COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.8.2007
COM(2007) 465 final

2007/0168 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

repealing Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

On 16 March 2005 the Commission adopted a key Communication on Better Regulation for Growth and Jobs in the European Union (COM (2005) 97 final) which stressed the importance of simplification of national and European legislation. Better Regulation is crucial for improving the competitiveness of European enterprises and for achieving the objectives of the Lisbon Agenda. Indeed, improving the quality of the regulatory framework helps cutting unnecessary costs and removing obstacles that hinder adaptation and innovation; it creates the right incentives for business and market framework conditions which allow business to thrive, so that it can create the wealth our economies need.

As stated in the Commission Communication on Implementing the Community Lisbon Programme: a strategy for the simplification of the regulatory environment (COM (2005) 535 final), the review of the "acquis" must become a continuous and systematic process, enabling the legislator to revise legislation by taking all legitimate private sector and public interests into account. The Communication sets out a rolling programme which forms part of a new strategy for simplification. This programme specifies those pieces of legislation that the Commission envisages reviewing and assessing, with the view to simplifying them.

In 2006 the Commission adopted its Commission Working Document, First progress report on the strategy for the simplification of the regulatory environment (COM(2006) 690 final). In view of the importance of the continuous re-examination of the acquis, the Commission has identified a further 43 additional initiatives with a potential simplification dimension for the period 2006-2009. Included in this re-examination is Council Directive 84/539/EEC, adopted on 17 September 1984, on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine.

Having reviewed the implementation and application of this Directive, the Commission has concluded to propose its repeal.

2. RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND ASSESSMENT

2.1. Consultations

The starting point for reviewing whether it would be useful to keep Directive 84/539/EEC, adopted on 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine, as part of the "acquis" or not, was the opinions expressed by Member States and industries that, over a number of years, the Directive had not been generally applied in the trade of these devices.

As part of the Commission preparatory work, and in accordance with the principles of Better Regulation, Member States and stakeholders were consulted.

A meeting was held with the Member States to establish whether the Directive was applied or not and to collect their views on a possible repeal of the Directive. The industry associations were also consulted on an individual basis. Both enquiries lead to the same conclusion: the Directive does not serve its purpose anymore.

2.2. Enquiry results and assessment

The main reasons mentioned for not applying the Directive 84/539/EEC were the following:

1. The application of Directive 84/539/EEC has been limited over the past years, since most manufacturers use Directive 93/42/EEC on medical devices (for human use) as their starting point.[1]

   Most electrical medical devices manufacturers placed their products on the Community market for 'dual use' meaning that they can be used both for human beings and animals. The rational behind the approach of manufacturers to aim for 'dual use' is that the market for electro-medical equipment used in veterinary medicine is very small. In addition, it appears that the Community regulatory framework for medical devices for human use is suitable for ensuring the quality and safety of electro-medical equipment for veterinary use.

   Article 2 of Directive 84/539/EEC is applied in cases of 'dual use'. This provision determines that where a medical device conforms to the requirements of Directive 93/42/EEC on medical devices (for human use) it is deemed to be in conformity with Directive 84/539/EEC.

2. Even in the case of specific products only used in veterinary medicine, the application of the current Community legislation in force is considered a better option offering the appropriate guarantees for health and safety aspects in this very small market. The general Community regulatory framework that provides adequate rules are:

   – Directive 2006/42/EC on machinery[2]

   – Directive 2004/108/EC relating to electromagnetic compatibility[3]

   – Directive 85/374/EEC on product liability[4]

3. The methods of conformity by means of the (compulsory) application of standard *HD 395-I: General Requirements (1979 edition – document based on IEC No 601-1of the International Electrotechnical Commission)* is no longer appropriate nor in force. The standard is statically referred to in Annex I of Directive 84/539/EEC. This standard has been revised during the past years, and is currently listed as a harmonised standard under Directive 93/42/EEC on medical device.[5]

---

1 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169/1, 12.7.1993, as last amended by Regulation (EC) No 1882/2003, OJ L 284/1, 31.10.2003.

2 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast), OJ L 157/24, 9.6.2006.

3 Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member Sates relating to electromagnetic compatibility and repealing Directive 89/336/EEC, OJ L 390/24, 31.12.2004.

4 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210/29, 7.8.1985, as last amended by Directive 1999/34/EC of 10 May 1999, OJ L 141/20, 4.6.1999.

5 EN 60601-1:1990 medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

4. Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine was adopted as a measure to develop the internal market for these devices.

   The internal market for these devices is seemingly without any hindrances due to the fact that other relevant Community legislation can be applied. It appears that the Directive 84/539/EEC is not necessary for the internal market trade or trade with third countries and no obstacles to trade have been noted in the sector concerned.

In light of the above, repealing of Directive 84/539/EEC is necessary to simplify the regulatory environment, by suppressing a non-essential legal instrument having a very limited application and which is not necessary for internal market reasons or for ensuring the health and safety aspects relating to these devices.

Therefore, it was decided not to replace the Directive by other legislative measures or to modify it.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Subsidiarity and proportionality principles

Following the results of the consultation and the assessment, it is evident that the objectives of Directive 84/539/EEC can be adequately achieved by other relevant Community legislation.

3.2. Choice of instrument: the form of the act

When an act is repealed the principle of "parallel forms" applies; that is to say, the repeal of Directive 84/539/EEC would be effected by a repealing Directive.

3.3. Budgetary implications

The proposal does not have any budgetary implications

4. CONCLUSION

The proposal to repeal Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine is in line with the results of the consultations with Member States and industry.

It is however important that the repeal of Directive 84/539/EEC be followed by the repeal of the corresponding national implementing measures, in order to have the desired practical effect. The specimen mark of conformity of Annex III will no longer be available for use.

In addition, it should be ensured that the advantages of the repeal are not cancelled out by new national rules or new technical barriers. Accordingly, it is important to note that any national rules on electro-medical equipment used in veterinary medicine are consistent with the principles of Article 28 of the EC-Treaty and do not constitute unjustified barriers to trade, and with the above mentioned applicable Community legislation. Moreover, any national

measures which might be considered to be technical regulations for the purpose of Directive 98/34/EC[6] must be notified to the Commission in draft form.

[6] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, OJ L 204/37, 21.7.1998, as last amended by Council Directive 2006/96/EC, OJ L 363/81, 20.12.2006.

2007/0168 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

repealing Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine

(text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[7],

Having regard to the opinion of the European Economic and Social Committee[8],

Having regard to the opinion of the Committee of the Regions[9],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[10],

Whereas:

(1) Community policies on better regulation stress the importance of simplification of national and Community legislation as a crucial element for improving the competitiveness of enterprises and for achieving the objectives of the Lisbon Agenda.

(2) The method of conformity assessment provided by Council Directive 84/539/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine[11] is no longer necessary for the purposes of the internal market and trade with third countries.

(3) The functioning of the internal market and the protection of users and animals can be better ensured by other Community legislation.

(4) Directive 84/539/EEC should therefore be repealed.

(5) The repeal of Council Directive 84/539/EEC entails that after 31 December 2008 the specimen mark of conformity of Annex III will no longer be used and that the corresponding national implementing measures have to be repealed accordingly,

---

7 OJ C , , p. .
8 OJ C , , p.
9 OJ C , , p.
10 OJ C , , p.
11 OJ L 300/179, 19.11.1984, as last amended by Regulation (EC) No 807/2003, OJ L 122/36 16.5.2003.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 84/539/EEC is repealed with effect from 31 December 2008.

Article 2

1. Member States shall adopt and publish, by 31 December 2008 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 January 2009.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*