

Brussels, 1 October 2001

OPINION

of the

Committee of the Regions

of 20 September 2001

on the

Proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Council Directive 89/381/EEC

(COM(2000) 816 final - 2000/0323 (COD))

The Committee of the Regions

HAVING REGARD TO the Proposal from the Commission for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Council Directive 89/381/EEC (COM(2000) 816 final – 2000/0323 (COD));

HAVING REGARD TO the decision by the Council on 12 February 2001, under the Articles 265 (1) and 152 of the Treaty establishing the European Community, to consult the Committee of the Regions on the matter;

HAVING REGARD TO its Bureau's decision of 13 June 2000 to instruct Commission 5 for Social Policy, Public Health, Consumer Protection, Research and Tourism to prepare the Committee's work on this subject;

HAVING REGARD TO its opinion on the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the health strategy of the European Community – Proposal for a Decision of the European Parliament and of the Council adopting a programme of Community action in the field of public health (2001-2006) (COM(2000) 285 final – 2000/0119 (COD)) (CdR 236/2000 fin)¹;

HAVING REGARD TO the Council Resolution of 12 November, 1996 on a Strategy Towards Blood Safety and Self Sufficiency in the European Community;

HAVING REGARD TO the Draft Opinion (CdR 66/2001 rev. 2) adopted by Commission 5 on 16 July 2001 (rapporteur: **Ms Sexton** (IRL/ELDR));

WHEREAS there have been serious issues affecting public health as a result of problems in the safety of the blood supply in several Member States in recent years and it is essential that all necessary measures are taken to prevent such events arising in the future.

unanimously adopted the following opinion at its 40th plenary session of 19-20 September 2001 (meeting of 20 September).

1. Introduction

1. The Committee of the Regions broadly welcomes the Proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Council Directive 89/381/EEC.
2. The safety of blood transfusion throughout the EU is of very great importance and the Committee considers that the proposed directive should go some way to establishing a coherent legislative framework to ensure a high level of quality of blood and its components and safety for donors and recipients.
3. The Committee believes that it is important to secure public confidence in the safety of blood and blood products and the proposal should contribute to this.

2. Views and recommendations

2.1 The Committee is aware that new technologies are becoming available that will improve safety in blood transfusion, such as increased specificity and sensitivity in tests of blood donations for infectious diseases, and additional processing techniques that may be applied to eradicate residual viruses or bacteria in the blood components. The Committee considers that it is important that the standards in use throughout the Union reflect these developments, and that they ensure that they are applied in a consistent and effective manner. There is clearly a need to regulate and inspect the application of appropriate standards throughout the Union, and the Proposal is to be warmly welcomed for this reason.

2.2 The Committee has however a number of concerns about the inadequacy of the content of some of the appendices accompanying the proposed directive. While it is not the CoR's role to discuss the technical and scientific components of the annexes in the proposed directive in detail, it does feel that they warrant new, up-dated and substantiated proposals by experts in the field.

2.3 The CoR believes that there is a clear need to ensure that the standards envisaged in the proposed directive always reflect best-established practice, and do not fall behind the state of the art in other countries or regions. It also considers that it is essential to ensure that the process of developing and maintaining the standards of quality and safety, which will always be subject to continuous change, is not inferior to the process that the Member States or the regions could, and in many cases currently do, implement and maintain themselves.

2.3.1 The CoR is aware that blood-transfusion services and regulatory bodies, whether organized and administered within national or regional structures, use existing technical, operational and quality standards. These standards are used for operational and quality assurance purposes and for regulatory and accreditation purposes, and are based on published guidelines continually up-dated by large panels of experts. The Committee considers that the proposed directive does not contain operational standards that compare favourably with such existing publications.

2.3.2 The Committee therefore feels that it could be difficult to resource in terms of available experts a parallel process of equal skill and expertise given that many of the best national and international experts in blood transfusion and in the regulatory processes in the EU are already engaged in the up-dating and drafting of the recognized guidelines or their own national standards.

2.3.3 Furthermore, the CoR feels that the process in the proposed directive for maintaining the EU standards for blood-transfusion establishments is manifestly not as good as the best already in existence. The proposed Directive should include a process for regular review (preferably an annual review) which allows for a wide consultation of experts before standards are adopted.

2.3.4 The CoR strongly recommends that the Union should give serious consideration to availing of the excellent and established processes currently available and in use in Member States, in particular through the Council of Europe. When the EU sets up its own technical standard drafting and review process, it would be more likely to achieve and maintain excellence in all aspects of the transfusion process throughout the Union and applicant states, if it were to use as a basis such a model. The Committee also recommends that the Union should consider the adoption of an effective mechanism to oversee the adherence to and proper implementation of these standards across the Member States.

2.3.5 The CoR also considers that Member States should have the option of setting other safety standards so that only blood and blood components meeting these standards would be imported into these States when necessary.

2.4 The CoR would like to highlight that regional differences exist within the EU in other aspects of the blood-transfusion process. There are different regional traditions in approaches to blood donation, as well as regional differences in prevalence of diseases that impact on blood-transfusion demands, (e.g. thalassaemia). In addition, seasonal movements of persons within the EU create regional demands and pressures that may impact on the ability of some regions to supply adequate, and therefore safe blood-transfusion services in a Community capacity.

2.4.1 The CoR therefore recognizes that the implementation of this proposed directive will place financial burdens on some blood-transfusion services and may also result in shortages of blood and blood product in some regions. The CoR would therefore like to remind the Commission that the Council in its Resolution of 12 November 1996, requires the issue of self sufficiency in blood to be addressed at the EU level and would welcome further proposals to overcome this problem.

2.4.2 While it is not envisaged in the proposal, the Committee feels that a Community initiative would be welcome to ensure that the influx of large numbers of persons on vacation to some regions does not stress the adequacy and therefore the safety of the blood supply in those regions. In general holiday visitors tend not to donate blood in the regions they are visiting, though the transfusion requirements of a large holiday population may be considerable in those regions. The Committee of the Regions therefore calls for Community initiatives to ensure self-sufficiency in blood during holiday periods in regions with particularly large numbers of tourists.

2.5 The Committee believes that the availability throughout the EU of high quality comparable data on blood transfusion matters in different regions is of considerable importance. Such information will be of benefit to all in establishing and maintaining the highest quality of blood-transfusion

service provision throughout the Union.

2.6 The CoR believes that the availability of such information throughout the Union will be facilitated by coherent information-technology practices in the Member States, and calls on the Commission to take account of the requirements for such information-technology practices in Member States.

2.7 The Committee believes that specific funds should be made available to applicant countries to ensure that any particular difficulties that may exist in rapidly achieving compliance with the provisions of the proposed directive are identified and resolved.

Brussels, 20 September 2001.

The President

The Secretary-General

of the

of the

Committee of the Regions

Committee of the Regions

Jos Chabert

Vincenzo Falcone

¹ OJ C 144 of 16.5.2001, p. 43

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