Joint Code of Statues regarding health and medical care, social services, medicinal products, public health etc.

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The Medical Products Agency's provisions (HSLF-FS 2015:14) on the sale of batches of vaccines and blood products for human use;

adopted on 31 August 2015.

Pursuant to Chapter 10, Section 5 of the Medicinal Products Ordinance (2006:272), the Medical Products Agency issues[1] the following.

Scope

Section 1 These provisions apply to batches of vaccines and blood products for human use which are to be sold on the Swedish market. The provisions also apply to parallel imported and parallel distributed batches.

The provisions do not apply to batches of the product groups' toxins, serums and allergens, nor to whole blood, plasma or blood cells of human origin.

Permits for sales of non-approved medicinal products are subject to the Medical Products Agency's provisions (LVFS 2008:1) on marketing authorisation for the sale of non-approved medicinal products (licensing provisions). Nor do the provisions apply to medicinal products where only the excipients are derived from human blood or plasma.

Definitions

Section 2 Expressions and names used in the Medicinal Products Act (2015:315) have the same meaning in these provisions. These provisions use the following terms with the specified definitions.

Blood product for human use: Medicinal products derived from human blood or plasma.

Direct imported medicinal product: The medicinal product which a parallel imported or parallel distributed medicinal product refers to in its application.

EU/EEA official control authority batch release certificate: A document showing that a batch of vaccines or blood products for human use has officially been released.

Parallel distribution: Import to Sweden of medicinal products approved for sales in accordance with the European Parliament and Council's Regulation (EC)

[1] C.f. the European Parliament and Council's Directive 2001/83/EC of 2 November 2001 on the Community code relating to medicinal products for human use, as formulated in the European Parliament and Council's Directive 2012/26/EU of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance. See also the European Parliament and Council's Directive 98/34/EC of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

726/2004 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, where the importation is being performed by someone else than the manufacturer or the holder of the marketing authorisation,.
Parallel distributor: A party which has notified the European Medicinal products Agency (EMA) about its intent to parallel distribute medicinal products.
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 or the holder of the marketing authorisation,
Parallel importer: The party that has a permit to sell a parallel imported medicinal product.
Batch: A fixed quantity of a product manufactured in one or more stages in such way that it may be regarded as homogenous
Final bulk: A product that has passed through all manufacturing steps up to final filling.
Vaccine: Agent used to induce active immunity.

Sales of batches for which EU batch release certificates have been issued

Section 3 A batch for which an *EU/EEA official control authority batch release certificate* has been issued may be sold on the Swedish market once the Medical Product Agency has confirmed that is has received a notifiaction including the documentation specified under points 1-3:
1. A covering letter specifying that the notification is for sales of a batch of vaccine or blood product for human use. The covering letter shall also include the trade name in Sweden, Asp number, batch number and contact person.
2. A copy of the *EU/EEA official control authority batch release certificate*.
3. A completed Marketing information form specified in Annex IV of the EC administrative procedure for official control authority batch release, PA/PH/OMCL [96]4, DEF.

Section 4 In cases where only the batch label differs from a previously notified and validated batch, it is sufficient to submit documentation according to Section 3, point 1 along with the batch number and date of the confirmation of the first batch to the Medical Products Agency.

Sales of batches for which EU batch release certificates have not been issued

Section 5 A batch for which an *EU/EEA official control authority batch release certificate* has not been issued may only be sold on the Swedish market if the Medical Products Agency has granted a license to sell. An application for a license to sell shall contain the following:

1. A covering letter specifying that the application is for sales of a batch of vaccine or blood product for human use. The covering letter shall also include the trade name in Sweden, Asp number, batch number and contact person.
2. Complete documentation according to Annex 1.
3. Where relevant, test results which should include the following information:

- Type of testing.
- Test status (e.g. European Pharmacopoeia or applicant's own testing method). Every time new reference material is used, test results and limits for approval of reference material shall be specified.
- Specification in accordance with the license to sell.
- Results (only specifying "pass" or "fail" is not enough).

4. Qualified person's certificate stating that each batch has passed quality control in accordance with Annex 1 and comply with the marketing authorisation. The certificate shall include the qualified person's name and position, as well as the product's name in Sweden. The certificate shall be dated.

Section 6 In cases where only the batch label differs from a previously notified and validated batch, it is sufficient to submit documentation according to Section 5, point 1 along with the batch number and date of the validation of the first batch to the Medical Products Agency.

Sales of parallel imported batches

Section 7 A batch that is parallel imported may be sold on the Swedish market if the Medical Products Agency has granted a license to sell.

An application for a license to sell shall contain the following:

1. A covering letter specifying that the application is for sales of a parallel imported batch of vaccine or blood product for human use. The covering letter shall also include the trade name in Sweden, Asp number and contact person.
2. Name or company and postal address of the responsible manufacturer and holder of the marketing authorisation for the direct imported medicinal product and corresponding information for the parallel importer.
3. Exporting country.
4. Trade name in the exporting country.
5. Batch number in the exporting country.
6. Batch number of the parallel imported batch.
7. Number of packs in the batch.
8. Number of doses or volume per pack.
9. Expiry date.
10. Authorisation number in Sweden and the exporting country.

Section 8 For a parallel imported batch to be sold on the Swedish market, in addition to the information in Section 7, the Medical Product Agency must also have received the documentation specified in Section 3, points 2-3 or Section 5, points 2-4. This documentation is obtained from the responsible Competent Authority in the exporting country or from the manufacturer of the direct imported medicinal product.

Sales of parallel distributed batches

Section 9 A batch that is parallel distributed may be sold on the Swedish market if the Medical Products Agency has granted a license to sell.

An application for a license to sell shall contain the following:

1. A covering letter specifying that the application is for sales of a parallel distributed batch of vaccine or blood product for human use. The covering letter shall also include the trade name in Sweden, EMA authorisation number and contact person.

2. Name or company and postal address of the responsible manufacturer and holder of the marketing authorisation for the direct imported medicine and corresponding information for the parallel distributor.
3. Exporting country.
4. Batch number in the exporting country.
5. Batch number of the parallel distributed batch.
6. Number of packs in the batch.
7. Number of doses or volume per pack.
8. Expiry date.

Section 10 For a parallel distributed batch to be sold on the Swedish market, in addition to the information in Section 9, the Medical Product Agency must also have received the documentation specified in Section 3, points 2-3 or Section 5, points 2-4. This documentation is obtained from the responsible Competent Authority in the exporting country or from the manufacturer of the direct imported medicinal product.

Section 11 The Medical Product Agency may grant exemptions (dispensation) from these provisions in special cases. However, dispensation may not be granted if it would result in a failure to comply with Sweden's responsibilities according to EU law.

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These provisions enter into force on 12 October 2015. There is a simultaneous revocation of the Medical Products Agency's provisions and guidelines (LVFS 2000:3) on the examination of production of batches of vaccines and blood products for human use prior to release on the Swedish market.

Transitionary provisions

1. References to provisions in LVFS 2000:3 shall be considered to constitute references to the corresponding provisions in the Medical Products Agency's regulations (HSLF-FS 2015: 14) on the sale of batches of vaccines and blood products for human use.
2. Permits granted in accordance with LVFS 2000:3 shall remain valid as permits according to the Medical Products Agency's provisions (HSLF-FS 2015: 4) on the sale of batches of vaccines and blood products for human use.

The Medical Products Agency

INGER ANDERSSON

Joakim Brandberg

Documentation which shall be submitted regarding batches for which EU batch release certificates have not been issued.

1 Summary information for finished products

1.1 Manufacturer's name or company and postal address, and corresponding information about the holder of the marketing authorisation for the product.

1.2 Trade name in Sweden.

1.3 INN, international non-proprietary name or the European Pharmacopoeia (Ph Eur) name (generic name).

1.4 Batch number.

1.5 Type of packs.

1.6 Total number of filled packs in the batch.

1.7 Number of doses or volume per pack.

1.8 Expiry date.

1.9 Storage conditions.

1.10 Authorisation number in Sweden and Asp number.

2 Product information

2.1 Place of manufacture.

2.2 Date of manufacture.

2.3 Production details (flow chart) including batch number and date of the different production steps.

3 Starting materials for medicinal products derived from human blood or plasma

3.1 Reference and date for Plasma Master File (PMF) certified by EMA, if applicable.

3.2 Individual donations.

3.2.1 Donation country of origin.

3.2.2 Confirmation that all donations have been tested and been found negative for the following viral markers: anti-HIV 1/2, HBsAg, anti-HCV.

3.3 Plasma pools

3.3.1 The plasma pool's identification code (code number/batch number).

3.3.2 Date of manufacture.

3.3.3 Pool volume/number of donations.

3.3.4 Country of origin and supplier of plasma pool.

3.3.5 Testing of infectious agents in accordance with existing requirements and PMF/marketing authorisation. Confirmation that the pool(s) have been checked and found negative for the following viral markers: Anti-HTV 1/2, HBsAg, HCV RNA with NAT, B 19 DNA with NAT (if applicable) and HAV RNA with NAT (if applicable). Additional tests for viral markers in accordance with the marketing authorisation or PMF shall be specified.

3.3.6 If an EU batch release certificate is issued for the plasma pool and attached, this is considered to be sufficient information about the starting materials of the plasma pool.

3.4 Intermediate products

3.4.1 Manufacturer.

3.4.2 Identification code (code number/batch number).

3.4.3 Date of manufacture.
3.4.4 Storage conditions, storage time for the batch in question and storage time according to the existing marketing permit.
3.4.5 Testing of intermediate products.
3.4.6 Identification code for the plasma pool involved in the production and information according to points 3.1 and 3.2 above.

4 Excipients derived from human blood or plasma (such as human albumin)

4.1 Batch number.

4.2 Manufacturer.

4.3 Place of manufacture.

4.4 Date of manufacture.

4.5 Expiry date.

4.6 Information about starting materials according to point 3 above.

4.7 If an EU batch release certificate is issued for the excipient and attached, this is considered to be sufficient information about the excipients derived from human blood.

5 Final bulk

5.1 Batch number.

5.2 Composition (quantity, identity, e.g. batch number for all constituents).

5.3 Testing of final bulk according to in Sweden approved specifications.

6 Final product

6.1 Batch number.

6.2 Complete composition.

6.3 Testing of final product according to in Sweden approved specifications.

6.4 Filling volume.

6.5 Date from which expiry date is calculated.

7 Final bulk or final product for certain multi-component products where sub-components are filled in separate containers that are packed together

7.1 For multi-component groups, where only the sub-components are tested and not the final product with complete composition, the documentation for each sub-component shall be submitted in accordance with points 5 and 6.1-6.4. Additionally, information about which date the expiry date is based on shall be specified for the multi-component product.

7.2 For multi-component products where the sub-components and a mixture which corresponds to the final product are tested, documentation for each sub-component shall be submitted in accordance with points 5 and 6.1-6.4 and for the mixture in accordance with point 6.3. Additionally, information in accordance with points 6.1, 6.2 and 6.5 shall be included regarding the multi-component product.

HSLF-FS can be downloaded from
the Medical Products Agency.
Website: www.lakemedelsverket.se

The Code of Statutes
can be ordered from:
Fritzes
106 47 Stockholm
Telephone: +46 (0)8-598 191
90 Fax: +46 (0)8-598 191 91
E-mail:
order.fritzes@nj.se
Website: fritzes.se

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