

YOUR LETTER FROM

YOUR REF.

OUR REF. 21841

DATE 27 FEBRUARY 2008

ANNEX

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Circular n° 513

- to the manufacturers, importers, wholesalers and holders of a marketing authorisation or of registration of medicines
- to the manufacturers, importers and wholesalers of medical devices

SUBJECT **Scientific event including at least one night
Reminder of the obligation of the Mdeon visa**

This document is a translation of the official and signed versions in Dutch and French

Dear Madam, Dear Sir,

At the end of one year of operating, the non-profit-making institution Mdeon has handed over to the Minister its business report for the year 2007. This communication is compulsory and comes within the framework of article 4 of the royal decree of 23 November 2006 enforcing article 10, §3 of the law of 25 March 1964 on medicines.

This way, through the detailed and full data that Mdeon has handed over to the authorities, I note that in 2007, **some companies have never submitted any visa request by Mdeon.**

Be that as it may, referring among others to circular 489 of 19/03/07ⁱ which was sent to you last year, I remind insistently that on 1st January 2007 came into effect article 10, §3 of the law of 25 March 1964 on medicines as amended by the law of 16 December 2004 modifying the regulation relating to the struggle against excessive promotion of medicines. In accordance with this provision, when pharmaceutical or medical devices companies want to intervene directly or indirectly, partially or completely, in the invitation or in the refunding of the participation costs of the practitioners to a scientific meeting including at least one night, **it is compulsory, prior to the meeting, to obtain a visa by the non-profit-making institution Mdeon** – (see www.mdeon.be).

Besides, breaches were noticed regarding the proper application of this legislation. Therefore, I would like to emphasise the next points:

1. This legislation also applies to **foreign companies**. Sponsorship given to a healthcare professional who practises his art in Belgium is therefore subject to prior visa obligation even supposing the funds come from a foreign company. I ask you then to remind your possible parent company, subsidiary, or sister company located abroad, of this obligationⁱⁱ.
2. The prior visa procedure applies also to the **sponsorship paid to the organisers of scientific meetings**, for example in compensation for the presence of your company with a representative and/or a stand. You should know that it is better if the organisers submit by themselves a grouped visa request for all their sponsors ; you should therefore ask them to see it and wait until they give you the visa number to refund the agreed amount. You



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- will find on Mdeon website (www.mdeon.be) a lot of information over this procedure, and in particular a communication intended for the organisers to explain them the procedure.
3. Regarding the sponsorship of participants in a scientific meeting, it is good to remind that the visa procedure also applies in the situation when the **invited professional is a speaker**. The hospitality offered to this person (transport, meals, nights, etc. but not the fees) has to be submitted to the visa procedure for the same reasons as the hospitality given to an ordinary participant. You should know that Mdeon gives the possibility to group certain sponsorships together in the same visa request when your company often calls in the same speaker.
 4. Let's remind again that the visa requests should be submitted **at the latest on the 15th working day preceding** the day of the beginning of the scientific meeting (see however the exception provided by article 17.4 of the Code of practice of Mdeon – www.mdeon.be) **and before having invited** the persons who benefit from your sponsorship. The Mdeon business report shows that in 2007, 30% of the refusal decisions were due to the lateness of the requests.
 5. Even more particularly when sponsorship is paid to the organisers of a scientific event, it is essential that **all the amounts** which will be allocated by your company to this sponsorship must be covered by one or several Mdeon visa(s) asked either by the organiser, either by yourself.
 6. It goes without saying that once the visa is obtained, the situation in the field has to be in perfect accordance with the elements of the file submitted during the request of this visa.
 7. Finally, let's underline for the record that **all the healthcare professionals** are aimed by the prior visa procedure, namely all these whose job leads them to prescribe, deliver or administer medicines or medical devices (doctors, veterinary surgeons, pharmacists, nurses, dentists, physiotherapists, etc.). The same applies for the institutions where take place the prescription, the delivery or the administration of medicines or of medical devices (hospitals, retirement homes, ...).

My services will watch over the strict application of this legislation. It goes without saying that from now on, **the control strategy which will be led by the FAMHP will also take account notably of the information contained in the Mdeon business report.** I hope I can count on your good collaboration.

Yours faithfully,

Xavier De Cuyper
General Administrator

ⁱ See www.afmps.be/ on the right of the screen, section '*Plus sur ce thème*' / *Liste des circulaires* / *Circulaire 489-English version*

ⁱⁱ This circular and circular 489 are available in French and English on www.afmps.be/ on the right of the screen, section '*Plus sur ce thème*' / *Liste des circulaires* / *Circulaire 513* or *Circulaire 489-English version*

This circular and circular 489 are available in Dutch and English on www.fagg.be/ on the right of the screen, section '*Meer over dit thema*' / *Lijst omzendbrieven* / *Omzendbrief 513* or *Omzendbrief 489-English version*