

Amendment to the Act on Medicinal Products and Medical Devices

taking effect on 1 January 2016 introduces several changes aimed at increasing transparency in relationships between the pharmaceutical industry and healthcare providers. Below we summarize the most important of them.



What shall NOT be considered a monetary / non-monetary income?

- A “monetary / non-monetary income” shall, for the purpose of the Act on Medicinal Products and Medical Devices* (“**the Act**”), not include income provided by a holder of the respective license in the ordinary course of business related to the sale or purchase of medicinal products. Unless it is proved that the conditions under which the income was provided can be considered as ordinary course of business and that they relate to the sale or purchase of medicinal products, such income is not considered as provided in the ordinary course of business;
- “Other non-monetary income” in the context of natural rebates / in-kind discounts (which are forbidden to be provided and to be received) shall, for the purpose of the Act, not include refreshment/meals provided during an educational event within the scope set by the Income Tax Act (specifically referring to provisions governing exemption of certain income of an individual from tax);



Extended definition of a pharmaceutical company

- Under the new definition a “pharmaceutical company” shall also include an entrepreneur or a legal entity performing activities in the area of registration, categorization, marketing or intermediation of purchase or sale of human medicinal products not only for a holder of license for production of medicinal products, license for wholesale distribution of medicinal products and holder of market authorization, but also for a holder of pharmacy license;
- Extension of the definition has also an indirect impact on the area of withholding tax, as pharmaceutical companies are explicitly included in the definition of a holder according to the Income Tax Act. Until now, companies providing the above activities for a holder of pharmacy license could be considered as a holder as a result of their position of a “third party”;
- Pharmaceutical companies performing the above activities for holders of pharmacy license are obliged to inform the Health Ministry of the Slovak Republic, (the “**Ministry**”) of the list of such holders until 31 March 2016;



New notification obligations

- The Act introduces new notification obligations for holders of license for production of human medicinal products, license for wholesale distribution of human medicinal products, pharmacy license, pharmaceutical companies, holders of market authorization (“**reporting entity**”) and so called third parties;
- For the purpose of public control of provision of monetary and non-monetary income the reporting entities are obliged to submit a report on expenses on advertising, marketing and on monetary and non-monetary income to the National Health Information Centre (“**NHIC**”) until January 31 and July 31 for the past calendar half-year in electronic form;
- The reporting entities are also obliged to inform the NHIC within the above deadlines that they did not incur any expenses on advertising, marketing and on monetary and non-monetary income for the past calendar half-year, if they did not incur any such expenses and that they did not directly or indirectly provide any monetary or non-monetary income to a health care provider (“**HCP**”);
- If monetary or non-monetary income is provided to a HCP through a third party, the reporting entity is obliged to report to the NHIC selected information about the third party through which the income was provided to the HCP as well as the amount of the provided income;
- A third party through which monetary or non-monetary income was provided to a HCP is obliged to notify the reporting entity of the list of HCPs to which the income was provided within 30 days of its provision. This notification shall also include information which the reporting entity is obliged to report to the NHIC (see above);
- The notification obligations do not relate to selected cases when a HCP is an employer of the reporting entity.



Income provided to HCPs obligatorily included in the report on expenses on advertising, marketing and on monetary and non-monetary income:

- ✓ Name, surname and healthcare occupation or name of the legal entity being a HCP,
- ✓ Name and address of the healthcare facility in which the HCP provides healthcare,
- ✓ Amount and purpose of the income provided directly or indirectly to the HCP and, if the income relates to a medicinal product or a substance also the name of the medicinal product or the name of a therapeutic group of the medicinal product according to the anatomical-therapeutic-chemical group of medicinal products.

Information in the report shall be divided in accordance with the Act – e.g. clinical trials, lectures, registration fees for participation in educational events, gifts, etc.). **The report template can be found on the website of the NHIC in the menu Medical statistics.**

The obligation to report the amount of remuneration of the responsible person for the clinical trial shall not relate to clinical trials started until 31 December 2015.

The reporting entities are obliged to submit the report to the NHIC **for the first time until 31 July 2016.**



How will be the information provided to the NHIC further handled?

- The NHIC publishes the information received from the reporting entities on its website without any delay;
- If a HCP discovers that the information about his monetary or non-monetary income published by the NHIC based on the information received from the reporting entities are incorrect, incomplete or untrue, he may file a petition with the NHIC;
- The NHIC shall decide on the filed petition within 30 days of its filing. In case the petition is relevant, the NHIC corrects or deletes the information without any delay;



Penalties for failure to meet obligations

- Based on the Amendment the Ministry is authorized to impose higher penalties for breaching obligations in the area of marketing activities. The Ministry shall impose a penalty of EUR 10,000 if the reporting entity:
 1. fails to submit the report on expenses on advertising, marketing and on monetary and non-monetary income for past calendar half-year to the NHIC in electronic form within the statutory deadline; or

2. fails to notify the NHIC of that it incurred no expenses on advertising, marketing and on monetary and non-monetary income for past calendar semester within the statutory deadline; or
 3. includes incorrect, incomplete, or untrue information in the report on expenses on advertising, marketing and on monetary and non-monetary income;
- The Ministry shall impose a penalty of EUR 10,000, if the third party:
 1. fails to notify the reporting entity of the list of HCPs to which the monetary or non-monetary income was provided within 30 days of its provision;
 2. includes incorrect, incomplete or untrue information in the list of HCPs;
 - The repetitive breach of obligation by the reporting entity / third party may result in the increase of the penalty up to three times the above amount.

* Act No. 362/2011 Coll. on Medicinal Products and Medical Devices and on the change and supplementing of certain acts as amended

AVENIAS Tax, s. r. o.
Apollo II, Regus Business Centre
Prievozská 4D
821 09 Bratislava

Michaela Stachova
Phone: +421 2 3237 3137
Mobile: +421 915 758 804
michaela.stachova@avenias.com

Jan Vajcik
Phone: +421 2 3237 3137
Mobile: +421 915 758 808
jan.vajcik@avenias.com