



Masterplan for Biomedical Research and Technology

Summary of Status Report 2017

The Federal Council's Masterplan for the promotion of biomedical research and technology is designed to strengthen Switzerland as a business location, while at the same time ensuring that newly developed biomedical products are accessible and affordable for the public. It is being implemented in close cooperation with partners from research, industry and healthcare. At a meeting on 21 June 2017, the Federal Council was informed about the status of implementation of measures.

The Masterplan comprises 23 measures in the areas of education and training, the legal and structural framework for research, health data, orphan diseases, market entry and reimbursement. In some cases, measures have already been implemented, and in others significant progress has been made. Current priority areas include support for research and young researchers, medical device safety and security of drug supplies, and optimisation of authorisation and reimbursement procedures.

Support for research and young researchers

The importance of human research for Switzerland has long been recognised by the Swiss National Science Foundation (SNSF), whose support has been crucial in improving the overall conditions for research. In 2016, the SNSF introduced two new funding instruments which are important for academic clinical research – the “Protected Research Time for Clinicians” scheme and a programme to support investigator-initiated clinical trials (IICTs) amounting to CHF 10 million per year. The evaluation of the first call for proposals (2016) showed that this programme is of great interest for academic researchers; the SNSF has therefore decided to issue annual calls for proposals for IICTs until 2020.

Successful clinical research requires appropriately trained professionals who have the necessary time, skills and resources to conduct research. In October 2016, the FOPH published a broad-based “Roadmap for developing the next generation of clinical researchers”. The first milestones have already been achieved. For example, the Swiss Academy of Medical Sciences (SAMS) has launched the “Young Talents in Clinical Research” programme to enable young physicians to gain initial research experience. Total funding of CHF 4 million is available for this programme from 2017 to 2020.

Health services research helps to improve the quality, effectiveness and cost-effectiveness of the health system and itself provides important health data. On 24 June 2015, the National Research Programme on “Smarter Health Care” (NRP 74) was launched by the Federal Council, with an overall budget of CHF 20 million. The goal of this NRP is to generate knowledge on the structure and utilisation of health services in Switzerland. In spring 2017, 29 projects out of a total of 43 submissions were approved under NRP 74.

In the medium term, the planned Federal Act on Cancer Registration should ensure that all new cases of cancer are comprehensively recorded, including data on the course of disease, survival time and treatment quality. This will provide an evidence base facilitating the development of prevention and screening measures; the evaluation of quality of care, diagnosis and treatment; and support for cantonal care planning and cancer research. The Act was adopted with a large majority in the Swiss Parliament on 18 March 2016. Data recorded in cancer registries is also to be made available for research purposes: accordingly, the periods for data retention (30 years after the patient's death for adults, 80 years for children) and anonymisation (80 years after the patient's death) have been significantly extended. The draft Cancer Registration Ordinance was put out for consultation by the Federal Council on 5 April 2017. The legislation is expected to come into effect in 2019.

Medical device safety and security of drug supplies

In May 2017, two new EU Regulations on medical devices came into effect, which are also relevant for healthcare in Switzerland. The aim of these new rules is to improve safety standards for medical devices and thus also patient safety. To ensure that the public can continue to access new and existing medical devices from the single European market, the legal framework in Switzerland will be adapted accordingly. Thanks to the Mutual Recognition Agreement (MRA) on the acceptance of conformity assessments, Switzerland is already integrated into the EU's market surveillance system.

The topic of security of drug supplies was first included in the Masterplan in 2016. With the aid of the Reporting Office of the Federal Office for National Economic Supply (FONES), the exchange of information between authorities, industry and service providers has been intensified, thus improving supplies of medicinal products. This exchange of information is among the measures mentioned by the Federal Council in its report prepared in response to the Heim postulate (12.3426). Additional measures have been adopted by Parliament with the revision of the Therapeutic Products Act, e.g. with regard to paediatric medicines, well-established use (WEU) medicines and niche products such as antidotes or radiopharmaceuticals.

Optimisation of authorisation and reimbursement procedures

The optimisation of authorisation and reimbursement procedures is a key goal defined in the Masterplan. In recent years, Swissmedic and the FOPH have invested successfully in shortening the duration of their procedures. In 2016, at Swissmedic, 99% of applications for the first marketing authorisation of innovative medicinal products were processed within the specified time limits, compared with only 73% five years ago; 100% of applications under the fast-track authorisation procedure and for the authorisation of new active substances were completed on time. In international analyses, Switzerland is highly rated compared to other OECD countries with regard to the authorisation and reimbursement of new medicines. Applications for authorisation are, however, often submitted several years earlier in the US – an important market for industry alongside the EU – than in Switzerland, which automatically delays the availability of medicinal products.

The Masterplan, which is part of the Federal Council's Health2020 Strategy, was adopted by the Federal Council in December 2013. The public was first informed about the implementation status in 2015. In 2018, the measures implemented to date are to be assessed and a decision is to be taken on further steps.

Bern, June 2017. Biomedicine Division, CRK