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Client Alert

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OGYÉI Guidance on the recent amendments of Act XCVIII of 2006 concerning medicine promotion and interactions with HCPs

The National Institute of Pharmacy and Nutrition ("OGYÉI") issued a Guidance on 20 September which contains useful information on the OGYÉI's interpretation of the recent legislative amendments of Act XCVIII of 2006 ("Medicine Economy Act") concerning medicine promotion, events and contracts with HCPs.

Section 3, point 10 of the Medicine Economy Act

*"3. § 10. 'commercial practice' shall mean any **professional, scientific or other** information, activity, display, marketing or commercial communication aimed at **or capable of** fostering the promotion, prescription, procurement, sale or supply of a medicinal product, dietary supplement or medical aid…."*

The phrase "*or capable of*" in the term of commercial practice enables the OGYÉI to assess not only the purpose of the different activities conducted by companies ("…*aimed at fostering*") but also the result/effect thereof. Therefore, the goal of the promoter of medicinal products (i.e. whether it wanted to engage in promotional or purely professional activities) does not have primary relevance; the OGYÉI will look into the ways the activity has actually been conducted / implemented.

So-called "Medical Science Liaisons" will not be considered as medical sales representatives provided that the information distributed by the MSL and the method of transmission thereof may entirely be separated from the intent of facilitating the sale of medicinal products. Thus, the MSL should not, even indirectly, conduct commercial practice under Section 3, point 10 of the Medicine Economy Act. In the OGYÉI's view, the above may be achieved lawfully if the statements in the materials / information on a medicinal product shared by MSLs are identical with the information contained in the product's accompanying documents (i.e. no off-label information is shared), or if the MSL is restricted to sharing recent scientific information on products prior to marketing authorization which is limited primarily to "pull" type of communication in accordance with the above considerations. According to the OGYÉI's standpoint, the platform for sharing of the most recent scientific information should primarily be the professional journals and the independent scientific congresses.

Section 12 (1) of the Medicine Economy Act

"*The promotion of medicinal products, reimbursed infant formula, follow-on formula, dietary supplements for special medicinal purposes as well as medical aids shall mean **any** commercial practice concerning medicinal products, dietary supplements and medical aids, **in particular** the composition, effects or application thereof, intended for or applied to healthcare professionals with proper entitlement for the prescription, training the use and distribution of medicinal products, dietary supplements and medical aids."*

The OGYÉI will review the recipients (HCPs) of the given activity as well as the activity's purpose and/or capability to foster the sale of medicinal products, medial aids or dietary supplements as decisive factors when assessing whether a respective activity

of the promoter of medicinal products may qualify as medicine promotion, irrespective of the facts as to whom, under which legal relationship, in what position or at which location the activity is being conducted.

The OGYÉI has confirmed that the following activities do not qualify as medicine promotion: (1) commercial price lists as well as information on the price and price margin of a product; (2) commercially usual application of prices and other discounts based on a contract (commercial action) and the related information; (3) stock inspection as well as the placing of orders at wholesalers or pharmacies in order to ensure the uninterrupted supply of medicinal products, medical aids and dietary supplements; (4) information and communication exclusively on charity events or corporate social responsibility (e.g. programs for health protection); (5) provision of information on human health or diseases to HCPs; (6) correspondence and attached materials sent for non-promotional purposes which are necessary for answering specific questions on a medicinal product; (7) factual, informative statements and reference materials which refer e.g. to the change of packaging or warning on side effects under general drug precautions; provided that the above activities [(1)-(7)] do not contain – even indirectly – any statements on medicinal products, medical aids or dietary supplements.

Section 13 (2) of the Medicine Economy Act

*"Persons having a legal relationship with healthcare service providers, or having a legal relationship entitling them to participate in the activity of healthcare providers shall not participate in the commercial practice of the promoter of medicinal products, except the **scientific and/or copyright-protected activities independent from the activity laid down by Section 3, point 10**" (i.e. the commercial practice).*

The OGYÉI interprets the scope of scientific activities broadly to include every activity which is conducted by HCPs using their independent professional expertise, which is of scientific value in the ordinary sense and/or generates scientific results. Therefore, the drafting or revising of educational materials intended for patients, professional proofreading activities or the holding of internal trainings for the employees of the pharma company may also qualify as scientific activities.

This new provision will not hinder pharma companies from engaging HCPs for professional services (such as speaker services at symposia or any other professional-scientific events) and obtaining information or training from them on scientific or other professional issues which require special expertise (not to include any issues / activities directly related to the company's commercial practice).

The provision on conflict of interest set out by Section 13 (2) shall not be applied to activities required for the completion of the mandatory practice time necessary for maintaining the professional exams of HCPs/pharmacists.

Section 14 (2) of the Medicine Economy Act

"*Events organized by the promoter of medicinal products for HCPs entitled to prescribe, provide instruction as to the use of and to distribute medicinal products, medical aids or dietary supplements **are events fostering promotion** that may be organized solely for professional, scientific and educational purposes. **The daily amount of costs spent on such events** by promoters of medicinal products and medical sales representatives may not exceed the limit specified in Section 3, point 8 of the Medicine Economy Act and shall remain secondary to the main purpose of the meeting….*"

Section 14 (2) of the Medicine Economy Act shall apply only to own events of companies. Therefore, this provision shall not apply to independent professional-scientific events organized by third parties. In respect of the latter type of events organized by persons independent from the pharmaceutical industry, Sections 14 (3), (5) and (6) shall apply that contain relevant requirements on sponsorship threshold, event venue or guest list. Given that Section 14 (3) of the Medicine Economy Act does not contain any requirement on the amount of hospitality provided at independent events, the OGYÉI thinks that the law enables Hungary to be a competitive location for international professional-scientific events and a venue for a wide range of professional-scientific events of high quality.

Although the Medicine Economy Act considers every event organized by promoters of medicinal products, intended for HCPs or held with the participation of HCPs as an event facilitating promotion, this shall not necessarily mean that promotional activities under Section 12 (1) are actually being conducted at each of such events. Thus, events facilitating medicine promotion or events actually realizing medicine promotion do not necessarily overlap, thus they shall not be considered synonyms. The OGYÉI will assess all the circumstances of the case to be able to determine whether medicine promotion has actually been conducted at an event, in the case of which additional regulatory requirements shall be applied (such as e.g. the presence of a medical sales rep will be required).

The OGYÉI interprets the provision on event costs narrowly. Only the cost of hospitality as well as the costs closely related to hospitality; i.e. typically the costs of ancillary services provided by the service provider ensuring the hospitality (such as room rental fees, projector, etc.) will be calculated as being part of event costs. Thus, the OGYÉI does not consider speaker fees or organizational costs incurred by service providers not offering hospitality to be included in the costs of event. Thus, in case of events where no hospitality is being offered (such as online events), the daily regulatory threshold for event costs per participant shall not be applied.

When assessing the compliance with the statutory threshold for event costs, the OGYÉI will divide the costs appearing in the invoices issued in relation to the event on items closely related to hospitality with the number of participants who are included in the attendance list and who verified their participation at the event by signing the attendance sheet. The OGYÉI will not take into account the employees of the company organizing the event because based on Section 14 (2) of the Medicine Economy Act, hospitality may only be provided to HCPs who actually attended the event.

The promoter of medicinal products may provide benefits in-kind (e.g. registration fees, accommodation costs, breakfast under the accommodation costs, parking fees) in respect of HCPs' participation in company-organized events. These costs shall not be added to the costs of organization of the event. The addition of such benefits to the event organization costs would render the organization of events impossible because of the low regulatory threshold and, in the OGYÉI's view, this could not have been the legislator's purpose. However, hospitality costs shall always be considered as part of event costs.

Section 14 (3) of the Medicine Economy Act which contains provisions on the sponsorship of independent professional-scientific events had not been amended. The amount spent on the purchase of sponsorship packages shall qualify as sponsorship irrespective of the fact that different services may be included as part of such sponsorship package. However, any fee paid for consideration or the purchase of services (e.g. booth rental) shall not be considered sponsorship provided that they were not sold as part of a sponsorship package.

Section 17 (8a) of the Medicine Economy Act

"It is prohibited to incentivize, compensate or reward in any way the collection, processing or transfer of data on diseases or medication habits under patient support programs or other programs in a personally identifiable way."

In the OGYÉI's view, the purpose of this provision is to set limits to self-serving phishing efforts and to achieve the expectation that patient support programs should not be aimed at collecting patient data in a personally identifiable way and/or incentivizing product sales. This, however, does not preclude the collection and processing of personally identifiable data in case of patient support programs provided that it is essential for achieving the goals of the patient support program.

The above restriction does not apply to HCPs engaging in healthcare activities (including screening programs) because specific rules are applicable to the processing of personal data by them. Similarly, the above provision does not affect the activities of patient organizations/patient advocacy groups, either.

The restriction laid down in Section 17 (8a) shall not be applicable to the lawful data collection of service providers and the participants of patient support programs if such activity is closely related to the purpose of the patient support program, does not have self-serving purposes and/or does not aim at incentivizing sales. Further, this provision does not apply to data collection/data processing activities which are necessary for complying with the regulatory requirements on pharmacovigilance.

The data collected during patient education or other programs (e.g. market research, patient satisfaction surveys) may be transferred to pharma companies in an aggregate form which is not capable of identifying individuals.

To conclude, it is possible to engage HCPs (including not only physicians but also nurses) to participate in patient support programs provided that the above requirements are met; i.e. the data processing is justified, necessary and of legitimate purpose.

It remains possible to provide to HCPs or patients tangible goods necessary for the implementation of the program during or related to patient support programs provided that such tangible goods shall only be given to patients who are already on the particular therapy. Otherwise, the provision of tangible goods may be considered as inappropriate incentive provided to patients that may fall foul of Section 17 (8) of the Medicine Economy Act.

Section 20 (4) and (4a) of the Medicine Economy Act

"With a view to ascertaining the relevant facts of the case, the government body for pharmaceuticals shall have authority to inspect:

a) the contract between a holder of the marketing authorization of a medicinal product, or the manufacturer or distributor of medical aids and promoter of medicinal products contracted,

b) the contract between a promoter of medicinal products and the person qualified to prescribe and supply medicinal products and medical aids, being the other party to the contract,

c) the contract between a subcontractor of a promoter of medicinal products and a person qualified to prescribe and supply medicinal products, and to make inquiries relating to activities which are in fact carried out to ascertain the justification and proportionality between the service and the fee….

(4a) For the inspection referred to in Subsection (4), the parties to the contract, and to the activity shall make available all evidence to show that the activities which are in fact carried out have been effectively implemented in conformity with the relevant contracts, and that they are not considered unlawful commercial practices, further, no unlawful monetary remuneration or material advantage is being provided. No information, activity, communication or display fostering the sale, prescription, distribution of the product of the promoter of medicinal products may be realized as a result of the contractual relationship between the promoter of medicinal products and the HCP."

During its inspections, the OGYÉI will assess the proportionality of contracts concluded with HCPs with a view to the amount/value/actual realization of the professional-scientific services instead of looking solely at the actual monetary amount paid to the HCPs. A disproportion may be established between the amount paid to HCPs and the services provided if the activity conducted by the HCP (e.g. speaker service or the drafting of an article) entirely lacks the scientific basis and the professional quality or the conducted activity does not require the HCPs to carry out professional work or preparation which would justify the remuneration provided for the service.

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