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Circular No 622  
For the attention of professionals in the  
human and veterinary health sector

Your letter dated	Your references	Our references AFMPS/INSP/DIST/	Annex(es)	Date 2015
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**Re: Reminder of the legislation relating to:**

- **relations between the medicinal product and medical devices industry on the one hand and professionals in the human and veterinary health sector on the other**
- **the sponsorship of scientific events: conditions and visa**

Dear Madam,

Dear Sir,

Following Circular 487 on the occasion of the entry into force of Article 10 of the Medicines Law of 25 March 1964 and Communication 518 reminding of the obligation of the visa granted by Mdeon for certain scientific events, I would like to remind you of some of the provisions of this regulation. Some years on, my departments have found that there is not always compliance with its strict provisions.

**Context**

I would like to remind you that the purpose of Article 10 of the Medicines Law of 25 March 1964 is to clarify the rules concerning bonuses and benefits, in order to ensure that the decision to prescribe, deliver or administer a medicinal product 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 interests or those of society<sup>1</sup>.

These rules apply to, among others, professionals in the human and veterinary health sector who are authorised to prescribe, deliver or administer medicinal products or medical devices (e.g. nurses, dentists, physiotherapists, doctors, veterinarians, pharmacists, paramedics, veterinary assistants, 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 mentions the following: 'It is forbidden, within the framework of the supply, prescription, dispensing or administration of medicinal products, to promise, offer or grant, direct 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. It is also forbidden, within the framework of the supply, prescription, dispensing or administration of medicinal products for veterinary use, to promise, offer or grant, directly or indirectly, bonuses, financial benefits or other advantages in kind to persons who supply themselves with medicinal products for veterinary use and, more specifically, to persons listed in article 1, 3 and 7 of the Law of 28 August 1991 on the practice of veterinary medicine.' 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 is a general prohibition on offering, soliciting or accepting bonuses or financial benefits or other advantages in kind, whether directly or indirectly. However, the law provides for specific exceptions to the ban, notably:

- **Bonuses and benefits**

Bonuses and benefits of negligible value (maximum 50 euros per benefit [according to the normal market value, incl. VAT] up to a maximum of 125 euros per year, per healthcare professional and per company) are authorised. Moreover, the bonus or benefit must be connected with the profession of the practitioner, including but not limited to medicine, dentistry, pharmacy, veterinary medicine, etc.

- **General sponsorship of scientific events**

It is permitted for you 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:

- a) the event is of an exclusively scientific nature, in the context of medical and pharmaceutical science; the event is not a promotional activity for a medicinal product or a medical device;
- b) the hospitality offered is reasonable and limited strictly to the scientific objective of the event. A maximum of 20 euros of hospitality per person and per complete hour of the scientific event is permitted in total, with however a maximum of 40 euros for a lunch and 80 euros for an evening meal (all inclusive: may include meals, all drinks, VAT, room hire, etc.);
- c) the location, date and duration of the event does not lead to any confusion regarding its scientific nature;
- d) attendance costs, including hospitality, may only be covered within the official duration of the scientific event and may not be extended to other natural or legal 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 associated hospitality), then that company must first obtain an **VISA** from the non-profit organisation Mdeon. The procedure for doing so may be found at [www.mdeon.be](http://www.mdeon.be). Once approved, an visa number will be assigned. The visa number should appear on every document that the company sends you concerning the event. Therefore, **you must always check whether the benefit that you are being offered is covered by a visa.**

In order that the procedure be correctly applied, I would like to emphasise the fact that the visa procedure applies equally:

- 1) if the sponsorship is offered by a company established abroad. If this is the case, please inform the foreign company in good time that it must apply to Mdeon for a visa for you.
- 2) if the hospitality and/or transport 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 (often groups or associations of health sector professionals). The organisers themselves submit a grouped visa application



on behalf of their sponsors. You will find all necessary information concerning this procedure on the Mdeon website.

One 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.

Please note: Mdeon has opened a free telephone line especially for healthcare professionals: 0800/64001.

### Co-responsibility

Finally, I would like to emphasise the fact 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 infractions 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 scrupulously that every benefit that you solicit or accept complies with the legal provisions.

I am counting on your collaboration 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.

Please accept the assurance of my highest consideration,

**Viviane HENRY,**

Head of Division Distribution  
Xavier De Cuypere  
DG Inspection - FAMHP.  
General Administrator