Tomáš Matějovský
Partner at CMS Cameron McKenna
T +420 2 96798 852
E tomas.matejovsky@cms-cmck.com

Denisa Assefová
Associate at CMS Cameron McKenna
T +420 2 96798 831
E denisa.assefova@cms-cmck.com

Czech Republic Lifesciences update: Spring 2012

Czech Republic to introduce amendments to health related laws changing legislative framework for pharmaceutical companies operating in the country

In order to make the Czech pharmaceutical and healthcare regulatory system compatible with the European Union legislation, the Ministry of Health in cooperation with the Ministry of Agriculture have prepared a new amendment to the Pharmaceuticals Act. Moreover, an amendment to the Advertisement Regulation Act has been discussed by the Czech government. The changes are expected to become effective from 1 January 2013. One of the changes that was introduced is the new system fixing the maximum prices of pharmaceuticals, which has been effective already from 1 December 2011. In addition, an amendment to the Public Health Insurance Act has brought about several legal changes in the area of health.

Proposed changes to the Pharmaceuticals Act to improve pharmacovigilance system?

The amendment aims to strengthen and rationalise the current system for monitoring the safety of pharmaceuticals on the European market and to improve patient safety and public health through better prevention, detection and assessment of adverse reactions to pharmaceuticals. In the opinion of CMS Cameron McKenna, it remains to be seen in practice to what extent the changes will actually improve the current system, but the proposed changes do seem to offer a good platform for effectuating the foreseen improvements in the current pharmacovigilance system.

Hence, a marketing authorisation holder should establish a new pharmacovigilance system (an electronic system for recording and evaluating data about registered pharmaceuticals) enabling the regular control of all data regarding pharmaceuticals. The State Institute for Drug Control (SUKL) would have access to this system whenever an inspection is conducted. To increase the benefit of pharmaceuticals, the SUKL may require additional safety studies to be taken in order for particular pharmaceuticals to be registered.

Concerning suspected adverse reactions in connection with the use of medicinal products, the amendment proposes all suspected adverse reactions to be reported solely to the European Union pharmacovigilance database 'Eudravigilance' maintained by the European Medicines Agency (and not through the SUKL).

Moreover, a new sub-category of pharmaceuticals available on prescription will be established. This group of pharmaceuticals may be provided to patients only in a limited amount (e.g. pharmaceuticals containing active substance pseudoephedrine). In order to control the dispensing of such pharmaceuticals, a new register will be established and maintained by the SUKL.

Prevention of shortages in medicinal products on the domestic market

The proposed amendments to the Pharmaceuticals Act address also significant problems which have arisen due to pharmaceutical re-exporting over the last couple of years. Pharmacy operators, who are also distributors of pharmaceuticals, used to export pharmaceuticals. Due to the significant export of pharmaceuticals, patients in the Czech Republic have faced a shortage of some medicines. Therefore, pharmacy operators will be obliged to specify which pharmaceuticals they intend to sell in the Czech Republic (in a pharmacy) and which pharmaceuticals they want to export.

Due to the fact that the amendment is inspired by the European legislation, especially by Directive 2010/84/EU of the European Parliament and of the Council, the Czech Republic is bound to change its regulations no later than by 21 July 2012. However, according to the latest announcement of the Czech government, if accepted, the amendment will become effective from 1 January 2013.

Proposed amendment to the Advertisement Regulation Act to prevent congress tourism

A new amendment to the Advertisement Regulation Act has been discussed by the Czech government. If approved, it will be put forward in the legislation process and is expected to become effective from 1 January 2013.

The proposed changes address the problems which have arisen in connection with so-called doctors' congress tourism. It is often perceived that the purpose of medical (academic) conferences or congresses is to support prescription or sale of pharmaceuticals or related products (such as dietary supplements). However, academic congresses are sometimes held in exotic destinations or other 'above standard' places in 'above standard' conditions.

Having benefitted from these 'extra' conditions, physicians feel obliged to prescribe specific pharmaceuticals. The whole situation could lead to the distortion of economic competition and/or can be considered a corruptive practice.

Therefore, the proposed amendment further specifies that the destination and duration of academic congresses must be adequate to the purpose of such meetings. In addition, the definition of pharmaceuticals should be extended. Not only the above-mentioned academic congresses but also 'other similar expert meetings' will be regarded as an advertisement on pharmaceuticals and thus will be regulated accordingly.

Non-interventional post-marketing studies will be expressly deemed to be advertisements on pharmaceuticals, on condition that that a promotional purpose is proved. Instead of having academic purposes, some non-interventional studies are, in fact, held to transfer patients to different medicines (mostly generic products). Therefore, non-interventional post-marketing studies should be subject to stricter legal regulation.

At present, an individual is penalised if she/he offers gifts, superfluous hospitality or other benefits to physicians, whereas legal entities or self-employed individuals are liable for such actions. Due to this legislative loophole, individuals have often been 'used' as intermediaries when providing benefits to healthcare specialists. Upon adoption of the aforesaid amendment, even such individuals will potentially be held liable and subjected to punishment for inadequate 'sponsoring' of physicians.

The 'Leniency programme' has been introduced by the proposed amendment. The programme offers accomplices to an offence the possibility of avoiding a fine. If an accomplice provides the respective authority with all available information, he or she may be completely relieved from the sanction or at least the assigned fine may be significantly reduced.

New maximum prices for original and generic pharmaceuticals

An approved amendment to the Public Health Insurance Act has brought about several legal changes in the area of health. One of the important changes is the new system determining the maximum prices of pharmaceuticals (effective from 1 December 2011).

From that date, so-called 'core reimbursement' (*jadrova uhrada*) of pharmaceuticals has been introduced in the Czech Republic. This means that 'only' the ex-factory price (*cena vyrobce*) of pharmaceuticals is regulated by the SUKL. However, this price does not include a wholesale margin (which is regulated by law) and VAT. In other words, the new system of setting pharmaceutical prices allows flexibility solely when e.g. tax laws or pricing regulations are changed.

The new rules have also been adopted regarding the pricing of generic pharmaceuticals. The previous regulation established that the price of the first generic pharmaceutical had to be reduced to 75% of the original pharmaceutical price and the price of the second generic pharmaceutical to 90% of the original pharmaceutical price.

The approved amendment has changed the rules for setting the price of generic pharmaceuticals. At present the price of the first generic pharmaceutical only is legally regulated. The first generic price must be reduced to 68% of the original pharmaceutical price.

When considering the potential impact of this part of the amendment, it should be noted that the new pricing rules might eventually lead to the reduction of prices of all pharmaceuticals (including original ones), due to competitive market prices of generics.

Confusion on the food and dietary products market

Due to the Regulation 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods, producers of dietary supplements (or any other food products) are currently facing a very difficult situation.

The above Regulation lays down strict rules relating to health claims made on food labels. Most health claims made on food labelling have to be approved by the European Commission in cooperation with the European Food Safety Authority.

Producers of food/dietary products were under an obligation to provide the relevant health claims to the 'national list of health claims' by no later than 31 January 2008. Then, the national list of health claims should have undergone the approval process of the European Commission. The whole procedure should have been completed by 31 January 2010.

However, as yet, no list of health claims has been finally approved by the European Commission. Despite this incorrect approach of the European Commission, national producers of food/dietary products (or food supplements) are being fined on the basis that their health claims do not meet the requirements set down by the Regulation.

Due to the inactivity of the European Union, there is no 'legal clue' as to whether any health claims are correct or not. Despite the fact that the European Commission is the only relevant body that is empowered to decide (and approve) the character of health claims, national authorities are imposing financial sanctions on local food/dietary producers for the incorrect character of health claims made on food products.

This article has appeared in Central Europe Pharma News bi-weekly newsletter published by research and consulting company PMR.