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Czech Republic Lifesciences update: Autumn 2012

New amendment to the Act on Pharmaceuticals in the Czech Republic to limit parallel exports?

The Czech Chamber of Deputies is currently processing a draft amendment to the Act on Pharmaceuticals. Prepared by the Ministry of Health and passed by the Government at the end of August 2012, the long-awaited amendment is now being debated in the Parliament. It addresses mainly the following three issues that have impact on the Czech health care system: re-exports of medicinal products abroad; patients' awareness of the prices and reimbursements of medicinal products and abuse of certain medicinal products. At the same time, it implements Directive 2011/62/EU, regarding the prevention of the entry of falsified medicinal products into the legal supply chain, and Directive 2010/84/EU regarding the pharmacovigilance.

Re-exports of medicinal products to be kept under strict surveillance

One of long-standing issues the Czech health care sector is facing is export and re-export of medicinal products. This is mainly due to relatively low prices of the medicinal products (pharmaceuticals) in the Czech Republic in comparison with neighbouring EU countries (e.g. Germany). As those products are often exported and re-exported (on some occasions on a rather massive scale) to take advantage of the higher prices outside the Czech Republic, there is a danger that the individual products may not be available on the Czech market for Czech patients. This already was the case in the past.

The Czech Ministry of Health intended to resolve this issue by restricting re-exporting by means of marking each supply of medicinal products according to whether it is intended for sale in a pharmacy or for further distribution. The products marked for sale in a pharmacy could not be re-exported. During the consultation process, the government however removed this provision from the draft amendment due to its alleged inadmissibility on the grounds that it would constitute a restriction on the free movement of goods. From the government's point of view, the individual problems cannot be resolved by regulation of the entire market. Such a restriction would destroy most of the small and medium-sized distributors and, therefore, unnecessarily restrict the medicine market in the Czech Republic.

However, as the re-exporting remains an issue, the government plans to prepare another amendment within the next few months. The Association of Innovative Pharmaceutical Industry came up with another solution inspired by the Slovak legislation and proposed that any export of medicinal products would have to be subject to a prior permit issued by the Czech regulator – the State Institute for Drug Control, in Czech known as SUKL. Under this proposal, if the SUKL finds out that there is only a small amount of the respective product on the Czech market and Czech patients are at risk of a lack thereof, it will not allow the export. Any exports made without the permit would be subject to a fine. According to the Association, the proposal does not breach the EU free movement of goods principle. It is, therefore, possible that this solution will be incorporated into the current draft amendment during the discussions in the Chamber of Deputies.

Patient to be informed on prices and reimbursements of medicinal products

The draft amendment introduces an obligation for pharmacists to inform patients whether the particular medicinal product is subsidised by the public health insurance and if so, in what amount. This is to allow the patients to make an informed decision when buying medicinal products that may be substituted (i.e. contain the same active substances) with medicines that are subsidised by the public health insurance. This change was included in order to increase transparency, in particular in cases where medicinal products are not fully subsidised and patients participate in the payment for a particular product.

Prevention of medicinal products abuse

To avoid the possible abuse of certain kinds of medicinal products (such as medicines containing pseudoephedrine, which is used as the source material for the manufacture of methamphetamine, or Subutex, which may be substituted for heroin), which does or may cause serious social problems and does or may lead to criminal acts, the draft amendment imposes quantitative restrictions on sales of such products and establishes a register monitoring their distribution. Based on the information about the amounts previously issued to a particular patient, pharmacists shall be able to determine what amount of the particular product may still be sold to the patient. If the amount was to exceed the specified limit, it could no longer be issued.

New manufacturers' and distributors' obligations

The draft also introduces a new obligation to provide all medicinal products for human use with protective features on their outer packaging. These features shall enable the distributors and persons authorised to supply them to verify their authenticity, identify the individual packaging and make sure the outer packaging has not been tampered with. However, the features shall not appear on medicinal products that are not subject to prescription or that are listed on the special list adopted by the European Commission.

Each company authorised to sell medicinal products will again be responsible for the continuous monitoring of the safety of its products after their launch. The aim is to help detect the previously unrecognised risks associated with the administration of the medicine.

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