

interpharmaph

The research-based pharmaceutical companies in Switzerland.

Pharma hub Switzerland 2030

Revised version 2022

Foreword	3
Switzerland needs to take action	
for the benefit of patients	
Vision for Switzerland as a pharma hub in 2030	4
Current situation	6
A strong industry in a challenging environment	
The pharmaceutical industry at a glance	8
Strategy and activities The best for patients, research and the economy	9
- Putting patients at the centre	10
 Leading in research and development 	14
 Strong economic-policy framework 	18
About Interpharma	22
List of sources	24

FOREWORD

Switzerland needs to take action for the benefit of patients



Jörg-Michael Rupp President of Interpharma



Dr René Buholzer CEO and Delegate of the Board

Dear reader,

Developing a new medicine is a test of endurance for researchers. Bringing just one medicine to market involves investigating 10,000 substances. Of these, only around ten undergo further clinical analysis until one molecule is ready for development into an effective medicine. Getting this far takes an average of twelve years of research and development. Although wearisome, this route is accepted because the ultimate goal of all research work is to improve human health. That's why the members of Interpharma, the association of Switzerland's research-based pharmaceutical companies want people to know: We keep researching.

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 improving its prosperity and quality of life for decades. The COVID pandemic in particular highlighted the strengths and significance of Switzerland as a pharma research and production hub.

However, the challenges – which include digitalisation, increasing restrictions on entrepreneurship, demands for sustainable funding for the healthcare system, the pandemic and its aftermath and a changed (geopolitical) 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. This is leading to new

companies entering the health market. At the same time, numerous countries are vying with each other to become the major centres of the global digitalised economy and the research-based pharmaceutical industry.

"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 remain Europe's leading pharma hub going forward. To achieve these goals, we must step up our efforts even further. 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 contributions we intend to make to actively and constructively 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 can enjoy sustainable access to innovative medicines. By doing so, we intend to contribute to the urgently needed discussion on the future of the pharma hub, so that Switzerland can continue to claim "We keep researching". We would invite you to join the discussion with us and all other stakeholders.

J. Rupp Per Balofa

We look forward to it.

Jörg-Michael Rupp President of Interpharma

Dr René Buholzer CEO and Delegate of the Board

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 investment 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

Putting at the

Strong economicpolicy framework

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

patients centre 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:



Leader in research and development

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

A digital health data ecosystem enhances 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.

Benefits for people and beyond

Everything the research-based pharmaceutical industry does revolves around people and their health. The overriding goal is to eradicate or at least alleviate disease. The core task of research-based pharmaceutical companies is therefore to develop innovative medicinal products and to make these medicines available to patients as quickly as possible. In doing so, these companies make a direct contribution to improving quality of life and extending life expectancy.

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 the quality of life of society. Diseases that used to be fatal or were associated with severe lifelong limitations - such as cancer or heart and lung diseases - can now be treated effectively and efficiently. Thanks to research by the pharmaceutical industry, it is now also possible to effectively treat a large number of rare diseases, enabling the people who have them to lead almost normal lives.

An industry with an impact on society

However, the effects of medical progress extend beyond patient benefits. The industry makes a large number of indirect contributions that benefit Switzerland's society and economy. Patients' family members and friends have fewer care obligations, while new, more effective medicines reduce the number of working days lost to illness. More efficient treatments mean that patients are able to resume work sooner. This reduces the burden on employers, family members and social security schemes and reduces their costs.

In addition, the Swiss pharmaceutical industry has deep roots in the country, and is an important pillar and driving force on both regional and national level. Pharmaceutical companies are not just important employers and contributors to regional value creation. Over the past ten years, they have been responsible for one third of Switzerland's economic growth, for example, and for nearly half the country's exports. In addition, many companies are actively involved in society, for example in the arts or sport, or at recreational events. The healthy balance between

men and women in the workforce is also evidence of the industry's pioneering role, particularly as regards the compatibility of family and career. One of the more important results of this is the above-average number of women in management positions.

The industry is committed to sustainable development, particularly global promotion of health and wellbeing and comprehensive measures to slow down climate change and reduce its impact. The pharmaceutical industry is in no doubt that a healthy climate is essential for human health.

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 sustainable development of Switzerland's healthcare system with the aim of ensuring that it will still be one of the world's best in 2030. The COVID pandemic in particular has shown the value of a strong healthcare system that is geared to people's needs.

Major economic significance

Switzerland and the pharmaceutical industry have been successfully following a common path for decades. An attractive economic-policy framework has facilitated the research-based pharmaceutical industry's impressive growth. People who work at pharmaceutical companies benefit directly from appealing jobs and development opportunities. 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. It is one of Switzerland's most significant private-industry sectors. The state receives substantial amounts in taxes and other levies.

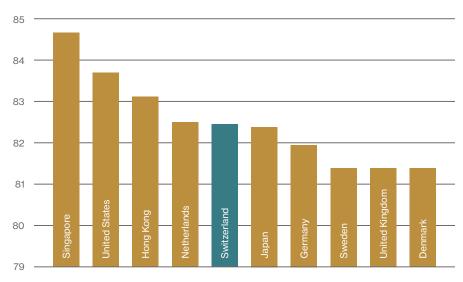
Today our country ranks alongside the USA as one of the most important centres of pharmaceutical research worldwide, with a reputation that reaches far beyond Europe. In 2020, the research-based pharmaceutical companies invested more than 7 billion Swiss francs in research and development (R&D) in Switzerland.

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, erosion of the bilateral agreements with the EU, regulatory barriers to research and growing bureaucratic and regulatory costs are jeopardising Switzerland's leading positions in innovation, productivity and exports. As a result of technological progress and advancing digitalisation, an increasing number of companies from outside the industry are entering the healthcare market.

Competition in the international location market, which has gained additional momentum from the COVID pandemic, is intensifying. Countries such as the UK and Denmark have recognised the value of the research-based pharmaceutical industry and developed their own pharma strategies to increase their appeal to this important sector. The pandemic has also highlighted the importance of the industry for a country such as Switzerland. Despite the exceptional and challenging circumstances, the Swiss public was still able to access patent-protected medicines. The pharmaceutical industry once again proved to be an economic powerhouse, posting

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)

strong export figures and demonstrating its crisis resilience in impressive fashion.

The impact of demographic change on the healthcare system is also 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, the recurring annual savings from which amount to over a billion francs. Though challenging, the discussion that is taking place in society on the economic and ethical effects of medical progress is and remains important. At the same time, the healthcare system has to adapt to the new requirements.

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. 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.

The pharmaceutical industry at a glance



Life expectancy **up 25%** in the last 50 years



Over CHF 7.5 bn in R&D in Switzerland per year



CHF 109 bn in global exports per year



1/3 share of added value growthin the last decade



181 medicines for rare diseases

Employment (2020)



47,000 Direct employment



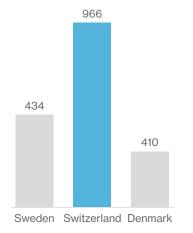
209,200 Indirect employment



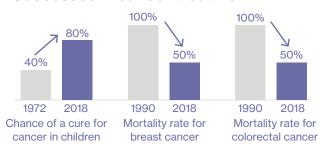
256,200 Total

Patents submitted

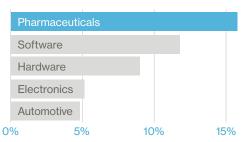
Patent applications per million inhabitants, 2020



Successes in cancer treatment



Average research and development intensity (R&D/turnover, 2019)



Value creation (2020)



CHF 36.8 bn
Direct value creation





CHF 26.4 bn Indirect value creation

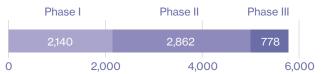




CHF

CHF 61.4 bn

APIs in development (2020)



Percentage of women/men (2020)

44%

Tertiary education/ researchers (2020)



28,500



9,800

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 over-riding 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 economicpolicy 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.



Putting the focus on patients

In 2030, all patients in Switzerland will have broad and fast access to innovative medicines. This requires rapid approval by Swissmedic, the Swiss therapeutic products regulatory agency, 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 fast access to innovative medicines and treatments. To ensure that new innovative 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 for approval and reimbursement earlier. Ideally, the aim is to submit in a time window between submissions to the US and European authorities.

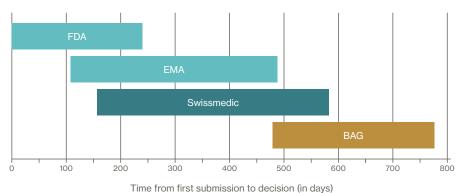
Ambition for 2030

Swissmedic is one of the world leading regulatory authorities for approval procedures for innovations.

Various regulatory authorities currently offer fast-track approval procedures for innovative medicines. During the review process, there is a more intensive, constructive dialogue between companies and the relevant authorities. In addition, Swissmedic works with other regulatory authorities to pool expertise and resources. By further optimising the fast-track procedures and regulatory environment, Swissmedic will help create a locational advantage for Switzerland. This will ultimately benefit patients because using

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 776 days. This is significantly longer than in many other European countries, and is attributable to three factors: pharmaceutical companies submit new medicines to Swissmedic 49 days later (median time) than to the European Medicines Agency (EMA). Swissmedic takes a median of 186 days longer to authorise medicines than the Food and Drug Administration (FDA). The FOPH needs a median of nearly 300 days for its final remuneration decision (instead of the 60 days specified in the Ordinance as the normal period).



Time from first submission to decision (in days)

Sources: Federal Office of Public Health FOPH (2017–2020), European Medicines Agency EMA (2017–2020), Food and Drug Administration FDA (2017–2020), Swissmedic (2017–2020), prepared by Interpharma (2022)

Assessment of overall cost-benefit ratio



Direct benefits to patients



- **Benefits** to society
- Greater life expectancy
- Faster recovery
- Chance of a cure
- Better quality of life
- 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

innovative medicines to treat diseases helps get the people affected back into their familiar daily routine faster.

To guarantee rapid approval, existing processes have to be regularly reviewed to identify potential for optimisation. If necessary, it must be possible to rapidly implement amended legal and regulatory requirements. This challenge affects the government and authorities too.

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, they 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 a continuous transparent 360° review of 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 people 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 augment expertise and 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 provisional prices and flexible pricing models.

Reward innovation

To keep innovations coming to the market, it is essential to ensure longterm 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.

Ambition for 2030

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

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.

Optimising pricing and tariff-setting creates 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.

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 leading Swissmedic as first wave agency.
- 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

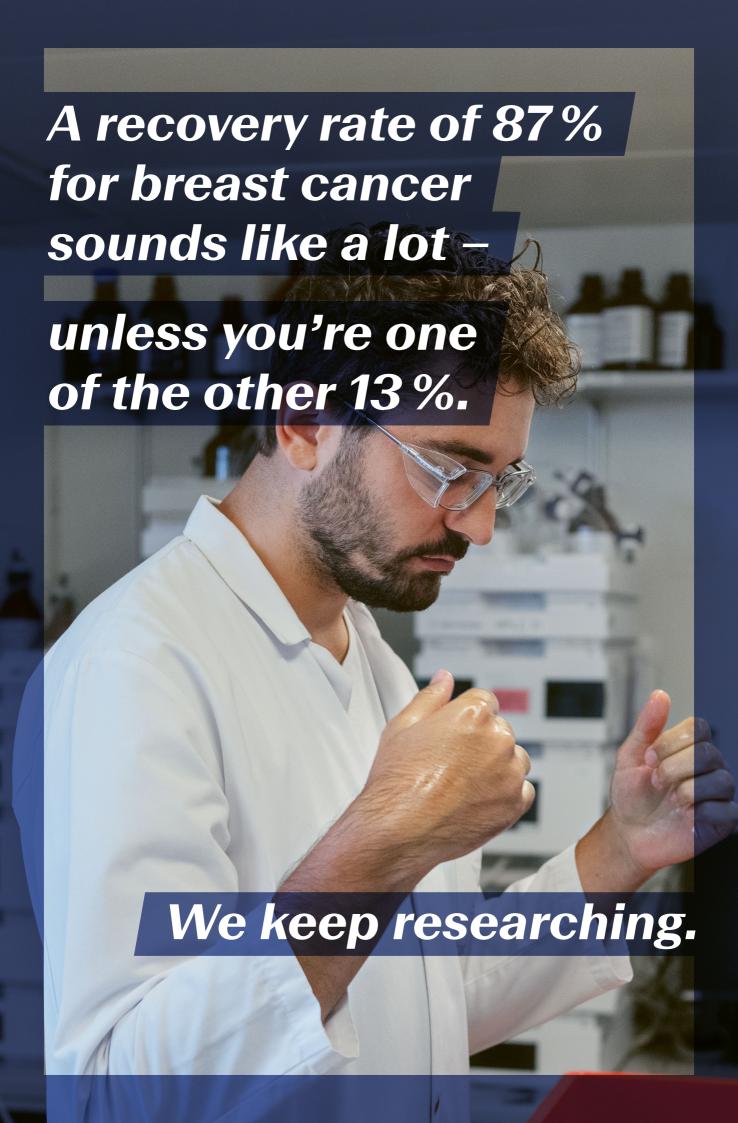
- The industry participates in the discussion taking place in society on the economic and ethical implications of personalised healthcare.
- Research-based industry carries out continuous horizon scanning – a transparent 360° review of innovations in development – with the government, authorities and 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.

- The Confederation institutionalises a broadly supported 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 provide innovations to Switzerland 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, RWE) and Patient Reported Outcome Measures (PROM)).
- 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 broadly supported 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

Rapid advances in digitalisation and persistent technological progress will facilitate new approaches in research to an even greater extent in the future. These create additional and major potential for medical progress and patient benefits. However, 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 patient benefits by delivering new treatments and 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 intellectual property (IP) framework 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 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

Ambition for 2030

Switzerland remains a world leader in protecting intellectual property

only possible with top-quality data that is obtained, recorded in standardised fashion and carefully evaluated under defined conditions. Here again, a framework must be created that guarantees fair financial compensation for the substantial cost and work involved in generating and curating such data and the innovations that result from the data.

Data that will further the development of the healthcare system should be broadly accessible. At the same time, care must be taken to ensure compliance with data protection regulations. 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.

Safeguard medical progress using high-quality health data

Interpharma members currently invest over 7 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 Asia 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 legal framework conditions and a partner-

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 (2007–2020), Interpharma



ship 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 people in Switzerland 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.

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.

Approve clinical trials swiftly and promote new research models

Switzerland has a long tradition of clinical research and boasts outstanding university hospitals. Clinical research gives patients rapid and sustainable access to innovative medicinal products and treatment methods and is essential for Switzerland as a research hub. However, the country does not provide an ideal framework for clinical research - as is reflected among other things in the declining number of clinical trials. 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. The current lean and fast approval process, which involves several local, autonomous ethics committees and the authorities working in a network, should be retained. However, there is potential for optimisation. Ethics committees in particular need to speed up and simplify their processes. Moreover, a fast-track approval procedure for clinical trials of products that meet urgent medical needs is required. Efforts should also be made to create a nationwide portal for the electronic submission of trial applications to the authorities.

It must be possible to rapidly implement future research models in Switzerland. Decentralised clinical trials are an ideal fit for Switzerland's decentralised delivery model. They put

patients centre-stage and give them easier access to research projects. Implementing new models will require an appropriate environment, particularly as regards digitalisation of the healthcare system and health data. This is an area where Switzerland lags significantly behind leading countries, and the gap is not shrinking. Action is therefore urgently required.

The industry will continue to pursue these goals in close dialogue with ethics committees, authorities and academic research 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.

Ambition for 2030

The approval process of clinical trials at the ethics committees and the authorities is one of the fastest and leanest in Europe. Switzerland is competitive in multinational, patient-centred clinical trials.

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 prevention and 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.

Safeguard medical progress using high-quality health data

Benchmark: USA, UK, Finland

- The industry works closely with authorities and partners to create an integrated health data ecosystem by providing an international network and expertise (e.g. from over 100 years of experience of sensitive data in clinical trials).
- Investments in cross-industry and multi-stakeholder partnerships (lighthouse projects) unleash the societal value of health data ecosystems.
- Advance digital skills of employees through education and vocational training.
- Increase awareness of the value of the health data ecosystem by participating in public and political dialogue.

- The creation of a world-leading health data ecosystem comprising Swiss data and access to foreign data is promoted. This requires the creation of a legal framework that transparently regulates the governance and the use of health data.
- 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 data protection (priority: EU, USA, UK) and by strengthening cyber security.
- A national dialogue on health data with all stakeholder groups is promoted with the goal of creating a leading digital health services and products cluster in Switzerland.
- Horizontally incorporate digital literacy in the educational system.

Approve clinical trials swiftly and promote new research models

Benchmark: EU

- Interpharma actively promotes the industry's needs during the evaluation of the Human Research Act.
- The industry maintains a close dialogue with ethics committees, authorities and clinical researchers' networks.
- Partnership with the authorities is intensified to support the optimisation of processes and the acceptance of new research models (such as decentralised clinical trials) at Swissmedic and in ethics committees.
- The Swiss authorities retain their own, autonomous, lean and fast authorisation process.
- Processes become faster and simpler overall.
 A new, fast-track procedure for trials of innovative medicines is created based on the successful pilot test with COVID-19 therapeutics.
- Ethics committees are not further centralised. Ethics committee decisions on multicentre trials are harmonised.





Strong economic-policy framework

Investment in research and development needs planning and legal certainty. In addition to access to procurement, sales 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, this stability has been subject to a process of erosion that is now being reflected in the relevant international indexes. Furthermore, 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 homemade and as such represents a threat to Switzerland's locational quality that comes from inside the country. In view of societal trends during the COVID crisis, the demographic challenges and the associated rising healthcare costs, 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 internation-

al 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. In view of the dynamic pace of developments, an institutionalised advisory board on the future of the life science hub could be helpful in advising the government and Federal Council. This would comprise high-ranking representatives of the scientific community, private sector and the authorities. In particular, it would advise the Federal Council in such a way that it is able to anticipate future developments in a sector that is important to the country.

Secure access to export and import markets

An internationally networked and export-driven country like Switzerland is reliant on working trade relations and open markets. Each year, the pharmaceutical industry exports goods worth approximately 90 billion Swiss francs.

Political stability in Switzerland

2020	Rank 10
2019	Rank 9
2018	Rank 11
2017	Rank 10
2016	Rank 9
2015	Rank 6
2014	Rank 3
2013	Rank 3
2012	Rank 1

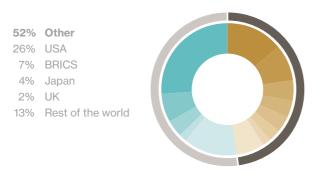
In 2012, Switzerland was regarded as the most politically stable country in the world. Today it is not even among the leaders. This fall in stability is also reducing legal and planning certainty, which, given its long-term investment horizons, is in turn reducing the pharmaceutical industry's willingness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

Source: The World Bank (2012-2020)

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

Swiss pharmaceutical exports in 2021 by destination



14% Germany
9% Spain
5% Slovenia
4% Italy
4% France
3% Austria
2% Netherlands
7% Rest of EU

48% EU

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 (2022)

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 on a regular basis. 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. Discrimination-free access to foreign markets for goods, services and labour is also essential for resilient supply chains and thus for security of supply in Switzerland. To ensure that these continue to be available in crisis situations, access must be safeguarded by additional treaties where appropriate.

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 and import markets while retaining strong protection for intellectual property.

Ensure access to top talents

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 fresh challenges about what occupational profiles will look like in the future.

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 international research landscape, for example by participating in European research programmes. 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 quality of education 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 crossborder 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. Swiss education providers must continue to respond agilely to the emergence of new professions such as data scientists, for example.

Create an attractive investment environment

At present, Switzerland still has a competitive fiscal environment. However, it does not alleviate the danger of international tax competition. 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 investment environment.

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

GOVERNMENT'S AND AUTHORITIES' CONTRIBUTIONS

Secure access to export and import markets

Benchmark: Switzerland, with a priority list

- The authorities receive support in negotiating country-specific free trade agreements (FTAs) with strong IP elements, for example by clear industry positioning and the provision of the necessary data basis.
- The industry regularly submits an updated FTA and mutual recognition agreement (MRA) priority list to the authorities.
- The industry offers support for negotiations on MRA with the relevant trading partners.
- The industry continues to support the well-established system of legally regulated compulsory declaration and storage. Any additional changes must be meaningful and sustainably financed.

- Stable trade relations with the EU are ensured.
- The authorities work towards upholding a multilateral trade regime, prevent new trade restrictions and focus on adequate updates of pharma-specific trade regimes, including the implementation of the 5th review of the WTO's Pharmaceutical Tariff Elimination Agreement together with a simplification of the review process.
- International cooperation on technical issues is strengthened (MoU). Swissmedic plays a key role in the International Conference on Harmonisation (ICH).
- The FTA network will be broadened and deepened with a focus on important (growth) markets. The level of TRIPS protection (according to the priority list) will be maintained (TRIPS = Trade-Related Aspects of Intellectual Property Rights). Gaps in the MRA area must be closed (e.g., with the USA).
- Security of supply through open borders for goods and labour, where appropriate negotiate state contracts.

Ensure access to top talents

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 demand-oriented, forward-looking education.
- The industry is committed to giving preference to domestic candidates with suitable qualifications as appropriate.

- Digital technology and interpersonal social skills are strengthened during school education.
- The flexibility of, and level of modularisation in, vocational training is increased and greater rolling planning of requirements is provided.
- The quality of Swiss universities is secured and they remain embedded in the international research landscape. The international reputation of universities of applied science and universities' level of specialisation in key areas are strengthened.
- 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 regarding flexible working models and modified accordingly.

Create an attractive investment environment

Benchmark: World-leading pharma hubs

- 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.
- The industry supports the Federal Council's call for proper consideration of the interests of small, innovative countries in the OECD tax reform.
- 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.
- An internationally accepted domestic reform plan that safeguards the attractiveness of the business location is developed.

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 must be built on a stable and long-term foundation, delivering the associated legal certainty.
- It continues to get easier to start up a company and administrative procedures are streamlined by systematically exploiting the opportunities of digitalisation.
- 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.



About Interpharma

Interpharma, the association of Switzerland's research-based pharmaceutical companies, was founded in 1933. Its 24 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 April 2022)









































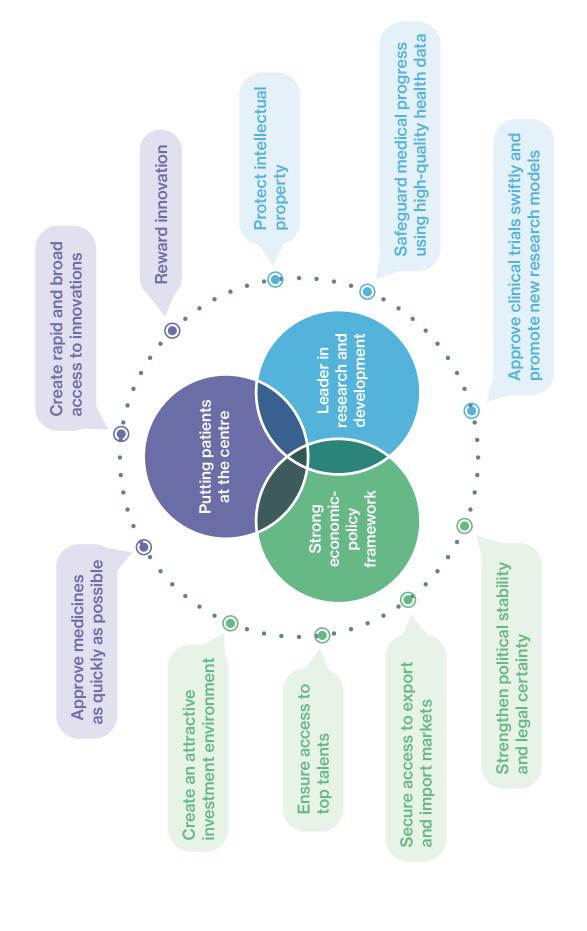








The 10 key areas that will ensure a strong pharmaceutical industry in 2030



List of sources

Switzerland's locational competitiveness

Source World Economic Forum (2019):

The Global Competitiveness Report

Page 8 The pharmaceutical industry at a glance

Sources BAK Economics (2021):

Page 7

Importance of the pharmaceuticals industry to

the Swiss economy

Federal Statistical Office (2022):

Employment statistics

Federal Statistical Office (2020):

Statistical Yearbook of Switzerland

Federal Statistical Office (2021):

Cause of death statistics

Federal Customs Administration (2022):

Foreign trade statistics

Ernst & Young (2020):

The Largest Pharmaceutical Companies

Worldwide. Analysis of Key Financial Indicators for Fiscal Years 2017, 2018 and 2019

European Patent Office (2021):

Patent Index 2020.

European Commission (2021):

The 2020 EU Industrial R&D Investment

Scoreboard

Interpharma (2021):

Member survey

Childhood Cancer Research Foundation

Switzerland (2021):

Chances of curing cancer in children

Swissmedic (2021):

Human medicinal products with orphan

drug status.

Page 10 Delays in the approval and

reimbursement process

Sources Federal Office of Public Health FOPH (2017–2020):

Bulletins

Federal Office of Public Health FOPH (2017–2020):

List of pharmaceutical specialities web page

European Commission (2017–2020): Union Register of medicinal products

European Medicines Agency EMA (2017–2020):

Annual reports and work programmes

European Medicines Agency EMA (2017–2020):

Medicines under evaluation

Food and Drug Administration FDA (2017–2020): Annual Performance Report to Congress for the

Prescription Drug User Fee Act

Food and Drug Administration FDA (2017-2020):

Drugs@FDA web page

Food and Drug Administration FDA (2017–2020):

Novel Drug Approvals web page

Swissmedic (2017-2020):

Extended list of authorised human

medicinal products

Swissmedic (2017-2020):

Annual Reports

Swissmedic (2017-2020):

Swissmedic Journal

Page 11 Assessment of overall cost-benefit ratio

Source Own research: Interpharma (2019)

Page 15 Number of clinical trials in Switzerland

Source Swissmedic (2007–2020):

Annual Reports

Page 18 Political stability in Switzerland

Source The World Bank (2012–2020):

Worldwide Governance Indicators

Page 19 Swiss pharmaceutical exports by

destination

Source Federal Customs Administration FCA (2022):

Foreign trade statistics

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



interpharmaph

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

interpharma_chinterpharmawww.interpharma.ch