

## HOPE Position n°6/2005

### Community regulatory framework on advanced therapies

Most of the research and development on advanced therapy has been and is still being performed by hospitals, in particular university/teaching hospitals. As HOPE reads it, the current proposal on a community regulatory framework on advanced therapies, if adopted, would be the end of most of those activities for all hospitals.

The main issue for HOPE is the scope of this proposed regulation. The distinction made in the consultation paper on page 9 (“examples”) does not find its translation in the article 1§2 of the Proposal for a regulation. The concept of “one-off basis...for an individual patient” is clearly too restrictive and should be enlarged to take into account the reality of hospital work. If not, most of the present activities of hospitals would fall under the proposed procedure.

Hospitals do not refuse quality control and quality management measures. But the regulatory framework, the marketing authorization procedure and requirements that are proposed today by the European Commission are clearly too restrictive and in some cases not necessary for quality reasons, as far as hospital activities are concerned.

HOPE fears that as a result of this proposed regulation, hospitals would no longer be able to produce their own supply of processed cells or tissues. This will seriously damage the research activities of hospitals and will create an un-necessary interruption of the process of patients’ treatment. Instead, they would only supply cells or tissues to the pharmaceutical industry that will process them. Finally the hospitals would have to costly re-buy the processed cells and tissues.

The major consequence of the regulatory framework would be that prices for processed tissues and cells would dramatically increase. Therefore an enormous increase of health expenditure would follow.

Concerning traceability (article 23), HOPE considers that before any attempt to follow the procedure used for blood products; evidence of the way it is currently done should be collected and analysed.

Finally, HOPE asks for a clear definition of the borders with the directive on tissues and cells (2004/23/EC).

*HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation fostering efficiency, effectiveness and humanity in hospitals and health care. HOPE is made up of members coming from 24 member states of the European Union (EU), plus 3 observer members. Those members are national hospital federations. Where there are no national hospital federation, members are local and regional authorities, owners of hospitals, as well as representatives from the national health systems. As an association, its mission is to promote improvements in the health of citizens throughout the countries of the EU and a uniformly high standard of hospital care throughout the EU. Further information can be obtained on [www.hope.be](http://www.hope.be)*

