

Eucomed Response to Commission Consultation on ‘The Future of Pharmaceuticals for Human Use in Europe’ - October 2007

Introduction

Eucomed represents 4,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of diseases and disability. Most of these companies are SMEs. The mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology. Eucomed is keen to contribute to the development of the thriving, innovative and world-beating pharmaceutical and medical technology market which the EU has the potential to be. Eucomed hopes that the contribution below will be helpful and is willing to be involved in any further work linked to the future of healthcare in Europe.

**Question 1. Do you agree with the analysis of the main challenges outlined above?
Do you see any other challenges?**

And

Question 2. Do you see other areas than those already targeted by the Commission where regulatory action should be taken?

We agree with the overall assessment of the challenges facing the EU. However one should not consider just pharmaceuticals when addressing “new public health, scientific and economic challenges” and “health threats”. Medical devices are vital for European healthcare, as they are involved in all stages from testing and diagnosis to treatment and recovery. Technological developments in healthcare, such as the use of nanotechnology, regenerative medicine and minimally invasive surgery have drawn the pharmaceuticals and devices closer together in terms of both development and usage. We believe that any new Commission initiative, be it of legislative or policy nature, should reflect this.

Against the background of a world increasingly becoming global, Eucomed believes that global solutions must be developed. Eucomed therefore encourages the EU adoption of the GHTF models as well as promotion of the GHTF model internationally. Similarly, Eucomed encourages the acceptance of internationally recognised standards.

Eucomed agrees that:

- 1) Patient safety/better protection of health of EU Citizens
 - 2) Strengthening the competitiveness of the EU healthcare sector
- are two most important objectives to be met.

Patient safety as an utmost priority should obviously remain a focus for all healthcare products, pharmaceuticals and medical devices. In terms of medical devices and patient safety, Eucomed is very concerned that the re-use of medical devices that are only intended for single use is creating a major threat to the safety of patients, a threat that could be avoided with appropriate actions by the Commission.

Before raising the question of what action should be taken, it is probably of significance to outline the various areas of healthcare affected by the themes addressed in the consultation paper. These clearly go beyond pharmaceuticals and the legislation it covers.

The sector of medical devices is equally affected by the mentioned “public health challenges» as well as “health threats”. Access to and availability of medical devices is just as important as access to the pharmaceuticals which they work together with in the treatment process. A good example of how this applies to “health threats” is with respect to the danger of a pandemic crisis, such as avian flu, in the EU. Both the availability of a medicinal product (e.g. vaccine), as well as a medical device (in order to deliver the vaccine to patients), would be needed in any effective public health action. Therefore in this instance, as in many others, medical devices and pharmaceuticals should be considered in tandem when planning for a timely and effective response.

In connection with competitiveness, Eucomed stresses the need for the European policy-makers to devise avenues that will lead to more rapid intake of innovation. Innovation is one of the most important engines facilitating the efficient use of scarce financial resources and contributing to the creation of health.

One of the hurdles to competitiveness in the EU is lack of consistent compliance with the EU rules. In the medical devices area, member states create additional hurdles allegedly linked to funding and reimbursement, but de facto tantamount to requesting more than the current legislation to launch new products. These additional requests usually trigger additional cost with no patient safety benefit, reducing the resources that can be made available to research and increasing the so called ‘time to patient’: whilst the member states create new hurdles, the patient waits ... Eucomed would welcome Commission initiatives in two specific areas: one in connection with the transposition and practical implementation of the MDD; two in the area of late payments, where too many member states ignore the relevant EU directive.

Question 3 – What would you suggest as concrete measures to ensure the safety of medicines supplied in the EU, addressing in particular counterfeited medicines and provision of high quality and affordable medicines also to third parties?

This question is so broad that it is hardly possible to comprehensively address all the points that it raises. Nevertheless, Eucomed would like to offer a few comments from the medical technology perspective:

- Counterfeited products constitute a genuine threat in the med tech sector. Counterfeited surgical instruments were identified at last year’s Medica event;
- One (amongst many) approach would be that the organizers of Medica and of similar exhibitions request the exhibitors to comply with a code of conducts covering in particular and specifically counterfeited products;
- The customs procedure of the member states should be adapted to this trend and respond to the need to better control imports from certain countries (not to limit the imports, but to ensure that only products meeting the EU safety requirements can be imported);

Question 4. What can be done to improve Europe’s international competitiveness?

Regarding the medical technology sector, the European Commission’s Medical Devices Competitiveness and Impact on Public Health Expenditures report of 2005 notes:

“With the appropriate use of market regulation, fiscal incentives and support to the disadvantaged categories of patients budget constraints on health systems could be reduced as well as the focus on cost-containment, and allow more room for high price-performance products both in the public and private markets. The industry of medical devices and of high-tech medicine could become one of the investment targets for health funds, and benefit from a significant financial source for R&D and innovation”

(European Commission’s Medical Devices Competitiveness and Impact on Public Health Expenditures report, Pammolli et al, 2005)

Eucomed has published a report on the competitiveness and innovativeness of the European Medical Technology Industry on 30 May 2007. This followed the European Commission's Medical Devices Competitiveness and Impact on Public Health Expenditures report from September 2005 (quoted above).

Although health is largely a Member State competency, EU can make a real difference in terms of using financial incentives to encourage research and development. This is especially important for SME's who have the expertise and drive to achieve, but often not the infrastructure and the financial resources. Small companies are a huge part of the future of European medicines and medical technologies, and their potential needs to be harnessed in order to compete with and eventually out-strip the US.

We at Eucomed believe that the following actions would significantly improve the medical technology economy in the EU:

R&D/ INNOVATION

- Promote education in fields where skills are lacking (e.g. biochemistry and nanotechnology).
- Offer incentives for the active use of new technologies in medicine (especially in the public sector).
- Streamline patent systems at Member State and EU level: the Community patent is what industry needs
- Increase R&D funding for medical technology, meaning public funding, bank credit and seed capital.

HEALTH TECHNOLOGY ASSESMENT

- More involvement of industry in the development and operation of HTA systems.
- Transparency of HTA process and methods used by authorities, and assurance that assessment is carried out by appropriately experienced clinicians.
- Harmonisation of HTA systems across Europe.

PUBLIC PROCUREMENT

- Ensure competition among purchasers to avoid monopoly purchaser-situations
- Streamline tender processes, especially for the sake of SMEs.

EXTERNAL TRADE

- Promote the GHTF (Global Harmonisation Task Force), both as it currently exists and for future development.
- Promote harmonised international standards so as to avoid duplicate administrative processes, especially translation into multiple languages.

Question 5 - What can be done to foster convergence and transparency as regards pricing and reimbursement in the EU?

With regards to medical devices the clear distinction between pricing and reimbursement must be recognized and understood by all stakeholders involved in the provision of healthcare. Reimbursement levels must be determined in such a way as to encourage the adoption and utilization of proven and innovative medical technologies thus ensuring patient access.

Funding and reimbursement mechanisms for medical devices either through prospective payment systems (DRG's) and/or global budget arrangements need to be transparent and allow appropriate stakeholder involvement. Such systems must focus on the value of a medical technology and not just the price. Where funding and reimbursement systems include a health technology assessment (HTA) component to evaluate a medical technology, standardization of assessment methodologies should be encouraged recognizing that appraisal and policy formulation will still need to take place locally.

Concerning pricing, the medical device sector is highly competitive which ensures that fair pricing levels are achieved. Market forces take into account the many differences between EU member state differences particularly when it comes to healthcare system structure, policies regarding patient access, and payment terms. Any monopolistic practices by publicly funded healthcare systems and procurement agencies should be actively discouraged.

Question 6. Do you think the current EU regulatory framework can accommodate emerging technologies like regenerative and personalised medicine, as well as nanobiotechnology?

Medical devices are key to European healthcare, as they are involved in all stages from testing and diagnosis to treatment and recovery. Technological developments in medicine which are a key tool in healthcare professionals' armoury, such as the use of nanotechnology, regenerative medicine and minimally invasive surgery all require or involve medical devices in some way.

Medical technology (i.e. Medical devices) is at the centre of new developments of regenerative medicine, nanotechnology and nanobiotechnology. Several medical devices already benefit from the use of nanotechnology. Nanotechnological material is incorporated in medical devices (e.g. bone replacement material, wound dressing, orthopaedic implants etc.). Regenerative technology is being used in or incorporated by a medical device.

It is therefore insufficient to only assess the appropriateness of the current pharmaceutical legislation for these technologies when these relate to healthcare. Rather than focusing exclusively on the current pharmaceutical legislative environment, it would be advisable to assess the actual new technologies and their specific use. These new technologies could well be used for medical interventions in the diagnostic field and by the use of medical devices. Therefore the legislation dealing with medical devices and diagnostic products also need to be considered.

In general, it can be said that the pharma legislation has been designed for products that are absorbed by the body, distributed in the body, metabolized and then excreted. This approach has certainly been successful, not the least because it is well adapted to the key features of medicinal products. When it comes to new breeds of products, one should consider their main mode of action. That mode of action should be a decisive factor when one decides upon the regulatory regime. Given the experience gained with the medical devices directives, Eucomed strongly believes that a risk-based approach can prove extremely valuable in the case of new types of products.

Brussels, October 2007