swissmedic

Guidance document
No marketing / interruption of distribution

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1 Terms, definitions, abbreviations

1.1 Abbreviations

KAS	Preparations with known active substance
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act) (SR 812.21)
TPO	Ordinance of 21. September 2018 on Therapeutic Products (Therapeutic Products Ordinance) (SR 812.212.21)

2 Introduction

Medicinal products that have been authorised in Switzerland should also be distributed in Switzerland shortly after authorisation. Otherwise Swissmedic may revoke the authorisation. The introduction of the so-called Sunset Clause in Art. 16a TPA on 1 October 2010 is designed to help an authorisation holder place its preparation on the market shortly after authorisation and thereby improve the overall access to medicinal products.

2.1 Legal basis

The procedure for notification in case of no marketing and interruption of distribution / resumption of distribution and the application of the Sunset Clause is based on the following legal documents in particular:

TPA

- Art. 16a (Revocation and transfer of the authorisation) paras. 1, 2 and 3

TPO

- Art. 11 (Notification in case of no marketing and cessation of distribution) paras. 1, 2 and 4

3 Objective

This Guidance document describes the mandatory notification of no marketing or interruption of distribution / resumption of distribution of authorised medicinal products according to Art. 16a TPA and Art. 11 TPO. Since this involves an Administrative Ordinance aimed at administrative bodies it does not directly specify the rights and obligations of private individuals. Swissmedic uses this Instruction first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the Instruction is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

4 Scope

The Guidance document applies to the Authorisation division of Swissmedic and is used during the processing of notifications according to Art. 11 para. 1, Art. 11 para. 2 and Art. 11 para. 4 TPO.
Art. 16a TPA does not apply to medicinal products authorised only for distribution abroad (export authorisations).

5 Other valid documents

- Renewal and discontinuation of authorisation on change of status (main authorisation/export licence) HMV4
- Authorisation of human medicinal products with known active substances HMV4
- No marketing / Interruption of distribution HMV4

6 Description

6.1 General requirements

Swissmedic revokes the authorisation of a medicinal product if it is not actually placed on the market within three years of the authorisation being granted (Art. 16a para. 1a TPA), or if it is no longer distributed for three consecutive years after being placed on the market (Art. 16a para. 1b TPA). If existing patent protection prevents the product from being placed on the market at the time of authorisation, the time limit begins only when the patent protection expires.

The provisions of Art. 11 paras. 1, 2 and 4 TPO regulate the mandatory notification on the part of the authorisation holder and ensure transparency, quality and the efficient enforcement of the Sunset Clause. This will enable Swissmedic to make the necessary information available on the actual marketing situation.

6.1.1 Mandatory notification ruling

- If a medicinal product is not placed on the market within one year of the authorisation being granted, the authorisation holder must notify Swissmedic accordingly within 30 days of the end of this year (Art. 11 para.1 TPO).
- If the medicinal product is placed on the market within one year of the authorisation being granted, which should normally be the case, Swissmedic does not need to be notified. This ruling is designed to minimise the notification workload for those concerned.
- If the distribution of a medicinal product is interrupted for longer than one year, the authorisation holder must notify Swissmedic accordingly by two months, at the latest, before the last package of the last batch is delivered to a wholesaler (Art. 11 para. 2 TPO).
  This two-month time limit does not need to be observed if the interruption is due to circumstances over which the authorisation holder has no control.
  The handling of the mandatory notification of the definitive cessation of distribution is described in the Guidance document *Renewal and discontinuation of authorisation on change of status (main authorisation/export licence) HMV4*.
- If a medicinal product that was not placed on the market within one year of authorisation (and which therefore had to be notified according to Art. 11 para. 1 TPO) is placed on the market for the first time, this must be reported to Swissmedic within 30 days of the first delivery to a wholesaler (Art. 11 para. 4 TPO).
- Mandatory notification also applies if, after a temporary interruption of distribution (which must be notified according to Art. 11 para. 2 TPO), the distribution of a medicinal product is resumed (Art. 11 para. 4 TPO).
- The mandatory notification does not apply to medicinal products authorised only for distribution abroad (export authorisations).

6.1.2 Publication of availability on the market

Notifications concerning the availability on the market are listed on the Swissmedic website in the form of a table that is updated monthly (see Meldung Nicht-Inverkehrbringen/Vertriebsunterbruch respectively Meldeverfahren HOMANT: Meldungen Nicht-Inverkehrbringen/Vertriebsunterbruch). This information is designed to help hospitals, medical practices, veterinary practices, pharmacies and druggists procure alternatives in good time when there is a supply shortage.

Veterinary medicines that are not available on the market will additionally be marked as „derzeit nicht erhältlich (Ausverkauft / Nicht lieferbar)!“ respectively « n'est pas disponible actuellement (en rupture de stock / n’est pas livrable) ! » in the electronic Compendium of veterinary medicines. To this end the authorisation holder forwards the notification to the editors of the electronic Compendium of veterinary medicines.

6.1.3 Handling of medicinal product information

The fact that a medicinal product is not available on the market does not release the authorisation holder from the obligation to adapt the medicinal product information – continuously and without being prompted – in line with the state of the art in science and technology and with new events and assessments (Art. 28 TPO).

Moreover, even while distribution is interrupted, persons authorised to prescribe, dispense or use these medicinal products must be provided with a current version of the product information, approved by Swissmedic, through the channels established for this purpose (as per Art. 67 para. 3 TPA). If the products are not placed on the market within one year after authorisation has been granted, this publication must at the latest appear when the products are first placed on the market (Art. 29 TPO).

Similarly, authorisation holders of preparations with a known active substance (KAS) whose product information is identical to that for the reference product (according to the criteria of the Guidance document *Authorisation of human medicinal products with known active substances HMV4*) and which are not placed on the market, or whose distribution is interrupted for a prolonged period, are still required to update the medicinal product information in the event of any changes to the reference product.

For co-marketed medicinal products, updates are likewise required in the event of any changes to the basic product.

6.2 Submitting the notification

Notifications according to Art. 11 TPO should be submitted using the form *No marketing / Interruption of distribution HMV4*. The applicant signs this form to confirm compliance with the requirements.

Change history

Version	Change	sig
2.2	New layout, no content adjustments to the previous version.	dei
2.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
2.0	Change relating to the publication of the medicinal product information	wph, ze
1.1	Correction in chapter 6.1.2 Publication of availability on the market: “the authorisation holder forwards the notification”	ze
1.0	Implementation of TPO4	ze