

CODE OF STATUTES

MEDICAL PRODUCTS AGENCY

ISSN 1101-5225

Legally responsible publisher: Gunnar Alvan, Director-General.

LVFS 2004:8
Published 22 April

2004.

The Medical Products Agency's Provisions and Guidelines for Marketing Authorisation of Parallel Imported Medicinal Products;

Adopted 31 March 2004

Pursuant to section 17 of the Medical Products Ordinance (1992:1752), the Medical Products Agency gives notice¹ of the following Provisions and Guidelines on marketing authorisation of parallel imported medicinal products.

Field of application

1 § A parallel imported medicinal product may not be marketed until it has been approved in accordance with the provisions stated herein.

These provisions do not apply in the case of medicinal products for which an application for authorisation has been approved in accordance with the Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products².

Guidelines relating to 1 §

Matters concerning parallel trading with, or distribution of, medicinal products authorised centrally in accordance with Council Regulation 2309/93 are dealt with by the European Medicines Agency, EMEA, in London.

Definitions

2 § Expressions and names used in the Medical Products Act (1992:859) have the same implications in the present Provisions.

In the present Provisions the following definitions are used

Marketing authorisation authorisation granted by the Medical Products Agency that entitles the holder to sell and market a medicinal product for a period of five years, with the possibility of extending the authorisation for further five-year periods.

Parallel import import to Sweden from a state within the European Union (EU)/European Economic Area (EEA) of a medicinal product that is approved for

¹ EC Commission no. C115/5 of 6 May 1982. Revised through COM (2003) 839 final 30 December 2003.

² OJ L 214, 24.8.93, p.1 (Celex 393R2309), latest revision through the Council's Regulation 1647/2003/EC (OJ L 245, 29.09.2003, p.19, Celex 303R1647).

marketing in Sweden and in the exporting state, but where the importation is managed by someone else than the manufacturer/holder of the marketing authorisation.

Direct imported medicinal product the medicinal product that the parallel imported medicinal product refers to. The definition is also used for medicinal products manufactured in Sweden that are retailed directly in Sweden.

Marketing of parallel imported medicinal products etc.

3 § An application for marketing authorisation in accordance with 1 § will be approved if the conditions listed below are fulfilled.

- The direct imported medicinal product shall have marketing authorisation in Sweden when the application for the parallel imported medicinal product is submitted to the Medical Products Agency for the first time.
- The parallel imported medicinal product shall have marketing authorisation in the exporting state.
- The exporting state shall be a member of EU/EEA.
- The parallel imported medicinal product shall be sufficiently similar to the direct imported medicinal product.

The Medical Products Agency may require special documentation for biological medicinal products (e.g. demonstrating the absence of HIV, HBV and HCV, etc.).

Guidelines relating to 3 §

Marketing in Sweden of parallel imported medicinal products shall not take place until authorisation has been granted by the Medical Products Agency. The same Swedish Legislation, Provisions and Directives, etc. apply to parallel imported medicinal products as to direct imported medicinal products. In the case of parallel imports of narcotic medicinal products, specific authorisation is required; see the Medical Products Agency's Provisions (LVFS 1997:11) dealing with control of narcotic drugs³. However, the same documentation are not required for parallel imported medicinal products as a prerequisite is that the parallel imported and the direct imported medicinal products have the same properties. The requirements of the Medical Products Agency concerning documentation and processing of applications for parallel imported medicinal products thus have a primary purpose in establishing that the medicinal product for which parallel importation has been applied for is similar to the direct imported medicinal product to *a sufficiently large extent*. In this assessment attention is paid to, e.g., whether the parallel imported medicinal product and the direct imported medicinal product have a common origin and contain the same active ingredient, and also that they have the same therapeutic effect.

The expression "common origin" refers, for example, to whether the holder of the marketing authorisation for the parallel imported medicinal product in the exporting state is the same, or represents the same group of companies, as the holder of the marketing authorisation for the direct imported medicinal product in Sweden. Common origin may also occur if the manufacturers of the direct imported medicinal product and the parallel imported medicinal product are part of the same group of companies, or if the manufacturers of the direct imported medicinal product and the

³ Revised LVFS 2001:3.

parallel imported product are independent companies that have entered into agreements with one and the same licensor.

A basic condition for parallel imports is, thus, that the parallel imported medicinal product is sufficiently similar to the direct imported medicinal product. Marketing authorisation may, however, be granted if minor differences (e.g., concerning colour, scoring, dosage form, size, excipients and manufacturing process) occur and that *these cannot be regarded as affecting the conditions relating to the medicinal product's quality, efficacy and safety*. These possible differences must be listed in the application, see the Annex to the present Provisions, (11). In deciding whether any possible differences are of therapeutic importance, the Medical Products Agency applies the same basis for assessment as applied in variations to the direct imported medicinal product.

Application

4 § The application for marketing authorisation shall contain:

- details and documentation as stated in the annex to the present Provisions,
- proposal on labelling of the medicinal product's package,
- proposal on the patient information leaflet, and
- samples of all packages and package sizes from the exporting state that are intended to be imported.

Separate applications shall be made for each strength and each pharmaceutical form and for each exporting state of the same medicinal product.

Guidelines relating to 4 §

An instructive application form "Application for marketing authorisation for parallel imported medicinal products" is available on the Medical Product Agency's web site.

For assessment of an application for marketing authorisation of parallel imported medicinal products it is necessary, and sufficient, that marketing authorisation of the direct imported medicinal product is still valid in Sweden at the time when the application is received.

5 § Application documents shall be written in Swedish or English.

Parallel imports from Estonia, Latvia, Lithuania, Poland, Slovakia, Slovenia, the Czech Republic and Hungary

6 § If the parallel importer intends to parallel import medicinal products from Estonia, Latvia, Lithuania, Poland, Slovakia, Slovenia, the Czech Republic or Hungary, and the direct imported medicinal product is protected by a patent or a supplementary protection certificate, the patent holder or his beneficiary or the holder of the marketing authorisation for the direct imported medicinal product shall be notified by the parallel importer at least 30 days before the application is submitted to the Medical Products Agency. The notification shall be performed if there was not the same possibility to obtain patent protection or a supplementary protection certificate for the medicinal product in the exporting country as for the direct imported medicinal product at the time of the application for authorisation of the latter.

Guidelines relating to 6 §

Notification to the holder, or his beneficiary, of a patent or a supplementary protection certificate or the holder of the marketing authorisation for the direct imported medicinal product should be dated and contain the following information:

- the trade name and generic name of the product,
- the strength of the product and
- the pharmaceutical form of the product.

Fees

7 § A condition for assessment of an application for marketing authorisation of parallel imported medicinal products by the Medical Products Agency is that the application fee is paid⁴.

Summary of product characteristics

8 § In some cases the Medical Products Agency may require a summary of product characteristics in Swedish for the parallel imported medicinal product.

Guidelines relating to 8 §

In cases when the direct imported medicinal product has been withdrawn in Sweden and there is a summary of product characteristics for the parallel imported medicinal product in the exporting state, the Medical Products Agency may request that the parallel importer submits this documentation.

Labelling and name

9 § The labelling and the patient information leaflet shall be designed in accordance with the Medical Product Agency's Provisions and Guidelines (LVFS 1994:11) on the packaging and the labelling of medicinal products⁵.

The name of parallel imported medicinal products must be approved by the Medical Products Agency. The same name as the direct imported product, generic name (with addition of the company name), or another name approved by the Medical Products Agency, may be used.

Guidelines relating to 9 §

In the case of parallel imported medicinal products that differ in some respect in relation to the direct imported medicinal product, e.g., with regard to taste, colour or appearance, the outer package shall be labelled with text providing information on this.

The inner and the outer packaging, as well as the patient information leaflet, will also provide information on the manufacturer's name and address, and also the parallel importer's and the re-packager's name and address. Instead of the manufacturer's address, the business name for the relevant group of companies may be given. On blisters it may be sufficient to state only the medicinal product's name, dosage form, strength, the name of the parallel importer, the expiry date and the batch number.

⁴ Further details, but not concerning the size of the fee, are found in the Medical Products Agency's Provisions and Guidelines (LVFS 1995:12) on the payment of application and annual fees for medicinal products. Revised and reprinted LVFS 2000:9.

⁵ Revised and reprinted LVFS 1995:11.

The patient information leaflet shall be designed to provide information in accordance with the valid patient information leaflet for the direct imported medicinal product, but with presentation of any notable differences.

Foreign text on the package can be accepted provided that it is not in conflict with the part of the labelling printed in Swedish. Labelling in Swedish may be used to paste over foreign text. Packages should be labelled in such a way that confounding is avoided to the greatest possible extent. For this purpose, for example, different colours or patterns may be used. Packages in black/white should, thus, be avoided. Neither is it suitable, foremost from the viewpoint of patient safety, that the parallel imported medicinal product is labelled with the direct importer's trademark. In addition, such use of a direct importer's trademark may be regarded as advertising. Nevertheless, this does not apply to the name of the medicinal product. Specimens of the finally approved packages and package sizes shall be sent to the Medical Products Agency in connection with the release of the medicinal product on the Swedish market.

It should be noted that in questions concerning labelling, the Medical Products Agency is required to apply directives as stated in the Medical Products Act (1992:859) together with subsequent provisions. In this process the Medical Products Agency has no obligation or possibility to ensure that legislation dealing with trademarks or patents is not violated.

Shelf life

10 § A parallel imported medicinal product shall normally be given the same shelf life as applicable in the exporting state.

If the shelf life in the exporting state is longer than the shelf life approved for the direct imported medicinal product, the Medical Products Agency will assess which shelf life is to be approved for the product.

A parallel imported medicinal product shall normally be given the same conditions for storage as the direct imported medicinal product.

Guidelines relating to 10 §

If the shelf life in the exporting state is revised a corresponding revision may be approved in Sweden following an application.

In the case of re-packaging that requires the breaking of the secondary package and that may affect the stability of the medicinal product, the shelf life in the new package shall be stated and documented.

The shelf life of a medicinal product is given for an unopened package and, in applicable cases, also for an opened package as well as an opened package where the medicinal product is prepared by a pharmacy. If the last-mentioned shelf life is shorter for the parallel imported medicinal product than for the direct imported then, after assessment by the Medical Products Agency, it may be given the same shelf life as the direct imported medicinal product.

Manufacturing authorisation

11 § Specific manufacturing authorisation by the Medical Products Agency is required for re-packaging or re-labelling⁶. Re-packing and re-labelling shall be done in accordance with good manufacturing practice⁷.

Re-packaging or re-labelling shall be done in such a manner that the original character of the medicinal product is not affected.

When re-packaging and re-labelling is done under contract from the parallel importer, a technical agreement shall be established.

Guidelines relating to 11 §

A technical agreement refers to an agreement that, among other things, regulates how responsibility is divided between the providers and receivers of a contract in order to fulfil the requirements of good manufacturing practice.

Wholesale authorisation, marketing and stock-keeping

12 § Wholesale with medicinal products may only be conducted by persons authorised by the Medical Products Agency⁸.

Variations

13 § The parallel importer shall keep himself informed about any variations that may be of importance for the marketing authorisation of the parallel imported medicinal product, and shall continuously inform the Medical Products Agency about these matters.

If the medicinal product's appearance, declaration, packaging type, marketing authorisation number, or other important parts of the marketing authorisation in the exporting state, are changed in relation to the current marketing authorisation for the parallel imported product in Sweden, the modified medicinal product shall not be sold before being given permission by the Medical Products Agency.

If the labelling or the patient information leaflet for the direct imported medicinal product is changed, then relevant parts shall also be changed for the parallel imported medicinal product. If the direct imported medicinal product has been withdrawn and the parallel importer has submitted a summary of product characteristics, this shall be up-dated when the summary of product characteristics is changed in the exporting state.

If the parallel importer wishes to make variations in relation to the approved marketing authorisation, the application or, alternatively, the notification on this, shall be submitted to the Medical Products Agency.

⁶ See the Medical Products Agency's Provisions and Guidelines (LVFS 2004:7) regarding authorisation for manufacturing and import of medicinal products.

⁷ See the Medical Product Agency's Provisions (LVFS 2004:6) concerning good manufacturing practice for medicinal products.

⁸ More detailed directives are given in the Medical Product Agency's Provisions (LVFS 1997:3) concerning authorisation for wholesale trading with medicinal products, and the Medical Product Agency's Provisions and Guidelines (LVFS 1997:5) concerning payment of application and annual fees for wholesale trading permits (latest revision and reprinting LVFS 2001:11).

Guidelines relating to 13 §

The application form with guidelines “Application for variations to parallel imported medicinal products” can be found in the Medical Products Agency’s web site.

Batch control

14 § The parallel importer shall document the origin, quantity and batch number of each imported batch of medicinal product and, when requested, submit these details to the Medical Products Agency.

Termination of marketing authorisation

15 § If the marketing authorisation is withdrawn for the parallel imported medicinal product in the exporting state, or for the direct imported medicinal product in Sweden, for reasons concerning quality, efficacy or safety, then the marketing authorisation for the parallel imported medicinal product will also be withdrawn.

Guidelines relating to 15 §

Reasons for withdrawal of marketing authorisation can be found in 12 § of the Medical Products Act (1992:859).

Marketing authorisation for the parallel imported medicinal product will not be revoked simply on account of the direct imported medicinal product’s marketing authorisation being withdrawn at the request of the holder. If, however, human health is endangered by a continuation of the marketing of the parallel imported medicinal product, the marketing authorisation for the parallel imported product will also be revoked.

Exemption

16 § The Medical Products Agency has the power to permit exemptions from these provisions.

-
1. These provisions come into force on the 1st of May 2004. The provisions imply the revoking of the Medical Products Agency’s Provisions (LVFS 1994:22) concerning the marketing authorisation of parallel imported medicinal products.
 2. These provisions shall be applied to applications for approval of marketing authorisation of parallel imported medicinal products that are submitted to the Medical Products Agency after the 30th of April 2004.

Medical Products Agency

GUNNAR ALVAN

Anna Maria Åslundh-Nilsson

LVFS 2004:8*Annex*

Marketing authorisation for parallel imported medicinal products requires that the person responsible for the marketing should apply for authorisation from the Medical Products Agency. The application shall be accompanied by the following information and documentation:

1. The applicant's name or trading name and address.
2. The name and address of the contact person appointed to represent the applicant.
3. The name, dosage form, strength and routes of administration of the medicinal product.
4. The exporting EU or EEA state.
5. Information if notification as described in the present Provisions section 6 shall be done and if such notification has been done.
6. The name, dosage form and strength of the medicinal product in the exporting state, and also the number of the marketing authorisation in the exporting state.
7. The name and address of the holder of the marketing authorisation in the exporting state, and corresponding data on the manufacturer.
8. The name and address of the supplier within the EU/EEA from which the medicinal product is obtained.
9. The name, dosage form and strength of the direct imported medicinal product, and the number of the marketing authorisation.
10. The name and address of the holder of the marketing authorisation for the direct imported medicinal product.
11. Description of differences between the direct imported and the parallel imported medicinal products.
12. Complete data concerning the re-labelling and re-packaging procedure.
13. Complete data concerning specifications and testing methods used in conducting quality controls conducted by the applicant.
14. Name, address and manufacturing authorisation and, when relevant, the technical agreement for the/those companies performing the re-packaging/re-labelling.
15. Packaging information relating to the parallel imported medicinal product in the form of packaging sizes and the packaging/container.
16. Shelf life (for unopened and opened packages) and, when relevant, the shelf life after preparation of the parallel imported medicinal product, and corresponding data for storage of the parallel imported medicinal product.