Federal Agency for Medicines and Health Products

Department
Proper Use of Medicines

DATE : 19/03/07

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Circular 489

To the manufacturers, importers, wholesalers and holders of marketing authorizations of medicines and medical devices

Subject: Scientific event including at least one night - Mdeon visa

Dear Madam,
Dear Sir,

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, came into force on January 1st, 2007. In accordance with this provision, **previously to** any event referred to in § 2, 2° of the law of 25 March 1964 and **including at least one night**, pharmaceutical companies and companies of medical devices are bound to apply for a visa to the Minister of Public Health or her or his delegate.

I find it useful to give you some practical information regarding this topic and to point out a few implications of these provisions.

1. In accordance with the royal decree of 23 November enforcing article 10, § 3 of the law of 25 March 1964 on medicines, the non-profit institution **Mdeon** was agreed by the King as organ ensuring the preliminary visa procedure concerning scientific events including at least one night (cf RD of 25 February 2007 concerning the agreement of the organs referred to in article 10, § 3 of the law of 25 March 1964 on medicines - Belgian Moniteur of 9 March 2007). Currently, Mdeon is the only organ agreed for the granting of visa. This means that at this moment, **ALL** requests for visa have to be submitted to Mdeon.

2. Mdeon receives, examines and grants the visa in accordance with the procedure and with the guidelines that this organ worked out and that were approved by the Minister. You will find all useful information relating to the procedure of visa (electronic request form for visa, **deadline to meet** to submit the request, costs…) on the website www.mdeon.be.

3. A visa is required for each pharmaceutical company or company of medical devices that wishes to play a part directly or indirectly, partially or completely, in the invitation or the defrayal of the participation fee for Belgian experts who assist a scientific event including at least one night. This regulation applies to Belgian firms as well as foreign firms. Therefore, you are requested to remind this obligation to your parent offices, as well as to your daughter of sister companies that are established abroad. Please note that the present circular is also available on our website:
   - **in English**: (surf to *www.afmps.be/* on the right hand side of the screen, heading '*Plus sur ce thème '/Liste des circulaires/Circulaire 489-English version*) ;
   - **in Dutch** (surf to *www.fagg.be/* on the right hand side of the screen, heading '*Meer over dit thema' /Lijst omzendbrieven/Omzendbrief 489-Nederlandse versie*) ;
   - **in French** (surf to *www.afmps.be/* on the right hand side of the screen, heading '*Plus sur ce thème '/Liste des circulaires/Circulaire 489-Version française*).

   If they wish so, firms that are established abroad can designate a third person to submit their requests to Mdeon. By way of example, the responsible for information who has been appointed in Belgium, or the Belgian daughter company of the firm or its authorized representative, can carry out this task.

4. All documents concerning a scientific event that will be diffused by a firm, which obtained a visa for this event, must mention the visa number the firm received.

For any additional information, please contact the following services :

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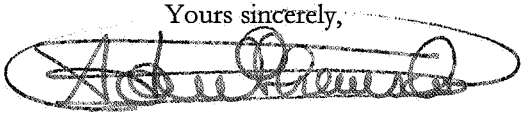
Thank you for your comprehension and your assistance in strictly enforcing these rules.
I also remind you of the principle of penal co responsibility of anyone who promises or offers and anyone who requests or accepts premiums and advantages in contravention of the legislation.

Thank you for your collaboration.

Yours sincerely,



Piet VANTHEMSCHE
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