

Medical Products Agency's Code of Statutes

ISSN 1101-5225

LVFS 2000:3

Published on 19 May 2000

Medical Products Agency's provisions and guidelines on the examination of production batches of vaccines and blood products for human use prior to release on the Swedish market;

adopted on 7 April 2000.

Pursuant to § 17 of the Medicinal Products Ordinance (1992:1752), the Medical Products Agency is issuing the following provisions and guidelines on the examination of production batches of vaccines and blood products for human use prior to release on the Swedish market.¹

Scope

§ 1 These provisions shall apply both to vaccines for human use and to medicinal products for human use originating from human blood or plasma and require the marketing authorisation holder for such medicinal products to supply the Medical Products Agency with either production and analysis protocols for the production batch or an EU official control authority batch release certificate before such products are sold.

Subject to the restrictions set out below, the provisions also cover parallel-imported products.

The provisions do not cover the product groups toxins, serums and allergens or whole blood, plasma or blood cells of human origin.

The provisions of § 6 of the Medical Products Agency's provisions and guidelines (LVFS 1995:7) on marketing authorisation for non-approved medicinal products (licence provisions) etc. shall apply in relation to marketing authorisation for non-approved medicinal products;²

1 Cf. Council Directive 89/342/EEC of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens (OJEC L 142, 25.5.1989, p.14, Celex 389L0342) and Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEG and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products derived from human blood or human plasma (OJEC L 181, 28.6.1989, p. 44, Celex 389L0381).

2 Amended via LVFS 2000:2

Definitions

§ 2 The expressions and terms used in the Medicinal Products Act (1992:859) shall have the same meaning in these provisions.

The following definitions shall apply to these provisions:

Vaccine: agent used to induce active immunity,

Blood product: medicinal product based on blood constituents which are prepared industrially, e.g. albumin, clotting factors and immunoglobulins of human origin,

Batch: a fixed quantity of a product manufactured in one or more stages in such a way that it may be regarded as homogeneous,

Final bulk: a product that has passed through all manufacturing stages up to final filling,

Official Medicines Control Laboratory (OMCL laboratory): Official laboratory authorised by the EU,

Official batch release: a batch approval procedure performed by an OMCL laboratory covering examination of the manufacturer's own production and analysis protocols together with experimental testing of samples submitted,

EU official control authority batch release certificate: a document indicating that official batch release has taken place.

Documentation requirements

§ 3 Full information pursuant to §§ 4 or 5 of these provisions shall be submitted to the Medical Products Agency for finished products.

In the case of finished products produced from previously approved final bulk, the information pursuant to § 4 sub-sections 1, 2, 6, (7) and 8 below or § 5 below shall be submitted to the Medical Products Agency together with details of batch numbers of the final bulk.

In the case of finished products in which only the labelling differs from previously approved batches, the information pursuant to § 5 below or information on batch numbers of current batches and previously approved batches to which reference is made shall be sent to the Medical Products Agency for information.

The documentation shall be accompanied by a covering letter showing that the matter concerns batch release of vaccine or blood product. In addition, the following information shall be given:

- 1. Trade name in Sweden**
- 2. Asp number**
- 3. Batch number**

4. Contact.

§ 4 In the case of production batches for which EU official control authority batch release certificates have not been issued, documentation pursuant to sub-sections 1-8 below shall be submitted to the Medical Products Agency.

Where results of tests are given, the details shall be as full as possible and contain the following information:

- Type of test**
- Status of test (e.g. European Pharmacopoeia, WHO, "in house" etc.)**
- Specification as approved by the Medical Products Agency**
- Results (an indication consisting simply of the words "pass" or "fail" is insufficient)**
- Whenever new "in house" reference material is used, test results and limits for the approval of reference material must be given.**

1. Summary information for finished products

1.1 The manufacturer's name or firm and postal address and corresponding information on the marketing authorisation holder for the product

1.2 Trade name in Sweden

1.3 Generic name (INN, international non-proprietary name/European Pharmacopoeia name)

1.4 Batch number

1.5 Type of container

1.6 Total number of filled containers in the batch

1.7 Number of doses or volume per container

1.8 Expiry date

1.9 Storage conditions

1.10 Marketing authorisation number in Sweden and Asp number

2. Production information

2.1 Site of manufacture

2.2 Date of manufacture

2.3 Production details (flow chart) containing the batch numbers and dates for the various production stages

3. Starting materials for medicinal products originating from human blood or plasma

3.1 Individual donations

3.1.1 Source country of donations

3.1.2 Statement that all donations have been tested and shown to be negative for the following viral markers: anti-HIV 1/2, HBsAg, anti-HCV

3.2 Plasma pools

3.2.1 Identification code of the plasma pool (code number/batch number)

3.2.2 Date of manufacture

3.2.3 Volume of pool/number of donations

3.2.4 Source country and supplier of plasma pool

3.2.5 Tests for infectious agents in accordance with applicable requirements. Statement that the pool/pools have been tested and shown to be negative for the following viral markers: Anti-HIV 1/2, HBsAg, anti-HCV and HCV RNA (NAT).

3.2.6 If an EU official control authority batch release certificate has been issued for plasma pools and is attached, this is considered to constitute adequate information on starting material concerning plasma pools

3.3 Intermediate products

3.3.1 Manufacturers

3.3.2 Identification code (code number/batch number)

3.3.3 Date of manufacture

3.3.4 Storage conditions, storage time for current batch and storage time in accordance with the applicable marketing authorisation

3.3.5 Tests on intermediate products

3.3.6 Identification code of plasma pool incorporated in the production and details pursuant to sub-sections 3.1 and 3.2 above

4. Excipients originating from human blood or plasma (e.g. human serum albumin)

4.1 Batch number

4.2 Manufacturer

4.3 Site of manufacture

4.4 Date of manufacture

4.5 Expiry date

4.6 Information on starting material pursuant to sub-section 3 above

4.7 If an EU official control authority batch release certificate has been issued for the excipient and is attached, this is considered to constitute adequate information on excipients originating from human blood or plasma

5. Final bulk

5.1 Batch number

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

5.3 Tests on final bulk in accordance with specifications approved in Sweden

6. Finished product

6.1 Batch number

6.2 Complete composition

6.3 Tests on finished product in accordance with specifications approved in Sweden

6.4 Filling volume

6.5 Starting date of period of validity

7. Final bulk and finished product for certain multi-component products in which sub-components are filled in separate containers that are packed together

7.1 In the case of multi-component products in which only the sub-components are tested and not the finished product with its entire composition, documentation for each sub-component shall be submitted in accordance with sub-sections 5 and 6.1–6.4. In addition, the starting date of the period of validity shall be specified for the multi-component product.

7.2 In the case of multi-component products in which the sub-components and a mixture corresponding to the finished product are tested, documentation for each sub-component shall be submitted in accordance with sub-sections 5 and 6.1–6.4 and also for the mixture in accordance with sub-section 6.3. In addition, information in accordance with sub-sections 6.1, 6.2 and 6.5 concerning the multi-component product shall be attached.

8. Certification

A qualified person shall take overall responsibility for production and control in accordance with § 4 sub-sections 1–7 of these provisions.

The qualified person shall certify in writing that each production batch meets these provisions and is in accordance with the marketing authorisation issued. In addition, the trade name of the product in Sweden, the batch number, the qualified person's name and position and the date of certification shall be specified.

§ 5 In the case of production batches for which an EU official control authority batch release certificate is issued, a copy thereof shall be submitted to the Medical Products Agency together with a completed and signed "Marketing information form" as indicated in Annex IV to the guideline on the administrative procedure for official control authority batch release issued by the Council of Europe.³

Following receipt of the documentation in accordance with the first section, the Medical Products Agency shall issue an acknowledgement of receipt and the production batch may thereafter be marketed.

³ EC administrative procedure for official control authority batch release, PA/PH/OMCL (96)4,DEF.

Approval

§ 6 Approval of production batches shall be issued by the Medical Products Agency following examination of the documentation pursuant to § 4 of these provisions and the production batch may thereafter be marketed.

Guidelines relating to § 6

Approval is national and does not have the same authority as an EU official control authority batch release certificate.

Parallel imports

§ 7 In the case of parallel-imported products, the parallel importer shall submit the following documentation:

1. The manufacturer's name or firm and postal address together with corresponding information on the marketing authorisation holder for directly imported products and the marketing authorisation holder for parallel-imported products

2. country of export

3. trade name in Sweden and in the country of export

4. batch number

5. type of container

6. number of containers in the batch

7. number of doses or volume per container

8. expiry date

9. storage conditions

10. marketing authorisation number in Sweden and the country of export and Asp number

11. a written assurance from the wholesaler who sold the batch to the parallel importer that the batch meets the applicable requirements in the country of export.

Guidelines relating to § 7

After the Medical Products Agency has received information pursuant to the first section, it shall request documentation in accordance with §§ 4 or 5 from the manufacturer or from the competent authority in the country of export.

Approval

§ 8 Approval of production batches of parallel-imported products shall be issued by the Medical Products Agency following examination pursuant to 4 § of these provisions, and thereafter the production batch may be marketed.

Guidelines relating to § 8

The approval is national and does not have the same authority as an EU official control authority batch release certificate.

Dispensations

§ 9 The Medical Products Agency may grant exemptions (dispensations) from these provisions in the case of events that may jeopardise public health.

This statute shall come into force on 1 November 2000.

The Medical Products Agency

GUNNAR ALVAN

Anna Maria Åslundh-Nilsson

Norstedts Tryckeri AB, Stockholm 2000

Senast ändrad 2005-02-01