

SIGNIFICANT AMENDMENTS IN PHARMACEUTICAL REGULATION

Recent amendments of Act XCVIII of 2006 („Medicine Economy Act”) have significant impact on medicine and device promotion, interactions with healthcare professionals as well as the pricing and reimbursement of medicinal products. The amendments blur the distinction between promotional and professional/scientific activities and communication which will require assessment of the types of events organized and HCP engagements concluded by pharma companies. The law applies a very low value threshold for costs of organization of events which will significantly hinder companies from organizing any kind of events for HCPs. The amendments were published on 28 June and already entered into force on 29 June requiring fast implementation by companies.

Commercial practice and promotion

The term ‘promotion’ has been amended in the Medicine Economy Act. According to the amendment, “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.*” By adding the terms ‘any’ and ‘in particular’, the Medicine Economy Act clarifies that not only the commercial practices relating to the composition, effects or application of the products, but also any other commercial practice or communication may qualify as promotion.

The term 'commercial practice' has been broadened significantly to include any “*professional, scientific or other information*”, activity, display, marketing or other commercial communication *directed to or capable of* fostering the prescription, procurement, sale or consumption of medicinal products, dietary supplements as well as medical aids. Thus, under the new rules of the Medicine Economy Act, any professional, scientific or other communication which may be capable of fostering the prescription, procurement, sale or consumption of a product may fall under the term of commercial practice. Therefore, it is recommended to assess what kind of effect the extension of the term may have on the activities of companies distributing medicinal products/dietary supplements/medical aids (e.g. the activities of medical departments or MSLs) as not only marketing communication but any professional

or scientific information may also be capable of fostering the prescription, procurement, etc. of the products.

Gifts and other benefits

A conceptual novelty of the new rules is that gifts, material benefits or other benefits in-kind shall only be provided to HCPs in the context of the commercial practice conducted by the promoter of medicinal products. (Further requirements not affected by the amendments are that the gift shall relate to the healthcare activity of the recipient and its value shall not exceed the statutory limit.) Therefore, companies may not raise as an argument that certain gifts and benefits have been provided outside of their commercial practice (e.g. courtesy flowers for an HCP's birthday or "friendly" lunch invitations) because these shall qualify as unlawful practices.

Furthermore, based on the Medicine Economy Act, **"no pecuniary remuneration or benefit shall be provided, offered or promised by the promoter of medicinal products"**. The Medicine Economy Act does not define the term "pecuniary remuneration" or "benefit", thus the question arises whether these also include the payments under the service contracts concluded with HCPs. According to the reasoning of the Medicine Economy Act, the above provision only prohibits *"pecuniary remunerations provided without consideration, without any professional, scientific work"* suggesting that it is probably still possible to engage HCPs for the provision of professional or scientific services.

Events

According to the Medicine Economy Act, any event organized for HCPs by the promoter of medicinal products shall qualify as a promotional event. Events can only be organized for professional, scientific or educational purposes. As a result of the amendment, the difference between promotional and professional/scientific events has practically disappeared. It may give rise to questions such as whether HCPs may be sponsored to participate in events organized by a company; or if this may have an effect on the qualification of the services of HCPs acting as speakers at such events.

An important amendment is that the statutory value threshold defined by the Medicine Economy Act (5 percent of the minimum wage per participant and per day), that was previously applied in respect of hospitality costs only, will now be applied to the total costs of the organization of the event (e.g. speaker fees, room rental fees, technical fees and hospitality). Considering the fact that the statutory threshold

is currently very low, HUF 8370 (EUR 24), the amendment may hinder the organization of events, in some cases may even make it impossible.

Contracts concluded with HCPs

Based on the Medicine Economy Act, *HCPs (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 commercial practice.*

In addition to that, according to the Medicine Economy Act, "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.

Companies will need to assess whether the contracts concluded with HCPs are in line with the above restrictions. Contracts concluded with HCPs may only be intended for scientific activities unrelated to the commercial practice of the company and they shall not result in communication, activities, etc. fostering the promotion of the company or its products.

This amendment reflects the case-law of the Hungarian regulatory authority (the National Institute of Pharmacy and Nutrition; the "OGYÉI"). Several recent decisions of the OGYÉI objected (i) the involvement of HCPs in the training of medical sales representatives such as role-play activities or other trainings; as well as (ii) services agreements for the development or reviewing of promotional materials.

The Medicine Economy Act may also have an even broader interpretation to affect the activities of advisory boards as those may relate to the company's commercial practice and discussions with HCPs in ad boards often go beyond independent scientific activities. The same applies to speaker agreements where the independence of the speaker and the scientific quality of the presentation should be ensured to avoid allegations that the activity relates to the company's commercial practice.

Patient support programs, the prohibition of data collection activities

The new rules of the Medicine Economy Act prohibit *“the fostering, remuneration or rewarding in any form of the collection, processing as well as the transfer of personal data relating to diseases or medication habits in an identifiable way under patient support or other programs.”*

According to the reasoning, the Medicine Economy Act was intended to prohibit the activities fostering drug use as well as data collection activities. Based on former OGYÉI guidelines, a patient support program shall not be directed to the collection of patient data in a personally identifiable way nor may be connected to the fostering of product sale. However, the wording of the Medicine Economy Act is so broad that it may include any patient support programs during which patient data is being processed and in relation to this, the participants (typically HCPs) receive payment. Therefore, for the future, it is of particular importance to assess regulatory compliance during the development of patient support programs and, if necessary, to consult with the OGYÉI.

Other amendments concerning promotion

The provisions on homeopathic preparations have also been amended. In commercial communication on monocomponent homeopathic preparations without indication, no additional information may be communicated other than what is indicated in the label text.

The Medicine Economy Act also clarifies that it is prohibited to publish medicine commercials in programs or publications intended for children.

Amendment of provisions on medicine reimbursement

The Medicine Economy Act defines the term ‘active substance under itemized reimbursement’ as *“medicinal products receiving special in-kind subsidy or reimbursement under a financial framework provided through public procurement by the health insurance body.”* Further, new indications of active substances falling under itemized reimbursement may only be included into reimbursement within the framework of a subsidy-volume agreement.

The health insurance fund may also conclude subsidy-volume agreements for the molecular diagnostic examinations necessary for the application of a medicinal product. Further, the health insurance fund may prescribe an obligation for advance payment in volume-subsidy agreements.

Based on a new rule, the health insurance fund may only include into reimbursement new active substances and the new indication of already reimbursed products within the framework of outcome-based subsidy-volume agreements containing value limits if the 12-month projected average reimbursement amount paid in respect of the product during the next 3 years will exceed the 0.3 percent of the appropriation of the health insurance fund's budget applicable on the first day of January of the reference year. This provision clearly aims at curbing spendings on very expensive medications.

Based on the previously applicable provisions of the Medicine Economy Act, a new active ingredient or a new indication could only be included into reimbursement if the manufacturing price of the product was not higher than the price of the lowest-priced product having the same or similar active ingredient distributed in EU or EEA Member States and the product was reimbursed in at least three of the above Member States. Based on the amendments of the Medicine Economy Act, the mathematical average of *the three lowest-priced medicinal products having the same or identical active ingredient distributed in the EU or EEA Member States shall be taken into account when forming the price of the product for purposes of reimbursement in Hungary.*

The conditions on inclusion into beneficiary reimbursement status have also been amended as the Medicine Economy Act raised the limit to be included in the subsidy- volume agreement from the current HUF 30 million to HUF 100 million.

Further, in case of fixed reimbursement, those medicinal products may also belong to the preferred price range which exceed the daily therapeutic costs of the reference medicinal products with a maximum of 20 percent (currently, a lower 15 percent price difference is taken account).



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