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1 Introduction
This guidance document explains the requirements that must be fulfilled for the authorisation of co-marketing medicinal products or for authorised co-marketing medicinal products.

2 Objective
This guidance document explains the requirements pertaining to the authorisation and lifecycle of co-marketing medicinal products and the consequences of certain changes to the basic product. The Information sheet replaces all publications in the Swissmedic Journal on the subject of co-marketing medicinal products.

3 Scope
The guidance document applies to the Authorisation division of Swissmedic in the process for co-marketing medicinal products.

4 Legal basis
Articles 34 ff of the Ordinance on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO).
5 Other valid documents

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6 Description

6.1 Co-marketing medicinal products

A co-marketing medicinal product is a medicinal product which, on the basis of written authorisation of the authorisation holder of an existing authorised medicinal product (basic product), can be substantiated by the authorisation documentation of that product. Detailed statements on the permitted deviations from the basic product are provided in sections 6.3.2, 6.3.3 and 6.3.6.

A co-marketing medicinal product can be authorised by the Agency merely on the basis of notification. The authorisation holder of the basic product can also be the applicant for the co-marketing medicinal product.

The number of co-marketing medicinal products per basic product is not limited.

6.2 Basic product

The basic product must be an existing authorised medicinal product that is substantiated by its own documentation.

A co-marketing medicinal product or a parallel-imported product cannot serve as a basic product for another co-marketing product.

If the authorisation holder of the co-marketing medicinal product wishes to change the basic product, the authorisation of the current co-marketing medicinal product must be discontinued and an application submitted for the new co-marketing product with the new basic product. A new product name must be selected.

6.3 General requirements

6.3.1 Authorisation status of basic product versus co-marketing medicinal product

a) A co-marketing medicinal product can be authorised only on the basis of an existing authorised basic product. If the basic product is not yet authorised at the time the application for the authorisation of the co-marketing medicinal product is submitted, the application will not be considered.

b) If the basic product is authorised only for distribution abroad, the co-marketing medicinal product may also only be authorised for distribution abroad, i.e. an authorisation for distribution in Switzerland (main authorisation) is not possible for the product.

c) If the basic product has one dosage strength (DS) that is authorised for distribution abroad, while a second dosage strength possesses a main authorisation, this should also apply to the co-marketing medicinal product. Corresponding changes to the authorisation status of the basic product should also be applied to the co-marketing product.

d) If there is a main authorisation for the basic product, just one application for authorisation needs to be submitted for the whole co-marketing medicinal product (all dosage strengths) for authorisation for distribution abroad.

e) If the authorisation of the basic product is suspended or revoked, this will result in simultaneous suspension or deletion of the co-marketing medicinal product.
f) If it is decided that the authorisation of the basic product is to be renounced or no longer renewed, then the authorisation of the co-marketing medicinal product must also be renounced at the latest when the authorisation of the basic product expires. Another option for the continuation of the authorisation of the co-marketing medicinal product is described in section 6.4.

g) If the main authorisation of the basic product is converted into an export authorisation, the main authorisation of the co-marketing product must likewise be converted into an export authorisation by means of a notifiable variation no. 6.

6.3.2 Pack sizes, dosage strengths and pharmaceutical forms

The co-marketing medicinal product should not have more pack sizes than the basic product. On the other hand, the co-marketing product can have fewer pack sizes than the basic product, provided the information relating to indication and dosing regimen in the Information for healthcare professionals, Patient information and Information for veterinary medicinal products matches the corresponding information for the basic product (see also section 6.3.5).

A co-marketing medicinal product may not have more or fewer dosage strengths than the basic product. In other words, basic product dosage strengths that are intended only for distribution abroad must also apply to the co-marketing product, likewise only for distribution abroad.

If grouped product information texts with several pharmaceutical forms exist for the basic product (medicinal product range), a corresponding co-marketing medicinal product must be authorised (or requested) for each pharmaceutical form included in the grouped texts (see also section 6.3.5).

Additional pharmaceutical forms not included in the basic product range are not permitted. Alternatively, the authorisation holder of the basic product must submit separate texts on the individual pharmaceutical forms and these must be approved before the co-marketing medicinal product can be authorised (see section 6.3.5).

6.3.3 Packaging – primary and secondary packaging

As a general rule, the information on the packaging items must match the information on those of the basic product. The information on active substances and excipients (declaration) must be identical to that for the basic product. The declaration of lactose is not permitted if the basic product has not declared this.

Minor textual differences from the basic product are permitted. For example, the wording of the note for children may differ, but the meaning must be identical ("keep out of the reach of children" or "keep away from children"). Under "Storage instructions", the words "keep" versus "store" are both accepted according to the respective corporate identities of the companies concerned. The design and the authorisation holder can also be different. Generic blister pack labelling according to corporate identity is also accepted. For human medicines, the wording of the brief description may differ, but the meaning must be the same. If the basic product does not include a brief description on the carton, the co-marketing product may nevertheless include a brief description.

The co-marketing medicinal product may depict the pharmaceutical form on the carton, even if this is not the case for the basic product.

However, additional information concerning the properties of the medicinal product, such as flavour (e.g. flavour: orange) may be included in the Information for healthcare professionals, Patient information and Information for veterinary medicinal products, or on the carton of a co-marketing medicinal product, only if a corresponding statement has been approved for the basic product.

The statements and text on the carton must be substantiated by the authorisation documents for the basic product. In other words, compared to the basic product, no extra statements may be added on the carton of the co-marketing medicinal product (see above for exception).

6.3.4 Imprint on solid dosage forms

A co-marketing medicinal product must also be identical to the basic product in respect of the manufacturing process. If something is printed on the solid dosage form of a basic product, the same imprint must also appear on the co-marketing medicinal product. Printing the product name or the logo of the authorisation holder of the basic product on a solid dosage form of the co-marketing medicinal product can potentially be misleading. Therefore, a co-marketing medicinal product with an
imprint of the product name or the logo of the authorisation holder of the basic product on the solid dosage form is not permitted.

6.3.5 Medicinal product information

The Information for healthcare professionals, Patient information and Information for veterinary medicinal products for the co-marketing product must be identical to that for the basic product, with the exception of the name, authorisation number, pack sizes and authorisation holder. The applicant must confirm that the Information for healthcare professionals and Patient information / Information for veterinary medicinal products of its co-marketing medicinal product is identical to the texts of the Information for healthcare professionals and Patient information / Information for veterinary medicinal products most recently approved by Swissmedic on (day/month/year) for the basic product, and that only the following permissible modifications or deletions approved in comparison to the basic product have been made:

- Replacement of the preparation name, authorisation number and authorisation holder of the basic product by the preparation name, authorisation number and authorisation holder (if applicable) of the co-marketing medicinal product.
- Deletion of the pack sizes not requested for the co-marketing medicinal product.

If grouped texts (Information for healthcare professionals and Patient information / Information for veterinary medicinal products) exist for the basic product, authorisation as a co-marketing medicinal product must be requested for all the pharmaceutical forms mentioned in the grouped text. Alternatively, the authorisation holder of the basic product must submit separate texts on the individual pharmaceutical forms, and these must be approved, before the co-marketing medicinal product can be authorised.

For the Information for healthcare professionals, Patient information and Information for veterinary medicinal products, the same date stated for the basic product must also be entered for the co-marketing medicinal product under "Date of revision of the text" (both for the first authorisation and all subsequent adaptations).

6.3.6 Basic product variations

If variations are made to the basic product that also affect the co-marketing medicinal product, these should be applied to the co-marketing product. The variations to the co-marketing medicinal product should be reported to the Agency within 30 days of the approval of the changes to the basic product. The variations approved for the basic product must also be taken over unchanged for the co-marketing medicinal product. To enable the authorisation holder of the co-marketing medicinal product to comply with these requirements, the authorisation holder of the basic product must inform it of the impending and subsequently approved variation. For each variation (application) to the basic product, a notifiable variation no. 6 should be submitted for the co-marketing medicinal product. This practice applies to all variation applications approved for the basic product. It is not permitted to submit a corresponding application for the basic product and the co-marketing medicinal product at the same time. The variation to the basic product must have been approved beforehand.

Additional secondary packers may be requested for the co-marketing medicinal product. This should be mentioned accordingly in the cover letter and in the Manufacturer information form. Corresponding valid GMP certificates should also be submitted.

6.4 Conversion of a co-marketing authorisation into a stand-alone authorisation

Any deletion or suspension of the basic product also requires the identical measures to be applied to the co-marketing medicinal product.

If no doubts have been raised regarding drug safety, the authorisation holder of the co-marketing medicinal product has the option of converting the authorisation as a co-marketing product into a stand-alone authorisation. The corresponding requirements are listed in the guidance document on Formal requirements.
The authorisation holder of the existing co-marketing medicinal product must now have at its disposal all the documents it requires to fulfil its healthcare-related responsibilities, and accept all the obligations associated with the authorisation of a stand-alone product. The documentation for the basic product can be taken over for this purpose.
A status change cannot be made without the written consent of both companies.

6.5 Changing status between basic product <-> co-marketing medicinal product

Changing the status between a basic product and a co-marketing medicinal product is permitted. The new authorisation holder of the basic product must submit all the documents described in section 6.4. The future authorisation holder of the co-marketing medicinal product must demonstrate conformity with the future basic product, i.e. the same authorisation documentation must be submitted as for a regular application for authorisation of a co-marketing medicinal product (see guidance document on Formal changes).