federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Frequently asked questions regarding circular letter 469
06/09/06

DECLARATION OF CONFORMITY REGARDING TRANSLATIONS

In case of a National procedure, from which moment may the translations be presented?

For a national procedure on the French language role, translations may be submitted after the French version of all concerned documents are finalised and approved. The DGMP will notify you when the French version is finally approved.
For a national procedure on the Dutch language role, translations may be submitted after the Dutch version of all concerned documents are finalised and approved. The DGMP will notify you when the Dutch version is finally approved.

Is the declaration of conformity also applicable to national five yearly renewals?

Yes.

For dossier X, I would like (not) to use the declaration of conformity since….?

Please, address all questions and remarks concerning specific dossiers to the assigned dossier manager.

Circular letter 469 limits the data allowed in header and footer, are these limitation also applicable to the version number of the document?

Yes, they are. However, in exceptional cases, you are allowed to mention the version number in the header/footer if this can not be avoided due to your internal quality control on document version numbering.

Do we always have to submit labelling full text in all languages or is a mock-up sufficient?

Yes, the labelling full text in all (Dutch, French, German) languages is always required even if a mock-up is presented.

Do all translations need to be submitted within 5 days after finalisation of the European timetable for MRP procedures?

The circular letters states that all translations need to be submitted as soon as possible. Meanwhile the clock will be stopped until the translations are received by the DGMP and the national dossier closing can start.

Regarding electronic submission, in which folder does the 'declaration of conformity' has to be enclosed?

At submission of the dossier, you only need to mention in the cover letter the intention to use the declaration of conformity at the end of the procedure. The declaration of conformity itself has to be submitted at the end of the procedure and can be enclosed in Module I / Additional data. A scanned and signed version is sufficient, no original signed versions are requested.

BRAILLE

Where can details concerning Braille requirements be found?

For further information, please refer to the Guidance concerning the Braille requirements for labelling and package leaflet, available on the European Commission website:
http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/04_05/Braille_text20050411.pdf

Please note that in the near future the update of the 'Guideline on the readability of the label and package leaflet of medicinal product for human use' will be published on the NtA website. This updated guideline will include the final Braille requirements.

Is the Braille requirement to be fulfilled when introducing the next national five-yearly renewal?

Yes.

Regarding the French text on the labelling, do we need to use Louis Braille or Antoine Braille?

You need to use standard non-contracted Braille format . As letter size 'marburg medium' is highly recommended. Please note that indicating numbers in Braille in the French text need to be done using Antoine Braille.

Are declarations of conformity to be submitted related to a specific dossier or can they be presented as non-dossier related documents?

The declaration of conformity always need to be submitted in view of a specific dossier.

READABILITY TESTING

Is a readability testing to be performed when introducing the next national five yearly-renewal?

Yes.

Where can we find al requirements regarding readability testing?

For further information, please refer to the document: Guidance concerning "consultation with target patient groups" for the package leaflet, available on the European Commission website.
http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/08_05/USERTESTING_20050817.pdf.

Please note that in the near future the update of the 'Guideline on the readability of the label and package leaflet of medicinal product for human use' will be published on the NtA website. This updated guideline will include the final Readability testing requirements.

Is readability testing requested when changing PIL to QRD template lay-out?

Readability testing should be performed within 5 years for existing medicinal products. However, the sooner the better.

Is readability testing a requirement for new MRP variations concerning existing medicinal products when Belgium is RMS?

Readability testing should be performed within 5 years for existing medicinal products. For MRP variations regarding existing medicinal products, the readability testing is highly recommended.

USE OF QRD TEMPLATES

Is the use of the QRD-template for PILs required when introducing the next five yearly renewal?

Yes.

Does circular letter 469 replace circular letter 423?

No, the requirements of both circulars are still applicable. However, for some issues circular letter 423 is contradictory to the QRD templates: for these issues priority has to be given to the QRD-templates.

Circular letter 423 requests to mention registration numbers, telephone number of poisoncentre and delivery modus, these requirements are not specified in the QRD-template, can these data be deleted in the future?

In fact, these are the Belgium PIL blue box requirements and will be published on the NtA website in the near future:

In section **3. HOW TO <TAKE> <USE> X**
If you <take> <use> more X than you should:
If you have taken/used too much X, contact your doctor, pharmacist or the poisoncentre (tel. 070/245 245)

In section 6. FURTHER INFORMATION
Supply classification of the medicinal product: <…>.
Mention the registration number of the medicinal product.

The latest version of the SPC/leaflet of product X contains additional data compared to the requirements of the QRD-template. Do these additional data need to be deleted?

No, they do not except if deletion of one of these data should be the subject of a variation dossier.

Does the date of the last revision still has to be mentioned as required by circular letter 423?

The applicant decide on the mentioning of the date of the last revision. However, the date of the last approval of the document always needs to be mentioned.

Note: date of first registration also needs to be mentioned.