INT/118
Medicinal products

Brussels, 18 September 2002

OPINION

of the

Economic and Social Committee

on the

Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Proposal for 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

Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products

COM(2001) 404 final - 2001/0252 (COD), 2001/0253 (COD), 2001/0254 (COD)

On 7 January 2002 the Council decided to consult the Economic and Social Committee, under Articles 95 and 152(4)(b) of the Treaty establishing the European Community, on the

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COM(2001) 404 final - 2001/0252 (COD), 2001/0253 (COD), 2001/0254 (COD).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 11 September 2002. The rapporteur was **Mr Fuchs**.

At its 393rd plenary session (meeting of 18 September 2002) the Committee adopted the following opinion by 112 votes to two with three abstentions:

0. Summary of the opinion

The Committee welcomes in principle the Commission proposals for revising and developing EU legislation with regard to medicinal products for human and veterinary use. It attaches great importance to the point that the protection of human and animal health must take precedence over all other areas of regulation.

The Committee

– supports the Commission in its efforts to enhance the safety of medicinal products by improving patient and consumer information about such products and to improve pharacovigilance by involving health professionals and patients as partners in the reporting of the risks associated with medicinal products;

– welcomes the Commission's efforts to promote new developments in the field of medicinal products and make them available as soon as possible for patient therapy. However, data protection must be guaranteed and competition between the manufacturers of generic medicinal products must not be hampered unduly;

– thinks that a balanced relationship must be maintained between the various authorisation systems (centralised authorisation, authorisation with mutual recognition and national authorisation) and that in principle applicants must be entitled to choose between the various systems;

– considers that it is necessary to improve and extend the supply of veterinary medicinal products and that a programme is required to promote the development of medicinal products for treating rare animal diseases;

– recommends that a clear distinction be drawn between medicinal products and other products such as medical devices, foodstuffs (including food supplements) and cosmetics;

– welcomes the Commission's intention to extend the rules on good manufacturing practice to starting materials and especially active substances;

– considers that it is necessary to harmonise the rules for the prescription of medicinal products in the Member States;

– proposes that the Commission accede to the European anti-doping convention as the Community's contribution to the fight against drugs in international sport.

1. **Background**

1.1 A Community procedure for the authorisation and supervision of medicinal products was introduced for the first time on 1 January 1995 on the basis of Regulation (EEC) No. 2309/93[1]. The European Agency for the Evaluation of Medicinal Products (hereinafter called the Agency) took up its work at the same time.

1.2 The Commission – acting on the basis of Article 71 of the aforementioned Regulation – has drawn up a report on the operation of Community procedures for authorising the placing of medicinal products on the market, which is now to serve as the basis for the further development of the legislation governing medicinal products.

1.3 European Parliament and Council Directive 2001/83/EC[2] consolidated – for reasons of clarity – the various directives on the approximation of legislative and administrative provisions for proprietary medicinal products adopted in the wake of Council Directive 65/65/EEC of 26 January 1965[3]. The wording of the text was also adapted as a result of the consolidation exercise.

1.4 For the same reason, and with the same objective in mind, various directives on the approximation of legislative and administrative provisions for veterinary medicinal products adopted

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1 OJ L 214, 24.8.1993

2 OJ L 311, 28.11.2001

3 OJ P 022, 9.2.1965, as most recently amended in OJ L 229, 15.8.1986

in the wake of Directive 81/851/EEC[4] were brought together in Directive 2001/82/EC[5] on the Community code relating to veterinary medicinal products.

1.5 The Commission has now presented three proposals for the further development of Community legislation on the basis of its report on the operation of Community procedures for authorising the placing of medicinal products on the market. Regulation (EEC) No. 2309/93 is to be recast and the two recently adopted directives on Community codes for human and veterinary medicinal products are to be amended.

2. Gist of the Commission proposals

2.1 Gist of the proposed regulation on medicinal products for human use

2.1.1 The proposal states that the centralised procedure for the authorisation of medicinal products is to be extended beyond the present framework to all new substances appearing on the Community market.

2.1.2 The composition of the Scientific Committee is to be amended (one representative per Member State) to take account of EU enlargement.

2.1.3 The centralised procedure itself is not to be changed substantially. One change concerns the appeal procedure for applicants who contest the scientific opinion of the committee. The purpose of this is to make it possible to clear up problems with the assessment of authorisation data at expert level, tighten up the formal authorisation procedure as a result and avoid legal disputes in the courts. The Commission is thus responding to the repeated criticism of the amount of time it takes for decisions to be reached.

2.1.4 The Commission proposes that the five-yearly renewal of marketing authorisations be abolished.

2.2 Gist of the proposed regulation on medicinal products for veterinary use

2.2.1 A large proportion of the amendments with regard to procedural matters have been aligned on the amendments for medicinal products for human use. Important changes have also been made to the scope and the general terminology.

2.2.1.1 For example, the definition of a veterinary medicinal product has been amended in order to ensure that the directive applies to preparations that must meet quality, safety and efficacy requirements, and new definitions have been added in order to harmonise and simplify conditions in the field of medicinal products.

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4 OJ L 317, 6.11.1981, as most recently amended in OJ L 87, 2.4.1992

5 OJ L 311, 28.11.2001

2.2.2 It is proposed that the application of the centralised procedure be adapted to the specific context in which certain veterinary medicinal products are used. This applies in particular to the regional occurrence of certain infectious diseases.

2.2.3 It is vital in the field of veterinary medicine to make it easier to use non-veterinary products, e.g. human medicines, if no approved veterinary products are available for a specific animal species or disease.

2.3 **Provisions on the Agency and general provisions**

2.3.1 The amendments concern the adaptation of the administrative and scientific structures to the new tasks.

2.3.2 The Commission proposes that the scientific advice provided for companies during the research and development of new medicinal products be strengthened and systematically developed in order to:

– stimulate pharmaceutical research in Europe;
– allow European patients to benefit earlier from more effective medicinal products; and
– promote the burgeoning of small and medium-sized enterprises.

2.3.3 The Commission proposes that the Agency participate in the compassionate use programme at Community level.

2.3.4 The Commission proposes that the Agency participate in international scientific cooperation. The Agency is to increase and develop its technical and scientific support for the Member States and the Commission.

2.3.5 The aim of a further proposal is to prevent or solve potential conflicts between the scientific opinions of the Agency and those of other scientific bodies in the Community.

2.3.6 The Commission thinks that the changes made to the Agency and the planned enlargement of the Community make it necessary to change the structure of the Agency's committees and the composition of the Management Board and to set up an Advisory Board.

2.3.7 Finally it is proposed that the 1993 Regulation's general provisions be amended and new provisions be introduced in order to create the requisite legal certainty and guarantee the Agency's proper functioning.

2.4 **Gist of the proposed directive on medicinal products for human use**

2.4.1 The definition of medicinal product is to be adapted to take account of new therapies and their particular method of application. Other necessary adaptations are to be made.

2.4.2 A definition of generic medicinal product and its reference medicinal product is to be introduced, the administrative protection of data is to be improved and the harmonisation of existing reference medicinal products is to be facilitated.

2.4.3 The proposal states that any medicinal product not compulsorily subject to the centralised procedure is to be covered by the decentralised or mutual recognition procedure on condition that it is intended for the markets in more than one Member State. The procedures are to be simplified as a result of the criticism that has been expressed.

2.4.4 The inspection and surveillance of medicinal products' manufacture and quality assurance is to be improved. The provisions regarding compliance with good manufacturing practice are to be extended to starting materials, and especially active substances used as starting materials.

2.4.5 Pharmacovigilance is to be improved by making greater use of electronic information technologies, and the exchange of data between all parties involved in the trade in medicinal products and the authorities is to be made easier.

2.4.6 Patient information is to be improved. By way of experiment, information about a limited number of prescription medicinal products is to be authorised.

2.5 **Gist of the proposed directive on veterinary medicinal products**

2.5.1 Definitions are to be adapted by analogy with the proposed directive on medicinal products for human use.

2.5.2 The aim of the proposal is to improve the supply of medicinal products for animals and to solve the special problems associated with the lack of availability of veterinary medicinal products, with due regard to health and consumer protection.

3. **Aims**

3.1 The general aim of the Commission proposals is to develop further the Community's legislation governing medicinal products for human and veterinary use on the basis of

– the report on the operation of Community procedures for authorising the placing of medicinal products on the market,

– the experience acquired between 1995 and 2000, and

– an analysis of the comments made by all the parties concerned (competent authorities from the Member States, doctors' and pharmacists' organisations, patient and consumer associations and associations representing the pharmaceutical industry).

3.2 The Commission thinks that the revision of the Community's legislation must be guided by the following objectives:

3.2.1 To guarantee a high level of health protection for the people of Europe, particularly by providing patients, as swiftly as possible, with innovative and reliable products and through increased market surveillance thanks to a strengthening of monitoring and pharmacovigilance procedures. In the case of veterinary medicinal products, to improve animal health, particularly by increasing the number of medicinal products available.

3.2.2 To complete the internal market in pharmaceutical products taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector.

3.2.3 To meet the challenges of the future enlargement of the European Union.

3.2.4 To rationalise and simplify the system as far as possible, thus improving its overall consistency and visibility, and the transparency of procedures and decision-making.

3.3 The purpose of the Community provisions concerning the placing on the market of medicinal products for human and veterinary use is to guarantee a high level of public health protection and to enable the rules of the internal market to operate effectively. No medicinal product may be placed on the market unless its quality, safety and efficacy have been previously demonstrated. These guarantees must be maintained when it is actually placed on the market.

4. General comments

4.1 The Committee attaches great importance to the point that the protection of human and animal health must take precedence over all other areas of regulation. It welcomes in principle the Commission proposals for revising and developing EU legislation with regard to medicinal products for human and veterinary use.

4.2 The Committee has carefully examined the Commission proposals and decided to focus on the following points in its opinion:

– the safety of medicinal products for patients and consumers, including the provision of comprehensible objective information on such products;

– the promotion of the development of new and better medicinal products as the sine qua non for therapeutic progress;

– the rapid availability of new medicinal products;

– effective and equivalent authorisation systems and procedures;

– effective risk monitoring with the aid of a comprehensive pharmacovigilance system.

4.3 The changes proposed by the Commission will be of great importance and consequence in future for

– the supply of safe medicinal products to EU citizens;

– the extension of the provisions to the new Member States;

– the functioning of the common market in medicinal products;

– competition worldwide and especially with the US and Japanese markets.

4.4 The Committee is well aware of the complexity of the subject-matter. This applies in particular to the difficulty of finding balanced solutions wherever a number of legitimate interests are at stake. These interests concern:

– the protection of patient and consumer health;

– the healing professions;

– pharmaceutical research;

– the pharmaceutical industry;

– trade in medicinal products.

4.5 The proposals for recasting the EC Regulation and amending the recently consolidated directives on medicinal products for human and veterinary use have been closely coordinated in terms of substance and form and together constitute a self-contained and transparent body of rules and regulations.

4.6 **Safety of medicinal products**

4.6.1 The Committee welcomes the Commission's efforts to make information about medicinal products more transparent, especially at a time when there is a growing desire on the part of patients to be involved in decisions about their health. They receive information from a variety of sources – both written and oral – and therefore need to be advised by doctors and pharmacists about the benefits and risks. Doctors, veterinarians and pharmacists are called on to advise consumers and patients about the benefits and risks of medicinal products.

4.6.1.1 There is therefore no reason why members of the medical and pharmaceutical professions – or even lay persons – should not be provided on request with the texts checked and approved by the relevant authority which serve as information for users or professionals or as the official assessment reports.

4.6.2 These texts, which have been officially checked and approved by the authorising authorities, are already available on the Internet in some cases and may be regarded by patients as being of a more objective and therefore reliable standard than information from other sources. Being able to receive objective, balanced and comparative information is very important because in some Member States medicinal products can already be ordered on the Internet. Also needed are studies into how to make information about medicinal products more intelligible for the lay person and, above all, to make it easier to read and understand.

4.6.3 The Committee attaches great importance to a clear de facto and de jure distinction between information that is vetted by the relevant authority about medicinal products – such as instructions for use, package leaflets and assessment reports – and commercial advertising material. It supports the Commission in its efforts to continue to ban public advertising of prescription medicinal products. Even in the case of those illnesses where information on certain prescription medicinal products is authorised under strict conditions in the interest of patients, such information must be objective and balanced and may not claim any benefits for the product that go beyond those set out in the official product information.

4.6.4 The Committee assumes that patients also need additional information about certain medicinal products in cases where these are prescription-only or available without prescription. The Committee is aware that the packaging insert leaflets (PILs) for all medicines are public documents and that several medicines agencies publish them on their websites. In addition the EMEA publishes on its website both PILs and a Summary of Products Characteristics (AmPC) of the medicines authorised via the centralised procedure. The Committee believes that it is necessary to increase the visibility and accessibility of this authorised and objective information to patients.

4.6.4.1 The Committee supports the principle expressed by the Commission to increase the availability of information especially in relation to prescription-only medicines. However, it believes that the Commission's proposal in Article 88(2) of the proposed directive does not provide the necessary guarantees to ensure complete, objective and comparative information in the best interest of the patient. Self-regulation of the industry and the establishment of guidelines do not seem to provide strong enough guarantees to prevent information becoming advertising in face of weakness in the implementation of the control mechanism.

4.7 **Promoting the development of innovative medicinal products**

4.7.1 The Committee welcomes in principle all the efforts made by the Commission to promote the development of new active principles in medicinal products. These represent a vital prerequisite for therapeutic progress – including the treatment of rare diseases. In order to make such medicinal products available as soon as possible for use in treatment, the provision of advice to applicants prior to authorisation by the authorising authority and the abridgement of testing and administrative procedures are very important for the authorisation process. The Committee would point out that speeding up the substantive testing procedure must not undermine the safety of medicinal products.

4.7.2 The Committee attaches great importance to the protection of the data setting out the findings of the tests for developing new medicinal products or extending the fields of application of existing products.

4.7.2.1 Given the high development costs, it is necessary to provide various incentives – not only of a financial nature – to induce the pharmaceutical industry to develop innovative medicines, research new therapeutic indications and carry out new studies into the therapeutic doses for known medicinal products. This applies in particular to their use with certain categories of patients such as children and the elderly.

4.7.2.2 The Committee would point to the need for the industry to make package leaflets more patient-friendly. These instructions for use should be tested on patients to see whether they find them clear, intelligible and easy to understand.

4.7.3 The Committee accordingly welcomes the Commission's efforts to extend data protection and in particular approves the extension of the protection to data which support new therapeutic indications for known preparations. However, it would like the period of protection to be extended from one to two years in such cases.

In this context no distinction should be made between the various authorisation systems in the Member States with regard to the duration of the data protection.

4.7.4 The Committee supports the Commission's proposal that, in order to improve competition for manufacturers of generic medicinal products, it be made easier to draw up authorisation data before the expiry of the data protection period.

4.8 **Authorisation of medicinal products**

4.8.1 In the Committee's view the division of tasks between the central Agency and Member States' authorities has proved on the whole to be a success. Responsibilities must be clearly allocated in this context (transparency).

4.8.2 In accordance with the rules on subsidiarity, only those tasks should be performed centrally which, by their very nature, are better performed by the Agency for all the Member States using a uniform procedure.

4.8.3 Centralised authorisation should be restricted in essence to medicinal products which have already been authorised by the Agency hitherto under existing laws. Applicants wishing to put medicinal products containing new substances on the market should be able to choose between centralised and decentralised authorisation. The decentralised mutual recognition procedure should be simplified, thereby making it more attractive.

4.8.4 National data banks should be networked. It should be the responsibility of the Agency to coordinate the assessment and upkeep of data – including data on pharmacovigilance.

4.8.5 Individual Member States' safety decisions should be coordinated by the Agency.

4.8.6 National authorities for medicinal products – with their expertise - should continue to exist and operate in order, in particular,

– to guarantee the safety of medicinal products at national level;
– to collate and assess the risks associated with medicinal products and to coordinate national measures;
– to facilitate national authorisations;
– to promote the mutual recognition of authorisations;
– to monitor trade in medicinal products;
– to observe the distinctive features of national prescribing habits and the market in medicinal products;
– to advise the government in the particular Member State;
– to provide the Agency with expert support in the performance of its tasks;
– to improve public awareness of the need to use medicinal products sensibly involving patients groups and health professionals.

4.8.7 The Committee thinks that an appropriate division of labour based on specialisation between the national authorities responsible for medicinal products is both possible and desirable.

4.9 **Pharmacovigilance**

4.9.1 The Committee welcomes the Commission's intention to improve pharmacovigilance through the use of modern information technologies. All parties handling medicinal products (doctors, veterinarians, pharmacists) should play an active part in providing advice about, and collecting information on, the risks associated with medicinal products and form part of the information network. Patients, too, should be involved as partners in the reporting of such risks.

4.9.2 The Committee welcomes the Commission's decision to exclude provisions from the proposals which primarily concern the cost of medicinal products and reimbursement by social security schemes. Such provisions would be out of place in this context. Nevertheless it is recognised that variations in costs for medicinal products and their reimbursement have a pervasive influence on the common market in medicinal products and competition. The Committee would therefore encourage the Commission to continue its efforts to improve the single market in medicinal products in the interest of patients.

5. **Specific comments**

5.1 The definition of "medicinal product" given in the proposal for a directive on medicinal products for human use seems to be very general and could be interpreted and applied differently in individual Member States. The Commission has attempted to provide a definition that takes account of new therapeutic methods. It should be made clear, the Committee thinks, that plant-based products which claim to deal with certain indications should be regarded as medicinal products. The definition is intended to make it possible to distinguish more easily between medicinal and other products, especially medical devices, foodstuffs (including food supplements) and cosmetics, since the legal consequences of being classified in a particular category are considerable. Given the cross-border trade in such products between Member States, the national differences in classification according to legal categories should be kept to a minimum in order to guarantee legal certainty for both consumers and businessmen.

5.2 The Commission proposal states that the marketing authorisation for a medicinal product does not need to be checked after five years and therefore it is not necessary to apply for an extension of the authorisation. Improvements in pharmacovigilance are the main reason given for this.

5.2.1 The Committee thinks that this proposal goes too far. The Committee broadly agrees with the Commission that it is not necessary to apply for an extension after five years, since adaptations to the state-of-the-art can be made at any time during that period by modifying the authorisation data. Nonetheless, this possibility should as a rule apply only to specific changes with regard to the quality or safety of the medicinal product. There is no doubt that this proposal would simplify the administrative formalities. However, the Committee thinks that a comprehensive check should be made after a longer period of time on the authorisation of the data and their adaptation to the state-of-the-art in terms of quality, efficacy and safety. It therefore considers that conducting such checks every ten years is an acceptable compromise.

5.3 The Committee does not agree that the marketing authorisation should be revoked if it is not used within two years of being granted. Such a measure would seem to make sense in terms of market transparency, but experience with such provisions has shown that it is difficult to prove the facts and hardly possible to implement measures.

5.4 The Committee welcomes the proposals regarding compassionate use so that patients can be treated with innovative medicinal products which are still being clinically tested or have been clinically tested but are still awaiting authorisation. However, it is absolutely necessary to stop a situation arising where the supply of unauthorised medicinal products cannot be checked. Therefore, this provision should be confined to absolutely necessary cases. The Committee would point out in this connection that the treatment of patients with medicinal products that have not yet been authorised requires arrangements to be made for having the costs reimbursed by social security systems.

5.5 The Committee welcomes the extension to active substances of the rules governing proper manufacture and quality controls. This will improve the quality of medicinal products. Member

States have recognised the need for this for many years, and the European Pharmacopoeia already contains such a requirement.

5.6 The Committee welcomes the Commission's efforts to extend and improve the supply of veterinary medicinal products. This applies in particular to cases where there is a shortage of medicinal products which are authorised for special indications or where there is a regional need for the supply of medicinal products (e.g. special vaccines, emergency medicines).

5.7 The Committee considers that the Commission's proposal asking for prescription only status for officinal preparations for animals (Article 67 (iv)(d) proposal to amend Directive 82/2001) is confusing. Officinal preparations are by definition prepared in a pharmacy according to a prescription as indicated in the relevant pharmacopoeia. The Committee does not see any justification for such a change, which would conflict with existing Community and national legislation and does not appear justified on public health grounds.

6. **Additional proposals**

6.1 The Committee is worried that there is still a long way to go before the free movement of goods comes into being in the field of medicinal products and before the conditions governing all EU citizens' access to medicinal products are progressively aligned, in keeping with the calls made by the Committee in all its earlier opinions.

6.2 The Committee therefore calls upon the Commission once again to ensure that rapid progress is made in EU legislation so that the necessary objectives can be achieved. These objectives were set out by the Committee some time ago in its own-initiative opinion on *the role of the European Union in promoting a pharmaceutical policy reflecting citizens' needs: improving care, boosting innovative research and controlling health spending trends*[6]. In view of developments in the sector, the Committee would like to highlight once again a number of aspects which a Community pharmaceutical policy can no longer ignore.

6.3 The Committee recommends in particular that the labelling of medicinal products authorised prior to Directive 92/27/EEC and the accompanying package leaflets be standardised within an appropriate timeframe in order to put an end to the differing presentations for one and the same product which are to be found in the Member States at the moment. The Committee thinks that there is a particularly urgent need to press ahead with the standardisation of the summary of product characteristics and the package leaflets accompanying generic medicines. In addition to the standardisation of package leaflets, the Committee thinks that better use should be made of the recommendations contained in Directive 92/27/EC so that medicinal products can be used on the basis of detailed and comprehensible information.

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6 OJ C 14, 16.1.2001

6.4 The Committee notes that the differing arrangements for fixing prices and reimbursing costs are mainly to blame for the fragmentation of the single market, although it admits that the Member States themselves must keep a watch on their expenditure in the field of medicinal products. However, this problem cannot be avoided if the competitiveness of the European pharmaceutical industry is to be guaranteed. It therefore calls on the Commission to continue to do what it can to obtain more satisfactory results than the G-10 pharmaceutical group of high-ranking representatives.

6.5 The Committee welcomes the planned revision of Directive 89/105/EEC on transparency, for the authorisation and price-fixing systems used in some Member States have proved not to be transparent or consistent with the basic aims of the current reform of the Community procedures.

6.6 In view of the growing movement of persons between Member States and the need to guarantee uniform protection for patients' health, the Committee recommends the gradual introduction of uniform rules for the mandatory prescription of medicinal products in the Member States. The general criteria classifying substances and preparations as prescription-only have already been laid down in the consolidated directive[7]. These criteria are not applied uniformly by the Member States. This confuses the general public and generates uncertainty with regard to the safety of medicinal products. The concrete provisions for the mandatory prescription of substances and preparations could be specified by EC regulation. In order to avoid unintentional repercussions on social insurance systems, the harmonised provisions should apply only to medicinal products which are brought onto the market after the EC regulation enters into force.

6.7 The Committee recommends that the Community contribute to the fight against drugs in international sport[8]. It therefore proposes that the Commission formally accede to the European anti-doping convention of 16 November 1989. With reference to the list appended to this convention, a ban should be introduced on medicinal products which are used for doping purposes in sport. This ban should cover these products' marketing, their use to treat third parties and their prescription by doctors.

6.8 The Committee recommends that a programme for developing veterinary medicinal products for rare animal diseases be drawn up and implemented. This programme should be similar to that already launched for medicinal products for human use[9].

Brussels, 18 September 2002.

The President The Secretary-General

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7 Article 71 of Directive 2001/83/EC of 6.11.2002 (OJ L 311, 28.11.2001); cf. the relevant ESC opinion in OJ C 368, 20.12.1999

8 Cf. the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions – Community support plan to combat doping in sport (COM(1999) 643), ESC opinion, OJ C 204, 18.7.2000

9 Cf. the ESC opinion (point 3.1.7) on the proposal for a European Parliament and Council Regulation (EC) on orphan medicinal products (COM(1998) 450 final), OJ C 101, 12.4.1999

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