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Change history

Version	Valid and binding as of	Description, comments (by author)	Author’s initials
1.1	01.03.2021	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.0	01.01.2019	Implementation of TPO4	spm

1 Objective

This guidance document describes simplified information requirements for the form *Manufacturer information HMV4* for homeopathic and anthroposophic medicinal products without any indication involving a reduced dossier. It also contains basic explanations regarding the information to be entered on the form for homeopathic and anthroposophic medicinal products.
Since this guidance document is aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

2 Scope

The guidance document is applicable to applications for the new authorisation of homeopathic and anthroposophic medicinal products without any indication involving a reduced dossier and to variation applications for homeopathic and anthroposophic medicinal products that have already been authorised using this procedure.

3 Simplification of the information on the form *Manufacturer information HMV4*

Art. 25 para. 1 KPTPO stipulates that the documents for an authorisation with reduced dossier must be submitted in full for each dossier in accordance with Annex 3.
Swissmedic has reviewed the scope of the administrative information again on the basis of the applications received. In addition to the simplifications relating to the submission of GMP certificates (publication dated 24.10.2008), the following simplification has now been introduced:

In the form Manufacturer information HMV4, under certain circumstances it is not necessary to list all the testing laboratories individually in Chapter 5.3 “Quality control of the ready-to-use

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medicinal product"; instead, reference may be made to an approved basic company dossier produced by the marketing authorisation holder.

This reference substantially reduces the effort associated with any changes to the testing laboratories since it is now only necessary to apply for a variation of the basic company dossier using the form *New authorisation variation in notification procedure KPTPO HMV4*.

3.1 Criteria for referencing Chapter 5.3 "Quality control of the ready-to-use medicinal product" in a company basic dossier:

- A positive partial official decision must have been issued for the basic company dossier.
- It is not possible to make a submission that refers to the basic company dossier of another marketing authorisation holder.
- All the testing laboratories applicable for the reduced dossier must be listed on the form *Manufacturer information HMV4* of the basic company dossier and must have been approved.
- If not all the relevant sites are listed in Chapter 5.3 "Quality control of the ready-to-use medicinal product" of the form *Manufacturer information HMV4* that is part of the basic company dossier or if modifications are required, an application for variation of the basic company dossier must be submitted beforehand or at the same time using the form *New authorisation variation in notification procedure KPTPO HMV4*.
- The form *Manufacturer information HMV4* in the reduced dossier must contain a specific reference under 5.3 "Quality control of the ready-to-use medicinal product" to the testing laboratories listed in a specific basic company dossier (e.g. testing laboratories as shown in basic company dossier 12345, Chapter 5.3).

3.2 Specific procedure

a) Procedure for new applications

Provided the principles listed under 1) are observed, the form can be submitted with a corresponding reference. However, there is no obligation to do this.

b) Procedure for applications currently in the authorisation process

Forms *Manufacturer information HMV4* have already been submitted for these applications. They already contain the information about the individual testing laboratories in Chapter 5.3 "Quality control of the ready-to-use medicinal product" in accordance with the previous regulations. These forms should not be submitted again in line with the simplification set out in Chapter 3 (see above) if the laboratories listed in the form *Manufacturer information HMV4* that has already been submitted are still applicable.

If it emerges during the review procedure that certain entries need to be updated, the applicant will be requested as part of the application for authorisation to submit a form *Manufacturer information HMV4* with the relevant corrections.

c) Procedure for medicinal products that have already been authorised with a reduced dossier

Forms *Manufacturer information HMV4* have already been approved for these applications. New Forms *Manufacturer information HMV4* should only be submitted if this is necessary, i.e. the information in the forms needs to be updated or modified.

New forms that are submitted will be processed as part of an application for variation of the reduced dossier and charged on the basis of the effort involved.

The form *Variations and extensions HMV4* must be used for the application for variation of a reduced dossier; it must be submitted in addition to the modified form *Manufacturer information HMV4*.

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3.3 Basic notes to the form *Manufacturer information HMV4* for homeopathic and anthroposophic medicinal products

For the manufacture of homeopathic active substances, the manufacture of the mother tincture is the first stage of the manufacturing process to which GMP requirements apply. This means that both the manufacturers of the final potencies and all the manufacturers of mother tinctures and intermediate potencies must be listed in Chapter 4.1 “Active pharmaceutical ingredient manufacture (incl. micronisation, stabilisation, sterilisation, (re)crystallisation)” of the form *Manufacturer information HMV4* and GMP certificates must be submitted for all of them.

If more than one site is involved in the manufacture of an active substance, the individual manufacturers can be listed on the form in the following way: Mother tincture to D3: xxyyzz, from D3: AABBCC.

For the testing laboratories for homeopathic medicinal products, all sites involved from testing of the starting materials onwards must be listed in Chapter 4.2 of the form *Manufacturer information HMV4*. The required GMP certificates must be submitted.

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