

18 December 2015

Big Brother wants to see you

OBLIGATORY DISCLOSURE OF MONETARY AND NON-MONETARY CONSIDERATIONS

As of 1 January 2016, the amendment to the Act on Drugs¹ introducing new transparency rules for pharmaceutical companies comes into effect. The declared aim of the amended wording is to increase transparency of dealings in the area of drug policy. Almost all considerations provided by the pharmaceutical companies to the healthcare professionals or providers will have to be disclosed in the registry of the National Health Information Center, including the personal data of the particular healthcare professional.

Besides increasing transparency and providing data on particular healthcare professionals, the amended Act increases the administrative burden imposed on the pharmaceutical industry. The failure to meet the imposed obligations may lead to financial sanctions. The obligation to disclose the required information arises for the first time on 31 July 2016.

This overview briefly summarizes the substantial changes introduced by the new regulation. Should you have any questions, please do not hesitate to contact us.

¹ Act No. 362/2011 Coll. on drugs and medical devices and on amendment and supplement of certain acts, as amended by the Act No. 393/2015 Coll. of 25 November 2015

Who is affected?

The amendment introduces new obligations for all players of the pharmaceutical industry including marketing authorization holders, manufacturers, wholesale distributors, pharmacies as well as “pharmaceutical companies” defined as companies that procure registration, categorization, marketing or other services for any of the above mentioned subjects. If any of these subjects provides a consideration, whether monetary or non-monetary, to a healthcare professional or healthcare provider, the new obligations will be applicable. The amendment also broadens the definition of a “pharmaceutical company”. While prior to the amendment, the definition encompassed the providers of the mentioned services to the registration holders, manufacturers and wholesale distributors, from now on, the definition will also include the provider of services to pharmacies. This is probably an attempt to include the companies, which procure purchase and other services for pharmacy chains.

What information needs to be disclosed?

The amendment of the Act on Drugs defines the extent of the disclosure duty in two ways.

Firstly, the amendment sets out four categories of expenses, which represent the extent of the disclosure duty, being the particular expenses on marketing, drug propagation and any direct or indirect considerations. The pharmaceutical companies will provide the information on the monetary and non-monetary considerations to the National Health Information Center via **a report on expenses on propagation, marketing and on monetary and non-monetary considerations**.

The amendment further sets out that the pharmaceutical companies do not have to disclose the considerations provided in **the ordinary course of business**. However, this exception needs to be construed carefully. Ordinary course of business is going to cover, for example, standard discounts in supplier-customer relations. Nevertheless, the burden of proof lies with the pharmaceutical companies, which will, in the case of doubt, have to prove that the arrangements with particular healthcare professionals or healthcare providers are considered ordinary in the area of sale or purchase of drugs.

The pharmaceutical company is not released from the disclosure duty even in case where the consideration is provided via third party. Existence of the third party intermediary adds to the disclosure duty, as besides the information on the consideration provided to the healthcare professional, the pharmaceutical company has to provide identification details of the third party, that facilitated the consideration.

What are the means of the disclosure?

The amendment sets out detailed information disclosure rules to be used when disclosing to the National health information center. In case of monetary and non-monetary considerations, the pharmaceutical company needs to disclose the exact information as to which drug or medicinal product it relates to and the name of the drug or its ATC group. The consideration will need to be further divided into one of the statutory categories:

- clinical trials, stating the name and surname and financial remuneration of the healthcare professional;
- non-interventional clinical study, stating the name and surname and financial remuneration of the professional sponsor;
- study on safety of a humane drug after registration, stating the name and surname of the healthcare professional, who performs the study;
- market survey;
- professional lectures;
- professional consultations;
- participation and registration fees for participation in professional events;
- gifts;
- travel expenses and expenses on accommodation and food;
- other purpose.

The data must be personalized, that means it must be attributable to a particular healthcare professional, or healthcare provider.

The pharmaceutical companies will also disclose and process personal data in the report. As this form of processing is regulated by a specific regulation, it is not necessary to obtain consent of the relevant healthcare professionals. Despite the fact that the consent of the relevant healthcare professionals will be no longer necessary, the pharmaceutical company will become a data controller pursuant to the Act on Personal Data Protection². Consequently, obligations arise for the pharmaceutical companies, the breach of which may be sanctioned by the Office for Personal Data Protection.

Under the AIFP Ethical Codex, certain pharmaceutical companies were already obliged to disclose the transfer of value for the benefit of healthcare professionals on individual basis. However, without the consent of the relevant healthcare professionals, such disclosure was impossible and in practice such consent was often refused. As this requirement is now included in the Act, the pharmaceutical companies no longer have to obtain specific consent.

² Act No. 122/2013 Coll. on personal data protection and on the amendment and supplement of certain acts

Possible sanctions for non-compliance?

Together with the introduction of the new obligations, the Act on Drugs also introduces new sanctions for cases of non-compliance. The Ministry of Health may fine the pharmaceutical company, if it does not submit a report on expenses and propagation to the National health information center or if the report includes false or incomplete information.

In a similar fashion, a third party that facilitates the consideration, is responsible for the non-compliance with the disclosure obligations. A third party commits an offence if, within 30 days of facilitating the consideration, it does not notify the pharmaceutical company as to whom such consideration was given. The third party will also be liable if it submits false or incomplete information.

A fine of **EUR 10,000** can be imposed by the Ministry of Health for the non-compliance with the new obligations. If the breach by the pharmaceutical company is repeated, the Ministry of Health can increase the amount of the fine **up to three times**.

Other relevant changes

Besides the above mentioned transparency rules, the amendment contains two other relevant changes.

Firstly, it is expressly set out that considerations provided in the ordinary course of business are not considered monetary or non-monetary considerations for the purposes of the Act on Drugs. This provision is relevant not only in relation to transparency, but also in relation to discounts and other business practices of the pharmaceutical sector. The question whether, for example, discounts in the ordinary course of business may be considered „monetary or non-monetary considerations“ is, to some extent, therefore partially solved. However, many questions concerning discounts and bonuses still remain open, mainly in connection with the recent decision of the Czech Supreme Administrative Court in the Walmark case.

Secondly, the Act on Drugs in the amended wording expressly states that licenses for wholesale distribution of medicinal products issued in another EU member state are recognized in Slovakia. After several years, the unclear situation and potential conflict with EU law is thus rectified. The legal situation of the pharmaceutical companies operating on the basis of a wholesale distribution permit issued in other member state is clearer now.

Contact details

This document does not represent an exhaustive list of all obligations introduced by the amendment. Should you be interested in more detailed information, we will gladly provide it to you.



Juraj Gyárfáš
Senior Associate

Contact

Tel +421 2 5920 2406
juraj.gyarfas@allenoverly.com



Michal Porubský
Lawyer

Contact

Tel +421 2 5920 2459
michal.porubsky@allenoverly.com