

# **Electro-medical equipment used in veterinary medicine: approximation of the laws of the Member States (repeal. Directive 84/539/EEC)**

2007/0168(COD) - 07/08/2007 - Legislative proposal

**PURPOSE:** to repeal Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine and not to replace it with any other legislative act.

**PROPOSED ACT:** Directive of the European Parliament and of the Council.

**CONTENT:** within the context of the Better Regulation initiative the Commission identified in 2006 43 legislative acts that require simplification. Included in this re-examination was Council Directive 84/539/EC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine.

The starting point of the review was whether or not to keep the Directive. The question of repealing and not replacing the Directive was raised by certain Member States and by industry who noted that the Directive was no longer being applied in the trade of these devices.

Prior to presenting this proposal the Commission held a wide-ranging consultation that involved both the Member States and industry. The consultation process led to the same conclusion – i.e. that the Directive no longer serves the purpose for which it was originally drafted.

The reasons for this are fourfold:

- Firstly, most manufacturers rarely rely on this Directive, preferring instead to apply Directive 93/42/EEC on medical devices (for human use). Further, most of the products manufactured are of “dual use” purposes meaning that they can be used both for humans as well as for animals. The market for electro-medical equipments used in veterinary medicine is, therefore, very small.
- Secondly, in cases where products are manufactured to be used specifically for veterinary medicine, manufacturers rely on other Community legislative acts since they are deemed a better option than Directive 84/539/EEC. The other legislative acts are: Directive 2006/42/EC on machinery; Directive 2004/108/EC relating to electromagnetic compatibility; and Directive 85/374/EEC on product liability.
- Thirdly, standards adopted within the context of Directive 84/539/EEC have been revised and are currently listed as harmonised standards under the Directive on medical devices.
- Fourthly, the Directive does not prevent a distortion of the single market since no complaints have been recorded.

It is important that the repeal of Directive 84/539/EEC be followed by the repeal of corresponding national implementing measures. Further, it should be ensured that the repeal of this Community act will not be 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 is consistent with the principles of Article 28 of the EU Treaty.

To conclude, the purpose of this proposal is to repeal Directive 84/539/EEC and not to replace the Directive by any other legislative act.

