Guidance document
Minimising the risk of TSE

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1 Terms, definitions, abbreviations

1.1 Abbreviations

EU	European Union
IOCM	Intercantonal Office for the Control of Medicines (1971– 2001)
MPLO	Ordinance of 14. November 2018 Licensing in the Medicinal Products Sector (SR 812.212.1)
Ph. Eur.	European Pharmacopoeia
PharmO	Ordinance of 17 October 2001 on the Pharmacopoeia (SR 812.211)
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)
TPO	Ordinance of 21. September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21)
TSE	Transmissible Spongiform Encephalopathies

2 Introduction

This guidance document describes ways of minimising the risk of passing on TSE of animal origin in human and veterinary medicinal products.

2.1 Legal framework

This guidance document is based on the following ordinances:

- Ordinance on Therapeutic Products (Therapeutic Products Ordinance, TPO, SR 812.212.21)
- Ordinance on Licensing in the Medicinal Products Sector (Medicinal Products Licensing Ordinance, MPLO; SR 812.212.1)
- Ordinance on the Pharmacopoeia (Pharmacopoeia Ordinance, PharmO, SR 812.211)
- Ordinance of the Swiss Agency for Therapeutic Products on the Licensing Requirements for Therapeutic Products (Therapeutic Products Licensing Requirements Ordinance, TPLRO; SR 812.212.22)
- Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Licensing of Therapeutic Products and the Notification Requirement for Therapeutic Products (TPLO; SR 812.212.23)

Ordinance of the Swiss Agency for Therapeutic Products on the Enactment of the Pharmacopoeia (SR 812.214.11)

3 Objective

The risk of transmitting TSE must be carefully assessed for authorised medicinal products and medicinal products subject to authorisation. Account must be taken of the country of origin of the animals, feeding practice, nature of the tissue(s) or organ(s) used and the way they are processed (manufacturing process), route of administration, quantity of tissue employed in the medicinal preparation, maximum therapeutic dosage and intended use of the medicinal preparation.

4 Scope

Within the context of authorisation at Swissmedic, this guidance document applies to all human and veterinary medicinal products that are subject to authorisation and which contain materials of animal origin, particularly materials from ruminants (cattle, sheep and goats), or which use such materials in their production process.

5 Description

5.1 Guidelines

This guidance document is subject to the current version of Chapter 5.2.8 of the European Pharmacopoeia, as stated in Article 1 letter a of the Ordinance of the Swiss Agency for Therapeutic Products on the Enactment of the Pharmacopoeia (SR 812.214.11).

The current versions of guidelines and policy papers relevant to TSE also apply. Furthermore, publications by the European Community's Scientific Steering Committee that are relevant to TSE should be taken into consideration, particularly those that deal with estimating the risk of TSE on the basis of animals' geographical origin. An up-to-date list of countries with incidences of TSE can be found on the website of the World Organisation for Animal Health[1]. Starting materials derived from ruminants should never be used if possible.

[1] http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/

5.2 Declaration

The origin (species and organ/tissue) of constituents within the meaning of the “Scope” section of Chapter 5.2.8 Ph. Eur. must be declared in the “Composition” section of the product information (both Patient information and Information for healthcare professionals for human medicinal products) in the prescribed official languages.

The following are exempt from the declaration requirement:

a) Milk, constituents of milk and their derivatives
b) Lanolin and lanolin derivatives
c) Tallow derivatives
d) Gelatine if not contained in medicinal products for parenteral administration
e) Chemically defined substances manufactured from starting materials of animal origin by extensive chemical transformation in several synthesis steps, e.g. corticosteroids

5.3 Forms

The form *Substances of animal and human origin HMV4* must be completed and submitted (particularly part A of the form for TSE substances). For first authorisations, this form should be submitted with a *New authorisation of a human medicinal products HMV4* form or a *New authorisation of a veterinary medicinal products HMV4* form; for authorisation extensions and/or variations, it should be submitted with a *Variations and authorisation extensions HMV4* form.
The form *Substances of animal and human origin HMV4* is based on the corresponding EU form and is intended to make it easier for applicants and authorisation holders to handle information on TSE material.

Change history

Version	Change	sig
1.2	New layout, no content adjustments to the previous version.	dei
1.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
1.0	Implementation of TPO4	stb