Contents

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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
1.2	01.10.2021	Section 5.2.4 Requirements for packaging New requirements resulting from reclassification of dispensing category (dispensing category C abolished). Section 8.3 inserted to explain requirements associated with the List of standard works (Annex 9 KPTPO) Section 8.4: Explanations of TAS List (Annex 10 KPTPO) adapted following the revision and publication of the TAS List dated 1 July 2021.	moj
1.1	01.03.2021	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
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1 Definitions, terms, abbreviations

1.1 Definitions and terms

According to KPTPO, Asian medicinal products are medicinal products used in Chinese, Ayurvedic, or Tibetan medicine whose composition, ingredients, preparations and medicinal application correspond to the Asian therapeutic principle in question and are derived from traditional practice.

1.2 Abbreviations

Art.	Article
EMA	European Medicines Agency
FeeO-Swissmedic	Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018 (SR 812.214.5)
HMP	Human Medicinal Products
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IHP	Information for healthcare professionals
KPTPO	Ordinance of 7 September 2018 of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Complementary and Phytotherapeutic Products (Complementary and Phytotherapeutic Products Ordinance, KPTPO; SR 812.212.24)
Let.	Letter
Para.	Paragraph

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Ph. Eur.	European Pharmacopoeia
PI	Patient information
PPRC	Pharmacopoeia of the People's Republic of China
Sec.	Section
TAS List	List of documented traditional Asian substances (Annex 10 KPTPO)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, 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 Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)

2 Introduction and objective

This guidance document describes the requirements to be met by documentation submitted in connection with the simplified authorisation of Asian medicinal products with and without an indication and for the purposes of authorisation by the notification procedure per Chapter 5 KPTPO. Since it is an Administrative Ordinance aimed at administrative bodies, this guidance document does not directly specify the rights and obligations of private individuals. Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The aim of publishing the guidance document is to make clear to third parties the requirements that have to be fulfilled under Swissmedic practice.

3 Scope

This guidance document applies to the authorisation of Asian medicinal products in accordance with Art. 4 para. 1 let. a^{ter} and a^{quater} TPO.
The guidance document also applies to the requirements relating to the quality documentation for applications for the authorisation of Asian medicinal products according to Art. 14 para. 1 let. a^{bis} – a^{quater} TPA and Art. 11 TPA. As regards the rest of the requirements for the corresponding applications, the guidance document *Authorisation in accordance with Art. 14 para. 1 abis-quater TPA HMV4* or *Authorisation of human medicinal product with new active substance HMV4* are applicable.

4 Legal framework

The procedures for authorising Asian medicinal products are based on the following legal foundations in particular:

TPA

- Art. 4 Definitions
- Art. 10 Conditions for granting a marketing authorisation
- Art. 11 Application for a marketing authorisation
- Art. 14 Simplified authorisation procedure
- Art. 15 Mandatory notification

TPLRO

- Art. 2 General preconditions
- Art. 3 Documentation on the analytical, chemical and pharmaceutical tests
- Art. 4 Documentation on the pharmacological and toxicology tests
- Annex1*b* Information and text on containers and packaging material of Asian medicinal products without an indication
- Annex 5.4 Requirements applicable to patient information for medicinal products used in Asian medicine without an indication

KPTPO

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- Chapter 5: Asian medicinal products
- Annex 9 List of standard works
- Annex 10 TAS List
- Art. 5 Principle of simplified authorisation
- Art. 6 Documentation on the pharmacological and toxicology tests
- Art. 7 Proof of therapeutic efficacy and safety
- Art. 9 Analytical, chemical and pharmaceutical documentation
- Art. 10 Toxicological and pharmacological documentation
- Art. 11 Clinical documentation

5 Description, general requirements and assessment principles

5.1 Procedure for authorising Asian medicinal products

Various authorisation procedures apply to the authorisation of Asian medicinal products according to Art. 4 para. 4 let. a KPTPO. The table below provides an overview of which procedure may be applicable to a particular medicinal product.

Asian medicinal product according to Art. 4 para. 4 KPTPO	**Requirements/authorisation procedure**	**Requirements**	**Key features of the authorised product**
With an indication	Simplified authorisation as per Art. 29 KPTPO	See section entitled "Simplified authorisation of Asian medicinal products with an indication" for information on requirements and documentation	Indication to be formulated in accordance with the therapeutic principles of the school of Asian medicine in question
Without an indication	Simplified authorisation as per Art. 30 KPTPO	See section entitled "Simplified authorisation of Asian medicinal products without an indication" for information on requirements and documentation	For individual therapy
Without an indication in notification procedure	Authorisation in notification procedure as per Chapter 31 KPTPO	See section entitled "Authorisation of Asian medicinal products without an indication in the notification procedure" for information on requirements and documentation	For individual therapy: only substances on the TAS List; only compositions that appear in one of the standard works listed in Annex 9 KPTPO.

5.2 General requirements

5.2.1 Declaration requirements

The declaration of composition for all Asian medicinal products is based on the requirements of Annex 1*b* TPLRO.

5.2.2 Requirements applicable to manufacture, pharmaceutical form and substances used

Substances (Art. 4 para. 4 let. e KPTPO), preparations (Art. 4 para. 4 let. f KPTPO) and pharmaceutical forms customarily used in the Asian school of therapy in question can be authorised. These must always be based on a corresponding traditional procedure and be derived from it while complying with the therapeutic principle.
The use of the substance(s) or preparations, combinations of the substance(s) or preparations and the pharmaceutical form must be substantiated and backed up by reference to the Asian school of therapy in question.

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5.2.3 Requirements for product information

Product information should be prepared for Asian medicinal products with an indication. The requirements applicable to product information are described in the guidance document *Formal requirements HMV4* and in the guidance document *Product information for human medicinal products HMV4*. The requirements set out in Annex 5.4 TPLRO should be applied to Asian medicinal products without an indication.

5.2.4 Requirements for packaging

The requirements applicable to packaging materials are described in the guidance document *Packaging materials for human medicinal products HMV4*. The requirements set out in Annex 1*b* TPLRO should be applied to Asian medicinal products without an indication.

For medicinal products without an indication – and for which product-specific patient information is therefore unavailable – patients must be instructed to seek the qualified advice of someone who has trained in the particular Asian school of therapy. To guarantee empirical innocuousness and safety, it is essential to ensure that the medicinal product is used in accordance with the relevant principles of the Asian therapy. For this reason, the packaging of these medicinal products **must** carry the standard text prescribed by number 2 of Annex 5.4 TPLRO for the patient information of Asian medicinal products without an indication as a boxed warning.

"**Use and safety are based entirely on traditional experience and have not been reviewed by the regulatory authorities. The medicinal product must therefore only be used on the prescription or recommendation of a professional who has trained specifically in Chinese [or Tibetan or Ayurvedic] medicine."**

5.3 Formal requirements

The formal requirements are based on the guidance document *Formal requirements HMV4* and the accompanying table *Documents to be submitted HMV4*.

5.4 Document protection

No document protection is granted for authorisations under the procedures described in this guidance document.

5.5 Documents on use in children and adolescents

Decisions on the documentation to be submitted for use in children and adolescents will be taken during meetings with applicants, if held, and/or in the course of processing the application in question.

5.6 Pharmacovigilance plan

Decisions on the need to submit a pharmacovigilance plan will be taken during meetings with applicants, if held, and/or in the course of processing the application in question.

5.7 Authorisation extensions and variation applications

Variations and authorisation extensions, including extensions of indications, are subject to the requirements of the guidance document *Variations and extensions HMV4*.

5.8 Time limits

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

5.9 Fees

The Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic) applies.

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6 Simplified authorisation of Asian medicinal products with an indication

6.1 Precondition for the application of the procedure

Under Art. 29 KPTPO, an Asian medicinal product with an indication can be authorised if it meets the requirements of the definition of a medicinal product in the relevant school of therapy as set out in Art. 4 para. 4 let. a KPTPO and quality, safety, innocuousness and proof of traditional use are adequately documented.

6.2 Documentation requirements

The principles governing the requirements and scope of documentation are defined in Art. 29 KPTPO.

6.2.1 Documentation on quality

The requirements applicable to documentation on quality are based on Art. 9 KPTPO if herbal substances are used and on the requirements of the Pharmacopoeia – to the extent that these are applicable – and on Art. 17 and 18 KPTPO if substances of animal or mineral origin are used.

The information below on the requirements applicable to documentation on quality are not definitive and merely explain certain aspects.
Swissmedic reserves the right to ask for additional documentation, for example in response to therapy-specific production processes (e.g. documentation on Pao Zhi preparation methods).

6.2.1.1 Documentation on the quality of the active substance (Module 3.2.S)

Starting materials

If the Pharmacopoeia contains a specific monograph for a starting material, the corresponding requirements of this monograph must be fulfilled. If the material is not described in the Pharmacopoeia but the PPRC or another official pharmacopoeia includes a monograph for it, the requirements described in this monograph must be observed. If there is no corresponding monograph for a particular starting material, the company must prepare its own. Quality criteria of the type specified in equivalent monographs in recognised pharmacopoeias must be specified.

The geographical origin, extraction process, storage and processing of the starting material must be documented.

Characterisation of contaminants

When testing for contaminants in materials of herbal origin, the requirements of the general Ph. Eur. monograph *Herbal Drugs / Plantae medicinales* must be taken into account. The methods used must be validated.

Manufacture of the active substance

If the active substance is not the drug (starting material) in unprocessed condition, but the drug after further processing, the quality documentation must take account of the aspects listed below and document them accordingly.

The manufacture of the active substance must be described in both narrative and schematic form. The implemented in-process controls must be documented (specifications, analytical methods and test frequencies). The standard batch size or a lot size must be defined.

The manufacturing process must be validated and the corresponding validation report submitted. If validation is not carried out, the omission must be substantiated by providing a risk assessment for the individual manufacturing steps.

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Control of the active substance

The requirements of the Pharmacopoeia must be taken into account where applicable. The specification for the active substance and a description of the analytical methods used must be available, as must documents on the validation of the analytical methods.

The quality documentation must incorporate analytical certificates for at least two active substance batches manufactured in close temporal proximity, including colour illustrations of the fingerprints obtained by thin-layer chromatography and/or GC/HPLC.

If the active substance is the unprocessed drug, the information in the ***Starting materials section*** must be taken into account.

Reference standards for the active substance

Reference substances used during the testing of starting materials or active substances must be documented.

Complete documentation on the primary standard used in each case must be submitted for reference substances used for assays.

Containers for the active substance

Documentation on the primary container must include specifications and design drawings, plus documentation on the materials used and their suitability. The required declarations of conformity must likewise be included. Potential interactions with container materials must be discussed.

Stability documentation for the active substance

Data on the stability of the active substance must be available. Justification of the requested retest period must be provided. The relevant ICH and EMA guidelines must be taken into account.

6.2.1.2 Documentation on the quality of the finished product (Module 3.2.P)

Composition of the finished product

The composition must be complete and list both active substances and all excipients. Both the quality and purpose of each component must be described.

Manufacture of the finished product

The manufacture of the finished product must be described in both narrative and schematic form. The implemented in-process controls must be documented (specifications, analytical methods and test frequencies). A standard batch size and/or batch size range must be defined.

The manufacturing process must be validated and the corresponding validation report submitted. The *Guideline on process validation for finished products, EMA/CHMP/CVMP/QWP/BWP/70278/2012* must be taken into account.

If validation is omitted, the reason for omitting it must be adequately substantiated and take account of the pharmaceutical form. A risk assessment of each manufacturing step must be carried out to demonstrate that the manufacturing process does not require validation.

Excipients

The specifications and analytical methods applicable to the excipients used must be documented. If excipients are the subject of a pharmacopoeia monograph, the requirements described in that monograph must be satisfied; in this case, a reference to it is sufficient. If excipients are not the subject of a pharmacopoeia monograph, the company must prepare its own and submit a sample analytical certificate.

Control of the finished product

The specifications and analytical methods must be available, as must documentation on method validation. The requirements of the Ph. Eur. monograph relevant to the particular case must be taken

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into account when preparing specifications. For oral pharmaceutical forms containing herbal active substances, the requirements applicable to microbiological quality must correspond to Ph. Eur. monograph 5.1.8. In all other cases, the requirements of Chapter 5.1.4 Ph. Eur. apply.

The quality documentation must incorporate analytical certificates for three production batches manufactured in close temporal proximity (two batches at the time of submission, one of which can be a pilot batch), including colour illustrations of the fingerprints obtained by thin-layer chromatography and/or GC/HPLC.

Reference standards for the finished product

Reference standards used during testing of the finished products are subject to the same requirements as reference standards used during testing of the active substance (cf. *Reference standards for the active substance*).

Container for the finished product

Containers used for the finished product are subject to the same requirements as active substance containers (cf. *Containers for the active substance*).

Stability documentation for the finished product

The stability of the finished product must be tested in accordance with ICH and EMA guidelines. Justification of the proposed shelf life must be provided.

The test results must be documented clearly in tabular form. For the stability batches, the manufacturing date, batch size and associated primary container must be stated. The quality documentation must incorporate colour illustrations of the fingerprints obtained at the individual test times by thin-layer chromatography and/or GC/HPLC.

The data submitted must be discussed and evaluated; this applies particularly to out-of-specification results and significant changes or tendencies that have been observed during storage.

If necessary, the finished product's stability after opening should be tested. A use-by period backed by appropriate reasons must be requested in this case.

6.2.2 Non-clinical documentation

The nature and scope of the documentation to be submitted on safety and innocuousness depend on the substance(s) chosen, the nature of the combination, the therapeutic use and index, and the method and duration of treatment. These can be ascertained from the Asian school of therapy in question.
For preparations containing substances that are not included in the TAS List for the method of administration in question, or whose familiarity and efficacy in the corresponding Asian school of therapy cannot be adequately demonstrated, documents according to the guidance document *Authorisation of Homeopathics, anthroposophics and other complementary medicinal products HMV4*, where applicable, must be submitted. Swissmedic reserves the right to ask for additional documentation in response to therapy-specific production processes (e.g. documentation on Pao Zhi preparation methods).

6.2.2.1 Herbal substances

The requirements applicable to non-clinical documentation for herbal substances are based on Art. 10 KPTPO and, to the extent applicable, on the requirements applicable to phytotherapeutic products described in the guidance document *Authorisation of herbal medicinal products*.

6.2.2.2 Substances of animal and mineral origin

For substances of animal and mineral origin, all aspects of safety and possible pharmacokinetic substance interactions should be addressed. These include information on general toxicity, genotoxicity, reproductive toxicity, carcinogenicity, immunotoxicity, local tolerance (e.g. allergenic potential) and, in the case of substances of animal origin, pathogenic contamination and disease transmission. Provided the substances concerned are known from their use in other areas (e.g.

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medical device, foods, cosmetics), the findings obtained in these areas must be documented and a risk assessment undertaken based on these findings.

6.2.3 Clinical documentation

The nature and scope of the documentation to be submitted depend on the substance(s) chosen, the nature of the combination, published safety data or safety data documented in databases and the requested indication, which must be in line with the Asian school of therapy in question.

Composition and indication must be backed up by bibliographical documentation that reflects the philosophy of the Asian school of therapy in question. Accordingly, the indication should be worded so that it is in line with the philosophy of the Asian school of therapy in question (e.g. “strengthens qi” in traditional Chinese medicine). This is intended to ensure that doctors and therapists with the appropriate federally recognised training choose the correct Asian medicine after they have made their diagnosis in accordance with the therapeutic principle.

In justified cases, the wording of the indication dictated by the Asian school of therapy can be reformulated or expanded to make it better comprehensible to patients.

Where applicable, the requirements applicable to phytotherapeutic products set out in the guidance document *Authorisation of herbal medicinal products HMV4* apply to proof of safety in the requested indication and requested recommended dosage.

7 Simplified authorisation of Asian medicinal products without an indication

7.1 Precondition for the application of the procedure

Under Art. 30 KPTPO, an Asian medicinal product without an indication can be authorised if it meets all the requirements of the definition of a medicinal product in the relevant school of therapy as set out in Art. 4 para. 4 let. a KPTPO and quality, safety and innocuousness are adequately documented.

7.2 Documentation requirements

The principles governing the requirements for the scope of the documentation are defined in Art. 30 KPTPO.

7.2.1 Documentation on quality

The requirements applicable to documentation on the quality of the medicinal product are based on those described in section 6.2.1.

7.2.2 Non-clinical documentation

The requirements applicable to documentation on the safety and innocuousness of the medicinal product are based on those described in section 6.2.2, where applicable. Since there is no reference in the form of a requested indication and recommended dosage, a toxicological risk assessment based on a maximum dosage that is customary and substantiated in the Asian school of therapy in question must be submitted.

7.2.3 Clinical documentation

Clinical documentation does not have to be submitted under this procedure provided the preconditions of Art. 30 KPTPO are fulfilled. Proof must be submitted that the requirements of Art. 30 para. 1 let. b KPTPO or the requirements applicable to fixed medicinal product combinations according to Art. 30 para. 2 KPTPO are fulfilled.

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8 Authorisation of Asian medicinal products without an indication by the notification procedure

8.1 Precondition for the application of the procedure

Under Art. 31 KPTPO, an Asian medicinal product without an indication can be authorised under the notification procedure if it meets the requirements of the definition of a medicinal product in the relevant Asian school of therapy and the active substances it contains all appear in the TAS List (Annex 10 KPTPO, cf. section 8.4 of this guidance document; Art. 15 para. 1 let. a TPO). Only classic formulations that appear and are documented in one of the standard works listed in Annex 9 KPTPO can obtain approval as a fixed-dose combination medicinal product under the notification procedure.

The company's basic dossier and a set of sample quality documentation still have to be approved beforehand in accordance with Art. 37, 38 and 40 KPTPO as a prerequisite for preparation notifications.

8.1.1 Basic company dossier

In accordance with the definition given in Art. 38 KPTPO, the basic company dossier brings together the regulatory documentation listed in the table *Documents to be submitted HMV4*.

Basic company dossiers must be manufacturer-specific. Details of companies involved in the manufacturing process and control must be provided in the form *Manufacturer Information HMV4*.

If medicinal products contain excipients of animal origin (e.g. gelatine), a form *Substances of animal and human origin HMV4* must be completed and submitted. The necessary safety documentation (e.g. a Certificate of Suitability [CEP] issued by the EDQM or corresponding confirmations from the manufacturer of the excipient in question) must be submitted for substances obtained from animals that could contract TSE and thus fall within the scope of Chapter 5.2.8 of the European Pharmacopoeia.

If part or all of a medicinal product is manufactured abroad, confirmation that the medicinal product in question was manufactured in accordance with the GMP rules in force in Switzerland must be available, as must a corresponding GMP certificate. If batch release takes place at different sites, a separate basic company dossier must be submitted for each site.

8.1.2 Documentation on quality

The requirements applicable to documentation on the quality of medicinal products are based on those described in section 6.2.1.
The quality of Asian medicinal products submitted for authorisation by the notification procedure is assessed during the review of so-called sample quality documentation. This applies both to medicinal products that are manufactured from just one substance and to fixed-dose combination medicinal products.
The following sets of sample quality documentation must be prepared:

- production site-specific, i.e. one set of sample documentation per finished product manufacturer and
- pharmaceutical form-specific, i.e. one set of sample documentation per pharmaceutical form

The sample quality documentation for medicinal products intended for authorisation under the notification procedure must also include preparation methods if Swissmedic deems this necessary.

Swissmedic reserves the right to choose the example medicinal products to be described by means of sample quality documentation.

If non-substance-specific quality variations have to be made, the documentation must be modified accordingly, and an application to this effect must be submitted to Swissmedic. The requirements given in the guidance document *Variations and extensions HMV4* must be taken into account as a matter of course.

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8.1.3 Non-clinical documentation

Preclinical documentation does not have to be submitted for the notification procedure. All active substances are substances that appear in the TAS List (Annex 10 KPTPO). The patient information must include the information on safety aspects (e.g. contraindication during pregnancy and lactation, maximum dosages) in accordance with Annex 5.4 TPLRO. During individual therapy, the doctors and/or therapists trained in the particular school of Asian medicine take account of – and are accountable for – the safety aspects.

8.1.4 Clinical documentation

Clinical documentation does not have to be submitted for the notification procedure. The product information must include the information on dosages and use that appears in the TAS List. During individual therapy, the doctors and/or therapists trained in the particular school of Asian medicine take account of – and are accountable for – dosage and use in accordance with the therapeutic principle of the school of Asian medicine in question.

8.2 Preparation notification

If the conditions for authorisation are fulfilled, authorisation holders can use the *Homant Asia* software provided by the Agency to notify individual and combination medicinal products (monopreparations and combination products). Authorisation holders should refer to the manual *Handbuch HOMANT Asia HMV4* for further instructions.

8.3 List of standard works (Annex 9 KPTPO)

The list of standard works is a list of literature references that contain traditional and established classic formulations for the authorisation of fixed-dose combination medicinal products without an indication in Asian medicine. These combinations can be authorised under the simplified procedure in accordance with Art. 30 para. 2 KPTPO or on the basis of a notification under Art. 31 para. 2 KPTPO.

As part of the authorisation procedure in question, the composition must be referenced to the classic formulation in the work in question (including page number). All referenced specifications for the classic formulation, such as composition and quantitative ratios, must be observed.

If a composition deviates from a classic formulation, reasons must be given and backed by evidence. Such compositions are not eligible for the notification procedure. In this case, the simplified procedure must be applied.

8.4 TAS List (Annex 10 KPTPO)

The TAS List is the basis for authorising Asian medicinal products without an indication by means of a notification under Art. 31 KPTPO (notification procedure; HOMANT Asia).

In accordance with the requirements of Art. 32 KPTPO, the TAS List contains substances that are established and customary in Asian medicine, that are of entirely plant or mineral origin, and for which the quality requirements are prescribed in an official pharmacopoeia monograph or in a substance monograph approved by Swissmedic.

If the European Pharmacopoeia (Ph. Eur.) contains a monograph for the substance, the requirements set out there must be fulfilled in their entirety in accordance with Art. 8 TPA. If no Ph. Eur. monograph exists, the requirements to be met by substances and the respective traditional preparation methods (Pao Zhi), as documented in the Pharmacopoeia of the People's Republic of China (PPRC), must be observed. Specifically, only the primary plants prescribed in the monograph must be used, and only then if they meet species conservation requirements.

The substances listed in the TAS List serve as starting materials for processing into active substances and/or preparations (e.g. pulverised and filled in capsules or for aqueous decoctions). Accordingly, the entries in the “Information on use and safety” column are not definitive and do not absolve

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professionals of their responsibility to assess the starting materials and active substances they use or any preparations derived from them in accordance with the current state of the art in science and technology and to ensure that any risk to users can be excluded if the medicinal product is used as directed. Specialists in possession of supplementary information, particularly concerning the safety of individual substances, are asked to notify Swissmedic.

Furthermore, it should be remembered that under Art. 59 TPA, anyone who manufactures, distributes or professionally administers therapeutic products is obliged to notify Swissmedic of quality defects and adverse reactions of medicinal products and to set up a pharmacovigilance system.

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