CPME/AD/Brd/210902/25/EN

At its Board meeting, Brussels, September 21st , 2002, the CPME adopted the following policy : **Manifesto : Calls for EU action to regulate the reprocessing of single use medical devices in order to protect the health and safety of patients and healthcare workers** (CPME 2002/114 Final EN)

Manifesto
Eucomed calls for EU action!

Eucomed and the Patients Association have drafted a Manifesto calling for EU action to regulate the reprocessing of single use medical devices in order to protect the health and safety of patients and healthcare workers.
Supporting organizations include the European Medical Association (EMA), the International Alliance of Patients' Organisations (IAPO), the Standing Committee of European Doctors of the EU (CPME) and the Standing Committee of Hospitals of the European Union (HOPE).

Resolution
by European Associations calling on EU action to regulate the reprocessing of single use medical devices in order to protect the Health and Safety of patients and healthcare workers

Why we need EU Action ?

The reuse of medical devices intended for single use is widespread throughout the EU, presenting significant risks to the health and safety of patients and healthcare workers. The Medical Devices Directive 93/42/EEC does not regulate the reprocessing of single use medical devices

What is our Common Aim ?

To call on the EU to regulate all reprocessing of medical devices intended for single use by hospitals, reprocessors and original manufacturers, in order to protect the health and safety of patients and healthcare workers.

What are the Issues for Patients and Healthcare Workers ?

- **General risk of infection:** Reuse of single use devices may introduce infectious organisms into the patient's blood stream, due to the difficulty (and often impossibility) of cleaning single-use devices. In many cases it is not possible to guarantee that all blood, tissue and body residues have been removed. If cleaning is not achieved inactivation of all micro organisms can not be guaranteed. Infections acquired in hospitals are an increasingly serious problem, putting the health and lives of patients and hospital staff at risk, putting pressure on waiting lists and adding sizeable costs to the Member State budgets.
- **Risk of device impairment:** Reprocessing a single-use device is contrary to the manufacturer's design and may alter the nature of the device. Research has shown that significant damage can be caused with consequent impairment of performance, and safety associated with diminished performance.
- **Informed consent:** It is a basic principle of medical treatment that the patient should consciously agree to the form of treatment, particularly if it involves surgery and puts the patient at risk without any patient benefit. That consent should be 'informed', which means that the patient should be clearly told of all relevant factors, including the fact that he is to be treated with a reused single-use device contrary to the manufacturer's instructions, and that this may expose the patient to infection and/or device malfunction.

What specific risks of infection are associated with the reuse of sinlge use instruments?

- **Specific risk of CJD infection:** The Scientific Committee on Medicinal Products and Medical Devices attached to the European Commission found 'transmission of CJD by silver electrodes used for stereotactic electroencephalography [used to record the electric activity of the brain] and by neurosurgical instruments has been described in single cases. In all these cases, the carrier of infectivity (i.e. tissues, instruments) was derived from or in close contact with the central nervous system of individuals infected with CJD.'

- **Specific risk of Hepatitis infection:** The Hepatitis virus is highly infectious and can be spread by contact with blood from an infected person. The virus has been contracted by patients and health care workers, through contact with a contaminated medical device or transfusion of infected blood and blood products

The basis for EU action to regulate the reprocessing of single use medical devices in order to protect the health and safety of patients and healthcare workers

- EU Member States regulate the reuse of single use medical devices in a non-harmonised manner with different national approaches from prohibiting to permitting reuse.
- France, Germany, Italy, Portugal, Spain, Sweden and UK have enforced measures against reuse of single use devices
- The Health Strategy of the European Union lays out that 'The Community's role in public health is to complement their efforts, to add value to their actions and in particular to deal with issues that Member States cannot handle on their own. Infectious diseases, for example do not respect national borders.'
- The European Health Council discussion on prevention of TSEs of 5 June 2001 agreed to 'Continuously review protective measures on medical devices, applying the precautionary principle.'
- Article 95 (ex Article100a) of the Treaty of Amsterdam states that 'The Commission, in its proposals concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.'
- Article 152 (ex Article 129) of the Treaty of Amsterdam stipulates that: "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities". It states that 'Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health'

- Article 153 (ex Article 129a) of the Amsterdam Treaty states that ‘In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information and education.’
- Communication from the Commission of 2 February 2000 on the precautionary principle