

## Switzerland: COVID-19 Disrupts Well-Established Safeguards for Medicinal Products

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We are used to being in control of our lives – or at least like to think we are. Part of this control is that we, as societies and as individuals, determine where we accept taking risks and where we don't. One thing we learned the hard way is that remedies for illnesses may be worse than the illness itself. After the Elixir Sulfanilamide disaster in the 1930s, followed by the Contergan catastrophe in the 1950s, states around the world developed sophisticated concepts and procedural safeguards against the risks that biological or chemical medicinal products may present to patients. The general consensus was that only drugs having a positive benefit/risk ratio may be allowed on the market.

The pressure put on governments to contain the threat posed by COVID-19 infections now seems to be so high that at least in Switzerland, the principle that a national competent agency has to ascertain that the benefits of a new product outweigh its risks if it is to be allowed on the market is put on hold.

### Swiss COVID-19 Ordinance

On April 3, 2020, the Swiss Federal Council, based on its emergency powers, issued Federal Ordinance #2 on Measures to Combat the Corona Virus ([COVID-19-Ordinance-2](#)), putting it into force the day after, April 4.

The COVID-19-Ordinance-2, *inter alia*, contains important and far-reaching changes to the current Swiss regulations of medicinal products. According to the COVID-19-Ordinance-2, new medicinal products containing certain active pharmaceutical ingredients (APIs) listed in Annex 5<sup>1</sup> and indicated for the treatment of COVID-19 patients may be put on the market without a Swiss marketing authorization (MA), only based on an application for an MA submitted to the Swiss national competent authority for medicinal products (Swissmedic), that is, without the prior assessment by Swissmedic (COVID-19-A). Not only new medicinal products but also variations of existing products such as new indications may be put on the market on the basis of a submission alone, provided the variations are COVID-19-related (the APIs for the respective products are listed in Annex 4<sup>2</sup>).

Furthermore, in assessing said new medicinal products and variations, Swissmedic has generally been authorized to deviate from the regulatory requirements (laid down in the Therapeutic Products Act [TPA] and its ordinances) based on its benefit/risk assessment. There are no limits to the deviations Swissmedic may decide on.

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<sup>1</sup> COVID-19-Ordinance-2, Annex 5: Currently the APIs listed are Hydroxychloroquine, Lopinavir/Ritonavir, Remdesivir and Tocilizumab. However, the Federal Office of Public Health has been mandated to extend this list to other APIs after consultation with Swissmedic.

<sup>2</sup> COVID-19-Ordinance-2, Annex 4, currently lists no fewer than 33 APIs plus all medical gases.

These emergency provisions raise several questions, *inter alia*:

- Are the provisions **proportionate** (and therefore constitutional)?
- Who will be **liable** if a drug put on the market according to these provisions is not safe?
- Who will **pay** for these drugs?

## **Desperate times call for desperate measures?**

It goes without saying that the COVID-19 pandemic is a huge challenge for every government — especially as it affects not only health but literally all aspects of life as we knew it. Therefore, the measures governments have to take are manifold, and only hindsight will show which measures were effective and which were not. In such times, we all have an inclination to agree that “Desperate times call for desperate measures,” a saying attributed to the Greek physician [Hippocrates](#).

However, we are a long way from physicians of ancient times. We are not only used to much more sophisticated means for curing diseases but in general have higher expectations regarding the caution to be exercised in treating patients. Even in times of public crisis, it is not enough that measures are effective; they also have to abide by the constitutional principles.

## **No alternatives?**

The modern constitutional state has, *inter alia*, to respect the principle of proportionality in everything it does and especially in drawing up and deciding on laws. Emergency laws are laws and therefore also must be constitutional. An example for proportionate measures can be found close by in the [Notice to Stakeholders](#), jointly published on April 10, 2020, by the European Commission, the European Heads of Medicines Agencies and the European Medicines Agency. The principle of proportionality contains a variety of elements, but in the stricter sense it asks whether the objectives targeted with a certain legal provisions or an individual decision could not be attained with a less drastic regulation or measure, that is, whether they are necessary in the first place. Do the exceptions laid down in COVID-19-Ordinance-2 regarding the premarket assessment of medicinal products live up to these restrictions?

The Federal Council’s [explanations](#) to Article 4/COVID-19-Ordinance-2 define the objectives of the exception to the principle of premarket authorization of medicinal products as follows: “[M]ake available as soon as possible to the patients in Switzerland the experience gained in the medical practice and the promising therapeutic options. At the same time, the competence of Swissmedic (assessment of quality and evaluation of the yet available evidence of the medicinal products) shall be used expediently without delaying the treatment of COVID-19. The precondition of submitting an application for a marketing authorization shall set an incentive for transferring such products into the ordinary authorization status” (original in German).

The proportionality analysis must also take into account the numerous exemptions the TPA provides, for example, the issuance by Swissmedic of temporary MAs (Art. 9a TPA) or of temporary authorizations for the use and restricted supply of medicinal products (Art. 9b TPA), to name only two. These two provisions have been issued in order for the competent authorities to react adequately to special therapeutic needs. At the same time they guarantee the premarket control of medicinal products.

One less drastic alternative might be, if it were deemed necessary due to the COVID-19 pandemic, to ask Swissmedic to set up a task force with the objective to decide on applications for new medicinal products or variations of known products within a few days. This would have maintained a minimal state control on the quality, safety and efficacy of medicinal products destined for patients suffering from COVID-19 infections without unduly delaying the supply with innovative products, thus protecting patients against the risks associated with all effective medicinal products. This protection is as important for patients having an unmet therapeutic need as for all other patients.

## **Liability: Whom to blame?**

According to Swiss law, the liability for the quality, safety and efficacy of medicinal products, generally speaking, lies with the marketing authorization holder (MAH). As the procedure leading to an MA contains the safeguards the legislature deemed adequate (and proportional) to guarantee the safety of a medicinal product's application, MAHs in Switzerland need fear liability claims only if their authorized products do not meet the conditions of the MA. Furthermore, there is a certain risk of liability for Swissmedic as the state authority assessing medicinal products premarket and controlling the products on the market. However, Swissmedic's risk is minimal and would come to pass only if there was negligence on its side. Last but not least, if a physician applies an authorized medicinal product outside of the indication covered by the MA (off-label use), possible negative consequences of this off-label use have to be covered by the physician and not the MAH.

Article 4/COVID-19-Ordinance-2 adds a new angle to the liability for medicinal products in Switzerland. Is a COVID-19-A to be seen as an MA by law; that is, could the Swiss Confederation be held liable for undesirable effects of products put on the market under this provision? Or is it the manufacturers' responsibility that the products they put on the market on the basis of a pure application for an MA are safe to use? Or is it Swissmedic's responsibility to ascertain, from day one after submission, that the products put on the market on the basis of the COVID-19-Ordinance-2 are safe?

Furthermore, how will liability be affected by the process of Swissmedic's assessment of the submission for a COVID-19-A? What is Swissmedic to do if, during its assessment of the submitted documentation, it becomes aware of risks regarding the quality, safety or efficacy of the product? Is Swissmedic allowed to deviate from Article 4/COVID-19-Ordinance-2 by suspending a COVID-19-A, or is the permission to supply the product on the basis of a submission valid until Swissmedic has issued its final decision on it (which, under normal circumstances, could take years)?

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## Costs: Who pays?

Pricing and reimbursement of medicinal products in Switzerland are regulated by the legislation on health insurance. As a principle, medicinal products on the Swiss market not only need an MA (i.e., have to be of high quality, safe and efficient) but also have to meet criteria laid down in the health insurance legislation. They have to be effective, appropriate and economically efficient (EAE criteria) if the health insurers are to be obligated to reimburse the costs. The Federal Office of Public Health (FOPH) is competent to assess medicinal products with regard to the EAE criteria. If a product meets the criteria, the FOPH fixes a price for the product and puts it on a list (SL, short for *Spezialitätenliste*, or list of pharmaceutical specialties). The listing for the SL is open only to medicinal products with an MA. COVID-19-A does not fulfill this precondition; therefore it is to be assumed that products put on the market based on Article 4/COVID-19-Ordinance-2 don't qualify for an SL listing (this assumption is supported by FOPH's stance that even authorizations based on Articles 9a and 9b TPA do not qualify as MAs).

If the FOPH should formally accept a COVID-19-A as having an MA based on the COVID-19-Ordinance-2, the office would have to deviate from its longstanding, consistent practice, demanding a high level of proof for the EAE criteria to be met. Given how restrictive FOPH's orphan drugs stance is, one is hard pressed to see how a medicinal product with a COVID-19-Ordinance-2 could meet these standards.

If — under exceptional circumstances allowed by law — a medicinal product that does not have an MA shall be used for a patient, Swiss health insurance regulation provides an alternative basis for pricing and reimbursement. In such cases, the patient's health insurer has to decide on a case-by-case basis whether the EAE criteria are met and — if it deems that they are — issue a decision on the price.

For lack of a special provision regarding pricing and reimbursement in the COVID-19-Ordinance-2, the latter will most probably become applicable in the cases at hand. However, Swiss health insurers are private companies. Therefore, the insurers' scrutiny of a medicinal product with regard to the EAE criteria in individual cases tends to be at least as intense and reserved as that of the FOPH in the process leading to the SL listing. It will remain to be seen whether insurers would agree to cover the costs of a treatment with a medicinal product put on the market under the COVID-19-Ordinance-2 if there is no provision obligating them to do so. Last but not least, it is doubtful whether this alternative to an FOPH SL listing is a practicable solution in view of the important number of patients and therefore applications for the coverage of costs.

There is room for improvement in the COVID-19 emergency legislation.