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***II
RECOMMENDATION FOR SECOND READING

on the common position established by the Council with a view to the adoption of a European Parliament and Council regulation on orphan medicinal products (9616/1/1999 - C5-0182/1999 – 1998/0240(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Françoise Grossetête

Symbols for procedures	
*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*
(The type of procedure depends on the legal basis proposed by the Commission)	

Abbreviations for committees		
I.	AFET	Committee on Foreign Affairs, Human Rights, Common Security and Defence Policy
II.	BUDG	Committee on Budgets
III.	CONT	Committee on Budgetary Control
IV.	LIBE	Committee on Citizens' Freedoms and Rights, Justice and Home Affairs
V.	ECON	Committee on Economic and Monetary Affairs
VI.	JURI	Committee on Legal Affairs and the Internal Market
VII.	INDU	Committee on Industry, External Trade, Research and Energy
VIII.	EMPL	Committee on Employment and Social Affairs
IX.	ENVI	Committee on the Environment, Public Health and Consumer Policy
X.	AGRI	Committee on Agriculture and Rural Development
XI.	PECH	Committee on Fisheries
XII.	REGI	Committee on Regional Policy, Transport and Tourism
XIII.	CULT	Committee on Culture, Youth, Education, the Media and Sport
XIV.	DEVE	Committee on Development and Cooperation
XV.	AFCO	Committee on Constitutional Affairs
XVI.	FEMM	Committee on Women's Rights and Equal Opportunities
XVII.	PETI	Committee on Petitions

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Procedural page

At its sitting of 9 March 1999 Parliament delivered its opinion at first reading on the proposal for a European Parliament and Council regulation on orphan medicinal products (COM(1998) 450 - 1998/0240(COD)).

At the sitting of 7 October 1999 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (9616/1/1999 - C5-0182/1999).

The committee had appointed Françoise Grossetête rapporteur at its meeting of 2 September 1999.

It considered the common position and the draft recommendation for second reading at its meeting of 25 November 1999.

At this meeting it adopted the draft legislative resolution unanimously.

The following were present for the vote: Lage, acting-chairman; De Roo, vice-chairman; Grossetete, rapporteur; Bowe, Bowis, Bushill-Matthews (for Arvidsson), Corbey, Fatuzzo (for Ayuso Gonzalez), Gorostiaga Atxalandabaso (for Kronberger), Graefe zu Baringdorf (for Schörling), Isler Béguin, Liese, Malliori, McKenna, Nistico, Paulsen, Redondo Jiménez (for De Sarnez), Roth-Behrendt, Sacconi, Staes (for Breyer), Sturdy (for Doyle), Whitehead

The recommendation for second reading was tabled on 25 November 1999.

The deadline for tabling amendments to the common position will be indicated in the draft agenda for the relevant part-session.

DRAFT LEGISLATIVE RESOLUTION

Legislative resolution of the European Parliament on the Council common position with a view to the adoption of a European Parliament and Council regulation on orphan medicinal products (9616/1/1999 – C5-0182/1999 – 1998/0240(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position 9616/1/1999 – C5-0182/1999),
- having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(1998)0450[2]),
- having regard to the Commission's amended proposal (COM(1999) 298)[3],
- having regard to Article 251(2) of the EC Treaty,
- having regard to Rule 78 of its Rules of Procedure,
- having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0080/1999),

1. Approves the common position;
2. Notes that the act is adopted in accordance with the common position;
3. Instructs its President to sign the act with the President of the Council pursuant to Article 254(1) of the EC Treaty;
4. Instructs its Secretary-General duly to sign the act and, in agreement with the Secretary-General of the Council, to have it published in the Official Journal of the European Communities;
5. Instructs its President to forward its position to the Council and Commission.

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1 OJ C 175, 21.6.1999, p.17.
2 OJ C 276, 4.9.1998, p.7.
3 OJ C not yet published

EXPLANATORY STATEMENT

1. Purpose of the proposal for a regulation

The purpose of this proposal, which was initiated in 1995 by the French Council Presidency, is to encourage the pharmaceutical industry to become involved in research, development and marketing of orphan medicinal products. As such products do not represent a sufficiently profitable market, the industry has little inclination to devote the necessary funding to them.

2. Definition of an orphan medicinal product

Orphan medicinal products concern primarily rare diseases as defined in the *Programme of Community action on rare diseases within the framework for action in the field of public health* (COM(97) 225). These are diseases whose prevalence in the Community population is less than five in ten thousand.

These medicinal products also concern other more widespread diseases for which medicinal products are deemed to be uneconomic in terms of justifying the necessary investment.

Pharmaceutical research and development are costly and uncertain. Laboratories suffer many setbacks before encountering success. Where rare diseases are concerned, research is all the more difficult and risky as the small number of patients makes testing and experimentation very tricky to carry out.

- The definition criteria that have been adopted fall into three categories:

- the first one is epidemiological : prevalence of less than five cases in ten thousand in the territory of the Community,

- the second is economic : presumed absence of an economic return where the prevalence is more than five in ten thousand in the case of life-threatening, seriously debilitating or serious and chronic conditions,

- the third is medical : in all cases, the new medicinal product must improve the method of diagnosis, prevention or treatment of the condition.

3. Community procedure and incentives contained in the common position

The proposal for a regulation allows the sponsors of orphan medicinal products to resort to a Community procedure similar to that governing the authorisation for the marketing of pharmaceuticals in force since 1 January 1995.

A Committee for Orphan Medicinal Products is to be set up within the European Agency for the Evaluation of Medicinal Products and will designate these products. In addition to the representatives of the Member States and experts, it will comprise three members representing patients' organisations.

The planned incentives are the following:

- market exclusivity for a period of ten years in respect of the two factors 'product/

indication' in conjunction,

- waiving, in part or in total, of registration fees,

- assistance during the development phase of the medicinal product (experimental protocols and clinical investigations),

- support for research, development and marketing through national and Community incentives, in particular to assist SMEs, as provided for in the framework programmes for research and technological development,

4. Reminder of legislative procedure.

On 9 March 1999, Parliament defined its position at first reading on the proposal for a Council regulation on orphan medicinal products.

20 amendments were adopted at the time.

The common position of the Council takes over nine amendments in full and two in part.

These amendments seek :

to broaden the criteria for designation :

- by extending the economic criteria for designating orphan medicinal products to all serious and chronic conditions (Amendments 3 and 7);

to render more flexible and expand the procedure for designation and removal from the register :

- by extending the submission of an application for registration of an orphan medicinal product to the entire development process (Amendment 11);

- by facilitating the transfer of this designation from one sponsor to another, e.g. in the event of corporate mergers or restructuring (Amendment 13);

- by defining in an implementing regulation (which is more flexible and hence more easily adaptable to scientific progress) the concepts of 'similar medicinal product' and 'clinical superiority' (Amendment 19);

- by stipulating an annual report from the sponsor to the Agency on the state of development of the designated medicinal product (Amendment 12);

to spell out that the designation of an orphan medicinal product does not jeopardise other intellectual property rights (Amendments 4 and 16);

to spell out the mission entrusted to the European Agency for the Evaluation of Medicinal Products, i.e.:

- by setting up within the European Agency for the Evaluation of Medicinal Products a Committee for Orphan Medicinal Products (Amendment 8);

- by imposing an obligation of professional secrecy on the members of the committee (Amendment 10);

to extend the incentives to include the framework programme for research and technological development (Amendment 21).

5. Budgetary problem

Article 7(2) of the proposal stipulates that the European Agency for the Evaluation of Medicinal Products in order to discharge this new responsibility is to be allocated 'a special contribution from the Community, distinct from that provided for in Article 57 of Regulation (EEC) No 2309/93, … The contribution shall be used exclusively by the Agency to waive, in part or in total, all the fees payable under Community rules adopted pursuant to Regulation (EEC) No 2309/93. A detailed report of the use made of this special contribution shall be presented by the Executive Director of the Agency at the end of each year. Any surplus occurring in a given year shall be carried forward and deducted from the special contribution for the following year.'

The budget for 2000 is currently under consideration but this question is an important one for the future. It is essential that the Agency has the budget necessary to implement this regulation.

6. Arguments in favour of this new regulation

The first argument is of an ethical nature. There are some 5000 rare diseases recorded today in Europe. They are all extremely serious, acutely debilitating and fatal in the longer term. They affect around 8% of Europe's population, between 25 and 30 million people. It is unacceptable that certain categories of patients should be left on the sidelines of scientific progress on the pretext that the disease from which they are suffering is a rare one.

The second argument is an economic one. The European Union, compared with the USA and Japan, is very backward in this area. Japan passed a law in 1993, while the USA adopted the Orphan Drugs Act back in 1983. Thanks to this legislation, approx. 900 orphan medicinal products have been designated and 190 are already on the market.

With more than 2000 companies engaged in pharmaceuticals and 500 in biotechnology, the Union possesses a research potential at least equivalent to that of the USA. If the American experience is anything to go by, innovative small and medium-sized companies are more likely to take advantage of these incentives than the major pharmaceutical laboratories. Small-scale companies specialising in biotechnology will have a particular role to play since the immense majority of rare diseases are of genetic origin.

The third argument is of a scientific nature. Research and development are of overriding importance where this kind of medicinal product is concerned. The example of AZT is highly significant: in 1985 the Wellcome laboratories registered this product in Washington with the status of an orphan drug. At the time, the number of seropositive persons was very low, making AIDS a rare disease. Without the specific status as an orphan medicinal product created by the 1983 Orphan Drugs Act, the odds are that Wellcome's financial backers would not have taken the risk of launching a research and development programme of this nature.

7. Rapporteur's conclusions

In the light of all these arguments, the Council's common position has to be considered a balanced one. The most substantial amendments adopted by Parliament have been taken over and have made it possible to clarify and sharpen up the wording while rendering the procedure more flexible.

Subject to the problem relating to the budget being resolved, your rapporteur is in favour of the common position being adopted as it stands.