The Medical Products Agency’s regulations on parallel imported medicinal products for human use;

adopted on XX xx 2021.

By virtue of Chapter 9, § 11 of the Medicinal Products Ordinance (2015:458), the Medical Products Agency hereby lays down[[1]](#footnote-1) the following.

Scope

**§ 1** These regulations apply to the entry of a parallel imported medicinal product for human use.

These regulations do not apply to medicinal products for human use for which the authorisation application has been reviewed in accordance with Regulation (EC) No 726/2004 of the European Parliament and of 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.

Definitions

**§ 2** The terms and concepts used in the Medicinal Products Act

(2015:315) have the same meanings in these regulations.

For the purposes of these regulations, the following definitions apply

*parallel import* entry into Sweden from a country within the European Economic Area (EEA) of a medicinal product for human use authorised for sale in Sweden and in the country of exit but the entry is handled by an entity other than the manufacturer or holder of the marketing authorisation,

*parallel importer* the holder of the marketing authorisation for a parallel imported medicinal product for human use,

*directly imported medicinal product for human use* the medicinal product to which the parallel imported medicinal product for human use refers to in the application.

Authorisation

**§ 3** A parallel imported medicinal product for human use may not be marketed until authorisation has been granted.

A marketing authorisation for a parallel imported medicinal product for human use is valid for five years. After the application, the authorisation can then be extended indefinitely. That which is stated on the renewal application in Chapter 4, § 17 of the Medicinal Products Act (2015:315) shall apply to such an application.

**§ 4** In order to be granted marketing authorisation for parallel imported medicinal products for human use, the following must be fulfilled:

1. the directly imported medicinal product for human use is already authorised for marketing in Sweden when the Medical Products Agency receives the application,

2. the parallel imported medicinal product for human use has marketing authorisation in the country of exit,

3. country of exit is a Member State of the EEA, and

4. the parallel imported medicinal product for human use is sufficiently similar to the direct imported medicinal product for human use.

**§ 5** A marketing authorisation application for parallel imported medicinal products for human use shall include:

1. information and documentation as specified in the annex to the regulations,

2. proposed labelling of immediate packaging,

3. proposed package leaflet, and

4. one copy of all packagings and packaging sizes, from the country of exit, intended for entry into Sweden.

Separate applications are required for each country of exit.

The Medical Products Agency reviews marketing authorisation applications for parallel imported medicinal products for human use once the application fee has been paid.

Application for human biologicals

**§ 6** In addition to that which is specified in § 5, the granting of marketing authorisation for parallel imported medicinal products for human use manufactured from blood or plasma from humans requires documentation regarding starting materials, traceability, and systems for reporting serious events related to potential contagion risks. Such documentation can also be requested when the application relates to other human biologicals.

**§ 7** Application documents as per §§ 5 and 6 shall be written in Swedish or English.

Notification

**§ 8** Those who intend to parallel import a medicinal product for human use shall notify their intention to the holder of the marketing authorisation for the direct imported medicinal product for human use. The notification shall take place before the parallel imported medicinal product for human use is marketed in Sweden.

Specific notification for parallel imports from certain countries

**§ 9** If the parallel importer intends to import medicinal products for human use from Bulgaria, Estonia, Croatia, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, the Czech Republic, or Hungary and the directly imported medicinal product for human use is protected by patents or supplementary protection certificate (SPC), the patent holder or beneficiary of the patent or SPC shall be notified no later than 30 days before the application is submitted to the Medical Products Agency. Notification shall take place unless the same possibility of patent protection or SPC was provided for the medicinal product for human use in the country of exit as for the direct imported medicinal product for human use at the time of its authorisation application.

Fees

**§ 10** Provisions regarding fees can be found in the Regulation (2010:1167) on fees for State control of medicinal products.

Summaries of product characteristics

**§ 11** The summary of product characteristics for the direct imported medicinal product for human use is also valid, mutatis mutandis, for the parallel imported medicinal product for human use.

If the direct imported medicinal product for human use is no longer authorised for marketing in Sweden and it lacks a summary of product characteristics, the parallel importer shall submit an application to switch to another suitable summary of product characteristics.

If there is not a suitable summary of product characteristics according to the second paragraph, the parallel importer shall submit a summary of product characteristics in Swedish for the parallel imported medicinal product for human use. When a summary of product characteristics is drawn up, it shall be formatted according to [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on marketing authorisation for medicinal products for human use].

Labelling and package leaflet

**§ 12** Labelling and name shall be formatted as per [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on labelling and package leaflets for medicinal products for human use]. In addition, the following shall be observed.

1. Immediate and outer packaging shall bear the names and addresses of the manufacturer, parallel importer, and repackager. Instead of the manufacturer’s name and address, a relevant name can be indicated.

2. If the parallel imported medicinal product for human use in any respect deviates from the direct imported medicinal product for human use, the outer packaging shall be labelled with text accordingly.

With the exception of point 1 of the first paragraph, immediate packaging in the form of blisters and other small immediate packaging can only bear the information specified in §§ 3–4 [HSLF-FS 2021:xx] and the parallel importer’s name.

The packaging may bear foreign text if the content of the text does not conflict with that which is stated on the label in Swedish.

**§ 13** The package leaflet shall be formatted as per [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on labelling and package leaflets for medicinal products for human use]. The content of the package leaflet shall follow the package leaflet for the direct imported medicinal product for human use, but be adapted for the parallel imported medicinal product for human use.

In addition to the manufacturer’s name and address, the names and addresses of the parallel importer and the repackager shall also be included on the package leaflet. Instead of the manufacturer’s name and address, a relevant name can be indicated.

The name of the medicinal product for human use

**§ 14** In addition to that which is stated regarding the name of the medicinal product for human use in § 1 [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on labelling and package leaflets for medicinal products for human use] the parallel imported medicinal product for human use may have the same name as the directly imported medicinal product for human use.

Shelf life and storage

**§ 15** A parallel imported medicinal product for human use shall have the same shelf life that the medicinal product for human use has in the country of exit unless the conditions in the individual case dictate otherwise. Shelf life shall be stated for unopened packaging and, where applicable, for opened packaging. If the medicinal product for human use is to be completed by pharmacies, the shelf life for opened packaging shall always be stated.

In cases where a secondary packaging is opened during repackaging and such affects the stability of the medicinal product for human use, the shelf life in the new packaging shall be documented and stated.

The parallel imported medicinal product for human use shall have the same storage instructions as the direct imported medicinal product for human use, unless the conditions in the individual case dictate otherwise.

Side-effect reporting

**§ 16** The parallel importer shall report all suspected side effects related to the parallel imported medicinal product for human use to the entity with marketing authorisation in Sweden for the direct imported medicinal product for human use.

The side-effects report shall instead be sent to the entity with marketing authorisation in the country of exit for the medicinal product for human use if

– the entity with marketing authorisation for the direct imported medicinal product for human use does not also have marketing authorisation in the country of exit for the medicinal product for human use, or

– the direct imported medicinal product for human use is no longer authorised for marketing in Sweden.

Suspected side effects shall be reported out as soon as possible after the parallel importer has been made aware of such information. A side-effects report to a recipient in Sweden shall be sent within seven days. A side-effects report to a recipient in another country shall be translated into English, or another language that the recipient understands, and sent within ten days. If the recipient of the side-effects report requests supplementary information, the parallel importer shall always provide such.

Manufacturing authorisation and good manufacturing practice

**§ 17** Repackaging or relabelling requires a special manufacturing authorisation issued in a State within the European Economic Area. Provisions on this can be found in [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on authorisation for the manufacture and import of medicinal products].

Repackaging and relabelling shall be done in accordance with the Medical Products Agency’s regulations (LVFS 2004:6) on good manufacturing practice and such that the original nature of the medicinal product for human use is not affected.

Wholesale

**§ 18** According to Chapter 3, § 1 of the Act (2009:366) on the trade of medicinal products, wholesale trade in medicinal products may only be carried out those who are so authorised. Additional provisions can be found in [the Medical Products Agency’s regulations (HSLF-FS 2021:xx) on wholesale trade of medicinal products].

Narcotic medicinal products for human use

**§ 19** The Medical Products Agency’s regulations (LVFS 2011:9) on the control of narcotic drugs contain provisions on the handling of narcotic medicinal products.

Sale of parallel imported vaccines and blood products for human use

**§ 20** The Medical Products Agency’s regulations (HSLF-FS 2015:14) on the marketing of production batches of vaccines and blood products for human use contain provisions on production batches of vaccines and blood products for human use that are to be sold on the Swedish market.

Changes and revocations

**§ 21** The parallel importer shall stay informed of any changes to the medicinal product for human use approved in the country of exit or the directly imported medicinal product for human use that may be of significance to the marketing authorisation for the parallel imported medicinal product for human use. The parallel importer shall keep the Medical Products Agency informed of such changes.

**§ 22** The parallel importer shall apply for the necessary changes in the marketing authorisation for the parallel imported medicinal product for human use.

In the event of significant changes to the authorisation in the country of exit, the changed parallel imported medicinal product for human use may not be sold until the corresponding changes have been authorised by the Medical Products Agency.

**§ 23** If the marketing authorisation for the parallel imported medicinal product for human use in the country of exit or for the direct imported medicinal product for human use in Sweden is revoked for reasons concerning quality, effect, or safety, the marketing authorisation for the parallel imported medicinal product for human use shall also be revoked.

A marketing authorisation for parallel imported medicinal products for human use may be revoked as per Chapter 11, § 2 of the Medicinal Products Act (2015:315) even in cases other than those stated in paragraph one.

Dispensation

**§ 24** The Medical Products Agency may, if there are particular reasons, issue an exemption (dispensation) from the provisions of these regulations. Exemptions may not, however, be granted if it would entail a disregard of Sweden’s obligations under EU law.

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1. These Regulations shall enter into force on 28 January 2022.

2. The regulations repeal the Medical Products Agency’s regulations (LVFS 2012:19) on parallel imported medicinal products.

3. Authorisations issued by virtue of the Medical Products Agency’s regulations (LVFS 2012:19) on parallel imported medicinal products shall be valid as authorisations in accordance with the new regulations.

Medical Products Agency

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Annex

Marketing authorisation applications for parallel imported medicinal products for human use shall be accompanied by the following information and documentation:

1. The applicant’s name or trade name and postal address, as well as contact information of a designated contact person for the application.

2. Name and postal address of local representatives.

3. The name of the medicinal product for human use, pharmaceutical form, strength, and routes of administration.

4. The EEA country from which the medicinal product for human use shall exit.

5. Information that notification according to § 8 of the regulation has been provided or will be provided.

6. Information that notification according to § 9 of the regulation shall take place and whether such notification has already taken place.

7. The name, pharmaceutical form, and strength of the medicinal product for human use in the country of exit and the marketing authorisation number in the country of exit.

8. The name and address of the marketing authorisation holder in the country of exit and corresponding information for the manufacturer.

9. Name, pharmaceutical form, strength, and marketing authorisation number of the direct imported medicinal product for human use.

10. The name and address of the marketing authorisation holder for the direct imported medicinal product for human use.

11. Description of the differences between the directly imported medicinal product for human use and the parallel imported medicinal product for human use.

12. A detailed description of how the relabelling or repackaging of the medicinal product for human use shall be done.

13. Information on instructions and quality controls for reception, storage, repackaging, release, and transport of parallel imported medicinal products for human use and systems for recalls.

14. Name, address, and manufacturing authorisation and, where applicable, written agreement for the company or companies that perform(s) the repackaging/relabelling.

15. Packaging information for the parallel imported medicinal product for human use in the form of packaging sizes(s) and packaging/pharmaceutical containers.

16. Shelf life (for unopened and opened packaging) and, where applicable, the shelf life after completion of the parallel imported medicinal product for human use and corresponding instructions for storage of the parallel imported medicinal product for human use.

HSLF-FS can be downloaded or ordered via

internet: www.xxxxxxxxxxxxx.xx

e-mail: xxxxxxxx@xxxxxxx.xx

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Address
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internet: www.xxxxxxxxxxxxx.xx

Printing site: Printing house and year of publication

1. Notification has been submitted in accordance with Directive (EU)

2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on

Information Society services. [↑](#footnote-ref-1)