

DG Inspection/Industry Division

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**Circular No 622bis**

To the attention of health professionals, manufacturers, importers, distributors of medicinal products and medical devices, holders of marketing authorisation and/or registration for medicines for human use

<b>Your letter from</b>	<b>Your reference</b>	<b>Our reference</b>	<b>Annex</b>	<b>Date</b> 23 December 2022
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**Re: Reminder of the legislation relating to:**

- **relations between the medicinal product and medical devices industry and professionals in the human health sector;**
- **the sponsorship of scientific events: conditions and visa.**

Dear Madam,

Dear Sir,

I would like to remind you again of some legal provisions as mentioned in Circulars 465, 487, 489, 513 and Communication 518 regarding the entry into force of article 10 of the Medicines Law of 25 March 1964, and of the visa obligation by Mdeon for certain scientific events. After several years, my services have found that the strict provisions are not always respected.

**Background**

Article 10 of the Medicines Law of 25 March 1964 clarifies the rules on bonuses and benefits, in order to ensure that the decision to prescribe, deliver or administer a medicinal product for human use or medical device is not influenced by incentives that have nothing to do with the objective properties of the medicinal product or medical device and/or with the patient's or society's interests<sup>1</sup>.

These rules apply to, among others, professionals in the human health sector who are authorised to prescribe, deliver or administer medicinal products or medical devices (e.g. nurses, dentists, physiotherapists, doctors, pharmacists, paramedics, etc.), as well as to establishments in which medicinal products or medical devices are prescribed, delivered or administered (e.g. healthcare establishments, hospitals, nursing homes, etc.).

<sup>1</sup> More precisely, paragraph 1 of this Article states the following: "It is forbidden, within the framework of the supply, prescription, dispensing or administration of medicinal products, to promise, offer or grant, directly or indirectly, bonuses, financial benefits or other advantages in kind to wholesalers, to persons carrying out brokering activities, to persons authorised to prescribe, dispense or administer medicinal products, as well as to establishments in which the prescription, dispensing or administration of medicinal products takes place." Paragraph 6 also provides as follows: "It is forbidden to solicit or accept, directly or indirectly, bonuses, benefits, invitations or hospitality that contravene this Article or Article 12 and their implementing decrees." Pursuant to paragraph 7, these provisions also apply to medical devices and accessories.

The basic principle consists of a general prohibition on offering, soliciting or accepting bonuses or financial benefits or other advantages in kind, whether directly or indirectly. The law does provide for well-defined exceptions to which the prohibition does not apply.

- **Bonuses and benefits**

Bonuses and benefits of negligible value (of up to 50 euros per benefit [according to the normal market value, VAT included] and up to 125 euros per year, per healthcare professional and per company) are allowed. In addition, the bonus or benefit must relate to the profession of the practitioner, including medicine, dentistry, pharmacy, etc.

- **Sponsorship of scientific events in general**

You are allowed to be invited to attend scientific events and for your attendance costs to be covered, including hospitality, provided that the following cumulative conditions are met:

1. the event is of an exclusively scientific character, in connection with the medical and pharmaceutical sciences; the event is not a promotional activity for a medicinal product or a medical device;
2. the hospitality offered is reasonable and limited strictly to the scientific purpose of the event. A maximum of 23 euros of hospitality per person and per complete hour of the scientific event is permitted in total, with however a maximum of 45 euros per lunch and 90 euros per dinner (may include meals, all drinks, coffee breaks, VAT, room hire, etc.). In other words, a maximum of 135 euros of hospitality for a day of at least six hours of the scientific event is allowed, all inclusive;
3. the place, date and duration of the event should not create confusion as to its scientific nature;
4. attendance costs, including hospitality, may only be covered within the official duration of the scientific event and cannot be extended to other legal entities or natural persons.

- **Sponsorship of scientific events lasting a number of days: the Mdeon visa**

Should a pharmaceutical company or medical devices company wish to intervene, directly or indirectly, wholly or partially, in covering the costs (registration, transport, overnight stays, meals, etc.) of your attendance at a scientific event taking place over a number of consecutive calendar days (including the related hospitality), that company must first obtain a **VISA** from the non-profit organisation Mdeon. The procedure for doing so can be found at [www.mdeon.be](http://www.mdeon.be). Once approved, a visa number will be assigned. The visa number should appear on any document that the company sends to you concerning the event. Therefore **you must always check whether the benefit that you are being offered is covered by a visa.**

For the correct application of the procedure, I would like to emphasise that the visa procedure applies equally :

1. if the sponsorship is offered by a company based abroad. In that case, the foreign company must apply to Mdeon for a visa for you in a timely manner.
2. If the hospitality and/or transportation is offered to you as a consultant or speaker (this has nothing to do with reasonable compensation associated with this legitimate service of a scientific nature);
3. to the direct **sponsorship of organisers** of scientific events (mainly groups or associations of health professionals). The organisers themselves submit a grouped visa application on behalf of their sponsors. You will find all necessary information regarding this procedure on the Mdeon website.

Very important point: visa applications must be submitted no later than the fifteenth working day preceding the first day of the scientific event and before the persons benefiting from the sponsorship



have been invited. Should you want to seek sponsorship from a company, it is therefore important to contact the company at least one month before the scientific event and then check whether the visa has been obtained.

Once the visa has been obtained, **the sponsorship must in practice correspond exactly to the elements in the file** as submitted in the visa application.

If you have any questions, please note that Mdeon can be reached by phone at +32 2 609 54 90 or by email at [secretariat@mdeon.be](mailto:secretariat@mdeon.be).

### Co-responsibility

Finally, I would like to emphasise that the legislator has attributed **criminal co-responsibility** to the company offering a benefit and to the healthcare professionals soliciting it or accepting it. The legislator has provided that infringements are liable to incur fines of 200 to 15,000 euros. These amounts must be multiplied by the applicable percentage stipulated by law. Furthermore, prison sentences of from one month to one year have also been provided for. You must therefore check strictly that any benefit that you solicit or accept complies with the legal provisions.

I am counting on your cooperation in rigorously applying these rules, which are intended to guarantee the support of companies in the ongoing training of healthcare professionals, but which are also intended to limit this support strictly to scientific activities. My departments will oversee compliance with the regulations and take such measures as are necessary in the event of any breaches thereof.

Thank you for your understanding.

Yours faithfully,

Xavier De Cuyper  
Chief Executive Officer