# FAMHP strategy on the delivery status

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## I. Introduction

This document describes the strategy used by the FAMHP in granting the delivery status for medicinal products.

The delivery status is defined as:

- the submission or not of a prescription (Art 6 §1bis of the Law of 25/03/1964 & Art. 61 or Art 65 §3 of the RD of 14/12/2006) as well as
- particular mentions for narcotics and medicinal products that present the risk of abuse or addiction (Art. 62 of the RD of 14/12/2006) and
- restricted prescriptions (Art. 63 of the RD of 14/12/2006).

For medicinal products for which the active ingredient is included in the Royal Decree of 06/02/1946 the delivery status is regulated by the provisions of this decree, except for injectable preparations which always have to be prescribed.

The delivery status is indicated on the marketing authorization (MA) of the medicinal product by means of a reference to the relevant articles from the Law of 25/03/1964, the RD of 14/12/2006, or, where relevant, by a reference to the Royal Decree of 06/02/1946.

The general idea behind the FAMHP strategy is that decisions which restrict delivery have to be legally and scientifically founded. Furthermore the restrictions imposed by the FAMHP should not obstruct the strategy on reimbursements as applied by the Belgian National Service for Medical and Disablement Insurance (INAMI/RIZIV) (for example for chronic illnesses).

The strategy was developed in consultation with the relevant FAMHP stakeholders and takes the recommendations from the European level into account.

## II. Delivery status: general rule and exceptions

As a general rule medicinal products having the same active ingredient, the same strength and the same pharmaceutical form should have one delivery status. A difference in delivery status due to a different strength or a different pharmaceutical form is possible if a risk analysis during the evaluation of the medicinal product indicates that it is necessary. If two medicinal products have the same composition but different indications, it is in principle also possible to have a different delivery status.

This means that, as a general rule, for medicinal products with the same active ingredient, the same strength and the same pharmaceutical form no distinction is made between the delivery status of different pack sizes or different packaging forms.

Although it is accepted that for some medicinal products the public health risk may depend on the pack size or packaging form, it is mainly the task of the prescriber to prescribe the most adequate size and/or form of packaging for the patient (e.g. depending on when he/she wants to see the patient again). Also the role of the pharmacist needs to be taken into account within the framework of pharmaceutical care.

For therapeutic classes where the pack size or form of packaging may present a considerable risk (e.g. antidepressants, antipsychotic drugs, combined analgesics and anaesthetics) it should be investigated whether an exception to the general rule is appropriate, e.g. in restricting the

delivery of bigger pack sizes or specific packaging forms to hospitals. Such an exception to the general rule should be laid down in a particular FAMHP guideline (please refer to point V).

## III. New applications for marketing authorisation (MA)

For new applications for marketing authorisation (MA) the delivery status has to be evalued during the procedure.

An internal FAMHP procedure has been developed.

For an application relating to a medicinal product having the same active ingredient, the same strength and the same pharmaceutical form as a medicinal product with an MA which has been obtained following the central procedure, the delivery status granted will be the same as for the centrally registered product.

The FAMHP may issue guidelines in order to make the awarded delivery status of medicinal products more efficient and more transparent (please refer to point V).

During the months before this document was developed, a number of new MAs were granted whereby the delivery status depended on the pack size or packaging form. The FAMHP will however retroactively apply the strategy described under point II and adapt the MA. The procedure is described under point VI.

## IV. Variations to the MA and renewals of the MA

For medicinal products that already have an MA, the delivery status will be adapted during the procedure for renewal or during variation procedures as for the reference to the actual legislation, without imposing additional restrictions with regard to the delivery status, compared to what has been approved in the past.

If the approved SPC explicitly states that the medicinal product has to be prescribed by a specialist or administered in a hospital-like environment, a modification of the delivery status during a renewal procedure is possible in order to avoid discrepancies between the SPC and the MA.

If a FAMHP guideline is issued (see point V) concerning the delivery status of medicinal products containing a particular active ingredient or medicinal products of a particular pharmacotherapeutic group, the MA of the relevant medicinal products will be adapted to this guideline during the next renewal or variation procedure when a new MA document is delivered.

During the months before this document was developed, a number of MA were adapted, i.e. restrictions concerning deliveries were added when a variation or renewal procedure was closed. The FAMHP will however retroactively apply the strategy described above and adapt the MA. The procedure is described under point VI.

## V. FAMHP guidelines

The FAMHP may issue and publish guidelines on the delivery status of medicinal products containing a particular active ingredient or medicinal products within a particular pharmacotherapeutic group.

These guidelines are meant to:

- restrict delivery if such is justified by a potentially significant public health risk;

- harmonise the delivery status of medicinal products with the same active ingredient or within the same group;
- enable the granting of the delivery status of new medicinal products in an efficient and transparent way.

FAMHP guidelines on the delivery status have to be justified, taking into account the potential public health risk. During the development of the guidelines advice is obtained from relevant experts in the area of all relevant stakeholders (e.g. industry, FPS Economy, INAMI/RIZIV, etc.).

When one of the medicinal products within the group for which a guideline is issued has been registered via the central procedure, the delivery status of the whole group will preferably be modified to the statute of the centrally registered product, unless there is a scientific and legal reason for a different approach.

After issuing a guideline the MA of the relevant products will, where necessary, be modified by the FAMHP during the next variation, when a new MA document is delivered, or renewal procedure. MA holders are meant to respect the published FAMHP guidelines, also in the field of advertising.

The guidelines are published on the FAMHP website.

## VI. Procedure for retroactive application

MA holders may request the strategy to be applied retroactively, if:

- a MA was delivered where the delivery status depends on the pack size or form of packaging (please also refer to points II and III) and if that is not justified by a published FAMHP guideline;
- a restriction on the delivery was implemented during the closure of a procedure on variation or renewal of the MA (please also refer to point IV) and if such is not justified by a published FAMHP guideline.

Applications for a modification of the MA should be sent to:

aflevering_delivrance@fagg-afmps.be

The persons responsible for managing this mailbox check whether the application falls within the scope of this procedure. If this is the case, the call center is asked to make a provisional correction of the MA, after which the annotated MA is sent back to the company. If the request for modifying the MA does not fall within the scope of this procedure the applicant is informed.

The provisional correction or the declaration of non-admissibility is made within 30 days after reception of the application.

If a provisional correction is made by the call center, the correction will be finally applied at the closing of the next variation when a new MA document is delivered, or the next renewal.

The change can also be made spontaneously, on the initiative of the FAMHP, when handling the next application for a variation or a renewal.