CODE OF STATUTES
MEDICAL PRODUCTS AGENCY

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The Medical Products Agency's Provisions on Parallel Imported Medicinal Products;
Adopted 25 June 2012.

Pursuant to chapter 4 section 7 and chapter 10 section 5 of the Medical Products Ordinance (2006:272), the Medical Products Agency issues[1] the following provisions.

Scope
1 § These provisions are applicable to importation of a parallel imported medicinal product.
These provisions do not apply in the case of medicinal products for which an application for authorisation has been approved in accordance with the Regulation (EC) No 726/2004 of the European parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.[2]

Definitions
2 § Expressions and names used in the Medical Products Act (1992:859) have the same implications in these provisions.
In these provisions the following definitions are used
Parallel import import to Sweden from a state within the European Economic Area (EEA) of a medicinal product that has a marketing authorisation in Sweden and in the exporting state, but where the importation is being performed by someone else than the manufacturer/holder of the marketing authorisation,
Parallel importer the holder of a license to sell a parallel imported medicinal product,
Direct imported medicinal product the medicinal product that the parallel imported medicinal product refers to.

License
3 § A parallel imported medicinal product may not be marketed until a license has been issued under the rules of these provisions.
A license to sell a parallel imported medicinal product is valid for a period of five years. Thereafter, on application by the parallel importer, the license can be renewed indefinitely. Section 8 e of the Medical Products Act (1992:859) shall apply to such an application.

4 § An application for a license to sell a parallel imported medicinal product will be approved if the conditions listed below are fulfilled.
1. The direct imported medicinal product shall have a marketing authorisation in Sweden when the application for the parallel imported medicinal product is submitted to the Medical Products Agency.

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[1] See EC Commission no. C115/5 of 6 May 1982. Revised through COM (2003) 839 final 30 December 2003.
[2] EUT L 136.30.4.2004 (Celex 32004R0726).

2. The parallel imported medicinal product shall have a marketing authorisation in the exporting state.
3. The exporting state shall be a member of the EEA.
4. The parallel imported medicinal product shall be sufficiently similar to the direct imported medicinal product.

Application
5 § An application for a license to sell parallel imported medicinal products must contain:

1. details and documentation as stated in the annex to these provisions,
2. proposal on labelling of the medicinal product's package,
3. proposal on the patient information leaflet, and
4. 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.

Application for biological medicinal products
6 § To obtain a license to sell a parallel imported medicinal product prepared from human blood or human plasma documentation regarding the starting material, traceability and reporting systems for serious adverse events related to the potential risk of infection must, in addition to what is required in Section 5, also be included in the application. Such documentation may also be required when the application relates to other biological medicinal products.

7 § Documentation mentioned in Sections 5 and 6 shall be written in English or Swedish.

Notification
8 § Anyone who intends to parallel import a medicinal product shall notify the holder of the marketing authorisation of the direct imported medicinal product of the intention. The notification shall be made before the parallel imported medicinal product goes on sale in Sweden.

Specific notification in case of parallel import from Bulgaria, Estonia, Latvia, Lithuania, Poland, Rumania, Slovakia, Slovenia, the Czech Republic or Hungary
9 § If the parallel importer intends to parallel import medicinal products from Bulgaria, Estonia, Latvia, Lithuania, Poland, Rumania, 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.

Fees
10 § A condition for assessment by the Medical Products Agency of an application for license to sell a parallel imported medicinal product is that the application fee has been paid. Fees are being regulated in the Ordinance (2010:1167) regarding fees for the governmental control of medicinal products.

Summary of product characteristics

11 § The summary of product characteristics (SPC) for the direct imported medicinal product is applicable to the parallel imported medicinal product in relevant parts.

If the direct imported medicinal product no longer has a marketing authorisation in Sweden, and there is no SPC to refer to, the parallel importer shall submit an application to refer to another appropriate SPC.

If there is no suitable alternative SPC under the second paragraph, the parallel importer should submit an SPC in Swedish for the parallel imported medicinal product. The SPC shall be designed in accordance with the Medical Products Agency´s provisions (LVFS 2006:11) on the approval of medicinal products for sale etc.

Labelling

12 § The labelling shall be designed in accordance with the Medical Product Agency's Provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products. In addition, the following should be observed.

1. Inner and outer packaging must be marked with the name and address of the manufacturer, the parallel importer and the re-packager. Instead of the manufacturer´s name and address, the business name for the relevant group of companies may be given.
2. If the parallel imported medicinal product differs in any way from the direct imported medicinal product the outer packaging should be labelled with text that points this out.

With exception from the first paragraph 1, blisters and small immediate packagings, in addition to the requirements in Sections 3-4 LVFS 2005:11, could be labelled with only the parallel importer´s name.

Foreign text on the packaging 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.

Package leaflet

13 § The package leaflet shall be designed in accordance with the Medical Product Agency's Provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products. The contents of the package leaflet shall follow the valid package leaflet for the direct imported medicinal product but must be adapted to the parallel imported medicinal product.

In addition to the manufacturer's name and address the parallel importer´s and re-packager´s name and address must also be specified in the package leaflet. Instead of the manufacturer´s name and address, the business name for the relevant group of companies may be given.

The name of the medicinal product

14 § The name of a parallel imported medicinal product must be approved by the Medical Products Agency. In addition to what is regulated concerning names for medicinal products in Section 1 in the Medical Product Agency's Provisions (LVFS 2005:11) on labelling and package leaflets for medicinal products the name of the parallel imported medicinal product may be the same as the name of the direct imported medicinal product.

Shelf life and storage

15 § A parallel imported medicinal product shall be given the same shelf life as the product has in the exporting state unless the circumstances for the specific medicinal product give reason for another shelf life. The shelf life shall be given for unopened packaging and, in applicable cases, also for an opened packaging. If the medicinal product is to be prepared by a pharmacy the shelf life for opened packaging should always be given.

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

A parallel imported medicinal product shall be given the same conditions for storage as the direct imported medicinal product unless the circumstances for the specific medicinal product give reason for other conditions.

Product sample

16 § Specimens of the approved and released packaging and package leaflet shall be submitted to the Medical Products Agency at the time when the parallel imported medicinal product is put on sale on the Swedish market.

Report on adverse reactions

17 § The parallel importer shall report all suspected adverse reactions related to the parallel imported medicinal product to the holder of the marketing authorisation for the direct imported medicinal product. This shall be done as soon as possible, within seven days, after the information has come to the parallel importer's knowledge.

If the direct imported medicinal product no longer has a marketing authorisation in Sweden, the adverse reaction report shall instead be sent to the holder of the marketing authorisation for the medicinal product in the country of export, after being translated to English or any other language that the addressee understands. This should be done as soon as possible, no later than ten days after the information came to the parallel importer's knowledge. In case the holder of the marketing authorisation for the medicinal product in the country of export requires additional information, the parallel importer shall be of assistance with this.

Manufacturing authorisation

18 § A specific manufacturing authorisation issued by the Medical Products Agency is required for re-packaging or re-labelling. The Medical Products Agency’s Provisions and Guidelines (LVFS 2004:7) regarding authorisation for manufacturing and import of medicinal products regulates this.

Re-packaging and re-labelling shall be done in accordance with the Medical Product Agency’s Provisions (LVFS 2004:6) concerning good manufacturing practice for medicinal products and in such a manner that the original character of the medicinal product is not affected.

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

Wholesale authorisation

19 § According to chapter 3 Section 1 of the Act (2009:366) on trading with medicinal products wholesale with medicinal products may only be conducted by persons authorised to do so. Additional provisions can be found in The Medical Products Agency´s Provisions (LVFS 2009:11) on wholesale distribution of medicinal products.

Sale of parallel imported narcotic medicinal products

20 § In the Medical Products Agency’s Provisions (LVFS 2011:9) on control of narcotic drugs there are provisions on how to handle narcotics.

Variations

21 § If there is a need to make a variation in a license to sell parallel imported medicinal products, the parallel importer shall submit a variation application to the Medical Products Agency.

22 § The parallel importer shall keep himself informed about any variations regarding the approved medicinal product in the export country and regarding the direct imported medicinal product that may be of importance for the license to sell the parallel imported medicinal product. The Medical Products Agency shall continuously be informed about these matters. If such variations make it necessary to do a variation in the license to sell a parallel imported medicinal product, a variation application shall be made in accordance with Section 21.

If important parts of the marketing authorisation in the exporting state are changed the modified parallel imported medicinal product must not be marketed until the corresponding variations have been approved by the Medical Products Agency.

Batch control

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

Withdrawal of marketing authorisation

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

Exemption

25 § The Medical Products Agency may permit exemptions from these provisions.

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1. These provisions come into force on the 21st of July 2012. Through these provisions the Medical Products Agency's Provisions and Guidelines (LVFS 2004:8) for marketing authorisation of Parallel Imported Medicinal Products are being revoked.

The Medical Products Agency

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Annex

An application for a license to sell parallel imported medicinal products shall contain the following information and documentation:

1. The applicant’s name or trading name and address.
2. The name and address of an appointed representative.
3. The name, dosage form, strength and routes of administration of the medicinal product.
4. The exporting EEA state.
5. Information if notification as described in Section 8 of these provisions has been given or will be given.
6. Information if notification as described in Section 9 of these provisions shall be done and if such notification has been done.
7. 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.
8. The name and address of the holder of the marketing authorisation in the exporting state and of the manufacturer.
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. A detailed description of the re-labelling and re-packaging procedures.
13.Data concerning specifications and testing methods used in conducting quality controls by the applicant when receiving, re-packaging and batch-releasing the parallel imported medicinal product.
14. Name, address and manufacturing authorisation and, when relevant, the technical agreement for the/those companies performing the re-packaging/relabelling.
15. Packaging information for the parallel imported medicinal product regarding packaging sizes and the outer and inner packaging.
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.