National Guideline to Marketing Authorisation Holders for the reclassification of a medicinal product for human use from "subject to medical prescription" to "not subject to a medical prescription"

Malta Medicines Authority
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Important to note

Kindly note that it is not within the remit of the Medicines Authority to switch a product from “Subject to a medical prescription” (POM) to “Not subject to a medical prescription” (OTC) unless a variation application is received from the Marketing Authorisation Holder.

Article 71 of Directive 2001/83/EC

Article 71 of Directive 2001/83/EC (Regulation 27 of the Medicines (Marketing Authorisation) Regulations) provides the criteria for classifying a medicinal product as subject to medical prescription. Thus a medicinal product which meets these criteria is subject to a medical prescription and a medicinal product which does not meet these criteria is not subject to a medical prescription, as stated in Article 72.

Principles

-National Decision

-Guideline was created to simplify the switches as previously all switches were a national type II complex variation

-Guideline applies to National and European approved products in Malta **only**

-Centralised have their own procedure and guideline

Procedures affected

- National Procedures including Article 126a's
- Decentralised/Mutual Recognition procedures
- Parallel Procedures as these follow the reference product with the MA in Malta.
- **Parenteral Products** will not be considered for switches

Procedure

- A type II national variation has to be submitted with proposed mock ups and names included in the submission.
- In cases where both the POM and OTC products are to be kept on the licence then a separate MA number will be given. Both products would need to have distinct and separate packaging.
- In cases of shared packs with other member states (MS) any pending variations relating to name changes in these MS should all be finalised before submission of the national variation.

Guideline points

The guideline does include information which the applicant should consider before applying for a switch.

These include:

1. *Safety*
2. *Self- assessment*
3. *Risk and consequences of incorrect use*

Pack sizes in OTC products

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- Pack size should be related to the duration of treatment
- A small pack size has been shown to restrict the availability of the product for misuse, overdose or a delay in seeking medical attention.

Data Requirements I

Type II **simple** variation if the product is POM in Malta but already authorised as OTC in another EU Member State.

Requirements –Type II Simple VAR

- Updated expert overview
- Updated product information to reflect the OTC status
- Proof of the legal status as OTC in the said EU state

Expert Overview-I

Critical analysis of the proposed availability of the product in question as OTC with respect to:

1. The maximum single dose
2. The maximum daily dose
3. Strength
4. Pharmaceutical form
5. Packaging and circumstances of use

Expert Overview-II

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- The safety profile of the drug as well as any data from post marketing studies locally and abroad
- Any published literature (if available)
- Any information on adverse drug reactions including experience of use without medical supervision in another EU state

Data requirements II

Type II **complex** variation for products already authorised in Malta as “subject to a medical prescription” for a switch to “not subject to a medical prescription”.

Updated expert overview

The expert should provide a critical analysis of the proposed availability of the product without a medical prescription with the dose and indications as already authorised, unless the pack size or the strength is decreasing. The expert should take a clear position, support the switch in light of current scientific knowledge and demonstrate why none of the criteria (with respect to safety) that determine classification for supply subject to a medical prescription apply to the product.

Safety needs to be discussed in line with the eight points discussed in the guideline section 3.b.i.

Safety

1. Experience in terms of patient exposure
2. Adverse Reactions
3. Safety Profile- Post marketing studies, clinical trials, recent literature
4. Potential for and consequences of drug interactions
5. Any consequences concerning misuse
6. Consequences of use of the product by a patient who has incorrectly assessed his condition or symptoms.
7. Incorrect or delayed diagnosis
8. Suitable time period for treatment in line with the indication should be justified.

Product information

Product information for OTC products differs from POM products.

1. It must contribute towards safe and effective use of the medicines.
2. Contraindications, interactions, warnings and precautions need to be clear and in layman's terms
3. Situations in which the product must **not** be used should be clearly stated
4. Use of the product and circumstances when referral for medical advice is appropriate should be listed clearly.
5. Instructions for use should be on the outer packaging or in cases where there is no outer carton- on the immediate packaging.
6. The product information must be written and presented in a way that is easily understood.

Summary

Two scenarios:

Type II simple – updated product information, proof of OTC status, expert overview

Type II complex- product information, expert overview

Thank you

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Questions?