

Safeguarding public health

Defective Medicines Report Centre & Unlicensed Import Notifications

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Defective Medicines Report Centre and Unlicensed Import Notifications Section

Policy Document

TSE Compliance Requirements for Exempt Imported Products



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1 Introduction

Importers of certain unlicensed medicines must comply with The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 (Statutory Instrument 2003 No. 1680).

Although, within the EU, Commission Directive 1999/82/EC requires all licensed medicines to comply with the TSE Guideline¹, the UK TSE Safety Regulations, SI 2003/1680 extend this requirement to certain medicinal products that are not the subject of current marketing authorisations granted by the UK licensing authority or the European Commission. This is particularly important for products originating outside of the EU, where manufacturers may not comply with the requirements of the TSE Guideline.

When notifications are received of the intended importation of unlicensed medicines, the MHRA does not routinely request evidence of compliance with these Regulations. The Regulations state that no person shall import or market an unlicensed product unless that product has been manufactured in accordance with the TSE Guideline, therefore the importer is expected to maintain records demonstrating compliance. These records may be requested during an MHRA inspection.

The TSE Regulations do not apply to unlicensed herbal remedies, Traditional Chinese Medicines and ayurvedic medicines.

This policy document outlines acceptable practices for importers in assessing compliance of prospective imports of exempt imported products as defined in Statutory Instrument 2005/2789, The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005/2789) with UK TSE regulations.

2 Assessment

2.1 Products acceptable by default

The MHRA Import Notifications Section accepts that:

- Licensed products from within the European Union (EU) / European Economic Area (EEA) are compliant with UK TSE requirements.
- Products manufactured in third countries with relevant Mutual Recognition Agreements (MRAs) with the EU, where those products are licensed in the third country, are deemed to be compliant with UK TSE requirements.
- Products for which statements of absence of TSE risk materials have been obtained are compliant with UK TSE requirements. Importers should be advised, however, that it is necessary to obtain a list of ingredients to allow evaluation of the reliability of the manufacturers' assurances. Evaluation is the responsibility of the importer, however such lists may be requested when MHRA inspections are performed.

¹ "The TSE Guideline" means the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" as published and updated by the European Commission.

2.2 Products requiring additional information

Where a manufacturer/supplier states that the product may contain TSE risk materials, the importer must obtain information to permit assessment of compliance of the product with UK TSE requirements. The importer is responsible for any assessments required.

- The MHRA Import Notifications Section accepts that products for which valid current European Directorate for the Quality of Medicines (EDQM) certificates are obtained for each TSE risk ingredient are compliant with UK TSE requirements.
- Products that are unlicensed in MRA countries or in the EU may not be subject to the same requirements as licensed products and are only acceptable without further assessment if the importer can obtain confirmation that unlicensed products from the country in question are subject to the same TSE requirements as licensed products.
- Where no EDQM certification is available for any ingredient, a full TSE risk assessment must be performed based upon the source, handling and processing of each affected ingredient. Other materials that may contact ingredients during processing must also be considered.