COVID-19 - A brief overview of the main impacts on the Life Sciences and Pharma industry in the Czech Republic

Dentons Prague Newsletter

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Drug manufacturers as a part of critical infrastructure

On April 9, 2020, the Czech Government decided to include drug manufacturers in the critical infrastructure regime, recognizing that the production of pharmaceuticals is essential in order to ensure that patients have access to the medicines and treatments they need. Critical infrastructure includes entities and assets, which are essential for the functioning of society and the economy, and whose disruption would have a serious impact on the security of the state, provision of basic needs, and/or health of the population(such as operators of oil or gas pipeline).

In practice, the regulation provides a description of procedures to follow in critical situations (for instance in case of a COVID-19 outbreak in the workplace) and requires manufacturers to ensure that the production will not be negatively affected.

Medical Devices Regulation to be postponed

Due to the COVID-19 situation, the European Commission suggested to postpone the date of application of the Medical Devices Regulation ("**MDR**") by one year. The Commission is seeking the adoption of the proposal by the European Parliament and the Council of the EU by the end of May. The MDR, originally effective on May 26, 2020, brings essential changes with regard to the classification of medical devices, clinical trials, and surveillance and information systems for medical devices. According to the European Commission, this decision will relieve pressure from national authorities, notified bodies, manufacturers and other industry actors, and will allow them to fully focus on the urgent priorities related to the coronavirus crisis.

Restriction on the export of drugs intended for the Czech market

Under the Regulation No. 146/2020 of April 1, 2020, the Government banned the export of drugs that are intended for the Czech market. The export ban shall apply to drugs listed in the attachment to the regulation but only to those labelled in the Czech language on the packaging. Drugs with a label in Czech and another foreign language will be assessed individually and their market destination, to be demonstrated by the exporter. The ban will expire at the end of the state of emergency. Non-compliance with the regulation will be considered a serious breach of statutory obligations, subject to a fine of up to CZK 5,000,000 (approximately €200,000).

Recommendations for ongoing and newly authorized clinical trials

The State Institute for Drug Control issued its opinion on ongoing and newly authorized clinical trials, which contains recommendations for investigators and sponsors. The Institute strongly advises against the commencement of newly authorized clinical trials and the enrolment of new patients in ongoing studies. The only exception are clinical trials for the treatment or prevention of COVID-19.

The Institute also strongly discourages:

- Conducting clinical trials involving healthy volunteers or clinical trials which do not have therapeutic benefits for the enrolled subjects;

- Initiating clinical trials involving treatments that can affect the immune system.

Click here to see the complete opinion of the Institute. The Institute's Medical Devices Department has also issued a similar opinion on ongoing and newly authorized clinical trials for medical devices, see here (the Czech version only).

If you have any additional inquiries, please do not hesitate to contact us.

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