



***European Health and SMEs:
Big Challenges, Small & Medium Sized Solutions***

*How to reap rich rewards for Europe by enhancing the environment for
Small and Medium-sized medical technology Enterprises*

Foreword

Europe 2020 Strategy focuses positively on strengthening and further developing EU policies that support innovation particularly for small and medium-sized enterprises (SMEs).

The European medical technology industry – one of the most innovative in the world – is well positioned for healthy growth under this policy objective. Comprised primarily of SMEs, which make up 80% of the industry, the sector is a major provider of jobs, especially highly skilled jobs in research and manufacturing, and employs nearly 534,000 people across Europe.

Eucomed's preliminary survey has shown that there are approximately 7,000 medical technology SMEs in Europe. Research in the medical technology industry, which typically occurs at the bedside not at the bench, is usually a result of small or micro collaborations between health professionals, academia and SMEs. This research model brings rapid innovation, which quickly tackles current and emerging medical needs. Fostering and maximising the value of this research in Europe will not only help the EU face the enormous healthcare and demographic challenges, but also position it as a leading geography in line with the goals of *Europe 2020 Strategy*.

The European Commission, in its recent Exploratory Process on the Future of the Medical Devices Sector, found that the sector depends on a healthy stream of SMEs to develop new ideas and create new technologies. One of the three issues emphasised by that process was the need to support SMEs "... to ensure the competitiveness of the sector through the encouragement of research and development, clusters and aspects of intellectual property, regulatory matters and general trade issues." SMEs are also important to Europe in that they can act as a barometer for EU competitiveness and innovativeness.

We believe that there is clear need for a comprehensive, in-depth analysis and monitoring programme for the sector which should be carried out in collaboration with the National Industry Associations in the EU Member States. This will play a key role in enabling the medical technology industry to reach its true potential. This will confirm that there are specific steps that can be taken immediately. The findings of our preliminary survey show that making some relatively minor, but critically important, interventions would radically improve the environment and enable these companies to develop and grow.

We are aware of a number of barriers to entry for SMEs that could be addressed in the short and medium term that would have an immediate positive impact on growth. The specific recommendations outlined in this document cover regulation, reimbursement, Health Technology Assessment, R&D funding and greater access to distribution channels.

We, therefore, call on the European Commission to take immediate action on these recommendations.

We in Eucomed together with the network of National Industry Associations look forward to working with all parties to provide the support that is required.

Executive Summary

The global medical technology industry has continued to grow through the current period of economic turmoil and the prospects for the sector continue to look positive.

According to Espicom's June 2010 report¹

'..The global market for medical equipment and supplies is valued at US\$245.6 billion in 2010, equal to just over US\$44 per capita. The CAGR for the 2006-2010 period is 5.3%, although this masks the major reduction in growth which has occurred in 2009 and 2010.

Market growth is expected to resume in 2011 and beyond, although it will not be as rapid as before the global economic downturn. Some of the best prospects for growth will be in the developing markets of Asia, Latin America and Central Europe, while traditional Western markets represent more steady performers.

The USA is the world's largest market, valued at US\$94.9 billion in 2010, equal to 38.6% of the global total. While the CAGR of 2.8% to 2015 is unspectacular, it will take the market value to over US\$100 billion for the first time...'

At the same time, Eucomed is very cognisant of the turmoil impacting European member states in particular as they work to reduce their deficits and the levels of public debt. While this will undoubtedly impact Healthcare growth, the support for SMEs will certainly provide long term benefits for healthcare systems across the EU.

Innovation in healthcare is essential to meet the challenges of sustainability in healthcare provision and to compete successfully. There is a new and strong demand for a different innovation for the medical Technologies: one that will improve Efficiency in the provision of Health Care, and will reduce the costs of the Episode of Care. Innovation in the medical device industry is unique in that most novel technologies originate mainly from small and medium-sized enterprises (SMEs) rather than the large multinationals. Therefore, medical technology SMEs are a central part of the solution to the economic difficulties of today and the impending health crisis of tomorrow. Failing to understand and act on the challenges SMEs face is, therefore, a threat to the future health and welfare of Europe.

A survey of 12 National Industry Associations (including all the major medical technology exporters) across Europe has identified almost 7,000 SMEs that design and manufacture medical devices and diagnostic products. These companies face significant barriers that prevent them from reaching their potential. Specifically, we have found that SMEs have difficulty with product registration, reimbursement, procurement, distribution channels, health technology assessment and access to R&D incentives.

Eucomed's survey findings highlight the significant role that could be played by the European Commission in dismantling those barriers. Eucomed requests that EU policy makers take the following steps as a matter of urgency.

- **It asks that the European Commission conduct a comprehensive, in-depth survey of medical technology SMEs, in conjunction with Eucomed and the National Trade Associations, to further map SMEs, identify measures such as Revenue, employment, R&D and their priority needs. This would help to clarify and target the needs demonstrated by Eucomed's preliminary survey.**

¹ http://www.espicom.com/ProdCat2.nsf/Product_Alt_URL_Lookup/world_medical_market_forecasts_2015?OpenDocument

- **Eucomed's analysis of the findings of its preliminary survey has identified several significant barriers that confront SMEs at EU level. To improve the business environment for these companies, it asks the European Commission to take immediate action to establish:**
 1. A coordinated and transparent programme of market surveillance by Member state Authorities targeting specific product groups so as to ensure a level playing field for both EU and imported medical devices
 2. A "smarter" regulatory process whereby novel technologies can be commercialised faster to give patients faster access to innovative treatments
 3. Easier processes for applying for EU R&D Funding Programmes, including the Framework Programme and Cohesion Funds, and options that allow SMEs to effectively access these funds
 4. Proactive sharing of information by Member State Competent Authorities on market access models and distribution channels to enlarge the overall market within the EU.

These four key issues are elaborated below in the main body of this document.

Two additional areas were highlighted by survey respondents as barriers to the successful operations of medical technology SMEs. Eucomed's analysis shows there is also a need for:

- Increased transparency and predictability in purchasing procedures in the EU so that the criteria applied in reimbursement and procurement are as clear as possible
- More approachable Health Technology Assessment processes for companies with limited resources such as most SMEs

Eucomed looks forward to making recommendations on these two issues in a separate document in the near future.

European Health and SMEs

Why European medical technology SMEs are so important

The central role of SMEs in novel technology innovation means they are vital to the competitiveness, growth and future prosperity of the healthcare sector as a whole. However, SMEs are being more exposed to the effects of the recession than the bigger companies, their needs in overcoming the recession are the concern of the entire industry, which represents more than 500 000 “white collar” jobs for EU citizens.

Trends present opportunities for Europe

Eurostat reported that the number of people of working age compared with retirees was 4:1 in 2008. It forecasts that this ratio is set to decrease to 3:1 in 2025 and to fall to 2:1 by 2060. This startling statistic dictates that we must do more with what we have, and the required increase in capacity must be created within constrained health budgets. The medical technology industry is already a large contributor to European GDPs in terms of jobs, generated revenues and the health and productivity of European citizens. There is a new and strong demand of a different innovation for the medical Technologies: the one that will improve Efficiency in the provision of Health Care , and will reduce the costs of the Episode of Care.

Innovation in medical technology has the power to increase the efficiency and effectiveness of care, either by revolutionary steps in medical prevention, diagnosis and treatment, or by the application of innovative technology that is able to do more with less. Innovative technologies will provide Europe with more sustainable healthcare delivery and a more competitive industry, and because SMEs are such a vital source of such solutions, their needs must be taken into account when drawing up successful policies for health and industry.

Where European policy has already identified the importance of SMEs

A number of EU policies already recognize the importance of SMEs to the medical technology sector. These policies propose concrete actions to develop a better business environment for SMEs that will add to Europe’s strength and deliver better healthcare.

These policies and initiatives are outlined in the Appendix to this document.

The Eucomed SME Survey Findings

In January 2010, Eucomed established an SME taskforceⁱ to determine the size of the medical technology industry and identify the specific challenges and opportunities that SMEs in Europeⁱⁱ face.

The taskforce conducted a survey of National Industry Associations in May 2010 (findings not yet published). Responses from 12 countriesⁱⁱⁱ indicate that there are more than 6,800 European SMEs that are manufacturing or designing medical technology products. Of these:

- 3702 companies employ fewer than 10 employees (micro)
- 1940 companies employ 10–50 employees (small)
- 1187 companies employ 50–250 employees (medium)

It is interesting to note that 10 out of the 12 National Association respondents believe that the medical technology sector is clearly identified by their governments as a strategically important growth industry.

The survey identified the most important challenges that micro/small and medium-sized companies face nationally, within the EU and as global exporters. Analysis of the survey results indicates that the top six barriers at EU level for all three sizes of these companies are the same (although the priorities differ slightly). The top four of these barriers are discussed in detail in this document. They are:

1. Consistent application of EU Regulation to all competitors
2. Regulation inhibiting novel technology commercialisation
3. Access to Framework/R&D funding programmes
4. Access to distribution channels in the EU

1. Consistent application of EU Regulation to all competitors

Today it is neither transparent nor evident that both EU and imported medical devices receive the same regulatory oversight from Authorities.

This is largely expected to be resolved when the European Notified Body and Post-Market Surveillance system is better controlled under the revised EU medical device legal framework, currently being worked on by the European Commission. A proposal is expected early in 2012. However, with debates in Council and the European Parliament and an expected implementation date close to 2020, this is some way off and action needs to be taken now.

Rather than wait for a revised framework and implementation in 2020, EU Member State Competent Authorities should conduct a coordinated and transparent programme of market surveillance, aimed specifically at those product sectors attracting concern, to ensure trust in CE marking.

This can be done now with the tools we have today, and it will be a guarantee for patients, purchasers, trade partners and the compliant industry that these markets are fully applying EU rules in terms of the performance and safety of their products.

2. Regulation inhibiting novel technology commercialisation

When innovation involves genuinely new technology there is a need for improved and faster regulatory procedures. At the time of their introduction, these technologies may represent risks that cannot always be fully assessed. Because wholly new technology is likely to present unquantified risks on introduction, the current regulatory system is not likely to allow that technology onto the market. This approach aims to minimise risk, but does so by ignoring the significant risk to the health of patients (and sometimes also clinicians) by making new and better treatments unavailable.

Product regulation must, therefore, recognise that new technologies should not require the same level of evidence as those that have been in place for a longer period of time. Their adoption should not be barred simply because of a lack of this information in the early adoption stages. Equally, companies putting novel technologies on the market need to accept that an early requirement will be the accumulation of data on the actual performance and safety of their novel products.

What is needed is a “smart” process. A process that efficiently and effectively brings the innovator, the Notified Bodies and the Competent Authorities together in determining the appropriate application of the essential requirements for the innovative device in terms of its safety and performance. This process would need to:

- Ensure that bureaucracy, costs and timing for are no greater, and perhaps even less, than today
- Better define specific product risks (for example, high risk, innovation, novelty and non-existence of standards or guidelines)
- Identify and designate specific Notified Bodies as competent to deal with these products
- Ensure that when intervention by Competent Authorities is justified, the Notified Bodies should seek an opinion on the clinical risk–benefit analysis from the Competent Authority prior to taking a final decision; this is similar to the current EU system employed by Competent Authorities for medical technologies that incorporate tissue of animal origin
- Be sufficiently flexible to ensure that these types of controls should only remain in place until the technology is proven, that is, until the “new” technology becomes “old” technology; this can be done through postmarket clinical follow-up or the development of standards.

3. Access to Framework/R&D funding programmes

R&D funding programmes are essential in getting some new technologies off the ground in start-up companies. However, after a successful project it can be impossible to hold together a small team while waiting six to twelve months until the next round of funding is approved. **Funding should therefore follow product development as it moves from one stage to another, from proof of concept to clinical investigations.** In addition, good assessment of the quality of projects is essential; public funding of a poor concept will simply result in the misallocation of resources.

Identifying ways to ease the process of accessing funding through the Framework Programme would reap significant benefits. The companies that need this support the most, often do not have sufficient resources for the application process and therefore cannot apply. A mechanism to support and simplify the process should be considered.

Furthermore, the framework programme contributions are paid much later than when the fragile Startup or SME finances would allow.

Larger companies and SMEs can benefit from working together in the same project, and structures could be designed to encourage this. Adapting the approach used in recent Framework Programme 7 calls, which requires that a significant proportion of the budget in large IPs is reserved for later allocation, would address this.

In addition, in the current Framework Programme all private sector participants are treated the same, regardless of size or scale, and all receive 50% funding. A worthwhile change would be to allow SMEs to receive a higher percentage of the funding. This would support the creation of a strong indigenous research community for the EU and recognise the higher financial commitment that SMEs make when seeking to participate in the application process. A further desirable change is that advance contributions, under the format of preventive grants could be paid as advances whilst the process of grant examination is pending.

The Small Business Innovation Research (SBIR) programme in the United States is frequently cited as an effective system for stimulating research and innovation in SMEs. It is a set-aside programme (2.5% of an agency's extramural budget) for domestic small business concerns to engage in research/R&D that has the potential for commercialisation. The medical technology industry therefore strongly supports the European Commission's call (in the Innovation Union initiative, listed in the Appendix) for a model similar to the SBIR to be implemented in Europe to help boost innovation and new business. The EU should consider a model that takes the best features of the SBIR programme by establishing a fund for procuring research based solutions to meet the business needs of government departments, agencies and local authorities.

4. Access to distribution channels in EU

Finding good distributors abroad is often one of the biggest barriers to growth for a SME. Many national trade associations offer help by organising network meetings that give access to larger companies and distributors. Some also arrange investment days when small companies have the opportunity to introduce themselves to venture capitalists, partners and/or distributors.

Although there are opportunities for SMEs to partner with global companies that provide a global or regional market access route, it is extremely difficult for the SMEs to win sales resources in competition with internal products from these international companies, irrespective of the relative merits of the products.

Unfortunately, there is no quick solution. The problem is likely to remain for the foreseeable future and unlikely to get any better unless government or trade bodies start to adopt a more proactive approach. Often this does not happen because there is a natural instinct to protect "home markets".

One option would be for the European Commission to encourage Member State Competent Authorities to share on a more comprehensive basis information on market access models in the interests of enlarging the overall market within the EU.

Additional barriers

The results of Eucomed's survey also highlighted the challenges posed by issues of reimbursement and late payments. These affect SMEs disproportionately and greatly limit their sphere of operations. Increased transparency and predictability in purchasing procedures in the EU is recommended to clarify the criteria that are applied in reimbursement and procurement.

In addition, Health Technology Assessment (HTA) is an increasingly important part of market access and it is a resource consuming process. The cost burden of this weighs more heavily on SME than larger companies. A more approachable HTA process for companies with limited resources such as most SMEs is recommended.

Eucomed will discuss these issues in more detail in a separate document.

Conclusion – Big challenges have small and medium-sized solutions

At national level, Member States need to improve the business environment, especially for innovative SMEs. This includes public sector procurement initiatives to promote innovation incentives, enhancing the conditions for greater enforcement intellectual property rights, and reducing the administrative burden on companies.

If purchasing procedures are more predictable, SMEs can make better informed assessments of the risks they face in doing business. The ability to correctly interpret this environment is what allows a business to assess its competitiveness and provides the premise on which it will operate successfully. The greater the uncertainty concerning these issues, the less willing anyone will be to invest in product development and new businesses, which in turn will lead to a less innovative and competitive European economy.

Appendix

Where European policy has already identified the importance of SMEs

A number of EU policies already recognise the importance of SMEs to the medical technology sector, as follows.

Europe 2020 Strategy is an ambitious plan to emerge from the current crisis as a smarter, greener and more inclusive social market economy. This strategy is the overarching EU policy for the next decade and it makes for a tremendous political and economic force within the EU. It outlines five targets that are to be met through seven flagship initiatives, and among these seven, three are particularly significant for medical device SMEs. These three initiatives are:

- 1. Innovation Union.** This calls for a refocusing of R&D and innovation policy towards the challenges facing our society such as climate change, health and demographic change. The Innovation Partnerships on Healthy Ageing, part of the Innovation Union initiative, is intended to create a coordinated effort to increase investment, fast-track necessary regulation and use public procurement strategically to ensure that breakthrough innovations are brought to market. In making healthy ageing a priority, the potential impact the healthcare industry has on Europe is recognised together with the importance of creating an environment that supports innovation. Further recognition of the critical role of SMEs in medical technology innovation would help contribute to the success of this partnership.
- 2. A Digital Agenda for Europe.** This principally relates to improving access to high speed Internet infrastructure, but includes deployment and usage of eHealth solutions.
- 3. European Platform against Poverty.** This initiative aims to identify ways to ensure better access to healthcare and ensure adequate income support. The call for innovation is clear.

Exploratory Process

Chaired by the Commission services, the Exploratory Process on the Future of the Medical Devices Sector mapped existing public health and industrial challenges in the sector and investigated possible topics for consideration on the European level. This process provided industry, users and consumers of medical devices with an opportunity to share their views on existing challenges.

Medical device SMEs were one of the three important issues identified by the process for further consideration. The report placed particular emphasis on creating a favourable environment for SMEs that will enhance the competitiveness of the EU medical device sector (e.g. R&D, clusters, intellectual property, regulatory and trade aspects).

The Small Business Act

Adopted in June 2008, the Small Business Act (SBA) for Europe put into place a comprehensive SME policy framework for the EU and its Member States. It aims to improve the overall approach to entrepreneurship, to irreversibly anchor the "Think Small first" principle in policy making in regulation and public service, and to promote SME's growth by helping them tackle the problems that hamper their development.

Speaking on the occasion of the Commission's adoption of the 2009 report on the SBA, Vice-President Günter Verheugen, Commissioner for Enterprise and Industry, said: "We must fully exploit the growth potential of European SMEs to create a sufficient number of new and highly qualified jobs.

Unlocking SME potential has been a key political priority of this Commission. Policies at all levels must encourage entrepreneurial risk taking and provide for the best possible framework conditions for SMEs."

The 2009 report states that it remains of utmost importance to continue to vigorously implement the SBA Action Plan at all levels and not to lose sight of the longer-term perspective of creating a world-class environment for SMEs, which is an important element of delivering *Europe 2020 Strategy*.

i) SME Taskforce Members

- IMDA: Sharon Higgins (Chair)
- ABHI: Mike Kreuzer
- Swedish MedTech: Anna Lefevre,
- Unamec: Richard Van den Broeck
- Ex Chairman: Luciano Cattani
- Fenin: Gloria Rodriguez
- Eucomed: John Brennan

ii) Scope of the survey, note that we focused only on companies

- that are designing and/or manufacturing medical technology products or are suppliers to the medical technology sector
- where the finished product is regulated under one of the EU medical device Directives
- that employ (globally) less than 250 people
- whose global head office is based in the EU
- that are legally incorporated

iii) Survey respondents

- ABHI (UK)
- Assobiomedica (Italy)
- Austromed (Austria)
- BVMed (Germany)
- FASMED (Switzerland)
- Fenin (Spain)
- Irish Medical Devices Association (Ireland)
- Medicoindustrien (Denmark)
- Romanian Association of Medical Product Suppliers (Romania)
- SNITEM (France)
- Swedish Medtech (Sweden)
- Unamec (Belgium)