EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 February 2011
EMA/793982/2010
Patient Health Protection

Changes to the provision of final language versions of the product information for medicinal products for veterinary use

1. Introduction

Since the creation of the European Medicines Agency (EMA), the number of applications, and in particular the applications for variations, has increased tremendously. Although the procedures to evaluate applications have been continuously scrutinised and improved, a need for more substantial administrative process improvements has been identified.

In 2008, the EMA changed the procedure for the provision of final language versions of product information for medicinal products for human use. This has resulted in a more efficient process for the preparation and submission of the product information, in particular this has improved the quality of documents sent to the European Commission.

A similar procedure has now been agreed for medicinal products for veterinary use and applicants are required as of opinion adopted at the March 2011 CVMP meeting to provide the final Annexes in all EU languages including Norwegian and Icelandic as bookmarked PDF documents.

Amendments to the Linguistic review process guideline to allow additional time for applicants to prepare the finalised PDF translations have been made.

2. Background

Applicants submit the Annexes (i.e. summary of product characteristics, Annex II, labelling, package leaflet) as one document in Microsoft Word format in English and in all EU languages including Norwegian and Icelandic. These Annexes are converted to the PDF format and bookmarked by the EMA before transmission to the European Commission for Decision making and before publication as part of the EPAR.

It has been the experience of the EMA that:

- applicants do not always strictly follow the mandatory “formatting guidelines” published on the EMA ‘s website (“QRD Convention”);

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- the formatting may be corrupted because of the use of the Microsoft Word format, which is not as robust as the PDF format for transmitting documents electronically, or because the Word file is processed on a computer different from the computer on which the files were created originally;
- converting the Word file into a PDF file may corrupt the formatting and, therefore, render the documents unfit for transmission to the European Commission and publication;
- converting the Word file into the PDF file requires setting bookmarks and document attributes after each conversion. More efficiently, bookmarks and document attributes can also be defined in the Word source files. This needs to be done only once per language version and allows automatic bookmarking of the PDF file for each subsequent conversion. Since the applicant is the owner of the Word source file, the benefits from this feature can only be gained if the applicant provides the product information as PDF files to the EMA;
- the EMA performs a check of the Annexes upon receipt and may have to send the documents back to the applicant for reformatting which may introduce an unnecessary delay to the Commission Decision
- in those cases where the EMA has directly introduced corrections into the applicant's Microsoft Word files to expedite a procedure, these corrected versions are rarely used by applicants for subsequent variations since companies rely on their own in-house version control system for the product information

3. Improved process

To circumvent the identified bottlenecks, applicants should provide the final Annexes in all EU languages and Norwegian and Icelandic as bookmarked PDF documents. The EMA is providing additional guidance on the EMA's website to assist applicants in the preparation of the PDF documents.

The QRD Convention published on the EMA's website should be followed and compliance should be checked and confirmed by the applicant using a dedicated check list form before submitting the final language versions of Annexes in PDF format.

Annexes that do not comply with the formatting guidelines will have to be rejected and the applicant will be required to resubmit them.