

Past Directive 2001/83

Articles directly in connection with homeopathic medicinal products

Article 1.5

Homeopathic medicinal products:

Any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.

A homeopathic medicinal product may also contain a number of principles.

Article 13

1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 14,15 and 16, except where the products are covered by a registration which was granted under national law on or before 31 December 1993 (and whether or not that registration or authorisation has been renewed after that date). Each Member State shall take due account of registrations and authorisations previously granted by another Member State.

2. A Member State may refrain from establishing a special, simplified registration procedure for the homeopathic medicinal products referred to in Article 14. A Member State shall inform the Commission accordingly. The Member State concerned shall allow the use in its territory of homeopathic medicinal products registered by other Member States in accordance with Article 14 and 15.

Article 14

1. Only homeopathic medicinal products which satisfy all the following conditions may be subject to a special, simplified registration procedure:

- they are administered orally or externally,
- no specific therapeutic indications appears on the labelling of the medicinal products or any information relating thereto

There is a sufficient degree of dilution to guarantee the safety of the medicinal products;
In particular the product may not contain

CURRENT Directive 2004/27 of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC

Articles directly in connection with homeopathic medicinal products

Article 1.5

Unchanged

Article 13

1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market within the Community are registered or authorised in accordance with Articles 14,15 and 16, except where the products are covered by a registration or authorisation issued in accordance with national legislation up to 31 December 1993. **In case of registrations, Article 28 and 29, paragraphs 1-3 shall apply.**

2. **A Member State shall establish** a special, simplified registration procedure for the homeopathic medicinal products referred to in Article 14.

Article 14

Unchanged

Unchanged

Unchanged

Unchanged

either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription

At the time of registration the Member State shall determine the classification for the dispensing of the medicinal product

Unchanged

If new scientific evidence so warrants, the Commission may amend the third indent of the first subparagraph by the procedure referred to in Article 121(2)

2. The criteria and rules of procedure provided for in Article 4(4), Article 17(1) and Articles 22 to 26, 112, 116 and 125 shall apply by analogy to the special, simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.

Unchanged

3. The proof of therapeutic efficacy shall not be required for homeopathic medicinal products registered in accordance with paragraph 1 of this Article, or, where appropriate, admitted in accordance with Article 13(2)

Deleted

Article 15

Article 15

An application for special, simplified registration may cover a series of medicinal products derived from the same homeopathic stock or stocks. The following documents shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the products concerned

Unchanged

- scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered

Unchanged

- dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their homeopathic nature, on the basis of an adequate bibliography

Unchanged

- manufacturing and control file for each pharmaceutical form and a prescription of the method of dilution and potentization.

Unchanged

- manufacturing authorisation for the medicinal product concerned.

Unchanged

- copies of any registrations or authorizations obtained for the same medicinal product in other Member States

Unchanged

- one or more *specimens or* mock-ups of the outer packaging and the immediate packaging of the medicinal product to be registered

- data concerning the stability of the medicinal product

Article 16

1. Homeopathic medicinal products other than those referred to in Article 14(1) shall be authorised and labelled in accordance with the Articles 8, 10 and 11

2. A member State may introduce or retain in its territory specific rules for the *toxicological and pharmacological tests* and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State.

In this case, the Member State concerned shall notify the Commission of the specific rules in force

3. Title IX shall apply to homeopathic medicinal products, with the exception of those referred to in Article 14(1)

Article 39

The provisions referred to in Articles 27 to 34 shall not apply to the homeopathic medicinal products referred to in Article 16(2)

Article 68

Whitout prejudice to the provisions of Article 69, homeopathic medicinal products shall be labelled in accordance with the provisions of this title and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.

Article 69

1. In addition to the clear mention of the words “homeopathic medicinal product”, the labelling and, where appropriate, the package insert for the medicinal products referred to in Article 14(1) shall bear the following, and no other , information

- one or more mock-ups of the outer packaging and the immediate packaging of the medicinal product to be registered

Unchanged

Article 16

1. Homeopathic medicinal products other than those referred to in Article 14(1) shall be authorised and labelled in accordance with the Articles 8, 10, **10a**, **10b**, **10c** and 11

2. A member State may introduce or retain in its territory specific rules for the **preclinical tests** and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State.

Unchanged

Unchanged

Article 39

Article 29(4), (5) and (6) and Articles 30 to 34 shall not apply to homeopathic medicinal products as referred to in Article 14

Articles **28** to 34 shall not apply to the homeopathic medicinal products referred to in Article 16(2)

Article 68

Unchanged

Article 69

Unchanged

- the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(5)	- the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 1(5); <i>if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name</i>
- name and address of the registration holder and, where appropriate, of the manufacturer	Unchanged
- method of administration and, if necessary, route,	Unchanged
- expiry date, in clear terms (month, year),	Unchanged
- pharmaceutical form,	Unchanged
- contents of the sales presentation,	Unchanged
- special storage precautions, if any,	Unchanged
- a special warning if necessary for the medicinal product,	Unchanged
- manufacturer's batch number,	Unchanged
- registration number,	Unchanged
- "homeopathic medicinal product without approved therapeutic indications	Unchanged
- a warning advising the user to consult a doctor if the symptoms persist <i>during the use of the medicinal product.</i>	- a warning advising the user to consult a doctor if the symptoms persist.
2. Notwithstanding paragraph 1, Member States require the use of certain types of labelling in order to show:	Unchanged
- the price of the medicinal product,	Unchanged
- the conditions for refunds by social security bodies	Unchanged

Article 100

Advertising of homeopathic medicinal products referred to in *Article 13 (2) and Article 14 (1)* shall be subject to the provisions of this title with the exception of Article 87 (1).

However, only the information specified in Article 69 (1) may be used in the advertising of such medicinal products.

Moreover, each Member State may prohibit in its territory any advertising of the homeopathic medicinal products referred to in Article 13 (2) and Article 14 (1)

Article 119

The provisions of this title shall apply to homeopathic medicinal products, *subject to the provisions of Article 14 (3)*

Article 100

Advertising of homeopathic medicinal products referred to in Article 14 (1) shall be subject to the provisions of this title with the exception of Article 87 (1).

Unchanged

Deleted

Article 119

The provisions of this title shall apply to homeopathic medicinal products.

Annexes:

- 1. Articles 27, 28 and 29(1-3)**
(mutual recognition procedure)
- 2. Article 121**
(comitology procedure; Art. 14.1)
- 3. Articles 10a, 10b and 10c**
(marketing authorisation; Art. 16.1)

**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 29 September 2003
(OR. en)**

**10950/3/03
REV 3**

**Interinstitutional File:
2001/0253 (COD)**

**ECO 140
AGRILEG 184
SAN 148
CODEC 921
OC 5**

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject : Common position adopted by the Council 29 September 2003 with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Annex 1

**Articles 27, 28 and 29(1-3)
(mutual recognition procedure)**

25) the heading of Chapter 4 of Title III shall be replaced by the following:

"Chapter 4

Mutual recognition procedure and decentralised procedure";

26) Articles 27 to 32 shall be replaced by the following:

"Article 27

1. A coordination group shall be set up for the examination of any question relating to marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in this Chapter. The Agency shall provide the secretariat of this coordination group.

2. The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.

3. The coordination group shall draw up its own Rules of Procedure, which shall enter into force after a favourable opinion has been given by the Commission. These Rules of Procedure shall be made public.

Article 28

1. With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as “reference Member State” and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3.

2. Where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. To this end, the marketing authorisation holder shall request the reference Member State either to prepare an assessment report on the medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be sent to the concerned Member States and to the applicant.

3. In cases where the medicinal product has not received a marketing authorisation at the time of application, the applicant shall request the reference Member State to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The reference Member State shall prepare these draft documents within 120 days after receipt of a valid application and shall send them to the concerned Member States and to the applicant.

4. Within 90 days of receipt of the documents referred to in paragraphs 2 and 3, the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

5. Each Member State in which an application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved, within 30 days after acknowledgement of the agreement.

Article 29

1. If, within the period laid down in Article 28(4), a Member State cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on the grounds of potential serious risk to public health, it shall give a detailed exposition of the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be forthwith referred to the coordination group.

2. Guidelines to be adopted by the Commission shall define a potential serious risk to public health.

3. Within the coordination group, all Member States referred to in paragraph 1 shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Article 28(5) shall apply.

4. If the Member States fail to reach an agreement within the 60-day period laid down in paragraph 3, the Agency shall be immediately informed, with a view to the application of the procedure under Articles 32, 33 and 34. The Agency shall be provided with a detailed statement of the matters on which the Member States have been unable to reach agreement and the reasons for their disagreement. A copy shall be forwarded to the applicant.

5. As soon as the applicant is informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in the first subparagraph of Article 28(1).

6. In the circumstances referred to in paragraph 4, Member States that have approved the assessment report, the draft summary of product characteristics and the labelling and package leaflet of the reference Member State may, at the request of the applicant, authorise the medicinal product without waiting for the outcome of the procedure laid down in Article 32. In that event, the authorisation granted shall be without prejudice to the outcome of that procedure.

**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 29 September 2003
(OR. en)**

**Interinstitutional File:
2001/0253 (COD)**

**10950/3/03
REV 3**

**ECO 140
AGRILEG 184
SAN 148
CODEC 921
OC 5**

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject : Common position adopted by the Council 29 September 2003 with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Annex 2

**Article 121
(comitology procedure; Art. 14.1)**

78) Article 119 shall be replaced by the following:

"Article 119

The provisions of this Title shall apply to homeopathic medicinal products.";

79) Articles 121 and 122 shall be replaced by the following:

"Article 121

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, hereinafter called "the Standing Committee", in the task of adapting to technical progress the directives on the removal of technical barriers to trade in the medicinal products sector.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

4. The Standing Committee shall adopt its own rules of procedure which shall be made public.

Article 122

1. Member States shall take all appropriate measures to ensure that the competent authorities concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 40 and 77, on the certificates referred to in Article 111(5) or on the marketing authorisations are fulfilled.
2. Upon reasoned request, Member States shall forthwith communicate the reports referred to in Article 111(3) to the competent authorities of another Member State.
3. The conclusions reached in accordance with Article 111(1) shall be valid throughout the Community.

**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 29 September 2003
(OR. en)**

**Interinstitutional File:
2001/0253 (COD)**

**10950/3/03
REV 3**

**ECO 140
AGRILEG 184
SAN 148
CODEC 921
OC 5**

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject : Common position adopted by the Council 29 September 2003 with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Annex 3

**Articles 10a, 10b and 10c
(marketing authorisation; Art. 16.1)**

- 9) the following Articles shall be inserted:

"Article 10a

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the test and trial results shall be replaced by appropriate scientific literature.

Article 10b

In the case of medicinal products containing active substances used in the composition of authorised medicinal products but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with Article 8(3)(i), but it shall not be necessary to provide scientific references relating to each individual active substance.

Article 10c

Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.";