

Opinion of the Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards traditional herbal medicinal products'

(2003/C 61/02)

On 22 February 2002, the Council decided to consult the Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the above-mentioned proposal.

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 Braghin.

At its 393rd Plenary Session (meeting of 18 September 2002), the Economic and Social Committee adopted the following opinion with 124 votes in favour and two abstentions.

1. Introduction

1.1. The proposal for a directive specifically concerns herbal medicinal products that have been well-established over time (defined as 'traditional'), not the use of substances or herbal preparations which do not come under the definition of a medicinal product contained in Directive 2001/83/EC⁽¹⁾, i.e. substances or preparations that do not have 'properties for treating or preventing disease in human beings' or for 'restoring, correcting or modifying physiological functions'⁽²⁾.

1.2. The market for herbal substances and preparations (plants, parts of plants, algae, fungi, lichen and related preparations obtained from various methods of treating herbal substances) has grown rapidly, and in some Member States it is not yet subject to satisfactory regulations. Furthermore, there is an increasing supply of non-traditional substances on the market in Europe, often associated with the spread of alternative therapies from other cultures.

1.3. Several factors have contributed to this development: the perception that 'natural' substances present fewer health risks, dissatisfaction with certain mainstream medical treatments for minor illnesses, the availability of such substances in alternative outlets (herbalists, health shops, mail order businesses — especially over the internet — etc.) and the rising

trend for patients to opt for self-treatment. The public is particularly attracted by the suggestion that such products can improve their health or physical appearance. These products are advertised in all forms of media, but especially in publications targeting groups of the population particularly sensitive to such forms of advertising, as well as in retail outlets with the use of apparently scientific leaflets. Often, however, there is no evidence to support the claims made, which are often based upon a supposed result of combining substances rather than on scientific studies. In addition, consumers do not always follow the recommendations for dosage in the erroneous conviction that herbal products do not present any health risks.

1.4. The use of herbal substances and preparations should be regulated as soon as possible to avoid public health risks (resulting from substandard preparation techniques; chemical, physical or biological contamination of raw materials; possible traces of undesired plant material; or interaction with food or other medicinal products, of which consumers are often unaware) and also to avoid unfair competition practices and unwarranted barriers to the free market.

1.5. The legal and practical status of such products varies significantly from one Member State to another. More comprehensive action is needed at Community level to deliver increased public health protection and to ensure the free and undistorted supply of these products within the EU. This would also aim to close legislative loopholes and remove the various 'grey areas' in the field of dietetic products, food

(1) Directive 2001/83/EC (OJ L 311, 28.11.2001) lays down the new Community code on medicinal products for human use, incorporating into one text the previous directives on medicinal products, which are hence repealed. On 26 January 2001 the Commission presented the Proposal for a Directive of the European Parliament and the Council amending the above Directive, regarding both medicinal products for human use and veterinary medicinal products (COM(2001) 404 final).

(2) Proposed amendment of Article 1 of Directive 2001/83/EC contained in COM(2001) 404 final.

supplements, herbal products and herbal medicinal products as well as to regulate or at least harmonise the use of claims to boost health or well-being, which sometimes mislead consumers or even amount to outright deceptive and fraudulent practice on the part of manufacturers.

1.6. The EESC therefore welcomes the Commission proposal which seeks to harmonise the market for traditional herbal medicinal products and close a loophole in existing legislation. Nevertheless, it calls on the Commission to speed up the tabling of proposals to regulate the whole sector of herbal substances.

2. Gist of the Commission proposal

2.1. The proposal for a directive aims to amend Directive 2001/83/EC⁽¹⁾ as regards traditional herbal medicinal products, the legal and practical situation of which varies significantly between Member States. The proposal provides for a special registration procedure which does not require particulars and documents regarding tests and trials on safety and efficacy, unlike the above-mentioned directive. Sufficient published scientific literature is not available for many such medicinal products, and new tests and trials cannot be justified since the traditional use of the medicinal product is of such a nature as to allow sound conclusions on its safety and efficacy.

2.2. The main objective of the draft directive is to establish a harmonised legislative framework for traditional herbal medicinal products, introducing those provisions considered indispensable to attain a sufficient degree of harmonisation while ensuring the utmost protection of public health and respecting the principles of proportionality and subsidiarity.

2.3. The proposal covers those traditional herbal medicinal products which are not eligible for authorisation under the simplified or normal registration procedure. It lays down the conditions to be fulfilled for a product to be authorised, concerning indications, ways the product can be administered, specified strength, and minimum period of traditional use. It also confirms the need for adequate documentation of results of physico-chemical, biological or micro-biological tests and quality of the medicinal product (the same criteria required by Directive 2001/83/EC). The conditions under which registration is to be refused are also laid down.

2.4. Under this proposal, the mutual recognition procedure cannot be applied to registrations of traditional herbal medicinal products, but Member States are invited to take due account of authorisations or registrations of certain products. To further facilitate such applications, a list of herbal substances fulfilling the conditions of eligibility is also to be drawn up.

2.5. The proposal contains the obligation to include in the labelling, the package leaflet and in any advertising the information that the product is a traditional herbal medicinal product and that its efficacy has not been clinically proven.

2.6. A new Committee for Herbal Medicinal Products is to be set up within the European Agency for the Evaluation of Medicinal Products. The committee's tasks will relate to the scientific issues with regard to herbal medicinal products and herbal substances, and it should work in close cooperation with the Committee for Proprietary Medicinal Products. It has the specific task of establishing Community herbal monographs (to be used as a basis for any application for registration under the new provisions) and of drawing up a list of herbal substances which can be considered traditional herbal medicinal products.

3. Comments

3.1. *Harmonisation and the internal market*

3.1.1. The EESC endorses the need for action to progressively harmonise the regulatory framework for traditional herbal medicinal products and first and foremost guarantee public health and safety. The aim is to remove the grey area surrounding traditional, well-established medicinal products and to some extent predating the first EC directive on medicinal products.

3.1.2. The specific inclusion of traditional herbal medicinal products in the recent consolidated legislation on medicinal products for human use⁽¹⁾ certainly encourages greater protection of public health and safety as it imposes minimum quality standards for manufacturers, harmonised and coherent systems for pharmacovigilance — and therefore more efficient data collection on potential negative side-effects — and lastly harmonised procedures by national authorities in classifying corresponding products which are not considered medicinal products across the board.

(1) Directive 2001/83/EC, (OJ L 311, 28.11.2001) lays down the new Community code on medicinal products for human use, incorporating into one text the previous directives on medicinal products, which are hence repealed.

3.1.3. The EESC considers the proposal to be appropriate and timely in that it will also apply to candidate countries, some of which have specific therapeutic traditions involving herbal medicinal products. The EESC invites the Commission to consider the case for transitional agreements in this specific field and to identify particular aspects that should be incorporated into the *acquis communautaire*.

3.1.4. The EESC endorses the need to keep traditional herbal medicinal products on the market which, despite their long tradition, do not fulfil the regulatory criteria laid down in existing legislation and welcomes the fact that by effectively incorporating these products into Directive 2001/83/EC, they will be subject to the same conditions guaranteeing the safety and quality of all medicinal products for human use.

3.1.5. The EESC considers, however, that the proposal does not resolve all the difficulties encountered which render the internal market for such products excessively fragmented and lacking in common or at least harmonised regulations. The EESC advocates taking a more decisive course of action to encourage the marketing of such products in countries other than those where they were originally marketed and/or registered, provided they fulfil the minimum criteria as laid down in the proposal.

3.1.6. The EESC also considers that the real state of the market has not been adequately gauged. In practice, essentially corresponding products are classified in some Member States as medicinal products and in others as foodstuffs. The EESC recommends applying the precautionary principle to unclear cases, thereby classifying them as traditional herbal medicinal products throughout the European Union, in order to guarantee a greater level of control on the quality and safety of such products.

3.2. Definitions

3.2.1. The definition of a 'herbal medicinal product' does not appear sufficient to redress the current discrepancies between Member States. Firstly, it refers to 'active ingredients' as if these were easily identifiable and distinguishable, when in fact all such medicinal products contain several active ingredients. The effect of each ingredient cannot always be readily identified or defined with precision, nor often can the cumulative effect of such ingredients be proven. Secondly, 'herbal preparations' are rather loosely and generically defined, without highlighting the properties necessary and sufficient for their authorisation, and thus for comparing medicinal products obtained from the same plant.

3.2.2. The EESC considers this aspect particularly important in order to differentiate between preparations obtained from the same plant in cases where some of these preparations are classified as medicinal products while others are not, because the concentration and dosage of the active ingredient does not give rise to a therapeutic effect that would warrant their classification as a medicinal product.

3.2.3. The definition of 'herbal substances' and 'herbal preparations' as referred to in new points 31 and 32 respectively is inconsistent with the definition of herbal substances laid down in Article 1(3) of Directive 2001/83/EC.

3.2.4. Another shortcoming is the absence of any statement specifying whether the term 'traditional herbal medicinal products' can also apply to products containing not only one or more herbal substances or herbal preparations or a combination of them, but also non-herbal ingredients, for example vitamins, minerals or mineral substances.

3.2.5. The words 'also in combination with non-herbal ingredients' should therefore be added at the end of Article 1(30). The EESC considers that, in order to avoid the persistence of an extensive grey area in the pharmaceuticals market, such products should be included in the definition of traditional herbal medicinal products if the main pharmacological action derives from herbal substances or herbal preparations contained in them.

3.2.6. The EESC considers the concept of 'corresponding medicinal products' (Article 16c(2)), referring to products containing the same active ingredients and an equivalent strength, to be inadequately defined and in any case difficult to apply, unless it is specified whether this refers to substances derived from the same plant.

3.2.7. In this context, it is useful to refer to monographs contained in existing and officially recognised Pharmacopoeia to define products containing herbal substances with properties listed therein as corresponding products. A reference to such Pharmacopoeia is thus advisable here.

3.2.8. As the conditions guaranteeing full safety of use are laid down in the monograph itself, the EESC considers that the following phrase in recital 11 should be deleted: 'unless there

are major objections of public health'. This has led to significant discrepancies in application and abuse.

3.3. *Period of use and other procedural aspects*

3.3.1. The requirement to show medicinal use throughout a period of thirty years seems excessive. Well-established use for twice the amount of time needed for simplified registration, i.e. a twenty-year period, could be considered sufficient to guarantee a good level of safety of use. However, the EESC welcomes the provision that the thirty-year period may be completed by a period of well-established use in territories outside the Community of at least the same duration as use within the EU, since this enriches the European medicinal arsenal with plants from other territories.

3.3.2. Transitional measures for products of well-established use in candidate countries should be introduced upon accession of these countries into the EU, so as to encourage the use of their traditional herbal medicinal products while ensuring that these meet Community standards of quality and safety.

3.3.3. Article 16e lists the conditions which would warrant refusal of the application for registration. The EESC recommends that if a product is refused for being potentially harmful under normal conditions of use, immediate measures should be in place to withdraw it and corresponding products from the market in other Member States, appropriate and reasoned measures should be taken to inform the public of the decision to refuse registration, and there should be an arbitration procedure to deal with disagreements between national authorities.

3.4. *The Committee for Herbal Medicinal Products*

3.4.1. The EESC endorses the proposal to set up a Committee for Herbal Medicinal Products under the European Agency for the Evaluation of Medicinal Products, with two main tasks: drawing up a list of herbal substances with the information needed to guarantee the safe use of such substances, and establishing Community monographs to be used as a basis for all applications for registration.

3.4.2. However, the EESC calls for deadlines to be set for the completion of such work in order that the framework for

all operators in the sector is established within a reasonable timescale.

3.4.3. The EESC urges the above committee, when drawing up Community monographs, to take into account material contained in existing official Pharmacopoeia, which are the result of centuries of work. This should lead to the creation of a database of medicinal herbal products and the safe use thereof, especially regarding pharmacological interactions and contraindications.

3.4.4. According to the EESC, in order to attain the objectives laid down concerning health protection and the free movement of herbal medicinal products, the new committee should have the task of assessing existing documentation on products and pharmacovigilance results in particular concerning interaction between foodstuffs and medicinal products — as well as playing an arbitration role in the case of disagreement between national authorities.

3.4.5. The responsibilities of the above committee should also be further clarified concerning the assessment of all medicinal products derived from herbal substances (not only traditional products), the possibility of issuing a prior scientific opinion on request, the binding nature of its opinions as well as the lists and monographs that it must provide as an institution.

3.4.6. Decisions made by the above committee (addition to or deletion from the list of herbal substance, monographs drawn up) are to become binding on registration holders without having previously been the subject of a Community decision to make them binding in EU territory. The EESC points out that this is inconsistent with the general regulatory framework, as it creates a risk that the work of the Committee for Herbal Medicinal Products will be considered as a non-binding scientific opinion and will be thwarted by non-recognition on the part of national authorities, who retain the final say in decisions on the authorisation and registration of medicinal products.

3.5. *Classification and labelling*

3.5.1. Article 16a(a) should be simplified as follows: 'indications consolidated by use, therefore may be sold without a medical prescription'.

3.5.2. As traditional herbal medicinal products are sold without a medical prescription, it is essential that the user package leaflet is clear, simple, readable and comprehensive in listing warnings, known contraindications and interactions in order to serve as a guide for the correct use of the product. The EESC believes that the Committee for Herbal Medicinal Products should also take these aspects into consideration when drawing up monographs.

3.5.3. In addition, the EESC emphasises the importance of including a specific reference in the Directive that labelling must contain an exact definition of the product (e.g. if it is a medicinal product in powder form or made from a dry or liquid plant extract, how it is standardised, etc.) since the different methods of preparation can change the bio-availability of active ingredients.

3.5.4. The user package leaflet and the packaging must clearly state that the user should consult a doctor or a pharmacist or seek professional advice from a qualified herbalist if symptoms persist. The EESC considers that Article 16g(b) should be supplemented with the above-mentioned details to give the patient a clearer course of action to follow.

3.5.5. The labelling provisions appear unsuitable for this type of product, since they refer to 'a specified indication' in the singular, whereas the products usually have several specific indications. In addition the phrase 'the efficacy of the product has not been clinically proven' could provoke unjustifiable concern amongst consumers over the safety of the product, and subsequently shift demand towards herbal products with even less documentation and control.

3.5.6. Article 16g(2)(a) on labelling and the user package leaflet should be amended as follows: 'the product is a herbal medicinal product for traditional use in specified indications and that the efficacy of the product is based exclusively on long-term use and experience'.

3.5.7. The EESC calls for the following sentence to be added to the second paragraph of Article 16h(3): 'If appropriate, the registration holder may however refer to other monographs from official Pharmacopoeia, publications and supporting data'.

Brussels, 18 September 2002.

The President
of the Economic and Social Committee
Göke FRERICHS
