FAMHP guideline on the mode of delivery of antidepressants, antipsychotics, hypnotics, sedatives, anxiolytics and antiepileptics

(Restriction of delivery in public pharmacies)

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I. Introduction

The general rule is that the FAMHP attributes the same delivery status to medicines that have the same active ingredient, the same strength and the same dosage form. For therapeutic classes where the pack size or form involves a potential risk, an exception to the general rule may be installed, i.e. by restricting larger packs or specific pack forms to hospital use. If there is an exception to the general rule, it should be established within a specific FAMHP guideline (see FAMHP strategy on the delivery status).

This document describes the strategy used by FAMHP to restrict the delivery in public pharmacies of antidepressants, antipsychotics, hypnotics, sedatives, anxiolytics, and by extension also antiepileptics.
The description of the indications in the approved SPC is used to identify whether a medicinal product belongs to one of these categories.

The objective of this guideline is to reduce the risk of accidental intoxication, voluntary intoxication and dependence without unnecessary affecting the treatment compliance or comfort of the patient.

This document is applicable to all medicinal products with a national Marketing Authorisation (MA), independent of the procedure that was use to obtain the MA (national, mutual recognition or decentral).

II. Pack form

Individual pack forms are preferred for the following reasons:

- treatment compliance
- reduced risk of accidental intoxication
- higher threshold in case of suicidal thoughts

Therefore the following strategy will be applied to solid oral forms of antidepressants, antipsychotics, hypnotics, sedatives, anxiolytics and antiepileptics:

- For a new marketing authorisation (MA): the containers are reserved for hospital use.

- For an existing MA:
    - ✓ If the product is presented both in containers and blisters, only the blisters can be delivered in public pharmacies.
    - ✓ If the product is presented only in containers, the delivery of the containers can be maintained in public pharmacies. However, the MA holder is recommended to investigate switching to a blister pack.

III. Pack size

- ### Antidepressants

For solid oral forms, the delivery of antidepressants in public pharmacies is limited to a pack size of maximum 120 units (tablets or capsules).
Pack sizes of 120 units can cover a sufficiently long period of treatment, which benefits the patient compliance.
Furthermore a limitation of the pack size to 120 tablets takes into account the propensity of the depressive patients to suicide and the risk in case of intentional overdose is reduced.
In patients with a clearly observable risk of suicide, it is the responsibility of the doctor to prescribe a small pack size in order to reduce the risk of suicide by a massive intake of antidepressants. It is recommended that companies make small packs of each antidepressant available to public pharmacies.

For oral liquid preparations the amounts are limited to a maximum of 1 month of treatment. The maximum amounts accepted per packaging are:

- mirtazapine : 1,5 g
- escitalopram : 600 mg
- paroxétine : 1,5 g
- sertraline : 6 g

For active substances that are currently not available in oral liquid forms, the mode of delivery will be evaluated as part of the assessment of the application. This guideline will then be adapted accordingly.

For parenteral forms of antidepressants no limitation applies to the sale in public pharmacies.

- ### Antipsychotics

For antipsychotics no limitation on the pack size applies to the delivery in public pharmacies, given the chronic nature of the disease, the absence of abuse and the importance of compliance.

- Antiepileptics

For antiepileptics, no limitation on the pack size applies to the delivery in public pharmacies, given the chronic nature of the disease, the absence of abuse and the importance of compliance

- Hypnotics, sedatives, anxiolytics : benzodiazepines and related products

Given the risk of dependence and abuse of those products, the pack size for delivery in a public pharmacy will be restricted.
The restriction should not hamper a normal treatment so that the duration of the treatment is taken into consideration.
In practice, the maximum pack sizes for the public pharmacy correspond to:

- 30 tablets/capsules per pack for benzodiazepines and related products that have only insomnia as indication.
- 60 tablets/capsules per pack for benzodiazepines that have other indications than insomnia or additional indications (e.g. anxiety, muscular relaxation).
- Flunitrazepam is a specially regulated medicine, for which no pack containing more than 10 tablets can be marketed.
- For oral liquid preparations the amounts are limited to a maximum of 1 month of treatment. Here are the maximum quantities authorized by pack :
    - alprazolam : 45 mg
    - prazépam : 2 g

For active substances that are not currently available in oral liquid forms, the mode of delivery will be evaluated as part of the assessment of the application. This guideline will then be adapted accordingly.

To prevent abuse, the maximum pack size of parenteral forms of benzodiazepines and related products for sale in public pharmacies is limited to 10 units.

IV. Application of this guideline

The strategy described above concerning the pack size and form will be applied immediately after the publication of this guideline for new applications for marketing authorization.

For existing MA:

- Upon publication of the guideline it is recommended that the MAH ensures compliance with this guideline. For example, when a new proposal of MA form is submitted in a variation of the renewal procedure
- From 6 months after publication of the guideline, the MA will be aligned to this guideline by FAMHP while processing of a variation or renewal.
- From 12 months after publication of the guideline, FAMHP may request an adjustment outside an ongoing variation or renewal procedure for products that have not yet been brought into conformity with this guideline.