## Basic information

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| **1997/2170(COS)**<br>COS - Procedure on a strategy paper (historic)<br>Homeopathic medicinal products: application of directives 92/73/EEC and 92/74/EEC. Commission report<br>**Subject**<br>4.20.04 Pharmaceutical products and industry | Procedure completed |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Consumer Protection | CHANTERIE Raphaël M. G. (PPE) | 08/10/1997 |

| Committee for opinion | Rapporteur for opinion | Appointed |
|---|---|---|
| AGRI Agriculture and Rural Development | HALLAM David John Alfred (PSE) | 26/11/1997 |
| ECON Economic and Monetary Affairs, Industrial Policy | HAUTALA Heidi (V) | 12/12/1997 |
| ENER Research, Technological Development and Energy | BREYER Hiltrud (V) | 09/12/1997 |
| JURI Legal Affairs, Citizens' Rights | ZIMMERMANN Wilmya (PSE) | 14/10/1997 |

### Council of the European Union

| Council configuration | Meetings | Date |
|---|---|---|
| Health | 2131 | 1998-11-12 |

## Key events

| Date | Event | Reference | Summary |
|---|---|---|---|
| 14/07/1997 | Non-legislative basic document published | COM(1997)0362 | Summary |
| 02/10/1997 | Committee referral announced in Parliament | | |
| 27/10/1998 | Vote in committee | | Summary |
| 27/10/1998 | Committee report tabled for plenary | A4-0378/1998 | |

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|---|---|---|---|
| 04/11/1998 | Debate in Parliament | | |
| 05/11/1998 | End of procedure in Parliament | | |
| 12/11/1998 | Debate in Council | | |
| 23/11/1998 | Final act published in Official Journal | | |

| Technical information | |
|---|---|
| **Procedure reference** | 1997/2170(COS) |
| **Procedure type** | COS - Procedure on a strategy paper (historic) |
| **Procedure subtype** | Commission strategy paper |
| **Legal basis** | Rules of Procedure EP 148 |
| **Stage reached in procedure** | Procedure completed |
| **Committee dossier** | ENVI/4/09116 |

Documentation gateway

**European Parliament**

| Document type | Committee | Reference | Date | Summary |
|---|---|---|---|---|
| Committee report tabled for plenary, single reading | | A4-0378/1998<br>OJ C 359 23.11.1998, p. 0004 | 27/10/1998 | |
| Text adopted by Parliament, single reading | | T4-0644/1998<br>OJ C 359 23.11.1998, p. 0015-0094 | 05/11/1998 | Summary |

**European Commission**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Non-legislative basic document | COM(1997)0362 | 14/07/1997 | Summary |

# Homeopathic medicinal products: application of directives 92/73/EEC and 92/74/EEC. Commission report

1997/2170(COS) - 14/07/1997 - Non-legislative basic document

OBJECTIVE: presentation of the Commission report to the European Parliament and Council on the application of Directives 92/73/EEC (homeopathic medicinal products for human use) and 92/74/EEC (homeopathic veterinary medicinal products). SUBSTANCE: the report is based on an in-depth study of the application of Directives 92/73/EEC and 92/74/EEC carried out by independent consultants on behalf of the European Commission. It notes a certain degree of disparity in the application of the Directives in the Member States and contradictions in their interpretation. Infringement procedures concerning full or partial non-transposition have been started (and are still in progress) against Belgium and France regarding Directive 92/73/EEC and against Belgium, France, Portugal and the United Kingdom regarding Directive 92/74/EEC. Before presenting a concrete proposal for the amendment of the Directives concerned, and in order to identify feasible solutions to the problems raised in the reports, the Commission is inviting the European Parliament and the Council to express their views and positions on the following suggestions: - the wording according to which each Member State must take due account of registrations and authorizations previously granted by another Member State could be reconsidered in order to define exactly the specific conditions under which existing national registrations should be mutually recognized or endorsed by other Member States; - Directive 92/73/EEC could be amended in order to increase the range of products subject to a simplified procedure; - Directive 92/74/EEC could be

amended in order to make the simplified registration procedure also applicable to homeopathics intended to be administered to food-producing animals; - the possibility of using fantasy names for combination preparations could be introduced. The normal daily dosage could also be included in the labelling, and a warning to consult a doctor could also be considered, in order to make the labelling more consumer-friendly; - consideration could be given to making the provisions on clinical trials binding and to demanding explicitly that the specific rules for clinical trials in Member States should provide for the involvement of suitable experts in homeopathic medicine.

# Homeopathic medicinal products: application of directives 92/73/EEC and 92/74/EEC. Commission report

1997/2170(COS) - 05/11/1998 - Text adopted by Parliament, single reading

In adopting the report by Mr Raphaël CHANTERIE (PPE, B), the European Parliament called for amendments to Directives 92/73/EEC and 92/74/EEC and for homeopathic anthroposophic medicinal products described in an official pharmacopoeia to be given the same status as homeopathic medicinal products. It called for a range of measures with regard to recognition, registration procedure and labelling. 1) Recognition: Parliament called on the Commission to investigate whether a system of mutual recognition of homeopathic medicinal products could be set up, which should be run by a Community body of duly authorised persons with expertise in this field. It called for the drawing up of rules on the compilation of files and applications for registration to be applied by Member States. Meanwhile, Member States should actually recognise registrations carried out, or authorizations granted, by other Member States. The conditions under which national registration should be mutually recognised or endorsed by other Member States should be defined. Parliament called for common safety criteria to be applied throughout the EU. 2) Registration: Parliament called on the Commission to investigate whether homeopathic medicinal products administered by means of injection, plaster, spray, drops, suppository or by any other route other than orally or for external use with no risk to the health or safety of the user could be considered for the special, simplified registration procedure. It called on the Commission to investigate ways and means of producing a valid Community list of degrees of dilution determined for the mother tincture and, in the absence of such a list, to revise and, if possible, to increase the existing degrees of dilution. 3) Labelling: Parliament called for the lifting of the ban on fantasy names, in particular for preparations. It advocated an obligatory indication of the dose or instructions for use on the label and, where appropriate, in the package insert. It called for an end to the obligation to use the statement 'homeopathic medicinal product without approved therapeutic indications', and for modification of the warning, on specific homeopathic medicinal products intended for humans, advising the user to consult a doctor if the symptoms persist 'during the use of the medicinal product'. It called on the Commission to submit a proposal, with the participation of experts, obliging Member States to draw up special rules for the pharmacological, toxicological and clinical tests for the testing of homeopathic medicinal products which were not eligible for the special, simplified registration procedure.