REACH AND THE MEDICAL DEVICES INDUSTRY

Brussels 26th October 2006

Our request

Having studied the compromise REACH proposal, and discussed with many stakeholders at the Commission, Parliament and Council level we would like to request that the following text which has already been approved once by the parliament be reintroduced:

> Under article 2 section 5 of the council common position[1]
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> ***c) medical devices within the scope of Council Directive 90/385/EEC[2], Council Directive 93/42/EEC[3] or Directive 98/79/EC of the European Parliament and of the Council[4];***

Background

During first reading of the REACH proposal the concerns of the medical devices industry, including the in vitro diagnostics (IVD) industry were presented to the parliament, (see annex I). An amendment which provided exclusions to some of the chapters of REACH for a number of sectors, including medical devices and in vitro diagnostics, was tabled and approved by the parliament. However in the recently published council common position (dated June 12th 2006) that particular amendment was not taken up by the council.

Our commitment

As part of the healthcare industry, the medical devices industry is acutely aware of the positive effects that obtaining the goals enshrined in the REACH proposal will have for the overall health of Europeans and for the environment. We will strive as an industry to reach those goals, however it is not surprising that we would like to do so in the most efficient way possible – as this will enable us to focus our resources on developing new assays and devices with which to diagnose and monitor for instance the treatment of cancers, degenerative diseases, protection of the blood supply and emerging threats to our health.

Medical Devices are regulated under directives 93/42/EEC and 90/385/EEC, while In Vitro Diagnostics are regulated under Directive 98/79/EC. These directives all provide the framework under which to address all risks posed by Medical Devices – be they risks to the patient, to the clinician, to third persons or to the environment. However detailed guidance on how to address risks to the environment has been lacking until recently.

In order to address environmental concerns the Medical Devices industry is developing the integrated risk management approach so as to ensure that these concerns are addressed adequately through our regulatory framework (see annex II). The end result will be the same as under REACH – increased protection for the environment and better health in Europe. However, being able to work within our existing regulatory framework would mean that those goals could be met faster and more efficiently which are critical considerations in an innovation driven sector where European industry successfully competes at the global level on all markets.

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[1] *Document 7524/06 as published 12 June 2006 by the Council of the European Union*
[2] *OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003.*
[3] *OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.*
[4] *OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.*

EDMA: Place des Maïeurs 2 ▪ B-1150 Brussels ▪ +32 2 772 2225 tel ▪ +32 2 772 2329 fax ▪ edma@edma-ivd.be ▪ www.edma-ivd.be
COCIR: Boulevard A. Reyers 80 ▪ B-1030 Brussels ▪ +32 2 706 8960 tel ▪ +32 2 706 8969 fax ▪ info@cocir.org ▪ www.cocir.org

Annex 1: In Vitro Diagnostics and REACH – Rationale for an exemption as approved by the European Parliament in first reading

This paper has been drawn up to inform key decision-makers of the consequences for the Medical Devices sector of the full implementation of the REACH proposal in its current form – which stresses the need for an exemption from REACH for medical devices along the lines of those approved by the European Parliament in first reading.

All substances used in medical devices are selected for their particular properties, including their specific interaction with human cells and tissues, and these are precisely the kind of substances which will be most significantly impacted by REACH.

- **Considerations for patient safety:** It would be counter productive if REACH, whose intended aim is to improve the health and quality of life of the European citizen, would result in the withdrawal of substances and consequentially potentially life-saving products from the market, that are needed to guarantee public health. Furthermore the inevitable delays in the development and improvement of existing medical devices (eg for the detection of new infectious agents such as flu strain H5N1) will further imperil patient safety.

- **Negative impact on healthcare systems –** The costs of REACH for the medical devices would have to be passed onto hospitals and health institutions, which already operate under severe cost constraints.

- **An imbalance in the consideration of risks (as defined by REACH) and benefits (patient safety and health):** According to existing EU legislation, throughout the design and manufacturing processes of all medical devices, risk-benefit analysis is the basis on which decisions are taken. Risks not only to the patient and the user, but also to all third parties and to the environment must be taken into account. Implementation of risk reduction proposed within the framework of REACH, which does not consider benefits in relation to risks, will result in a distortion and undermining of the effective regulatory system already in place for medical devices.

- **Adverse consequences for European Industry:** The increased regulatory burden would put an industry which is largely comprised of small and medium enterprises (94% of medical device companies) at a serious competitive disadvantage in Europe as compared to other regions. The local regulatory framework is clearly an important factor considered by companies when deciding where to place manufacturing facilities. An unnecessary and unjustified additional burden will almost certainly jeopardize the competitiveness of the industry in Europe.

- **Negative impact on innovation** of the medical devices industry is a research and innovation-driven industry - investment in R&D can reach 50%[1] of company turnover for parts of the sector. The key regulatory parameters have been safety and performance and this has been an innovation-driver in the sector. Any restriction of the selection and utilization of the most appropriate and effective substances for use in devices (which are already effectively regulated) will severely impact innovation and will be against the spirit of the Lisbon Agenda.

[1] EU Commission Study: "Medical Devices Competitiveness and Impact on Public Health Expenditure"

Annex 2: Proposed Integrated Risk Management Approach for Medical Devices.