



Masterplan Biomedical Research and Technology

Summary status report 2015

The Masterplan for the promotion of biomedical research and technology is currently being successfully implemented. The Federal Council has taken note of a status report to this effect issued by the Federal Department of Home Affairs. The Masterplan is designed to strengthen the Swiss workplace while at the same time ensuring that the Swiss public has access to new biomedical products.

The interim report shows that progress has been made in all the action areas defined in the Masterplan. In particular, the Federal Act on Research involving Human Beings (Human Research Act, HRA), which came into effect at the beginning of 2014, significantly strengthens Switzerland's position as a research centre by providing better protection for study participants, promoting high-quality research and ensuring greater transparency. Here, Switzerland is assuming a pioneering role within Europe. Thanks to simplified, standardised and professionalised processes, the duration of procedures has been markedly reduced, even though potential for improvement still exists in certain areas.

The importance of human research for Switzerland has long been recognised by the Swiss National Science Foundation (SNSF), whose support has been instrumental in improving the overall conditions for research. Among the various activities currently being pursued by the SNSF in this area are a special funding programme for independent clinical research and an initiative to promote the next generation of researchers, which should enable young physicians to devote at least 30% of their working hours to a clinical research project. In view of the essential role played by appropriately trained physician-researchers in strengthening biomedical research, technology and innovation, a situation report on this topic was commissioned by the federal and cantonal authorities under the Masterplan. This report concludes that, to date, not enough has been done to promote the next generation of clinical researchers, and it proposes measures to ensure that more targeted and systematic support is provided for young physicians at each stage of their clinical research career. A national expert group is currently working on the implementation of these measures.

Collection and targeted use of comprehensive health data

In the area of health services research, the National Research Programme on "Smarter Health Care" (NRP 74) was launched by the Federal Council on 24 June 2015. This programme is primarily concerned with the optimisation of resource allocation. In addition, it will focus on the prevention and treatment of multiple chronic disorders. Lastly, NRP 74 should help to improve the availability, linkage and comparability of health data. The Cancer

Registry Act, expected to come into force in 2019, should also help to improve the availability of health data by providing a data base to facilitate the development of preventive and early-detection measures, the evaluation of quality of care, and support for cantonal care planning and cancer research.

Substantial improvements in the areas of reimbursement and market entry

In the area of reimbursement under social insurance, progress has been made on several fronts. The modified price-setting system adopted for medicinal products on 1 June 2015 should help to ensure efficient and cost-conscious reimbursement of medicines and access to innovations, while at the same time enhancing the transparency of price-setting. The aim here is to stabilise rising costs without jeopardising Switzerland's position as an industrial centre. In addition, the processing of applications submitted to the Federal Medicinal Products Committee (EAK) for the inclusion of new pharmaceutical products in the Specialties List has been streamlined.

The findings of the evaluation of the early revision of the Therapeutic Products Act (1st stage) are encouraging: the legal framework for the achievement of overarching goals – such as improving drug supplies while maintaining product safety – is viewed as largely appropriate by the stakeholders surveyed. The 2nd stage of the revision of the Act should further simplify the authorisation of certain medicinal products. In addition, the research and development of new drugs for children is to be promoted or rewarded by a 6-month extension of patent protection. The bill is currently at the “resolution of differences” stage, and the revised Act is expected to come into effect in January 2018. Swissmedic has achieved its strategic goal of complying with processing times for 99% of applications for authorisation by the end of 2014, as well as implementing a new procedure with prior notification. In addition, the new agreement with the European Commission concerning cooperation between the European Medicines Agency and Swissmedic, which came into effect in July 2015, will support efforts by European and Swiss regulators to improve the oversight of medicines for human and animal health.

In the Federal Council's view, Switzerland's international competitiveness in biomedical research and technology is excellent. The interdepartmental working group led by the Federal Office of Public Health (FOPH) has been requested to prepare a further report on the status of implementation of measures by the middle of 2017.

Berne, October 2015. Biomedicine Division, CRK