Federal Agency for Medicines
and Health Products

DG POST Authorisation
Proper Use of Medicines

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CONTACT Ann Van Den Broucke
TEL. 00 32 (0) 2 524 83 57
FAX 00 32 (0) 2 524 80 01
E-MAIL ann.vandenbroucke@fagg.be

Circular n° 547

To the marketing authorisation holders

SUBJECT **Communication of data with reference to the actual presence on the Belgian market of medicines authorised by the European Commission (central procedure).**

Dear Madam,
Dear Sir,

As a holder of a marketing authorisation or registration of a medicine you have to inform the Federal Agency for Medicines and Health Products on which date this medicine will actually be marketed. The temporary or permanent suspension of the marketing must be notified as well, at the latest two months before the marketing is interrupted.
This obligation is a result of the application of article 6, §1 sexies of the law of March 25, 1964 on medicines.

This information is also **mandatory** for medicines authorised by the European Commission (central procedure).
We have noticed however that we do not have received all data concerning these medicines. In order to complete our database we request that you inform us for all medicines for which you are holder of a marketing authorisation authorised by the European Commission whether these are available or not on the Belgian market on **September 1, 2009**.

Being on the market is interpreted as being freely available for commercial operators other than the marketing authorisation holder, such as distributors and pharmacists. Medicines which are made available in the form of samples or as a compassionate use or medical need program are not.

We would like to inform you how this information has to be submitted. Please be so kind as to follow these steps:

1. On the FAMHP website (www.fagg.be) (right-hand column – *List of circulars – Annex of circular n° 547 of 29/07/2009)* you will find the following files:

Human (zip)
= an overview of all medicines for human use to which a marketing authorisation has been given by the European Commission, arranged firstly according to the name of the marketing authorisation holder (MAH) and secondly according to authorisation number. Each authorisation number has its own row in the table.

Vet (zip)
= an overview of all medicines for veterinary use to which a marketing authorisation has been given by the European Commission, arranged firstly according to the name of the marketing authorisation holder (MAH) and secondly according to authorisation number. Each authorisation number has its own row in the table.

Each file contains an Access table with following data:

▪ holder of the MA	*mah*
▪ name of the medicine	*mp_name*
▪ pharmaceutical form – packaging – package size	*galenic_form_appl*
▪ authorisation number	*regist_num*
▪ commercialisation	*commercialised*
▪ comments	*comment*

2. Please download the required file on your PC. You can find more details about the way to proceed on the above-mentioned web page (*link to document 'Operating procedure'*).

3. Complete the data for the medicines for which you have a marketing authorisation as follows:

Column '**commercialised**'
Choose for each medicine between the following possibilities (via drop down menu):

Yes	=	medicine is available on the Belgian market on 1/9/2009 (Sep 1)
No	=	medicine is not available on the Belgian market on 1/9/2009

Column '**comment**'

In this column you can put your **comments**, if any
(e.g. data which are not correct in the table).

It is possible that some medicines are not yet appearing in this list because they have been authorised after June 1, 2009. These medicines are considered to be not commercialised on September 1, 2009. Thus there is no need to mention these kind of incompletions.

If medicines which have been authorised before June 1, 2009 are not appearing in the list at all, please indicate this in the e-mail mentioning clearly the name, dose, pharmaceutical form, authorisation number and commercialisation status.

! The first four columns are protected. Only data mentioned in the columns 'commercialised' and 'comment' will be taken into account.

4. Save the MS Access database without changing the file name.

5. Send the completed table **before October 1, 2009** to the following e-mail address: **commercialisation@fagg-afmps.be**.

In the subject field of the e-mail you indicate:
- HUM → in case the list is about medicines for human use
- VET → in case the list is about medicines for veterinary use
- the company to which the data relate to

E.g. *Subject: HUM – name of company*

If you are holder of a marketing authorisation for medicines for both human and veterinary use, please send two separate e-mails.

If you are authorised to complete the attached table for another company as well (e.g. a sister company located abroad, ...) please clearly mention this in the e-mail.

The medicines for which we have not received the requested information will be indicated as 'not commercialised'. It is thus in your own interest to send us a fully completed table.

In order to be able to verify whether all companies have sent us the necessary data, the marketing authorisation holders who do not have medicines falling under the scope of this circular letter are requested to let us know through the above-mentioned e-mail address.

Please also keep us informed **after September 1, 2009** in case of **changes** with regard to the commercialisation, i.e. in case a medicine is marketed in Belgium or in case the commercialisation is suspended.

Such changes are preferably communicated via e-mail to commercialisation@fagg-afmps.be, with the following data clearly mentioned:

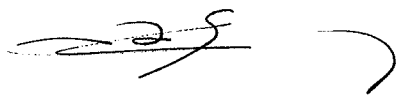
- name of the medicine,
- authorisation number,
- authorisation holder,
- nature of the modification in commercialisation and date of the modification.

The data you have sent us in accordance with the indications of this circular letter will be used to complete our database and to get a clear picture of the Belgian market. They will be adapted according to the changes with regard to the status of commercialisation we are informed about afterwards.
As far as the medicines authorised through the central procedure are concerned, these data are not intended for the application of the sunset clause regulation.

For further questions, please contact Ms. Ann Van Den Broucke (Tel: 00 32 (0) 2 524 83 57 – E-mail: ann.vandenbroucke@fagg.be).

Thank you for your cooperation.

Yours faithfully,



X. DE CUYPER
Chief Executive Officer