NKF Client News

MARCH 2020

Life Sciences – Coronavirus Update

1. Overview

Currently, the global impact of the COVID-19 pandemic is rapidly escalating. It is difficult to keep up and to stay on top of things. This newsletter is intended to help.

In a first section (see 2. below), you will find the coronavirus newsflash on the following topics: (2.1) the Federal Council's restriction on the dispensing of certain drugs; (2.2) the European Commission's announcement on a possible postponement of the MDR's entry into force; and (2.3) the Federal Council's approval of restrictions on the export of medical protective equipment.

The second part of this newsletter is dedicated to the pressing question of security of supply. Even in times of coronavirus, must all regulatory requirements continue to be strictly adhered to in order to place scarce goods such as ventilators, face masks, disposable gloves and hand sanitizers on the Swiss market, or are relaxations granted based on emergency laws? Which regulations are applicable to the various products? You will find answers to these questions in section 3.

The last section of this newsletter discusses how sponsors, investigators and project leaders should proceed with ongoing clinical trials and other human research projects in the face of the COVID-19 pandemic. Various life science companies are working day and night to develop a treatment / vaccine against the virus. However, also the impact on ongoing procedures for market access of other drugs should not be disregarded. What should be considered in this respect? This newsletters provides an up-to-date overview in section 4.

2. Coronavirus Newsflash

2.1 Federal Council Restricts Dispensing of Certain Drugs

Based on an ordinance of the Federal Council,[1] physicians, pharmacies and other businesses that are authorised to dispense medicinal products are currently and since 18 March 2020 (2 pm) only allowed to dispense one package of certain drugs (e.g. paracetamol, ibuprofen, mefenamic acid, codeine) per customer and per purchase. Exceptions apply to chronically ill persons, to whom the drugs covered by the ordinance may be dispensed – per purchase – in the amount prescribed by a physician or to cover the person's need for a maximum of two months. With this measure, the Federal Council intends to secure the ongoing supply of important medicines, such as painkillers.

2.2 European Commission Announces a Possible Postponement of the MDR's Entry into Force

According to a press release of 23 March 2020,[2] MedTech Europe (MTE) has called for a pause on the implementation of the EU Medical Devices Regulation (MDR)[3] and the EU In-Vitro Diagnostics

1 Ordinance on the restriction of the dispensing of medicinal products of 18 March 2020 (*Verordnung über die Beschränkung der Abgabe von Arzneimitteln vom 18. März 2020*).
2 Press release available through MedTech Europe's website at <https://www.medtecheurope.org/news-and-events/press-releases/> (website last visited on 28 March 2020).
3 Regulation (EU) 2017/745 on Medical Devices.

Regulation (IVDR)[4] to facilitate the fight against COVID-19 and to safeguard the functioning of healthcare systems. MTE asked the European institutions to suspend the implementation of both regulations until six months after the crisis has passed. Swiss MedTech, as a member of MTE, welcomed the motion.[5] On 25 March 2020, the European Commission (EC) announced a one-year moratorium on the implementation of the MDR. The EC is currently working on a respective proposal to be presented to the Parliament and the Council in early April.

In consideration of the currently dormant negotiations between Switzerland and the EU regarding the renewal of the Mutual Recognition Agreement (MRA)[6], a moratorium on the implementation of the MDR would be very good news for the industry. This is particularly true as the deadline for MDR implementation lapses on 26 May 2020.

2.3 Federal Council Approves Restrictions on the Export of Medical Protective Equipment

On 25 March 2020, the Federal Council decided to introduce an authorisation requirement for the export of medical protective equipment. The corresponding amendment to COVID 19 Ordinance 2[7] came into force on 26 March 2020 (Art. 10d and 10e). The goods concerned, including protective goggles, protective clothing and gloves, are listed in Annex 3 to COVID 19 Ordinance 2. Exemptions from the authorisation requirement apply to exports to EU and EFTA countries, provided reciprocity is granted. The measures taken by the Federal Council are largely in line with the measures adopted by the EU.

The State Secretariat for Economic Affairs (SECO) is responsible for issuing the export authorisations (Art. 10d para. 1). Applications must be submitted via the existing electronic platform "ELIC" of SECO (Art. 10e para. 1). SECO shall take a decision within five working days from receipt of the complete application (Art. 10e para. 2).[8]

3. Security of Supply: Ventilators, Face Masks, Disposable Gloves and Hand Sanitizers – What Applies?

Under Swiss law, medical devices are not subject to authorisation. However, medical devices placed on the Swiss market must comply with the applicable regulatory requirements and must generally be CE-marked. The Swiss Agency for Therapeutic Products (Swissmedic) is responsible for market surveillance of medical devices.

With the exception of ventilators (see below), it appears that so far Swissmedic has not, under emergency law, eased the requirements for placing medical devices on the market. For instance, tests for the novel coronavirus in human samples (e.g. saliva, blood) are still subject to the "normal" regulations applicable to in-vitro diagnostic medical devices.[9]

The regulations that are currently applicable to the marketing of ventilators, face masks, disposable gloves and hand sanitizers during the fight against the COVID-19 pandemic are discussed below.

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4 Regulation (EU) 2017/746 on In-Vitro Diagnostic Medical Devices.

5 See Swiss MedTech's website at <https://www.swiss-medtech.ch/> (website last visited on 28 March 2020).

6 Agreement of 21 June 1999 between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessments (*Abkommen vom 21. Juni 1999 zwischen der Schweizerischen Eidgenossenschaft und der Europäischen Gemeinschaft über die gegenseitige Anerkennung von Konformitätsbewertungen*).

7 The COVID-19 Ordinance 2 is available in German, French and Italian at <https://www.admin.ch/opc/de/classified-compilation/20200744/index.html> (website last visited on 28 March 2020).

8 See the Federal Council's press release at <https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-78576.html> (website last visited on 28 March 2020).

9 See Swissmedic's website at <https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/marktkontrolle-medizinprodukte/mitteilungen-zu-marktkontrollthemen.html> and the respective information leaflet entitled "MU500_00_014e_MB Coronavirus Covid 2019" of 16 March 2020 (website last visited on 28 March 2020).

Ventilators:

According to its communication of 24 March 2020, Swissmedic confirmed that it intends to contribute to ensuring the supply of healthcare facilities with "vital medical devices" during the current "extraordinary situation".[10] At the moment, Swissmedic deems the supply of ventilators to healthcare institutions to be essential.

In this regard, Swissmedic indicated that it can grant exemptions for placing non-compliant medical devices on the market based on Art. 9 para. 4 of the Medical Devices Ordinance (MedDO) if the following conditions are met: (i) the non-conforming device serves to avert life-threatening conditions or to resolve the permanent impairment of a bodily function; (ii) no conforming device is available for this indication; and (iii) the non-conforming device will be used on individual persons only.

Swissmedic confirmed that it will process exemption applications promptly and pragmatically and will interpret the conditions of Art. 9 para. 4 MedDO as outlined above generously (especially the criterion of application for individuals). Applications may be submitted by either manufacturers and distributors or by healthcare professionals and institutions in Switzerland. The file to be submitted to Swissmedic must in particular include information and documentation on the device's safety and an assessment of potential risks relating to the intended use versus benefits for the patient.[11]

Face Masks:

"Surgical masks" or "medical face masks" as well as similar face masks advertised as protection against diseases and thus for medical use are considered medical devices and must, therefore, fulfil the respective requirements and bear the CE mark. These kinds of masks are, in line with the applicable harmonised standard EN 14683, primarily designed to protect people in the wearer's proximity (rather than the wearer him- or herself) from contamination.[12]

In contrast, so called FFP masks (respiratory protection masks) protect the wearer from solid and liquid aerosols. These masks, which are not advertised for medical use, do not qualify as medical devices. They do, however, also bear the CE mark according to applicable regulations regarding personal protective equipment.[13]

Disposable Gloves:

The regulation is similar with regard to disposable gloves: Disposable gloves intended for medical use (such as surgical gloves and examination gloves) generally qualify as medical devices and must fulfill the relevant requirements, including bearing the CE mark.

In contrast, disposable gloves not intended for medical use (e.g. for household use) are not considered medical devices.[14]

Hand Sanitizers:

Hand sanitizers do usually not qualify as medical devices, but as biocidal products. For these products, the Federal Office of Public Health (FOPH) is responsible and grants the relevant authorisations.[15]

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10 See Swissmedic's website at <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-surveillance-of-medical-devices/announcements-on-market-control-issues/inverkehrbringung_lebenswichtiger_beatmungsgeraete.html> (website last visited on 28 March 2020).

11 For more information on the documentation to be submitted please see Swissmedic's website at <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/exemptions-for-non-conforming-medical-devices.html> (website last visited on 28 March 2020).

12 See fn. 9.

13 For further information please see the website of the SECO at <https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit/Persoenliche-Schutzausruestungen-PSA.html> (website last visited on 28 March 2020).

14 See fn. 9.

15 For further information please see the FOPH's and the Notification Authority for Chemical's website respectively at <https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html> (website last visited on 28 March 2020).

As a result of the ongoing COVID-19 pandemic and to counter supply shortages, the FOPH issued an exceptional authorisation for alcohol-based disinfectants in the form of a general order (*Allgemeinverfügung*) on 28 February 2020, which is valid until 31 August 2020.[16] In addition to hand sanitizers, the exceptional authorisation also covers certain surface disinfectants. Accordingly, for these disinfectants, no approval application needs to be submitted to the Notification Authority for Chemicals. Various regulations on labelling and composition must, however, be observed.

Further information on the relaxation of legal measures to secure supply:

- In view of the objective to ensure the availability of personal protective equipment (such as face masks, protective suits or goggles) and medical devices (such as surgical masks, examination gloves and certain types of gowns) during the COVID-19 threat, the EC issued a recommendation on 13 March 2020 on facilitating conformity assessment and market surveillance procedures.[17]
- In view of the exceptional situation, the Swiss Association for Standardization (SNV) has recently made available on its website, free of charge, some standards (e.g. on respiratory protective devices) relevant in the context of the fight against the COVID-19 pandemic.[18]

4. Handling of Ongoing Human Research Projects

Recommendations for the EU:

On 20 March 2020, the EC, the European Medicines Agency (EMA) as well as different working and expert groups issued a "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic" (hereinafter the "EC Guidance").[19] Similar non-binding recommendations for the industry, investigators and Institutional Review Boards have been issued by the US Food and Drug Administration (FDA) under the title "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic".[20]

The EC Guidance mainly aims at providing harmonised recommendations at EU level on how to handle changes and protocol deviations triggered by the COVID-19 pandemic with a focus on trial subject safety and preservation of data quality. If these two basic principles conflict, safety always prevails according to the EC Guidance. The EC Guidance further advises on the initiation of new clinical trials for potential COVID-19 treatments. It is important to note that there might be specific legislation and guidance in place at EU member state level that must be consulted and which may take priority over the harmonised recommendations.

Recommendations for Switzerland:

On 18 March 2020, Swissethics published on its website similar guidelines for clinical trials and research projects conducted in Switzerland.[21] These guidelines were updated, firmed up and

16 General order of the Notification Authority for Chemicals of 28 February 2020 on the authorisation of biocidal products to overcome exceptional situations under Article 30 of the Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (*Allgemeinverfügung der Anmeldestelle Chemikalien vom 28. Februar 2020 über die Zulassung von Biozidprodukten zur Bewältigung von Ausnahmesituationen nach Artikel 30 der Verordnung über das Inverkehrbringen von und den Umgang mit Biozidprodukten vom 18. Mai 2005*).

17 Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H0403> (website last visited on 28 March 2020).

18 See the SNV's website at <https://www.snv.ch/de/news/news-details/informationen-der-snv-gesch%C3%A4ftsstelle-zu-covid-19-coronavirus.html> (website last visited on 28 March 2020).

19 EC-Guidance available at <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf> (website last visited on 28 March 2020).

20 See the FDA's website at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trials> (website last visited on 28 March 2020).

21 See Swissethics' website at <https://www.swissethics.ch/news/2020/03/18/information-on-the-coronavirus> (website last visited on 28 March 2020).

transformed into joint guidelines of Swissmedic and Swissethics on 25 March 2020 (hereinafter the "Joint Guidance").[22]

According to the Joint Guidance, sponsors, investigators and project leaders of clinical trials and human research projects must ensure that studies are conducted in line with the COVID-19 Ordinance 2. This ordinance provides, inter alia, that:

- recommendations of the Federal Office of Public Health (FOPH) regarding hygiene and social distancing must be followed and that the number of persons present must be limited accordingly (Art. 6 para. 4);
- the Cantons may oblige private hospitals and clinics to make their capacities available for the admission of patients (Art. 10a para. 1);
- healthcare establishments – in particular hospitals, clinics and doctor's surgeries – are prohibited from carrying out non-urgent medical examinations, treatments and therapies, including interventions (Art. 10a para. 2);
- persons at particular risk from COVID-19 (e.g. persons aged 65) should stay home and avoid crowds (Art. 10b).

Persons involved in the conduct of clinical trials and research projects must not only ensure the safety and wellbeing of all participants, but may also need to take extraordinary measures to take account of the fact that participants may be in self-isolation / quarantine, that they may have limited access to public places (including hospitals), and that healthcare professionals are currently assigned to critical tasks. In short, the Swiss emergency law provisions impose significant restrictions on sponsors, investigators and other stakeholders in their continuation of their research activities. Accordingly, postponement of follow-up visits or interruption of treatment, among other things, must be considered.

Need for action and how to proceed (Switzerland):

Consequently, there is an immediate need for sponsors and investigators to review all ongoing clinical trials and human research projects as well as each individual participant (e.g. with regard to age and previous health problems) and to carry out respective risk assessments on a regular basis. Based on these assessments, the necessary measures to ensure the safety of all those involved must be taken, documented and, if required, notified to the competent authorities.

- If clinical trials need to be temporarily interrupted or definitely discontinued, the sponsor must notify the competent ethics committee or Swissmedic respectively within 15 days (Art. 38 para. 2 and 5 Clinical Trials Ordinance [ClinO]).
- A temporary interruption of recruitment during an active ongoing clinical trial need not be notified if patients who have already been recruited continue to be treated as planned.
- However, other amendments to or deviations from the protocol and changes of participants' rights and obligations still need to be submitted to and approved by the competent authority prior to implementation; this applies to both clinical trials and research projects according to Chapter 2 of the Human Research Ordinance (i.e. research projects involving measures for sampling of biological material or collection of health-related personal data from persons).
- Exceptions to this obligation of prior notification apply if deviations from and changes to the protocol are needed to avert immediate dangers for the participants. Such deviations and changes may be notified subsequently (within 7 days according to Art. 37 para. 1 and para. 3 ClinO).

22 See document entitled "Joint guidance of Swissmedic and Swissethics on the conduct of clinical trials during COVID-19 pandemic" available at <https://www.swissethics.ch/covid-19/guidance-docs> (website last visited on 28 March 2020).

— In general, it is strongly recommended that all decisions and measures taken due to the exceptional situation be well documented.

— Direct monitoring of patients should be reduced to an absolute minimum and a switch to other methods of monitoring (e.g. telephone) should be considered. At the same time, it should be remembered that "remote monitoring" by sharing patient data via computer screens (using Skype or similar methods) is still not acceptable, as the necessary legal basis for this is lacking. Adapted monitoring plans have to be submitted to the Lead Ethics Committee for silent acknowledgement. Delayed submissions are acceptable. Participants must be informed, ideally by using the template "Addendum to the patients information and consent form of clinical trials during the COVID-19 pandemic: telephone visits and home delivery of the investigational study drug" provided on Swissmedic's / Swissethic's website.[23]

— If the investigational drug products (IMPs) are suitable for use at home and if the prerequisites according to the Joint Guidance are met, also direct to patient delivery of IMPs may be considered during the COVID-19 pandemic period. Changes in the distribution of the study medication need to be notified to Swissmedic and Swissethics respectively. Participants have to be informed appropriately upfront. Their written consent may be given later by using the template mentioned above provided on Swissmedic's / Swissethic's website.[24]

In summary, it should be noted that, in general, all notification duties and obligations of sponsors, investigators and project leaders of clinical trials and research projects involving human beings remain the same as before the coronavirus spread. Swissmedic and the competent ethics committee(s) will, however, accept the submission of a single information letter / bulk submissions for several studies conducted by one and the same company. Submissions to Swissmedic can be filed electronically.

Research Projects on COVID-19 in Switzerland:

With regard to studies on COVID-19 or on corresponding investigational medicinal products, Swissmedic and Swissethics ask for coordination as early as possible. The authorities have committed to treat such requests as a matter of priority and within a very short time.

This prioritization, as well as other measures needing to be implemented to comply with emergency measures ordered by the Federal Council (such as relocating and rescheduling ethics committee meetings), will lead to delays which all persons involved should be aware of.

Due to the rapidly evolving situation, further updates to the Swissethics and Swissmedic guidelines summarised herein are possible and likely. A regular check of the respective websites is thus highly recommended.

If you have further questions or comments on this topic, please reach out to your regular NKF contact.

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23 See Swissethics' website at <https://www.swissethics.ch/covid-19/guidance-docs> (website last visited on 28 March 2020).
24 See fn. 23.

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