swissmedic

Guidance document
Authorisation of co-marketing medicinal product

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List of contents

1 Terms, definitions, abbreviations

1.1 Definitions

1.1.1 Co-marketing medicinal products

A co-marketing medicinal product is a medicinal product which, on the basis of written authorisation of the holder of authorisation for an existing authorised medicinal product (basic product), can be substantiated by the authorisation documentation of that product. A co-marketing medicinal product can be authorised by Swissmedic simply on the basis of notification.

1.1.2 Basic product

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

1.2 Abbreviations

FeeO Swissmedic	Ordinance of the Swiss Agency for Therapeutic Products of 21 September 2018 on Fees (SR 812.214.5)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure (SR 812.212.23)

2 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. As this is a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals.

2.1 Legal framework

Article 34ff of the *Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure* (TPLO).

3 Objective

Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner.
This guidance document explains the requirements pertaining to the authorisation and life cycle of co-marketing medicinal products and the consequences of certain changes to the basic product. This information sheet replaces all publications in the Swissmedic Journal on the subject of co-marketing medicinal products.

4 Scope

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

5 Other valid documents

- *Variations and extensions HMP HMV4*
- *Variations VMP HMV4*
- *Formal requirements HMV4*
- *Overview of documents to be submitted HMV4*
- *Manufacturer information HMV4*
- *Time limits for authorisation applications HMV4*

6 Description

6.1 Description of the co-marketing medicinal product

The co-marketing medicinal product must be fundamentally identical to the basic product. Detailed information on the permitted deviations from the basic product is provided in the sections *Pack sizes, dosage strengths and pharmaceutical forms*; *Packaging – primary and secondary packaging* and *Product information*.
The holder of authorisation for the basic product can also be the applicant for the co-marketing medicinal product.
There is no limit on the number of co-marketing medicinal products per basic product.

6.2 Description of the basic product

A co-marketing medicinal product or a parallel-imported product cannot serve as a basic product for another co-marketing product.
If the holder of authorisation for the co-marketing medicinal product wishes to change the basic product, the authorisation for the current co-marketing medicinal product must be discontinued and an application submitted for authorisation of the new co-marketing product with the new basic product. A new name must be chosen for the new co-marketing product.

6.3 Authorisation status of basic product and 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 authorisation of the co-marketing medicinal product is submitted, the application will not be considered.
b) If there is a main authorisation for the basic product, the option exists to apply for either a main authorisation or export licence for the entire co-marketing medicinal product (all dosage strengths).
c) If the basic product is only authorised for export, the co-marketing medicinal product may also only be authorised for export, i.e. the co-marketing medicinal product cannot be authorised for distribution in Switzerland (main authorisation).
d) If the basic product has one dosage strength that is authorised for export and a second dosage strength with main authorisation, this should be applied to the co-marketing medicinal product. Relevant changes to the authorisation status of the basic product should also be applied to the co-marketing product.
e) If the authorisation of the basic product is suspended or revoked, the co-marketing medicinal product will be simultaneously suspended or deleted.
f) If the authorisation holder decides to discontinue or no longer renew authorisation for the basic product, authorisation for the co-marketing medicinal product must also be discontinued at the latest when the authorisation for the basic product expires. The section *Conversion of a co-marketing authorisation into a stand-alone authorisation* describes an alternative option for continuing authorisation for the co-marketing medicinal product.
g) If the main authorisation for the basic product is converted into an export licence, the main authorisation for the co-marketing medicinal product must also be converted into an export licence (see forms *Variations and extensions HMP HMV4*, variation A.101 b / *Variations VMP HMV4,* variation A.101).

6.4 Pack sizes, dosage strengths and pharmaceutical forms

The co-marketing medicinal product must not have more pack sizes than the basic product. Conversely, the co-marketing product can have fewer pack sizes than the basic product provided the information relating to the 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 *Product information* section). When using the co-marketing medicinal product, it must always be possible to follow the same dosage recommendation and duration of treatment as for the basic product.
A co-marketing medicinal product may not have more or fewer dosage strengths than the basic product (see also section *Authorisation status of basic product and co-marketing medicinal product*.
If grouped product information texts covering several pharmaceutical forms exist for the basic product (medicinal product range), a co-marketing medicinal product corresponding to each pharmaceutical form included in the grouped texts must have been authorised or requested (see also *Product information* section). Additional pharmaceutical forms not included in the basic product range are not permitted.
Alternatively, the holder of authorisation for the basic product must submit separate texts for the individual pharmaceutical forms, which must be approved before the co-marketing medicinal product can be authorised (see *Product information* section).

6.5 Packaging – primary and secondary packaging

As a general rule, the information on the packaging must match the information on the packaging of the basic product. The information on active substances and excipients (declaration) must be identical to that for the basic product.
Minor deviations from the text for the basic product are permitted. For example, the wording of the note concerning storage out of children's reach may differ, but the meaning must be identical ("keep out of reach of children" or "keep away from children"). The words "keep" and "store", according to the corporate preference of the company concerned, are both accepted in the "Storage instructions" section. The design and authorisation holder can also be different. Generic blister pack labelling in line with the company's corporate identity is also accepted. 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 medicinal 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. This also applies conversely.
However, the Information for healthcare professionals, Patient information, Information for veterinary medicinal products or carton of a co-marketing medicinal product may only contain additional information on the properties of the medicinal product, such as its flavour (e.g. "orange flavour"), if a statement to this effect 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, the carton of the co-marketing medicinal product may not carry additional statements compared with the basic product (see above for exceptions).

6.6 Imprint on solid dosage forms

A co-marketing medicinal product must also be identical to the basic product in terms of its 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 name of the medicinal product of the basic product on a solid dosage form of the co-marketing medicinal product is potentially misleading. Therefore, solid dosage forms of co-marketing medicinal products must not carry imprints of the name of the medicinal product of the basic product. In this case, the co-marketing medicinal product may only be authorised if the relevant imprint is removed from the basic product.

6.7 Name of the medicinal product

The name of a co-marketing medicinal product must satisfy the requirements of Art. 9 para. 4 TPO. In particular, the name of the medicinal product must not contain the core brand of the basic product (example: core brand xy thyme tea (basic product) - core brand xy cough-relieving tea (co-marketing medicinal product)).

6.8 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. Applicants must confirm that the Information for healthcare professionals and Patient information / Information for veterinary medicinal products of their co-marketing medicinal product is identical to the texts of the Information for healthcare professionals and Patient information / Information for veterinary medicinal products for the basic product most recently approved by Swissmedic on (day/month/year), and that only the following permissible modifications or deletions have been made in comparison to texts for the basic product:
Replacement of the name, authorisation number and holder of authorisation for the basic product by the name, authorisation number and holder of authorisation (if applicable) for the co-marketing medicinal product.
Deletion of 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 holder of authorisation for the basic product must submit separate texts for the individual pharmaceutical forms, which must be approved before the co-marketing medicinal product can be authorised.
The Information for healthcare professionals, Patient information and Information for veterinary medicinal products for a co-marketing medicinal product must always carry the same "Date of revision of the text" as the basic product (both for the first authorisation and all subsequent adaptations).

6.9 Authorisation of co-marketing medicinal product

The formal requirements for new applications for co-marketing medicinal products are based on the guidance document *Formal requirements HMV4* in conjunction with the *Overview of documents to be submitted HMV4*.
Additional secondary packers may be requested for the co-marketing medicinal product. This should be mentioned accordingly in the cover letter and in the form *Manufacturer information HMV4*.
Corresponding valid GMP certificates should also be submitted.

6.10 Changes to the basic product

If the basic product is deleted or suspended, the identical measures must be applied to the co-marketing medicinal product. Provided drug safety is undisputed, authorisation as a co-marketing medicinal product can be transformed into a stand-alone authorisation (see section *Conversion of a co-marketing authorisation into a stand-alone authorisation*).
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 Swissmedic within 30 days of variations to the basic product being approved.
The variations approved for the basic product must be adopted unchanged for the co-marketing medicinal product. To enable the holder of authorisation for the co-marketing medicinal product to comply with these requirements, the holder of authorisation for the basic product must inform it of the impending variation and subsequently of its approval. For each variation (application) to the basic product, an A.101 variation must be submitted for the co-marketing medicinal product of a human medicinal product (see form *Variations and extensions HMP HMV4*). Depending on the type of variation, a type IA/IA_{IN} (A101 b) variation must be subsequently notified or a type IB minor variation (A.101 a) must be notified in advance. A variation without assessment (A.101) or a variation with assessment with time limit “Reduced” (E.105) must be submitted for the co-marketing medicinal product in the case of veterinary medicinal products, depending on the type of variation (see form *Variations VMP HMV4*).
This practice applies to all variation applications approved for the basic product.
It is not permitted to submit corresponding applications 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.

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

Holders of authorisation for co-marketing medicinal products have the option of converting the authorisation as a co-marketing product into a stand-alone authorisation (see form *Variations and extensions HMP HMV4*, A.106 or form *Variations VMP HMV4,* E.103). The holder of authorisation for the existing co-marketing medicinal product must 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 medicinal product.
The formal requirements for submitting applications are described in the guidance document *Formal requirements HMV4* in conjunction with the form *Variations and extensions HMP HMV4* or form *Variations VMP HMV4*.

6.12 Change in status basic product ⇔ co-marketing medicinal product

It is permissible for basic products and their co-marketing medicinal products to exchange status. Status cannot be exchanged without the written consent of both companies.
To exchange status, the holder of authorisation for the current co-marketing medicinal product must apply to have its co-marketing authorisation converted into a stand-alone authorisation (see form *Variations and extensions HMP HMV4*, A.106 or form *Variations VMP HMV4*, E.103). The holder of authorisation for the basic product can give its written consent to the documentation in Swissmedic's possession being formally transferred to the co-marketing medicinal product. However, this is not possible if the authorisation documentation exists in eCTD format. In this case, all affected modules for the future basic product have to be submitted as a new eCTD sequence.

Parallel to this, the holder of authorisation for the basic product has to submit an application for conversion of the authorisation from a stand-alone authorisation (basic product) to co-marketing medicinal product (see form *Variations and extensions HMP HMV4*, A.107 or form *Variations VMP HMV4*, E.104). See the guidance document *Formal requirements HMV4* in conjunction with the form *Variations and extensions HMP HMV4* or form *Variations VMP HMV4* for the formal requirements.
A previously stand-alone authorisation cannot be converted to co-marketing authorisation unless its co-marketing medicinal product adopts the status of the basic product. This would require an application for a new authorisation of a co-marketing medicinal product (see the *Description of the basic product* section).

6.13 Time limits

The time limits for processing applications are based on the guidance document *Time limits for authorisation applications HMV4*.

6.14 Fees

Fees are charged in accordance with the *Ordinance of 14 September 2018 on the Fees charged by the Swiss Agency for Therapeutic Products* (FeeO-Swissmedic).

Change history

Version	Change	sig
4.1	New layout, no content adjustments to the previous version.	dei
4.0	Chapter 6.6: Adaption of requirements for imprint on solid dosage forms	dsc
3.0	Adaptation of guidance document due to new structure of VMP variations (early revision of VMP regulations)	fg, ps
2.1	Incorrect reference section 6.7	wh
2.0	Editorial changes Sections 6.3, 6.4, 6.9, 6.10, 6.11 + 6.12: clarifications	lm, vy
1.2	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.1	Explanation of core brand	ze
1.0	Implementation of TPO4	ze