federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Directorate-general for Medicinal Products
Registration Department

YOUR LETTER
YOUR REF.

OUR REF. DGG/JVC/AL/AVE
DATE 24/07/06

ANNEXE(S) 6

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Circular no. 469
To the marketing authorisation holders for medicinal products for human use

SUBJECT

- **Declaration of conformity for translations of the Summary of Product Characteristics (SPC), of the Leaflet and of the Labelling in view of the Mutual Recognition Procedure (MRP), the Decentralised Procedure (DCP) and the National Procedure (NP) for medicinal products for human use.**
- **Template to be used for editing the leaflet and the labelling in Dutch, French and German.**
- **Readability test for leaflets.**
- **Braille format on labelling.**

PLEASE REMARK THAT THIS CIRCULAR LETTER EDITED IN ENGLISH IS A CORRECT TRANSLATION OF THE FRENCH AND DUTCH VERSION OF CIRCULAR LETTER 469

Dear Sir or Madam

Awaiting the publication of the executing decree of the Law of 1st may 2006 concerning the pharmaceutical review, the registration department of the Directorate-general for Medicinal Products (DGMP) highly recommends you to use the declaration of conformity for translations of the Summary of Product Characteristics (SPC), the Leaflet and the Labelling for both registration files for new applications and variations submitted in view of the Mutual Recognition Procedure (MRP), the Decentralised Procedure (DCP) and the National procedure (NP) for medicinal products for human use.

Concerning the MRP and the DCP this means that you present the translations into Dutch and French of the SPC and the translations into Dutch, French and German of the Leaflet and the Labelling, to the DGMP, and that these translations are accepted on the basis of the declaration of conformity.

Concerning the NP this means that you present the translations whether into Dutch (for marketing authorisation holders on the French language role) whether into French (for marketing authorisation holders in the Dutch language role) of the SPC, and the translations whether into Dutch and German (for marketing authorisation holders on the French language role) whether into French and German (for marketing authorisation holders in the Dutch language role) of the Leaflet and the Labelling, to the DGMP, and that these translations are accepted on the basis of the declaration of conformity.

The declaration of conformity to be used in view of the European procedure (MRP and DCP), and the one to be used in view of the NP are annexed to this circular letter. Both declarations of conformity are available in Dutch, French and English.

In the cover letter of the respective registration file for new application or the respective variation you state your intention to use the declaration of conformity. Declarations of conformity may be used for both existing and new registration files for new applications and variations that lead to amendments of the SPC or Leaflet.

The medicinal information responsible of your company, recognised in Belgium, must sign the declaration of conformity.

The declaration of conformity for the translations of the SPC, the Leaflet and the Labelling, must be submitted as soon as possible, together with the corresponding translations.
Regarding the MRP and the DCP the concerned translations are those of the final approved Summary of Product Characteristics (final SPC), of the approved harmonised Leaflet (approved harmonised PIL) and of the approved Labelling.
Regarding the NP the concerned translations are those of the SPC, Leaflet and Labelling already approved by the DGMP in one national language (French or Dutch).

The translations referred to in the declarations of conformity will be checked by random sampling.
If this check is performed before granting the Marketing Authorisation (MA), you will be requested to make the necessary corrections, in case non-conformities were remarked. In that case, there will be a clock stop during the stage of national closure and you will be held responsible for the delay.
If this check is performed after the MA was granted, the corrections must be submitted by a rectification without delay following consultations between the contact person of the DGMP and the company.

In both cases the remarks will be notified all at once. When any corrections have been submitted, additional comment may be introduced only when it refers to inaccurate or incomplete rectifications introduced by you.

The translations should meet the requirements of Volume 2 of the ‘Rules governing medicinal products in the European Union’, particularly those of the current version of ‘A guideline on the readability of the label and package leaflet of medicinal products for human use’.

In addition, the following must be met:

- Documents must be in MS-Word format.
- On the far left hand corner of the header, the type of document must be mentioned in full in small letters (neither fat nor italic): Summary of the Product Characteristics, Leaflet or Labelling. There should be no other information in the header.
- The ‘page number/total number of pages’ must be mentioned in the far right hand corner of the footer. There should be no other information in the footer.
- The use of logos should be avoided.

The DGMP will only indicate the date of approval in the foreseen section of the SPC and Leaflet.

The MA will be granted only when all translations referred to in the declaration of conformity, have been submitted.

However, only the documents that are in the language of the marketing authorisation holder will be attached to the MA.

If the registration file or variation refers to a medicinal product for human use that is intended to be delivered by healthcare professionals only, a derogation on request can be granted concerning the requirement to mention certain data in the Labelling or Leaflet and concerning the requirement to edit the Leaflet in all three national languages. This is based on article 6septies of the Law on Medicinal Products of 25 March 1964.

Additional information:

The DGMP points out that from now on it will be necessary for the Leaflets and the Labelling submitted under the MRP, the DCP and the NP for medicinal products for human use to comply with the 'CMD(h) QRD template for MR/DC procedures' (drafted for the final harmonised package leaflet and labelling under the MRP and the DCP) as made available on the EMEA website:
(http://www.emea.eu.int/htms/human/qrd/qrdtemplate.htm)

A readability test for leaflets and the inclusion of braille on the package (article 6septies of the Law on medicinal Products of 25/03/64) is being mandatory for all new registration files in view of the NP since 26 May 2006 (consequential to the Law of 1st may 2006 – publication in Belgian Law Gazette on 16 may 2006).

De readability testing is to be performed in any recognised EU language. The results of the test are to be submitted in English for European procedures, and in English or any national language for national procedures in section 1.3.4 of Module I.

Braille is to be mentioned in standard text format in the proposed Labelling, and with dots on the proposed mock-up. You should address the implementation of the braille requirement in section 1.3.6 of Module I.

Regarding readability testing and the mentioning of braille for MA's granted before May 26 2006, and for registration files submitted before May 26 2006, for which no MA was granted on May 26 2006 a transitional period of 5 years is foreseen, as far as MA's in view of the National Procedure are concerned.

Thank you very much for your much-appreciated cooperation.

Sincerely,

Director-general Head of Registration Department