WRITTEN QUESTION E-1749/09
by Margie Sudre (PPE-DE)
to the Commission

Subject: Recasting of directives on medical devices

The Commission held a consultation in 2008 with a view to revising the legislative framework for medical devices. The conclusions of that consultation show very clearly that the current legislative system is too fragmented and that it is interpreted differently from one Member State to another. The professionals are particularly critical of the definition of medical devices, which leads in practice to confusion with medicines.

This has serious implications: patients' health may suffer, as does the smooth operation of the single market, since uniform application of the legislative framework has not been achieved.

What clarification does the Commission intend to make, therefore, to the definition of medical devices in its forthcoming revision? In addition, the Commission had agreed to update its MEDDEV 2.1/3 guide, which is intended precisely to clarify the difference between medical devices and medicines. Does it plan to consult interested parties in advance of this update, and when does it intend to carry out the update?