MEDICINES EVALUATION BOARD

Policy document: Replica marketing authorisation

MEB 15

28 October 2014

REPLICA MARKETING AUTHORISATION FOR PRODUCTS THAT ARE IDENTICAL TO PHARMACEUTICAL PRODUCTS THAT HAVE ALREADY BEEN AUTHORISED

Introduction

The following text will specify under which conditions a product can be considered a “replica”. The product for which the application for a replica marketing authorisation is requested will be referred to as “product A” and the (future) license holder will be called “(legal) person A” or “replica applicant”. The original product will be referred to as “product B” and the license holder of that product will be called “(legal) person B” or “replica granting party”.

Since 2003, it is no longer possible to obtain a new marketing authorisation via the replica marketing authorisation procedure. The marketing authorisation for replica products that have already been authorised will remain valid, unless one of the situations described under condition 9 occurs.

Conditions

1. The product A is equal to product B. This means that:
   1.1 product A is prepared entirely according to the dossier of product B and meets all the specifications recorded in the dossier of product B,
   1.2 product A is prepared by the same manufacturer(s) as product B and is released by the same manufacturer as product B,
   1.3 the nature of the packaging (packaging forms and materials) and packaging size of product A are identical to those of product B.

2. The same Product Information (SmPC) as for product B applies exclusively for product A. The Product Information SmPC for product B has been appended to the marketing authorisation of product A.
   This means that product A does not have its “own” SmPC text, but that the SmPC text for product B is linked to product A.

3. Package leaflet/label text:
   3.1 The text for the package leaflet and the label of product A is identical to that for product B, with the exception of the following information that applies specifically to product A: the name of the product, the name and the address of the marketing authorisation holder and the RVG number.
   3.2 The package leaflet and label text of product B meet the requirements set out in the policy documents Package leaflet of pharmaceutical products (MEB 5) and Labelling of pharmaceutical products (MEB 6).

4. The legal status of supply of product A is the same as that of product B.

5. (Legal) person B must inform (legal) person A of all variations relating to product B. In other words, the replica product follows the original in everything and the initiative rests with the marketing authorisation holder of product B.

6. A summary of the Pharmacovigilance System Master File (PSMF) must be added to the dossier for replica marketing authorisations. It is permitted to outsource - partially or completely -the obligation regarding the PSMF to the replica granting party. In such circumstances, both the replica applicant and the replica granting party must draft a statement to that effect. The statement must state clearly which activities regarding pharmacovigilance will be outsourced and which will be performed by the replica applicant himself. However, the obligation to append the summary of the PSMF to the authorisation dossier remains in full force. If the obligation regarding the PSMF is outsourced, then the statements from the replica granting party and the replica applicant must be submitted along with the variation in order to append the summary of the PSMF to the authorisation dossier.

7. For the marketing authorisation, the same Product Information (SmPC) as for product B applies exclusively to product A. This means that for the replica product, all products listed in this SmPC are authorised. This also means that the various products must be authorised under one name, namely that of (legal) person A. The products must be derived from products that are authorised under the name of one and the same authorisation, holder (legal) person B.

8. The marketing authorisation of product A will be suspended if the marketing authorisation of product B is suspended and for the same period as the suspension pertaining to the marketing authorisation of the latter product.

9. The marketing authorisation of product A will be revoked
   - 9.1 if the marketing authorisation of product B is revoked or expires,
   - 9.2 at the request of (legal) person A,
   - 9.3 following receipt of a letter from (legal) person B, stating that the permission granted to (legal) person A to market the product has been revoked,
   - 9.4 if one or more of the elements in the statement appended to the application for authorisation by (legal) person B is/are (found to be) no longer correct,
   - 9.5 if, upon transfer of the authorisation for product B from (legal) person B to another (legal) person B*, this (legal) person B* does not accept the rights and obligations regarding the replica marketing authorisation of product A.

   Exception to the revocation of product A is described in the Addendum (see end of document)

10. If the marketing authorisation of product B is revoked and then authorised once more following an objection procedure under the Dutch General administrative law act, then product A, for which the marketing authorisation was revoked pursuant to 9.1 above, will also be reinstated in the relevant register under the original number on the same date.

11. (Legal) person A requests the suspension or revocation of the marketing authorisation for product A, in the event that the situation described above under points 9 and 10 actually occurs in relation to product B.

12. Transfer of the authorisation for product A from (legal) person A to another (legal) person is not allowed.

13. During the transfer of the authorisation for product B from (legal) person B to another (legal) person B*, (legal) person B will inform the MEB immediately if this (legal) person B* does not accept the rights and obligations regarding the replica marketing authorisation of product A.

Comments

1 The authorisation number is composed of two sections, separated by an = sign: an RVG number for the replica product (product A), followed by the RVG number of the original product (product B).
2 If the dosage units (for example, capsules) of product B are embossed, then only the text may differ. The composition of the embossing ink may not differ.
3 If tablets of product B carry an imprint, then the imprint on the tablets of product A is allowed to differ.
4 Differences between products A en B with regard to break lines or break crosses are not permitted.

Variation of package leaflet of the reference product

In the event of a variation of the package leaflet of the reference product, the license holder of the replica product must submit a variation within 3 months (see date of approval in section 10 of the SmPC of the reference product or the date at the bottom of the package leaflet), in order to align the package leaflet with the package leaflet of the reference product.

ADDENDUM

Since the replica granting party (holder of product B) is responsible for the dossier, as a general rule A1 (replica applicant) is not permitted to sell the dossier on to A2 (new replica applicant). However, an exception will be made if A1 is affiliated to B1 and B1 is taken over by B2. In that case (take-over of replica supplier B1 by B2), B2 has the option to become the new replica supplier. A1 is then permitted to sell the dossier on to A2, whereby B2 and A2 again become affiliated by means of a “mother-daughter company”.
It is important to ensure that there are enough distinguishing features in the trade name.