

## EUCOMED Comments on the Commission Working Document – Consultation on the Future “EU 2020” Strategy

Eucomed represents 4.500 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. The medical technology sector employs 435,000 people across Europe and it is growing at an annual rate of between 5 % and 6%.

Medical technology is one of the most innovative industries in Europe. Up to 8% (or €5.8bn) of medical technology sales are reinvested in R&D. Products have an average life cycle of only 18 months before an improved product is developed.

Eucomed applauds the intention and objectives of the EU 2020 Strategy paper . One of the major challenges though will be to ensure that future– and the review of current – policies and their implementation will be in line with the outlined strategy. A clear example of this is the issue around late payments (review of the EU Directive on Late Payments – see under 2).

Eucomed believes it can be an important partner in the discussion on how to further refine and implement such strategy.

### 1. General comments

The paper rightly indicates that cutting public spending in forward looking areas such as research, could jeopardize achieving the EU 2020 objectives. This is also true for spending in health and healthcare. While often considered by governments as a cost, providing sufficient funding for healthcare and striving to make the healthcare system more efficient by early adoption of new technologies, is instead an invaluable investment in society. A healthy society is one that is more likely to have better economic growth.

For the EU 2020 Strategy to be successful, the EU and the member states will need to work together to make healthcare provision and the healthcare systems overall more efficient, not only by sharing best practices, but also by evaluating on an ongoing basis how such best practices in one member state can be implemented successfully in another member state.

### 2. How can the medical technology sector contribute to the goals of the EU 2020 Strategy?

#### 2.1. Creation of jobs by maintaining and enhancing global competitiveness

The medical technology sector is a major employer. It currently employs 435,000 people across Europe and is growing at 5% to 6% annually. Safeguarding and further encouraging innovation could maintain and perhaps increase such employment growth rate.

This requires a number of mechanisms to ensure ongoing innovation within the EU, as well as a clear strategy to ensure the European medical technology sector can compete at equal level playing field globally.

## → Within the EU

### Research and Development (R & D)

There is a need for more enhanced R&D support at the EU level, combined with a clear structure and better access to funding. In particular SME's should benefit of increased incentives for innovation purposes.

### Regulatory Framework

The current regulatory framework for medical technology has fostered great safety, innovation and growth in the EU. A particular success story under the Lisbon Strategy. EU citizens enjoy the most innovative medical technologies 2 years ahead of their US counterparts and up to 10 years earlier than Japanese citizens.

There are current plans to recast the legal framework. It is critical for the continuation of this success story, and the success of the EU 2020 Strategy, that any change to the framework preserves or even enhances the key successful aspects.

In particular we should be mindful not to import the bureaucratic inefficiencies of our major trading partners' systems. Nor should we confuse medical technology with pharmaceutical technology. The two sectors have different safety, innovation and economic dynamics. Blindly applying or transferring pharmaceutical policy and controls to medical technology would strangle the sector and deny future health and wealth to EU citizens.

### Late payment

A major concern to Eucomed is the situation of SME's, one of the major engines of innovation and employment. In the context of the review of the EU Directive on Late Payments, Eucomed is concerned that public hospitals would be excluded from the scope of the Directive, which would undermine its purpose, as in many EU member states the public hospital sector is by far the largest purchaser of medical technologies. As SME's are extremely vulnerable to the effects of late payment, excluding the public hospitals sector would go against the EU 2020 goals.

### Procurement

Procurement procedures are not always incentivizing innovation. The process is rather volume supply and price oriented than innovation/quality driven. The societal aspect is thus ignored. Moreover, the length of supply contracts can block competition by keeping players out of the market, limiting the introduction of new products and therefore the innovation in the sector. In addition, there is a tendency to establish centralized tenders with increased size (e.g. purchasing consortia) which may reduce competition and may block innovation. In particular, this could have severe effects on the viability of SME's and stifle their innovation capacity.

### EU patent system

Recent developments around a single EU patent and a unified European Patent Court are very encouraging. Eucomed urges the EU and the member states to work together in a diligent way so that there will be no unnecessary further delays in establishing an efficient EU patent system.

## → Global competitiveness

The EU should continue to ensure that the European medical technology sector can compete globally at equal level playing field. Particular attention should be paid to global harmonization of regulatory systems, the fight against counterfeits and technical and non-technical barriers to trade.

The EU, together with industry, should strive for global harmonization of regulatory systems, based on further improvements of the EU system. Our European system is already at the centre of a voluntary ‘Global Regulatory Model’ for harmonization with our major trading partners. To take this to the next step, Europe needs to make the bold political commitment. Europe, at the highest political level, needs to agree a process with our major trading partners to move from voluntary to mandatory, and achieve global efficiency and safety.

The EU, the industry and other EU and international stakeholders need to continue the fight against counterfeits, infringements of intellectual property rights in international markets and other barriers to trade.

In recent years, the EU has been instrumental in supporting the European industry on trade barriers in a number of international markets. In some cases it has added experts to its Delegations, e.g. on intellectual property, one of the key concerns of any innovative industry. With the EU 2020 Strategy in mind, the EU might consider to set up ‘innovation teams’ in priority countries, with experts who support the European innovative industry on market access to those countries, but also work with governments and other stakeholders on accelerating the acceptance of new technologies.

## 2.2. Contribution to the health of citizens

The medical technology sector is one of the most innovative sectors, improving and saving lives every day, by providing innovative solutions for diagnosis, prevention and treatment.

While the organization and the funding of healthcare systems is the member states’ remit, the EU and member states should work together to ensure that healthcare systems evolve in a direction that make them more efficient and more patient-centered, taking optimal advantage of new technologies. Best practices, such as on e-health and other new technologies, whether related to diagnosis, prevention or treatment, should be shared and used where appropriate.

## → Patient-centered healthcare systems, ensuring early access to innovative technologies

The increasing prevalence of chronic diseases driven by demographics and the move of many fatal diseases to chronic conditions will put financial pressure on healthcare systems. Resource constraints, emanating from the increasing needs of European patients and citizens, will require the development of Efficiency-Based Medicine, including the uptake of technologies that improve efficiency and quality and which supports the roll-out of public health management programs around patient safety and in general the productivity of healthcare systems. A holistic approach is needed, moving from a cure-based health system to a comprehensive, patient-centered disease management approach and ultimately to an appropriate health management throughout the entire life of people.

- ➔ Harmonization of best practices and guidelines in healthcare (diagnosis, prevention, treatment) to ensure optimal healthcare.

To this end, an overall vision for the medical technology sector and its contributions to the economy and healthcare should be strengthened. The EU should aspire to be the global lead market for medical technologies, a fact that supports a potentially broader EU vision, i.e. the EU as the healthiest region.

- ➔ Sustainable funding / reimbursement

The financing of efficient national healthcare systems within the EU should be considered as an important investment in society, not as a cost. A healthy society is a wealthy society. It requires clear, patient-centered public health policies and strategies, with planning on both short and long term. The EU should play a crucial role in coordinating harmonization of best practices and guidelines and in supporting the funding of priority programs related to health.

Reimbursement and funding schemes differ significantly across Europe. Reimbursement decision-making is not always incentivizing innovation, as it does not always recognize the entire care process and long-term patient outcomes. The length/timing of the procedures is not adequate for the innovation path of medical devices and the benefits for prevention are not sufficiently recognized. There are few common assessment criteria to evaluate whether and when a product which is still in the pipeline, will be reimbursed in order to enhance predictability.

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