# Procedure file

## Basic information

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| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Directive | 1995/0013B(COD) |
| Medical devices including blood and plasma derivates<br>See also 2001/0186(COD)<br><br>Subject<br>4.20.04.02 Safety of blood and transfusion<br>4.60.02 Consumer information, advertising, labelling | Procedure completed |

## Key players

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|---|---|---|---|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | ENVI Environment, Public Health and Consumer Protection | PPE-DE TRAKATELLIS Antonios | 12/07/2000 |
| | Former committee responsible | | |
| | ECON Economic and Monetary Affairs, Industrial Policy | RDE POMPIDOU Alain | 24/05/1995 |
| | Former committee for opinion | | |
| | ENVI Environment, Public Health and Consumer Protection | PPE TRAKATELLIS Antonios | 19/04/1995 |
| Council of the European Union | Council configuration | Meeting | Date |
| | Health | 2281 | 29/06/2000 |

## Key events

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| 19/04/1995 | Legislative proposal published | COM(1995)0130 | Summary |
| 15/05/1995 | Committee referral announced in Parliament, 1st reading | | |
| 06/02/1996 | Vote in committee, 1st reading | | Summary |
| 06/02/1996 | Committee report tabled for plenary, 1st reading | A4-0031/1996 | |
| 12/03/1996 | Decision by Parliament, 1st reading | T4-0115/1996 | |
| 29/06/2000 | Council position published | 13561/1/1999 | Summary |
| 06/07/2000 | Committee referral announced in Parliament, 2nd reading | | |
| 10/10/2000 | Vote in committee, 2nd reading | | Summary |

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| 10/10/2000 | Committee recommendation tabled for plenary, 2nd reading | A5-0268/2000 | |
| 24/10/2000 | Decision by Parliament, 2nd reading | T5-0451/2000 | Summary |
| 16/11/2000 | Final act signed | | |
| 16/11/2000 | End of procedure in Parliament | | |
| 13/12/2000 | Final act published in Official Journal | | |

## Technical information

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|---|---|
| Procedure reference | 1995/0013B(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Directive |
| | See also 2001/0186(COD) |
| Legal basis | EC Treaty (after Amsterdam) EC 095 |
| Stage reached in procedure | Procedure completed |
| Committee dossier | ENVI/5/12916 |

## Documentation gateway

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|---|---|---|---|---|---|
| Legislative proposal | | COM(1995)0130<br>OJ C 172 07.07.1995, p. 0021 | 19/04/1995 | EC | Summary |
| Economic and Social Committee: opinion, report | | CES1153/1995<br>OJ C 018 22.01.1996, p. 0012 | 25/10/1995 | ESC | |
| Committee report tabled for plenary, 1st reading/single reading | | A4-0031/1996<br>OJ C 078 18.03.1996, p. 0002 | 06/02/1996 | EP | |
| Text adopted by Parliament, 1st reading/single reading | | T4-0115/1996<br>OJ C 096 01.04.1996, p. 0017-0031 | 12/03/1996 | EP | |
| Council position | | 13561/1/1999<br>OJ C 245 25.08.2000, p. 0019 | 29/06/2000 | CSL | Summary |
| Commission communication on Council's position | | SEC(2000)1134 | 30/06/2000 | EC | Summary |
| Committee recommendation tabled for plenary, 2nd reading | | A5-0268/2000<br>OJ C 197 12.07.2001, p. 0009 | 10/10/2000 | EP | |
| Text adopted by Parliament, 2nd reading | | T5-0451/2000<br>OJ C 197 12.07.2001, p. 0023-0074 | 24/10/2000 | EP | Summary |

## Additional information

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| European Commission | EUR-Lex |

## Final act

Directive 2000/70
OJ L 313 13.12.2000, p. 0022 Summary

## Medical devices including blood and plasma derivates

Following the splitting of the initial Commission proposal and the adoption of Directive 98/79/EC concerning in vitro diagnostic medical devices, the proposed amendment seeks to extend the scope of application of Directive 93/42/EEC to medical devices incorporating derivatives of human blood and human plasma only.?

## Medical devices including blood and plasma derivates

The committee made substantial changes to the report by Mr Alain POMPIDOU (UPE, F) concerning the directive on in vitro diagnostic medical devices. The directive hoped to establish harmonised standards with a view to completing the internal market for these products. Nevertheless, since in vitro diagnostic reagents were derived from the human body, it was important to draw up provisions to provide the maximum guarantees for users. The Committee on Economic and Monetary Affairs did not adopt the amendments tabled by Mr POMPIDOU aimed at defining three types of reagents to enable specific standards to be drawn up in accordance with the risk of error these products might entail. However, the members retained the idea of establishing a European database bringing together all the information provided by manufacturers and agreed on the need for Member States to apply continual surveillance of the quality and safety of these devices after being placed on the market. The other amendments were aimed at: - improving safety, particularly with regard to packaging; - reducing the risk of infection and eliminating the risks for users and patients; - ensuring that when the products were placed on the market, the information accompanying them was in the national language(s) and, if symbols or codes were used, that they were easily understood by non-professional users (self-testing devices); - ensuring extensive information, including the requirement for manufacturers to notify the relevant authorities in each Member State involved when their product was placed on the market. ?

## Medical devices including blood and plasma derivates

The Commission included in its amended proposal almost all of the amendments suggested by the Parliament. More importantly, during the legislative procedure on the proposal, the Council in agreement with the Commission, decided to make a split and initially to draw up a common position only on in vitro diagnostic medical devices. For that part of the proposal, all the amendments proposed by the Parliament were adopted by the Council. The European Parliament approved the split and proposal at second reading an amendment to that effect, stressing the need to legislate rapidly on medical devices manufactured from substances of human origin. That amendment was incorporated in Recital no 35 of Directive 98/79/EC on in vitro diagnostic medical devices, adopted on 27 October 1998. The text of the present common position is the result of the continuation of work at Council level on the part of the proposal still outstanding. However, agreement could be reached only on a Directive limited to devices containing derivatives of human blood or plasma. Devices incorporating other substances derived from human tissue will have to be the subject of a specific Directive. Accordingly, the text of the common position is limited to amending Directive 93/42/EEC to incorporate provisions on substances derived from human blood or plasma. Consequently, two of the five amendments relating to the inclusion of medical devices made from products derived from tissues and cells from the human body in Directive 93/42/EEC, proposed by the Parliament and adopted by the Commission have become irrelevant because the scope of the common position is limited. Furthermore, amendments concerning an addition to the labelling requirements, requirements on the EU conformity declaration and the addition of medical devices covered by this Directive to class III of the classification system were all adopted by the Council with necessary adjustment to take account of the fact that the scope is limited to devices incorporating stable derivatives of human blood or plasma. Since derivatives of human blood are considered to be a medicinal product within the meaning of Directive 89/381/EEC on special provisions for medicinal products derived from human blood or plasma, and, accordingly, medical devices containing those derivatives must guarantee the same level of quality and safety as medicinal products when used, they must be subject to the existing Community evaluation and verification procedures for medicinal products.?

## Medical devices including blood and plasma derivates

The Commission's proposal, resulting from the COREPER decision of October 1997 and based on Article 95 of the Treaty seeks to harmonise national provisions governing the placing on the market of medical devices incorporating tissues of human origin. During the discussions in the Council, it emerged that it would be advisable to restrict the scope of the proposal to devices containing derivatives of human blood and human plasma, and that devices incorporating other derivatives of human tissues should be the subject of a specific directive. The common position is consequently restricted to amending Directive 93/42/EEC with a view to introducing provisions concerning derivatives of blood and plasma. The Commission accepts the constituent parts of the common position. It notes that the latter is in line with the amendments proposed by the European Parliament. It therefore calls on the two institutions to conclude the legislative procedure as quickly as possible so that the necessary improvement in health protection in the sector concerned can be achieved. In addition, the Commission will begin preliminary work in order to consider the advisability of submitting a proposal for a directive concerning substances other than those derived from human blood and human plasma.?

## Medical devices including blood and plasma derivates

The committee adopted the recommendation for second reading (under the codecision procedure) by Antonios TRAKATELLIS (EPP-ED, GR) approving the common position of the Council on amending directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma. The common position had incorporated all the relevant amendments adopted by Parliament at first reading and the committee therefore felt that the directive should be adopted without delay. It nevertheless specifically urged the Commission and Council to declare that they would proceed very rapidly to draw up a proposal for a directive covering the establishment of rules on non-viable tissues or substances of human origin, derived from those tissues, so as to complete legislation in this very important sector.?

## Medical devices including blood and plasma derivates

The European Parliament adopted the report, drafted by Mr Antonios TRAKATELLIS (EPP/ED, Gr) without amendment. ?

## Medical devices including blood and plasma derivates

PURPOSE : to amend Directive 93/42/EEC, as regards medical devices incorporating stable derivates of human blood or human plasma. COMMUNITY MEASURE : Directive 2000/70/EC of the European Parliament and of the Council. CONTENT : the Directive aims at amending Directive 93/42/EEC so as to include in its scope only devices which incorporate, as an integral part, substances derived from human blood or plasma. However, medical devices incorporating other substances derived from human tissue remain excluded from the scope of the Directive. ENTRY INTO FORCE : 13/12/2000. DEADLINE SET FOR TRANSPOSITION : 13/12/2001.?