LEGAL UPDATE

COVID-19 LEGAL CHALLENGES FOR PHARMACEUTICAL COMPANIES

ČECHOVÁ & PARTNERS

Pharmaceutical companies are meeting with numerous legal challenges resulting from the ongoing COVID-19 pandemic and the corresponding Government measures. Among the most discussed topics are the legal obligations relating to availability of medicinal products, securing of medicinal products for treatment of patients with COVID-19, control over the distribution channel, clinical trials, and relations with healthcare professionals.

AVAILABILITY OF MEDICINAL PRODUCTS

During the COVOD-19 pandemic, legal obligations of marketing authorisation holders and wholesalers relating to availability of medicinal products are of utmost importance. Even though these measures have applied regardless of the pandemic, in the present situation, they should be given proper attention.

1. Availability in sufficient quantity

A marketing authorisation holder of a medicinal products listed in the list of reimbursed medicinal products is obliged to ensure availability of the product in sufficient quantity, being the stock sufficient to cover the estimated monthly consumption in the Slovak Republic, calculated based on:

- the actual consumption of medicinal products in the same reference group (same active substance, way of administration, drug form, and amount of active substance) for the last calendar quarter,
- the actual consumption of medicinal products in the same reference group for the calendar quarter preceding by 12 months the relevant time, in case for products for seasonal use,
- estimated consumption according to pharmaco-economic analysis, in case for products listed in the list of reimbursed medicinal products for less than six months not belonging to any pre-existing reference group at the time of entry to the reimbursement list, or
- estimated market share.

The requirement does not apply to orphan drugs. Seasonal products must be available only in the respective season. Breach of this obligation is not subject to any fine, however, if a product is not available in sufficient quantity for 60 consecutive days, the Ministry of Health may delete it from the list of reimbursed medicinal products.

2. Emergency channel

Marketing authorisation holders are obliged to set up and operate online systems for emergency ordering of medicinal products listed in the list of reimbursed medicinal products. Upon receipt of an order through the emergency ordering system from a retail or hospital pharmacy with an anonymised medical prescription, hospital order form, or an electronic prescription, submitted when a product cannot be procured from a wholesaler within 24 hours, a marketing authorisation holder is obliged to supply the product within 24 hours to the respective pharmacy, or to a wholesaler, which is further obliged to supply the product to the respective pharmacy in the overall period of 48 hours since an emergency order is made (or within 72 hours, if the 48 hours period ends on Sunday).

The supply obligation does not apply if a marketing authorisation holder has outstanding claims against the pharmacy overdue for twice of their agreed maturity period, or in case of

ongoing proceedings on deletion of the product from the list of reimbursed medicinal products.

Breach of the marketing authorisation holders' supply obligation is subject to fines from EUR 5,000 to EUR 100,000, or from EUR 100,000 to EUR 1 Million in case of repeated breach within three months.

A marketing authorisation holder can be discharged from liability if it proves that the obligation could not be met due to circumstances beyond its control. Unexpected demand or disruptions in manufacturing and distribution due to COVID-19 crisis could be considered such a circumstance, however, relevant case law is yet to develop.

The authorities understand that strict rules of the emergency distribution channel could potentially jeopardise effective distribution and availability of medicines. On 24 March 2020, the Ministry of Health issued an extraordinary measure prohibiting the emergency ordering and supply of hydroxychloroquine prescribed by physicians other than in seven enumerated specialisations, or in quantities above three packages for retail pharmacies, and 10 packages for hospitals.

3. Wholesaler supply obligation

Wholesalers are obliged to ensure supply of medicinal products listed in the list of reimbursed medicinal products to retail or hospital pharmacies within 24 hours from the receipt of an order, unless the wholesaler has outstanding claims against the pharmacy overdue for twice of their agreed maturity period, and to provide other medicinal products based on request of, and in the time determined by the Ministry of Health. Breach of this obligation is subject to fine from EUR 300 to EUR 35,000. This obligation is relevant not only to standard wholesalers, but also for numerous local affiliated companies of marketing authorisation holders, if they hold a wholesale distribution authorisation.

4. Restrictions for pharmacies

On 20 March 2020, the State Institute for Drug Control issued non-binding recommendation for the pharmacies to refuse to dispense prescription products prescribed by physicians not meeting the prescription limitation according to the list of reimbursed medicinal products, dispense medicinal products in the quantity covering only one treatment cycle, and restrict dispensation of OTC products to one package of the same active substance per patient.

Pharmacies, according to restrictions currently being finalised, are also subject to general restrictions and recommendations for retail activities: restriction of number of customers to one per 25 sqm of the store, mandatory hand sanitisers or disposable gloves in the stores, mandatory wearing of mouth and nose covers, keeping at least two metres distance in the queues, prohibition of sale of respirators to general public, and prohibition of sale on Sundays, except in emergency pharmacies. Time between 9:00 and 12:00 is reserved for customers over 65 years old.

COVID-19 TREATMENT

There are currently no medicinal products standardly authorised for treatment of COVID-19 indication. Such a treatment is possible only based on an individual or group permission of the Ministry of Health for use of non-authorised medicinal product, or off-label use of an authorised medicinal product.

Therapeutic use of a non-authorised product, or off-label use, may be permitted in case of a threat to life or risk of serious health deterioration, upon request of a healthcare provider or

at the Ministry's own initiative, if no comparable authorised treatment is available. A prescribing physician takes full responsibility for the treatment, which requires a prior written consent of a patient.

The medicinal product provided under the rules described above can be reimbursed by a health insurance company in the exceptional reimbursement regime (based on individual decision of a health insurance company upon its discretion), provided by a pharmaceutical company free of charge, or purchased from the hospital budget.

Group permissions for therapeutic use are published on the website of the Ministry of Health.

Permission of therapeutic use of a product does not constitute an obligation of the marketing authorisation holder to supply the product – the conditions and capacities are negotiated individually between the Ministry of Health and the marketing authorisation holder or its local representative.

DISTRIBUTION CHANNEL

Effective from 23 March 2020, the Ministry of Heath issued an extraordinary measure prohibiting export of any authorised medicinal products, medical devices, or in vitro diagnostic devices, to any EU or EEA Member State, or to any third country. The only exception are medicinal products manufactured in Slovakia for another state, and medical devices and in-vitro diagnostic devices manufactured in Slovakia for a foreign customer based on a contract concluded before declaration of the state of emergency (effective from 16 March 2020, 6 AM).

The question of control over the distribution channel to ensure effective allocation of medicinal products and medical devices has become especially relevant. Direct-to-pharmacy / direct-to-hospital distribution is uncommon in Slovakia. The majority of innovative pharmaceutical companies distribute their products through the network of independent wholesalers. As a result, competition rules prevent them from intervening in the commercial decisions of the wholesalers, such as selection of the customers, quantities, sold, and prices and discounts. These competition restrictions remain relevant, nevertheless, a more lenient approach may be expected in reasonable cases.

According to the Joint statement by the European Competition Network on application of competition law during the Corona crisis, published on 23 March 2020, the competition authorities understand that this extraordinary situation may trigger the need for companies to cooperate in order to ensure the supply and fair distribution of scarce products to all consumers. In the current circumstances, the competition authorities will not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply. Considering the current circumstances, such measures are unlikely to be problematic, since they would either not amount to a restriction of competition, or generate efficiencies that would most likely outweigh any such restriction. In this context, the competition authorities pointed out that the existing rules allow manufacturers to set maximum resale prices for their products, which could prove useful to limit unjustified price increase at the distribution level.

The statement of the EU competition authorities cannot be considered as a license for restrictions of competition, and all measures potentially restricting competition should be given proper legal scrutiny. The competition authorities further emphasised that the utmost importance to ensure that products considered essential to protect the health of consumers in the current situation (e.g. face masks and sanitising gel) remain available at competitive

prices, which may result in strict enforcement of competition rules against companies taking advantage of the current situation by cartelising or abusing their dominant position.

CLINICAL TRIALS

Already on 16 March 2020, the State Institute for Drug Control published extraordinary measures and recommendations for clinical trials, instructing trial sponsors to take into account quarantine and other measures, which are likely to result in numerous deviations from clinical trial protocols. In important cases, these should be implemented as urgent safety measures without prior approval of the State Institute for Drug Control. The authority also opened a telephone and e-mail address for urgent questions related to clinical trials.

On 20 March 2020, the European Medicines Agency and other authorities issued the Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic. The guidelines recommend critical assessment of the feasibility of starting a new clinical trial or including new trial participants in an ongoing trial by sponsors in the light of ongoing pandemic. In ongoing trials, the following measures are recommended to consider:

- Conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that only strictly necessary visits are performed at sites;
- A temporary halt of the trial at some or all trial sites;
- Suspension or slowing down of recruitment of new trial participants;
- Extension of the duration of the trial;
- Postponement of trials or activation of sites that have not yet been initiated;
- Closing of sites;
- If unavoidable, transfer of participants to investigational sites away from risk zones, or closer to their home, to sites already participating in the trial, or new ones. If there is an urgent need to open a new trial site for critical trial visits for example outside the hospital, this may be implemented as an urgent safety measure first, with a substantial amendment application submitted later.
- There may be a need for critical laboratory tests, imaging or another diagnostic test to be performed for patient safety. In case the trial participant cannot reach the site to have these performed, it is acceptable that tests are done at a local laboratory authorised to perform such tests routinely, if this can be done within local restrictions on social distancing. The sites should inform the sponsor about such cases. If this is a trial endpoint and the samples cannot be shipped to the central lab, analysis should be performed locally and then explained, assessed and reported in the clinical study report.

All decisions to adjust clinical trial conduct should be based on a risk assessment by the sponsor. In communication with the authorities, priority is given to any (new) clinical trial applications for the treatment or prevention of COVID-19 infection, and substantial amendment applications to existing clinical trials necessary as a result of COVID-19. Any changes in agreements with sites may be documented as e-mail exchange. Changes in distribution of investigative medicinal products, trial monitoring.

In case a sponsor plans to initiate a trial aiming to test new treatments for COVID-19, the Guidance recommends finding alternative procedures to obtain informed consent, as it is likely that the physical consent cannot leave the isolation room, and therefore is not appropriate as trial documentation. In case of emergency situations, when trial participants are incapable of giving their informed consent (for example because they are under intensive medical care), sponsors shall adhere to the rules on clinical trials on incapacitated adults not able to give informed legal consent.

RELATIONS WITH HEALTHCARE PROFESSIONALS

Pharmaceutical companies are addressing numerous questions relating to relations with healthcare professionals. The most common questions are:

- Mutual contractual obligations, such as consultancy services, sponsorship of professional events: COVID-19 pandemic may constitute a force majeure event discharging a contracting party from liability (see our separate legal summary). It is recommended to amend or terminate the agreements as soon as possible;

- One-on-one visits of physicians by pharmaceutical representatives are replaced by alterative contacts, such as online contacts (which might need to comply with the legal requirements for visits in person), or static content (e-mail newsletters, websites), which are subject to advertising restrictions;

- Payment of withholding tax from considerations to healthcare professionals, healthcare providers and their employees, and submission of notifications on tax withholding and payment by marketing authorisation holders, pharmaceutical companies, manufacturers and wholesalers, may be delayed without sanction until 30 June 2020. Conversely, healthcare professionals, healthcare providers and their employees will not be sanctioned if they fail to pay the withholding tax from in-kind considerations until 30 March 2020, since the deadline was extended until 30 June 2020.