

Decree of 15 July 1993, standing rules with regard to registering and putting immunological pharmaceutical products on the market

(Immunological Medicinal Products Decree [Version valid from 01-08-2001])

History: Staatsblad (Bulletin of Acts and Decrees of the Kingdom of the Netherlands) 1998, 139; Staatsblad 2001, 270

We Beatrix, by the grace of God, Queen of the Netherlands, Princess of Oranje-Nassau, etc., etc., etc.

On the recommendation of the State Secretary of Welfare, Health and Cultural Affairs of 3 March 1993, GMV/G no. 93247;

Considering the

- Guideline 89/342/EEG of the Council of the European Communities of 3 May 1989 for extending the sphere of influence of the Guidelines 65/65/EEG and 175/319/EEG and for establishing the attendant provisions for immunological pharmaceutical products consisting of vaccines, toxins, sera or allergens (*PbEG L 142*);
 - Guideline 91/507/EEG of the Commission of the European Communities of 19 July 1991 for amending the appendix of Guideline 75/318/EEG of the Council of the European Communities regarding the mutual alteration of the law of the Member States in the matter of the analytical, toxicopharmacological and clinical norms and instructions regarding tests on pharmaceutical specialities (*PbEG L 270*);
 - Article 1, point 3, of Guideline 89/341/EEG of 3 May 1989 altering the Guidelines 65/65/EEG, 75/318/EEG and 75/319/EEG regarding the adjustment of the legal provisions and such provisions as are a matter for regulation or administration regarding pharmaceutical specialities (*PbEG L 142*);
 - The articles 1, third part, 3, sixth part, 3a, 4, first part, under *c* and 26, under *f*, of the Medicines Act;
 - Article II, first part, of the act of 14 November 1991 (*Staatsblad 670*);
- and
- Article 6, first part, of the Exceptional Medical Expenses Act;

Seeing the advice of the Medicines Committee (21 January 1992, no. Geco 4630);

The Council of State having been heard (advice of 26 May 1993, no. W13.93.0137);

Considering the further report of the State Secretary of Welfare, Health and Cultural Affairs of 1 July 1993, GMV/G no. 932035;

Have approved and understood:

Article 1

In this decree the following is understood:

- a. The act: the Medicines Act;
- b. Pharmaceutical product: pharmaceutical speciality or pharmaceutical preparation;
- c. Immunological pharmaceutical products: allergens, vaccines, toxins and sera;
- d. Allergen: any pharmaceutical product that is intended to determine or to bring about a specific change in the immunological reaction to an allergy-causing agent;
- e. Vaccine, toxins and sera: the substances described in the appendix belonging to this decree.

Article 2

1. For the application of article 2, first part, under *d*, of the Pharmaceuticals Registration Decree, insofar as immunological pharmaceutical products are concerned:

- a. The quantitative composition is expressed in mass, international units, units or biological activity or, as far as possible, specific protein content, depending on the pharmaceutical product in question;

- b. The qualitative and quantitative composition of the components also includes data relevant to the biological activity of the protein content;
 - c. The qualitative and quantitative composition means the composition of the product expressed in terms of biological activity or protein content.
2. The usual or scientific names of the active components are always added to the names as meant for the immunological pharmaceutical products in article 2, first part, under *b*, of the Pharmaceuticals Registration Decree.
3. In addition to the data as meant in article 2, tenth part, under *f*, 4°, of the Pharmaceuticals Registration Decree, as far as immunological pharmaceutical products are concerned, data are reported that are relevant to the special precautionary measures that must be taken by people who handle these products and by people who administer them to patients. There are also data reported that are relevant to the precautionary measures that may have to be taken by the patient.

Article 3

For the application of sections 2 and 3 of the Medicinal Products (Labelling and Patient Information) Decree, regarding the immunological pharmaceutical products, the provisions in article 2, first and second parts, are of conformable application.

Article 4

[Abrogated.]

Article 5

1. The following medicines may only be supplied after release of the lots to which they belong by the authority named in the third part:
- a. Live vaccines;
 - b. Immunological pharmaceutical products that are used for the first vaccination of young children or other risk groups;
 - c. Immunological pharmaceutical products that are used in immunisation programmes within the framework of public health;
 - d. New immunological pharmaceutical products or immunological pharmaceutical products that are manufactured with the aid of altered techniques or that are new to a given manufacturer, such as during a period fixed at the registration, as meant in article 3 of the act;
 - e. The immunological pharmaceutical products named in points a to d inclusive with which tests are done in the framework of medical and scientific clinical research and that are not entered in a register as meant in article 3, first part, of the act.
2. A request for release of medicines as meant in the first part, under e, contains the following data:
- a. The name and address of the applicant;
 - b. The name of the medicine;
 - c. The coding of the lot in question;
 - d. The mention of the pharmaceutical form;
 - e. A statement of the qualitative and quantitative composition of the medicine or, if this is not possible, a statement of the basic materials used, and the processing to which they have been subjected, all with indications of the active components;
 - f. A description of the method of preparation of the medicine as well as of the active component in it;
 - g. Data regarding the microbial quality and viral safety of the medicine and the biological components in it;
 - h. A description of the analysis method and other control methods that were used in the research of the components of the medicine, accompanied by a statement of the results of the analyses of the lot in question, carried out with the aforementioned methods;
 - i. Data regarding the shelf life of the medicine;
 - j. A description of the predicted pharmacological effect of the medicine, insofar as it is known; a statement of the intended indications; the contra-indications and the side effects, as well as a statement of the dosage, the way it is to be used, the means of administration of the medicine, and the currently available data of a clinical nature;
 - k. A statement of the results of the preclinical tests of a pharmacological and toxicological nature carried out with the medicine and the active components of the medicine.

The data and documents are in Dutch or English.

3. The Chief Inspector of Pharmacy and Medical Technology is appointed as the government authority, as meant in article 3a, first part, of the act.

Article 6

Article 3, fifth part of the act, is not applicable to:

- a. An allergen that is prepared according to the given specifications of the patient's doctor in aid of the treatment of the patient to whom it is supplied, or
- b. A serum that is applied according to the specification of the patient's doctor as an antidote to bites of foreign snakes, or bites or other consequences damaging to health due to coming in contact with other foreign kinds of animals, insofar as the use of the serum by the patient takes place under the direct, personal responsibility of the aforementioned doctor.

Article 7

1. Without prejudice to article 41, first part of the Medicinal Products (Preparation and Supply) Decree, vaccines, toxins and sera can be supplied to:

- a. Institutions that carry out national programmes directed at the prevention of disease; however, the supply is provided exclusively in aid of these programmes;
- b. The offices appointed by Our Minister, by virtue of article 26 of the Quarantine Act for inoculation against yellow fever; however, the supply is provided exclusively in aid of vaccination against exotic diseases, vaccination of risk groups against contagious diseases and the tracking down of infectious diseases;
- c. Doctors, with regard to sera that are applied as antidotes to bites of foreign snakes, or bites or other consequences damaging to health due to coming in contact with other foreign kinds of animals.

2. The institutions and offices meant in the first part, under *a* and *b*, respectively, store and handle the pharmaceutical products duly. They also maintain a sound administration from which it is clear at what time the pharmaceutical products have been taken into supply, as well as to whom and on what date they were delivered. The supervision of these actions is carried out by a pharmacist who is qualified to do so.

Article 8

[Contains changes in other regulations.]

Article 9

With respect to the allergens that were lawfully on the market in the Netherlands at the time of implementation of this decree, the ban in article 3, fifth part, contained in the act is invalid until twelve months after the implementation. If registration in a register as meant in article 3 of the act within three months after the implementation is applied for, then the ban in question is also invalid until the time when a decision has been made about the application for registration.

Article 10

For an application for registration as meant in article II, first part, of the act of 14 November 1991 (*Staatsblad* 670) the data meant in article 2, second part, of the Pharmaceuticals Registration Decree are considered, on condition that the data meant in that article part under *e*, *f* and *i*, need only be supplied after they have been requested by the Committee for the Safety of Medicines, named in article 29, first part, of the act.

Article 11

The act of 14 November 1991 (*Staatsblad* 670) for alteration of the Medicines Act is effective from the time this decree takes effect.

Article 12

[Contains changes in other regulations.]

Article 13

This decree is effective starting on the day after the publication of the *Staatsblad* in which it is placed.

Article 14

This decree is known as the Immunological Medicinal Products Decree.

Charged and ordered that this decree with the accompanying note of explanation shall be placed in the *Staatsblad* (*Bulletin of Acts and Decrees of the Kingdom of the Netherlands*).

Tavarnelle, 15 July 1993

The State Secretary of Welfare, Health and Cultural Affairs,
H. J. Simons

Beatrix

Published 2 September 1993

The Minister of Justice,
E. M. H. Hirsch Ballin

Appendix. Belonging to article 1, under e, of the Immunological Medicinal Products Decree

The substances meant in article 1, under e, are:

- Substances that are used to bring about an active immunity (such as cholera vaccine, BCG vaccine, the vaccines against poliomyelitis and smallpox);
- Substances that are used to determine immunity; these substances include tuberculin and PPD tuberculin, the Schick and Dick toxins, brucellin;
- Substances that are used to bring about a passive immunity (such as diphtheria antitoxin, the globulins against smallpox and against lymphocytosis).