COMMISSION OF THE EUROPEAN COMMUNITIES

SEC (91)2066 final - SYN 229-230-231-273 Brussels, 12 November 1991

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

pursuant to Article 149.2(b) of the EEC Treaty

Common positions of the Council on four proposals for directives on medicinal products for human use :

- Proposal for a Council Directive on the wholesale distribution of medicinal products for human use (SYN 229)
- Proposal for a Council Directive on the legal status for the supply of medicinal products for human use (SYN 230)
- Proposal for a Council Directive on the labelling of medicinal products for human use and for package leaflets (SYN 231)
- Proposal for a Council Directive on the advertising of medicinal products for human use (SYN 273)

COMMUNICATION FROM THE COMMISSION TO PARLIAMENT

On 26 January 1990 the Commission sent the Council three proposals for directives on the rational use of medicinal products (COM(89)607 final):

- Proposal for a Council Directive on the wholesale distribution of medicinal products for human use (SYN 229)

- Proposal for a Council Directive on the legal status for the supply medicinal products for human use (SYN 230)

- Proposal for a Council Directive on the labelling of medicinal products for human use and for package leaflets (SYN 231)

On 6 June 1990 the Commission furthermore sent it a proposal for a Council Directive on the advertising of medicinal products for human use (SYN 273) (COM(90)212 final).

In the light of Parliament's opinions of 12 June 1991 on these four proposals, the Commission amended its proposals on 18 July 1991 (COM(91)245 final).

On 21 October 1991 the Council adopted common positions on these four proposals.

The Commission hereby submits the following comments to Parliament in accordance with Article 149(2)(b) of the EEC Treaty.

Commission comments on the Council's common position on the wholesale distribution of medicinal products for human use (SYN 229)

1. General

For the most part, the Council's common position is in line with the Commission's original proposal. The main amendment by the Council corresponds to an amendment by Parliament which the Commission had included in its amended proposal (see point 3 below).

2. Links between authorization of manufacture and authorization of distribution

Parliament had proposed spelling out, in a recital, the relationship between the authorization to manufacture medicinal products (provided for in Article 16 of Directive 75/319/EEC), authorization for the wholesale distribution of medicinal products, and authorization for the supply of medicinal products to the public. The Council adopted these details but incorporated them in the body of the directive (Article 3(2) and (3)).

3. Public service obligations

The Commission had included, in its amended proposal, a definition of public service obligations (Article 1(2a) and the principle that these obligations are not affected by the directive under consideration (Article 7). The Council adopted the definition but retained the text of the Commission's initial proposal as regards Article 7. Furthermore, the Council made it clear that the public service obligations cannot be imposed on a wholesaler established in another Member States unless these obligations are justified on grounds of public health protection and are in proportion to the objective of protection. The Commission has accepted this addition, which merely embodies a general principle of Community law.

4. Reference to the batch number in the documents retained by wholesalers

The Council has deleted the batch number from the information which must appear in the documents retained by wholesalers (Article 6(e)). This deletion had been requested by Parliament but the Commission had not included it in its proposal. The Council and the Commission have agreed, in a statement in the minutes, that the question of the batch number will be dealt with in the framework of the guidelines referred to in Article 10.

5. Publication of guidelines

In its amended proposal, the Commission proposed, as suggested by Parliament, a period of two years for the publication of the guidelines referred to in Article 10. The Council has not specified any period. This will obviously not prevent the Commission from publishing the guidelines within two years of adoption of the directive.

6. Entry into force of the directive

The Council has postponed the entry into force of the directive by one year (1 January 1993 instead of 1 January 1992). This postponement would seem to be essential in view of the time which has elapsed since the Commission put forward its proposal.

Commission comments on the Council's common position on the legal status for the supply of medicinal products for human use (SYN 230)

1. General

The Council's common position includes most of the amendments which the Commission made to its proposal in the light of Parliament's opinion.

2. Subcategories of medicinal products available on prescription only

The Council has adopted, as provided for in the amended proposal, two subcategories of medicinal products available on prescription only (Article 3(2) and (3)). The common position specifies that the competent authorities may waive the application of these subcategories under certain conditions which are specified (Article 3(4)). Furthermore, it lays down that, where a Member State does not introduce the subcategories, it must nevertheless take account of the criteria referred to in paragraphs 2 and 3 of Article 3 to determine whether a medicinal product should be included among the category of products supplied on prescription only. These additions are in keeping with the spirit of the amended proposal and the Commission therefore accepts them.

3. Clarification with regard to classification in the marketing authorization file

The common position does not specify that the legal status of supply of a medicinal product and its classification are to be set out in the marketing authorization and included in the summary of the product characteristics (Article 4 of the amended proposal). The Council has taken the view that this should be included in the corresponding provisions of Directive 65/65/EEC (Articles 4 and 4a) and the Commission has accepted this viewpoint.

4. Establishment of common lists

In its common position, the Council has not provided for the establishment by the Commission, within five years of the adoption of the directive, of common lists of medicinal products available on prescription only and of those which are available without medical prescription (Article 5(3) and (4) of the amended proposal). The Council has not accepted this provision, but has laid down that, within four years, the Commission is to report to it on the application of the directive, the report being accompanied, if necessary, by appropriate proposals.

5. Entry into force of the directive

The Council has postponed the entry into force of the directive by one year (1 January 1993 instead of 1 January 1992). This postponement would seem to be essential in view of the time which has elapsed since the Commission put forward its proposal.

Commission comments on the Council's common position of the Council on the labelling of medicinal products for human use and on package leaflets

(SYN 231)

1. General

The common position contains several amendments to the amended proposal. The amendments are mostly technical and are mainly aimed at specifying the obligations under the Directive. The Commission therefore accepts the common position.

2. Definitions

The Council has added a definition of the dose of a medicinal product and a definition of the manufacturer to the definitions appearing in the amended proposal. The Commission believes these two additions are useful.

3. Deletion of Article 2

The Council has taken the view that it is not necessary to state that an unauthorized medicinal product may not be authorized. The Commission shares this viewpoint, the principle of which is already included in Community law (Article 3 of Directive 65/65/EEC).

4. Compulsory labelling

The Council's common position (Article 2) adds four additional points of detail to the amended proposal (Article 3):

- where there are several pharmaceutical forms or several doses for a medicinal product, the pharmaceutical form or dose is to be included in the name of the medicinal product (paragraph 1(a)),
- all of the excipients are to be mentioned in the case of an injectable product, a topical preparation or an eyewash (paragraph 1(d)),

- where a special warning is required, it is to appear on the labelling (paragraph 1(g)),
- for medicinal products for self-medication, information regarding use is to appear on the labelling (paragraph 1(n)).

The Commission has accepted these four points of detail which are in keeping with its amended proposal.

5. Labelling particulars

The Council's common position does away with the need to include certain particulars in the same visual area (Article 5(2) of the proposal) and states that the outer packaging may include symbols or pictogrammes useful for health education but not any promotional material (Article 2(2) of the common position). These amendments bring the labelling provisions into line with those for the leaflet.

6. Package leaflet

The common position (Article 7) contains only minor amendments as regards the package leaflet as compared with the amended proposal.

7. Guidelines

The common position (Article 12) does not lay any deadline for the adoption of guidelines. However, it does specify that these guidelines are to be adopted in the form of a directive sent to the Member States in accordance with the procedure laid down in Article 2(d) of Directive 75/318/EEC. As the measures to be taken are regulatory and the procedure concerned is customary in the field of medicinal products for human use, the Commission has accepted this amendment.

8. Entry into force of the Directive

The Council has postponed the entry into force of the directive by one year (1 January 1993 and 1 January 1994 instead of 1 January 1992 and 1 January 1993 respectively). This postponement would seem to be essential in view of the time which has elapsed since the Commission put forward its proposal.

Commission comments on the Council's common position on the advertising of medicinal products for human use (SYN 273)

1. General

The Council's common position contains several major amendments as compared with the Commission's amended proposal as it leaves a number of matters (the authorization of reminder advertising, indication of the sales price in publicity supplied to professionals, the number of free samples which may be given to health care professionals) to the discretion of the Member States. However, the Commission has accepted these amendments, taking the view that they do not distort the general balance of the text and they reflect the still profound differences between medical conventions in the various Member States, that the differences between the national laws which may result will not affect the functioning of the internal market and that fuller harmonization can take place at a later date if the need is felt.

2. Definitions

The common position defines the "advertising of medicinal products" and lists various forms of advertising (Article 1(3)). It also refers to certain forms of communication which are not considered to be covered by the directive (Article 1(4)). The Commission has accepted these amendments which add useful additional information as regards the scope of the directive without narrowing or widening it.

3. Medicinal products which may be advertised to the public

The common position retains the principle on which the Commission's amended proposal was based. However, it defines self-medication (Article 3(2)) and

allows the Member States to prohibit the advertising of medicinal products subject to reimbursement and to authorize the direct distribution of medicinal products to the public in exceptional cases and for non-promotional purposes. The common position does not expressly prohibit the advertising to the public of medicinal products which are habit-forming or addictive (Article 3(1) of the amended proposal). However, it should be borne in mind that such medicinal products will normally be available on medical prescription only and that advertising of them will therefore be prohibited.

4. Reminder advertising

The common position allows the Member States to authorize reminder advertising to the public (Article 4(2)). The Commission had already informed Parliament that it was itself not opposed to such authorization.

5. Prohibition of certain forms of advertising

The Council has extended the list of forms of advertising to the public which are prohibited (Article 5(i), (j), (k), (l)). The addition actually illustrates the general principle that the advertising of medicinal products must promote their rational use and may not be misleading.

6. Sponsorship of promotional events

With regard to the sponsorship of scientific congresses, the common position (Article 10) includes what is set out in the amended proposal in the light of Parliament's opinion. Furthermore, the common position extends this principle to promotional events for medicinal products (Article 9(2)). This does not create any problems.

7. Free samples

The amended proposal limited the number of free samples which may be given each year to any doctor to 2. The common position states that only a "limited number" of samples may be given, thereby allowing the Member States a certain degree of flexibility in applying the principle. While it believes that it would have been better to state specifically in the directive the number of samples which may be given away, the Commission agrees that monitoring of the compliance with such a provision would be difficult and that a slight divergence in the application of this rule is of no consequence as regards the functioning of the internal market.

8. Monitoring of advertising

First, the common position states that the means used by the Member States to monitor the advertising of medicinal products may be based on a system of prior control (Article 12(1)). This point of detail, which is in keeping with Parliament's request, does not pose any problems for the Commission. Second, the Council has aligned the provisions on monitoring of the advertising of medicinal products (Article 12(2)) with those in Directive 84/450/EEC on misleading advertising (Article 4(2)). This solution has the advantage of harmonizing the provisions under Community law on the monitoring of advertising.

9. Entry into force of the Directive

The Council has postponed the entry into force of the Directive by one year (1 January 1993 instead of 1 January 1992). This postponement would seem to be essential in view of the time which has elapsed since the Commission put forward its proposal.