Innovation backgrounder

Background

Eucomed is the Voice of the medical technology industry in Europe. Eucomed represents directly and indirectly 4500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. The mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology.

Small and medium sized companies make up more than 80% of the medical technology industry. In 2005, the sector invested some €3,7 billion in R&D and employed 445.000 highly skilled workers. However the industry in the European Union is still lagging behind the US and Japan in terms of both innovativeness and competitiveness.

Summary

In order to improve the innovation environment for the medical technology sector in the European Union, Eucomed has made the following 10 key recommendations:

1. The establishment of an autonomous network of "Medical Technology Innovation Centres" in Member States, coordinated centrally.

2. Innovation- (and patient-) friendly regulation in the medical technology sector

3. Coherent Healthcare Technology Assessment (HTA) schemes to provide patients with access to new medical technology. HTA schemes are not uniform and do not reflect new technologies sufficiently. Furthermore, they vary considerably in their design and application in the different Member States.

4. Making Europe attractive to the best researchers and innovators

5. European governance that takes account of the specific needs of medical technology

6. Structuring of EU Framework Programmes to support Small to Medium Medical Enterprises (SMEs)

7. Securing access to Framework Programme projects for medical technology innovation

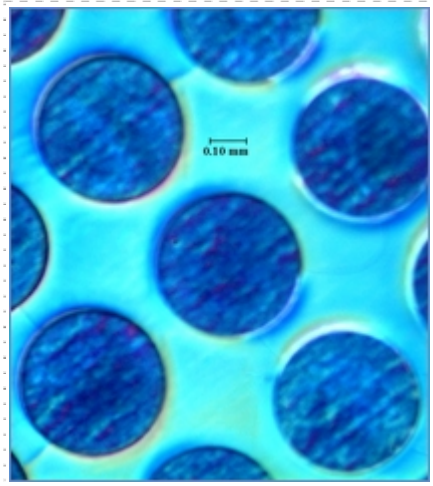
8. Securing intellectual property right protection and creating an EU Community Patent

9. Defining and supporting educational needs

10. Establishing a system of financing and improvement of capital conditions for medical technology innovation (especially for SMEs) and better protecting the interests of innovators

Detailed recommendations

Creation of Medical Technology Innovation Centres in Member States



Eucomed strongly recommends the establishment of an autonomous network of "Medical Technology Innovation Centres" in Member States, coordinated centrally. The key role for such Centres would be to facilitate the dissemination of "innovation skills" and networking between the European medical technology industry, research establishments, universities and other key European stakeholders, with an approach centred on bringing new medical technologies as quickly as possible to the patient.

Such Medical Technology Innovation Centres would:

- assist companies with business plans, protection of intellectual property, locating financing partners, etc., in order to facilitate new technology evolution and allow them to share ideas for further exploitation
- secure information, networking, and new business opportunities to medical companies
- collect a wide range of relevant information and provide statistical data (e.g. number of innovation companies, capital, turn-over, number of employees, etc.), to support medical technology development and innovation at the EU level

In addition, in the medical technology sector, funding for research has been difficult to obtain in some Member States. Better coordination is needed and will reduce the risk of parallel research (and subsequent wastage of public money) in different Member States.

Note: Eucomed and its national association members are in the process of preparing a submission to the European Commission for financial support to the establishment of national medical technology innovation centres.

Innovation- (and patient-) friendly regulation

In the field of medical technology, it is extremely important that any new European Directives or Regulations are "innovation friendly". To date, much of the success and growth of the European medical devices industry has been due to the flexibility afforded by the three "New Approach" medical devices directives. These have essentially addressed requirements from the point of view of managing risks and ensuring the intended performance of medical devices without imposing strict, detailed technical requirements. This can be shown to have resulted in a high level of innovation of technologies and products without compromising patient safety.

Given that medical innovation is continuing rapidly and that there is an increasing trend towards convergence of technologies such as advanced materials science, cell and tissue biology, IT and nanotechnology, Eucomed wishes to strongly emphasise the importance of ensuring that any future Directives/Regulations are as flexible as possible regarding innovation and promoting a variety of technical solutions whilst remaining robust enough to guarantee patient safety and effective performance of medical technology products.

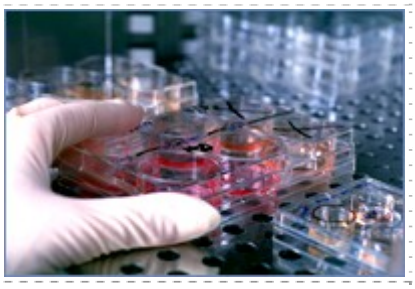
Healthcare Technology Assessment (HTA) should be transparent and involve all stakeholders

"Healthcare Technology Assessment" (HTA) is one of the instruments used by decision-makers to manage the introduction and diffusion of technological innovation. Eucomed therefore:

- acknowledges that HTA can be beneficial to decision-makers, and the Industry values its potential benefits, and considers it critical to be more involved in the growing number of European/national HTA projects and initiatives (e.g. EUnetHTA).
- encourages fostering initiatives that establish HTA methodologies and processes for medical devices that are designed in a transparent and collaborative way encouraging innovation and rapid patient access to innovative, reliable and safe technologies.

Making Europe attractive to the best researchers and innovators

Over the past decade there has clearly been a loss of key researchers to other regions of the world because of the more favourable climate in those areas for research and innovation. This situation cannot be allowed to continue and could directly and adversely affect the interests of European patients. Areas for action include, as outlined in the European Commission's Communication "Science and Technology, the key to Europe's future - Guidelines for future European Union policy to support research":



- attracting young people to science and the initial training of researchers through support for the structuring of training, in particular trans-disciplinary training;
- the role and place of women in science and research;
- the transfer of knowledge, for the benefit in particular of the technologically least advanced regions and SMEs;
- the international dimension of training and mobility through increased exchanges with other parts of the world;
- life-long learning and career development

Some other factors impacting on this issue, e.g. education and investment, are detailed in other key recommendations in this paper.

European governance that takes account of the specific needs of medical technology

Medical technology has a number of particular characteristics that necessitate a creative and specific approach. Eucomed would, therefore, like to encourage the European Commission to establish a European governance system for medical technology innovation that takes into account the particular needs of medical innovation. These include:

- the need to give European patients access to new medical technology and better quality of life;
- the need to take account of frequently underestimated or neglected benefits of medical innovation such as earlier disease detection, better treatments and prognosis and more efficient healthcare procedures (resulting in reduced hospital stays, faster recovery and return to a contributive role in society of patients);
- the need to balance risks, benefits and costs;
- the EU´s social responsibility of the well-being of the patients and the need to take account of the medical consequences of the demographic changes in society, e.g. the generally ageing European population.

Structuring of EU Framework Programmes to better support SMEs

SMEs are responsible for some of the most active areas of medical technology innovation and for some of the most exciting new treatments for patients. SMEs do not necessarily have the means or expertise to access EU R&D programmes. Eucomed is strongly of the opinion that the administration of, and access to, EU R&D research programmes should be greatly simplified.

Eucomed puts emphasis behind highlighting the low priority of medical innovation in comparison with some other subjects, e.g. agriculture, in the Structural Funds, and suggests, given the demographically important impact of improved healthcare provision in the future, that a better complementarity can be found between the Structural Funds and EU Research to support medical innovation and new technology in the future.

Improving access to Framework Programme projects

As health is always a primary concern of individual citizens, as well as a key cornerstone of EU policymaking, there should be a much-increased focus on medical technology innovation in European Framework Programme projects. We welcome progress on this front in FP7.

In addition to their scientific excellence, Eucomed recommends that additional weighting could be given to projects based on their medical contribution to improving society and the quality of life of lots of individual patients.

In general we have seen, in the past, an overly bureaucratic approach to EU R&D programmes and will welcome all efforts to focus in the future on access and results.

Improving intellectual property right protection

Eucomed considers that the Commission should pay particular attention to:

- reaching the objective of creating a community patent, possibly in addition to national patents;
- deepening the contacts with the European Patents Office (EPO) and developing and implementing simplified procedures;
- establishing and maintaining contacts with the OECD and other stakeholders.

Eucomed would also recommend a strategy to improve the overall EU IPR framework and to limit isolated actions/initiatives.

Intellectual property protection can be used positively or negatively and Eucomed has the following additional comments:

- IPR is an absolute prerequisite to technological progress;
- for every invention that leads to commercial success, there are many that will never be commercially exploited or deliver return to their inventors or venture investors

The best facilitator of the knowledge flow is intellectual property and, more specifically patents. Patents are double-sided and are thus characterized by two words: disclosure and exclusivity. Their main function is to disclose inventions; as a consideration for that disclosure, the inventor is granted an exclusive right of use for a limited period of time. (Such exclusive right is not a monopoly: it is a right to prevent others from using the invention, whilst a monopoly consists in a government giving to one entity only the right to exert a given activity).

In view of the disclosure function of the patents, they act as disseminators of research results and they can create or enhance competition within the research community.

EU Community patents

In Europe there is an obligation to pay fees in all countries versus one fee only, e.g. in the US. Eucomed is, therefore, strongly in favour of a simplification of the existing patent procedures and proposes that the European Commission to take steps, in conjunction with the EPO, to simplify patent systems.

The decreasing European share of world wide patent revenues is not caused by companies not seizing opportunities, but in Eucomed's view, is probably rather a consequence of the existing legal framework.

Counterfeiting

A further problem is the counterfeiting of valuable medical technology from outside Europe, particularly the Far East. Eucomed proposes that the European Commission should take measures to prevent the access to the European market of counterfeited innovative technology products and, furthermore, should work with its regulatory counterparts internationally in order to seek a global solution to this increasing problem.

Public Sector

EU-Recommendations for predictable transfer of intellectual knowledge between the public and private sectors are needed.

Better defining educational needs

Specifically in relation to medical technology innovation, Eucomed would also propose that the European Commission should undertake an EU-wide study in cooperation with future national medical innovation centres to:

- define the volume and types of medical technology innovation;
- characterize and quantify tertiary educational and professional training needs to meet these innovation challenges for the future and to ensure delivery of innovation to patients;
- encourage and support relevant educational activities at national or regional level
- establish the current level of synergy between academic establishments and industry with a view to strengthening the education momentum in such links

The financing and improvement of capital conditions for innovation (especially for SMEs)

It is absolutely essential that the EU provide substantial funding for capital for innovation in the medical technology sector. As well as being necessary for the patient and for society in the longer term, innovation will be vital in retaining the competitiveness of industry and the creation of employment in Europe.

It is Eucomed´s view that far better financial support mechanisms are required to support the interests of innovators and entrepreneurs in the innovation process, and the EU should encourage such support amongst its Member States.

The interests of the original innovator - private or public - are easily lost due to short-term, non-innovator friendly investments. This has often resulted in the original technical expertise being lost from projects. It is important to keep motivated innovators in the management structures of companies.

The establishment of Innovation Centres can contribute to a better dialogue between innovators, the industry and the investors to secure that the innovative expertise will be to the benefit of the EU society and the patients.

There are a number of facets to the capital conditions for innovations in the medical technology sector, including elements outside the immediate influence of the European Commission, such as the level of investment by venture capital organizations and cultural differences between the US, Japan and EU in approaching "business risk". A study of such differences between the United States, Japan and Europe is urgently required to take the necessary EU actions to establish a balance between US, Japan and EU innovation economy.