singapore lags behind Switzerland. It would therefore have been useful if research output had also been

[163] Research capabilities were developed in the areas of bioprocessing, chemical synthesis, genomics and proteomics, molecular and cell biology, bioengineering and nanotechnology.

[164] The Singapore Institute for Clinical Sciences (SICS) and the Institute of Medical Biology (IMB) conduct translational and clinical research. Various consortia initiatives have also been launched, such as the Singapore Cancer Syndicate, the Singapore Bioimaging Consortium, the Singapore Stem Cell Consortium and the Singapore Immunology Network (cf. the general information on translational research in Chapter 2).

[165] The USD 210 million Biopolis hub hosts, for example, the Swiss House and the UK Science and Technology Office.

[166] An overview of the various instruments can be found on the website of the Singapore Economic Development Board (EDB) (www.edb.gov.sg)

[167] Singapore Institute of International Affairs, Sustainable development impacts of investment incentives: a case study of the pharmaceutical industry in Singapore, International Institute for Sustainable Development / Trade Knowledge Network, 2010

[168] Singapore Government, Department of Statistics, accessed 2013 (www.singstat.gov.sg); authors' calculations

[169] Clusters have been developed in pharmaceuticals, biotechnology, medical technology and health care services.

[170] Cf. the discussion in Section 5.1

taken into consideration in the metrobasel study.

The key question remains whether massive investments are actually translated into lasting commercial success. Even though, in biomedical research and technology, successes are not to be expected for at least 10 years, it would appear that, up to 2010, the main beneficiaries of Singapore's efforts were foreign companies rather than local SMEs.[171] In addition – compared to the electronics industry – the number of new jobs created has been limited. According to the authors of the study, there is a risk that, unless spillovers are appropriately exploited, foreign companies could be induced to relocate to other countries, nullifying the effects of the investments made to date. They conclude that the coming years will show to what extent Singapore can make the transition from largely investment-driven to innovation-driven development. There is a need to manage knowledge and skills more effectively than in the past and to encourage partnerships between local research institutes, hospitals and universities so as to spur innovation among local researchers.

For the future, the report recommends that Singapore should focus on research in selected disease areas where it has comparative advantages based on its multiethnic population (which includes Chinese, Indian and Malaysian groups) – e.g. tropical and communicable diseases, such as avian flu. This effort should be funded through the government's commitment to invest USD 1 billion in translational and clinical research. Singapore could also tap into the ASEAN health care market, with its expanding middle class of demanding consumers.

[171] On this controversial question, cf. the review in: Singapore Institute of International Affairs, Sustainable development impacts of investment incentives: a case study of the pharmaceutical industry in Singapore, 2010, p. 12

D. UK

Reasons given for the assessment

The authors perceive a marked difference between the incentive effects of supply-side and demand-side regulation in the UK: on account of the National Health Service (NHS), demand-side regulation in particular receives a low rating for research-friendliness. This is because the state itself acts as a service provider, allocates drug budgets and issues clinical guidelines through the National Institute for Health and Care Excellence (NICE); the services offered are thus much more tightly controlled than in other countries. For reimbursement regulation, the UK obtains the same scores as Germany and Switzerland. Although extensive health economic evaluations are performed by NICE, pharmaceutical companies are able to place products on the market without delay. The negative list for drugs is more favourably rated than Switzerland's positive list. The regulation of patients in the UK is considered to be more research-friendly than in Germany, Singapore and Switzerland, with the flat-rate prescription charge for patients being regarded by the authors as comparatively research-friendly.

Supply-side regulation in the UK is rated as considerably more research-friendly than in the two other European countries. Owing to the liberal approach to stem cell research, in particular, it shares the leading position with Singapore in the regulation of research. Being an EU member country, it obtains the same scores as Germany for regulation of authorisation and intellectual property protection. Price regulation is rated as less research-friendly than in 2008, following the substantial reduction in prices of existing drugs negotiated by the Department of Health under the revised Pharmaceutical Price Regulation Scheme (PPRS) which came into effect in 2009. In contrast to many other European countries, the UK sets the maximum level for profits that pharmaceutical companies may earn from sales of products with a new active substance.

Broader context

The current 5-year agreement between the Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI) expires at the end of 2013. Thereafter, the government wishes to introduce a value-based pricing system; this would involve switching from profit controls to price setting for new drugs. The aim of this measure is to improve access to effective drugs for NHS patients, to promote innovation in under-researched areas and to ensure optimal use of NHS resources. This could possibly result in lower prices for existing drugs and higher prices for breakthrough or radical innovations. The consultation period ran from 20 June to 31 July 2013.[172]

The intention to provide greater support for innovation arises firstly from the fact that, compared with other European countries, there is a certain delay before innovative new drugs are used in the NHS. Secondly, it forms part of the government's long-term strategy of supporting the UK life sciences industry with a variety of measures. The foundations for this were established in two government papers:

The Strategy for UK Life Sciences[173] is a long-term strategy which aims to create a sustainable operating environment for the life sciences industry by improving collaboration between academia and business, improving the economic framework conditions and ensuring that the requisite skills are available over the long term. For example, the speed and efficiency of market approval for innovative breakthrough therapies is to be increased under the Early Access Scheme, GBP 310 million is to be invested to support biomedical research (including GBP 130 million for stratified medicine) and an enhanced web-based Clinical Trials Gateway is to be

[172] Government decisions based on the results of the consultation were not yet known at the time of writing.

[173] Department for Business Innovation and Skills (BIS), Office for Life Sciences, Strategy for UK Life Sciences, 2011

launched, providing information for the public. In addition, with the development of a National Institute for Health Research (NIHR), the UK is to be positioned as a centre for experimental medicine. The government also plans to expand vocational training and improve collaboration across UK clusters and within government.

Innovation, health and wealth[174] is designed to overcome the barriers which have emerged in recent decades to the use of cost-effective innovations across the NHS. Among the long-term actions envisaged are the creation of a system to ensure – and enhance transparency concerning – the adoption and diffusion of innovative treatments within the NHS. Academic Health Science Networks (AHSNs) established for this purpose will bring together representatives of the NHS, academia and industry.

E. US

Reasons given for the assessment

Regulation of the US health system is considered to be highly liberal, even if government programmes such as Medicare and Medicaid – covering about a third of the population – are included in the analysis. Around 15% are not insured either under government schemes or via employers.

According to the authors of the metrobasel study, the 0.02 point (or 3.3%) decrease in the overall index for the US is due to President Obama's health care reform, although they believe this effect will only be temporary. In 2009, the pharmaceutical industry undertook – under the new Patient Protection and Affordable Care Act – to offer 50% discounts for Medicare patients with large deductibles and greater discounts for Medicaid enrollees, and to contribute a total of USD 28 billion in financing for the health care reform. However, the government's plans for expansion of insurance coverage could more than compensate for the losses associated with discounts.

On the supply side, the lack of restrictive price regulation (despite the various measures mentioned), the rapid approval of new drugs (median: 395 days; fast-track procedure: 274 days) and strong intellectual property protection are rated as research-friendly. Although the period of data exclusivity in the US (5 years) is considerably shorter than in Europe or Switzerland; this is offset in the overall assessment by, for example, patent linkage (i.e. denial of marketing approval to products which could infringe patent rights). Research regulation is rated as much less research-friendly than in Singapore or the UK, given the restrictions on the use of public funds in stem cell research.

Demand-side regulation is rated as much more research-friendly in the US than in Switzerland, as drugs can be placed on the market and appropriately promoted without delay; in addition, drug lists, support for generics and capitation models are rare, except in government programmes.

Broader context

Advances in biomedical research and technology in the 20th century were made thanks to countries such as the US, where the publicly funded National Institutes of Health (NIH) contributed significantly to breakthroughs in areas such as gene therapy or artificial tissue. In the period after 1980, in particular, US leadership was strengthened as a result of the large market, (largely) unrestricted price setting for biomedical products, the protection of intellectual property and the ability of top universities to attract talented researchers from abroad.

Representatives of academia, industry and independent institutes believe that the predominance

[174] Department of Health, NHS Improvement & Efficiency Directorate, Innovation, health and wealth: Accelerating adoption and diffusion in the NHS, 2011

of the US could be challenged by countries such as China, Germany, India, Sweden, Singapore, Switzerland and the UK.

These countries have significantly increased the financial support provided for biomedical research: China, for example – which already has more than a third of total global gene sequencing capacity – is to invest USD 308.5 billion in biotech research by 2015. Other countries, such as Singapore and the UK, are investing much more (as a share of GDP) in applied research than the US.

The lack of consistency and predictability in public funding for research in the US has also been severely criticised, as it creates uncertainty for private investors.[175]

As well as improving the quality and quantity of their research, countries competing with the US have developed mechanisms to support entrepreneurs in the biomedical field and to strengthen the commercialisation of products and techniques.[176] These countries are also implementing long-term strategies to enhance their biomedical innovation ecosystems, introducing tax incentives (e.g. so-called patent boxes) and regulatory reforms to speed up drug approvals.

Weaknesses of the US system include the uncertainty associated with the increasingly complex and rigid FDA approval process, uncompetitive corporate taxation (including the question of R&D tax credits) and an unfavourable reimbursement policy, which restricts access to medical services.

The following measures could help the US to reassert its global leadership:

- promoting regenerative medicine, e.g. by using patent law, tax and quality assurance incentives and appropriate funding to strengthen embryonic stem cell research or the development of nanomedical techniques;
- facilitating permanent residence so as to encourage foreign scientists to pursue their biomedical research activities;
- strengthening the role of universities in technology transfers;
- providing additional resources to expedite FDA and NIH procedures;
- streamlining approval processes for medical devices;
- reducing corporate tax rates from 35% to match the OECD average rate of 22%;
- increasing R&D investment tax credits.

[175] Robert D. Atkinson et al., Leadership in decline: Assessing U.S. international competitiveness in biomedical research, The Information Technology and Innovation Foundation/United for Medical Research, 2012

[176] Ross C. DeVol, Armen Bedroussian, Benjamin Yeo, The Global Biomedical Industry: Preserving U.S. Leadership, Milken Institute, 2011

5.4 Conclusions

It is apparent from various international comparisons that:

- Switzerland has created an ecosystem which makes it highly competitive and innovative – and thus offers an attractive framework for biomedical research and technology.
- Switzerland has an outstanding capacity to generate new knowledge and is highly efficient in translating this into patents, scientific publications and practical applications. The broad-based nature of Switzerland's success is demonstrated by the leading positions it holds in a wide variety of areas such as education and labour market policy, monetary and fiscal policy, strong protection of intellectual property, active collaboration between academia and industry, and the availability of a sound infrastructure and institutional framework.
- The success of Swiss policy in biomedical research and technology is reflected not only by the growth of value added in these sectors and Switzerland's top ranking in various international innovation indices, but also by the acknowledged high-quality provision of health products and services for the public.
- Numerous countries are also investing in biomedical research and technology as drivers of economic growth, given the growing proportion of consumers with rising incomes, marked demographic changes in many parts of the world, a resultant increase in demand for health services and the associated economic potential.
- For want of promising alternatives, countries which are among the global innovation leaders, such as Denmark, Finland and Sweden, are increasingly positioning themselves in biomedicine.
- Key competitors such as Germany, the UK, Singapore or Northern European countries have, like Switzerland, adopted long-term strategies for promoting innovation and enhancing the attractiveness of the location, based on the individual countries' needs. In the case of Singapore, in particular, which has invested heavily in its location policy, there are concerns over whether these efforts are producing sustainable results and also benefiting local businesses.
- As competitors, Germany, Singapore, the US, the UK and Switzerland differ above all in the research-friendliness of their regulation of service providers and pricing, and of their regulations directly affecting patients. In the international comparison, the research-friendliness of Switzerland is rated as comparatively low for pricing and patients in particular.
- If Switzerland wished to change this, it would have to forgo measures which are designed to contain rising costs and which enjoy broad political support, such as the setting of maximum prices, support for use of generics and the levying of co-payments.
- Switzerland must continue to implement its long-term strategy.
- Numerous factors at the local, regional and national level contribute to competitiveness. To maintain Switzerland's position as a location for a variety of innovation-intensive sectors, it is therefore necessary to consider entire value chains. It should be borne in mind that the various activities involved in value creation (research, development, sales) are often based in different countries, where they are subject to local regulations.
- Isolated measures may lead to improvements in individual cases, but will often not have the desired lasting effects.
- All actors in the political, academic and industrial spheres must help to ensure that Switzerland remains a leading location. The goal of maintaining or establishing the best possible framework for biomedical research and technology thus represents a continuous process, which

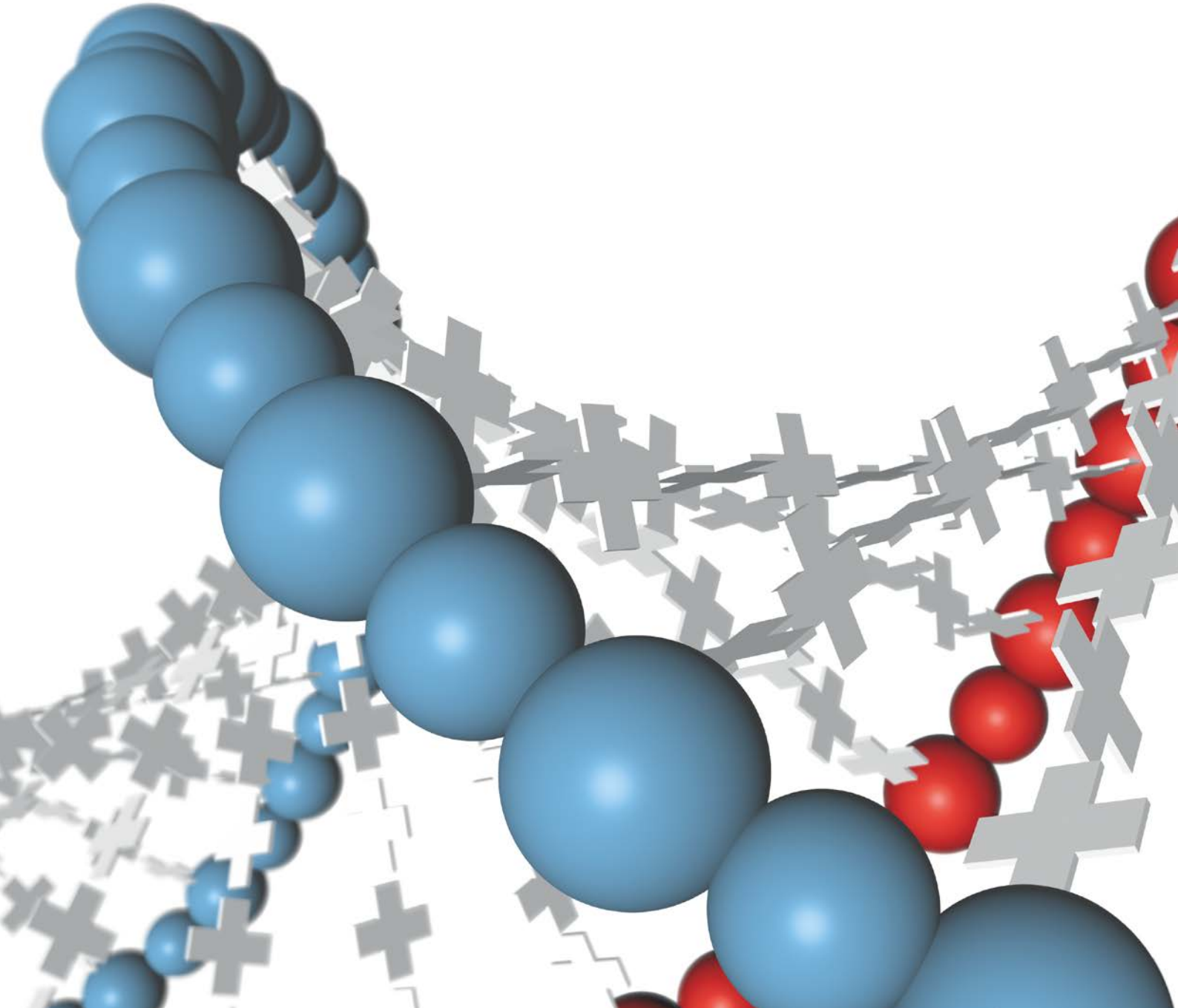
is to be pursued within and beyond the master plan.

– The effectiveness, appropriateness and cost-effectiveness of public and private measures is to be regularly reviewed.

6 FEDERAL COUNCIL'S MASTER PLAN

Firstly, on the basis of the aims formulated, the success factors for strong biomedical research and technology are enumerated in the light of the findings discussed above; potential areas for action are thus also identified. An overview is then given of the measures adopted by the Federal Council. To ensure that the intended lasting effects are achieved, the Federal Council is also taking supporting measures.

The individual areas for action, the goals pursued by the Federal Council, the measures required and the assessment of goal attainment are discussed in detail in Chapters 7–9.



6.1 Aims of the master plan

The Federal Council wishes to maintain or establish the best possible framework conditions for biomedical research and technology and, at the same time, ensure that the Swiss public has (affordable) access to the resultant advances and new products.

6.2 Success factors for biomedical research and technology

In the light of the international comparisons, the literature and discussions with stakeholders, the following are key requirements for competitive biomedical research and technology:

- a pool of skilled personnel is available for research and industry;
- in accordance with the freedom of research sanctioned by society, research in promising fields such as embryonic stem cells, biotechnology and nanomedicine is permitted as far as possible and, if necessary, supported with appropriate funding instruments;
- the health market must be capable of absorbing innovations and thus new products;
- newly generated knowledge must be rapidly translated into marketable applications, with a key role being played by exchanges between academia, industry and users, and the readiness of entrepreneurs to invest;
- research and development of biomedical technologies should be supported by patent law and data exclusivity incentives;
- regulatory requirements for marketing authorisation ensure high-quality, safe and effective applications, strengthening patients' confidence in biomedical technologies;
- biomedical technologies have a good cost-benefit ratio, creating incentives for innovation;
- lean administrative processes are required, e.g. for the approval of clinical trials, the authorisation of medicinal products and medical devices, and decisions on reimbursement under mandatory health insurance.

6.3 Focus on sector-specific measures

Efforts to improve the attractiveness of a location encompass a wide variety of goals and measures, operating at two different levels.

The first level involves framework conditions which shape business activities across all sectors in Switzerland. These include monetary and fiscal policy, maintenance of an open and flexible labour market, a good education system and a sound infrastructure.

The second level involves the influence of selected policy areas on specific opportunities for biomedical research and technology.

6.3.1 General economic policy measures

Companies' choice of location is demonstrably influenced by instruments such as education policy, labour market regulation or the design of the tax system. However, these instruments concern the framework conditions for business activities in general and can contribute to the concentration of high-value-added jobs in Switzerland. Given the breadth of their effects, they are not to be the subject of the Federal Council's master plan: fundamental economic policy concepts cannot be discussed and reformed from the perspective of individual sectors, even if the measures in question are of major importance for biomedical research and technology. This applies, for example, to tax policy measures, such as those called for in the parliamentary motions concerning the present master plan.

6.3.2 Specific measures

The master plan will therefore set out federal measures which should make it possible to maintain or establish the best possible framework conditions for biomedical research and technology, by enhancing the attractiveness of the environment which is of particular relevance for the research, development and production of biomedical technologies.

- Targeted support for innovation and research is to be combined with an internationally accepted regulatory framework to protect the dignity, privacy and health of human subjects involved in research.
- Innovation, the marketing of products and services and (possibly) the choice of location are influenced by the regulation of market entry, the market surveillance system and the reimbursement of biomedical technologies under social insurance schemes.
- Because the federal government must pursue other goals as well as the promotion of research and technology – e.g. ensuring the affordability of social insurance or the security of provision – the regulation of product markets is to be assessed in the context of the Federal Council's "Health2020" agenda.

6.4 Action areas and measures

6.4.1 Action areas

The following eight action areas identified by the Federal Council were subjected to in-depth analysis:

1. Education/training and continuing education
2. Structural framework for publicly funded research
3. Legal framework for human research
4. Availability of health data
5. Market entry and surveillance system
6. Reimbursement under social insurance
7. Orphan diseases
8. Intellectual property protection

For each of these areas, the need for action was determined based on an analysis of the issues. Various measures were then adopted in order to achieve the goals formulated for each area. If appropriate, the stakeholders concerned were involved in the planning or implementation of measures. Lastly, the Federal Council also decided how the attainment of goals is to be evaluated. Detailed discussions of the individual action areas are to be found in Chapters 7–9.

6.4.2 Integration of measures into federal government strategy

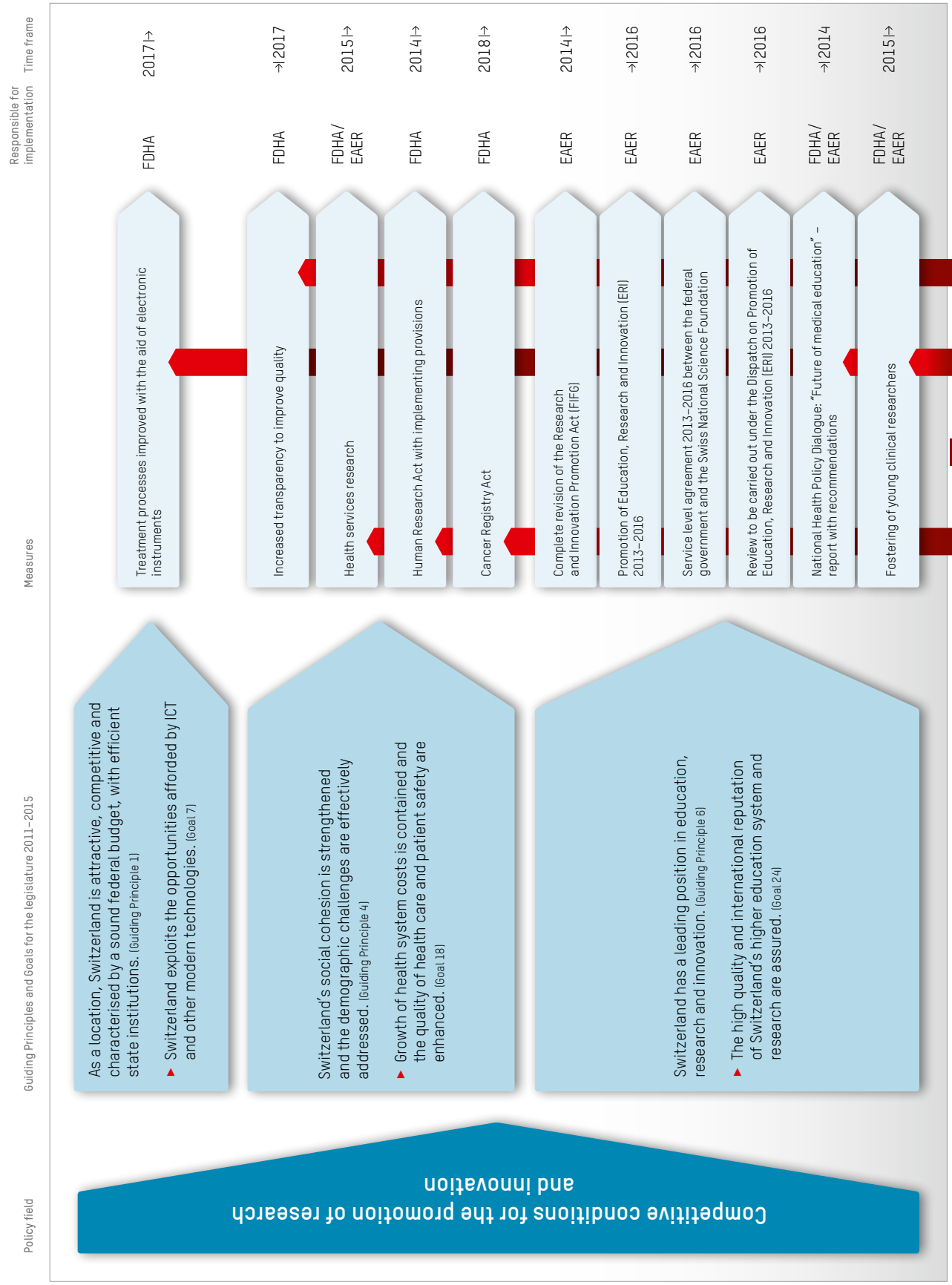
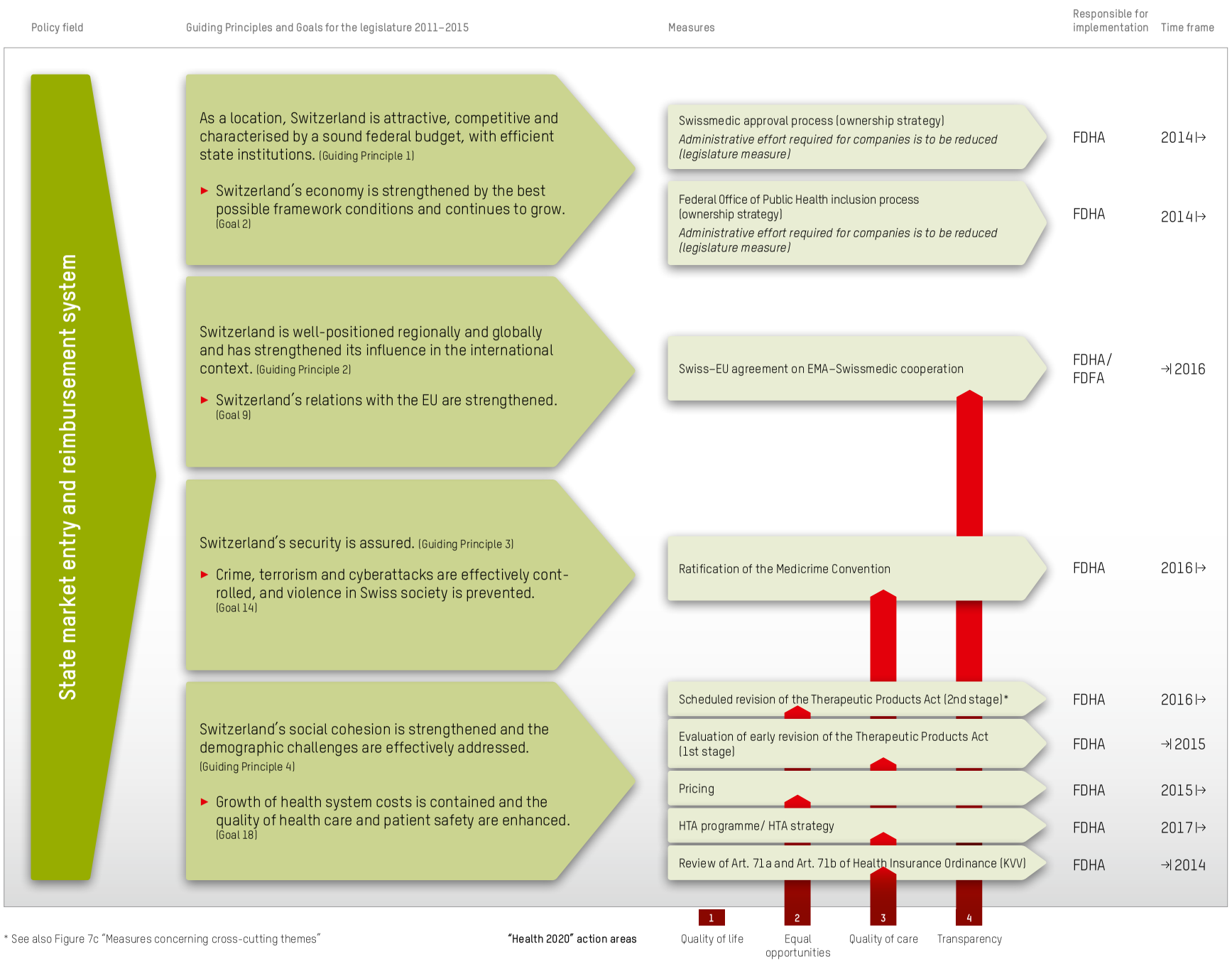


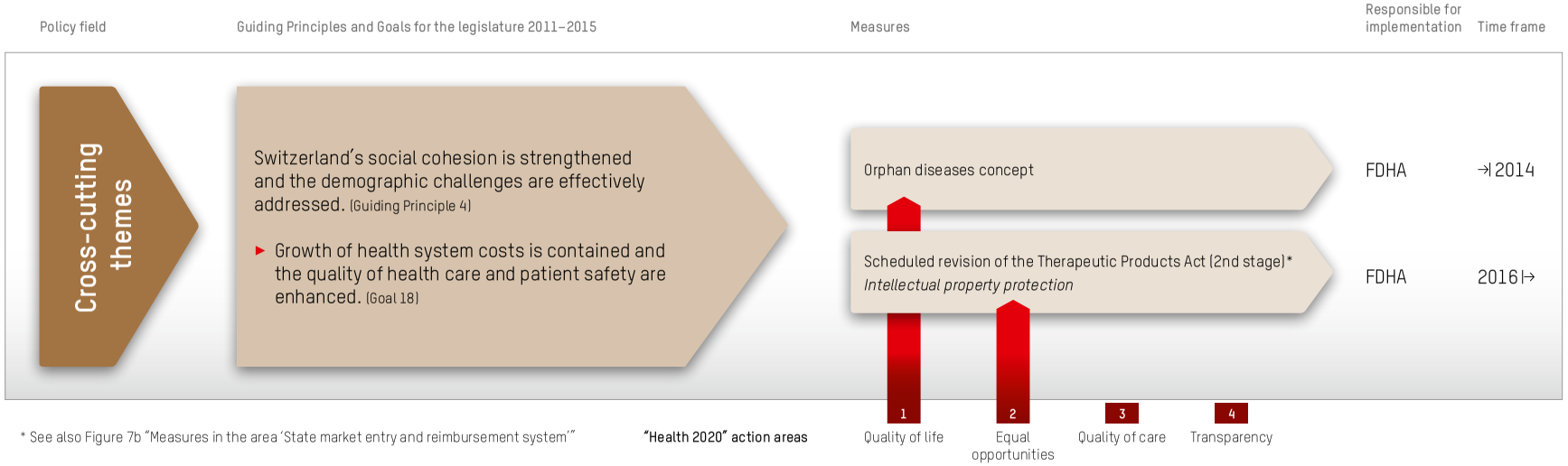
Figure 7a: Measures in the area "Competitive conditions for the promotion of research and innovation"

Figure 7b: Measures in the area "State market entry and reimbursement system"



* See also Figure 7c "Measures concerning cross-cutting themes"

Figure 7c: Measures concerning cross-cutting themes



* See also Figure 7b "Measures in the area 'State market entry and reimbursement system'"

In Figures 7a, 7b and 7c, the horizontal axis shows how the measures fit into the strategy adopted by the Federal Council for the legislature.[177] In some cases, the measures are explicitly included in the Legislature Planning – e.g. the complete revision of the Research and Innovation Promotion Act or the ordinary revision of the Therapeutic Products Act. Other measures are in accordance with the goals of the Legislature Planning but are not explicitly included, as these are measures to be implemented by the Department responsible – e.g. the efforts to increase the efficiency of authorisation and listing procedures, which should ultimately also reduce the administrative burden for companies.

The vertical axis in Figures 7a, 7b and 7c shows which of the measures form part of the Federal Council's "Health2020" agenda.

[177] Cf. the discussion in Section 1.2

6.5 Supporting measures

In order to ensure that the measures adopted by the Federal Council in the master plan achieve the desired lasting effects, the following supporting measures are to be taken.

6.5.1 Regulatory impact assessments

At present, few regulatory impact assessments (RIAs) explicitly indicate effects on biomedical research and technology. In order to make it easier to assess the effectiveness of government action, federal administrative units are to systematically analyse relevant legislative and other projects, in advance, for potential effects on biomedical research and technology. This applies, for example, to therapeutic products and human research law, social insurance law, or legislation on the promotion of research and innovation.

6.5.2 Evaluation of individual areas

Assessment of federal measures in accordance with Article 170 of the Federal Constitution entails regular evaluation of legislation and the enforcement thereof. The measures specified in the master plan are to be evaluated after implementation, unless they already involve evaluations.

6.5.3 Public information

The Federal Office of Public Health will provide regular information, in a suitable form, on the status of implementation of the master plan.

6.5.4 Platforms for sharing information

Work undertaken in connection with the master plan showed that there is a need to improve exchanges not only between stakeholder groups but also within the Federal Administration. From 2014, appropriate external and internal platforms will be established or, in some cases, expanded. These include the stakeholder platforms already mentioned in various measures and a new interdepartmental working group. The frequency of exchanges will depend on the requirements of the individual platforms.

6.5.5 Review of the situation in 2018

The Federal Council is aware that the present report merely provides a snapshot of the decisions taken by Parliament and the Federal Council to make the environment for biomedical research and technology as attractive as possible.

In five years' time, it will present a further report, reviewing the latest developments, providing an interim assessment of the measures adopted today and, if necessary, proposing additional measures. This will require data which, to a large extent, is currently unavailable.

7 COMPETITIVE CONDITIONS FOR THE PROMOTION OF RESEARCH AND INNOVATION

This chapter begins with a detailed account of the factors influencing clinical research in Switzerland. A variety of global and national factors can be identified. Competitive conditions for the promotion of research and innovation are dependent on human research law, the structural framework for publicly funded research, education/training and continuing education, and the availability of health data. For the individual areas, therefore, a description is given of the need for action, the aims of measures designed to improve the situation, the measures already adopted or planned, and the measurement of goal attainment.

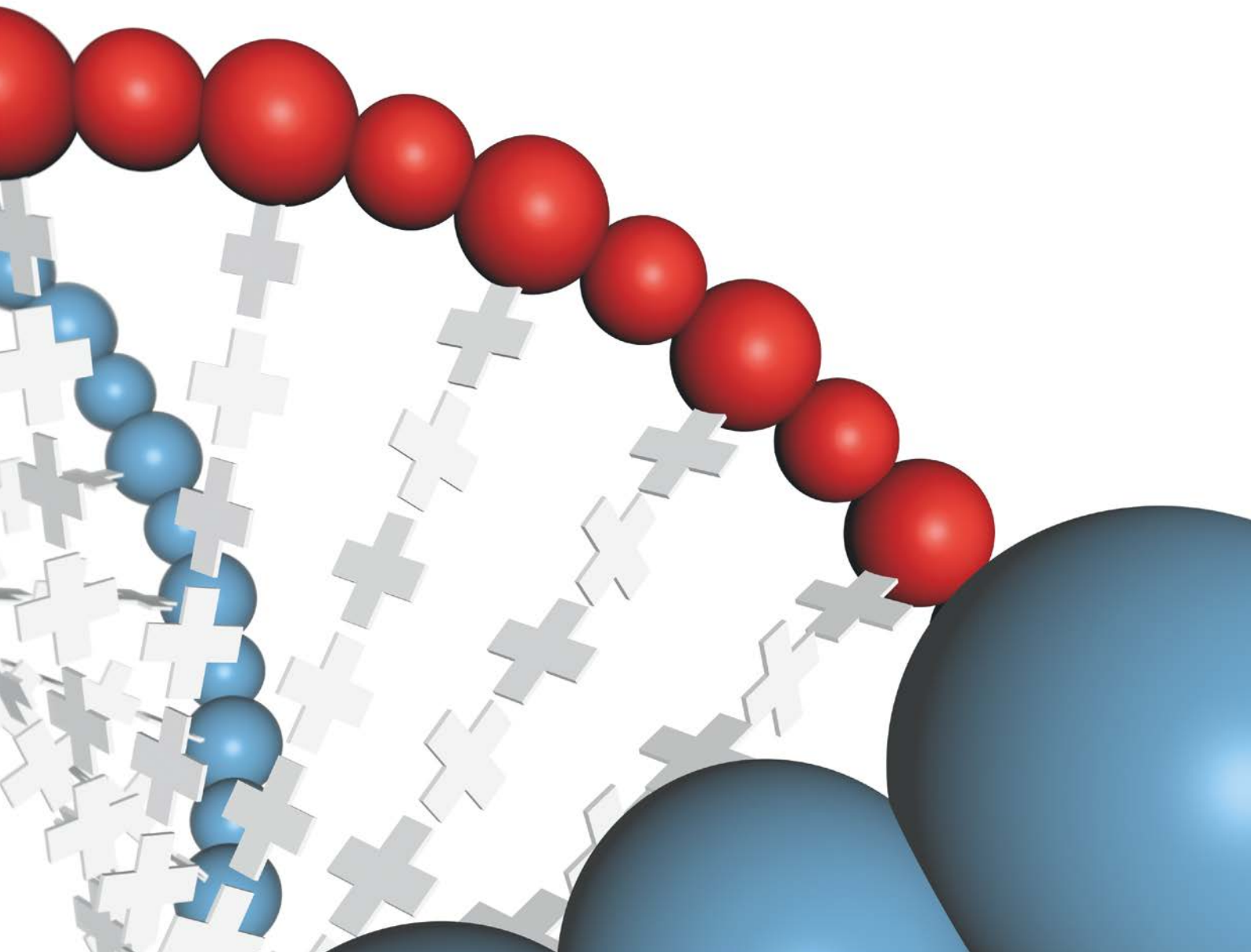
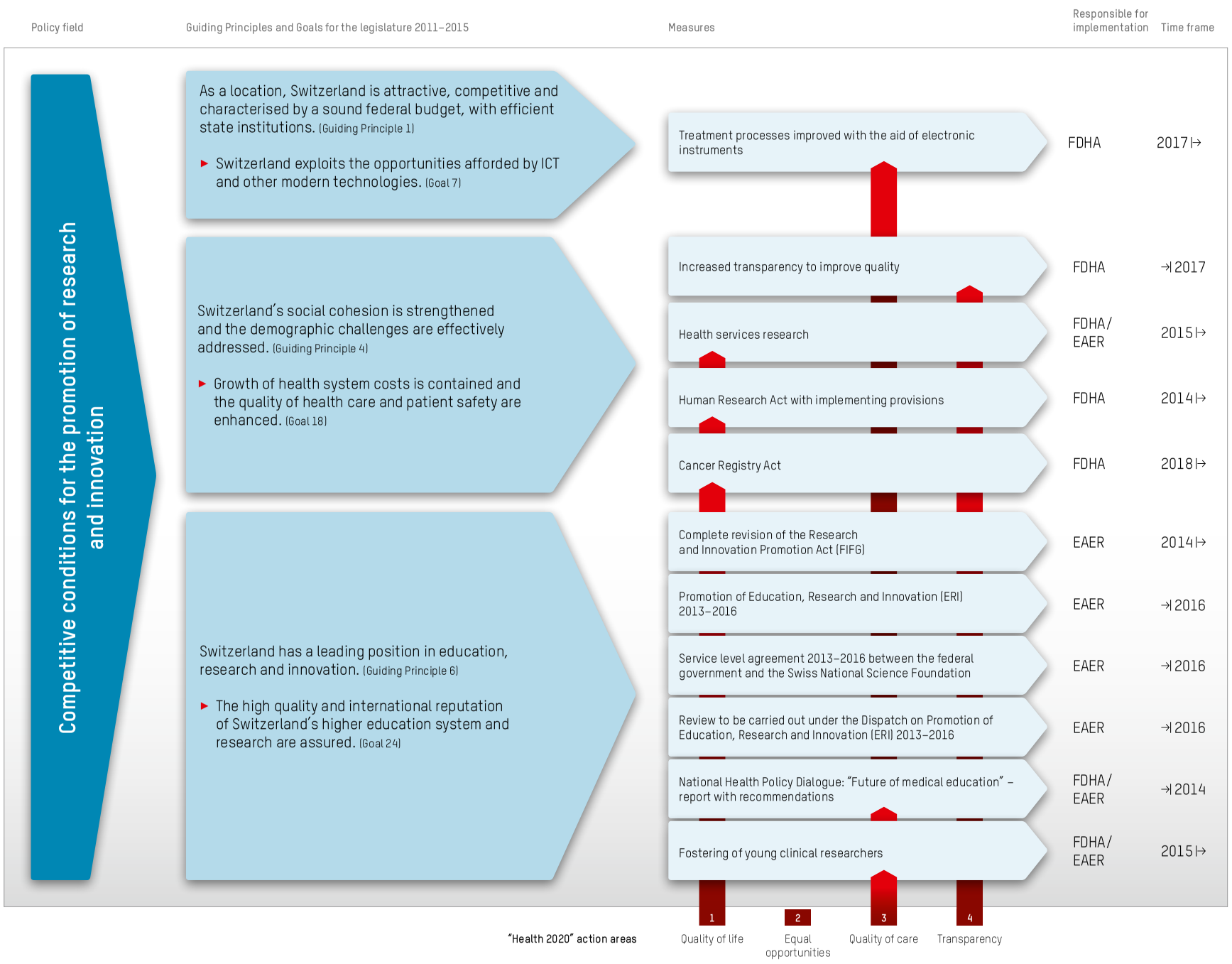


Figure 7a: Measures in the area "Competitive conditions for the promotion of research and innovation"



7.1 Factors influencing clinical research in Switzerland

According to the 2012 Annual Report of the Swiss Agency for Therapeutic Products (Swissmedic), the number of notified clinical trials with medicinal products has fallen, from 318 in 2009 to 273 in 2010 and 237 in 2012.[178] A comparable decline of around 25% can be seen in applications for clinical trials in the EU from 2007 to 2011.[179] In seeking to determine the reasons for this decline, further documents were examined.[180] Overall, 16 factors were identified and classified under 4 headings:

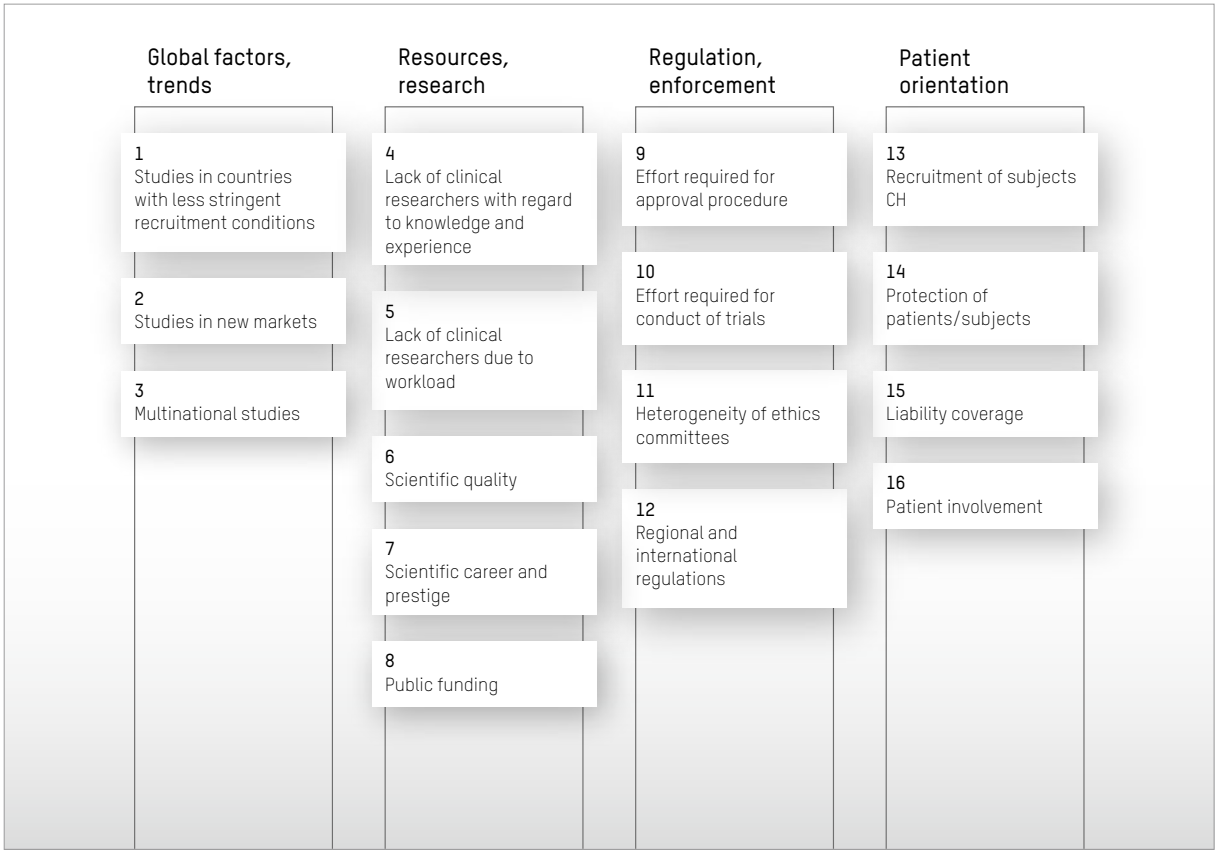


Figure 8: Factors influencing clinical research in Switzerland

[178] Swissmedic, Annual Report 2012

[179] European Commission. Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Brussels, 17 July 2012

[180] Klinische Forschung in der Schweiz: Empfehlungen des Schweizerischen Wissenschafts- und Technologierates, SWTR-Schrift 3/2002
Nationales Krebsprogramm für die Schweiz 2011–2015, oncosuisse 2012
OECD Global Science Forum, Explanatory Memorandum for the Recommendation of the Council on the Governance of Clinical Trials, Version 7, 22 September 2012

How do all these factors influence the development of clinical research in Switzerland?

In various quarters, Switzerland's legal framework is frequently claimed to be the main reason for the decline in clinical research. This claim was investigated with the aid of guided expert interviews conducted in October and November 2012.[181]

The findings are grouped under various headings below. The first group consists of global factors and trends (7.1.1), which are rated as having a substantial influence on clinical research in Switzerland. These factors are not amenable to control by Swiss regulations. The second group comprises national factors (7.1.2), which may also affect clinical research but which are amenable to Swiss influence.

7.1.1 Global factors

The respondents are agreed that three global factors (factors 1–3) are playing a significant role in the decline of clinical research in Switzerland.

Relocation to countries with less stringent recruitment conditions (factor 1)
The large populations in Asian and South American countries facilitate large-scale studies. These countries are attractive locations for studies of common diseases. Participation in studies allows patients in these countries to access medical care. The standard of research in Asian and South American countries is said to be comparable to the European level, while costs are substantially lower. Based on an international comparison, it was estimated that in 2005 a clinical trial performed in Germany cost over 1.5 times as much as in the US, while trials in Argentina, China and India cost about a third as much as in Germany.[182]

Shifting of studies towards "new" markets (factor 2)
The size of markets is a key factor in selecting the location for studies. A local presence gives pharmaceutical companies a competitive advantage. Drugs are increasingly being tested in the regions where they are ultimately sold.

[181] In this exploratory investigation, a total of twelve people were interviewed. The selection of interviewees was designed to ensure that, firstly, all clinical research stakeholders were represented as far as possible and, secondly, information was obtained from recognised experts. The interviewees were representatives of academic and non-academic research, federal authorities, the Swiss Association of Ethics Committees for research on humans (AGEK), non-profit organisations, associations and the pharmaceutical industry. The evaluation was qualitative. The respondents' views on the individual factors were collected and shown in tabular form. The findings permit conclusions as to the influence exerted by these factors. Conclusions can also be drawn concerning the extent to which respondents agreed in their assessments. As the method is essentially exploratory, neither quantifiable nor generalisable conclusions can be drawn.

[182] Ross C. DeVol, Armen Bedroussian, Benjamin Yeo, The Global Biomedical Industry: Preserving U.S. Leadership, Milken Institute, 2011, p. 44

Increase in multinational studies (factor 3)

For large, pivotal Phase III trials,[183] multinational companies choose locations such as the US or the EU, as their protocol specifies a high standard and large numbers of patients are available for the studies. In Switzerland, the market is comparatively small, and the costs of studies are relatively high. The conditions for commercial research in Switzerland are favourable for Phase I and II trials of therapeutic products in particular, as the numbers of participants required are fairly small and the quality requirements for research and care are met.

The trend towards multinational – especially Europe-wide – studies is also evident in academic research. According to the respondents, this means that more funding is transferred from Europe to Swiss research than vice versa.

7.1.2 National factors

Resources for research (factors 4–8)

There is a consensus among the respondents concerning the lack of clinical researchers, both with regard to knowledge and experience (factor 4) and on account of the workload (factor 5). According to the respondents, there has been an improvement in the situation criticised in a 2002 Swiss Science and Technology Council (SWTR) report on clinical research in Switzerland[184] – the lack of familiarity on the part of clinical researchers both with the latest molecular biological and epidemiological knowledge and with clinical issues – thanks to various measures (establishment of clinical trial units [CTUs], expansion of education and training programmes). However, a need for greater professionalisation continues to be seen with regard to cantonal hospitals. Among the main reasons cited for the lack of clinical researchers are growing cost pressures in hospitals. As a result of these pressures, priority is being accorded to the treatment of patients rather than to research, which is pursued in leisure time. One possible solution suggested is the "protected time" model, under which income and working hours for clinical and research activities would be separated. Experience in both areas is considered to be important for research, as this facilitates the formulation of clinically relevant questions for investigators.

Scientific quality (factor 6) is generally rated by the respondents as high, especially by international standards. The quality of studies is said to be dependent on the degree of professionalisation, which could be seen from the content of the protocol. According to one respondent, similar studies are often performed with different protocols. Harmonisation – e.g. a standardised protocol – would be necessary for widespread indications. Greater attention would need to be paid to this point in so-called free research.

For some respondents, a career in clinical research (factor 7) is not sufficiently attractive, and the prestige of clinical research is too low. The threshold for a postdoctoral academic career is perceived as generally too high in Switzerland. Other respondents stress the crucial role of the intrinsic motivation to pursue research.

---

[183] After the completion of preclinical studies, drug development is divided into 4 clinical phases (cf. http://en.wikipedia.org/wiki/Clinical_trial):
Phase I trials are generally designed to obtain initial data on the safety and (adverse) effects of various doses. The number of participants tends to be small (20–80).
In Phase II trials, the drug is studied in patients for the first time. The therapeutic concept is tested and dose-finding is performed. The number of subjects involved is approx. 50–200.
Phase III trials are generally multicentre studies involving large numbers of participants. The aims are to demonstrate significant efficacy and to obtain marketing authorisation.
Phase IV trials are performed after authorisation has been granted for the approved indications. They are used to identify very rare adverse effects which can only be detected in very large patient populations. However, Phase IV trials are frequently also used for marketing purposes.

[184] Klinische Forschung in der Schweiz: Empfehlungen des Schweizerischen Wissenschafts- und Technologierates, SWTR-Schrift 3/2002

There is also disagreement among the respondents as to the influence of public funding (factor 8). Around half take the view that insufficient funding is available in general and specifically for studies on treatment optimisation and health services. The other half emphasise that scientific quality rather than funding is the main issue. The availability of an adequate infrastructure is regarded as a prerequisite.

Regulation and enforcement (factors 9–12)

The respondents are agreed that the efforts required for the current approval procedure (factor 9) are generally excessive and serve as an impediment. Planning certainty is regarded as indispensable for studies because subjects have to be recruited at an early stage, and preparations (e.g. for informed consent and documentation) take place before the start of a study. By comparison with other countries, however, Switzerland is said to perform well. The efforts required depend on (the degree of professionalisation of) the approval authority (factor 11). According to all the respondents, there is room for optimisation particularly in the standardisation of procedures, harmonisation with international regulations (factor 12), and a reduction in the number of procedures and ethics committees, as well as in the setting of deadlines.

There is disagreement among the respondents concerning the efforts involved in conducting a clinical trial (factor 10) which are a result of legal requirements. Reporting on changes to projects, in particular, is felt to be very cumbersome and is perceived as excessive. At the same time, a third of the respondents take the view that quality management efforts are necessary and justified in the interests of transparency.

Patient orientation (factors 13–16)

The respondents agree in their assessment of the possibilities for recruiting trial subjects in Switzerland (factor 13). Whether it is possible to enrol sufficient participants depends on the indication. Because of the high standard of medical care and the small population size, few studies are carried out on common conditions such as diabetes. But in the case of rare conditions and serious, non-communicable diseases (e.g. cancer), patients are eager to participate, as they hope to receive optimised therapy. The more invasive the interventions, however, the lower the readiness to participate. Even blood sampling is reported to be perceived as invasive.

There is also a consensus that the regulations ensure adequate protection of trial subjects (factor 14). Only one respondent expresses concerns as to whether patient protection receives due attention in day-to-day research activities.

The majority of respondents agree that the costs of a study are not driven up by liability (factor 15), since coverage is provided by the sponsor.

Different views are expressed regarding the involvement of patients in decision-making processes in clinical research (factor 16). Representatives of commercial research, in particular, welcome such involvement, as they believe it promotes the acceptance of clinical research. Some respondents approve of patient involvement in specific cases, e.g. for rare diseases, the selection of research topics and the preparation of package leaflets. A few others take a more sceptical view.

The following overview indicates where agreement or disagreement exists among the experts interviewed as to the influence of individual factors:

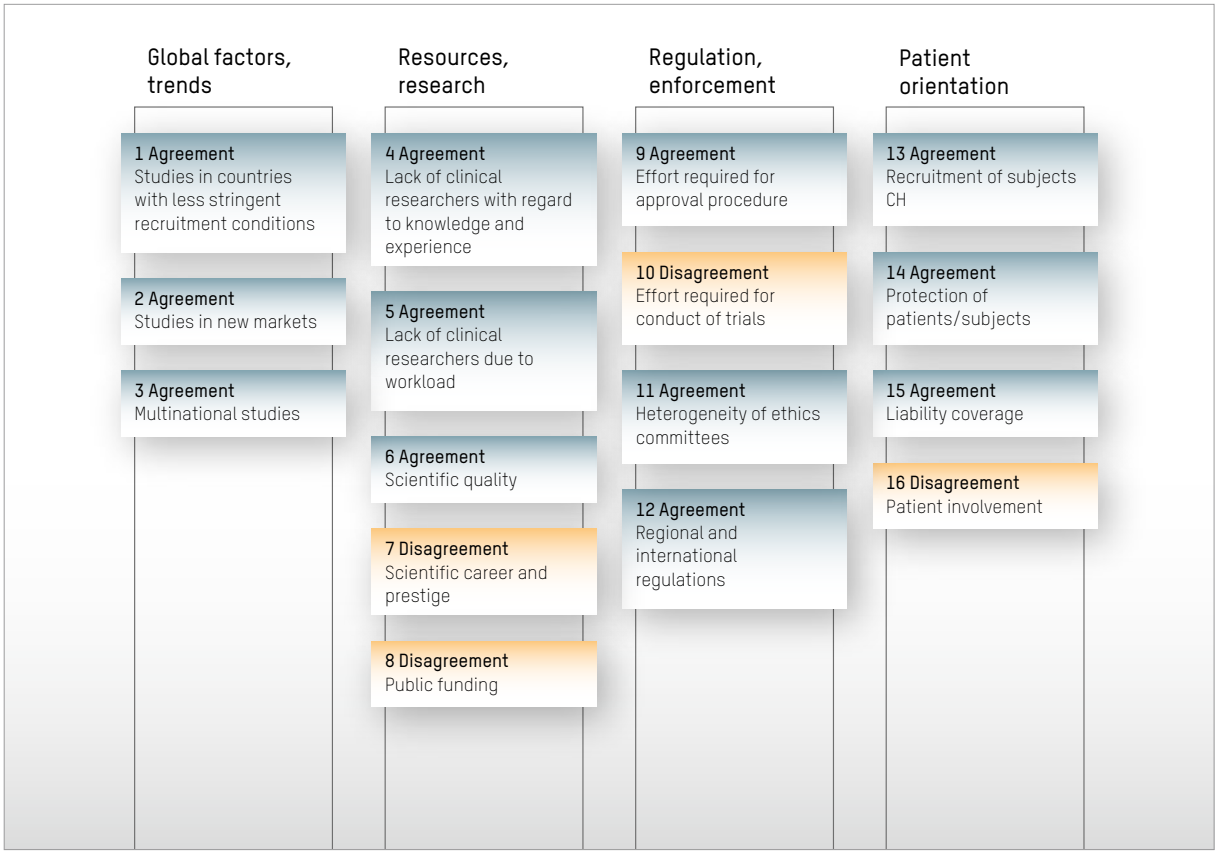


Figure 9: Summary of respondents' agreement/disagreement with regard to individual factors

7.1.3 Rejection of a niche strategy

One of the questions discussed at the round-table events was whether Switzerland should pursue a niche strategy in clinical research. This idea was rejected by the organisations participating, on the grounds that research in all phases of the development of medicinal products and medical devices is vital for Switzerland as a location.

7.2 Regulatory framework for human research

7.2.1 Background

The regulation of human research in Switzerland is guided by ethical principles which are recognised as binding worldwide.

The Declaration of Helsinki[185] (1964/2008), issued by the World Medical Association (a confederation of national medical associations), has established standards for medical research which are widely respected – not only by the medical profession. As well as research involving human subjects, the Declaration also covers research on identifiable human material and data. The most important principles relate to the need for a comprehensive written research protocol, the scientific requirements to be met, the registration of research in a publicly accessible database, participants' voluntary informed consent, the careful assessment of predictable risks and burdens in comparison with foreseeable benefits, and the submission of each research protocol for review by an independent ethics committee.

Also widely respected internationally is the Guideline for Good Clinical Practice (GCP, 1996) of the ICH,[186] a non-governmental organisation representing the pharmaceutical industry and regulatory authorities of Europe, the US and Japan. It specifies requirements for the conduct of clinical trials of pharmaceutical products in human subjects and is recognised in Switzerland's therapeutic products legislation[187] as a binding standard to be complied with in clinical drug trials. In practice, however, the GCP principles are also applied for other human research projects. The ICH GCP Guideline also makes reference to the Declaration of Helsinki and includes, in particular, the generally recognised principles concerning informed consent, the acceptable risk-benefit ratio, scientific requirements and review by an independent ethics committee.

Both of these guidance documents have been officially adopted by the World Health Organization (WHO) and the UN Educational, Scientific and Cultural Organization (UNESCO).

Although these principles are not disputed and in some cases have been declared to be directly applicable, regulation in Switzerland remains incomplete and the overall picture is somewhat complex.

At the level of federal legislation, general requirements for the protection of persons participating in research projects arise from the protection of the personality under civil law and from criminal law provisions, in particular concerning the protection of life and limb. Research-specific regulations are only to be found in certain areas listed below, based on provisions included in the Federal Constitution.[188]

[185] www.wma.net

[186] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (www.ich.org)

[187] Art. 4 para. 1 of the Ordinance of 17 October 2001 on Clinical Trials (VKlin; SR 812.214.2)

[188] Provisions which are also relevant for research are to be found in the consitutional articles on reproductive medicine and gene technology involving human beings (Art. 119) and on transplantation medicine (Art. 119a).

Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act)
Before they are placed on the market, the safety and efficacy of medicinal products and medical devices have to be assessed in clinical trials. The requirements included in the Therapeutic Products Act concerning the protection of persons participating in such trials are specified in more detail in the Ordinance on Clinical Trials of Therapeutic Products. The most important requirements concern compliance with the principles of GCP, the need to obtain informed consent and the provision of full compensation for any harm caused to participants.

The Therapeutic Products Act (TPA) also regulates the supervision of clinical trials: as well as being approved by the relevant ethics committee, each clinical drug trial has to be submitted to the Swiss Agency for Therapeutic Products (Swissmedic) for review and approval (notification procedure). The ethics committees appointed by the cantons evaluate trials from an ethical perspective and review their scientific quality, taking local conditions into account.

Transplantation Act
The Transplantation Act (TA) regulates clinical trials involving the transplantation of human organs, tissues or cells. Essentially, the provisions of the Therapeutic Products Act are declared to be applicable mutatis mutandis.

Stem Cell Research Act
The Stem Cell Research Act (StRA) specifies the conditions under which it is permissible for human embryonic stem cells to be derived from surplus embryos (produced in the course of IVF procedures) and used for research purposes. Research on IVF embryos is prohibited.

Reproductive Medicine Act
The Reproductive Medicine Act (RMA) regulates the techniques of medically assisted reproduction but does not generally cover research in this field. It does, however, include a number of prohibitions which also apply to research: for example, it is prohibited to produce an embryo for research purposes, to genetically modify germline cells, to carry out germline therapy, or to create a clone, chimera or hybrid. The RMA does not, however, regulate sperm and ovum donation for research purposes or research involving pregnant women, embryos and foetuses in vivo or from terminations or miscarriages, or stillbirths.

Federal Act on Human Genetic Testing
The Federal Act on Human Genetic Testing (HGTA) regulates research only with regard to the further use of biological material for genetic testing. Under the HGTA, genetic tests for research purposes may be performed on biological material obtained for other purposes provided that the anonymity of the person concerned is ensured and that, having been informed of their rights, they have not expressly forbidden such use of the material.

In addition, regulations on human research – especially medical research – exist in most cantons; however, these vary widely in their extent and degree of detail. With the exception of a small number of cantons which have not issued any regulations on human research, provisions concerning medical research are to be found in cantonal legislation.

In many cases, the guidelines on human research issued by the Swiss Academy of Medical Sciences or the ICH GCP Guideline are declared to be binding.[189]

[189] Cf. also the discussion in the Federal Council Dispatch of 21 October 2009 on the Federal Act on Research involving Human Beings (BBl 2009 8045)

7.2.2 Need for action to improve the situation

The Swiss Parliament recognised the lack of standardised nationwide regulations for human research some time ago and, accordingly, submitted various requests to the Federal Council.[190]

The electorate and policymakers acknowledge the importance of human research.

In recent years, Switzerland has signed international agreements such as the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997),[191] which came into force in Switzerland on 1 November 2008. This includes provisions concerning human research. For example, research on humans is only permitted if there is no alternative of comparable effectiveness.[192] Also specified are the general principles for informed consent, the risk-benefit ratio and independent examination of research projects. Individual parties remain free to grant a wider measure of protection than is provided for in the Convention.

The Additional Protocol concerning Biomedical Research (2005) builds on the principles embodied in the Biomedicine Convention. It covers the full range of research activities in the health field involving interventions on human beings. It also includes detailed provisions concerning the examination to be conducted by an ethics committee and the information to be submitted to this body.

Since 7 March 2010, when Article 118b of the Federal Constitution was adopted, the Confederation has had comprehensive powers to legislate on human research. On 30 September 2011, the Federal Act on Research involving Human Beings (Human Research Act, HRA) was adopted by Parliament;[193] this Act, together with the associated ordinances, comes into effect on 1 January 2014.

[190] The following parliamentary motions are being implemented:
98.3543 Mo. Plattner, "Creation of a Federal Act on medical research involving human beings"
04.3105 Mo. Dunant, "Support for medical research"
04.3742 Mo. Hochreutener, "Standard procedure for clinical trials"
05.3136 Mo. Hubmann, "Greater transparency in clinical trials"

[191] http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

[192] General principle of subsidiarity

[193] BBl 2011 7415; the referendum deadline expired on 19 January 2012 with no referendum being called.

7.2.3 Aims of measures designed to improve the situation

The Human Research Act implements the constitutional mandate to regulate research involving human beings where this is required in order to protect their dignity and privacy. At the same time, it should help to establish a favourable framework for human research.

The provisions concerning human research currently contained in a variety of federal and cantonal laws are thus consolidated and supplemented in uniform legislation. The provisions of the Human Research Act supersede the general requirements concerning research specified, in particular, in the Transplantation Act and the Therapeutic Products Act and also certain cantonal regulations.

7.2.4 Measures already adopted or planned

In 2012, the Federal Council conducted a hearing on the implementing provisions relating to the Human Research Act (Human Research Ordinances, HRO). The Ordinances expand on the goals of the Act, specifying in particular the ethical, scientific and legal requirements to be complied with in human research. The administrative and legal requirements are dependent on the level of risk to which persons participating in the research are exposed.

Where possible, this risk-adapted approach is based on procedures which are already established in practice. It has an effect on safety-related requirements, liability, and the approval and notification procedures, and it should relieve the administrative burden especially in the case of research projects where the potential risks are comparatively low. This approach was developed in close consultation with the authorities and organisations concerned and with representatives of research. At the same time, by standardising the administrative procedures among cantonal ethics committees and ensuring harmonisation with international guidelines, the ordinances promote the establishment of a favourable framework for research in Switzerland.

Switzerland will be the first country worldwide to introduce the internationally recommended risk categorisation in legislation. For this reason, the categories and criteria proposed in the draft ordinances during the hearing were tested in practice. The pilot project was conducted in cooperation with a number of relatively large ethics committees.[194] Over 230 researchers agreed to make their study protocols available for the pilot project and to categorise the (already approved) study using the new criteria. Overall, the pilot project demonstrated that the categorisation and the proposed criteria can be readily applied in most cases, resulting in the desired simplification of procedures.

The appropriate and practicable categorisation of clinical trials by risk is currently also the goal of efforts being pursued within the OECD and the EU. On 17 July 2012, a proposal for a new Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use was published by the European Commission. The proposed Regulation – which also includes risk-adapted provisions – would replace the existing Directive 2001/20/EC. Based on an initial review of this new proposal and the information received to date from contacts with representatives of the Commission, it may be assumed that the Human Research Ordinances will allow a greater reduction in administrative burdens than the proposed Regulation.

The recommendations developed by the OECD concerning risk categories for clinical trials on

[194] The pilot project was actively supported by the Ethics Committees of Cantons Aargau, Bern, Geneva, St. Gallen, Ticino, Vaud and Zurich.

medicinal products were published in March 2013.[195] The Federal Office of Public Health was involved in the preparation of the recommendations, thus ensuring that the Swiss ordinances comply with the OECD recommendations.

The implementing provisions relating to the Human Research Act were adopted by the Federal Council on 20 September 2013, and they came into force, together with the Act, on 1 January 2014.

7.2.5 Assessment of measures additionally proposed

Implementing provisions for the Human Research Act

At the two master plan round-table events, the SAMS/SAKK/oncosuisse and the pharmaceutical industry called for a reduction in the administrative burden currently associated with the submission of studies and an overall increase in the efficiency of ethics committee and Swissmedic approval procedures. Other proposals concerned parallel submissions to ethics committees and Swissmedic, and the professionalisation of ethics committees.

Different views are taken with regard to the application of internationally recognised guidance such as the ICH GCP Guideline. According to the SAKK/oncosuisse, compliance with this Guideline should only be mandatory in the case of studies required for the authorisation of therapeutic products. For clinical research on "academic questions", compliance with the principles of GCP is considered sufficient. In the view of the DVSP, the application of this Guideline plays a key role in ensuring the quality of clinical research.

The SPO and the DVSP emphasise the need for independent research: essential measures would include disclosure of sources of financing, guidance for researchers and a registry of approved research projects. As regards the latter, Interpharma/Scienceindustries/vips argue that a central portal for submissions would reduce the effort involved for the sponsor.

The Human Research Ordinances address these concerns within the framework set by the Human Research Act. In the area of clinical trials, the total administrative effort and time involved for researchers is likely to decrease; in particular, the burden will be eased appreciably for low-risk clinical research. Positive effects will arise from improvements in the approval procedure, particularly as a result of the division of responsibilities and parallel procedures within the ethics committees and other regulatory authorities (especially Swissmedic, FOPH), as well as the introduction of lead committees for multicentre research projects. The duration of procedures can be significantly shortened as a result. The risk categorisation will also lead to less burdensome requirements for the approval and conduct of trials which involve relatively low risks for participants (Category A).

On the other hand, researchers will be required to justify the proposed risk category, entailing a slight increase in the effort involved in preparing the application documents. Another new requirement is mandatory registration for clinical trials, so as to meet the political demand for increased research transparency.

As regards the independence of research, the sponsor, the investigator and the other persons involved in the clinical trial are required to maintain scientific integrity. In addition, the sponsor and the main sources of financing for the clinical trial must be disclosed to the participants and to the ethics committee.

[195] www.oecd.org/sti/sci-tech/oecdrecommendationonthegovernanceofclinicaltrials.htm

The Swiss Pediatric Oncology Group (SPOG) proposes that tax-exempt organisations in the field of academic clinical research involving children should be exempted from fees for inspections and procedures carried out by ethics committees and Swissmedic.

With the new division of responsibilities, fees will arise mainly for cantonal ethics committee procedures. Responsibility for the charging of fees thus rests entirely with the canton concerned. Here, the Confederation deliberately chose not to exert any influence.[196] If, in exceptional cases, the services of Swissmedic should also be required for such studies, any exemption from fees would have to be covered by federal contributions.[197]

7.2.6 Federal Council's position regarding additional proposals

The Federal Council paid particular attention to these proposals in the process of preparing the implementing provisions for the Human Research Act. At the beginning of 2013, the Federal Department of Home Affairs instructed the Administration – bearing in mind the aims of the Human Research Act and the master plan – to involve representatives of the groups directly concerned in the preparation of the Human Research Ordinances. This involvement elicited a favourable response from key stakeholders.

7.2.7 Measurement of goal attainment

The goals set are to be evaluated four years after the entry into force of the Human Research Act.

[196] Art. 54 para. 5 Human Research Act

[197] Art. 65 para. 6 Therapeutic Products Act

7.3 Structural framework for publicly funded research

7.3.1 Switzerland's funding system

The Federal Act on the Promotion of Research and Innovation (Research and Innovation Promotion Act, FIFG[198]) regulates the tasks and responsibilities of research organs with regard to their role and function in the federal promotion of research and innovation. The main subject of regulation is thus the public funding system. The effectiveness of the Swiss funding system is demonstrated by Switzerland's success rate in securing funding under EU Research Framework Programmes[199] (particularly the "Health" and European Research Council [ERC] programmes) and also by the fact that scientific publications by researchers working in Switzerland are highly regarded internationally (as shown by an SER bibliometric study[200]). This conclusion is also confirmed by a comparison of funding instruments and mechanisms in three European countries (Germany, the UK, the Netherlands) which appeared in a report[201] recently issued by the Federal Council. However, in view of major differences in political systems, and the varying types of organisation and responsibilities associated with the different political levels in other countries, a direct comparison of funding systems and the underlying legislation is an extremely complex undertaking. Here, therefore, the most important characteristics of the Swiss funding system will be considered.

According to the Federal Constitution, the promotion of scientific research and innovation is a key federal responsibility (Art. 64). Under the FIFG, implementation of the Swiss funding system is centrally organised, and in practice it involves two funding organs (the SNSF and the CTI) – in contrast to other European countries (e.g. Germany, France, the UK), which have a number of funding organs. Another distinctive feature of the Swiss system is that the financing of research and innovation funding through the SNSF and the CTI is exclusively a federal responsibility – unlike in Germany, for example, where the German Research Foundation (DFG), which is comparable to the SNSF, is co-financed by the states (Länder).

Public funding of research and innovation by the SNSF and the CTI is organised on a competitive basis, and the generation of research topics is essentially a bottom-up process. Even in cases where the Confederation establishes thematic guidelines and priorities, these are prepared in close consultation with scientific committees (bottom-up participation) and implemented via SNSF and CTI funding instruments exclusively in accordance with competitive criteria. Neither for SNSF nor for CTI funding do any quotas exist for the benefit of higher education institutions or specific research centres. In both cases, resources are allocated through project funding. The key selection criterion is – depending on the function of the funding organ – either the scientific excellence (SNSF) or the (market-oriented) innovation potential (CTI) of the projects.

Competitive research is also funded via (federally financed) Swiss contributions to the EU Research Framework Programmes. In addition, the Confederation directly supports the basic financing of higher education institutions (cantonal universities and universities of applied sciences, institutions of the ETH domain), which in turn dedicate part (or, in the case of the ETH domain, most) of their budget to research. The excellent standard of research in Switzerland is also attributable to this stable, high level of higher education financing.

198 SR 420.1

199 Swiss Participation in the EU's Seventh Research Framework Programme, Interim Report 2007–2012, Facts and Figures. SERI 2013 (www.sbfi.admin.ch/themen/01370/01683/index.html?lang=en&download=NHzLpZeg7t,lnp6I0NTU042l2Z6ln1ad1IZn4Z2qZpnO2Yuq2Z6gpJCEdH93hGym162epYbg2c_JjKbNoKSn6A--).

200 Bibliometrische Untersuchung zur Forschung in der Schweiz 1981–2009, SBF, 2011.

201 Effect of steering measures in education and research: Federal Council Report in fulfilment of Postulate 01.3534 Fetz (http://edudoc.ch/record/4161/).

Other federal measures at the national level include subsidiary support for research institutions outside the higher education system and the departmental research undertaken in fulfilment of the tasks of the Federal Administration. Here, too, there are significant systemic differences between Switzerland and other countries. While in countries such as Germany or France numerous publicly financed research institutions exist alongside the universities, the extent of such institutions in Switzerland is very limited. The same is also true of departmental research, where other European countries have numerous research institutes attached to specific ministries (and in some cases also thematically specialised funding bodies).

In Switzerland – as already discussed – the federal promotion of research and innovation is reinforced by a level of private-sector research activity which is extremely high by international standards. This represents one of Switzerland's outstanding advantages compared with other OECD countries.

7.3.2 Specific measures to promote research

A. FOUNDATIONS AND ANALYSES

In the reports published by the Swiss Science and Technology Council (SWTR) on clinical research (in 2002[202]) and on university medicine (in 2006[203]), specific measures are recommended for the promotion of clinical and translational research in particular. The Dispatches on the Promotion of Education, Research and Innovation for the periods 2008–2011 and 2013–2016 indicate the measures adopted by the federal government – within the framework of its powers and financial resources – to support biomedical and, specifically, clinical or translational research, both within the ETH domain and via SNSF funding.

Bibliometric analyses show that the impact of Swiss publications in the field of clinical medicine has risen sharply. In the early 2000s, it surpassed the global mean, having been almost 30% below this level in the early 1980s. For the period 2005–2009, Switzerland ranks in fifth place worldwide, behind the US, the Netherlands, Belgium and Denmark.[204]

B. SWISS NATIONAL SCIENCE FOUNDATION

I. Measures in biomedical and clinical research

In recent years, the Swiss National Science Foundation (SNSF) has contributed to efforts to raise clinical research in Switzerland to an internationally competitive level. With the provision of support for cohort studies, the establishment of networks of Clinical Trial Units and the Special Programme University Medicine (SPUM), important infrastructure has been developed and initiatives launched which should bear fruit in the coming years. A major challenge over the next few years will be to expand, further optimise and coordinate these instruments where necessary.

202 Klinische Forschung in der Schweiz: Empfehlungen des Schweizerischen Wissenschafts- und Technologierats, SWTR-Schrift 3/2002.

203 Für eine zukunftsorientierte Hochschulmedizin, SWTR-Schrift 1/2006.

204 Bibliometrische Untersuchung zur Forschung in der Schweiz, 1981–2009, SBF, 2011.

Clinical Trial Units and the Swiss Clinical Trial Organisation

In the ERI period 2008–2011/2012, the SNSF provided initial funding for the development of six Clinical Trial Units (CTUs) – at the University Hospitals of Basel, Bern, Geneva, Lausanne and Zurich and the Cantonal Hospital of St Gallen. A CTU generally assumes the role of an academic contract research organisation (CRO). The three main functions of the CTUs are:[205]

- quality assurance in the preparation of clinical trials prior to approval (ethics committees, Swissmedic/notification),
- quality assurance and control during the conduct phase,
- education/training responsibilities.

In autumn 2009, the Swiss Clinical Trial Organisation (SCTO) was established by the CTU sponsors (University/Cantonal Hospitals), the Deans of the Swiss Medical Faculties and the SAMS. The SCTO is the central platform for collaboration on patient-centred clinical research in Switzerland. Its primary objective is to ensure that Swiss clinical research is attractively and competitively positioned at the international level with regard to innovation and quality. The SCTO seeks to achieve these goals by promoting a high-quality, nationally harmonised trial culture (including the requisite training and continuing education); supporting the development of a national network; promoting the integration of national clinical research into international networks; and building bridges between academia, industry and authorities. In addition, the SCTO seeks to secure a favourable framework for clinical research and assumes coordinating functions with regard to multicentre trials and trial placement.

The SCTO also serves as the Swiss national hub partner of the European Clinical Research Infrastructures Network (ECRIN), which plays an important role in orphan disease research in particular. Because efficient research in this field is dependent on adequate numbers of patients, international cooperation – e.g. within the ECRIN framework – is crucial.

[205] See also: Guidelines for Good Operational Practice for the Swiss CTU Network and SAKK, Version 1/2011.

ERI period 2013–2016

The need for optimisation is particularly apparent in the translation of findings from basic to applied, patient-centred research (translational research), the fostering of young clinical researchers and the provision of support for academic clinical trials.

Under the federal service level agreement for the ERI period 2013–2016, the SNSF is to implement the following measures in the area of biomedical and clinical research in accordance with the financial resources available:

- Individual project funding
- Support for CTUs: coverage of service costs via project contributions
- Promotion of translational research: as a continuation of the SPUM (see above), multicentre, multiyear studies are to be supported – with no thematic requirements specified – so as to promote knowledge transfer from basic to medical research.
- Promotion of investigator-driven clinical research (IDCR) – i.e. projects initiated and conducted by researchers. IDCR is an important element of patient-centred clinical research and a prerequisite for continuous improvement of medicine. For multicentre clinical trials involving large consortiums – the high costs of which have rarely been covered in the past by SNSF funding – a budget will now be available outside of the "free" project funding programme.
- Workload-reducing measures to foster research careers: to provide additional support for the development of careers in medical research, the SNSF is introducing partial exemption from clinical duties (so-called protected time) for researchers.
- Biomedical research infrastructure:
  - Support for existing cohort studies, involving the collection and evaluation of specific disease data over a prolonged period, is to be continued and extended to longitudinal studies of human populations.
  - Support is now to be provided for national and international networking of biobanks with research relevance.
  - With this infrastructural support, the SNSF will create a nationally and internationally networked data base with major benefits for research and society.

II. National Centres of Competence in Research in medicine

In addition to the above-mentioned specific measures to promote clinical research, four National Centres of Competence in Research (NCCRs) are operating in the medical and biomedical field; these are expected to provide a significant stimulus for translational research in terms of content and structure.

NCCR "TransCure"

The NCCR "TransCure – From Transport Physiology to Identification of Therapeutic Targets" seeks to integrate the disciplines of physiology, structural biology and chemistry and to develop new therapeutic strategies for treating the most important diseases. Transport proteins and ion channels play a key role in all physiological processes in the human body. Malfunctions in these proteins may contribute to the occurrence of diseases such as diabetes, high blood pressure, osteoporosis and neurodegeneration, and play a role in heart disease and cancers. The NCCR "TransCure" researchers aim to achieve a more profound understanding of the structures and mechanisms of these proteins. By broadening their knowledge of how transport proteins and channels work, they hope to develop new medicines.

NCCR "SYNAPSY"

The NCCR "SYNAPSY – Synaptic Bases of Mental Diseases" aims to discover the neurobiological mechanisms of mental and cognitive disorders, since one of the major challenges in psychiatry is to achieve a better understanding of how these illnesses originate. It is hoped that this research will lead to the development of improved diagnostic tools and therapeutic approaches. The NCCR "SYNAPSY" focuses on the interface between preclinical research and clinical development, combining neuroscience with psychiatry. This research focus will help train a new generation of psychiatrists who will possess both high clinical expertise and a sound knowledge of the basic neurobiological aspects of mental functions and dysfunctions.

NCCR "Molecular Oncology"

The NCCR "Molecular Oncology – From Basic Research to Therapeutic Approaches" strengthens cancer research in Switzerland. Working with partners from different university hospitals and the pharmaceutical industry, the researchers seek new cancer therapies, discover mechanisms of tumour formation and endeavour to translate these findings into therapeutic approaches. The NCCR "Molecular Oncology" thus creates bridges between basic and clinical cancer research. The research projects target different aspects of the fundamental biology of tumours and the response of healthy cells to cancer. Thanks to this NCCR, cancer research in Lausanne is being strengthened and reorganised. A cancer research centre, where teams from EPF Lausanne and the University of Lausanne will work closely together, is being set up at the University Hospital Centre (CHUV) Lausanne.

NCCR "Kidney.CH"

The NCCR "Kidney.CH – Kidney Control of Homeostasis" is the world's first research network to explore the physiological processes in healthy and diseased kidneys across a broad thematic spectrum. The aim is to seek insights for new preventive, diagnostic and therapeutic approaches to treating kidney patients. The motivation is that kidney diseases have increased dramatically in recent years. Patients with chronic kidney diseases risk exposure to further secondary diseases such as high blood pressure or osteoporosis. Reduced kidney function has drastic consequences for the body as the kidneys are responsible for maintaining the balance between the most varied of substances in the body (homeostasis). Homeostasis is of central importance to body functions and thus a healthy life.

C. HIGHER EDUCATION SECTOR

I. ETH Medical Strategy

The Federal Institutes of Technology (ETH Zurich and EPF Lausanne) are currently participating in a wide range of technological developments with the potential to help improve the diagnosis and treatment of numerous diseases. The growing importance of the life sciences and medical technology provides opportunities for fruitful collaboration between the Federal Institutes of Technology, university hospitals and medical faculties. Under the ETH Medical Strategy, close cooperation in teaching and research is to be pursued – across institutional and disciplinary boundaries – between the ETH domain, the medical faculties at the Universities of Bern, Lausanne, Geneva, Zurich and Basel, and university hospitals (development of Medical Schools systematically combining engineering, medicine and biology).

Teaching goals:

– ensuring scientific and technical education of future physicians;
– training research-oriented physicians for cutting-edge translational research.

Research goals:

– forming consortiums including representatives of the university hospitals, medical faculties and institutions within the ETH domain;
– initiative for coordinated translational and clinical research (see below, SwissTransMed).

II. Platforms for translational research in medicine (SwissTransMed)

Over the period 2013–2016, project-specific grants awarded by the Swiss University Conference (SUK/CUS) will be used to support the cooperation and innovation project SwissTransMed, which brings together all the universities with a medical faculty and the two Federal Institutes of Technology. The goal of the platforms for translational research in medicine can be described as follows:

"The goal is to bring together basic researchers and clinical scientists, engineers, clinicians and students in all key disciplines so as to promote a better understanding of diseases, the development of new diagnostic, preventive and therapeutic approaches, and improved clinical management of patients. The platforms are to be seen as national 'innovation centres' in the clinical area concerned, promoting a shared understanding of the molecular and pathophysiological basis of diseases, clinical manifestations and challenges for therapy, epidemiology and prevention, and developing technological and pharmaceutical approaches to address these challenges.

The platforms should facilitate mutual understanding among basic researchers, engineers, clinical researchers, methodologists and clinicians, taking advantage of their different cultures and helping to develop a common language. They should offer an optimal environment for promoting and enhancing skills in basic and clinical research methods, and for promoting the clinical skills required in treating patients.

The platforms should represent – at a high academic level – innovative areas of the medical sciences, and their members should be seen as pioneers in their field. Up to six translational research platforms are to be established, each focusing on a specific clinical area."

III. "Hochschulmedizin Zürich"

September 2012 saw the launch of "Hochschulmedizin Zürich", an umbrella organisation designed to strengthen and establish closer links between research and teaching activities at the ETH Zurich, the University of Zurich and University Hospital Zurich. For the ETH Zurich, the creation of this organisation marks a further step in the ongoing process of expanding medical research. With the establishment of the new Health Sciences and Technology Department at the ETH Zurich, research in different areas has been consolidated. The "Hochschulmedizin Zürich" organisation should help in particular to accelerate and optimise the translation of research findings into clinical medicine.

D. DIRECT FEDERAL SUPPORT

Since 1992, the Swiss Group for Clinical Cancer Research (SAKK, including the SPOG) has received direct federal support as a disease-specific cooperative group under Art. 16 of the FIFG. It receives federal contributions for infrastructure (specifically, the central coordination office) and for the development and conduct of multicentre clinical trials at the national and international level. The SAKK thus assumes the role of a sponsor. The research activities of the SAKK take a multimodal approach. The SAKK develops both Phase I/II and Phase III trials, which are conducted in Switzerland and with partners abroad.

7.3.3 Need for action to improve the situation

The need for action and the measures planned are described in the 2012–2016 multi-year programme of the SNSF and in the Federal Council's Dispatch on the Promotion of Education, Research and Innovation for the period 2013–2016.

7.3.4 Aims of measures designed to improve the situation

Securing the future of the competence centres for the planning and conduct of clinical trials established at the university hospitals and at St Gallen Cantonal Hospital (CTUs/SCTO).

Ensuring coverage of the costs of treatment and care provided in accordance with established standard therapy (but sometimes involving off-label use) in academic clinical trials.

7.3.5 Measures already adopted or planned

A. CTUS/SCTO

In the ERI period 2013–2016, it is to be examined how structural financing can be secured over the long term for the entire SCTO network. In addition, looking ahead to the ERI period 2017–2020, it should be established how direct federal financing of clinical research is to be organised under the future Art. 15 of the FIFG.

Reporting on the implementation of measures or the attainment of goals will be included in the next scheduled ERI Dispatch for the period 2017–2020.

B. COVERAGE OF TREATMENT AND CARE COSTS IN TRIALS

The following approaches are to be examined for the coverage of costs of treatment and care in academic trials.

Collaboration between research and industry

Research/industry collaboration is strengthened so that manufacturers can submit, as rapidly as possible, applications for amendments to prescribing information which reflect new research findings/standard therapies. Researchers are to establish how the standard therapy in question can be defined.

Reimbursement under mandatory health insurance

The FOPH is to examine whether, by an amendment of the provisions of Articles 71a and 71b of the Health Insurance Ordinance (KVV),[206] the requirement for a review of individual cases could be waived for patients participating in academic clinical trials.

The implementation of Articles 71a and 71b KVV, in general, is to be evaluated by the FOPH by the end of 2013. Based on this evaluation, it should be established by mid-2014 whether there is a need for improvements in the implementation of the provisions or amendments to Articles 71a and 71b KVV.[207] In parallel, the FOPH is to examine the question of the coverage of costs of treatment and care in academic trials.

[206] SR 832.102

[207] Cf. the discussion in Section 8.2

7.3.6 Assessment of measures additionally proposed

Financing and support for clinical research

The SAMS proposes that clinical research structures should be independently financed, so that independent centres for translational and clinical research can be developed at all university hospitals. Together with H+ and Intergenerika, it calls for assured financing and strengthening of the CTUs and SCTO.

The DVSP takes the view that the quality of clinical research should be assured with support from specialised research units or CTUs. At the same time, it calls for more public funds for research and innovation activities, which should also remain under public control. The FMH recommends funding programmes for clinical research and for young clinical researchers.

The SAKK/SPOG calls for the maintenance of direct federal funding under Art. 16 FIFG.

These concerns are already the subject of the SERI review (2013–2016) requested by the federal government, the results of which will be reported in the Federal Council's ERI Dispatch for 2017–2020. Under the federal service level agreement with the SNSF, special programmes in the areas of biology and medicine are planned for 2013–2016.

Support for paediatric drug research

The SPOG proposes that support and funding should be provided for paediatric drug research conducted by non-profit organisations with new and existing (authorised) substances; this is said to be the only way of closing major gaps in our knowledge regarding the use of drugs already established in adult medicine.

With the ordinary revision of the Therapeutic Products Act, the federal government is already making considerable efforts in the area of paediatric drugs. However, funding and support for research is provided through the general instruments for research promotion. Responsibility for supporting studies and developing trial networks rests with the SNSF. Within the framework of the SCTO, the SNSF is supporting the initiation of a project to develop a paediatric research network (Swiss PedNet) in Basel in connection with the newly established Professorship in Paediatric Pharmacology. Specific experience with the conduct of paediatric clinical trials at the national and international level can be fed into this network. In addition, specialists have suggested that a database of information on paediatric use should be attached to this Professorship.

7.3.7 Federal Council's position regarding additional proposals

At present, the Federal Council sees no need for any further measures within its area of responsibility.

7.3.8 Measurement of goal attainment

The Federal Council will report in the ERI Dispatch for 2017–2020 on the results of the requested review and on the measures adopted by the SNSF.

7.4 Education/training and continuing education

7.4.1 Background

Since 2007, the education/training, continuing education and professional practice of physicians, dentists, chiropractors, pharmacists and veterinarians has been regulated by the Federal Act on University-Level Health care Professions (Health Care Professions Act, MedBG).[208] In the interests of public health, this Act specifies requirements designed to promote the quality of education/training and professional practice. The Act specifies general and specific professional competencies (i.e. knowledge, skills and attitudes) and regulates federal examinations and the accreditation of undergraduate and specialist training courses, as well as the requirements for the granting of a licence to practise and professional duties. A normative framework (with a health policy legitimation) is thus provided for these regulated professions, which still accords the greatest possible autonomy to the faculties and to the organisations responsible for specialist training.

A. EDUCATION

A full six-year medical course (i.e. Bachelor's and Master's degree) can be taken at the five faculties of medicine in Basel, Bern, Geneva, Lausanne and Zurich. At the University of Neuchâtel, the first year of the Bachelor's course can be taken. At Fribourg, a Bachelor's degree can be obtained after a three-year course; studies can then be pursued to Master's level elsewhere. At present, around 800 medical students per year are awarded the Swiss medical diploma. As indicated in the report entitled "Strategy to combat the shortage of physicians and to promote primary care" (issued in response to Motion 08.3608), this total is to be increased to 1200–1300 per year. This increase is required as a stabilisation measure, to ensure that the current volume of medical activity can be maintained without recourse to physicians trained outside Switzerland. An increase in training capacity is also urgently required from the perspective of clinical and translational research.

As discussed, the content of the courses for university-level health care professions is regulated by the Health Care Professions Act (MedBG).

With regard to research, Art. 6 MedBG specifies as a general goal of undergraduate education – which thus applies both for human medicine and for pharmaceutical sciences – the ability to understand the principles and methods of scientific research.

How the educational goals are to be achieved is a matter to be determined by the faculties. On the basis of the goals specified in the MedBG, the Swiss Catalogue of Learning Objectives (SCLO) for Undergraduate Medical Training was developed by the Joint Commission of the Swiss Medical Schools (SMIFK), in cooperation with the faculties, representatives of the medical profession and the federal authorities.[209] The SCLO clearly defines the goals of undergraduate medical education and serves as a basis for the federal medical diploma examination. In numerous general and discipline-related objectives, reference is made to scientific skills and research activities. A Catalogue of Learning Objectives for Pharmaceutical Sciences has likewise been developed – in consultation with pharmaSuisse – by the Pharmaceutical Sciences Education Platform (PAP), which includes representatives of all pharmaceutical science faculties or departments

[208] www.admin.ch/ch/d/sr/c811_11.html

[209] Swiss Catalogue of Learning Objectives for Undergraduate Medical Training http://sclo.smifk.ch/sclo2008; also www.bag.admin.ch/themen/berufe/00408/00557/

in Switzerland.[210] In this Catalogue, scientific skills are explicitly covered. The content also serves as a basis for the federal examination.

The ETH domain, within the scope of its autonomy, is also examining measures to strengthen medical education (ETH Medical Strategy). The two Federal Institutes of Technology are seeking closer cooperation with the medical faculties with the aim of creating links between courses within the medical education system. It should in future be possible, under certain conditions, for holders of an ETH Bachelor's degree to transfer to an advanced semester of a medical course at a cantonal university. The scientific and technical training of future physicians would thus be assured, and more research-oriented physicians would be available for cutting-edge translational research.

In Pharmaceutical Sciences, around 170 students per year are awarded the federal diploma, having passed the federal examination. The course is offered at the Universities of Geneva and Basel, and at the ETH Zurich.

B. SPECIALIST TRAINING

In human medicine, responsibility for the development of specialist training and implementation of the specialist training goals defined in the MedBG lies with the Swiss Institute of Medical Education (SIWF) of the FMH. The FMH Specialist Training Regulations (WBO) provide a common basis and guidance for the 43 specialist associations responsible for specialist training courses. The individual specialist training programmes are conceived and organised by the specialist associations in accordance with this guidance. The courses leading to the award of a federal specialist title are accredited every seven years, as specified in the MedBG. All the specialist training courses were last successfully accredited in 2011. Under Art. 17 para. 1 MedBG, the knowledge, skills, behaviours and social competencies acquired during undergraduate training are to be broadened and deepened. In addition, mandatory continuing education is specified as a professional duty in the MedBG. Legal foundations thus essentially exist for the continuity and coherence of education and training, both in human medicine and in pharmaceutical sciences, also with regard to research – and clinical and health services research in particular.

[210] Catalogue of Learning Objectives for Pharmaceutical Sciences according to MedBG 2008 (only available in French/German): www.bag.admin.ch/themen/berufe/00408/00557/

7.4.2 Need for action to improve the situation

It should be noted that the normative framework for education and training is provided by the MedBG, and that there is no need for action as regards amendments to legislation. In addition, it should be emphasised that numerous measures have already been taken to strengthen clinical research. In order to obtain sufficient numbers of appropriately trained young clinical researchers, greater incentives must be created for scientific and research activities during undergraduate studies. This entails providing opportunities for students to pursue certain topics in greater depth (elective modules) and, above all, allowing for coordination and integration with the specialist training phase at an earlier stage. It must be borne in mind, however, that clinical researchers in particular – despite an early focus on research activities – are to be trained as physicians, since both clinical and health services research involve contacts with patients and thus differ from basic biomedical research. Those interested in research should therefore continue to take the federal examination and obtain the medical diploma.

It must be established whether and how, to a greater extent than in the past, systematic and transparent career paths can be established for young scientists; in addition, the establishment of training networks for aspiring researchers should be promoted. This requires transparency concerning contact persons and structures within the specialist associations and the organisations responsible for specialist training, as well as the faculties and hospitals. The primary need for action, however, appears to lie in the specialist training phase. In this phase, the demands and interests of hospitals, universities, disciplines and professions are closely intertwined. On the one hand, the involvement of trainees as assistant physicians in day-to-day hospital activities ensures that they can extend their knowledge and skills in a clinical setting and pursue their specialist training under supervision; on the other hand, they are also subject to constant work and time pressures. For aspiring researchers in particular, it often seems to be difficult to combine a research career with specialist training and hospital duties. Accordingly, there have been repeated calls for defined "research time" during the specialist training phase. In addition, especially after research visits abroad, it appears to be difficult to find appropriate structures for pursuing a research career in Switzerland. In this connection, it should be noted that each year around 70 people leave Switzerland for purely research purposes or for purposes of research, education and specialist training, generally with the intention of returning to Switzerland. There is thus a need for structures to facilitate the reintegration of researchers returning from abroad – for research work and coordination with specialist training. No specialist training programme exists for clinical researchers as such. The question thus arises whether this represents a real gap, and who could provide such specialist training, if necessary. The question of a professional academic career also arises – i.e. the desirability and feasibility of dual professorships.

7.4.3 Aims of measures designed to improve the situation

Education/training structures and profiles should be designed in such a way that more (specially trained) young scientists are available to work in clinical research and are prepared for professional careers within university hospitals, research centres, authorities or industry.

7.4.4 Measures already adopted or planned

Decisions concerning the creation of additional places for medical students can only be taken by the universities, or their funding bodies. Responsibility for the training of physicians rests with the cantons, which are aware of the urgent need for action and have either already approved increases in training capacity (Zurich, Lausanne) or are considering such action (Basel, Bern, Geneva). Other higher education institutions are also considering making a contribution to medical education (e.g. St Gallen, Lucerne, Ticino). The Università della Svizzera italiana (USI) has already been requested by the Grand Council of Ticino to develop a Master's degree course in Medicine. The providers of Pharmaceutical Science courses at the Universities and at the ETH acknowledge that Formulation Science represents a problem, as was evident from the federal examination. Consequently, the faculties now intend to improve and extend these skills.

7.4.5 Assessment of measures additionally proposed

More, better-trained clinical researchers

The SAMS notes that there is a shortage of well-trained young scientists for translational and clinical research in Switzerland. It proposes that a clinical research track should be established in specialist training, with skills possibly already being acquired during basic medical education. The medical faculties should be requested to initiate appropriate measures in undergraduate education and specialist training. The Clinical Trial Units should be given responsibility – and accredited – for basic and specialist training in clinical research, and the skills acquired should be certified in an official document. A need to improve the basic and specialist training of clinical researchers is also seen by H+ and Interpharma/Scienceindustries/vips.

According to the FMH, the number of clinical researchers is inadequate. Education and training for clinical research is to be strengthened via assured financing for the education of more medical students and the training of more assistant physicians as potential researchers.

The SAKK/oncosuisse takes the view that clinical research should be included as a basic subject in university curricula, and that collaboration with other faculties (Biology/Statistics) should be intensified. In addition, arrangements for authorship and for working hours should be clearly defined so as to create incentives and a degree of (career) planability for young medical graduates.

Following the round-table events, discussions were held with various parties directly concerned, in order to explore in depth the issues raised. It transpired that, while there is a basic readiness to help find solutions, the nature of the problems and the actual need for action remain poorly defined.

In consultation with clinical researchers, the following questions need to be addressed:

1. Why is there currently a shortage of young researchers?
2. What is the demand for young researchers?
3. What obstacles currently stand in the way of a research career or make it appear unattractive?

To address these questions, a working group is to be established within the "Future of medical education" (ZäB) platform, which will identify the reasons for the current shortage, discuss how existing measures could be optimised and propose specific short- and medium-term measures. As a permanent platform bringing together the protagonists of health and education policy, the ZäB is ideally suited for this task. This working group must include representatives not only from the State Secretariat for Education, Research and Innovation (SERI), the Swiss University Conference (CUS/SUK) or the Rectors' Conference of the Swiss Universities (CRUS) and the FOPH, but also from the medical faculties (SMIFK) or departments and the organisations responsible for specialist training (SIWF and pharmaSuisse). The Swiss Academy of Medical Sciences (SAMS), the Swiss Clinical Trial Organisation (SCTO) and other representatives of the hospital and industrial sectors must also be involved. Preparations for the working group are under way, and a mandate has been granted. It will report by spring 2014.

After the report has been issued, short- and medium-term measures can be agreed with the parties concerned.

More pharmaceutical scientists

Intergenerika sees a need for action with regard to the recruitment of well-trained professionals in the area of pharmaceutical development: the pharmaceutical industry's demand for pharmaceutical scientists should be met by enhancing the attractiveness of undergraduate courses in Pharmaceutical Sciences.

7.4.6 Federal Council's position regarding additional proposals

The Federal Council wishes to see greater clarity as to where action is required in the area of clinical research and what measures are to be taken, since the effects of education/training and continuing education measures designed to improve the situation will only be seen after a certain delay.

At the same time, several proposals concern, not the federal government, but above all the cantons, the universities, the hospitals and the professional organisations. This makes concerted efforts all the more necessary if Switzerland's position as a centre of research and technology is to be secured over the medium to long term.

By the end of 2014, the Federal Council wishes to be informed of the need for action and the measures planned.

7.4.7 Measurement of goal attainment

By spring 2014, an initial report will be issued by the ZäB platform working group, including recommendations which are based on existing measures and thus continue, but intensify, the policy pursued to date. By the end of 2014, the Federal Council wishes to be informed of the need for action and the measures planned. After four years, the measures will be evaluated and fed into the accreditation of undergraduate courses in accordance with the Federal Act on Funding and Coordination of the Swiss Higher Education Sector (HFKG), and of specialist training courses in accordance with the MedBG, so that any conditions required can be stipulated by the federal authorities.

7.5 Health data

7.5.1 Background

The systematic collection, analysis and interpretation of disease-related data is fundamental to the control of communicable and non-communicable diseases (e.g. cancer). The Federal Act of 18 December 1970[211] on the Control of Communicable Human Diseases (Epidemics Act) attaches great importance to disease surveillance. Experience shows that information of this kind is crucial for the development and implementation of measures to protect public health.

The World Health Organization (WHO) defines the use of surveillance systems and standardised data collection on risk factors, disease incidence and mortality by cause as one of six objectives for the prevention and control of non-communicable diseases.[212]

Registries play a key role in the systematic collection and analysis of disease-related data.[213] Clinical registries collect detailed data on the condition and treatment of patients in a given hospital, hospital association or care network, so as to permit comparison and evaluation of different therapeutic approaches or care structures.

Epidemiological registries are used to monitor the incidence of disease in a defined population group (population-based registry). Registration of all new cases of a given disease over an extended period makes it possible to detect the occurrence of changes over time or disease clusters (monitoring). This requires the most complete possible recording of cases of disease.

At the end of 2012, in addition to the Swiss Childhood Cancer Registry, there were 14 cantonal or regional cancer registries, documenting cases of cancer for around 80% of the Swiss population. The data collected is aggregated at the national level by the National Institute for Cancer Epidemiology and Registration (NICER Foundation).

Alongside the cantonal or regional cancer registries, a variety of registries in Switzerland record other diseases. In most cases, efforts are focused on improving the quality of treatment and carrying out research. One example is the National Registry of Acute Myocardial Infarction in Switzerland (AMIS Plus), where, for patients suffering heart attacks, diagnostic and therapeutic measures at participating hospitals are documented and evaluated. The data collected can be used to show how risk factors for heart attacks change over time, how new treatment strategies are adopted in clinical practice and their implications for outcomes and costs.

Other examples of disease-specific clinical registries in Switzerland are the rheumatic diseases registries run by the SCQM Foundation (Swiss Clinical Quality Management in Rheumatic Diseases), the national registry for autosomal dominant polycystic kidney disease (ADPKD), the registry of the Swiss group for Interstitial and Orphan Lung Diseases (SIOLD), and the haemophilia registry of the Swiss Haemophilia Society (SHG). These registries do not receive federal or cantonal funding but are financed by professional associations or organisations, service providers and industry.[214]

But information is not only important for purposes of prevention and treatment. If complex systems such as the health system are to operate efficiently and effectively, the parties concerned require information relevant to the provision, billing and management of services.

[211] SR 818.101

[212] 2008–2013 Action plan for the global strategy for the prevention and control of noncommunicable diseases: prevent and control cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, WHO, 2008.

[213] Cf. also the Explanatory Report of 7 December 2012 on the Federal Act on the Registration of Cancers (Cancer Registry Act, KRG) (www.bag.admin.ch)

[214] Further information on the Swiss Medical Registries Forum: www.fmh.ch/saqm/_service/forum_medizinische_register.cfm

Essentially, service providers in the Swiss health system have the information they require for the direct provision of services. At both the cantonal and the federal level, the supervision and management functions of health authorities are based on legal foundations for data collection which are a result of political processes. Nonetheless, there is a need for action on various fronts.

7.5.2 Need for action to improve the situation

According to a detailed OECD/WHO analysis[215] of Switzerland's health system, action is required with regard to limited transparency, a lack of strategic governance and inadequate statistical and analytical foundations.

In this connection, the Federal Council identifies the following action areas in its Health2020 agenda.

Increased transparency to improve quality
Although Switzerland has an excellent health system, there is a lack of transparency concerning the services provided and the benefits and costs thereof, which complicates management and prevents or impedes improvements. In addition, patients do not have sufficient information when choosing service providers. There is a lack of true competition on quality, which has positive effects on the quality, or benefits and costs, of treatment. Quality develops through measurement and transparency. The quality improvement process is supported and accelerated by the publication of quality data at the individual service provider level. This is indeed one of the objectives of the publication of quality indicators by the FOPH.

Access to health data via electronic instruments
At present, patients' medical records are only kept in an electronic form by around 50% of hospitals and by less than a third of physicians' practices. In addition, there is currently no agreement on semantic standards for medical data.

Health services research
The information (practical and orientational knowledge) required to optimise health care provision is currently lacking. The data base is incomplete and scientific health services research is underdeveloped. In this field of research, Switzerland lags behind other countries, such as the US, the UK, the Netherlands and Germany. In many areas of service provision, there is no scientific basis for evidence-based decisions. At the institutional level, health services research is scarcely or poorly established. There is a lack of networks of actors and coordination of activities, and comprehensive national support for research – based on a strategic plan – is also lacking.

Support for registration of non-communicable diseases
As a result of varying cantonal legal foundations and arrangements, the organisation and implementation of cancer registration is not standardised, and data at the national level is thus incomplete. The Federal Council wishes to remedy the weaknesses of the current cancer registration system and promote the registration of other widespread or serious non-communicable diseases. A need for action has also been identified by Parliament, in the form of the parliamentary initiative "National Cancer Registry" (07.501).

[215] OECD Reviews of Health Systems: Switzerland, 2011

7.5.3 Aims of measures designed to improve the situation

Increased transparency to improve quality

Orientation within the health system is to be improved by ensuring transparency for all stakeholders and in particular for the public. This requires an improved data base and targeted evaluation. Data collection and the publication of quality indicators under Article 22a of the Health Insurance Act (KVG) are to be continued and expanded. Evaluation should take the form of integrated, level-appropriate processing for the various stakeholder groups.

Access to health data via electronic instruments

Support is to be provided for the application of uniform semantic standards for medical data and the use of medical documentation systems (patient records) by all groups of service providers.

Health services research

Health services research helps to improve the quality, effectiveness and cost-effectiveness of our health system. It focuses on the delivery of services to the public in hospital, practice and other health settings and also covers preventive and screening services.

Support for registration of non-communicable diseases

A standardised national system is to be established with the goal of achieving, in the medium term, universal, complete and comprehensive registration of all new cases of cancer, as well as data on disease course, survival time and treatment quality.

7.5.4 Measures already adopted or planned

Increased transparency to improve quality

Since 2006, medical hospital data prepared by the Swiss Federal Statistical Office (SFSO) has been systematically evaluated by the FOPH, which produces a file of approx. 310 pages on each acute care hospital in Switzerland. This is based on case numbers, mortality rates and percentages (providing information on treatment practices). The detailed individual evaluation allows hospitals to carry out an in-depth analysis. The final publication, as well as presenting around 170 indicators (on five pages) per hospital, includes the hospitals' explanatory comments. The indicators relate to 40 specific disease groups, such as myocardial infarction, stroke, pneumonia, breast surgery, or hip/knee replacement. From the caseload, it can be estimated how much experience a given hospital has in treating a specific condition. The mortality statistics show not only the crude mortality rate (number of deaths observed divided by number of cases treated) but also the expected mortality rate (adjusted for age and sex). A quality indicator can be derived from a comparison of the crude and the expected rate. The mortality rates also serve as a starting point for in-depth hospital analyses and improvements. During the initial two-year pilot phase, hospitals' consent was required for publication; since the reporting year 2008, data has been published for all acute care hospitals.

With the current data base, it is difficult to define quality indicators for service providers other than acute care hospitals, although explicit provision is made in the legislation for the compilation and publication of such indicators. It is therefore planned to extend and improve the availability and analysis of data. The SFSO intends to introduce a series of outpatient health care statistics (MARS project). Also being examined is the collection of policyholder data at the individual level, so as to improve health system transparency and management.

Access to health data via electronic instruments

The definition of semantic standards is one of the main tasks involved in the implementation of the "eHealth Strategy for Switzerland" in the coming years. In addition, with the Federal Act on the Electronic Patient Record (13.050, BBl 2013 5321ff.), the framework will be set for a nationwide standard electronic patient record (so-called secondary system). This will also contribute indirectly to the spread of electronic record keeping by service providers themselves (primary systems).

Health services research

By the end of 2013, the Swiss Academy of Medical Sciences (SAMS) is to prepare – on behalf of the FOPH and in consultation with various stakeholders (federal/cantonal authorities, service providers, insurers, patients, etc.) – a comprehensive health services research plan, which will serve as a basis for a new National Research Programme (NRP). This plan will essentially answer the question of what kind of health services research Switzerland requires. Among the topics to be covered is primary care.[216]

The proposal for a Health Services Research NRP will be submitted in January 2014. The Federal Council will decide by the end of 2014 whether the NRP is to be launched or not.

In addition, health services and accompanying research is defined as one of the relevant action areas in the Federal Quality Strategy, providing an essential basis for improvements in the quality of health care. Health services research is also an integral part of the National Strategy against Cancer 2014–2017.

[216] It is thus linked to the "Primary Care" master plan.

Support for registration of non-communicable diseases
On 7 December 2012, the Federal Council submitted for consultation the Federal Act on the Registration of Cancer (Cancer Registration Act, KRG). The consultation ran until 22 March 2013. On 30 October 2013, having taken note of the results of the consultation procedure, the Federal Council requested the FDHA to prepare the Act and the Dispatch by the end of 2014.

7.5.5 Assessment of measures additionally proposed

At the round-table events, the following proposal was raised:

Health database
Thanks to technological advances in the methods of molecular genetics, personalised medicine has become a reality. This involves huge volumes of data, which have to be collected in an efficient, reliable, durable and anonymised way and made available for clinical research. According to the SAMS, Switzerland's competitiveness in human research cannot be maintained over the long term unless well-designed health databases are available for clinical research: here, the British and Scandinavian health systems are clearly at an advantage, and the US and China have also invested heavily in this area. The EU is planning the IT Future of Medicine (IT FoM) Flagship initiative.[217]

The IT FoM initiative aims to harness the vast potential of ICT to revolutionise human health care. The unprecedented amounts of data generated for individual people need to be turned into exploitable knowledge, which should help patients take medical and lifestyle decisions. By integrating the available data, computational models will be constructed of the biological processes that occur in every human. Since everybody is different, the models will be tailored to each individual to reflect their own unique anatomical, physiological and genetic make-up. IT FoM should thus lead the way towards truly personalised health care.

Recent technological advances – it is argued – will soon make it possible to analyse a patient's genome, proteins and metabolites in just a few hours. On the basis of this data, physicians using innovative computer systems will be able to offer more precise treatment recommendations or individual advice concerning drugs, possible health risks, consequences of lifestyle changes, or recommendations for diets or rehabilitation measures. The latest computer modelling will provide the treating physician with information on expected benefits and risks based directly on the patient's individual data. Personalised models will accompany patients through the entire health system, thus making treatments much more effective while reducing side effects to a minimum.

A health database was also proposed in a motion submitted by the National Council Committee for Science, Education and Culture – "Creation of a genetic testing database" (12.3978). In this motion, the Federal Council is requested, inter alia, to create a national database for the results of genetic tests. The content of the database would be made available in anonymised form for research purposes. The Federal Council rejected this motion on various grounds, including the fact that the creation of a new database of this kind, initiated and operated by the federal authorities, is not a federal responsibility. It would be a matter for interested researchers, should they so wish, to create such a database, which could possibly be supported using the standard

[217] IT Future of Medicine is one of six selected pilot actions in the Future and Emerging Technologies (FET) Flagship Scheme funded over a period of 12 months starting from May 2011. These are science-driven, large-scale, multidisciplinary research initiatives oriented towards a unifying goal, with a transformational impact on science and technology and substantial benefits for European competitiveness and society. The goals of such initiatives should be visionary and highly ambitious in terms of scientific challenges, resources required and coordinated efforts. They require cooperation among a range of disciplines, communities and programmes, extending over a long period (in the order of 10 years' duration). FET Flagships are based on partnerships that enable effective coordination of efforts. (Source: www.itfom.eu/flagships)

instruments and resources available for the promotion of research. On 20 March 2013, the National Council, accepting the arguments put forward by the Federal Council, rejected this and a related motion.[218]

Collection of data on off-label use

The SAKK/oncosuisse proposes that the off-label use of new drugs should be registered and periodically evaluated with regard to safety and efficacy.

Monitoring of off-label use (i.e. use outside the indications approved by Swissmedic) is a cantonal responsibility. Such measures would need to be undertaken by the cantons.

[218] Official Bulletin: www.parlament.ch

7.5.6 Federal Council's position regarding additional proposals

The desire to exploit the data generated by molecular genetic testing for purposes of clinical research is understandable. The Federal Council takes the view that the creation of a new database initiated and operated by the federal authorities is not a federal responsibility, but would be a matter for interested researchers, who could possibly be supported using the standard instruments and resources available for the promotion of research.

7.5.7 Measurement of goal attainment

Increased transparency to improve quality

Appropriate national structures have been created and sustained financing assured for quality improvement. In addition, quality reporting has been further expanded.

Improved treatment processes thanks to electronic instruments

By the end of 2014, consensus is to be reached among the actors concerned as regards the key semantic standards to be adopted.

Health services research

Approval of the "Health services research" plan by the FOPH; submission of an NRP proposal by mid-January 2014; positive decision by the Federal Council on the initiation of an NRP on health services research by the end of 2014.

Support for registration of non-communicable diseases

By the end of 2014, the Dispatch and draft Federal Act on the Registration of Cancer are to be adopted by the Federal Council and referred to Parliament.

8 STATE MARKET ENTRY AND REIMBURSEMENT SYSTEM

The framework for biomedical research and technology is influenced by the regulation of market entry and by the reimbursement of biomedical products and techniques under state social insurance schemes. This chapter describes the need for action in this area, the aims of measures designed to improve the situation, the measures already adopted or planned and the measurement of goal attainment.

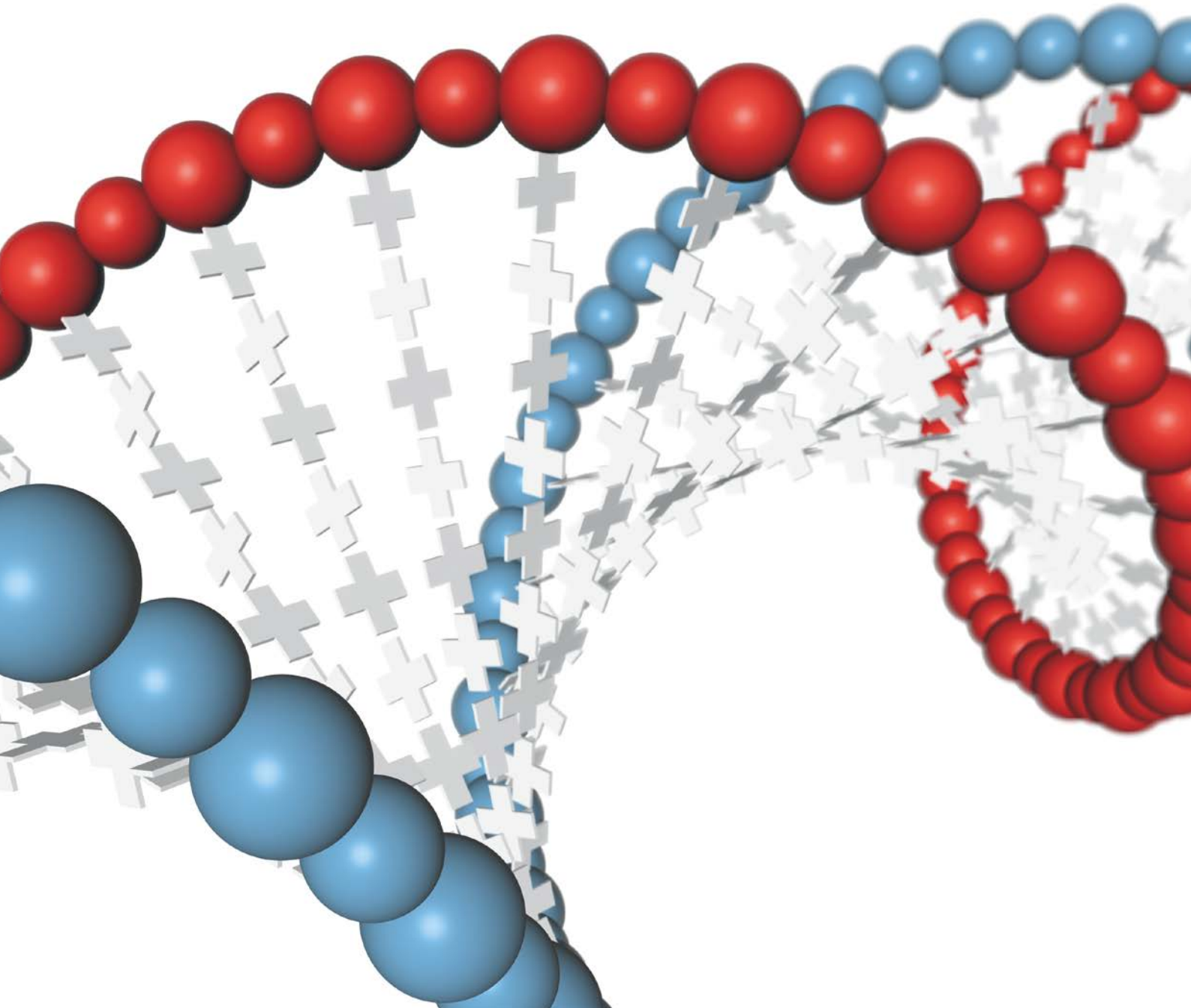
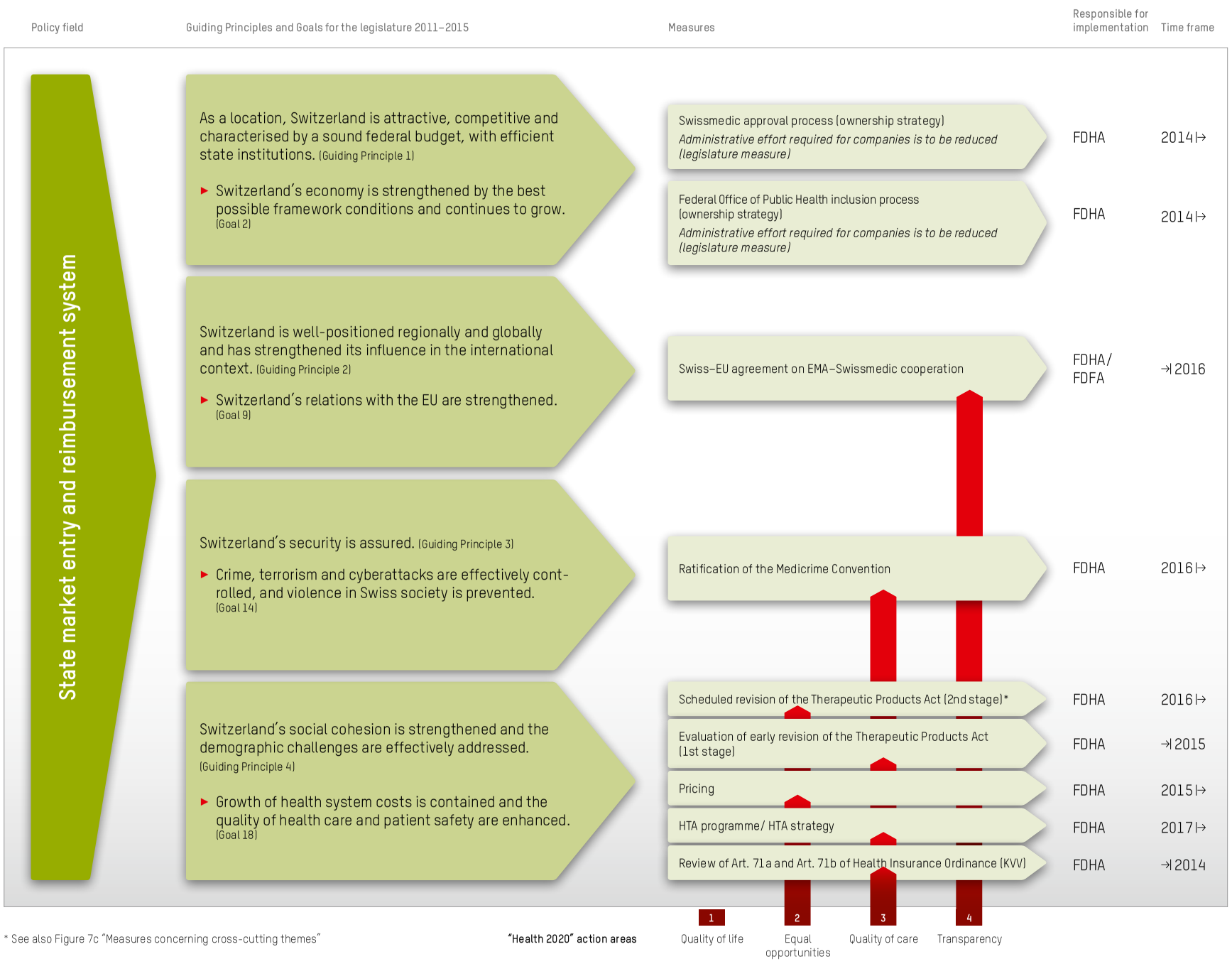


Figure 7b: Measures in the area "State market entry and reimbursement system"



* See also Figure 7c "Measures concerning cross-cutting themes"

8.1 Market entry and surveillance system for therapeutic products

8.1.1 Background

On 1 January 2002, after around 10 years of preparatory work, the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) came into force. According to the Dispatch of the Federal Council,[219] the following goals were to be achieved with the aid of the new Act:

- The availability of high-quality, safe and effective therapeutic products makes a significant contribution to public health.
- The individual provisions are patient-friendly, and the legislation also helps to address the concerns of consumers (prevention of fraud).
- Switzerland is strengthened as a location for business and research, as the provisions for the control of therapeutic products are designed to be compatible not only with the relevant EU legislation in particular, but also as far as possible with other international law.
- Technical barriers to trade with other important trading partners are removed or avoided.
- Official control of therapeutic products is effective and not unduly costly. To this end, responsibility for the authorisation and control of all therapeutic products is concentrated within one institution. The cantons and existing institutions are involved in enforcement. Once the necessary conditions have been established, international cooperation can be expanded.

Ten years after the entry into force of the Therapeutic Products Act, these goals have largely been achieved; overall, the regulations have proved effective.[220]

The Therapeutic Products Act and the implementing provisions are in line with current international standards. The market entry and surveillance system ensures the quality, safety and effectiveness of the therapeutic products used. It makes a significant contribution to the protection of human and animal health.

This is thanks, firstly, to a national regulatory authority responsible for the review, authorisation and subsequent surveillance of medicinal products. Secondly, under the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (Mutual Recognition Agreement, MRA), Switzerland is integrated into the European market entry and surveillance system for medical devices; the review of medical devices prior to market entry involves a conformity assessment procedure.

This framework ensures that patients can obtain relatively rapid access to almost 8000 human medicinal products and around 10,000 types of medical device. For animal health, approx. 700 veterinary medicinal products are authorised. In addition, Switzerland has a strong therapeutic products industry and a well-developed distribution and dispensing system.

[219] Cf. the discussion in the Federal Council Dispatch of 1 March 1999 on the Therapeutic Products Act, BBl 1999 3453ff.

[220] Cf. the Federal Council Dispatch of 7 November 2012 on the Amendment of the Therapeutic Products Act BBl 2013 1.

8.1.2 Need for action to improve the situation

New knowledge concerning the use of therapeutic products, technical advances and competitive pressures among market participants create a dynamic which means that – given the complexity of the issues – society and policymakers are repeatedly confronted with new challenges. The production, distribution and dispensing of medicinal products and medical devices are shaped by ongoing research and development of new products and forms of distribution.

At the same time, there is controversy as to what risks associated with therapeutic products society considers it acceptable for individuals to be exposed to. Also related to this is the question to what extent, for example, existing regulations make it unduly difficult for medicinal products to enter the market, which in turn would adversely affect the attractiveness of Switzerland as a location for the biomedical industry.

In addition, certain goals which were set when the Therapeutic Products Act was introduced could not be fully attained, or their attainment was delayed – for example, security of supplies.

Against this background, Parliament and the Federal Council identified a need for action in the following areas.

A. SECURE SUPPLIES OF IMPORTANT DRUGS FOR THE PUBLIC

Supplies of important (niche) drugs for the public can be threatened, either temporarily or for longer periods. This problem has been addressed via the early revision of the Therapeutic Products Act (1st stage, hospital drugs).[221] These amendments, together with the Federal Council's implementing provisions, came into force on 1 October 2010. In response to a parliamentary request, the Federal Council will report on the current situation by the end of 2014.[222] However, action continues to be required with regard to supplies of paediatric drugs, and this is to be addressed via the ordinary revision of the Therapeutic Products Act (2nd stage).[223]

B. SIMPLIFICATION OF MARKET ENTRY AND INCREASED TRANSPARENCY

Parliament and the Federal Council take the view that the state has a legitimate interest in controlling the market entry of medicinal products; however, the limited resources available should be used more efficiently than in the past to protect human and animal health.

In a report on the simplification of existing authorisation procedures, adopted on 25 June 2008 in connection with the Dispatch on the Partial Revision of the Federal Act on Technical Barriers to Trade (TBT Revision report),[224] the Federal Council approved a series of measures aimed at reducing technical barriers to trade in the medicinal products sector.

At the same time, the Federal Council was requested by Parliament to revise various aspects of the therapeutic products legislation. The proposed amendments include simplified authorisation of complementary and herbal medicines, exemption from mandatory authorisation for individual drugs only produced in small quantities, provisions concerning the dispensing of medicinal products, the strengthening of market surveillance, the improvement of paediatric pharmacotherapy

[221] Cf. the Federal Council Dispatch of 28 February 2007 on the Amendment of the Therapeutic Products Act (hospital drugs), BBl 2007 2393ff.

[222] 12.3426 Po. Heim, "Security of drug supplies"

[223] Cf. the discussion in Section 8.1.4

[224] Report on the simplification of existing authorisation procedures for products already approved in another country with equivalent regulatory requirements, Annex to the Dispatch on the Partial Revision of the Federal Act on Technical Barriers to Trade, BBl 2008 7367ff.

and the regulation of pecuniary advantages.[225] These proposals are to be implemented via the ordinary revision of the Therapeutic Products Act (2nd stage).

C. PROTECTION AGAINST THERAPEUTIC PRODUCT CRIME

The highly lucrative trade in counterfeit and illicit therapeutic products is increasing worldwide. At the same time, the risk of prosecution for the dealers involved has been low to date. The international distribution of counterfeit therapeutic products has been further simplified by the growth of online trade. Counterfeit therapeutic products can pose a risk to public health if they are ineffective or have undesirable effects. For example, ineffective medicines delay effective treatment of diseases and at worst can cause death or disability in patients. At the same time, the industry's reputation can be damaged and confidence lost if patients take or use counterfeit products in the belief that they are genuine. For manufacturers of medicinal products and medical devices, counterfeiting can result in revenue losses running into the millions. Unless countermeasures are taken, manufacturers face ever-rising costs for the production of counterfeit-proof products.

The issue of counterfeit therapeutic products was taken up by Parliament,[226] which on 30 May 2011 requested the Federal Council to propose an amendment to legislation that would strengthen efforts to combat smuggling and counterfeiting at all levels – in criminal law, in administrative law and with regard to the financial consequences. The provisions for combating trade in illicit narcotics were to serve as a model for the Federal Council.

The need for joint action in combating the trade in counterfeit therapeutic products has also been recognised at the international level: between 2007 and 2010, the Council of Europe developed the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention[227]), with the participation of Swiss experts. The text of the Convention was formally adopted by the Committee of Ministers of the Council of Europe on 8 December 2010.

In parallel to the efforts of the Council of Europe, an EU Directive designed to prevent falsified medicinal products from entering the legal supply chain was also prepared and adopted.[228] The Directive and the Medicrime Convention are mutually complementary: the former focuses on product safety within the legal supply chain, while the latter is concerned with the definition of criminal offences relating to illegal trade. Accordingly, ratification of the Medicrime Convention will not restrict Switzerland's options regarding the possible independent adoption of the EU provisions.

---

225 The following requests were made in Parliament:
06.3380 Po. Robbiani "Information on the composition of medicines"
05.3391 Mo. Kleiner, "Facilitated marketing authorisation for OTC products approved in EU countries"
06.3420 Mo. Council of States Committee for Social Security and Health (SGK-S), "Clarification of Article 33 of the Therapeutic Products Act"
07.3290 Mo. National Council Committee for Social Security and Health (SGK-N), "New regulation of self-medication"
05.3016 Mo. CVP parliamentary party, "Independence in the prescription and dispensing of drugs"
08.3827 Mo. Altherr, "More transparency at Swissmedic"
09.3208 Mo. Maury Pasquier, "Simplified access to recognised drugs"
08.3365 Mo. Heim, "Improvement of paediatric drug safety"
10.3669 Po. National Council Committee for Social Security and Health (SGK-N), "Prescription of drugs by hospitals"

226 10.3786 Mo. Parmelin, "More severe penalties for smuggling and counterfeiting of medicinal products"

227 Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health

228 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L 174, 1 July 2011, p. 74.

8.1.3. Aims of measures designed to improve the situation

A wide range of high-quality, safe and effective medicinal products are to be made available to health professionals and patients at lower economic costs than in the past.

The administrative costs for applicants and also for the authority responsible are to be reduced by eliminating unnecessary requirements and making procedures more efficient. At the same time, facilitated market entry should not only promote international trade in goods but also strengthen the domestic market in Switzerland.

Among the strategic goals for the organisation and governance of Swissmedic is that, by the end of 2014, processing times are to be complied with for 99% of applications for authorisation and, in addition, a new procedure with prior notification is to be implemented. In the middle of 2013, the average rate of compliance with deadlines across all submission categories was over 97% and for (innovative and non-innovative) first authorisation applications, deadlines were met in around 90% of cases.

8.1.4 Measures already adopted or planned

A. SECURE SUPPLIES OF IMPORTANT DRUGS FOR THE PUBLIC

This problem has been addressed via the early revision of the Therapeutic Products Act (1st stage, hospital drugs).[229] These amendments, together with the Federal Council's implementing provisions, came into force on 1 October 2010. Improvement of the availability of paediatric drugs is to be addressed via the ordinary revision of the Therapeutic Products Act.

B. SIMPLIFICATION OF MARKET ENTRY AND INCREASED TRANSPARENCY

In 2010, as part of the third package of Ordinances relating to the Therapeutic Products Act, the Federal Council specified in more detail the conditions under which Swissmedic is to take into account the results of tests carried out in a country with a comparable regulatory system if a medicinal product or technique submitted for registration is already authorised in that country (Art. 13 Therapeutic Products Act). The revised Medicinal Products Ordinance ensures, firstly, an efficient simplified authorisation procedure for medicinal products already authorised abroad in accordance with equivalent requirements. In certain cases, a scientific review by Swissmedic is dispensed with altogether. The Federal Council expects that these measures will ease the burden on Swissmedic, which should make it possible for the other processing times to be shortened. At the same time, the availability of medicinal products should be improved. In addition, the provisions specify the requirements and the procedure to be followed in cases where parallel applications for authorisation are submitted in Switzerland and abroad.

The proposals made by Parliament and the Federal Council have been implemented in the ordinary revision of the Therapeutic Products Act (2nd stage),[230] which is to be considered from mid-February 2013 by the National Council Committee responsible for preliminary deliberations.

The draft Act includes, for example, measures to simplify the authorisation of complementary medicines and to improve the availability of paediatric drugs.

For non-prescription drugs in traditional use, the Federal Council wishes to reduce the requirements for evidence of safety and efficacy.

To improve the availability of paediatric drugs, the Federal Council proposes a "three-pillar strategy".

[229] Cf. the Federal Council Dispatch of 28 February 2007 on the Amendment of the Therapeutic Products Act (hospital drugs), BBl 2007 2393ff.

[230] Cf. the Federal Council Dispatch of 7 November 2012 on the Amendment of the Therapeutic Products Act, BBl 2013 1.

Pillar 1 More medicinal products suitable for children are to be authorised and available. In the authorisation procedure, documentation on paediatric use. Applications for authorisation in Switzerland must, as specified in Regulation (EC) No. 1901/2006 on medicinal products for paediatric use, include data on paediatric use, based on a paediatric investigation plan. The industry can benefit from incentives such as extension of the supplementary protection certificate (patent extension) and/or extended data exclusivity. The provisions are essentially to be adapted to the applicable EU legislation (Regulation [EC] 1902/2006).

Pillar 2 Facilitated access to expertise from paediatric practice: existing knowledge should be transparent and available. Valid information on the paediatric use of medicinal products is to be made available in a national database, thus contributing to treatment safety.

Pillar 3 To improve drug prescription and dispensing processes, the Federal Council is to be given the power to issue appropriate guidelines.

On the basis of studies carried out abroad, it can be estimated that, in Switzerland, medication errors in children and adolescents alone give rise to costs of at least CHF 70 million per year. Savings in health expenditures resulting from improvements in paediatric drug use can be invested in the research and development of new treatments.

To promote the development of paediatric drugs, the pharmaceutical industry should be rewarded for its additional efforts. The Federal Council's draft Act provides for improvements in patent protection and data exclusivity.[231]

[231] Cf. the discussion in Section 9.2

C. PROTECTION AGAINST THERAPEUTIC PRODUCT CRIME

On 10 June 2011, the Federal Council approved the signature of the Medicrime Convention, which was duly signed by Switzerland, along with eleven other countries, in Moscow on 28 October 2011.[232] The Convention will enter into force once it has been ratified by five parties, including at least three member states of the Council of Europe. The proposal for ratification of the Convention by Switzerland is to be put out for consultation by the end of 2013.

The Council of Europe Medicrime Convention is the first international agreement designed to prevent threats to public health arising from counterfeit therapeutic products (medicinal products and medical devices). The Convention defines criminal offences which involve manufacturing, supplying or trafficking in counterfeit therapeutic products, as well as the protection of the rights of victims of such offences. It also regulates the cooperation of the authorities concerned at the national and international level. Issues concerning intellectual property rights (in particular, patent protection) are explicitly not addressed in the Convention.

With the Therapeutic Products Act and the associated Ordinances, Switzerland already has an excellent legal basis for the prosecution of drug counterfeiters and persons trafficking in counterfeit medicinal products. Certain elements of the Convention have already been adopted as part of the ordinary revision of the Therapeutic Products Act (2nd stage). However, ratification of the Medicrime Convention will necessitate various additional amendments to the Therapeutic Products Act and to other federal legislation. The necessary legal amendments are currently being prepared within the Federal Administration. The adoption of the Dispatch and the Federal Decree is scheduled for 2016.

D. ORGANISATION AND GOVERNANCE OF SWISSMEDIC

As part of the revision of the Therapeutic Products Act, the relevant provisions are to be adapted to the principles given in the Corporate Governance Report.[233]

In recent years, Swissmedic has further streamlined its processes, optimised the organisation and expanded its resources.

Since 1 January 2013, a new procedure with prior notification has permitted a more rapid authorisation procedure for applicants submitting innovative medicinal products. This involves payment of a surcharge – to cover Swissmedic's more intensive planning and coordination efforts – which is, however, only levied if Swissmedic complies with the shorter processing time frame.

[232] On 28 October 2011, the Convention was signed by Germany, Finland, France, Iceland, Israel, Italy, Austria, Portugal, Russia, Switzerland, Ukraine and Cyprus. Liechtenstein signed the Convention on 4 November 2011. Since then, it has also been signed by the following countries: Armenia, Belgium, Denmark, Guinea, Luxembourg, Morocco, Moldova, Turkey and Spain. The Convention has been ratified by Ukraine.

[233] In September 2006, in response to a postulate of the Council of States Control Committee (GPK-S), the Federal Council adopted the Corporate Governance Report, which contains a standardised analytical procedure for the outsourcing of federal tasks and 28 guiding principles for the management of independent entities (BBl 2006 8233ff.)

8.1.5 Assessment of measures additionally proposed

At the two master plan round-table events, the following additional proposals were submitted.

Use of the same nomenclature as in the EU

Intergenerika calls for the harmonisation of terminology with the EU, arguing that there is no good reason why a product (with an identical dossier) should be authorised in Europe as a generic and in Switzerland as a product with a "known active pharmaceutical ingredient". This gives rise to special solutions, which put the generics industry at a disadvantage and lead to higher costs and prices.

The types of authorisation in Switzerland very largely conform to those in the EU. Differences exist with regard to authorisations under transitional regulations and the authorisation of complementary medicines. In contrast to the EU, Swiss therapeutic products legislation does not use the term "generics", referring instead to "medicinal products made with known active pharmaceutical ingredients"; generics are, however, defined in health insurance legislation. Although it is not responsible for the enforcement of health insurance legislation, Swissmedic has to date decided on whether medicinal products are to be assigned generic status. From the end of 2013, Swissmedic will discontinue this practice, and the FOPH will assume responsibility for the relevant assessment.

Authorisation of generics already authorised abroad

Intergenerika calls for increased use of Article 13 of the Therapeutic Products Act, so as to further simplify the authorisation of generics.

As discussed, this provision has been specified in more detail by the Federal Council.[234] The requirements are being implemented by Swissmedic. The procedure may be used at any time for medicines with known active pharmaceutical ingredients, provided that the applications are identical and the applicant submits all the relevant documentation on which the decision of the foreign regulatory authority is based.

Application processing times

Interpharma, Scienceindustries and vips emphasise the importance of Swissmedic for Switzerland, as an independent and efficient therapeutic products agency. They see a need for action in the area of marketing authorisation, where they call for an increase in the efficiency of Swissmedic, so that Switzerland becomes more attractive for first authorisations and thus also more attractive for clinical research. A key role here is played by the application with prior notification, which reduces the length of the procedure by 20% (compared to the standard procedure) and involves a 100% surcharge.

The increase in charges for the authorisation procedure should allow Swissmedic to finance the additional resources required to meet the following targets: from 2013, according to the industry associations, 95% of all applications with prior notification should be processed within 270 days. For other applications, according to the industry associations, the same percentage should be completed within 330 days, from 2015.

In recent years, as discussed, Swissmedic has streamlined its processes, optimised the organisation and expanded its resources. The processing time frames proposed by the industry can already be complied with today. The Agency Council has set even more ambitious targets for authorisation time frames:[235] by the end of 2014, Swissmedic aims to comply with the above-mentioned processing times for authorisation applications in 99% of cases.

[234] Art. 5a–5d Medicinal Products Ordinance (VAM) (SR 812.212.21)

[235] Cf. the discussion in Section 8.1

Memorandum of Understanding / Confidentiality Agreement

According to Interpharma, Scienceindustries and vips, the effectiveness of Swissmedic would be strengthened by agreements on the exchange of information or more comprehensive agreements between the EU/EMA and Switzerland.

Such an agreement should cover the following points:

1. exchange of information and data, including confidential data;
2. access to documentation used for decision-making and the option for discussion of unresolved questions among responsible reviewers;
3. dialogue during ongoing authorisation and market surveillance procedures to improve coordination of decisions;
4. participation in each other's training events;
5. (mutual) participation in expert groups (particularly relevant are EMA Working Parties, where current developments and issues are discussed and guidelines are elaborated);
6. access to databases and public registries (e.g. paediatrics).

A measure of this kind would be in line with the Federal Council's policy to date, but would depend on whether the EU is prepared to conclude such an agreement.

Governance of Swissmedic

To guarantee independence and expertise, two measures are proposed by the SAKK/oncosuisse: firstly, a supervisory body should be established for Swissmedic; secondly, provisions ensuring continuing professional education for Swissmedic should be included in therapeutic products legislation.

At present, the activities of Swissmedic are already controlled as follows:

1. If authorisation/notification is not granted, applicants can appeal to the Federal Administrative Court and the Federal Supreme Court; i.e. provision is made not only for a hierarchical appeal but for a legal appeal.
2. At the same time, continuous controlling by the Federal Department of Home Affairs (as the owner's representative) and periodic inspections and audits by the Federal Audit Office ensure that the federal government's interests in an efficient and effective therapeutic products agency are safeguarded.

The Agency Council, as a strategic body, has a crucial function in the management of Swissmedic. Together with the Management Board, it is responsible for ensuring that staff meet the education and training demands placed on regulatory authorities in an international context.

The SPO argues that Swissmedic should be financially independent of the pharmaceutical industry. As a political measure, it calls for transparency with regard to personal interests and disclosure of the sum received by Swissmedic for sales of medicinal products by the pharmaceutical industry.

Swissmedic has created Codes of Conduct for members of the Agency Council, for the Management Board and staff, and for members of the advisory committees composed of external experts. These Codes serve to exclude conflicts of interests and require the persons concerned to make periodic declarations regarding potential sources of conflicts of interests. The above-mentioned Codes – including detailed information on the question of possible personal interests on the part of members of the Agency Council and external experts – are available on the Swissmedic website.

Also open to public inspection are the annual accounts of Swissmedic, which indicate how the Agency is financed – in particular, the level of income received from supervisory levies to be paid by the companies regulated (so-called levies on sales) and from procedural fees.[236] The various sources of financing are thus publicised and transparent.

Extension of the prohibition on pecuniary advantages to cover medical devices
Medtech is opposed to medical devices being included under the prohibition on pecuniary advantages, as proposed by the Federal Council as part of the revision of the Therapeutic Products Act.

The medical devices market is not transparent as regards the number and types of products available or sales, since these therapeutic products are not authorised by Swissmedic. However, as in the case of medicinal products, pecuniary advantages may have an influence on the choice of product and also, depending on the particular device, on the quantities used (cf. the Infras study assessing the impact of existing regulations and options for the revision of Art. 33 of the Therapeutic Products Act[237]). The lack of transparency certainly not only makes it difficult to formulate precise health regulations but also impedes the enforcement of social insurance legislation (e.g. the Health Insurance Act or the Federal Act on Disability Insurance). For this reason, in response to a parliamentary motion[238] and aware of the position of the medtech sector, the Federal Council proposed – in its Dispatch of 7 November 2012 on the Revision of the Therapeutic Products Act – provisions designed to increase transparency with regard to pecuniary advantages in the case of medical devices. Once these provisions have been implemented and more information is available on the extent and type of pecuniary advantages in question, and on the associated effects, the next step will involve the consideration of more comprehensive regulations and the submission of proposals addressing as effectively as possible the particular features of this product market.

The draft Act has been before Parliament since mid-February 2013.

Transfer of research findings to authorisation
According to the SPOG, knowledge in the area of paediatric drug use needs to be expanded. The regulatory and financial conditions for the pursuit of academic clinical research in paediatrics should be improved. Specifically, there is a need to find a format allowing the authorisation status of medicines to reflect the findings of academic research.

Under the ordinary revision of the Therapeutic Products Act, incentives will be created for further development of already authorised medicines for paediatric use. If a medicine containing an off-patent active substance is newly authorised for paediatric use, data exclusivity is to be granted for a period of 10 years (12 years for orphan drugs).

The draft Act has been before Parliament since mid-February 2013.

[236] http://www.swissmedic.ch/org/00064/00066/00323/index.html?lang=de

[237] Regulierungsfolgen und Lösungsansätze zur Revision von Artikel 33 Heilmittelgesetz (study commissioned by the FOPH), Infras, 2009

[238] 06.3420 Mo. SGK-N, "Clarification of Article 33 of the Therapeutic Products Act"

8.1.6 Federal Council's position regarding additional proposals

Use of the same nomenclature as in the EU and authorisation of generics already authorised abroad

The Federal Council has requested the Federal Administration to review the interpretation of the law in the area of nomenclature and to further optimise enforcement with regard to Article 13 of the Therapeutic Products Act.

Memorandum of Understanding / Confidentiality Agreement

The Federal Council is seeking closer cooperation with the EU in the area of drug authorisation and market surveillance. To date, the EU Commission has made the initiation of formal negotiations subject to progress on institutional matters. In parallel to the negotiations sought on institutional matters, the Federal Council will raise the issue of continued discussion of unresolved material questions.

Governance of Swissmedic

The Federal Council is convinced that the goal of an independent, internationally and nationally recognised therapeutic products agency can be achieved via the current owner policy. As far as the questions of independence, expertise and transparency are concerned, the Federal Council takes the view that no action is required beyond that already envisaged under the ordinary revision of the Therapeutic Products Act (amendments to the organisation and governance of Swissmedic), which should ensure that the requirements for decentralised supervisory entities specified in the Federal Council's Corporate Governance Report are also fully met in the case of Swissmedic. It sees no need for additional action at present.

Extension of the prohibition on pecuniary advantages to cover medical devices

The Federal Council remains convinced of the need to include medical devices under the prohibition on pecuniary advantages. Parliament must now consider the various arguments and decide on this matter.

8.1.7 Measurement of goal attainment

A. SECURE SUPPLIES OF IMPORTANT DRUGS FOR THE PUBLIC

Firstly, in response to a parliamentary request concerning the security of supplies, the Federal Council will issue a report by the end of 2014 at the latest.[239] Here, initial conclusions will be drawn concerning the measures already adopted.

Secondly, the effects of the early revision of the Therapeutic Products Act (1st stage, hospital drugs) are to be evaluated in a separate project.[240]

On the basis of these findings, which should also be available in 2014, it will be apparent to what extent further action is required.

B. SIMPLIFICATION OF MARKET ENTRY AND INCREASED TRANSPARENCY

The changes made as part of the ordinary revision of the Therapeutic Products Act, together with the related amendments to the implementing provisions, are expected to come into force in 2016. The effects of the proposed changes are also to be the subject of a summative evaluation. The timing will depend on the definitive amendments and the commencement date.

C. PROTECTION AGAINST THERAPEUTIC PRODUCT CRIME

To what extent the goals of the Convention can be achieved will be apparent from the results of the consultation which is to begin at the end of 2013.

If the general aims of the proposal are essentially approved by a majority of those participating in the consultation procedure, then the Convention is to be ratified by the end of 2016.

D. ORGANISATION AND GOVERNANCE OF SWISSMEDIC

Attainment of the targets set for compliance with processing times will be assessed annually.

E. MEMORANDUM OF UNDERSTANDING / CONFIDENTIALITY AGREEMENT

The Federal Council aims to secure a memorandum of understanding between Swissmedic and the EMA. This goal will be attained when negotiations are completed and cooperation between Swissmedic and the EMA is strengthened. The timetable partly depends on the general context of Swiss–EU relations and negotiations with the EU on health matters.

[239] 12.3426 Po. Heim, "Security of drug supplies"

[240] The "Evaluation of the revision of the Therapeutic Products Act on the provision of drug supplies during shortages, particularly in hospitals" is to review experience to date with the revision that came into effect on 1 October 2010. As part of this evaluation, it is to be investigated to what extent the measures adopted are effective in combating drug shortages and supply bottlenecks. This should provide a basis for future development of therapeutic products legislation as regards improving drug supplies while at the same time maintaining product safety for the protection of patients.

8.2 Mandatory health insurance reimbursement system

8.2.1 Background

In Switzerland, health goods and services are financed by social insurance schemes, private insurers[241] and households. This applies to investigation and treatment services provided by physicians and chiropractors or by non-university-trained health care professionals (e.g. physiotherapists, midwives, psychologists), medicinal products, medical devices and laboratory tests.

In financial terms, the most important payer is the mandatory health insurance scheme, which since 1 January 1996 has been regulated by the Federal Act on Health Insurance (KVG).[242] With the introduction of this Act, access to high-quality health care was to be guaranteed for the entire population (care goal). Additional goals were to reduce the financial burden of premiums for those living in modest economic circumstances (solidarity goal) and to contain rising health and health insurance costs (cost containment goal).

Of particular interest here – in the context of the federal government's efforts to create attractive framework conditions for biomedical research and technology – is the reimbursement of medicinal products and medical devices. In 2011, reimbursement of medicinal products amounted to around CHF 5.5 billion, accounting for 21.9% of total mandatory health insurance expenditures. The costs of outpatient aids and appliances came to around CHF 380 million in 2011 (1.5% of mandatory health insurance expenditures). Statistics are not available for total expenditures on medical devices under tariff agreements.

[241] The Federal Act on Insurance Policies (VVG, SR 221.229.1) provides the legal foundations.

[242] SR 832.10; the provisions of the Federal Act of 6 October 2000 on the General Part of Social Insurance Law (ATSG, SR 830.1) are also applicable, subject to explicit provisions to the contrary in the KVG.

A. REIMBURSEMENT OF MEDICINAL PRODUCTS AS A GENERAL RULE AND IN INDIVIDUAL CASES

I. Reimbursement as a general rule

For a medicinal product to be reimbursed under mandatory health insurance, it must have been included in the List of Pharmaceutical Specialties (SL) and prescribed by a physician.

The SL specifies the maximum price applicable in the case of dispensing by pharmacists, physicians, hospitals and nursing homes. This is made up of the ex-factory price,[243] the distribution margin[244] and VAT.

The conditions for inclusion of a medicinal product in the SL are:

– it is authorised by Swissmedic and
– it meets the criteria for efficacy, appropriateness and cost-effectiveness.

Assessment of the cost-effectiveness of a listed medicinal product is based not only on therapeutic benchmarking (i.e. comparison with drugs having an identical or similar mechanism of action) but also on international price benchmarking (i.e. comparison with ex-factory prices in Germany, the Netherlands, France, Austria, Denmark and the UK).

Since 1 January 2012, price setting for generics has involved five levels (10%, 20%, 40%, 50% and 60%), depending on the market volume of the originator product and its co-marketing products. The calculation of prices for generics is based on the average price level in comparator countries at the time of patent expiry for the originator product in Switzerland, using the top-selling presentation of the originator product. Upon patent expiry, marketing authorisation holders are free to reduce the prices of the originator products to a level the same as or below the generic price level.

Prices are reviewed when a medicinal product is included in the SL, in the event of new indications or modified restrictions and when the conditions for listing are re-evaluated (every 3 years). The criteria used for the assessment of cost-effectiveness are international price benchmarking and therapeutic benchmarking. Since 1 June 2013, application of the so-called prevalence model can also be requested in connection with new indications or modified restrictions. Here, the authorisation holder agrees to forgo 35% of the additional sales expected as a result of the new indication. In this case, cost-effectiveness will only be reassessed on the basis of international price and therapeutic benchmarking when the next 3-yearly re-evaluation of the listing conditions takes place. When a review is carried out after patent expiry or in the event of voluntary price cuts within 18 months after inclusion in the SL, only international price benchmarking is used.

Re-evaluation of the conditions for listing every 3 years has been in force since 1 October 2009. The prices of medicinal products included in the SL are now subject to 3-yearly reviews. Each year since 2012, about a third of the 2500 products listed have been re-evaluated to determine whether they still meet the conditions for listing.

---

[243] The ex-factory price covers the expenses (including taxes) of the manufacturer and distributor up to the time when goods leave the warehouse in Switzerland (Art. 67 para. 1ter KVV).

[244] The distribution margin compensates for logistical costs. Its composition is as follows:

[for] prescription drugs, it comprises:

[a m]ark-up calculated as a percentage of the ex-factory price (price-related mark-up), in respect of capital costs, storage and receivables,

[a m]ark-up per pack, in respect of transport, infrastructure and personnel costs;

[for] non-prescription drugs, it consists of a price-related mark-up (Art. 67 para. 1quater KVV)

In the course of the 3-yearly re-evaluation of the conditions for listing of originator products, the prices of the corresponding generics are also reviewed. Here, a generic is considered to be cost-effective if the ex-factory price is at least 20% lower than the average price level for the originator product in the comparator countries. In cases where a generic was considered cost-effective when included in the SL if its price was 10% lower than the average price level in the comparator countries, it is also considered to be cost-effective in the 3-yearly re-evaluation of the conditions for listing if the price is 10% lower than the average price level for the originator product.

The review is based primarily on the international price benchmarking. To compensate for fluctuations in exchange rates, the Federal Council decided on 21 March 2012 that:

– The existing tolerance margin is to be increased from 3% to 5%. This means that, on request, the Swiss ex-factory price is only to be reduced to a price that exceeds the international benchmark price by the applicable tolerance margin.
– Therapeutic benchmarking is only to be taken into consideration in the review if international price benchmarking is not possible – i.e. if the product is not marketed in any of the six comparator countries – or if a request for application of the prevalence model has been made since cost-effectiveness was last reviewed.

II. Reimbursement in individual cases

Under the long-standing jurisprudence of the Federal Supreme Court, medicinal products used off-label or beyond the limits specified in the SL may also, in exceptional cases, be reimbursed under the mandatory health insurance scheme, provided that they meet certain criteria. This is the case if a medicine is prescribed as part of a reimbursable treatment (a so-called therapeutic complex), or if it is used – in the absence of an effective alternative method – to treat a disease which is life-threatening or associated with serious and chronic health problems. In this case, the medicinal product must offer a substantial therapeutic benefit. These regulations – covering all medicinal products, including orphan drugs[245] – were established by the Federal Council with effect from 1 March 2011 in the Health Insurance Ordinance (KVV),[246] in response to a parliamentary request.[247]

In such cases, the costs of the medicinal product will only be reimbursed under mandatory health insurance if a special undertaking is issued by the health insurer, upon the recommendation of an independent medical adviser. The level of reimbursement is determined by the insurer. In the case of medicinal products used off-label or beyond the limits specified in the SL, the price listed in the SL must not be exceeded. In the case of medicinal products not included in the SL, the costs must be proportionate to the therapeutic benefits.

245 Cf. also Section 9.1

246 Article 71a KVV regulates the reimbursement – in exceptional cases – of medicinal products included in the SL which are used in a way not covered by the Swissmedic prescribing information (off-label use) or beyond the limits specified in the SL.
Article 71b KVV regulates the reimbursement – in exceptional cases – of medicinal products not included in the SL which are used either in accordance with the prescribing information or off-label. However, additional questions arise concerning the level of reimbursement and compliance with therapeutic products legislation. Paragraph 2 of Article 71b KVV relates to medicinal products which have not been authorised by Swissmedic and are therefore not included in the SL, but which may be imported in accordance with the Therapeutic Products Act for use in individual cases (Art. 20 para. 2 TPA in conjunction with Art. 36 para. 2 and 3 of the Medicinal Product Authorisation Ordinance/AMBV). This may involve, for example, low-cost, existing substances for a very small target population, for which the manufacturer considers it not worthwhile to obtain authorisation in Switzerland or for which authorisation has not been sought on economic grounds. An additional requirement is that the medicinal product should be authorised for the relevant indication in a country recognised by Swissmedic as having an equivalent regulatory system. A list of such countries is maintained by Swissmedic.

247 10.3261 Po. Berberat, "Reimbursement of the costs of treatment of rare diseases involving off-label use of drugs"

B. REIMBURSEMENT OF MEDICAL DEVICES[248]

Aids and appliances used for the investigation or treatment of a disease and its consequences are among the items reimbursable under mandatory health insurance. These are also required to be effective, appropriate and cost-effective.[249] Provisions concerning mandatory reimbursement and the level of reimbursement for aids and appliances are issued by the FDHA in the form of the Aids and Appliances List (MiGeL).[250] This list only includes aids and appliances which can be used by the patient directly or with the assistance of persons not professionally involved in the investigation or treatment.[251]

Not included in the MiGeL, however, are other medical devices which are used by health care professionals in the course of their activities, and implants in particular. Reimbursement of these devices is regulated by the tariff agreements of the service providers concerned.

The costs of aids and appliances listed in the MiGeL are covered under mandatory health insurance up to the maximum reimbursement level specified, provided that they

- meet the product description of a listed item,
- are authorised for the Swiss market,[252]
- fulfil the appropriate therapeutic purpose or the purpose of monitoring the treatment of a disease and its consequences,
- are prescribed by a physician or chiropractor[253] and
- are issued directly to the patient by an authorised centre.[254]

The maximum reimbursement level generally corresponds to the average price of appropriate products available on the market.

The patient is free to choose a suitable product up to the maximum reimbursement level. Any additional costs[255] are to be borne by the patient. Aids and appliances – unlike medicinal products included in the SL – are thus not covered by the provisions concerning binding maximum prices.[256]

248 The legal basis for mandatory reimbursement of the costs of products under social health insurance is provided by the Federal Act of 18 March 1994 on Health Insurance (KVG; SR 832.10). More detailed information is to be found in the Ordinance of 27 June 1995 on Health Insurance (KVV; SR 832.102), which is supplemented by the provisions of the Federal Department of Home Affairs (FDHA) Health Care Benefits Ordinance of 29 September 1995 (KLV; SR 832.112.31).

249 Art. 32 para. 1 and 2 KVG

250 Art. 52 para. 1 let. a no. 3 KVG; Art. 33 let. e KVV

251 Art. 20 KLV

252 With regard to authorisation for the Swiss market, the products must meet the requirements specified in the Medical Devices Ordinance of 17 October 2001 (MepV; SR 812.213) (Art. 23 KLV).

253 Art. 4 let. c KLV

254 Art. 55 KVV

255 Art. 24 para. 2 KLV

256 Art. 44 para. 1 KVG

8.2.2 Need for action to improve the situation

A need for action in the following areas has been identified by Parliament and the Federal Council.

A. PRICE-SETTING SYSTEM FOR MEDICINAL PRODUCTS

The measures adopted by the Federal Council on 21 March 2012 gave rise to divergent responses among the stakeholders concerned. Against this background, in August 2012, the Federal Council recommended the adoption of a parliamentary postulate,[257],[258] in which it is requested to prepare a report proposing a new method for the next round of price setting (starting in 2015). The Federal Council has also agreed to examine whether and how the price-setting mechanism is to be adapted in the medium term (i.e. from 2015).

B. HEALTH TECHNOLOGY ASSESSMENT

The FDHA is responsible for defining mandatory health insurance benefits, while the FOPH is responsible for the inclusion of medicinal products in the SL. Updating of the lists essentially involves a submissions system. Both the Department and the Office seek the advice of committees, whose secretariats are operated by the FOPH.

The processes for the definition of benefits – and the results – have recently been criticised by various parties. In this context, and in connection with proposals for improvements from policymakers, stakeholders and the Administration, health technology assessment (HTA) is frequently invoked as a key concept for resolving the issues.

The National Council Control Committee (GPK-N)[259] considers the existing structures and processes to be appropriate overall, but deficient particularly with regard to the re-evaluation of services[260] and early identification of innovations (horizon scanning[261]); the Administration's resources are said to be inadequate. The Committee also argues that the terms "efficacy", "appropriateness" and "cost-effectiveness" are not adequately defined and operationalised. In its responses, the Federal Council emphasises the importance of HTA principles and methods, proposes international cooperation in the area of HTA and mentions a small-scale HTA programme which would address selected topics. Some of the recommendations have already been implemented by the FOPH; other measures are in preparation.

The institutionalisation of HTA is also the subject of two parliamentary requests.[262] This would provide support for the federal authorities in the definition of benefits.

---

257 12.3614 Po. Schenker, "New method for setting drug prices"

258 Further requests were submitted on the same topic:
12.3342 Mo. SGK-N, "New setting of drug prices"
12.3396 Po Bortoluzzi, "Adjustment of the drug price setting system"
12.3373 Ip. Frehner, "Amendments of the Health Care Benefits Ordinance and the Health Insurance Ordinance with effect from 1 May 2012"
12.3049 Ip. de Courten, "Master plan to strengthen Switzerland as a research and pharma location"

259 Inspection of "Definition and review of medical services in mandatory health insurance"; letter dated 26 January 2009 from the National Council Control Committee (GPK-N) to the Federal Council. On the basis of the similarly entitled report (dated 21 August 2008) of the Parliamentary Control of the Administration, the GPK-N welcomes the existing implementation – involving a submissions system, an advisory committee and the FDHA as the decision-making authority – as a lean solution. However, the GPK-N identifies varies deficiencies and offers a total of 19 recommendations.

260 Art. 32 para. 2 KVG

261 Systematic collection of information on new technologies, allowing assessments to be initiated before they are widely adopted. Information is collected on pharmaceuticals in Phase II and III trials and on technologies prior to approval or in the early stages of marketing (source: Institute of Technology Assessment of the Austrian Academy of Sciences, Vienna).

262 10.3353 Mo. SGK-S, "Quality assurance for mandatory health insurance"
10.3451 FDP-Liberal parliamentary party, "For an effective national Health Technology Assessment Agency"

C. PROCESS FOR INCLUSION OF MEDICINAL PRODUCTS IN THE SL

The processing of a standard application, which is not reviewed under the fast-track procedure but is submitted to the Federal Medicinal Products Committee (EAK), takes at least 18 weeks (126 calendar days), given the existing time frames.

The duration of individual procedures will depend, not least, on the extent to which the submission allows all the questions concerning the medicinal product's efficacy, appropriateness and cost-effectiveness to be answered. Deficiencies in submissions (incomplete data, failure to report negative study outcomes, unclear indications or dosage due to provisional prescribing information, as the Swissmedic authorisation process has not yet been completed) can lead to delays, with the revised application having to be re-submitted to the EAK. Differences in the assessment of clinical benefits and/or cost-effectiveness by the FOPH and the applicant may also give rise to delays.

The FOPH, within the scope of its responsibilities, is seeking to take measures to expedite the process. Since 2009, for example, requests for the listing of generics and co-marketing products have no longer been submitted to the EAK.

8.2.3 Aims of measures designed to improve the situation

A. PRICE-SETTING SYSTEM

In order to ensure efficient and cost-conscious reimbursement of medicinal products and access to innovations, it is to be established by 2015 whether and to what extent the existing price-setting system should be adapted.

B. HEALTH TECHNOLOGY ASSESSMENT

The institutionalisation of HTA should supplement the existing submissions system particularly in the following cases – complex questions, comparative assessments of new and established services in a given application, and re-evaluation of existing (groups of) services under Article 32 paragraph 2 KVG. Mandates for the preparation of HTA reports on existing services are to be defined in the HTA programme. Horizon scanning is to be undertaken as an additional task.

C. PROCESS FOR INCLUSION OF MEDICINAL PRODUCTS IN THE SL

The processing of applications which have to be presented to the EAK is to be expedited; within 60 calendar days after authorisation by Swissmedic, the FOPH is to reach a decision on a new listing or extended indications / modified restrictions.

D. REIMBURSEMENT IN INDIVIDUAL CASES

The regulation or enforcement of reimbursement in individual cases (Articles 71a and 71b KVV) is to be optimised.

8.2.4 Measures already adopted or planned

A. PRICE-SETTING SYSTEM

On 30 August 2012, at a meeting of the National Council Committee for Social Security and Health (SGK-N), representatives of the pharmaceutical industry associations, insurers, patient organisations and hospitals were asked to share their views on the topic of drug price setting. In addition, discussions with stakeholders, chaired by the Head of the FDHA, were held on three occasions. Based on the results of these exchanges and ongoing discussions with stakeholders, the relevant legal foundations for the price-setting system are to be adapted with effect from 1 January 2015. A hearing on this topic is scheduled for May 2014.

B. HEALTH TECHNOLOGY ASSESSMENT

The optimal solution, as regards structure and financing, would involve integration of the agency into the structures designed to implement the national quality strategy. As soon as the options for the latter have been determined, the Federal Council can hold discussions on the key parameters of a Health Technology Assessment Agency and decide on the next steps.

C. PROCESS FOR INCLUSION OF MEDICINAL PRODUCTS IN THE SL

The Federal Council has decided that, with effect from 1 June 2013, decisions on new listing or extended indications / modified restrictions are to be taken by the FOPH within 60 calender days after authorisation is granted by Swissmedic. This accelerated process will be implemented at the FOPH via an increase in human resources, improved preparation of documents for the advisory Federal Medicinal Products Committee (EAK) and more EAK meetings. The decision on acceleration of the process was associated with an increase in fees for SL applications with effect from 1 January 2014.

D. REIMBURSEMENT IN INDIVIDUAL CASES

The implementation of Articles 71a and 71b KVV is to be evaluated by the FOPH by the end of 2013.[263] In this connection, all health insurers will be asked to disclose any guarantees of coverage granted or refused under Articles 71a and 71b KVV. Should the evaluation show that, for example, requests for guarantees of coverage under Article 71a or Article 71b KVV are systematically rejected by health insurers, even though there is a requirement to reimburse the medicinal products in question, then the FOPH, as a supervisory authority, will intervene and take appropriate action.

[263] Cf. the response of the Federal Council to: 12.3634, Ip. Bruderer Wyss, "Is access to cancer drugs at risk?"

8.2.5 Assessment of measures additionally proposed

At the two master plan round-table events, the following additional proposals were submitted.

Processes for inclusion in the SL

The representatives of the pharmaceutical industry (manufacturers of proprietary drugs and generics) propose that the process for the inclusion of medicinal products in the SL should be accelerated. The FMH supports this proposal, as long as the quality of the process and patient safety are assured.

Intergenerika calls for rapid, straightforward reimbursement for generics and biosimilars, with the decision being taken without consulting the EAK.

This proposal has been implemented since 2009 for generics, which – like co-marketing products and new pharmaceutical forms offered at the same price as existing presentations of a medicinal product – are no longer submitted to the EAK. If all the criteria are met, listing generally takes place six weeks after submission of the application.

Applications for new listing of proprietary products, or for modified restrictions and extended indications, are generally the most complex submissions – with extensive documentation – which have to be presented to the Committee.[264] This also applies for the listing of biosimilars.

Interpharma, Scienceindustries and vips propose that new medicinal products and indications should generally be included in the SL within 60 days after authorisation is granted by Swissmedic; they also call for a more efficient listing procedure at the FOPH and meetings of the advisory EAK every two months. As a measure of goal attainment, it is proposed that the proportion of applications for inclusion in the SL decided on within 60 days should be 80% in 2013 and 95% in 2014. Compliance with the targets should be subject to regular monitoring, and the results published.

The Federal Council has decided that, with effect from 1 June 2013, the time to reimbursement of an authorised medicinal product by the mandatory health insurance is to be shortened. The minimum processing time for an application which has to be presented to the EAK continues to be 18 weeks (126 days). This period cannot be shortened: it is also taken by the SwissHTA to be the minimum duration. It will, however, be possible for processing of the application to be completed 60 days after the product has been authorised by Swissmedic if the application is submitted to the FOPH before authorisation has been granted (on the basis of a positive advance notification). Optimisation is possible particularly in the case of applications which have to be presented to the EAK more than once. As in the Swissmedic authorisation process, applicants can favourably influence the processing period by ensuring that the documentation is compiled with the requisite care.

Special SL for paediatric drugs

The SPOG calls for a special SL for medicinal products which are used in children but not authorised by Swissmedic for this purpose.

Under the ordinary revision of the Therapeutic Products Act (2nd stage) – with preliminary deliberations beginning in mid-February 2013 – the Federal Council has proposed a number of measures to increase the availability of authorised paediatric drugs. In cases where a product is generally reimbursed under mandatory health insurance, the FOPH today already interprets the

[264] Applications for price rises, applications for inclusion of different pack sizes and dosage strengths, and certain new listings of proprietary products with known active pharmaceutical ingredients are generally easier to assess. Assessment by the EAK is only welcomed if individual Committee members wish to comment or the FOPH explicitly requires a recommendation from the EAK. Such applications are not discussed by the EAK on a regular basis.

requirements for individual cases – as far as the law allows – in the applicant's favour, if care can thereby be improved. Off-label use is governed by the provisions for reimbursement in individual cases specified in Articles 71a and 71b KVV.

Reimbursement of new services under mandatory health insurance

FASMED does not wish access to social insurance to be obstructed by unnecessary or prolonged HTA. In addition, it is proposed that new medical services should appear in the SwissDRG catalogue sooner than after five years and appropriately represented in terms of a flat rate per case. In the view of the Federal Council, the "trust principle" (under which services provided by physicians are assumed to be reimbursable) is not to be called into question. Regular assessment of services already reimbursed is to be improved by greater use of HTA. The SwissDRG catalogue is revised every year. If new services meet the criteria of efficacy, appropriateness and cost-effectiveness, or if they can be subsumed under an existing DRG, then they are fed directly into the revision. If mandatory reimbursement needs to be evaluated, this is subject to the usual application process at the FOPH.

8.2.6 Federal Council's position regarding additional proposals

The FDHA has already implemented measures to expedite the processes in question. The Federal Council is opposed to a specific SL for uses of paediatric drugs not authorised by Swissmedic. As regards the reimbursement of new services, the Federal Council sees no need for further action.

8.2.7 Measurement of goal attainment

A. PRICE-SETTING SYSTEM

The system is to be adapted from 2015. The requisite amendments to the legal foundations are to be prepared in 2014.

B. HEALTH TECHNOLOGY ASSESSMENT

The consultation on the draft legislation to strengthen quality and health technology assessment is to take place in spring 2014.

C. PROCESS FOR INCLUSION OF MEDICINAL PRODUCTS IN THE SL

Attainment of targets for compliance with processing times is to be assessed annually.

D. REIMBURSEMENT IN INDIVIDUAL CASES

Based on the evaluation, it is to be established by mid-2014 whether there is a need for improvements in the implementation of the provisions or amendments to Articles 71a and 71b KVV.

9 CROSS-CUTTING THEMES

Orphan diseases are conditions affecting relatively small numbers of people. This chapter describes where the Federal Council sees a need for action in this area, the aims of measures designed to improve the situation, the measures already adopted or planned and the measurement of goal attainment. Also associated with the development of new drugs – particularly for orphan diseases – is the question of intellectual property protection, which is discussed in the second part of this chapter.

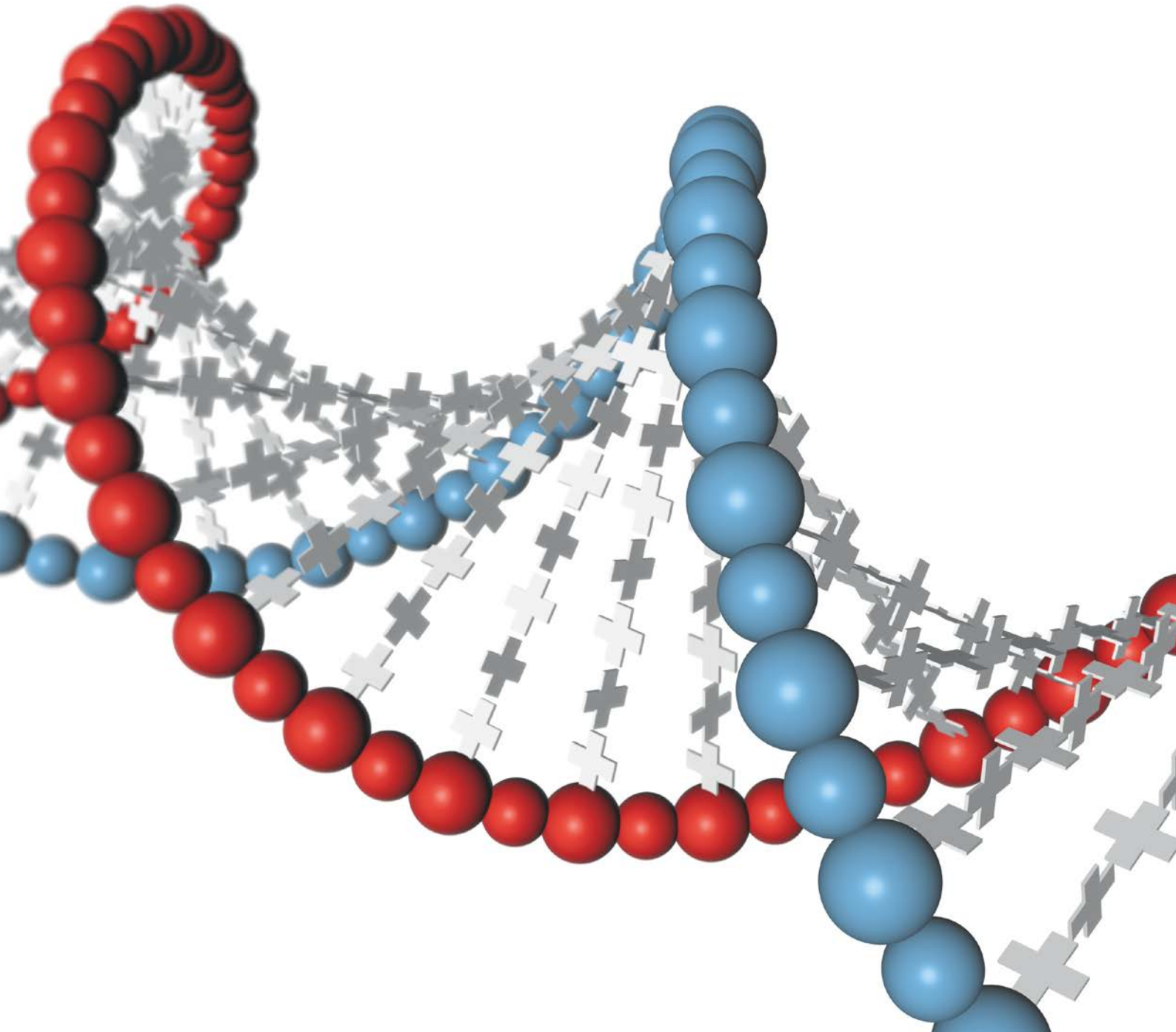
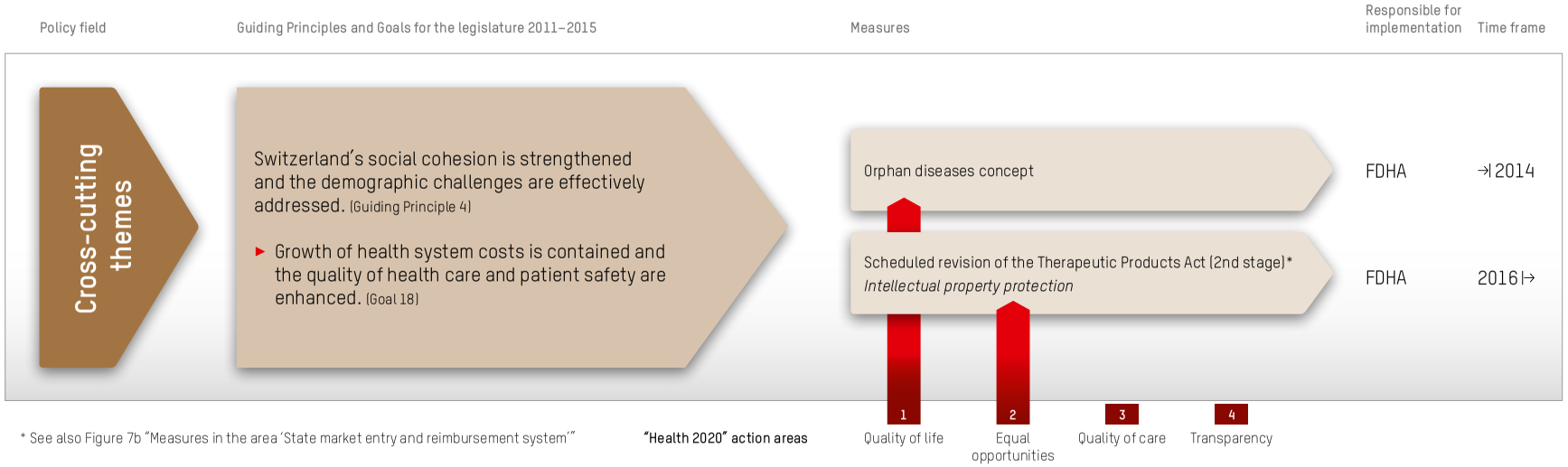


Figure 7c: Measures concerning cross-cutting themes



* See also Figure 7b "Measures in the area 'State market entry and reimbursement system'"

9.1 Orphan diseases and orphan drugs

9.1.1 Background

Orphan diseases are conditions which occur in a relatively small number of people. In the EU, conditions affecting no more than 1 in 2000 people are classified as orphan diseases. To date, an estimated 6000 to 8000 orphan diseases have been described. Such conditions are often caused by a gene defect, although they also include rare infectious diseases and autoimmune disorders. The first symptoms frequently occur at birth or in early childhood; in over 50% of cases, however, they only appear in adulthood.

Around five new rare diseases are described in the medical literature each week. The decision whether a disease is to be classified as rare from a medical viewpoint depends on the level of definition of the analysis – with more detailed analyses, more differences can be detected between individual subpopulations of patients with a given disease. It is thus conceivable that in the future, with the aid of new diagnostic methods, diseases currently regarded as common will be divided into numerous different conditions and thus become rare diseases. Today, in the field of oncology in particular, many conditions further subdivided on the basis of histology, genotype and stage are already classified as rare diseases. Using pharmacogenomic methods, it may thus be possible in future to develop individualised drug treatments for genetically similar groups of patients (personalised medicine). This issue arises mainly with regard to medicinal products.

The difficulties currently faced by patients relate to diagnosis, referral to expert centres and the availability of relevant information. There may be an unacceptable delay before patients obtain a diagnosis, as rare diseases are frequently not identified, or misdiagnosed, owing to a lack of adequate scientific and medical knowledge. Also frequently lacking are knowledge about the course of the disease and appropriate treatment options.

Drugs are often used in the management of rare diseases. If they are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in Switzerland,[265],[266] then they are assigned orphan drug status.[267] The same applies to drugs / active pharmaceutical ingredients which have been assigned orphan drug status by another country with equivalent medicinal product control, in accordance with Article 13 of the Therapeutic Products Act.[268]

At present, Swissmedic has granted this status to approx. 140 medicinal products, 71 of which are authorised by the Agency. In contrast to the standard Swissmedic procedure for authorisation of medicinal products, orphan drugs are subject to a simplified authorisation procedure.[269] No fees are charged by Swissmedic for the orphan drug authorisation procedure or for applications for changes to authorisation.

Among the medicinal products with orphan drug status authorised by Swissmedic, 70% are included in the SL and reimbursed under mandatory health insurance.

---

[265] As specified in Article 3 of Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

[266] Art. 4 para. 1 let. a of the Ordinance of 22 June 2006 of the Swiss Agency for Therapeutic Products on the simplified authorisation of medicinal products and the authorisation of medicinal products with the notification procedure (VAZV; SR 812.212.23)

[267] The criterion for the rarity of a disease always applies to the disease in its entirety, including all stages. The criterion therefore does not apply to an isolated stage in the course of the disease or to a subgroup defined by molecular genetic markers, unless the clinical picture is so distinct that it is recognised and classified as a separate disease. A subgroup (e.g. HER2-positive breast cancer) thus no more qualifies as an independent, rare disease than, for example, the restriction of an indication to second-line treatment (cf. Swissmedic information sheet dated 18.12.2012: Explanations regarding Orphan Drugs).

[268] Art. 4 para. 1 let. b VAZV

[269] Art. 14 para. 1 let. f of the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (TPA; SR 812.21) in conjunction with Art. 26 para. 2 VAZV.

No specific legal foundations exist in Switzerland for the reimbursement of orphan drugs. In general, they are only reimbursed under mandatory health insurance if – like other medicinal products – they are authorised by Swissmedic and included in the SL and thus meet the criteria of efficacy, appropriateness and cost-effectiveness. Here, too, use of the drug must correspond to an indication authorised by Swissmedic and must not be excluded from reimbursement under mandatory health insurance by a restriction specified in the SL. If an orphan drug is used by the treating physician in an indication other than those authorised by Swissmedic, mandatory reimbursement is also subject to the criteria for off-label use.[270] To ensure that the costs are reimbursed under mandatory health insurance in these individual cases, a guarantee of coverage must be obtained from the insurer, following prior consultation of the independent medical adviser.[271]

Because orphan drugs are only indicated for the treatment of a small number of patients and the costs of development tend to be high, these products can sometimes be extremely expensive.

The high costs lead to the general question of what costs the economy is capable of bearing in the health sector, or whether every medical/technical advance can be financed and what criteria are to be used in allocating the available financial resources – without jeopardising product development in this area, as suitable treatments do not yet exist for every rare disease.

Various steps have already been taken with regard to the provision of care for patients with rare diseases. On 2 February 2011, the Federal Council incorporated into the KVV the criteria defined by the Federal Supreme Court for the reimbursement of medicinal products in individual cases, thus creating a uniform, binding legal basis for reimbursement. Since 1 April 2011, molecular genetic testing for rare genetic diseases has also been generally reimbursed.

As regards the authorisation of medicinal products by Swissmedic, improvements in the safety of treatment for small numbers of patients have also been included in both stages of the revision of the Therapeutic Products Act. In addition, at the national level, a preliminary draft of a federal law on the maintenance of registries for cancer and other diagnoses is in preparation. The new law should provide a basis for harmonisation of the varying cantonal frameworks for cancer registration.

[270] Art. 71a para. 1 KVV

[271] Art. 71a para. 3 KVV in conjunction with Art. 71b para. 3 KVV

9.1.2 Need for action to improve the situation

Parliament requested the Federal Council[272] to develop a national strategy for orphan diseases, in collaboration with the cantons and with the organisations and professionals concerned. The aim is that patients with rare diseases should receive equally good medical care throughout Switzerland – including timely diagnostic measures, appropriate treatment and equal access to effective, evidence-based therapies and drugs. This would necessitate coordination of specialists, use of ICT for knowledge transfer, and cooperation at the national and international level.

In its response on 11 March 2011, the Federal Council said it was prepared to examine possible measures with regard to orphan diseases – in consultation with the stakeholders concerned – and to issue a report. It acknowledged that there was still a need for action and improvements in certain areas and thus recommended that the postulate should be adopted.

9.1.3 Aims of measures designed to improve the situation

The aim is to improve medical care for people with rare diseases. These should be correctly diagnosed and treated as rapidly as possible.

In view of European efforts to develop a community-wide rare diseases strategy, and the growing personalisation of medicine, it is important from a health policy perspective to have an appropriate instrument whereby the numerous federal and cantonal efforts undertaken at different levels can be coordinated, if necessary intensified, and assigned to the most suitable actor.

9.1.4 Measures already adopted or planned

In response to the parliamentary request, the FOPH – as part of the Orphan Diseases Plan project – discussed fundamental aspects of this issue with stakeholders at two round-table events. The goal was to identify areas where there is still a need for action or improvements. The discussions focused on the questions of diagnosis of rare diseases, treatment, and reimbursement of drugs and therapies for these diseases. Possible solutions were explored in an endeavour to define a national strategy to improve the health situation of people with orphan diseases. As well as addressing the questions of diagnosis, treatment and reimbursement, a need for action was identified in the area of research – particularly in the coordination and funding of national research projects on orphan diseases.

The project has been launched by the FOPH. The issues are extremely complex, and various groups need to be involved in the work. Two workshops have already been held for interested parties – on 1 October and on 18 November 2013. A further workshop is scheduled for January 2014. A report on the Orphan Diseases Plan is to be issued in the second quarter of 2014.

[272] 10.4055 Po. Humbel, "National strategy to improve the health situation of people with orphan diseases"

9.1.5 Assessment of measures additionally proposed

At the two master plan round-table events, the following additional proposals were submitted.

Simplified authorisation procedures for clinical trials
To promote research on orphan diseases, the SAKK/oncosuisse propose that authorisation procedures should be simplified for clinical trials in this field, and that the risk categories defined in the Human Research Ordinances should be revised.

Market exclusivity for orphan drugs
In addition to implementation of the national action plan by mid-2013, the representatives of the pharmaceutical industry propose that 10 years of market exclusivity should be granted for orphan drugs. The attractiveness of Switzerland as a location should thus be enhanced via specific measures for the protection of intellectual property. Research incentives should be introduced in those areas where a potential or need exists.[273]

International collaboration
To promote participation in global networks, the SAKK/oncosuisse wish to establish highly specialised medical centres and networks. Interaction with reference and competence centres abroad is supported by the representatives of the pharmaceutical industry.

National collaboration and access to registries
With the aim of integrating clinical research conducted in Switzerland at the national level and having access to the pool of patients with rare diseases via appropriate registries, the SAMS proposes the establishment of registries in addition to an efficient and well-structured CTU network (cf. also Section 7.5 "Health data").

Reimbursement and transparency regarding guarantees of coverage
According to the SPO, patients with orphan diseases are dependent on the goodwill of health insurers: not all health insurance organisations are prepared to enter into negotiations with the pharmaceutical industry. To ensure that all patients with orphan diseases in Switzerland receive equal treatment, health insurers should be required to disclose their practice concerning guarantees of coverage in their annual report.

9.1.6 Federal Council's position regarding additional proposals

In the view of the Federal Council, the implementation of these proposals needs to be evaluated in conjunction with other measures designed to improve the situation with regard to orphan diseases. The Federal Council is prepared to consider the various proposals within the framework of work on the Orphan Diseases Plan and to present recommendations concerning their implementation.

9.1.7 Measurement of goal attainment

The report on the Orphan Diseases Plan is to be submitted to the Federal Council by the second quarter of 2014 at the latest.

[273] Cf. the discussion in Section 9.2

9.2 Intellectual property protection

9.2.1 Background

A. DATA EXCLUSIVITY

Data exclusivity prevents third parties, for a given period, from making commercial use of data which has to be submitted to the regulatory authority for the authorisation of medicinal products. Protection is thus provided for the preclinical and clinical data[274] on a given product submitted by a company to the regulatory authority. A subsequent applicant (manufacturer of a generic) is prohibited, for a certain period, from making use of test results without the consent of the first applicant. Under the TRIPS Agreement,[275] GATT/WTO member states are required to ensure such protection.

When the Therapeutic Products Act was established, data exclusivity was defined in accordance with the regulations then applicable in the EU. A 10-year protection period was specified,[276] and this was restricted to data for products with new active pharmaceutical ingredients – i.e. substances placed on the Swiss market for the first time in the medicinal product concerned (hence the use of the term "first applicant protection" in Switzerland).

With the aim of also promoting innovations in products for which data exclusivity has expired, an additional 3 years of protection (restricted to the innovation-related data) is granted when new indications, routes of administration, pharmaceutical forms or dosages are authorised.[277] Here, too, data exclusivity is restricted to products which have already been granted initial protection (first applicant protection). Data exclusivity is not granted for innovations in generics.

The protection period can be extended by 2 years – i.e. to a total of 5 years – if the innovations forming the subject of the application offer a significant clinical benefit over existing treatments.[278]

A few years after the Therapeutic Products Act came into force, the EU legislation on data exclusivity was amended. It now provides for comprehensive data exclusivity for a period of 8 years; after this period, generics manufacturers can submit applications for authorisation making reference to scientific data submitted for the originator product. A generic product may only be authorised after another 2 years – i.e. a total of 10 years after the authorisation of the originator product. Finally, the period of data exclusivity can be extended by 1 year if a new indication, offering a significant clinical benefit over existing treatments, has been authorised during the first 8 years (e.g. "analgesic" in addition to "antipyretic").

During the consultation on the preliminary draft for the ordinary revision of the Therapeutic Products Act, the Federal Council proposed that the provisions on data exclusivity should be adapted to the new EU legislation. Under these proposals, data exclusivity was no longer to be granted for new routes of administration, pharmaceutical forms or dosages, while the protection period for new indications was to be reduced to 1 year.

These proposals were opposed in particular by various pharmaceutical industry associations and by business federations on the grounds that they ran counter to legislators' efforts to create a

[274] Preclinical data comprises the results of physical, chemical, pharmaceutical, biological or microbiological, pharmacological and toxicological tests; clinical data comprises the results of pharmacological, pharmacokinetic and pharmacodynamic tests in human subjects (cf. Art. 11 para. 1 let. g and h TPA)

[275] Agreement on Trade-Related Aspects of Intellectual Property Rights (SR 0.632.20 [Annex 1C to the GATT/WTO Agreement]), Art. 39

[276] Art. 12 para. 2 of the currently applicable Therapeutic Products Act

[277] Cf. Art. 17 para. 2 VAM

[278] Cf. Art. 17 para. 3 VAM

favourable framework for biomedical research and development.

In April 2011, taking into account the results of the consultation procedure and bearing in mind the importance of research promotion, the Federal Council decided to maintain the existing regulations (10-3/5 system) and thus to forgo harmonisation with the EU legislation.

Applicable regulations		
Subject	CH regulations	EU regulations
Regulatory submission for an essentially similar product	No earlier than 10 years after authorisation of the reference medicinal product	No earlier than 8 years after authorisation
Time of authorisation of an essentially similar product	After completion of regulatory review (10 years + period of authorisation procedure, approx. 11 months)	No earlier than 10 years after authorisation (or 11 years, if a new indication is approved)
Protection of new indications for originator products	3 years of additional protection, but only for the new indication (or 5 years if the new indication offers a significant clinical benefit over existing treatments)	1 year of additional protection, also covering existing indications (= total of 11 years), if there is a significant clinical benefit over existing treatments
Protection of new indications for products with known active substances	Data exclusivity not possible	Data exclusivity for 1 year, restricted to the new indication
Protection of new routes of administration, dosage forms or strengths, or application to a new target species	3 years of additional protection, but only for the innovation (or 5 years if the innovation offers a significant clinical benefit over existing treatments)	No additional protection
New combination of active substances	Data exclusivity not possible	Data exclusivity possible

Table 8: Comparison of applicable regulations for data exclusivity in Switzerland and the EU

B. PATENT PROTECTION

To be distinguished from data exclusivity is patent protection, which covers an invention (e.g. an active pharmaceutical ingredient, process or manufacture) and prevents competitors from entering the market for a given period (maximum term: 20 years from the date on which a patent application is filed).

Since – given the requirements for marketing authorisation – there is generally a considerable passage of time (often 10 years or more) between the invention of an active ingredient and the marketing of a medicinal product, the instrument known as a supplementary protection certificate was created. This makes it possible to extend the effects of a patent by up to 5 years, thus providing de facto protection for a maximum period of 15 years. The aim is to compensate patent holders for the efforts required to obtain marketing authorisation.

The question of whether patent protection exists is not examined as part of the authorisation procedure. Disputes concerning patent rights are to be resolved solely under civil law procedures (before the Federal Patent Court).

At present, the existing national framework for patent protection appears to be appropriate, so that no further changes are required in the short term.[279]

Switzerland does, however, have an interest in the existence of a coherent framework ensuring appropriate protection also at the international level, with these rights being respected in third countries where the Swiss pharmaceutical industry carries out research and/or production. Appropriate regulations for the protection of intellectual property (in particular, substance and process protection for chemical, biotechnological and pharmaceutical inventions, protection of testing data, supplementary protection certificates and recognition of imports as the exercise of patent rights) should also be assured via free trade agreements.

C. MARKET EXCLUSIVITY

In the case of orphan diseases, it may be that the costs of developing and obtaining authorisation for a diagnostic, preventive or therapeutic drug cannot be covered by the expected sales. The pharmaceutical industry is therefore not prepared to develop such products under normal market conditions. Accordingly, some countries have introduced market exclusivity regulations to provide an additional incentive for the development and marketing of orphan drugs.

Country	Classification as orphan disease	Market exclusivity regulations
US	<7.5 cases per 10,000 people (or <200 000 patients per year)	7 years after authorisation
EU	<5 cases per 10,000 people	10 years after authorisation (period can be reduced to 6 years if the orphan drug criteria are no longer met after 5 years)
Australia	<1.1 cases per 10,000 people	5 years after authorisation
Japan	<4 cases per 10,000 people	10 years after authorisation
Switzerland	<5 cases per 10,000 people	No such instrument exists

Table 9: Comparison of regulations for market exclusivity in various OECD countries[280]

The EU legislation can be taken as an example to illustrate this instrument.

If a medicinal product has orphan drug status, the marketing authorisation holder – with certain exceptions and restrictions – can benefit from market exclusivity for a period of 10 years.[281] This means that the authorities cannot accept another application for authorisation, or grant authorisation, or extend an existing authorisation, for the same therapeutic indication, in respect of a similar medicinal product. Exclusive marketing rights may, however, be withdrawn after 6 years at the request of a member state, if it can demonstrate that the criteria for designation as an orphan medicinal product are no longer met, or that the product is sufficiently profitable not to justify maintenance of market exclusivity.

No provision is currently made for such market exclusivity in Switzerland.

[279] Cf. 8.1.4 Extension to the duration of supplementary protection certificates for paediatric drugs in the scheduled revision of the Therapeutic Products Act (2nd stage)

[280] Source: www.orpha.net.

[281] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products. OJ L 18/1, 22.1.2000.

9.2.2. Need for action to improve the situation

The returns which the pharmaceutical industry has been able to achieve to date on investments in the research and development of new paediatric drugs have not provided a sufficient stimulus to market adequate numbers of medicinal products suitable for children. It has therefore been necessary to seek new solutions. One new approach which has gained international (EU, US) acceptance is to create an incentive by extending the term of the supplementary protection certificate by 6 months. For high-selling drugs, this can generate additional revenues of up to USD 1 billion. In the US, the provision of this incentive has led to an increase in the number of drugs tested in children; at the same time, children have been subjected to unnecessary studies.

For this reason, the extension of the supplementary protection certificate in European legislation was associated with a requirement to develop paediatric drugs and to submit a paediatric investigation plan to the regulatory authority.

The Therapeutic Products Act and the Patents Act are now to be adapted to this European standard so that children in Switzerland can also benefit from new developments.

9.2.3 Aims of measures designed to improve the situation

As part of the overall efforts to increase the availability of drugs suitable for children, the pharmaceutical industry is to be compensated for the extra costs arising from the additional requirements.

9.2.4 Measures already adopted or planned

A/B. DATA EXCLUSIVITY AND PATENT PROTECTION

To promote the development of paediatric drugs, the Federal Council's Dispatch on the Revision of the Therapeutic Products Act envisages measures in the areas of patent protection and data exclusivity. These are to be dependent on the submission of and compliance with a paediatric investigation plan.[282]

For the provision of incentives, various situations are to be distinguished.

In the case of medicinal products protected by a patent or a supplementary protection certificate, this certificate is to be extended by 6 months under certain conditions (Art. 140n of the Federal Act of 25 June 1954 on Patents for Inventions [Patents Act]).

If this bonus is claimed, the approved investigation plan must be presented together with the results of the relevant paediatric studies when the application for authorisation is submitted.

In the case of medicinal products specifically and exclusively for paediatric use developed in accordance with an approved paediatric investigation plan, data exclusivity of 10 years is to be granted, provided that no other medicinal product with the same active ingredient is authorised for the same specific paediatric indication in a comparable pharmaceutical form.[283]

For paediatric orphan drugs, there is often no patent protection to be extended. For indications of this kind, paediatric drug development is particularly difficult. For such drugs, the period of data exclusivity is to be extended to 12 years.[284]

[282] Dispatch on the Revision of the TPA (2nd stage), p. 36

[283] Art. 11b para. 3 draft revision of the TPA

[284] Art. 11b para. 4 draft revision of the TPA

Under the EU regulations concerning incentives for the development and authorisation of paediatric drugs, the provision of dual incentives is excluded – i.e. if data exclusivity is granted, extension of the supplementary protection certificate is generally excluded. In the case of orphan drugs, while the EU regulations generally rule out extension of the supplementary protection certificate, market exclusivity is granted and extended. Here, the Swiss system of incentives is less stringent, and dual incentives are not to be excluded.

9.2.5 Assessment of measures additionally proposed

At the two master plan round-table events, the following additional proposals were submitted.

Market exclusivity for orphan drugs
In addition to implementation of the national action plan by mid-2013, the representatives of Interpharma/Scienceindustries/Vips propose that 10 years of market exclusivity should be granted for orphan drugs.

The attractiveness of Switzerland as a location should thus be enhanced via specific measures for the protection of intellectual property. Research incentives should be introduced in those areas where a potential or need exists.

In the view of the Federal Council, the following points need to be taken into consideration with regard to the introduction of exclusive marketing rights in Switzerland:

1. The introduction of exclusive marketing rights would severely restrict economic freedom, as it would make it impossible for competing products to enter the market for a prolonged period. This restriction would need to be offset by positive effects on the availability of orphan drugs and on treatment costs.

2. In the US, extended market exclusivity was introduced in 1983 under the Orphan Drug Act. The effects of the various incentives, which also include financial support and tax credits, are analysed in a scientific paper which was published in October 2012.[285] Since 1983, as the authors point out, at least 378 orphan drugs have been approved; however, they conclude that "extended market exclusivity has been associated with unacceptably high drug costs, both for newly developed drugs and even for drugs which were previously widely available," and that "a paradoxical effect of orphan product exclusivity can be reduced patient access to existing drugs." The authors note that one possible solution is a separate price review process, and that there is extensive government intervention in orphan drug markets in Europe.

3. EU member states have so far adopted a variety of approaches to regulating the orphan drugs market. According to a comparative study, the availability of orphan drugs varies between Belgium, France, Italy, the Netherlands, Sweden and the UK.[286] Strategies for controlling prices include public procurement (Sweden), profit controls (UK) and price comparisons with other countries (Belgium, France, Italy, Netherlands). The authors attribute the higher prices of orphan drugs partly to market exclusivity. Under EU legislation, the period of market exclusivity can be reduced if a product is shown to be "sufficiently profitable";[287] however, as it is not clear what this expression means, the provision has never

[285] Murphy SM, Puwanant A and Griggs RC, Unintended effects of orphan product designation for rare neurological diseases. Annals of Neurology 2012; 72:481–490.

[286] Denis A, Mergaert L, Fostier C, et al., A comparative study of European rare disease and orphan drug markets. Health Policy 2010; 97:173–179.

[287] Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products. OJ L 18/1, 22.1.2000

been put into practice.[288] Various authors have suggested that the notion should be more clearly defined.[289]

4. In addition, given the small size of the Swiss market, the effects of such a measure would be negligible; for this market, there would thus be very little to be gained from granting exclusive marketing rights of the kind that exist in the US and the EU. According to legal experts, it would merely serve the interests of harmonisation and have a certain symbolic value.[290]

Data exclusivity for new indications

A further proposal made by Interpharma/Scienceindustries/vips is that, when a completely new indication is developed for a well-established active substance, a 10-year period of data exclusivity should be granted for the relevant submissions. A development of this kind, based on Phase III clinical studies, can result in new dosages and new pharmaceutical forms. As an illustration, Interpharma/Scienceindustries/vips cite the example of a new drug with a new active substance first introduced in 1996 for the treatment of tumour-induced hypercalcaemia (high levels of calcium in the blood). A completely new indication was subsequently developed for the same substance – namely, treatment of osteoporosis to reduce the risk of vertebral fractures in postmenopausal women. A development of this kind is said to require investments of CF 300 to 500 million.

The proposal does not involve any distinction between new indications that offer a significant clinical benefit and others that do not. The doubling of the existing period of data exclusivity – to 10 years – for new indications offering a significant clinical benefit, and its tripling for other indications, would exclude for much longer than in the past generic products where the application for authorisation is based on the first applicant's data. From a business viewpoint, this makes sense if the research and development of new active ingredients has become more difficult.

From a public health viewpoint, the authorisation of new indications is particularly valuable in cases where

1. a significant clinical benefit is created,
2. a common off-label use is covered and
3. at the same time, information on the risks associated with indications already authorised is continuously updated. The authorisation holder would have to ensure, via clinical trials, that the necessary knowledge is obtained and that the information for prescribers and patients is appropriately updated.

[288] Cf. also Steven Simoens, Pricing and reimbursement of orphan drugs: the need for more transparency. Orphanet Journal of Rare Diseases, 2011; 6:42

[289] Cf., for example, Panos Kanavos and Elena Nicod, What Is Wrong with Orphan Drug Policies? Suggestions for Ways Forward. Value in Health 2012; 15:1182–1184

[290] Franziska Sprecher, Arzneimittel für seltene Krankheiten (orphan drugs): Das schweizerische Heilmittelrecht im Vergleich mit der orphan drug Regulierung der EU, Aktuelle Juristische Praxis 2012, p. 1746, citing Nikolaus Stürchler, Heilmittel für seltene Krankheiten: Schlüssel zu wirksamer Regulierung in der Schweiz, Aktuelle Juristische Praxis 2002, p. 893.

General extension of patent protection for paediatric drugs

According to Interpharma/Scienceindustries/vips, the 6-month period of protection for the development of paediatric drugs should be granted in all cases, rather than being subject to the requirement that a certificate already exists.

In this connection, the Federal Council's draft for the ordinary revision of the Therapeutic Products Act was adapted to the relevant EU Directive. In the meantime, the European Court of Justice (ECJ)[291] has ruled that a supplementary protection certificate (SPC, so-called paediatric extension) can also be granted if the period between the filing of the patent application and the granting of marketing authorisation is less than 5 years. In such a case, the period of the paediatric extension starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period elapsing between the patent application and the first marketing authorisation. According to the ECJ, a negative duration is not to be rounded to zero.

A 6-month period of protection divorced from the original SPC, as proposed by the pharmaceutical industry associations, does not conform to the EU Directive or to the above-mentioned ECJ ruling.

On 6 April 2011, the Federal Council took note of the results of the consultation on the draft legislation. The responses to the Federal Council's proposal to create incentives for the development of paediatric drugs, such as extension of the SPC and extension of data exclusivity, varied widely. From the viewpoint of the pharmaceutical industry, the incentives did not and do not currently go far enough, while patient and consumer organisations took the view that, with an incentives system of this kind, there was a risk that all existing reservations vis-à-vis research in children would be abandoned, and that children's status as subjects deserving special protection would be undermined.

Information on applications submitted by second applicants and parallel importers

According to Interpharma/Scienceindustries/vips, the situation at the interface between the patent rights of the originator and authorisations for second applicants is unsatisfactory: this is because communication is not actively pursued between Swissmedic and the market participants concerned (authorisation holders of originator products, generics manufacturers and parallel importers), which may in turn – in the view of these associations – lead to avoidable legal uncertainty and conflicts.

During the consultation on the ordinary revision of the Therapeutic Products Act, Interpharma/Scienceindustries/vips submitted two proposals designed to increase transparency and legal certainty, and to allow possible conflicts of interest to be settled out of court. This measure, they claimed, would not impose any new workload or extraneous tasks on Swissmedic, nor would it have any effect on the speed of procedures.

The associations propose that the first applicant should be notified of second applications for marketing authorisation submitted by parallel importers or generics manufacturers. Another conceivable approach would involve publication: in the absence of countervailing non-disclosure interests, applications for marketing authorisation would be published in an appropriate form by the competent authority.

The Federal Council has already been requested by Parliament[292] to propose an amendment to the Therapeutic Products Act which, in the absence of legitimate non-disclosure interests, would

[291] Case C-125/10, Judgment of the Court, 8 December 2011

[292] 08.3827 Mo. Altherr, "Greater transparency at Swissmedic"

stipulate a general requirement for transparency in the procedures of Swissmedic (specifically, medicinal product authorisation procedures). Transparency would involve in particular the disclosure of facts, information and procedures (or parts thereof) in which there is a public or other legitimate interest, or where disclosure is desired on competitive grounds. Subject to the protection of legitimate non-disclosure interests, interested parties should be able to find out what medicinal products and indications are the subject of applications for authorisation, and details of the subsequent Swissmedic procedure.

The aim of greater transparency can be achieved under the existing provisions for informing the public.[293] By amending the implementing legislation, the Federal Council intends to meet the indisputable demand for additional information, such as the assessment reports on which authorisations are based, in line with EU practice.

A number of issues are raised by the granting of access to official documents in the course of authorisation procedures. On the one hand, the manufacturer's professional, commercial and manufacturing secrets have to be protected and, on the other hand, it must be ensured that Swissmedic can carry out an independent assessment of the application for authorisation. If the first applicant is informed of a second applicant's submission, the latter loses the element of surprise which represents a strategic competitive aspect of the market launch.

[293] Art. 67 TPA

9.2.6 Federal Council's position regarding additional proposals

General extension of patent protection for paediatric drugs

On 7 November 2012, the Federal Council decided not to pursue this proposal, as it considers arrangements comparable to those of the EU to be appropriate.

Data exclusivity for new indications

For the Federal Council, it is conceivable that an extension of data exclusivity could be appropriate for orphan disease indications. The key question will be the requirements to which such an extension is subject. The Federal Administration has therefore been requested to develop a proposal giving due consideration to the interests of public health.

To maintain the relative advantage vis-à-vis the EU, the Federal Council decided on 7 November 2012 not to amend the existing regulations, and thus not to adapt them to those of the EU.

However, in order not to delay the consideration of the ordinary revision of the Therapeutic Products Act, it decided – in view of the numerous unresolved issues – that the proposal to extend data exclusivity should not be included in the relevant Dispatch. In the meantime, however, this question has been taken up by the National Council Committee responsible for preliminary deliberations on the revision of the Therapeutic Products Act.

Market exclusivity for orphan drugs

In the view of the Federal Council, this proposal can only be evaluated in conjunction with other measures designed to improve the situation with regard to orphan diseases. It therefore decided not to include this proposal in the Dispatch on the Revision of the Therapeutic Products Act. In the meantime, however, this question has been taken up by the National Council Committee responsible for preliminary deliberations on the revision of the Therapeutic Products Act.

Information on applications submitted by second applicants and parallel importers

In the view of the Federal Council, no fundamental objections can be made to greater transparency regarding applications for authorisation submitted to Swissmedic. Firstly, however, it would have to be generally applicable (i.e. it could not be restricted to medicinal products with known active pharmaceutical ingredients and parallel import products) and, secondly, the information obtained as a result of this transparency should not serve to keep second applicants and parallel importers from entering the market. To address this issue, taking the EU procedure as a model, submissions from second applicants could already be reviewed by Swissmedic in the final stage of the originator's data exclusivity period.

9.2.7 Measurement of goal attainment

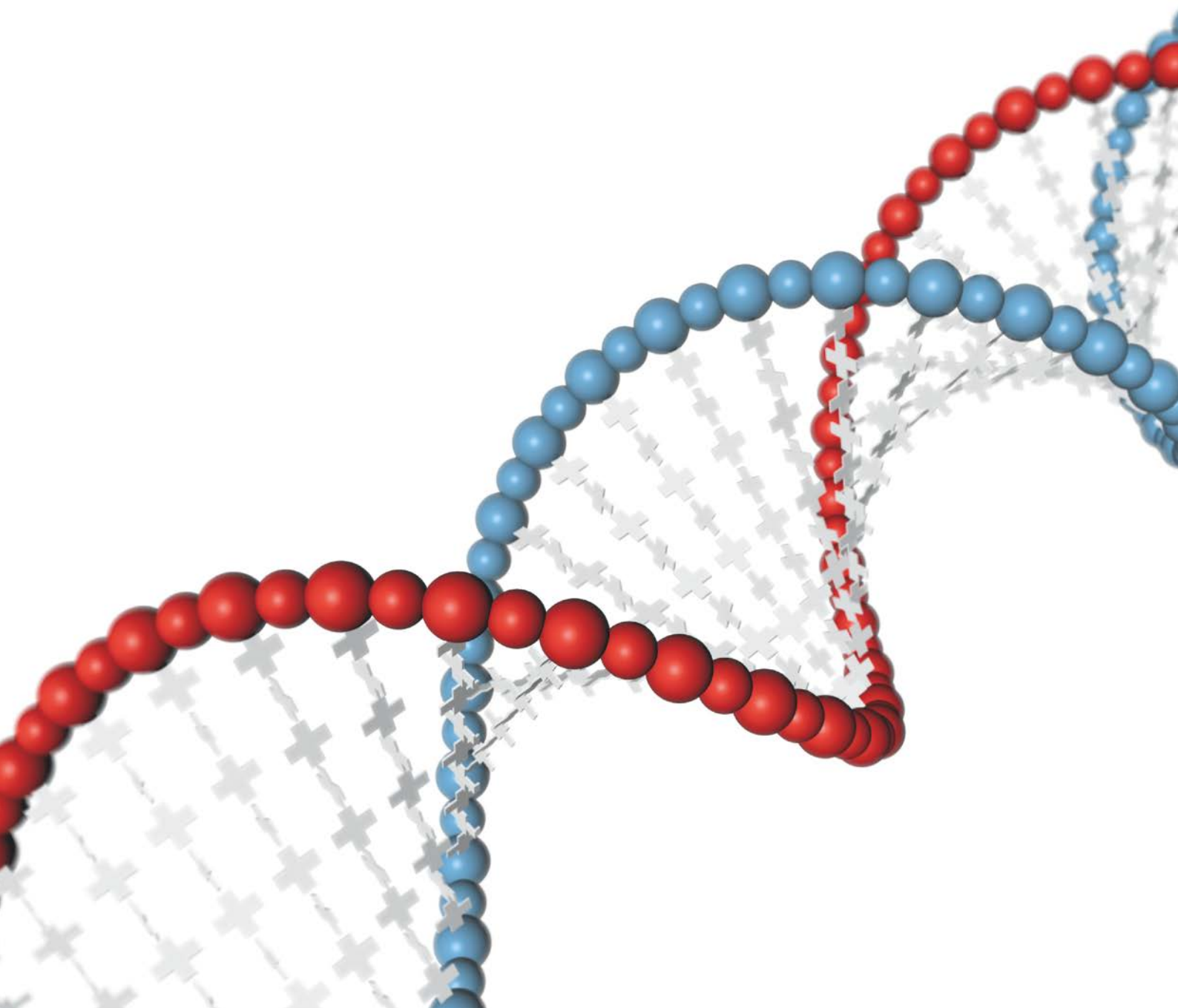
A/B. PATENT LAW / DATA EXCLUSIVITY FOR PAEDIATRIC DRUGS

The changes made as part of the ordinary revision of the Therapeutic Products Act (2nd stage),[294] together with the related amendments to the implementing provisions, are expected to come into force in 2016. The effects of the proposed changes are also to be the subject of a summative evaluation. The timing will depend on the definitive amendments and the commencement date.

[294] Cf. Dispatch of the Federal Council of 7 November 2012 on the Revision of the Therapeutic Products Act, BBl 2013 1

10 OVERVIEW OF MEASURES ADOPTED IN THE MASTER PLAN

This chapter provides a summary of all the goals defined and the measures adopted by the Federal Council in its master plan for the promotion of biomedical research and technology. It also indicates how goal attainment is to be measured and specifies the time frame for the preparation and implementation of measures.



Action area	Measure	Goal of measures	Measurement of goal attainment	Preparation	Implementation
Legal framework for human research	**Human Research Act, with implementing provisions**	The Human Research Act implements the constitutional mandate to regulate research involving human beings where this is required in order to protect their dignity and privacy. At the same time, it should help to establish a favourable framework for human research. The provisions concerning human research currently contained in a variety of federal and cantonal laws are consolidated and supplemented in uniform legislation. The provisions of the Human Research Act supersede the general requirements concerning research specified, in particular, in the Transplantation Act and the Therapeutic Products Act and also certain cantonal regulations.	The goals set are to be evaluated four years after the entry into force of the Human Research Act.	By 2013	2014 ff.
Structural framework for publicly funded research	**Complete revision of the Research and Innovation Promotion Act (FIFG)**	Strengthens Switzerland as a location by meeting contemporary requirements for federal promotion of research and innovation.	Scheduled to come into effect on 1 January 2014.	By 2013	2014 ff.
Education/training and continuing education / Structural framework for publicly funded research	**Promotion of Education, Research and Innovation (ERI Dispatch) 2013–2016**	Education: Meeting the demand for persons with a general education and professional skills Research and innovation: Consolidation of competitive funding at a high level and further strengthening of Switzerland's international competitiveness. Overarching aspects of the ERI system: development of Switzerland as a centre of intellectual activity and industry, committed to the principles of equal opportunities, sustainability and competitiveness.	In the subsequent Dispatch on Promotion of Education, Research and Innovation (ERI) 2017–2020, the attainment of goals in the period 2013–2016 will be reviewed.	By 2013	2013–2016
Structural framework for publicly funded research	**Federal service level agreement with the Swiss National Science Foundation 2013–2016**	• By supporting population-based and disease-specific longitudinal studies, the SNSF contributes to the development of a national data base for research and society. • The SNSF continues its initiatives to strengthen medical research. • The SNSF supports the consolidation of the SCTO and the CTU network (including international linkages). • Biobanks relevant for research are better integrated into national and international networks. • The SNSF manages the National Centres of Competence in Research in the relevant thematic areas (NCCR TransCure, NCCR SYNAPSY, NCCR Molecular Oncology, NCCR Kidney.ch) in accordance with existing guidelines.	Goal attainment reviewed via annual monitoring.	By 2012	2013–2016
Structural framework for publicly funded research	**Review to be carried out under the Dispatch on Promotion of ERI 2013–2016**	Securing the future of the competence centres for the planning and conduct of clinical trials established at the university hospitals and at St Gallen Cantonal Hospital (CTUs/SCTO) and strengthening of the Swiss Clinical Trial Organisation.	The Federal Council will report in the ERI Dispatch for 2017–2020 on the results of the requested review.	2013–2016	2017–2020

Action area	Measure	Goal of measures	Measurement of goal attainment	Preparation	Implementation
Education/training and continuing education	**National Health Policy Dialogue: "Future of medical education" (ZäB) – report including recommendations**	By spring 2014, the ZäB platform working group will issue an initial report, analysing the problems, defining action areas and making recommendations on this basis.	By the end of 2014, the Federal Council wishes to be informed of the need for action and the measures planned.	2013–2014	2014 ff.
Education/training and continuing education	**Fostering of young clinical researchers**	Education/training structures and profiles should be designed in such a way that more (specially trained) young scientists are available to work in clinical research and are prepared for professional careers within university hospitals, research centres, authorities or industry.	After four years, the measures will be evaluated and fed into the accreditation of undergraduate courses in accordance with the Federal Act on Funding and Coordination of the Swiss Higher Education Sector (HFKG), and of specialist training courses in accordance with the MedBG, so that any conditions required can be stipulated by the federal authorities.	2014–2015	2015 ff.
Availability of health data	**Increased transparency to improve quality**	Orientation within the health system is to be improved by ensuring transparency for all stakeholders and in particular for the public. This requires an improved data base and targeted evaluation. Data collection and the publication of quality indicators under Article 22a of the Health Insurance Act (KVG) are to be continued and expanded. Evaluation should take the form of integrated, level-appropriate processing for the various stakeholder groups.	Appropriate national structures have been created and sustained financing assured for quality improvement. In addition, quality reporting has been further expanded.	2013–2016	2017 ff.
Availability of health data	**Improved treatment processes thanks to electronic instruments**	Support is to be provided for the application of uniform semantic standards for medical data and the use of medical documentation systems (patient records) by all groups of service providers.	By the end of 2014, consensus is to be reached among the actors concerned as regards the key semantic standards to be adopted.	By 2016	2017 ff.
Availability of health data	**Health services research**	Health services research helps to improve the quality, effectiveness and cost-effectiveness of our health system. It focuses on the delivery of services to the public in hospital, practice and other health settings and also covers preventive and screening services.	Approval of the "Health services research" plan by the FOPH; submission of an NRP proposal by mid-January 2014. Decision by the Federal Council on the initiation of an NRP on health services research by the end of 2014.	2013–2014	2015 ff.
Availability of health data	**Cancer Registration Act**	A standardised national system is to be established with the goal of achieving, in the medium term, universal, complete and comprehensive registration of all new cases of cancer, as well as data on disease course, survival time and treatment quality.	By the end of 2014, the Dispatch and draft Federal Act on the Registration of Cancer are to be adopted by the Federal Council and referred to Parliament.	By 2017	2018 ff.

Action area	Measure	Goal of measures	Measurement of goal attainment	Preparation	Implementation
Market entry and surveillance system	**Evaluation of early revision of the Therapeutic Products Act (1st stage) – provision**	A wide range of high-quality, safe and effective medicinal products are to be made available to health professionals and patients at lower economic costs than in the past.	Firstly, in response to a parliamentary request concerning the security of supplies, the Federal Council will issue a report by the end of 2014 at the latest. Here, initial conclusions will be drawn concerning the measures already adopted. Secondly, the effects of the early revision of the Therapeutic Products Act (1st stage, hospital drugs) are to be evaluated in a separate project. On the basis of these findings, which should also be available in 2014, it will be apparent to what extent further action is required.	2013-2014	2015
Market entry and surveillance system / Intellectual property protection	**Ordinary revision of the Therapeutic Products Act (2nd stage)**	A wide range of high-quality, safe and effective medicinal products are to be made available to health professionals and patients at lower economic costs than in the past. The administrative costs for applicants and also for the authority responsible are to be reduced by eliminating unnecessary requirements and making procedures more efficient. At the same time, facilitated market entry should not only promote international trade in goods but also strengthen the domestic market in Switzerland. As part of the overall efforts to increase the availability of drugs suitable for children, the pharmaceutical industry is to be compensated for the extra costs arising from the additional requirements.	The changes made as part of the ordinary revision of the Therapeutic Products Act, together with the related amendments to the implementing provisions, are expected to come into force in 2016. The effects of the proposed changes are also to be the subject of a summative evaluation. The timing will depend on the definitive amendments and the commencement date.	By 2015	2016 ff.
Market entry and surveillance system	**Ratification of the Medicrime Convention**	A wide range of high-quality, safe and effective medicinal products are to be made available to health professionals and patients at lower economic costs than in the past.	To what extent the goals of the Convention can be achieved will be apparent from the results of the consultation which is to begin at the end of 2013. If the general aims of the proposal are essentially approved by a majority of those participating in the consultation procedure, then the Convention is to be ratified by the end of 2016.	By 2015	2016 ff.
Market entry and surveillance system	**Swissmedic authorisation process (owner strategy)**	Among the strategic goals for the organisation and governance of Swissmedic is that, by the end of 2014, processing times are to be complied with for 99% of applications for authorisation and, in addition, a new procedure with prior notification is to be implemented.	Attainment of the targets set for compliance with processing times will be assessed annually.	2013	2014 ff.

Action area	Measure	Goal of measures	Measurement of goal attainment	Preparation	Implementation
Market entry and surveillance system	**Swiss–EU agreement on EMA–Swissmedic cooperation**	The Federal Council is seeking closer cooperation with the EU in the area of drug authorisation and market surveillance.	The Federal Council aims to secure a memorandum of understanding between Swissmedic and the EMA. This goal will be attained when negotiations are completed and cooperation between Swissmedic and the EMA is strengthened. The timetable partly depends on the general context of Swiss–EU relations and negotiations with the EU on health matters.	2013–2015	2016 ff.
Reimbursement under social insurance	**Price setting**	In order to ensure efficient and cost-conscious reimbursement of medicinal products and access to innovations, it is to be established by 2015 whether and to what extent the existing price-setting system should be adapted.	The system is to be adapted from 2015. The requisite amendments to the legal foundations are to be prepared in 2014.	2013–2014	2015 ff.
Reimbursement under social insurance	**HTA programme/strategy**	The institutionalisation of HTA should supplement the existing submissions system particularly in the following cases – complex questions, comparative assessments of new and established services in a given application, and re-evaluation of existing (groups of) services under Article 32 paragraph 2 KVG. Mandates for the preparation of HTA reports on existing services are to be defined in the HTA programme. Horizon scanning is to be undertaken as an additional task.	The consultation on the draft legislation to strengthen quality and health technology assessment is to take place in spring 2014.	2014–2016	2017 ff.
Reimbursement under social insurance	**FOPH listing process (owner strategy)**	The processing of applications which have to be presented to the EAK is to be expedited; within 60 calendar days after authorisation by Swissmedic, the FOPH is to reach a decision on a new listing or extended indications / modified restrictions.	Attainment of targets for compliance with processing times is to be assessed annually.	2013	2014 ff.
Reimbursement under social insurance	**Review of Art. 71a and 71b of Health Insurance Ordinance (KVV)**	The regulation or enforcement of reimbursement in individual cases (Articles 71a and 71b KVV) is to be optimised. Coverage of the costs of treatment and care provided in accordance with established standard therapy (but sometimes involving off-label use) in academic clinical trials is to be ensured.	Based on the evaluation, it is to be established by mid-2014 whether there is a need for improvements in the implementation of the provisions or amendments to Articles 71a and 71b KVV.	2013–2014	2014 ff.
Orphan diseases / Intellectual property protection	**Orphan Diseases Plan**	The aim is to improve medical care for people with rare diseases. These should be correctly diagnosed and treated as rapidly as possible. In view of European efforts to develop a community-wide rare diseases strategy, and the growing personalisation of medicine, it is important from a health policy perspective to have an appropriate instrument whereby the numerous federal and cantonal efforts undertaken at different levels can be coordinated, if necessary intensified, and assigned to the most suitable actor.	The report on the Orphan Diseases Plan is to be submitted to the Federal Council by the second quarter of 2014 at the latest.	By 2014	2014 ff.

Annex: Participants at round-table events

The following individuals attended the round-table events:

Name	Institution
Alain Berset	Federal Department of Home Affairs (FDHA)
Thomas Christen	General Secretariat of the FDHA
Katharina Füglister	General Secretariat of the FDHA
Pascal Strupler	Federal Office of Public Health
Matthias Enderle	Federal Office of Public Health
Brigitte Meier	Federal Office of Public Health
Catherine Gasser	Federal Office of Public Health
Eric Scheidegger	State Secretariat for Economic Affairs
Katharina Eggenberger	State Secretariat for Education and Research
Corina Wirth	State Secretariat for Education and Research
Felix Addor	Federal Institute of Intellectual Property
Andreas Balsiger	Swissmedic
Erika Ziltener	Umbrella organisation of Swiss patient centres (DVSP)
Melchior Buchs	Federation of Swiss Medical Devices Trade and Industry Associations (FASMED)
Jürg Schlup	Swiss Medical Association (FMH)
Werner Kübler	H+ Swiss Hospital Association
Peter Huber	Intergenerika
Thomas Cueni / Heiner Sandmeier	Interpharma
Christoph Meier / Christian Affolter	santésuisse – Swiss Health Insurers' Association
Peter Meier-Abt	Swiss Academy of Medical Sciences
Richard Herrmann	Swiss Group for Clinical Cancer Research
Ewa Mariéthoz	Conference of Cantonal Health Directors
Margrit Kessler	Swiss Patient Organisation
Martina Weiss	Swiss University Conference
Pascal Brenneisen / Dieter Grauer	Scienceindustries
Walter Hölzle	Association of Swiss Pharmaceutical Companies (vips)

Publication details

Published by
Federal Council, publication date 2013

Members of the editorial committee
Representatives of the Federal Office of Public Health, the State Secretariat for Education, Research and Innovation, the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Institute of Intellectual Property

Further information
Federal Office of Public Health (FOPH)
Matthias Enderle
P.O. Box
CH-3003 Bern
biomedizin@bag.admin.ch

This publication is available as a PDF file in English, French, German and Italian at:
www.bag.admin.ch

English translation: Jeff Acheson, Bottmingen