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Life Sciences

Switzerland
Trends and Developments
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Trends and Developments

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Institutions in Crisis Mode

For the last year, governments, the economy and society as a whole have been confronted with tremendous challenges in tackling the COVID-19 pandemic. The life sciences sector and, in particular, the healthcare system, has had to adapt to new demands, changing priorities and an unprecedented amount and pace of regulations coming from the different levels of government in Switzerland, ie, the federal state, the cantons and even the municipalities. In a number of instances, it was not even clear whether the federal government had the power to adopt certain rules to combat the pandemic because the healthcare system is basically within the powers of the cantons.

In addition, the relationship between expert bodies staffed with scientists covering all relevant areas on one side and the competent governmental bodies, such as the Federal Office of Public Health (FOPH), the Federal Council, ie, the Swiss federal government, and the Conference of Cantonal Health Ministers (GDK), on the other side, was not always clear either. Finally, combating the pandemic has put the parliamentary system to a hard test as well. While, during the first wave, the federal parliament suddenly stopped its deliberations and left all decision-taking to the executive branch, parliamentary control has resurged during the second wave and the question about the right amount and type of measures the government should impose on individuals, businesses and society is now being debated vigorously across the entire political spectrum.

The Healthcare System in the Spotlight

Besides institutional difficulties, the pandemic has brought to light a number of substantive issues in the healthcare sector, most of which had already been known but which had been neglected in the past. While a specific Federal Statute on Epidemics had been enacted in 2012 and already put into force in 2016, when the pandemic hit the healthcare system it was almost unprepared. The systems to detect a threat and take proactive measures which the act provides for proved to be highly ineffective. Fundamental resources such as the necessary quantities of masks, but also reliable and statistical information regarding the spread of the virus, were missing.

Massive deficiencies of the entire healthcare system – from the general practitioners' practices up to the competent governmental bodies – were detected with regard to digitalisation. This led to a lack of data and a substantial time-lag when it came to tracing the spread of the virus and taking effective counter-measures. It may be noted in this respect that a Federal Statute on the Electronic Patient File had already been adopted in 2015, but that the project has not yet come to its implementation stage.

For the hospital sector, the pandemic has had somewhat contradictory effects. On the one side, hospitals very quickly and effectively increased their ability to treat patients with serious symptoms of COVID-19, so that none of those patients had to be left untreated. Rules regarding an ethically and legally acceptable prioritisation of patients in the case of a capacity shortage, which the Swiss Academy of Arts and Sciences (SAMW) had developed in 2020, did not, therefore, need to be put to the test. On the other side, hospitals were prohibited from carrying out elective surgeries and other non-urgent interventions on other patients. This has led to substantial losses, both for public and private hospitals. It still remains unclear whether there will be any compensation for such losses from the federal government.

Another important point of discussion throughout the pandemic has been the question of who should pay for tests and under what circumstances. While there has long been a rule that only persons with typical symptoms should be tested and reimbursed, the Federal Council has only recently suggested the introduction of periodic country-wide mass testing, irrespective of individual symptoms. However, only antigen tests are reimbursed unconditionally, not the so-called PCR tests, for which reimbursement still requires the presence of typical symptoms.

With regard to pharmaceuticals, the Swiss Agency for Therapeutic Products (Swissmedic) has put into effect specific fast-track procedures relating to the granting of marketing authorisations for medicines intended for the prevention or treatment of COVID-19-related diseases. For some known medicines, the mere submission of an authorisation request for the treatment of COVID-19-related diseases is sufficient for the placing on the market, ie, there is no need to wait for the marketing authorisation to be granted. For new medicines intended for the treatment of COVID-19-related diseases, Swissmedic may allow either a so-called "rolling submission" procedure (where the data required for the

authorisation does not need to be provided with the initial submission but will be collected and compiled continually by the applicant and made available to Swissmedic as soon as possible) or a "rolling questions" procedure (where Swissmedic asks its questions that must be answered by the applicant within the specified time-limit on an ongoing basis and not all at once as a separate milestone). While Swissmedic granted the marketing authorisations for the COVID-19 vaccines from Pfizer/BioNTech on 19 December 2020 (ie, two months after receiving the application) and from Moderna on 12 January 2021, respectively, it has not so far approved the vaccine from AstraZeneca.

Costs of Healthcare under Scrutiny

Apart from the various problems associated with the reaction to the COVID-19 pandemic, the one issue that is most prominent when it comes to healthcare law and policy (and politics) is its financing, ie, the question(s) of who should pay how much and for what. In a nutshell, the Swiss healthcare system is based on a mandatory health insurance provided by different private insurers which, in principle, covers all inpatient and outpatient treatments. While outpatient treatments are fully covered by the insurance after deduction of a contribution by the insured, the insurance only covers up to 45% of the inpatient treatment costs. A minimum of 55% of such costs must be borne by the canton in which the respective insured lives. The prices of treatment are determined based on tariffs, which are either agreed between the service-providers (hospitals, doctors' associations, etc) and the insurers, or which are ordered by the federal government. Insurance premiums differ from insurer to insurer, but must be identical for all insureds from a certain canton. Young adults and children pay reduced premiums, and the cantons pay contributions to persons for whom the premiums constitute a considerable financial burden.

Because of the ageing of society, advancements in medicine, and misaligned incentives, the costs of healthcare are constantly increasing, both per capita and globally. However, since its inception in 1995, the current financing scheme has in principle remained unchanged. In 2019 and 2020 respectively, the federal government presented two sets of measures which aim to reduce the increase of costs permanently. The second set of measures is also a counterproposal to a popular initiative which requires that costs of healthcare be linked to the development of the Swiss economy and the average level of salaries. Currently, both the initiative and the measures suggested by the government are under parliamentary discussion.

The measures suggested by the government include the introduction of flat fees for ambulatory treatments, the obligation of insureds to contact a primary point of advice before initiating any treatment, the creation of networks for co-ordinated treatment, electronic invoicing and a series of modifications regarding pricing and reimbursement of medicines. While these measures do not fundamentally change the current healthcare system, the proposal to define certain cost targets on a national and cantonal level, as well as coercive measures in case these targets are exceeded, could be characterised as a change of one of the system's fundamental principles.

So far, the mandatory health insurance was basically obliged to pay all costs of treatment as long as such treatment met the requirements of effectiveness, adequacy and economic efficiency. In a recent leading case, the Swiss Supreme Court clearly held that an insurer could not stop or limit its payments only because total treatment costs had exceeded a certain amount in an individual case (BGE 145 V 116). It is therefore more than doubtful whether the FOPH's current practice to limit the total turnover of a pharmaceutical company with a given medicine that may be charged to the mandatory health insurance (so-called "cost caps") is actually legal. Should cost targets and corrective measures be implemented as suggested by the government, this could lead to a wider use of cost caps with regard to all types of goods and services in the healthcare sector.

Pricing of Medicines Revisited

With regard to medicines in particular, the government's proposals include the introduction of uniform reference prices for generics, and the creation of an explicit basis for confidential paybacks from pharmaceutical companies to insurers (so-called "price models").

Price-models were initially created in order to allow for indication-specific pricing. In this scheme, the FOPH defines uniform ex-factory and public prices for all indications of a medicine, but also orders different amounts to be paid back by the pharmaceutical company to the respective insurer, depending on the indication for which the medicine has been prescribed. Such refund obligations are contained in the so-called "limitations" which describe the conditions under which a medicine is reimbursed (eg, only for certain indications or only for a specific duration of treatment, etc).

Because the limitations are not considered to be part of the official price determination, pharmaceutical companies have asked for confidential price models in order not to disclose publicly the net price paid by the insurer. In this scheme, the refund obligation is only mentioned in the limitation as a principle, and the amount of the refund is communicated by the pharmaceutical company to the insurer upon request.

The FOPH has, so far, accepted such confidential price models without an explicit legal basis. The proposal to provide for an explicit legal basis is therefore a clear improvement. However, the confidentiality of prices within a healthcare system based on a mandatory health insurance is certainly problematic and has already triggered fundamental criticism. It remains to be seen whether the proposal will ultimately be accepted by the federal parliament and become binding law.

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Bär & Karrer is a leading Swiss law firm with more than 170 lawyers in Zurich, Geneva, Lugano and Zug. The firm's core business is advising clients on innovative and complex transactions and representing them in litigation, arbitration and regulatory proceedings. Clients range from multinational corporations to private individuals in Switzerland and around the world. The life science team consists of 11 partners and 13 other qualified lawyers and advises on all regulatory and legal topics relating to the healthcare and life science industries. Clients include pharmaceutical companies, medtech companies, hospitals, laboratories, manufacturers, suppliers, distributors and other healthcare providers. The firm represents clients in contractual matters, M&A, administrative investigations and proceedings as well as in litigation and arbitration. Moreover, the team drafts and negotiates agreements relating to the development and distribution of pharmaceutical and other products as well as the use of the intellectual property on which they rely.

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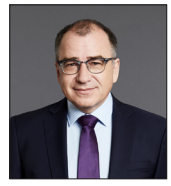

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