PHARMA HUB SWITZERLAND 2030

Current situation – Strategy – Measures

Pharma hub Switzerland 2030

FOREWORD

Switzerland needs to take action for the benefit of patients

Dear reader,
Switzerland and its research-based pharmaceutical companies are a success story. The attractive environment that the country offers and the innovativeness of its pharmaceutical industry have been drivers of its prosperity and quality of life for decades.

However, the challenges – which include digitalisation, ensuring sustainable funding for the healthcare system and a changed operating environment, to name just a few – are growing. Digitalisation, with the accompanying opportunities presented by new technologies and big data, has huge potential as a source of medical progress and patient benefits. At the same time though, new companies are entering the healthcare market and numerous countries are vying with each other to become the major centres of the global digitalised economy.

"This strategy paper outlines ways in which the pharmaceutical industry, government and the authorities can contribute to Switzerland's success as a pharma hub in 2030 and to patients' wellbeing.

Switzerland must continue to generate maximum patient benefit in this digitalised age and remain Europe's leading centre of pharmaceutical activity. To achieve these goals, we must adopt a more spirited approach. A better operating environment for start-up companies, modernised and effective protection of intellectual property, and faster approval and reimbursement processes for innovative medicines are just a few of the many areas where action is needed.

We in the research-based pharmaceutical industry will play our part in equal measure. The promotion of a world-leading ecosystem for health data, flexible reimbursement models for innovation and intensified partnership with the authorities are examples of how we intend to actively help forge solutions.

In this strategy paper, Interpharma outlines ways in which the pharmaceutical industry, government and the authorities can help ensure that Switzerland is still a successful pharma hub in 2030 and that patients will have sustainable access to innovative medicines. As President of Interpharma, I have made it a priority to initiate and drive forward a dialogue on Switzerland's future as a pharma hub with all stakeholder groups.

I would invite you to join the discussion with us and all other stakeholders.

I look forward to it.

J. Rupp

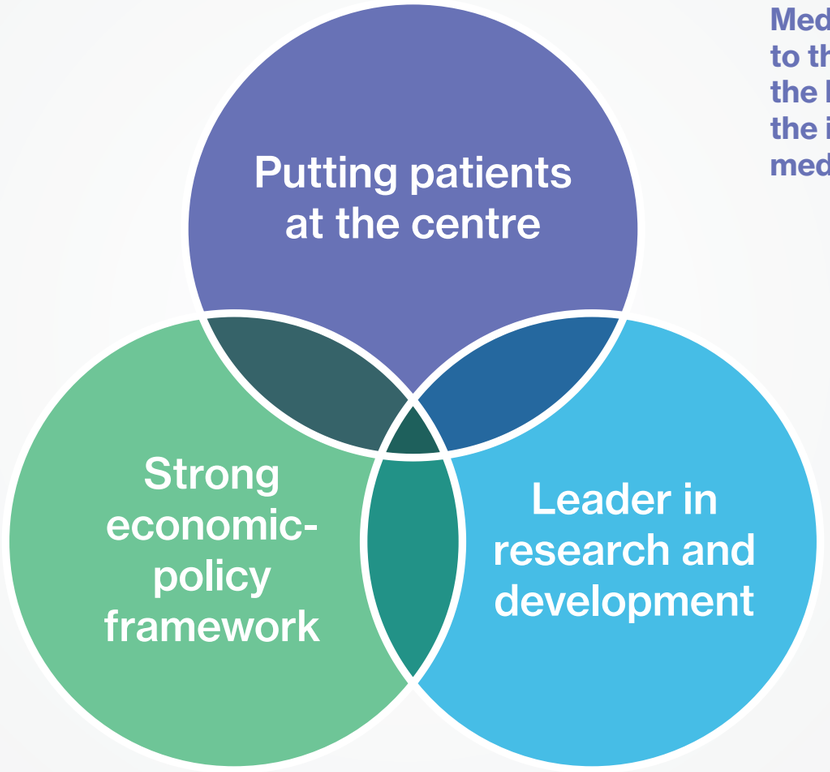
Jörg-Michael Rupp
Vice-President, Pharma International, Roche, President of Interpharma

Vision for Switzerland as a pharma hub in 2030

“Switzerland is still Europe’s leading pharma hub in 2030. It benefits from high-quality medical innovation and is able to fund this innovation in the long run and sustainably. The pharmaceutical industry is a key contributor to the prosperity and quality of life of people in Switzerland.”

A strong economic-policy framework means in 2030:

- Switzerland has a highly skilled labour force at all levels
- An attractive fiscal environment safeguards employment in the pharmaceutical industry and the industry’s contribution to national prosperity
- The Swiss economy benefits from the industry’s high export volumes
- The pharmaceutical industry is a driving force of the sustainable economy



Putting patients at the centre means in 2030:

- Patients in Switzerland have fast access to innovative medicines
- All patients receive reimbursement for innovative medicines right from the day the medicines are authorised
- Medicine costs are proportionate to the benefits to patients and the healthcare system, and also to the industry’s investment in those medicines

Being leader in research and development means in 2030:

- Effective and modern patent protection enables the pharmaceutical industry to invest in research and development of innovative medicines
- Clinical trials in Switzerland give patients early access to life-saving treatments
- High-quality health data enhance treatment quality and accelerate medical progress

CURRENT SITUATION

A strong industry in a challenging environment

The pharmaceutical industry is a major contributor to quality of life and prosperity in Switzerland. At the same time, Switzerland traditionally provides an attractive operating environment for innovative pharmaceutical companies. However, it is increasingly losing ground in terms of competiveness to other countries. There is therefore a greater need than ever for a concerted strategy that embraces all stakeholders.

An industry with an impact on society

Today, people in Switzerland are living longer, better lives because they benefit from innovative medicines and access to high-quality healthcare provision. By developing and launching innovative medicines, research-based pharmaceutical companies are making a major contribution to quality of life of the society. Diseases that used to be fatal or were associated with severe lifelong limitations can now be treated effectively and efficiently. Thanks to investment by the pharmaceutical industry, it is now also possible to effectively treat a large number of rare diseases, enabling the people who suffer from them to lead almost normal lives.

The effects of medical progress extend far beyond direct patient benefits. Family members and friends have fewer care obligations, while more efficient treatments mean that patients are able to resume work sooner. This in turn reduces the costs borne by employers, social security schemes and the healthcare system.

The Swiss pharmaceutical industry has deep roots in the country, and is an important pillar and driving force on both regional and national level. Many companies are actively involved in society, for example in the arts or sport, or at leisure time events. With women accounting for almost 45 percent of the workforce as well as efforts by several companies to extend paternity leave, the industry is also leading in the area of compatibility of family and career. It is also reducing climate-relevant emissions and is committed to sustainable development.

Major economic significance

Switzerland and the pharmaceutical industry have been following a common path for decades. An attractive economic-policy framework has facilitated the research-based pharmaceutical industry's impressive growth. At the same time, the industry makes a particularly large contribution to prosperity in Switzerland as one of the cornerstones of the country's economy. Its 5.4 percent direct contribution to gross domestic product (GDP) makes it one of Switzerland's most significant private-industry sectors.

Today our country ranks alongside the USA as one of the most important centres of pharmaceutical research worldwide, with a reputation that reaches far beyond Europe. In 2017, Interpharma member companies invested more than 6.5 billion Swiss francs in research and development (R&D) in Switzerland – almost twice what they earn from sales in the country. For every franc that flows into pharmaceutical industry via the Swiss healthcare system, almost two are reinvested in Switzerland.

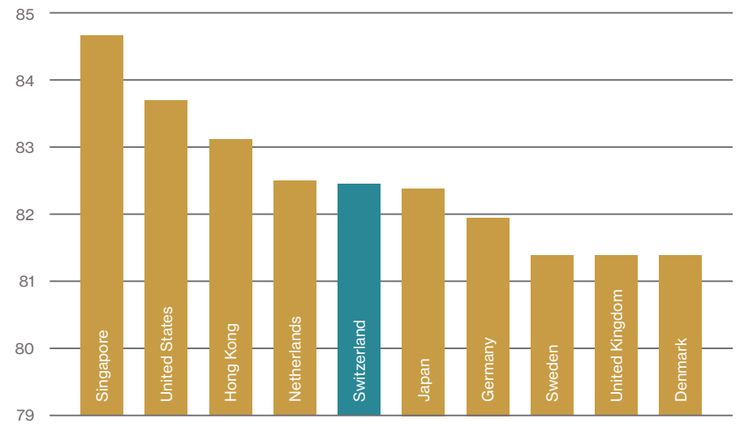
The value generated annually by the industry's 46,800-strong workforce amounts to 36 billion francs. A total of 254,100 jobs depend on the success of the pharmaceutical industry.

Employment and nominal value creation in the pharmaceutical industry, 2018

Economic interdependencies mean that many jobs in other sectors are linked to pharmaceutical companies' production activities. These indirect and induced effects make the industry a key pillar of the Swiss economy.

Sources: BAK Economics (2019)

Switzerland's competitiveness



In just a few years, Switzerland has fallen from first to fifth place in the Global Competitiveness Index. The country is also losing ground in various subindexes, such as that for information and communication technologies, where it ranks 15th. Other studies highlight further weaknesses. For example, Switzerland is at the back of the midfield in terms of the availability of electronic patient data and the associated regulatory framework.

Source: World Economic Forum (2019)

Growing challenges for Switzerland as a location

An optimal operating environment is essential if the country is to remain a successful and internationally competitive pharma hub. However, the country's attractiveness is under pressure from many sides. Anti-business initiatives, the threat of the bilateral agreements with the EU being eroded and growing bureaucratic and regulatory costs are jeopardising Switzerland's leading positions in innovation, productivity and exports. Furthermore, pharmaceutical research is facing regulatory hurdles.

"By proposing these core measures, Interpharma hopes to spark broad nationwide dialogue on Switzerland's position as a pharma and healthcare hub."

Mark Never, Novartis,
Vice-President of Interpharma

The impact of demographic change on the healthcare system is a challenge for all stakeholder groups. The industry is taking seriously apprehensions about whether it will be possible to finance the healthcare system in the long term. It is already helping to reduce costs by regularly lowering prices, with reductions between 2012 and 2018 amounting to 1 billion francs. Though challenging, the discussion that is taking place in society on the economic and ethical implications of medical progress is and remains important. At the same time, the healthcare system has to adapt to the new requirements.

As a result of technological progress and advancing digitalisation, an increasing number of companies from outside the industry are entering the healthcare market. Switzerland needs to act urgently if it wants to be a key player in digital transformation in the future.

Overcoming challenges together

No single stakeholder can overcome the current challenges unassisted. Doing so will instead require a strategy that is shared by all stakeholder groups. By publishing "Switzerland as a pharma hub in 2030" and the core measures it proposes, Interpharma is launching the discussion on Switzerland's future in this field. On the one hand, this brochure provides an analysis. On the other, it outlines a strategy for the operating environment that the pharmaceutical industry will need if it is to continue making a key contribution to Switzerland's attractiveness as a place in which to do business, research and reside.

The prospects for a successful partnership look good. Despite the many challenges and different perspectives, Switzerland still has a strong culture of people pulling together to find solutions. Moreover, stakeholders share the same overarching goals of patient wellbeing, a strong business location and a good quality of life for the country's society.

STRATEGY AND ACTIVITIES

The best for patients, research and the economy

In this strategy report, Interpharma outlines a way in which the pharma industry can continue to create higher than average value for Switzerland and its inhabitants in 2030. The report is divided into three thematic areas: patients and their environment, Switzerland as a centre of research activity, and the economic policy framework. The main points of leverage will be identified for each, and the report will highlight the contributions required from the industry, government and the authorities to ensure a successful future.

The 3 main themes of the strategy

Putting patients at the centre

Ensuring the health of the Swiss population will remain the overriding goal of every stakeholder. The aim is to give patients fast and broad access to innovations. This requires an environment that drives medical progress by rewarding innovation.

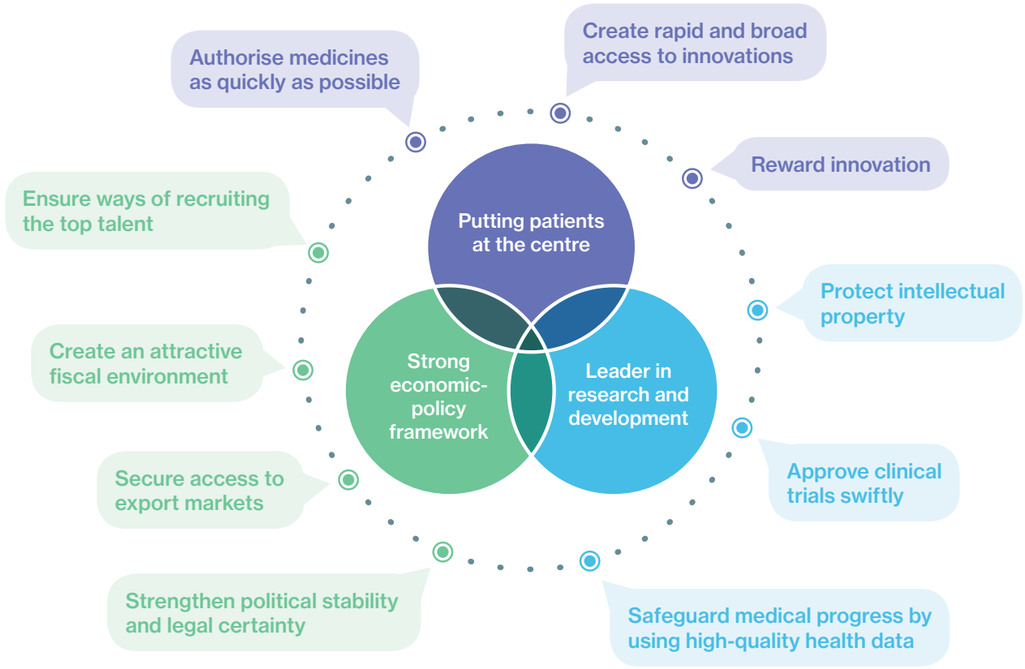
Leader in research and development (R&D)

Research and development are essential for a country like Switzerland, which has few natural resources. An effective and modern system of protecting intellectual property is essential if Switzerland is to remain a thriving centre of research activity, while global access to high-quality health data represents a new and additional success factor in our increasingly digitalised world.

Strong economic-policy framework

The pharmaceutical industry needs favourable operating parameters, while Switzerland needs successful companies. Political stability, legal certainty, open export markets, the availability of a skilled workforce and an attractive fiscal environment all play an important role in this symbiotic relationship.

The 10 key areas that will ensure a strong pharmaceutical industry in 2030



The pharmaceutical industry's direct and indirect contributions

The core task of research-based pharmaceutical companies is to combat disease by developing innovative medicinal products and to make these medicines available to patients as quickly as possible. The industry does so by delivering maximum standards of quality and safety. In doing so, it makes a direct contribution to improving people's quality of life and extending their life expectancy. The people who work at pharmaceutical companies benefit directly from appealing jobs and development opportunities. The state receives substantial amounts in taxes and other levies.

In addition to these direct contributions, the industry also makes a large number of indirect contributions that benefit Switzerland's society and economy. New, more effective medicines reduce the number of working days lost to illness. They reduce the burden on employers, family members and social security schemes. Every franc of value that the pharmaceutical industry creates generates an additional 73 cents of value in other sectors of Swiss industry. Pharmaceutical companies and their employees also play an active role in social and cultural projects. The partnership is an important source of incentive for clinical and academic research. Finally, but by no means least, the industry plays an active role in the discussion surrounding the future development of Switzerland's healthcare system with the aim of ensuring that it will still be one of the world's best in 2030.

Putting patients at the centre

In 2030, all patients in Switzerland will have broad and rapid access to innovative medicines. This requires rapid approval by Swissmedic, reimbursement through patients' basic health insurance from the day of approval and sustainable models that reward innovation.

Approve medicines as quickly as possible

Switzerland will continue to need an autonomous regulatory authority. Lean and structured processes will enable Swissmedic to give all patients broad and rapid access to innovative medicines and treatments. To ensure that new medicines are authorised as a priority and by using fast-track procedures, Swissmedic will have to create a reputation for itself internationally as an autonomous agency with strong competencies in innovations. The pharmaceutical industry wants to raise Swissmedic's profile by having Interpharma members submit new medicines earlier. The aim is to submit as promptly as possible, ideally in the time window between submissions to the US and European authorities.

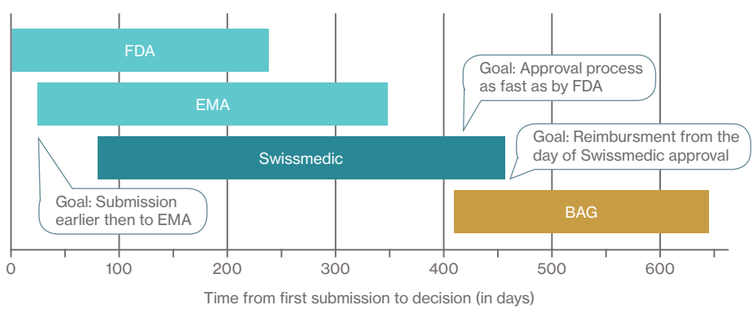
Various regulatory authorities currently offer fast-track approval procedures for innovative medicines. Under these procedures, it is generally possible to submit approval dossiers earlier than is the case with standard procedures. Furthermore, there is a more intensive, constructive dialogue between companies and the relevant authorities before and during the review process. By optimising both its fast-track procedure and the regulatory environment, Swissmedic will create an additional locational advantage for Switzerland. Additionally, close cooperation between all stakeholders creates trust – among manufacturers, the authorities and ultimately among patients, who, at the end of the day, are what everything revolves around. Using innovative medicines to treat diseases helps get the people affected back into their familiar daily routine faster.

Ambition for 2030

Swissmedic is one of the top two regulatory authorities for approval procedures for innovations.

Delays in the approval and reimbursement process

In Switzerland, the median time from first submission by a pharmaceutical company to availability to patients is almost 650 days. This is significantly longer than in many other European countries, and is attributable to three factors: pharmaceutical companies submit new medicines to Swissmedic 35 days later (median time) than to the European Medicines Agency (EMA). Swissmedic takes a median of 133 days longer to authorise medicines than the Food and Drug Administration (FDA). The FOPH needs a median of around 200 days for its final remuneration decision (instead of the 60 days specified in the Ordinance as the normal period).



Sources: Federal Office of Public Health FOPH (2014–2017), European Medicines Agency EMA (2014–2017), Food and Drug Administration FDA (2014–2017), Swissmedic (2014–2017), prepared by Interpharma (2019)

Assessment of overall cost-benefit ratio

Direct benefits to patients

- Greater life expectancy
- Faster recovery
- Chance of a cure
- Better quality of life

+

Benefits to society

- Shorter recovery time reduces costs
- Faster return to work
- Reduced nursing costs
- Impact on other social security schemes (ALV, IV)
- Successful research

Modern-day pricing and tariff-setting are based on a broad evaluation of costs and benefits that not only considers the direct benefits to patients, but endeavours to adopt a comprehensive perspective. Consequently, many innovative medicines have beneficial effects for social security schemes such as unemployment (ALV) or disability (IV) insurance, resulting in the long term in major savings and efficiency gains across the entire healthcare system. Faster reintegration into the working environment also benefits society.

Source: Interpharma

To guarantee faster access, approval must follow defined milestones and timetables. This is an area where the current system has potential for optimisation. The responsibility here lies with the government and authorities, who may be called on to adapt legal and regulatory requirements.

Create rapid and broad access to innovations

Under the current system, there is a delay between Swissmedic authorising a medicine and it becoming available to patients while the Federal Office of Public Health (FOPH) determines its reimbursement status under basic health insurance. Only then do patients actually have access to it. In the future, patients should have access to innovative medicines from "Day 0" – i.e. the day the product is authorised by Swissmedic. Guaranteeing that this is the case will require a faster and clearly defined access and reimbursement process. As an accompanying measure, Interpharma proposes carrying out an annual, transparent 360° review of trends in upcoming innovations with the authorities and stakeholder groups. This will identify upcoming innovations at an early stage and enable any work on modifying processes and regulations that may be necessary to start in good time.

Ambition for 2030

All patients in Switzerland have access to medicines from the day Swissmedic authorises them. Reimbursement by payers is guaranteed.

Giving patients in Switzerland access to innovations from "Day 0" will require improvements and a nationwide approach. Early-stage dialogue between the FOPH and manufacturers and having a new expert committee to advise the FOPH will help accelerate the process. Binding timelines and predictable processes will make the reimbursement process more efficient. At the same time, it must be possible to provide reimbursement through flexible pricing models.

Reward innovation

To keep innovations coming to the market, it is essential to ensure long-term funding for them. However, the current system is not designed for innovative treatments. The institutionalised innovation and reimbursement procedure therefore requires tools that evaluate the result using defined criteria and incorporate the overall patient benefits and all cost-related consequences into this process. The process must also be data-driven and involve the relevant stakeholder groups.

Prices and tariffs must be based on a cost-benefit assessment and employ suitable mechanisms from flexible reimbursement models (e.g. Pay for Performance) to safeguard efficacy, appropriateness and cost-effectiveness during the introductory phase. Coverage of off-label use and unlicensed treatments via Article 71 a–d of the Health Insurance Ordinance (HIO) will continue to be crucial for patients who rely on experimental treatments. The procedural improvements outlined by Interpharma should help reduce the number of cases covered by this article and so reinstate its original purpose.

Ambition for 2030

Switzerland is a global leader in the incentivised promotion of medical progress. This has been achieved by applying a value-based evaluation, pricing and tariff-setting system.

Optimising pricing and tariff-setting create incentives to improve efficiency in the healthcare system. This makes cost savings more reliably predictable and serves to ensure that innovations can be funded in the long term. If the quantitative cost-benefit assessment of a breakthrough innovation reveals significant uncertainty, pharmaceutical companies will be willing to share that uncertainty through flexible reimbursement models.

KEY AREAS	PHARMACEUTICAL INDUSTRY'S CONTRIBUTION	GOVERNMENT'S AND AUTHORITIES' CONTRIBUTIONS
Authorise medicines as quickly as possible **Benchmark:** USA (agility), Europe (submission timing)	– The industry is committed to a strong Swissmedic that is an international leader. – Interpharma members endeavour to submit new applications for approval as promptly as possible, ideally in the time window between submissions to the US and European authorities. – Interpharma and its members identify the advantages, disadvantages, opportunities and risks of the fast-track procedures used by Swissmedic, the FDA and EMA, and identify areas with potential for optimisation.	– Swissmedic approves innovative medicines using fast-track procedures and establishes an international reputation as an autonomous agency with strong competencies in innovations. – Swissmedic focuses on first approvals of innovative new active substances (NAS) and indication extensions (type II variations). – The potential for optimising approval processes is realised, where necessary by modifying legal and regulatory requirements.
Create rapid and broad access to innovations **Benchmark:** 0 days difference between marketing approval by Swissmedic and reimbursement by cost payers	– The industry participates in the discussion taking place in society on the economic and ethical implications of personalised healthcare. – Research-based industry carries out annual horizon scanning – a transparent 360° review of innovations in development – with the government, authorities and other stakeholder groups. – When research-based companies have an innovation that opens up new treatment options and is indispensable to patients, they commence dialogue with the FOPH at an early stage. – Research-based companies submit data on incremental innovations to the FOPH so that it can rapidly assess their benefits and cost implications.	– The Confederation institutionalises horizon scanning. – The Confederation implants the necessary new processes at approval and reimbursement levels on a needs-driven and immediate basis, thereby ensuring broad access to innovative treatment forms and models from "Day 0". – The FOPH ensures that reimbursement is efficient and based on a comprehensive, independent medical and economic assessment.
Reward innovation **Benchmark:** Switzerland is one of the first countries where technology leaders launch innovations that improve effectiveness and efficiency in the healthcare systems.	– Interpharma members develop innovations in dialogue with the leading regulatory authorities, health technology assessment (HTA) agencies and patient representative organisations. – Interpharma members work with the relevant stakeholder groups to record and analyse data with which to measure the real-world efficacy of treatments (real-world evidence). – If the quantitative cost-benefit assessment of a breakthrough innovation reveals significant uncertainty, pharmaceutical companies are willing to share that uncertainty through flexible reimbursement models.	– Institutionalised horizon scanning assesses the potential of breakthrough innovations to bring about a paradigm shift. If necessary, action is taken to develop suitable financing solutions. – The benefit assessment elements are evaluated against recognised criteria for the purposes of early-stage institutionalised dialogue and the process of inclusion in positive lists (e.g. list of pharmaceutical specialities). – Pricing and tariff-setting are based on a cost-benefit assessment. Suitable instruments are used to ensure that efficacy, appropriateness and cost-effectiveness criteria are met during the introductory phase. Pricing and tariff-setting create incentives to improve efficiency in the healthcare system.

Leader in research and development

Digitalisation and technological progress are facilitating new approaches in research. These create major potential for medical progress and patient benefits. Achieving all this will require a concerted effort by all stakeholder groups.

Protecting intellectual property

Pharmacological and technological innovations will lead to fast-paced improvements in medicines, while digitalisation will fundamentally change the way medicines are developed and used. As yet, there is inadequate protection for the data, algorithms and results of data analysis that give rise to innovative treatments. The legal framework for intellectual property (IP) will therefore have to be enhanced so that it provides adequate protection for innovations. Close industry cooperation with Swiss authorities and other partners in establishing a globally leading data protection and IP environment will therefore be key for the future of the pharma hub Switzerland.

Generating clinical data as part of the process of obtaining approval for new medicines is both time-consuming and costly. Companies that create this data are entitled to compensation for generating it in the form of document protection that meets both current and future needs. Document protection is crucial in cases where it is not possible to patent a treatment.

Real-world data (RWD) is becoming increasingly significant for pharmacological innovations alongside conventional clinical data. However, this is only possible with high-quality data that is obtained and carefully evaluated under defined conditions. Here again, a framework must be created that guarantees fair compensation for the substantial cost and work involved in generating and curating such data and the innovations that result from the data.

Ambition for 2030

Switzerland remains a world leader in protecting intellectual property

Data that will further the development of the healthcare system should be broadly accessible. However, care must be taken to ensure compliance with data protection regulations. The work and expense that go into generating, curating and providing the data must be acknowledged. An awareness of the different types of RWD needs to be created. On the one hand, there is RWD that is obtained almost incidentally under uncontrolled conditions, while on the other hand there is RWD that has to satisfy extremely high quality requirements. RWD that is collected specifically for clinical approvals should be subject to a level of protection comparable to that given to clinical data.

Individualised treatments such as gene or cell therapy can only achieve a weaker level of patent protection than conventional medicines. Effective product protection is not available. This is also why it is generally not possible to extend the patents on individualised treatments. Options for strengthening the proprietary rights system for individualised treatment need to be analysed and driven forward.

Approve clinical trials swiftly

Switzerland has a long tradition of clinical research and boasts outstanding university hospitals. However, the country does not provide an ideal framework for clinical research – as is reflected in the declining number of clinical trials.

Although the Human Research Act (HRA), which entered into force in early 2014, laid the foundations for more efficient approval of clinical trials by ethics committees, implementation has thrown up a number of challenges.

The inherently autonomous, lean and rapid approval process must be retained. However, there is also potential for optimisation. Processes have to become faster, simpler and more compliant with requirements, for example by adhering to the time limits prescribed by law. Efforts should also be made to create a nationwide portal for submitting trial applications. Furthermore, a fast-track procedure is needed for trials involving innovative medicines and treatments.

Ambition for 2030

Swiss ethics committees are among the fastest in Europe and adopt a patient-centred approach to reviewing the relevant content.

This will not mean centralising ethics committees. However, decisions on multicentre trials need to be harmonised more effectively. The industry will pursue these goals in close dialogue with the Federal Office of Public Health, Swissethics, the ethics committees, Swissmedic and clinical researchers' networks. It will do so with the aim of stopping the decline in the number of clinical trials conducted in Switzerland and returning it to an upwards trajectory for the benefit of patients and the research location.

Safeguard medical progress using high-quality health data

Interpharma members currently invest around 6.5 billion francs a year in research and development in Switzerland. Given the growing importance of big data and digitalisation for research and development, coupled with the leadership of the USA and China in this area, two questions arise: where will this money be invested in the future and which external factors have a determining influence on these decisions?

In the future, research and development will be carried out in countries that offer guaranteed protection of intellectual property and maximum access to talents, high-quality health data and partners.

In terms of Switzerland as a location, it is important to create a globally leading, integrated health data ecosystem comprising Swiss data and access to foreign data. This will require a partnership between the industry, authorities and further relevant partners. One example of this is the Swiss Personalized Health Network, an initiative by universities and university hospitals.

Ambition for 2030

Switzerland has a world-leading data ecosystem and can use global health data to conduct R&D from a Swiss base.

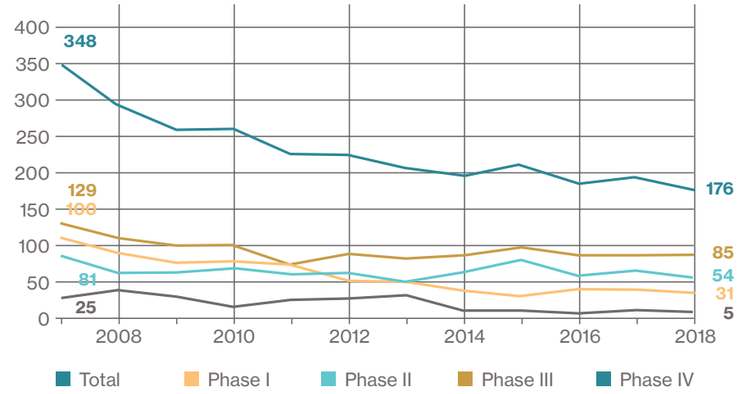
An ecosystem of this type would create a basis not only for successful research and development, but also for a benefits-based pricing system for medical innovations. Moreover, the development and broad adoption of personalised healthcare for Swiss patients will be facilitated and promoted. At a global level, health data transfer from around the world to Switzerland and vice versa must be guaranteed by ensuring equivalent data protection. Appropriate attention must also be paid to cyber security. Furthermore, work on setting up a globally leading institute to research health data (particularly big data) in partnership with Swiss universities must be driven forward.

However, data in itself is not enough. New developments in artificial intelligence (AI) could help Switzerland achieve a key locational advantage as well as differentiating it from other countries. In particular, applying modern algorithms in everyday work and research in a symbiotic relationship between humans and machines represents a source of potential that has as yet barely been exploited. Projects that involve the various stakeholder groups could lay the foundations of a successful future.

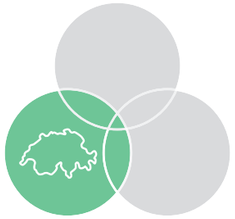
Number of clinical trials in Switzerland

The number of clinical trials being carried out in Switzerland has been in decline for years. This trend can be reversed by complying with legal time limits and introducing a fast-track procedure for trials involving innovative treatments.

Swissmedic (2019), Interpharma



KEY AREAS	PHARMACEUTICAL INDUSTRY'S CONTRIBUTION	GOVERNMENT'S AND AUTHORITIES' CONTRIBUTIONS
Protect intellectual property **Benchmark:** Switzerland is a world leader.	– The industry creates awareness of the importance of good-quality real-world data for use in the clinical environment and of the benefits of digital innovations. – The industry works actively with Swiss authorities and partners to create a world-leading data protection and IP environment for pharmaceutical R&D. – The industry creates an awareness of the benefits of new indications and the reasoning behind indication-specific reimbursement.	– Digital innovation in healthcare is rewarded, particularly if it significantly improves treatment. – New applications of medicines are granted additional protection and indication-related reimbursement is introduced. – A world-leading data protection and IP environment is created for R&D. – National patent exhaustion of medicines ensures security of supply.
Approve clinical trials swiftly **Benchmark:** Belgium	– Interpharma actively promotes the industry's needs during the evaluation of the Human Research Act. – The industry maintains a close dialogue with the FOPH, Swissethics, ethics committees, Swissmedic and clinical researchers' networks. – Partnership with the authorities is intensified to support optimisation of processes at Swissmedic and in ethics committees.	– The authorities retain their own, autonomous, lean and fast approval process. – Processes become faster and simpler overall. A new, fast-track procedure for trials of innovative medicines is created. – Ethics committees are not centralised. Ethics committee decisions on multicentre trials are harmonised.
Safeguard medical progress using high-quality health data **Benchmark:** USA, UK, China	– The industry works closely with authorities and partners to create an integrated health data ecosystem. – The industry partners with Swiss universities to set up a globally leading institute to research health data (particularly big data). – The possibility of setting up a big healthcare data venture capital fund with industry partners is examined for the purpose of strengthening Switzerland's healthcare/life science artificial intelligence cluster. – Cross-industry partnerships are set up. Project portfolio for students and/or post-docs on the application of AI R&D in healthcare and support for national initiatives in AI.	– The creation of a world-leading health data ecosystem comprising Swiss data and access to foreign data is promoted. This creates the basis for world-leading R&D in Switzerland and a benefits-based pricing system for medical innovations. – The in-depth development and broad application of personalised healthcare for Swiss patients is facilitated and promoted. – Health data transfer from around the world to Switzerland and vice versa is promoted by ensuring equivalent data protection (priority: EU, USA, UK) and by strengthening cyber security. – A national dialogue on AI with all stakeholder groups is promoted with the goal of creating a leading healthcare/life science artificial intelligence cluster in Switzerland.



Strong economic-policy framework

Investment in research and development needs planning and legal certainty. In addition to access to foreign markets and labour markets, an appealing tax framework is of crucial importance to Switzerland as a location.

Strengthen political stability and legal certainty

Political stability and legal certainty are traditional Swiss strengths. Over the last few years, however, there has been a process of erosion that is now being reflected in the relevant international indexes. In particular, the growing tensions in Switzerland's relationship with the EU are leading to legal uncertainty. Switzerland needs to cement its bilateral relationship with the EU in the long term.

Ambition for 2030

Switzerland recovers its leadership in political stability and legal certainty and succeeds in breaking the downwards trend.

The legal uncertainty is partly home-made and as such represents a threat to Switzerland's locational quality that comes from inside the country. As healthcare costs continue to rise, there are likely to be increasing calls to restrict entrepreneurial freedom. This makes it all the more important for the industry to set new standards for environmental and social responsibility and corporate management in the future. In addition to complying with the relevant national and international standards, the industry intends to make environmental and social considerations a greater part of corporate decision-making processes. This includes actively contributing to the Sustainable Development Goals (SDGs) in partnership with other stakeholder groups, particularly with regard to the targets for health, diversity and inclusion and climate protection.

This will involve conducting a transparent dialogue with society and the government on the pharmaceutical industry's importance to Switzerland and the operating framework that the industry will need in the future. Doing so requires an institutionalised advisory board on the future of the pharmaceutical industry. This should comprise high-ranking representatives of the scientific community, private sector and the authorities. It should advise the Federal Council on how to anticipate future developments in a sector that is important to the country.

Secure access to export markets

An export-driven country like Switzerland is reliant on working trade relations. Each year, the pharmaceutical industry exports goods worth approximately 90 billion Swiss francs. Around half of these go to the European Union. Orderly and stable trade relations with the EU are therefore essential to the pharmaceutical industry.

Switzerland has to sign free trade agreements with additional countries. This will necessitate a country-specific procedure that is dependent on each country's level of development. By this means, countries with less purchasing power will obtain access to innovative medicines. The pharmaceutical industry will actively address the issue of free trade agreements and will send a list of priorities to the relevant authorities every two years. When new agreements are signed, there must always be a full guarantee of compliance with minimum standards, including effective protection of intellectual property. In addition to multilateral agreements – the most effective means of securing market access – industry-specific mutual recognition agreements (MRA) will be needed.

Political stability in Switzerland

2017	Rank 12
2016	Rank 9
2015	Rank 6
2014	Rank 3
2013	Rank 3
2012	Rank 1

In 2012, Switzerland was regarded as the most politically stable country in the world. Today it is not even among the leaders. This fall in stability is also reducing legal and planning certainty, which, given its long-term investment horizons, is in turn reducing the pharmaceutical industry's willingness to set up new operations or invest.

Source: The World Bank (2012–2017)

Swiss pharmaceutical exports in 2018 by destination

The EU is the Swiss pharmaceutical industry's biggest trading partner, accounting for roughly half of total exports. This underscores the crucial importance of reliable bilateral relations and the associated legal certainty.

Source: Federal Customs Administration FCA (2019)

Ambition for 2030

Switzerland has stable and orderly access to the EU's single market and barrier-free access to the world's most important export markets while retaining strong protection for intellectual property.

Ensure ways of recruiting the top talent

The pharmaceutical industry employs a greater than average number of highly skilled employees. However, innovation is not determined solely by the scientific expertise of individual top-flight researchers. The skill level of the entire workforce also plays a key determining role. Switzerland is well placed against other countries in terms of quality of education, not least because of its dual education system. Nevertheless, there is still potential for improvement, given that technological change is creating uncertainty about what occupational profiles will look like in the future and raising associated challenges.

Digitalisation is transforming skills requirements. Mandatory schooling needs to focus more on developing pupils' digital technology and interpersonal social skills. Although Switzerland's dual education system is a major asset, the rapid pace of digital change is confronting it with fresh challenges. The flexibility of, and level of modularisation in, vocational training need to be increased. Furthermore, given the long lead times for new vocational training courses, early-stage, rolling planning needs to be introduced.

Switzerland's universities and universities of applied science are also in a strong position and frequently achieve top places in international rankings. International networks and connections are key to high-quality university-level research and teaching. It is therefore important to ensure that Swiss universities remain embedded in the European research landscape through initiatives such as Horizon Europe. At the same time, specialisation needs to be accelerated so that universities can compete successfully at international level.

Ambition for 2030

Switzerland retains its leadership in educational quality and has unbureaucratic access to foreign experts, subject specialists and executives. Furthermore, stable and unimpeded access to the EU employment market ensures the availability of cross-border commuters.

While the flexible labour market is one of Switzerland's strengths, access to top-quality foreign subject specialists is not. Safeguarding the free movement of people will therefore be one of the great challenges of the years ahead. In addition, there must be sufficiently large third-country quotas and distribution ratios will have to be revised. Strong, needs-driven distribution based on simplified processes is needed. This is the only way that the industry can remain competitive in the market for skilled labour, particularly when it comes to new professions such as data scientists.

Create an attractive fiscal environment

At present, Switzerland still has a competitive fiscal environment. This is now accepted internationally following the adoption of the Federal Act on Tax Reform and AHV Financing (TRAF) in a referendum. This has given companies planning and legal certainty on tax issues at least for the short term.

However, it does not alleviate the danger of international tax competition. Ireland, the USA and emerging locations such as Singapore already offer a more enticing tax environment than Switzerland. Various measures will have to be taken to make up ground on these countries. One example would be to eliminate the issuance stamp tax on equity, a step that would particularly benefit start-up companies.

Ambition for 2030

Switzerland offers an attractive, internationally accepted tax environment.

OECD demands for harmonised taxes or a digital tax are jeopardising one of Switzerland's key locational factors. This is an area where it is as much incumbent on industry associations as on government to exert influence on decision makers at international level to ensure the continued existence of a liberal tax system.

KEY AREAS	PHARMACEUTICAL INDUSTRY'S CONTRIBUTION	GOVERNMENT'S AND AUTHORITIES' CONTRIBUTIONS
Strengthen political stability and legal certainty **Benchmark:** Switzerland is a world leader.	– Interpharma and its members maintain an active, transparent dialogue with all stakeholder groups on the necessary social and political framework. – The industry supports Switzerland's militia political system. – The industry actively contributes to the implementation of the Sustainable Development Goals (SDGs), particularly Goal 3 "Good Health and Well-Being", Goal 5 "Gender Equality" and Goal 13 "Climate Action".	– Bilateral relations with the EU are consolidated, delivering the associated legal certainty. – It continues to get easier to start up a company and administrative procedures are streamlined. The transparency of support for financial lending and the framework conditions for start-ups and venture capital are improved. – An advisory board of high-ranking representatives of the scientific community, private sector and the authorities is set up and institutionalised so it can advise the Federal Council on issues relating to the future of the pharmaceutical industry in Switzerland.

KEY AREAS	PHARMACEUTICAL INDUSTRY'S CONTRIBUTION	GOVERNMENT'S AND AUTHORITIES' CONTRIBUTIONS
Secure access to export markets **Benchmark:** Switzerland, with a geographical and textual wish list	– The authorities receive support in negotiating country-specific free trade agreements (FTAs), for example by clear industry positioning and the provision of the necessary data basis. – The industry submits an updated FTA priority list to the authorities every two years. – The industry offers support for negotiations on mutual recognition agreements (MRA) with the relevant trading partners.	– Orderly trade relations with the EU are ensured. – The authorities work towards a multilateral trade regime, prevent new trade restrictions and focus on rapidly completing the 5th review of the WTO's Pharmaceutical Tariff Elimination Agreement and simplifying the review process. – The FTA network is expanded and intensified in a way that focuses on key growth markets while retaining TRIPS protection levels (in accordance with the priority list). – International cooperation on technical issues is strengthened (MoU). Swissmedic plays a key role in the International Conference on Harmonisation (ICH).
Ensure ways of recruiting the top talent **Benchmark:** Finland	– The industry intensifies investments in professional development, employee retraining (as needed) and attractive vocational training opportunities. – The industry takes an active role in adapting apprenticeships to changing needs, and in so doing commits to post-apprenticeship employment opportunities. – The industry intensifies cooperation with universities on providing needs-appropriate, forward-looking education. – The industry consistently gives preference to domestic candidates with suitable qualifications.	– Digital technology and interpersonal social skills are strengthened during school education. – The flexibility of, and level of modularisation in, vocational training is increased and there is greater rolling planning of requirements. – The quality of Swiss universities is secured and they remain embedded in the European research landscape. The international reputation of universities of applied science and universities' level of specialisation in key areas are strengthened, for example in the form of an international centre of excellence in health data. – Free movement of people and appropriate quotas for the Swiss economy are ensured. Distribution ratios are shifted towards needs-driven distribution with simplified processes. Legal parameters are reviewed with regard to flexible working models and modified accordingly.
Create an attractive fiscal environment **Benchmark:** Ireland, USA	– The industry's demands relate solely to competitive and accepted taxes. – Swiss companies and industry associations lobby the relevant bodies – including international bodies – for liberal tax regimes and against harmonised taxes.	– Start-ups are promoted by eliminating issuance stamp tax on equity. – Income tax can be offset against tax on capital. – The option of offsetting losses is available for an unlimited period. – Withholding tax on Swiss bonds is eliminated in order to strengthen the Swiss capital market. – Income from earnings is directly exempted.

About Interpharma

Interpharma, the association of Switzerland's research-based pharmaceutical industry, was founded in 1933. Its 23 member companies together account for 90 percent of market share in patented medicines in Switzerland and invest 6.5 billion francs annually in research and development in the country. Interpharma is a driving force of an efficient, high-quality healthcare system that gives patients rapid access to innovative treatments and the best possible care. Both in Switzerland and abroad we are committed to ensuring that patients receive first-class healthcare, that innovations are rewarded and that our industry is able to make a key contribution to Switzerland's prosperity, growth and competitiveness.

Interpharma member companies (as at November 2019)

NOVARTIS · Roche · Johnson & Johnson

abbvie · Allergan · AMGEN · AstraZeneca

BAYER · Biogen · Boehringer Ingelheim · Bristol-Myers Squibb

Celgene · GILEAD · GlaxoSmithKline · Lilly

Lundbeck · MERCK · MSD INVENTING FOR LIFE · Pfizer

SANOFI · Takeda · UCB CNS · VIFOR PHARMA

List of sources

Page 6 **Employment and nominal value creation in the pharmaceutical industry, 2018**

Source BAK Economics (2019): The importance of the pharmaceuticals industry to the Swiss economy

Page 7 **Switzerland's locational competitiveness**

Source World Economic Forum (2019): The Global Competitiveness Report

Page 10 **Delays in the approval and reimbursement process**

Sources
- Federal Office of Public Health FOPH (2014–2017): Bulletins
- Federal Office of Public Health FOPH (2014–2017): List of pharmaceutical specialities web page
- European Medicines Agency EMA (2014–2017): Medicines under evaluation
- European Medicines Agency EMA (2014–2017): Annual reports and work programmes
- European Commission (2014–2017): Union Register of medicinal products
- Food and Drug Administration FDA (2014–2017): Novel Drug Approvals web page
- Food and Drug Administration FDA (2014–2017): Drugs@FDA web page
- Food and Drug Administration FDA (2014–2017): Annual Performance Report to Congress for the Prescription Drug User Fee Act
- Swissmedic (2014–2017): Swissmedic Journal
- Swissmedic (2014–2017): Extended list of authorised human medicinal products
- Swissmedic (2014–2017): Annual Reports
- Data preparation: Interpharma (2019)

Page 11 **Assessment of overall cost-benefit ratio**

Source Own research

Page 15 **Number of clinical trials in Switzerland**

Source
- Swissmedic (2007–2018): Annual Reports
- Data preparation: Interpharma (2019)

Page 18 **Political stability in Switzerland**

Source The World Bank (2012–2017): Worldwide Governance Indicators

Page 19 **Swiss pharmaceutical exports by destination**

Source Federal Customs Administration FCA (2019): Foreign trade statistics

We would like to thank the many people who have contributed to the development of the strategy paper "Pharma Hub 2030".

interpharma

Petersgraben 35, P.O. Box
CH-4009 Basel
Phone +41 (0)61 264 34 00
info@interpharma.ch

interpharma_ch
interpharma
www.interpharma.ch