Federal Agency for Medicines and Health Products

Department **Registration**

YOUR LETTER FROM

YOUR REF.

OUR REF.

DATE

ANNEX AMM LIGHT TEMPLATE

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Circular letter N° 522
To all Marketing Authorisation Holders for medicinal products for human use

SUBJECT: Simplified marketing authorisation for medicinal products for human use – unique registration number for medicinal products for human use

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

Dear colleague, Madam, Sir,

In this circular letter N° 522 the Federal Agency for Medicines and Health Products (FAMHP) wants to provide you information concerning the correct use of the simplified Marketing Authorization (MA) for medicinal products for human use, as it will be implemented starting from 09/06/2008.

Moreover we want to inform you about the switch from current national registration number towards a unique national registration number for medicinal products for human use.

This circular letter N° 522 is not applicable to the authorizations of parallel import, homeopathic medicinal products and the traditional herbal medicinal products

I. Simplified MA

The simplified MA will include less data compared to the current MA. This is highlighted further in this letter.
The number of MA per medicinal product for human use remains unchanged.
Therefore, you are kindly asked to take into account the rules determining the number of MA per medicinal product for human use as described in 'circular letter 439'.

The replacement of the current MA to the simplified MA for medicinal products for human use is done in following cases:

- when closing a new marketing authorization application
- when closing a packaged of changes to an existing marketing authorization for which an adapted MA is delivered
- when closing a five-yearly renewal of an existing marketing authorization.

Simplification of existing MA is therefore only possible in the above mentioned cases, this is valid for both already submitted as new dossiers.

Adaptation of current MA to simplified MA for medicinal products for human use

a. Content of the simplified MA

- **Composition**

The qualitative composition and quantitative composition is mentioned on the simplified MA following the rules described in circular letter 439 with the following exception: The excipients do not have to be split per part of the medicinal product: e.g. tablet core/coating, content capsule/body capsule. If you dispose of the exact quantities of the excipients per part of the medicinal product, you make the sum, and only mention once the total quantity together with the concerned ingredient. If you do not dispose of the exact quantities per part of the medicinal product, it is allowed not to comply to this rule.
When the same excipient appears in different recipients, the quantity of the excipient should be mentioned per recipient: e.g. powder and solvent in two vials.

- **Analytical references**

The analytical references are no longer to be mentioned.

- **Analytical norms for content of active components**

The release and shelf-life limits are no longer to be mentioned.

- **Denomination**

The denomination is to be mentioned according to circular letter 439. Please keep in mind the requirements concerning denomination as mentioned in the 'QRD annotated template', as available on:
http://www.emea.europa.eu/htms/human/qrd/qrdreference.htm

- **Specific characteristics**

The specific characteristics are no longer to be mentioned.

- **Route of administration**

The route of administration is no longer to be mentioned.

- **Packaging material and packsize**

The packaging material is to be mentioned according to circular letter 439. The pack size will from now on be mentioned on the first page of the MA under the section 'pack sizes' in order to clarify the relation between pack size and corresponding delivery modus. Therefore the name of this section will be changed into 'primary packaging, packaging material and presence of devices' (both measuring and administration devices). The information in this section needs to be in compliance with the information given in the summary of product characteristics (SPC).

- **Shelf life**

The shelf life is no longer to be mentioned.

- **Special precautions for storage**

The special precautions for storage are no longer to be mentioned.

- **Annex to the marketing authorization**

The annex to the MA is replaced by the mentioning of the responsible(s) for batch release in the EEA according to article 40 and 51 of Directive 2001/83EC, at the bottom of the second page.

b. Template simplified MA

The template for the (simplified) MA can be downloaded from following web address:
General website: http://www.fagg.be/ (Choose language 'nederlands'. Click at top 'geneesmiddelen', click left 'humaan gebruik' – 'registratieprocedures', click right 'dispatching-vereisten-eSubmission': consult the section 'formulieren' on this webpage.)
Webpage where template for (simplified) MA can be downloaded:
https://portal.health.fgov.be/portal/page?_pageid=56,1364388&_dad=portal&_schema=PORTAL#formulieren
This template is regularly updated. You can always find the date of the latest update on the template. In annex of this circular letter, you'll find the latest updated template. (You only need to adapt to the latest updated version in case of the first variation to be submitted, with impact of the MA.)

c. Implementation of simplified MA

After the circular letter N° 522 has been published, for medicinal products for human use, a **full completed** 4 pages MA will be asked once, together with the simplified MA proposal, in the following cases:

- new marketing authorization application
- registered medicinal products for which the FAMHP does not dispose of the 4 pages MA up till now (this is the case for both submitted dossiers as news dossiers)

The 4 pages MA proposal is used for the update of the data model of the FAMHP. After verification, the FAMHP will return the 4 pages MA to you with mentioning of the data as completed in the data model.

For medicinal products for human use for which the FAMHP already disposes of a 4 pages MA, only a simplified MA proposal will be asked once this circular letter N° 522 has been published. This is valid for both already submitted dossiers and new dossiers.

In all cases, the first MA delivered and approved by the FAMHP after publication of this circular letter, is the simplified MA.

Once the simplified MA approved by the FAMHP is in your possession, only a simplified MA proposal will be requested for each future dossier dealing with the concerned medicinal product for human use.

!Note: at submission a MA proposal is only mandatory in case of a new marketing authorization application, a type II variation or a renewal.

II. Unique national registration number

At delivery of the first simplified MA the current national registration number will be replaced by a unique national registration number, with following structure:
BExxxxx
BE means that the number is valid in Belgium, and 'xxxxxx' is a unique combination of 6 numbers which is created for each registered medicinal product for human use by an automatic tool.
Once created for a specific medicinal product, this number remains the same independent from any change.

! For each simplified MA only one unique registration number will be created, even in these cases where the current MA mentions more than one registration number.

The implementation of the unique national registration number has the following consequences:

- The reservation of a registration number for a new marketing authorization application is no longer possible after publication of this circular letter.
- For a registered medicinal product for human use, the unique registration number can be reserved at the submission of any kind of variation (IA, IB, administrative, II analytical and II clinical) as well as at the submission of a renewal. The request should be sent by e-mail to the following address uniqueregistrationnumber@afmps.be. The following information should accompany the request: the subject of the request, name of the medicinal

product, the current registration number(s) and a clear mention of the dossier ID for which the registration number is asked.

The unique registration number, asked at the submission of a type IA, IB, administrative and type II analytical variation should be implemented within the 6 months following the date of which the variation can be implemented. This period will be extended to 9 months if the only change to the MA, SPC, leaflet and labelling is the registration number.

For a type II clinical variation and a renewal, the unique registration number should be implemented within the 6 months after the delivery of the MA.

- Already reserved registration numbers (current format) for medicinal products for human use, which may be implemented based on automatic mails but for which the FAMHP has not yet delivered the updated MA, will be replaced by the unique registration numbers when closing the concerned dossiers. This means that the unique registration number has to be implemented within 6 months after the delivery of the MA.

We hope that the information provided in this circular letter sufficiently clarifies both the implementation of the simplified MA and the unique registration number, as far as medicinal products for human use are concerned.

Yours sincerely,

Chief executive

Mr. X. De Cuyper

Head of Registration Department

Mr. A. Lhoir

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