DENTONS

Amendment to the Medicines Act

Dentons Alert

January 2024

Grow | **Protect** | **Operate** | Finance

Dear readers, during the New Year's rush, it may have escaped your attention that on 29 December, the Amendment to the Medicines Act was published in the Collection of Laws, in volume 203 under number 456/2023 Coll. Barring one exception, which we discuss below, the amendment already went into effect on 1 January 2024.

Let us take a brief look at the amendment and on few of the new obligations, as the changes will have a fairly significant impact on the pharmaceutical market.

A. Supply obligations after an interruption or discontinuation of medicinal products already put on the market

Regarding medicinal products that have a maximum price or are reimbursed from public health insurance, marketing authorization holders (MAHs) will be obliged to continue the supply of the statutory minimum quantity of the medicinal product on the market after the date of interruption or termination of supply.

In such cases the volume of medicines that MAHs will have to supply will depend on past interruptions. If the medicine in question has been placed on market without interruption or if supply was interrupted for no longer than 20 days in the last two years (cumulatively), the required quantity will be the average monthly supply. If the interruption was longer, it will be up to double of that volume.

The Ministry of Health is currently preparing a decree with a list of medicines that are exempt from this obligation. In general, however, an exemption from the above will apply across the board to all medicines for the first 12 months after being placed on the market in the Czech Republic.

B. Medicinal products reserve system

The Ministry of Health is now authorized to monitor, with the help of data obtained by the State Institute for Drug Control (SÚKL), whether the planned supply of medicinal products corresponds to the predicted need of the Czech Republic. If it concludes that a particular medicinal product is at risk of a shortage, it will include it in the so-called “reserve stock system.” For distributors, this step automatically implies an obligation to establish and maintain stocks of the medicinal product in question in a quantity corresponding to the average monthly supply of the product to Czech pharmacies as well as abroad.

The amendment does not specify the exact location or nature of the stockpiles but, according to the Ministry of Health, the stockpiles may be located in another member state.

It is clear from the above new stipulations that MAHs will have to adjust their production, supply and storage plans in order to maintain sufficient quantities of medicinal products. Distributors, on the other hand, will incur new costs to establish and maintain mandatory reserve stocks. Compensation for these costs will be in accordance with the conditions and regulations set out in the Ministry of Health's price regulation. Distributors can expect a special surcharge for packaging medicines included in the reserve stock system.

A breach of the new stock obligations can result in a maximum administrative fine of CZK 20 million. Distributors that do not comply with the obligations related to the reserve stock system and those who violate the obligations related to medicines labelled as "restricted" can also face penalties in the same amount.

C. Possibility to import prescription and over-the-counter medicinal products with foreign language information or labeling

SÚKL is newly explicitly authorized to permit the supply medicinal products whose labelling and package leaflet is not in Czech. In contrast to the interpretation of the law to date, this now explicitly allows for the authorization of import of a foreign language batch even for OTC medicinal products, as some necessary OTC products have recently been unavailable on the Czech market and their provision for the needs of Czech patients was difficult to resolve under the previous legislation.

The considerable amendments to the Public Health Insurance Act should not be overlooked either. Most significant is SÚKL being newly authorized to issue, in price and reimbursement regulations, "measures to maintain the availability of non-substitutable reimbursable medicines and measures to ensure the availability of medicines important from the point of view of public health protection."

Finally, it is worth mentioning the introduction of an "e-prescription monitoring service," which will allow the professional providing the prescription to have up-to-date information on available quantities of the prescribed medicine as well as which healthcare providers (pharmacies) have this medicine in stock.

One change brought by the amendment to the Medicinal Products Act has yet to come into effect. After the date a MAH interrupts or terminates placement on the market of a particular medicinal product, it will obliged to continue to supply medicines and to label them with "restricted availability." This change will come into force on the first day of the sixth calendar month following the date of promulgation of the amendment; that is 1 June 2024.

We will continue to monitor the developments surrounding the amendment to the Medicines Act and the impact on practice for you. If you have any questions, please don't hesitate to contact us.

Contacts

Tomáš Bílek
partner, Prague
T +420 236 082 226
tomas.bilek@dentons.com

Adam Přerovský
senior associate, Prague
T +420 236 082 241
adam.prerovsky@dentons.com

Anna Urbanová
associate, Prague
T +420 236 082 289
anna.urbanova@dentons.com

ABOUT DENTONS

Dentons is designed to be different. As the world's largest global law firm with 21,000 professionals in over 200 locations in more than 80 countries, we can help you grow, protect, operate and finance your business. Our polycentric and purpose-driven approach, together with our commitment to inclusion, diversity, equity and ESG, ensures we challenge the status quo to stay focused on what matters most to you.

dentons.com

© 2024 Dentons. Dentons is a global legal practice providing client services worldwide through its member firms and affiliates. This publication is not designed to provide legal or other advice and you should not take, or refrain from taking, action based on its content. Please see dentons.com for legal notices.