

## AMENDMENT TO THE ACT ON MEDICINAL PRODUCTS AND MEDICAL DEVICES



The Slovak National Council voted to discuss draft Amendment to the Act on medicinal products and medical devices<sup>1</sup> submitted by the Government in the second reading. Who should be interested in the new regulation and what is its contents?

### Pharmacies

- Holders of licenses for provision of pharmacy care (pharmacies) will have imposed upon them an explicit obligation to give out categorized medicinal products in the pharmacy only. This new obligation should lead to the elimination of sale of medicinal products to wholesalers for the purpose of their export. The proposed Amendment stipulates that a repetitive breach of this obligation may be penalized by a forfeiture of the license for provision of pharmacy care.
- In case of shortages of categorized medicinal products at wholesalers, the pharmacy will be obliged to arrange for its supply by placing an order through the so called information system for extraordinary ordering of medicinal products created and operated by a Marketing Authorization Holder (MAH).
- A pharmacy will be entitled to sell medicinal products only to the wholesaler from whom they acquired the goods or to another pharmacy for the purpose of their supply in a pharmacy.

### Wholesalers

- Holders of a license for wholesale distribution of human medicinal products (wholesalers) will be obliged to prepare themselves for restrictions to be imposed on their activities.
- According to the new law, in certain cases the regulation will include the purpose of the supply of categorized medicinal products. Sale of categorized medicinal products to another wholesaler will, in general, only be allowed in case it is for the purpose of its further sale in the pharmacy. Penalties for repetitive breach of the new regulation include the forfeiture of the license for wholesale distribution of human medicinal products.
- Wholesalers will also be obliged to arrange for the pick-up of the categorized medicinal product ordered by a pharmacy through the information system for extraordinary ordering of medicinal products within 48 hours of the placement of the order and deliver it to the pharmacy.
- Export of categorized medicinal products by wholesalers will be conditioned by the existence of a written power of attorney granted by MAH.

### Marketing Authorization Holders

- Marketing Authorization Holders (MAHs) shall be prescribed by the law to deliver medicinal products only to wholesalers for the purpose of their delivery to pharmacies. In the case of export of medicinal products by a wholesaler an MAH will be obliged to notify The State Institute for Drug Control within seven days of the date when the export took place.
- The Government further proposes that MAHs arrange for the creation and operation of an information system for the extraordinary ordering of medicinal products. In extraordinary cases MAHs will also be obliged to arrange for delivery of medicinal products to the pharmacy within 24 hours.
- MAHs seated abroad will be obliged to appoint a Slovak representative who will arrange for delivery of categorized medicinal products in the above cases.

### Penalties

- In addition to the mentioned potential forfeiture of license, entities involved in the delivery of human medicinal products to the Slovak market will also face monetary penalties for failure to comply with new rules.
- Depending on the type and seriousness of the breach of obligations, the minimum penalties should be EUR 5,000 or EUR 100,000 and the maximum penalties should be EUR 100,000 or EUR 1,000,000. In case of repetitive breach of obligations, the amount of penalty may be doubled or tripled.

### Effectiveness

- If enacted the Amendment will take effect on 1 January 2017. However, selected provisions governing extraordinary ordering and delivery of medicinal products shall generally be effective as of 1 April 2017.

<sup>1</sup> Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on amendment of other laws as amended

### Draft Amendment on the website of the Slovak National Council

<https://www.nrsr.sk/web/Default.aspx?sid=zakony/zakon&ZakZborID=13&CisObdobia=7&CPT=196>

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