WRITTEN QUESTION E-2167/09
by Malcolm Harbour (PPE-DE)
to the Commission

Subject: Medical devices and medicinal products

The demarcation between the Medical Devices Directives (93/42/EEC[1] as amended by 2007/47/EC[2]) and the Medicinal Products Directives (2001/83/EC[3]) remains both complex and challenging. It has led to significant national variation, which continues to undermine the smooth running of the internal market and, potentially, patient safety.

How does the Commission intend to resolve this issue and ensure uniform application of relevant Directive provisions? Can it be dealt with via the Commission's proposed recast of medical devices legislation or should it be tackled through changes to the MedDev, the Commission's guidance document that seeks to address certain basic principles on demarcation between medicinal products and medical devices?

1 OJ L 169, 12.7.1993, p. 1.
2 OJ L 247, 21.9.2007, p. 21.
3 OJ L 311, 28.11.2001, p. 67.