



Strategy report on the long-term promotion of research, development and production of vaccines in Switzerland

Summary

The COVID-19 pandemic has shown just how suddenly a pandemic or epidemic scenario can arise and produce far-reaching consequences even in the western world. Faced with the health threat posed by the SARS-CoV-2 pathogen, governments introduced sweeping and radical measures – including restrictions on contact with others and curfews – to control the pandemic. The outbreak of the pandemic also marked the start of the intensive search for an effective vaccine in order to curb its spread and a comprehensive immunisation strategy to achieve lasting protection and enable public and economic life to return to normal.

The worldwide search for a suitable vaccine has shown what capabilities and resources are critical, from both the global and national standpoint, for developing and producing a vaccine in quantities sufficient to vaccinate large swathes of the world's population as quickly as possible.

Vaccine research and development was able to build on existing mRNA technology research findings. But since this technology evolved mainly in the context of its potential in oncology, no mRNA-based marketable vaccine existed. The breakthrough in mRNA technology enabled vaccines to be developed, authorised and manufactured very quickly, with the first vaccines appearing on the market at the end of 2020. Although a wealth of experience had been accumulated in the classical vaccine technologies, the fairly prolonged development cycles meant that the small number of currently authorised vaccines based on these technologies were almost irrelevant in the largest markets.

The development of COVID-19 vaccines was paralleled by an expansion of production capacities worldwide with the aim of meeting future vaccine demand for the entire global population several times over. This resulted in multiple shortfalls in terms of skills, equipment, infrastructure and materials at various levels.

In light of these challenges and the preparations for possible future pandemics, and based on the Federal Council decision of 19 May 2021, the aim of this strategy report is to formulate a strategy for the long-term promotion of research, development and production of vaccines in Switzerland.

In order to achieve the overriding goal of long-term strengthening, the following secondary aims were formulated:

- 1) Switzerland bases its vaccine strategy on the ability to react quickly and flexibly in future epidemics in respect of the supply of vaccines.
- 2) Switzerland invests in a broadly-based partnership and collaboration network (countries and international organisations), preferably focusing on Europe.
- 3) Switzerland exploits its already strong position as a production site and builds on this in a targeted manner.

- 4) Switzerland strengthens its position as a significant global player in the research and development of key vaccine technologies.
- 5) Switzerland commits as a matter of principle to market-driven vaccine production.

Based on a comprehensive analysis, measures have been identified to strengthen R&D and production in the context of the Federal Council's goals. The measures have been grouped into two categories:

- Proposed measures that relate directly to detailed planning and implementation. The corresponding analysis has shown that such measures strengthen the entire vaccine-related value-added chain and thereby improve the future supply of vaccines.
- Measures whose contribution to the achievement of the goals was initially rated as substantial but, because of their complexity and implications, were recommended for further investigation. These measures can be complementary or (partly) substitutable. In this case, they should be jointly analysed, formulated and resubmitted for a decision on implementation.

I Research & development:

Priority pathogens. Supplying Switzerland with relevant vaccines in the event of a future epidemic requires possible epidemic-triggering pathogens to be identified. Pathogens that are most likely to trigger a future epidemic or pandemic: Respiratory viruses, vector-transmitted diseases and an unknown pathogen X. Since it is not really possible to predict what pathogen will trigger a pandemic, the vaccine strategy should allow for maximum flexibility in terms of research, development and production.

Basic research. Although vaccine-related basic research in Switzerland is already very comprehensive, a stronger focus on vaccinology could lead to more relevant findings and strengthen the research and teaching skills in this field. This might then accelerate vaccine development and authorisation – which can begin only when it is clear what pathogen has the potential to trigger an epidemic or pandemic.

Measures recommended for implementation:

- Support the acquisition of academic skills in the field of vaccinology
- Additional funding for specific projects in vaccine research

Translational and applied research & development. The lack of relevant COVID-19 vaccine candidates from Switzerland can be attributed to two trends. Firstly, although Switzerland possesses comprehensive vaccine-related basic research, many research projects founder when it comes to the stage of translation to applied research. This means that they fail to reach the level of maturity needed to be picked up by industry. Secondly, the relevant pharmaceutical companies in Switzerland have largely withdrawn from vaccine development over the last decade. Indeed, in the years leading up to COVID-19 hardly any vaccines were in clinical phases I and II in Switzerland.

Promoting translational research and continuing vaccine-related research projects would strengthen Switzerland's position. In particular, this could lead to a broader portfolio of possible vaccine candidates and – in the event of a pandemic – increase the likelihood of developing a vaccine with intellectual property in Switzerland. The creation of an institute for vaccine research and the upgrading of existing structures to form an innovation hub should also be investigated. Although individual measures in R&D may be effective on their own, a holistic, centrally coordinated approach could further reinforce their impact.

National clinical study networks already exist in clinical development. However, only a small number of the research institutions involved focus on vaccines. Expanding these networks to include vaccines and the creation of new functional skills could enhance both the ability to conduct clinical studies in Switzerland and their quality. Access to a high-quality GMP production infrastructure for researchers, which is hardly available at present, would also help achieve this goal. Various GMP production sites already exist in Switzerland thanks to the large number of pharmaceutical companies. To give vaccine research projects access to these GMP facilities, the federal government could establish partnerships with private stakeholders or promote the construction of a GMP production site specifically for R&D.

Measures recommended for implementation:

- Additional funding for the translation from basic to clinical research
- Promote access to the GMP production infrastructure for the production of vaccines in R&D

Recommended measures for further analysis:

- Create an institute for vaccine research
- Optimise national clinical study networks and coordination offices
- Promote biotech companies through venture capital
- Upgrade and combine existing structures to form an innovation hub for vaccine R&D

II Technology analysis and value-added chain:

Priority vaccine technologies. Switzerland's vaccine strategy aims to make sufficient vaccines against an epidemic pathogen available as quickly as possible. This will involve an appropriate mix of next-gen and classical vaccine technologies. The mix of four technologies (mRNA, RVV, protein subunits and virus-like particles) will facilitate a quick response to differing pathogens. The advantage of next-gen technologies is the ability to produce vaccines quickly, flexibly and in substantial quantities.

Domestic production. The access to priority vaccine technologies can be achieved via a "make strategy" and/or via a "buy strategy". For pharmaceutical companies in Switzerland, focusing primarily on the production of selected value-added stages of next-gen vaccine technologies is a worthwhile strategy. Going beyond immunology, mRNA technology in particular has been shown to offer a wide range of possible applications that are economically attractive and have excellent growth potential. Not only is Switzerland well placed in this respect (e.g. in terms of existing know-how, highly qualified specialists and high wage levels), it is also – unlike the situation for classical vaccines – active in the production of various input factors along the value-added chain. The expansion of capacities in next-gen vaccine production could be supported, for example, by government incentives. Multimodal production sites would be particularly suitable for expanding domestic production capacities. They are specifically designed for the production of various vaccines and can be converted from one technology to the other relatively quickly.

Measures recommended for implementation:

- Improve the structural conditions for expanding and converting multimodal production infrastructure
- Train additional specialists for vaccine production
- Incentivise domestic production and training of critical input factors for the next-gen value-added chain

Recommended measure for further analysis:

- Promote an E2E next-gen production hub

Alternative types of access. Since the aspiration for self-sufficient domestic vaccine production is unrealistic, strengthening local access to critical input factors in order to increase the security of supply in Switzerland should be considered. To this end – and complementing the domestic production of input materials – producers could be compelled to ensure the availability of critical and scarce input materials by means of nearshore contracts or – if possible – via minimum stocks. An appropriate balance between domestic production, hedging with nearshore contracts and stockpiling should be designed to achieve the desired security of supply.

Recommended measures for further analysis:

- Maintain minimum stocks of certain materials that are critical for next-gen
- Secure critical input factors for the onshore production of next-gen vaccines by means of nearshore contracts

III Vaccine policy and international collaborations:

Instruments of vaccine policy. 16 generic instruments are available for the long-term strengthening of national vaccine research, development and production. Although Switzerland already actively uses a large proportion of these instruments, there is room for improvement in government funding to promote domestic R&D and production, the networking of stakeholders and the bundling of critical skills.

Measures recommended for implementation:

- Periodically review and revise the vaccine strategy and its implementation plan
- Monitor vaccine-related capabilities and resources in Switzerland

Recommended measure for further analysis:

- Create a national centre of excellence for vaccines

International collaborations. Switzerland appears to be involved in fewer international collaborations than comparable countries. Expanding existing, or establishing new, collaborations with companies, international organisations and other countries would enable Switzerland to improve its development and production capabilities, obtain access to vaccine-related know-how and improve security of supply.

Measures recommended for implementation:

- Participate in initiatives to control pandemics and epidemics
- Expand links with European clinical study networks
- Enter into bilateral and multilateral alliances involving the research and development (R&D) and production of vaccines

As well as selecting specific measures, the Federal Council should decide whether and, if so, with what overriding motive (innovation leader, production hub or networked E2E vaccine location), it wishes to pursue the vaccine strategy. This overriding motive determines which measures for further analysis should be prioritised for in-depth review.

Based on existing capabilities and future development potential in the vaccine market, the analyses indicate that Switzerland should position itself as an innovation leader in order to build up a competitive advantage and secure the long-term supply of vaccines.