

# New pharmaceutical industry rules

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**The pharmaceutical industry is currently undergoing major changes. Recently enacted new legislation, Act on medicinal products and devices and Act on conditions of payment for medicinal products, medical devices and dietetic foodstuffs from public health insurance, constitutes a major reform of current legislation on medicinal products.**

Provisions dealing with anti-corruption measures are among the most important changes in the new legislation. The old legislation on medicinal products prohibited offering and accepting discounts and rebates in kind. The new legislation prohibits the offering and accepting of discounts in kind by pharmacists, license holders who produce medicinal products, wholesale distributors of medicinal products, and registration holders for a medicinal product for human use only. These are defined in the new act as samples of medicinal products for human use requiring a prescription, devices specified in the list of categorized medical devices, or other non-financial benefits. According to this definition, offering and accepting financial discounts is not prohibited.

The legislation also prohibits license and registration holders from financing, sponsoring or otherwise supporting a health worker's attendance at a convention (either directly or through a third party) except for conventions dedicated exclusively to professional and scientific purposes or further education. This is connected to a reciprocal ban on health workers attending such events.

Thus, pharmaceutical companies cannot organize domestic or foreign conventions with a professional or scientific program during the day and entertainment during the evening—conventions must concentrate strictly on

professional issues. Medical doctors and their family members are also not allowed to participate in any entertainment events organized by pharmaceutical companies. Violation of these rules by pharmaceutical companies brings a fine of up to 25,000 euros; if broken by health workers the fine can be as high as 35,000 euros.

Another anti-corruption measure included in the new legislation prohibits license and registration holders from encouraging, manipulating or influencing health care workers in any other way directly, indirectly or through a third party doctor regarding medicinal products they prescribe for human use. Violations of this measure carry fines up to 25,000 euros.

The new legislation also includes changes regarding the advertising and marketing of medicinal products. The previous legislation allowed pharmaceutical companies to supply, offer, or promise small gifts or small financial and non-financial benefits if they were relevant for medical or pharmacy practice. This is no longer allowed by the new act, which prohibits the supply, offer or promise of gifts or financial and non-financial benefits. Doctors can still accept small social gifts (such as flowers or cakes) that are not meant to advertise medicinal products, medical devices or a pharmaceutical company. However, small gifts (such as

calendars or pens) which can be used in an office to advertise a medicinal product are also not allowed, even if they are used to provide medical care or are educational.

The law also prohibits advertising medicinal products through personal visits by those authorized to prescribe medicinal products during their on-duty hours. However, pharmaceutical companies will be able to advertise their medicinal products outside on-duty hours.

The new act aims to give the Ministry of Health of the Slovak Republic a better overview of the marketing expenses of license and registration holders. These individuals must present an annual report to the Ministry on the amount spent on advertising, marketing and non-financial benefits granted directly or indirectly to health care providers in the previous year by January 31st. The Ministry will then publish these reports on its website. Similarly, license and registration holders are obligated to give the National Center for Health-Related Information a list of health workers who attend a convention for strictly professional, scientific, or educational purposes. This list will also be published online. Violation of publication duties carries a fine of up to 25,000 euros.

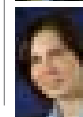
Further significant changes include introduction of a European Reference Price for medicinal

products and devices. The reference price will be based on the second lowest price of a medicinal product or device in other EU member states. Another change is the introduction of the loyalty system for pharmacies, which allows a pharmacist to give the patient a discount or promise a future discount in a public pharmacy or a pharmacy that specializes in medical devices. Wholesale distribution of medical devices no longer requires a license issued by the Ministry of Health of the Slovak Republic—free trade is sufficient. Categorization of medicinal products will now be performed monthly rather than quarterly. To reduce prescriptions of more expensive medicinal products, doctors cannot prescribe a specific medicinal product. Rather, only the active ingredient may be prescribed. The new legislation enables the establishment of a pharmacy network, since the provision enabling issuance of licenses for only one pharmacy and one subsidiary to a license holder was deleted.

Since December 2011, when the new act on medicinal products came into force, two amendments have been proposed. This could be viewed as evidence that the pharmaceutical industry is experiencing dynamic development. However, it could also indicate that practical implementation, although still in the early stages, has shown the impracticability and vagueness of the legislation, which requires some changes.



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