



# **Competitiveness and Innovativeness of the European Medical Technology Industry**

Evaluation of the Survey Results

30 May 2007

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## Executive Summary

Following the publication of the European Commission's *Medical Devices Competitiveness and Impact on Public Health Expenditure* report – hereinafter referred to as the Pammolli Report – in September 2005, Eucomed began exploring ways to address and expand upon the conclusions of this report.

To assess the limiters of European competitiveness and innovativeness vis-à-vis medical technology, Eucomed conducted a survey of its membership (corporate and association members), questioning them on various aspects of the European market which may hinder (or help) the health and growth of the medical technology industry.

This survey was launched in July 2006 and finished at the end of September. Overall, 63 organisations completed the survey, comprising 42 Eucomed corporate members, 20 Eucomed association members, and 1 other European medical technology industry association. Overall, 73% of those invited to participate did so, and over 70% of participants completed the survey.

The survey was divided among three principal areas: part A gathered general information on the respondents to provide a basis for analysis; part B gathered economic data about the medical technology industry, with the goal of updating Eucomed's benchmark economic figures on the industry; part C is the core of the survey, and was further subdivided among three areas: European market access, external trade, and R&D and innovation.

### Participants

Among the corporate members, the majority had their headquarters in the United States, while 43% had their headquarters in Europe. Within Europe, a plurality of the respondents have their headquarters in Germany (12%). 17% of corporate respondents reported having being small or medium-sized enterprises (fewer than 250 employees). The largest business focus group among corporate respondents is single-use technology, followed closely by non-active implantable technology. Among corporate respondents, 92% reported having sales in all pre-2004 EU member states and 80% reported having sales in the post-2004 EU member states. In terms of manufacturing, 42% had manufacturing operations in Germany, and roughly the same percentage had manufacturing operations in France. Among the post-2004 member states, Poland and Hungary have the highest share of companies with manufacturing operations in their countries, each representing about 4% of participants. 32% of participants had in-house research and development operations in Germany, while about 30% had R&D operations in France and Switzerland.

The participating national industry associations were evenly split between small, medium, large and very large associations. The largest group of national associations represented "mainly" medical device corporations (as opposed to distributors). Moreover, the majority of national association participants represented "mainly" domestic companies. Finally, 36% of participating national industry associations represented "mainly" micro-enterprises (fewer than 10 employees and/or less than €2 million in turnover and/or less than €2 million on the balance sheet). The largest

business focus group represented by the participating national associations is single-use technology.

## **Medical Technology Industry Data**

Based on the data provided by participants, we estimate that the medical technology industry in Europe had sales of approximately €63.6 billion in 2005. The annual growth rate of the industry is between 5% and 6%. This total represents about one third of the global market for medical technology of €187 billion, compared to the US's share of 42% during the same time period. Per capita, Europe spent €128 on medical technology in 2005, while the US spent €270.

Germany was the biggest exporter as well as the biggest importer of medical technology. All European countries except Germany, the UK, Ireland, Sweden, Denmark, and Finland imported more medical technology than they exported.

Approximately 435,000 people were employed by the medical technology industry in Europe in 2005. This figure has grown by 15% since 2003. Germany represents a quarter of total European employment while new member states represent about 10% of total European employment. There were about 11,000 medical technology companies in Europe in 2005. Finally, the European medical technology industry spent about 3% to 6% of its sales on research and development.

## **European Market Access**

The first area on which respondents were questioned was regarding CE marking and notified bodies. Generally, respondents had a favourable view of the CE marking system. Obtaining a CE marking is seen as a clear and predictable process. However, most respondents felt that the process could be improved through simplification, harmonisation, and better use of IT. Regarding notified bodies, respondents had a fairly favourable view, but noted a probable lack of technical expertise to assess innovative products and of harmonisation among notified bodies. Regarding legislation and regulations, respondents noted that there still remains significant divergence among member states regarding standards and requirements for product approval. Finally, respondents said that market vigilance could be improved, and the administrative burden for companies could be diminished, through harmonisation and coordination (i.e. to prevent repetitive or duplicative requests for additional information), more rational information requests, and better use of IT.

Respondents were next asked for their views on health technology assessment (HTA). Since not all respondents are affected by HTA, the analysis refers to those members who are currently affected by HTA. Responses indicate a cautious optimism towards the HTA system. Generally, however, respondents did not seem to feel that the medical technology industry has been adequately involved in the development of HTA. Furthermore, the level of information required by HTA authorities, both clinical and economic, does not always seem to be reasonable, based on responses. The HTA system as it exists today excessively delays the launch of new products, and puts significant strains on budgets. Respondents were

optimistic regarding European initiatives in the HTA area, but consider them of limited potential, as HTA is still fundamentally a national issue.

Attitudes towards funding and reimbursement were surveyed next. The implementation of diagnosis-related group (DRG) payment systems in larger countries has affected the level of reimbursement for products. There is a large variation among the countries, mainly based on the transition period to DRGs, the means of calculating DRGs, and the inclusion or lack of a mechanism to introduce innovation in the system. The last point seems to be very important to respondents. Moreover, a plurality of respondents said that DRG systems in the larger countries do not include adequate means to introduce innovation. The introduction of DRG systems has exerted a serious downward price pressure on products, and has caused respondents to incur higher personnel costs (i.e. from the need to hire DRG specialists). Silo budgeting is seen to have a negative impact on competitiveness at all levels of the health system. In regards to home care and outpatient care, an increasingly important part of the healthcare sector, respondents seemed to feel hampered by low reimbursement levels and problems related to the application for inclusion of products on a positive list. Regarding reimbursement generally, respondents complained that there is no coordination between HTA activities and reimbursement processes and that DRG systems are frequently allowed to become out of date.

Regarding public procurement, respondents said that current trends in public procurement cause serious distortions in the market and hamper competition. The concentration of purchasing among a handful of buyers, as well as the consideration of price alone when awarding contracts, will create monopolies for several years, and may drive companies not winning a tender out of certain countries. This in turn could lead to shortages and difficulties in supply. A third of respondents report having to restrict R&D spending because of failure to win a tender. A plurality report that they have been discouraged from increasing their workforce. A significant share of spending needs to be redirected towards the very act of participating in tenders. Small and medium-sized companies, which make up  $\pm 80\%$  of the industry, are disproportionately affected by the market distortions caused by centralised public procurement.

Late payments appear to be a significant problem to the medical technology industry. For more than half of respondents, the ability to stay in business is threatened by late payments. Late payments are most common in Southern Europe, particularly Italy, Spain and Greece. While late payments are less of a problem for large, global enterprises, SMEs are strongly affected. As the companies get smaller and the late payments problem becomes bigger, late payments may impact the rate of innovation. Local payment practices clearly affect the ability and willingness to do business in a certain country. SMEs may be forced to avoid certain countries, while global enterprises may direct investment to another country based on payment culture. European initiatives (i.e. Directive 2000/35/EC) have not had a noticeable impact on late payments. Moreover, responses seem to suggest that several member states neither enforce nor comply with this directive. Nonetheless, most respondents seem to think that measures could be taken at the European and/or national level to alleviate this problem.

## **External Trade**

Many companies report difficulties in starting export operations. The most problems were reported in regards to local authorization, late payments, and copyrights, and in Japan, China, India, Brazil, Turkey and Russia. Despite harmonisation efforts (i.e. GHTF), a large portion of respondents report not having seen improvement. Nonetheless, respondents did seem to see opportunities for harmonisation, particularly in regards to country-specific marketing authorisation and better recognition of international standards. A large majority of respondents expect the EU/US mutual recognition agreement (MRA) to be beneficial for their business (if it is implemented), and hope for more MRAs to be negotiated with other countries. A plurality of respondents report having had customs problems, particularly with China, Brazil and India. Labelling and packaging requirements also seem to be a problem. Most respondents feel that paperwork requirements for certain countries create a costly barrier to international trade. Information on distributors and partners in other countries, however, does not seem hard to come by. Respondents consider public support (at both the European and national levels) of international trade to be very important. However, it seems that most corporate respondents are not aware of public incentives aimed at increasing trade. In terms of imports, most respondents report increased competition from low cost, low quality, and/or counterfeit products coming from abroad. Eucomed's attention has been drawn, for example, to counterfeited surgical instruments from China.

## **R&D and Innovation**

Respondents consider the European education system adequate to prepare candidates for employment in the medical technology industry. However, they do see a particular lack of skilled personnel in certain technical disciplines (e.g. biomedicine, biochemistry, etc.). Most respondents consider the educational system adequate for preparing medical professionals for work in the development of new products, but particular complaints were that medical professionals are not connected with technology early enough, had limited time to get involved in the development of new technology, and that the industry had to bear a significant portion of training vis-à-vis technology. Receptivity of physicians to new technology was seen as good, but problems were noted in regards to cardiac surgery, homecare technology, and preventative treatment. A slight difference in receptivity was noted between physicians in the public sector versus those in the private sector. Respondents reported more limited receptivity among public sector physicians, which they felt is driven by budgetary constraints. Healthcare administrators, however, are seen as highly unreceptive to new technologies. Moreover, medical professionals do not have the right incentives to encourage them to use the best treatment/technology. Europe is seen to be satisfactory in regards to environment, infrastructure, and facilities for the development of new products. Drivers include good clusters and centres of excellence, while limiters include lack of funding for R&D and fragmentation. Lack of multidisciplinary is also holding back research but is improving, say respondents. Respondents report that the conditions for clinical effectiveness studies are seen to be adequate.

The administrative burden vis-à-vis applying for patents is considered excessive. On the other hand, access to information about patents, as well as the protection given to patents, is considered satisfactory.

Access to information about public incentives for R&D, both European and national, is insufficient. A large number of respondents benefit from such incentives, but must rely on costly specialists to find them. There is a need for better targeting of incentives: respondents report that medical technology is not directly targeted, that application procedures are cumbersome, and that, especially for larger companies, the sums of money on offer are not large enough to influence investment decisions.

The vast majority of respondents benefited from collaboration with universities. However, respondents said that the career scheme of academic researchers was overly focused on publications and not enough on developing products. Business incubators are seen to be useful in turning ideas in to products. However, respondents say that the US is far head in this regard. Respondents further assert that Europe lags behind the US vis-à-vis innovation clusters.

Most respondents felt that Europe is more business risk-averse than the US. Furthermore, they think that current trend towards mergers in the medical technology industry will continue. This could be interpreted as meaning that the overall business conditions in Europe are becoming more difficult and that this may force a number of companies to join forces. Access to information about potential investors was seen as satisfactory. Efforts should be made to encourage investors to invest early. Bank credit for R&D, however, was insufficient, as was the availability of seed capital. Moreover, respondents seemed to feel that investors did not fully understand the medical technology industry.

*For conclusions and recommendations, please see page 78.*

## Introduction

Following the publication of the report *Medical Devices Competitiveness and Impact on Public Health Expenditure*, hereinafter referred to as the Pammolli report, in September 2005, Eucomed sought to address the issues raised by the report and embarked on its Medical Technology Competitiveness and Innovativeness Survey.

Commissioned by the Directorate General for Enterprise and Industry (DG Enterprise) of the European Commission and prepared by the research centre CERM (Competitiveness, Markets and Regulation) in Rome, the Pammolli Report attempted to shed light on the status of the medical technology industry in Europe. In particular, one of its main objectives was to assess the competitiveness and innovativeness of the medical technology industry in Europe as compared with those of US and Japan.

In response to this question, the main conclusion of the Pammolli Report was that Europe is lagging behind US and Japan in terms of competitiveness and innovativeness, as shown by the main traditional economic indicators (e.g. productivity, R&D investments, number of patents, and scientific publications).

This result certainly suggests a trend but, as the authors acknowledged, it needs further investigation for two main reasons:

- There is a lack of data on the medical technology industry, which makes it hard to compare countries and sectors' performances;
- Due to the peculiarities of the medical technology market, traditional paradigms and indicators do not fully fit the sector (e.g. patents and publications, economic benefits).

Furthermore, the Pammolli Report does not investigate beyond the above-mentioned standard indicators and leaves major questions regarding the key determinants of competitiveness and innovativeness of the European medical technology industry unanswered (e.g. regulatory fragmentation, reimbursement and procurement policies, health technology assessments, private insurance funding).

In light of these shortcomings, it was proposed at the Eucomed annual general meeting in 2005, and subsequently discussed in bilateral discussions with DG Enterprise, that further research was needed on the medical technology sector in order to gain a more comprehensive and reliable view on the actual problems and obstacles facing the medical technology industry.

Eucomed agreed to take the lead in a new, ambitious initiative: the Competitiveness and Innovativeness Survey, whose ultimate goal would be to contribute to the ongoing debate around industry competitiveness and innovativeness and to better inform policy action.

Ms Georgette Lalis, Director of Directorate F, Internal Market and Legislation for Consumer Goods, at DG Enterprise, has deemed this project of "paramount importance" for the European Commission to understand the concrete needs of the European medical technology industry and help it enhance its competitive position.

# 1. Objectives

The main objectives of the project are:

1. To study the key determinants of the medical technology sector's competitiveness and innovativeness in light of the specific conditions of the European market; in particular:
  - European market access (CE marking, notified bodies, procurement rules, late payments, etc.)
  - External trade (technical barriers, Global Harmonisation Task Force (GHTF), import duties, cheap products, counterfeited products, etc.)
  - R&D and innovation (human resources, public incentives, resistance to change, etc.).
2. To update Eucomed's European medical technology industry statistics (employment, market size, etc.).
3. To provide the European Commission and national governments with evidence and arguments supporting specific actions in favour of our sector.

This project – the first so far – represents an important milestone in the analysis of the medical technology industry in Europe.

## 2. Design of the Survey

In order to achieve the above-mentioned objectives, a comprehensive 120-item questionnaire was designed to be submitted to Eucomed members (corporate and national associations) as well as to the other European medical technology industry associations.

The questionnaire was prepared by the Economic Affairs Department at Eucomed in collaboration with Ms Sabine Lecrenier, Head of Unit F3, Cosmetics and Medical Devices, DG Enterprise, European Commission, with the advice of the Eucomed Advisory Council (ADV) and Association Secretaries' Council (ASC), and with the support of other Eucomed departments and key expert members.

The questionnaire consists of 3 sections.

SECTION A gathers information about the respondents in order to describe the sample and enable analysis based on respondent characteristics (e.g. organization size, market segment coverage).

SECTION B collects basic quantitative data (e.g. sales, employment, R&D) to update the Eucomed's medical technology industry statistics with more recent data.

SECTION C is the "core" section of the questionnaire and elicits respondents' opinions on the main issues related to competitiveness and innovativeness of the European medical technology industry. This section consists of 3 sub-sections:

1. European Market Access;
2. External Trade;
3. R&D and Innovation.

This section consists of multiple choice questions combined with open-ended questions where respondents could express their views and provide background information to enrich the debate and help Eucomed understand the opinion of the industry. This combination allows for a simple approach whereby respondents face a limited number of "easy to choose" options along with open space where they are given the opportunity to provide more details and explain the reasons behind their choice.

In order to ensure the feasibility and intelligibility of the questions, the questionnaire was submitted as a "pilot" to one Eucomed corporate member (Medtronic) and to one Eucomed association member (Assobiomedica - Italy) who commented on it and helped to fine-tune the questions prior to the official launch. This exercise was extremely helpful because it allowed for the detection of some missing options (e.g. breaking down of the classification of SMEs to the Micro-Enterprise level) and some weaknesses in the way the questions were formulated (e.g. lack of clarity that was addressed with more precise formulation of the questions).

Furthermore, in order to make its completion easier and quicker, the questionnaire was implemented on a secure, web-based, custom-made platform. This system allowed respondents to begin filling in responses, save their partially completed work,

log off, and resume work afterwards. The system also allowed for collaborative work – One could assign the completion of certain sections to different persons by simply sharing the log-in details within the organisation.

Data confidentiality was ensured by contractual provisions enforced between Eucomed and its web contractor. Moreover, Eucomed committed to treat the information received as confidential and not to disclose any individual set of responses, fully respecting confidentiality and competition laws. To this end, Eucomed appointed only three persons within its staff who were entitled to access raw data and were responsible for data handling:

- Rosanna Tarricone, Eucomed Economic Affairs Director;
- Marco Cortopassi, Eucomed Economic Affairs Specialist on Medical Technology Competitiveness;
- Eric de Regnacourt, Eucomed Data Collection Expert.

These staff members signed specific confidentiality agreements.

### **3. Analysis of the Results**

The survey was officially launched on the 28 July 2006. All Eucomed members (companies and associations), as well as other European medical technology industry associations, were invited to participate.

Respondents were given six weeks to fill in their questionnaire and full assistance was provided by the Eucomed Economic Affairs Department during this period.

At the closing date (30 September 2006), the participation rate was 73% and the completion rate was well over 70%.

The Eucomed Economic Affairs Department worked on the assessment of the responses using both quantitative and qualitative methods.

Descriptive statistics (e.g. mean, variance) were used to show results and whenever possible, answers were correlated to respondents' characteristics (Chi-square test) in order to elicit possible relations between the specific answer and the type of respondent. The interpretation of the statistical data was supported by a detailed review of all textual information provided by respondents on each question. This process allowed for data quality checks and validation as well as in-depth understanding of individual positions.

On top of that, if results appeared ambiguous, experts from the Eucomed staff were asked to help interpret the responses.

This report presents the results in the same order as they were gathered in the questionnaire.

## 4. Participants

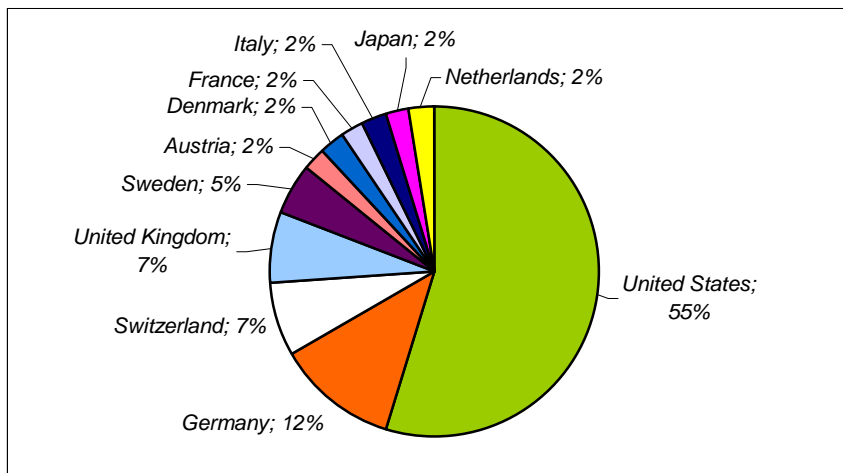
The sample was made up of 63 organizations:

- 42 Eucomed corporate members (of which 6 contributed to Section A only);
- 20 Eucomed member associations (of which 3 contributed to Section A only);
- 1 European medical technology industry association.

### 4.1 *Eucomed corporate members*

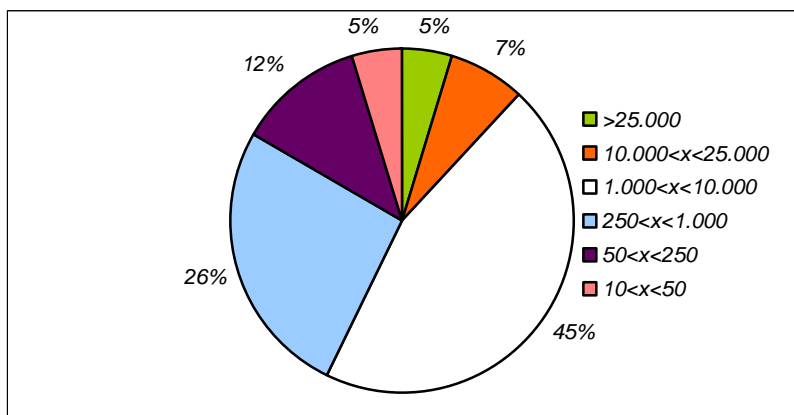
The majority of corporate participants have their headquarters located in the US (55%). Europe follows with 43% whereas Japan accounts for 2% of the sample. Within Europe, Germany is the country where a plurality of corporate participants has their headquarters (12%), followed by Switzerland (7%) and UK (7%) (figure 1).

**Figure 1: Corporate Respondents' Headquarters Location**



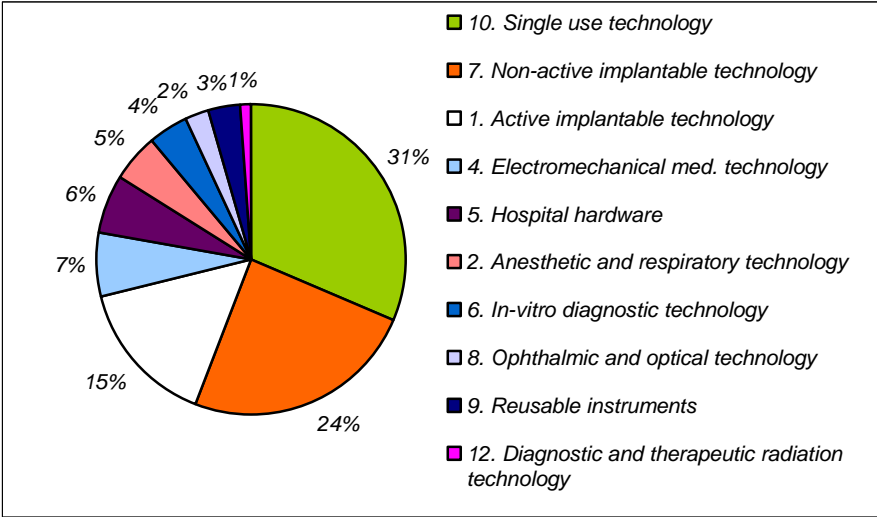
In terms of corporate respondents' size, the largest group (45%) consists of companies with between 1,000 and 10,000 employees, followed by those employing between 250 and 1,000. Small and medium-sized enterprises (SMEs) account for 17% of the sample (figure 2).

**Figure 2: Number of Employees in Europe**



As for business sectors - as defined by the Global Medical Device Nomenclature (GMDN) - the most represented in our sample is “Single Use Technology” (31% of sales in Europe), followed by “Non-active Implantable Technology” with 24% and “Active Implantable Technology” with 15% (figure 3). Please note that the numbers in the legend of figure 3 refer to the sector’s number in the GMDN.

**Figure 3: Business focus (i.e. average % of sales) across the GMDN sectors**



An in-depth analysis of our sample shows that all corporate participants have sales operations in the top 4 European markets by sales (i.e. Germany, France, the UK and Italy), 92% of them sell products in all pre-2004 EU member states and 80% are present in the post-2004 member states. The vast majority of the corporate participants therefore have business operations all across Europe.

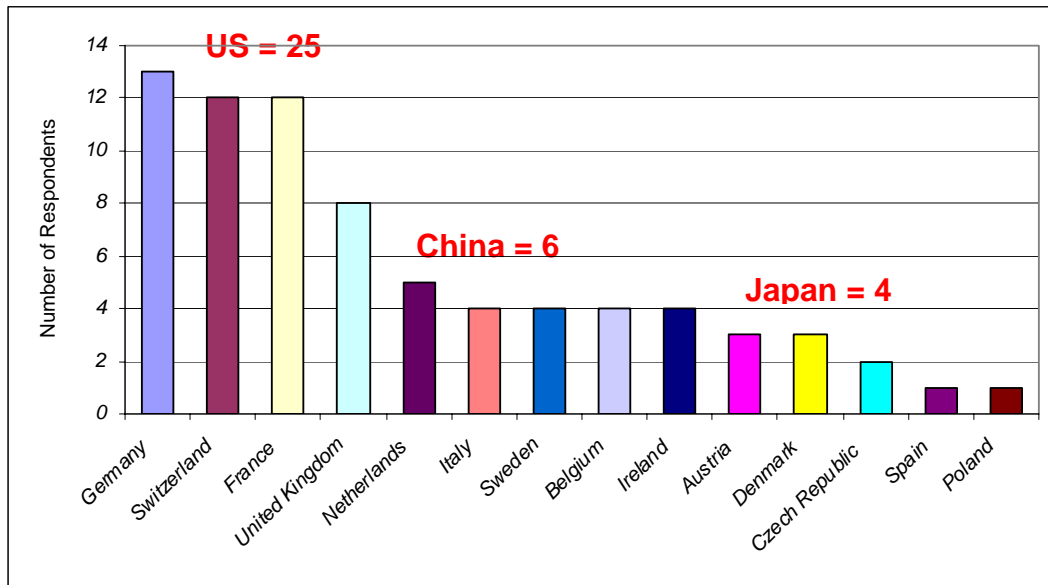
As for the distribution of manufacturing operations in Europe, it emerges that 42% of corporate participants have manufacturing operations in Germany; a similar number have manufacturing operations in France. The UK and Switzerland account for 37% of the sample; Ireland and Italy follow with 22% and 17% respectively. As far as the post-2004 member states are concerned, Poland and Hungary (4%) are the countries with the highest number of companies having manufacturing operations.

It is interesting to note that the US remains the most attractive destination for productive investments, and 67% of the sample reporting having manufacturing operations overseas.

In terms of in-house R&D investments (i.e. direct investments into corporate R&D units), 32% of the sample reported having R&D operations in Germany. France and Switzerland account for 30% each, whereas the UK accounts for 20% of the corporate participants (figure 4).

It is interesting to note again the comparison with the US where 62% of the participants reported having invested in R&D (i.e. almost twice as much as in Germany, the most attractive European Country).

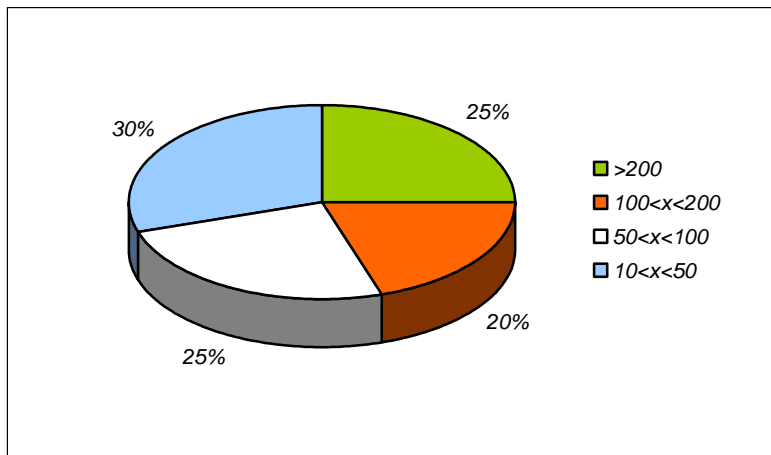
**Figure 4: Country distribution of R&D operations**



## 4.2 *Eucomed Member Associations*

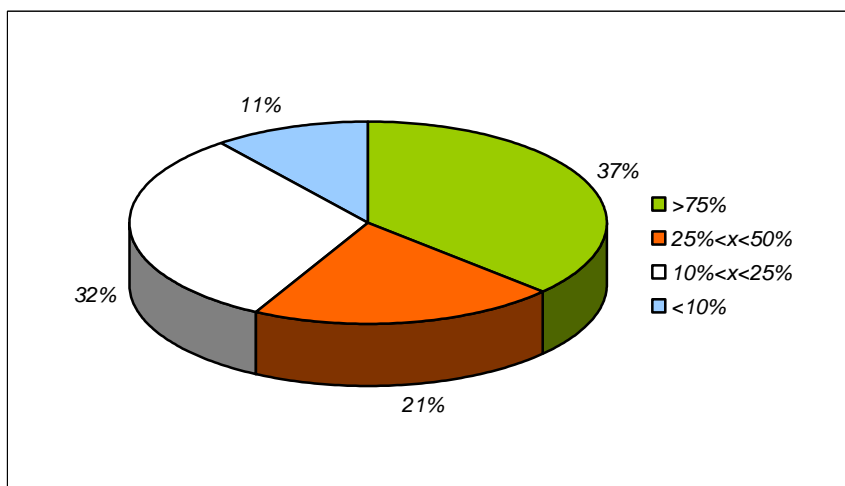
The national associations (NAs) that participated in the survey fairly evenly cover the different size categories. 25% of the sample is represented by very large associations made up of more than 200 members. Large associations (i.e. counting between 100 and 200 organizations among their membership) account for 20% of the sample. Medium size associations (i.e. between 50 and 100 members) account for another 25% whereas small associations made up of fewer than 50 members represent 30% of the participants (figure 5).

**Figure 5: NAs by number of members**



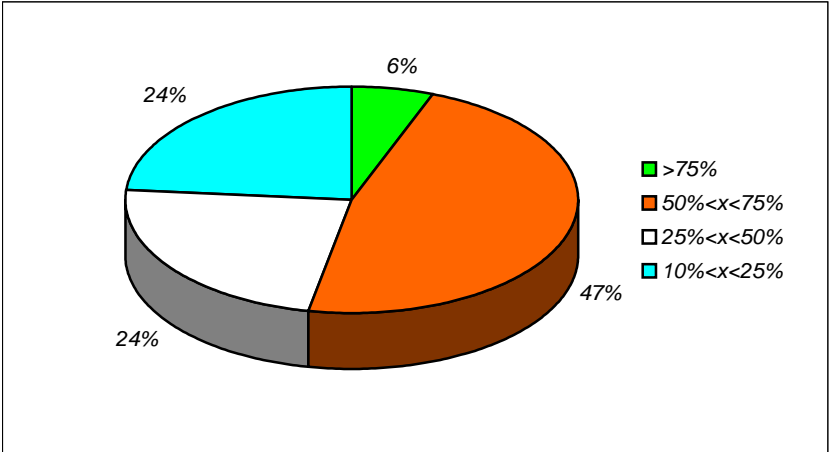
In figure 6 the characteristics of NAs' membership (manufacturers versus distributors/retailers) are reported. The largest group of NAs (37%) are mainly made up of manufacturers (i.e. more than 75% manufacturing companies). 21% of the sample consists of associations of which between 25% and 50% of their members are manufacturers. National associations with a clear majority of distributors among their members (i.e. between 10% and 25% manufacturers) account for 32% of the sample whereas national associations representing a low percentage of manufacturers (i.e. fewer than 10%) account for 11% of the respondents.

**Figure 6: NAs by Manufacturing Companies represented**



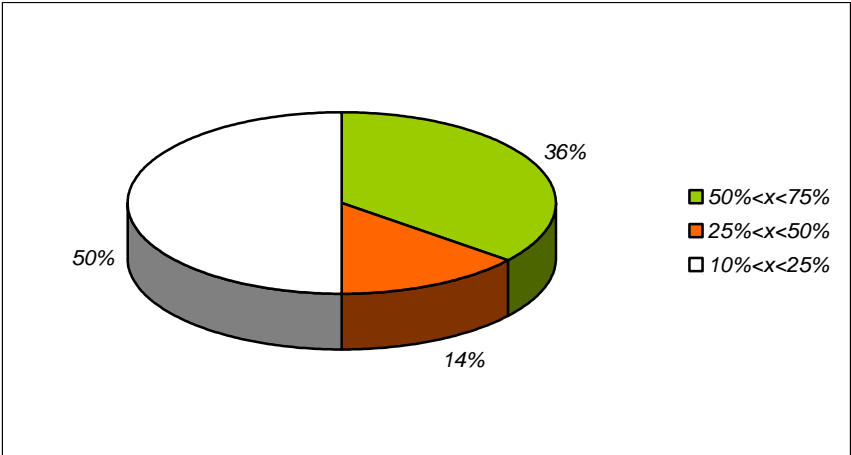
As shown in figure 7, the majority of respondents (53%) represent “mainly” domestic companies (i.e. domestic companies account for more than 50% of the members). National associations comprising a “significant proportion” of domestic companies (i.e. between 25% and 50% of the members) represent 24% of respondents whereas the remaining 24% represent national associations composed of only a small fraction of domestic companies (i.e. domestic companies accounting only for proportion between 10% and 25%).

**Figure 7: NAs by Domestic Companies represented**



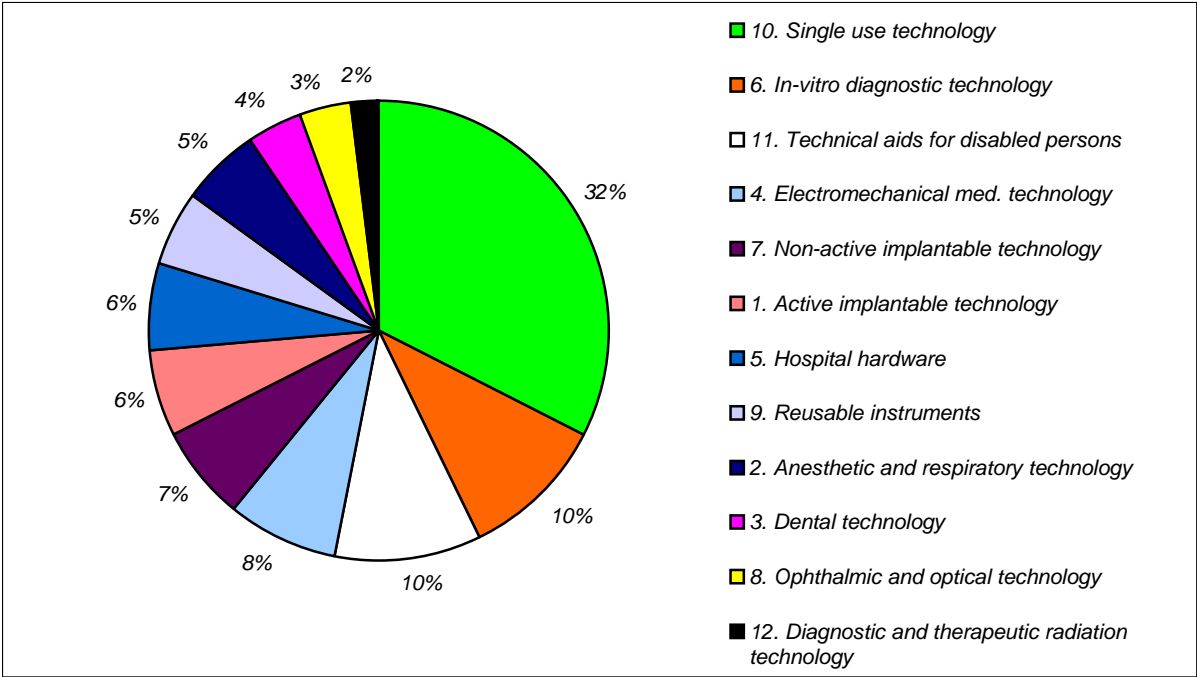
Considering representation of micro-enterprises (MEs) – here defined as companies with fewer than 10 employees and/or less than €2 million of turnover and/or less than €2 million on the annual balance sheet – 36% of the responding national associations had membership composed of between 50% and 75% micro-enterprises. 14% were composed of between 25% and 50% micro-enterprises, while the rest, 50% of the sample, is made up of associations where the proportion of micro-enterprises is still significant, varying from 10% to 25%.

**Figure 8: NAs by MEs represented**



As for business sectors - as defined by the GMDN - the most represented in our sample are “Single Use Technology” (32%), followed by “In-vitro Diagnostic” with 10% and “Technical Aids for Disabled Persons” with 10% (figure 9). As above, please note that the numbers in the legend of the chart below refer to the sector’s number in the GMDN.

**Figure 9: GMDN sectors represented (weighed by sales)**



## 5. Medical Technology Industry Data

Eucomed has periodically published figures on the state of the medical technology industry in Europe. This was last done in 2004 in the form of the Medical Technology Brief. This publication was based on the latest available data at the time, which was mainly from 2003.

Normally, updating these statistics would be an independent exercise. However, the Competitiveness Survey presented a prime opportunity. It allowed us to speak with all of our members, both association and corporate. Corporate members had not been surveyed in this way before.

### 5.1 *Response and Methodology*

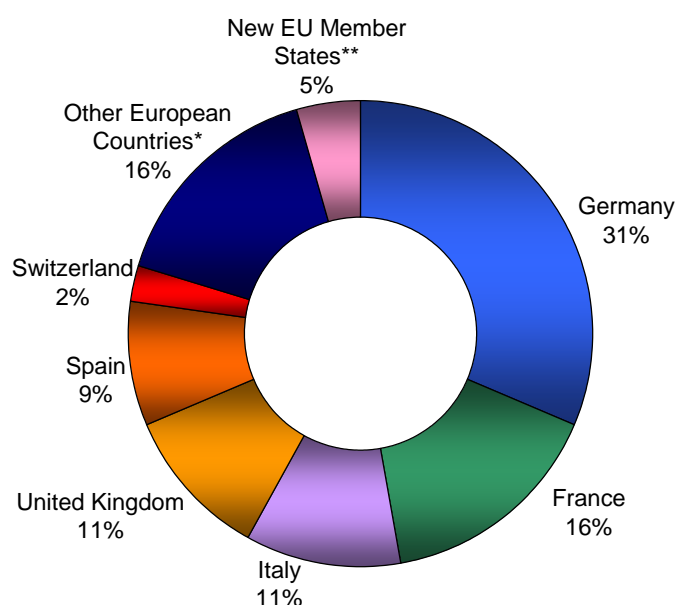
We received a moderate level of response to the data section. For no question did we have more than half of respondents answering. Because of the moderate response, most data presented in this section is the result of a composite of multiple data sources, including Espicom's Medistat publication, OECD Health Data 2006, and Eurostat.

### 5.2 *Size of the European Medical Technology Industry*

Based on the data received through the Competitiveness Survey, we estimate that the European medical technology industry had sales of €63.6 billion in 2005. This total includes all 27 European Union member states, as well as Norway and Switzerland. This figure represents an increase of 15% since our last publication, and is consistent with an annual growth rate of 5% to 6%, which is agreed upon by many sources.

The global medical technology market was worth about €187 billion in 2005, of which about one third is the European market and 42% is the United States market.

**Figure 10: European Medical Technology Sales broken down by Country (as % of total)**



Germany is by far the biggest player in the European market (31%). The top five countries – Germany, France, Italy, the United Kingdom, and Spain – make up 78% of the market, while Germany and France together make up nearly half. However, in the latter case, this is a slightly smaller portion than in 2003, suggesting that the market may be becoming more evenly spread across the continent.

The twelve countries that have joined the EU\*\* since 2004 make up 4.6% of the market, up from 3.5% in 2003. Spain has also seen growth in its share of the market.

Figure 11: Population, Healthcare Spending, and Medical Technology Spending<sup>1,2</sup>

Country	Population (1,000)	THE (€ Bn)	THE/GDP	EMT (€ Bn)	EMT/THE
Austria	8,175	22.6	9.1%	0.83	3.7%
Belgium	10,421	27.6	9.2%	0.90	3.3%
Bulgaria	7,732	1.6	7.5%	0.11	6.6%
Cyprus	835	0.8	5.7%	0.04	4.7%
Czech Republic	10,212	6.3	6.4%	0.50	8.0%
Denmark	5,401	17.6	8.5%	1.01	5.7%
Estonia	1,345	0.6	5.5%	0.09	14.1%
Finland	5,228	11.2	7.1%	0.50	4.5%
France	60,200	172.6	10.5%	9.96	5.8%
Germany	82,491	232.2	10.3%	20.00	8.6%
Greece	11,062	16.6	10.0%	0.80	4.8%
Hungary	10,107	6.5	7.4%	0.51	7.8%
Ireland	4,044	10.5	7.1%	0.38	3.7%
Italy	57,553	126.0	8.8%	7.01	5.6%
Latvia	2,300	0.7	5.1%	0.08	11.7%
Lithuania	3,413	1.2	6.0%	0.11	9.0%
Luxembourg	452	2.2	8.0%	0.06	2.6%
Malta	404	0.4	8.9%	0.02	6.1%
Netherlands	16,282	44.7	8.9%	2.50	5.6%
Norway	4,592	21.9	9.2%	1.00	4.6%
Poland	38,180	12.6	6.5%	0.88	6.9%
Portugal	10,509	13.5	10.1%	0.65	4.8%
Romania	21,631	5.0	6.3%	0.17	3.3%
Slovakia	5,382	1.7	5.1%	0.21	12.3%
Slovenia	2,001	3.2	8.4%	0.19	6.0%
Spain	42,692	67.3	7.4%	5.50	8.2%
Sweden	8,994	25.5	8.9%	1.33	5.2%
Switzerland	7,390	33.5	11.6%	1.59	4.7%
United Kingdom	59,834	148.3	8.4%	6.70	4.5%
<b>Europe Total/Average</b>	<b>498,863</b>	<b>1,034.4</b>	<b>8.7%</b>	<b>63.62</b>	<b>6.3%</b>
<b>United States</b>	<b>293,655</b>	<b>1,440.5</b>	<b>15.3%</b>	<b>79.43</b>	<b>5.5%</b>

The chart above presents medical technology spending as a portion of total healthcare spending, and total healthcare spending as a portion of GDP. Overall in Europe, 8.7% of GDP was spent on healthcare – an increase of one percentage point in the last two years – and 6.3% of healthcare spending was spent on medical

<sup>1</sup> THE: Total Healthcare Expenditure; GDP: Gross Domestic Product; EMT: Expenditure on Medical Technology

<sup>2</sup> Source: (Population, GDP, THE) OECD Health Data 2006; (EMT) Eucomed calculations

technology. Slightly more than half of one percent of GDP was therefore spent on medical technology. Medical technology spending was 6.4% of healthcare spending two years ago, indicating a slight drop since that time.

Countries showing the largest portion of their healthcare spending on medical technology were new member states, Estonia (14.1%), Slovakia (12.3%), and Latvia (11.7%). These countries have small populations (5 million or fewer) and relatively small healthcare budgets. Contrastingly, the countries with the smallest portion of healthcare spending on medical technology were Luxembourg (2.6%), Belgium (3.3%) and Romania (3.3%).

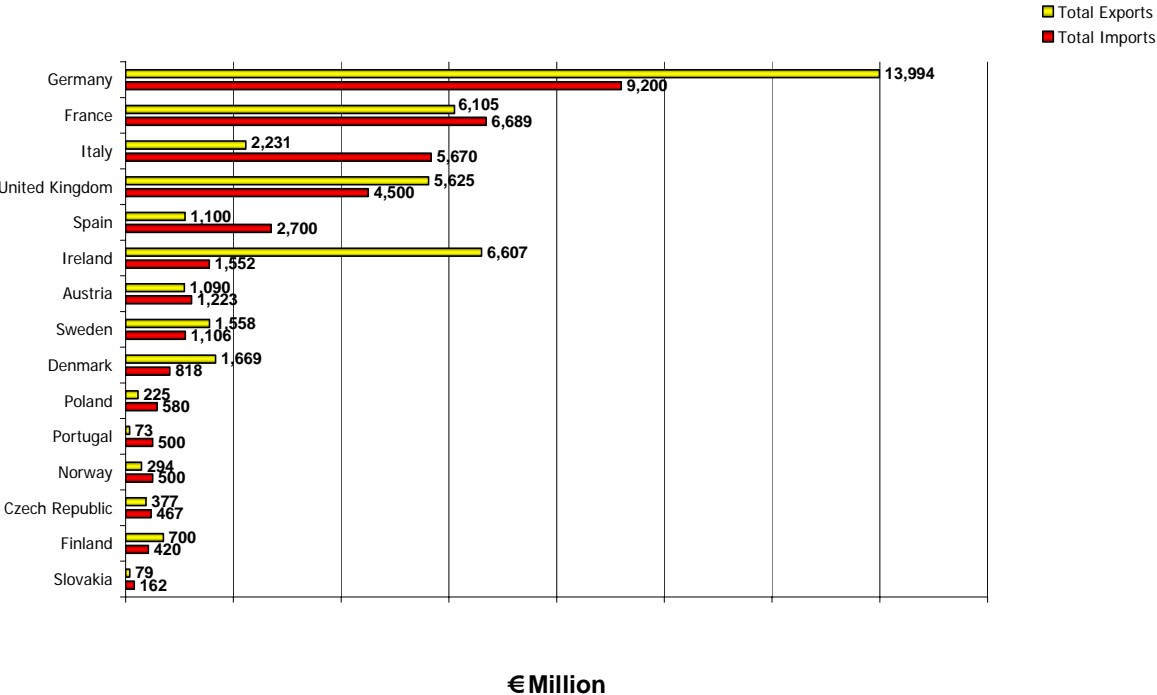
In terms of healthcare expenditure as a percentage of GDP, the highest spending countries were Switzerland (11.6%), France (10.5%) and Germany (10.1%), while the lowest were Latvia (5.1%), Slovakia (5.1%), and Estonia (5.5%).

Europe spent on average €128 per capita on medical technology, less than half the average US spending of €270 per capita.

### 5.3 Trade in Medical Technology

As for external trade, the biggest importer and the biggest exporter were one in the same – Germany. In 2005, Germany exported almost €14 billion worth of medical technology items, and imported €9.2 billion. Following Germany are Ireland, France, and the United Kingdom. These four countries dwarf the remaining countries in terms of exports. This is not surprising, as Germany, France and the UK are home to a number of large medical technology companies, and Ireland is well known for its high-tech economy.

Figure 12: Imports & Exports of Medical Technology

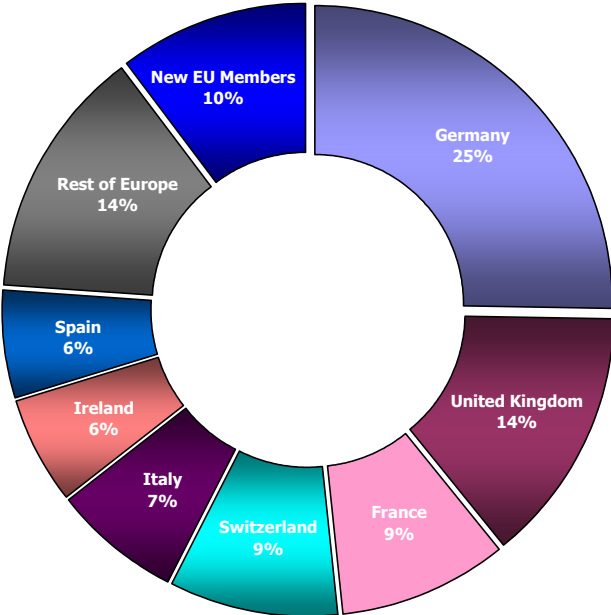


In terms of imports, Germany is followed by France, Italy, the UK and Spain, exactly mirroring their positions in the overall medical technology industry. Countries with a trade surplus in medical technology items include Germany, the UK, Ireland, Sweden, Denmark, and Finland. All the rest have a trade deficit in this sector.

### 5.4 *Employment*

Approximately 435,000 people are employed in the European medical technology industry. This represents an increase of 15% since 2003. Such a number, and the fact that it is growing, further indicates the importance of the medical technology industry in the wider European economy. Germany represents a quarter of the total employment (110,000), followed by the UK, France, Switzerland, Italy, Ireland, and Spain. New member states (10 in 2004 and 2 in 2007) represent 10% of the total. Growth is particularly pronounced in Spain; its share of the total has roughly doubled since 2003.

Figure 13: Employment in Medical Technology broken down by country (as a % of total)



**Figure 14: Employment in Medical Technology**

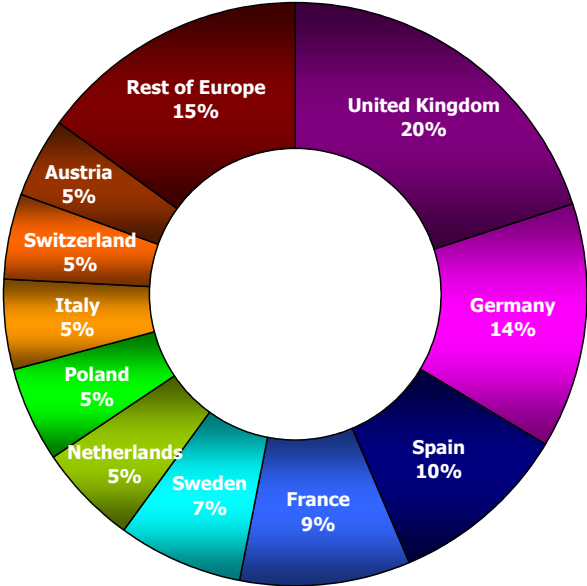
<b>Country</b>	<b>Nº of Employees</b>	<b>% of European Total</b>
Austria	6,000	1.4%
Belgium	5,500	1.3%
Czech Republic	12,760	2.9%
Denmark	14,000	3.2%
Finland	3,000	0.7%
France	40,000	9.2%
Germany	110,000	25.3%
Greece	2,500	0.6%
Hungary	4,250	1.0%
Ireland	26,000	6.0%
Italy	29,815	6.9%
Netherlands	9,500	2.2%
Norway	500	0.1%
Poland	8,700	2.0%
Portugal	3,200	0.7%
Romania	15,000	3.5%
Slovakia	2,198	0.5%
Slovenia	1,237	0.3%
Spain	25,400	5.8%
Sweden	15,000	3.5%
Switzerland	40,000	9.2%
United Kingdom	60,000	13.8%
<b>Total Europe</b>	<b>434,560</b>	<b>100%</b>

Taken individually, we see that Poland is the largest of the new EU member states in terms of medical technology employment. The countries where medical technology employees make up the biggest share of the population are Ireland, Switzerland, Denmark, Sweden and Germany, respectively.

#### **5.4 Number of Medical Technology Companies**

There are about 11,000 medical technology companies in Europe. The largest share of these is based in the United Kingdom, disproportionately to its share of sales or of exports. However, the UK is widely known for its favourable corporate law and tax regimes and life sciences industries. After the UK, the leaders in terms of number of companies are Germany, Spain, France, and Sweden.

Figure 15: Number of Medical Technology Companies broken down by country (as a % of total)



5.6 **Research and Development Spending**

The research and development spending of the European medical technology industry amounts to between three percent and six percent of total sales. This translates to R&D spending of €3.8 billion annual across Europe. By comparison, in the US, the average is estimated to be 12 percent to 13 percent of sales.

## 6. European Market Access

This section is made up of 46 questions on different topics surrounding market access.

The number of respondents varies from 48 to 53.

For ease of analysis, this section is broken into several of sub-sections:

- Regulatory matters;
- Health Technology Assessment;
- Funding and Reimbursement;
- Public Procurement;
- Late payments.

### 6.1 *Regulatory matters*

It must be noted that the questionnaire on regulatory issues has been answered on the basis of the current version of the Medical Devices Directives (MDD). The directives are currently under revision and some points might be re-assessed on the basis of the final results of such revision.<sup>3</sup>

#### **C1-1) How do you rate the actual level of understanding of end users of the meaning of CE marking?**

The majority of respondents are satisfied with the actual level of self-reported understanding of the CE marking among end users (i.e. clinicians, administrators) (i.e. sufficient 40%, good 18% and very good 7%). There is however a significant group of the respondents who consider it “poor” (33%).

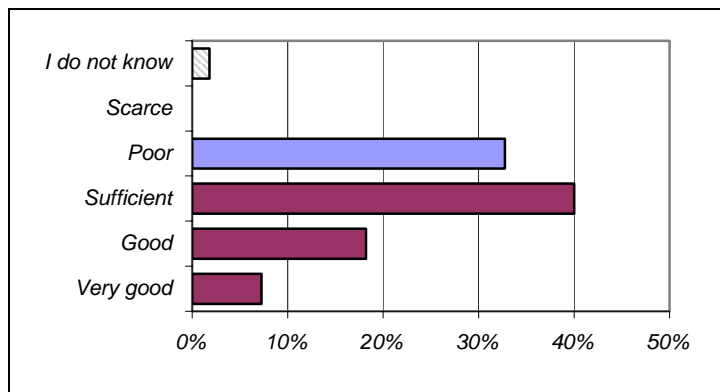
It should be noted that the level of understanding may vary considerably among end users; it seems also that only a few end users would be able to explain the procedure leading to the CE marking.

The open-ended comments point out that the risk of accepting a poor level of understanding is that end users may impose additional quality requirements on top of CE marking (e.g. as part of tender procedures).

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<sup>3</sup> In particular, the following parts of the MDD are going to be modified:

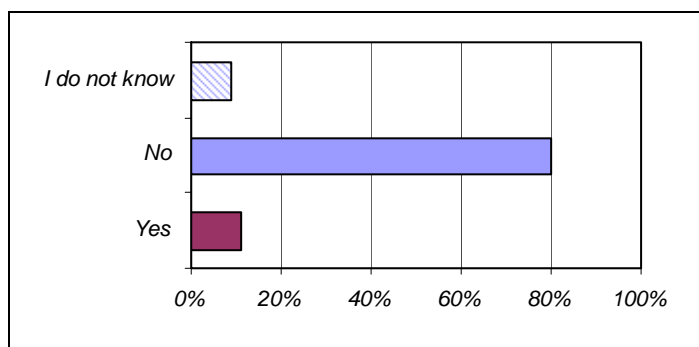
- European database: the revised text of the MDD should enlarge the amount of data which could be included in the European database (Eudamed). The issue remains, however, on the accessibility of Eudamed, which is limited to the member states' competent authorities only
- Guidance documents: there is the intention to endorse some guidance documents (the Meddev) by the procedure of article 7. This procedure, however, will be modified to include a formal scrutiny by the European Parliament. This might dilute the value of the Meddev as consensus documents
- Assessment modules: the quality modules are going to be modified by clarifying that even for devices in class IIa and IIb, the notified body (NB) has the duty to evaluate samples of the design dossier in the framework of the overall assessment of the quality system. This was already implied in the original text, but very seldom applied
- Amount of information supplied with the technical file: there will be a greater emphasis on clinical data.



**C1-2) Have you experienced the application of the so called “safeguard clause”?**

The “safeguard clause” does not seem to constitute a significant concern for the medical technology industry (80%). On the contrary, the position of Eucomed is that the industry welcomes thorough market surveillance.

Respondents report that very few safeguard clauses have been applied by member states, and then on a very limited number of families of products (e.g. catgut sutures).

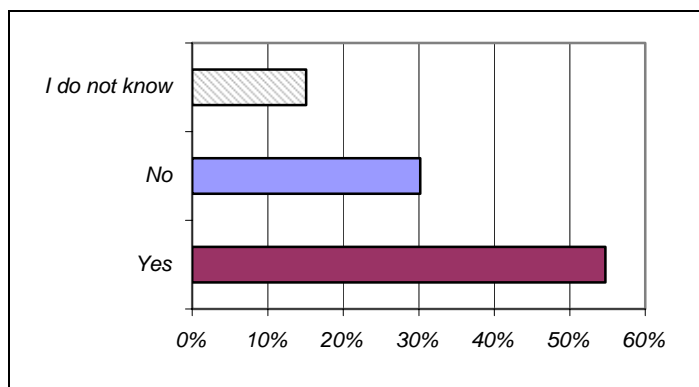


**C1-4) Do you see any part of the CE marking process which could be improved?**

The majority of the respondents report that parts of the CE marking process could be improved (55%).

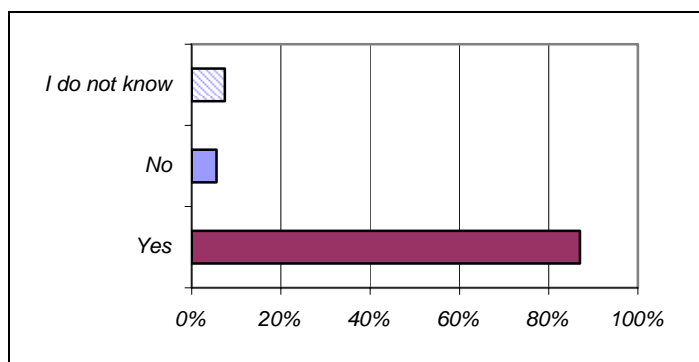
Some suggestions have been put forward:

- More and better communication with end users to increase the level of understanding;
- Harmonisation and surveillance of the way notified bodies (NBs) work;
- Need for a European database for registration procedures, surveillance and adverse events reporting;
- Promotion of the CE marking inside and outside EU (e.g. China, Japan and India);
- Guidance for clear classification would be very beneficial;
- Guidance for border-line products would be very beneficial;
- Strong approval time-lines are needed as time schedule is very often exceeded.



**C1-5) Do you consider that the “assessment modules” available for medical technology products are appropriate for the scope of the conformity assessment?**

The vast majority of the respondents believe that the “assessment modules” are appropriate for the scope of the conformity assessment (87%). It has been generally reported that the current system allows for adequate choice for manufacturers and flexibility for the diverse product range while providing adequate protection for patients.



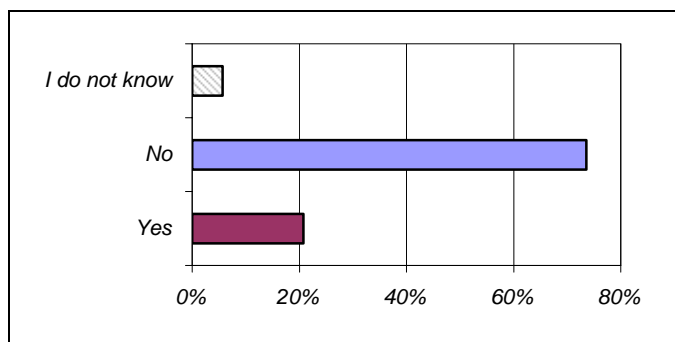
**C1-6) Have you encountered any major problem concerning product classification?**

Even though 74% of the respondents have not had major problems, a fairly important share of 22% has encountered major problems concerning product classification. In particular the following cases have been reported as problematic:

- Catheters and guidewires;
- Gases, for instance cryogenic;
- Disinfectants;
- Breast implants (reclassified to class III despite lack of scientific evidence);
- Orthopaedic implants;
- Insulin pumps;

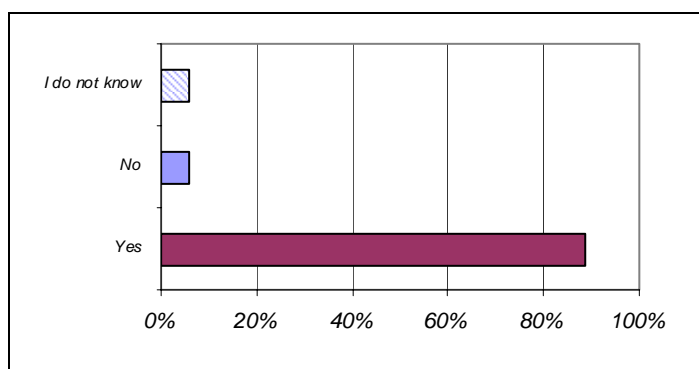
Moreover, some general concern has been expressed by those respondents who had not encountered major problems with product classification, regarding:

- Borderline products which are not easy to classify, such as drug-device combinations, human tissue or nanotechnology-based devices;
- Tendency to over-classify;



**C1-7) Do you consider that the amount of information required by the technical file is appropriate for the scope of the assessment?**

The vast majority of respondents (89%) reported having no major problem regarding the technical file. Respondents want to supply the best possible technical data, while avoiding the need to submit unnecessary or redundant data.

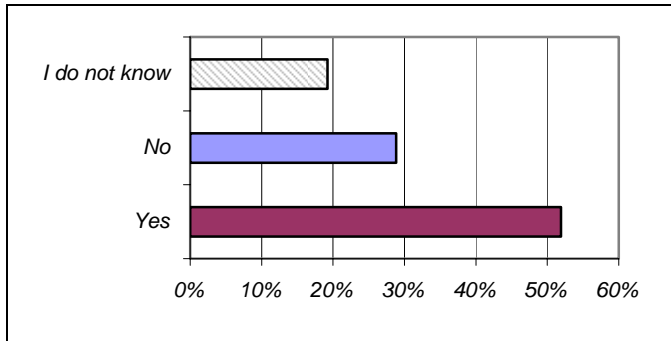


**C1-8) Do you believe that the administrative activities related to the conformity assessment procedure can be further simplified?**

The majority of the respondents think that parts of the CE marking process could be improved (52%).

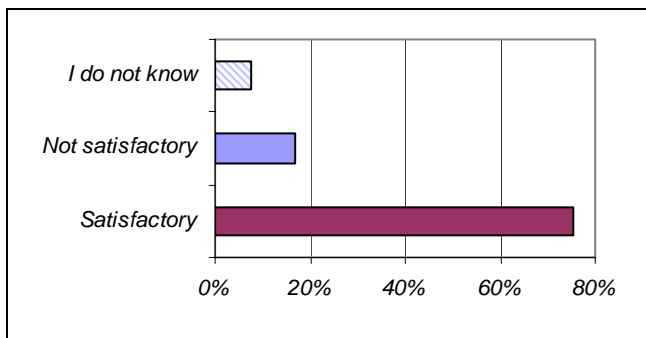
Some suggestions have been put forward:

- Standardization of data and documents supplied (particularly taking into account GHTF principles);
- Mutual full acknowledgement of audits performed by NBs;
- Need to have EUDAMED in place to allow the efficient registration of devices;
- Encouraging electronic submissions to NBs.



**C1-9) How do you rate the general level of competence/skills of the notified bodies?**

The vast majority of the respondents are satisfied with the general level of competencies/skills of the NBs (75%). However, among both the “satisfied” and “not satisfied” respondents, comments suggest that large differences in competence exist among NBs. The efforts of NBOG (notified body operation group) to promote consistency and competence in the NBs may help addressing this issue.

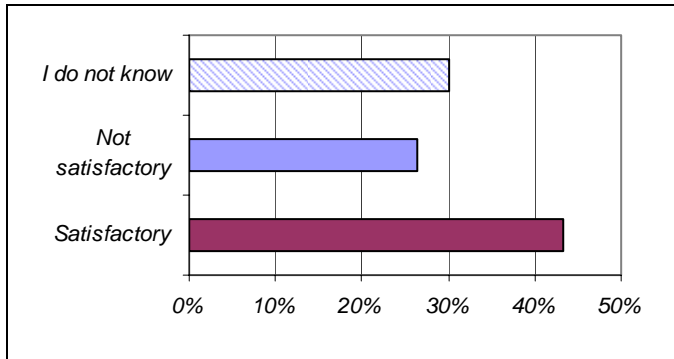


**C1-10) How do you rate the general level of competence/skills of the notified bodies with regard to new and emerging technologies?**

With specific regards to new and emerging technologies, the group of respondents who are satisfied with the level of competence/skills of the notified bodies shrinks to 43% while the number of unsatisfied respondents increases to 26%.

Analysis of the comments brought up a number of relevant points:

- There seems to be a lack of technical staff specialized in specific product categories; in other words, too many with merely general competencies;
- In general, there are too many administrators and not enough scientists;
- Competencies are often limited to a certain frame of work or type of available existing technologies;
- Particular problems have been experienced with drug-device combination products.

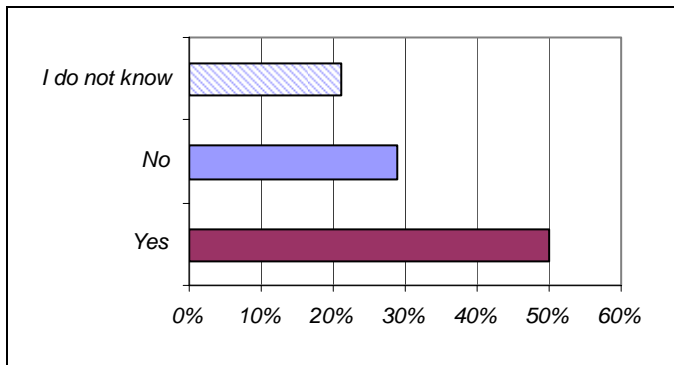


**C1-11) As far as the number of specialized notified bodies is concerned, would you be in favour of a more centralized approach (e.g. a limited number of "centres of excellence" dealing with new and emerging technologies)?**

Half of all respondents (50%) would be in favour of NB Centres of Excellence, but not without concern, as is shown by several comments.

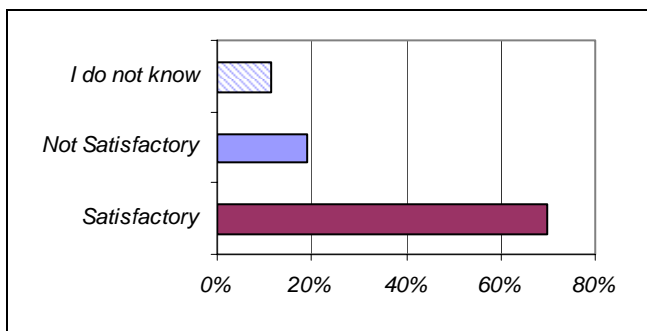
In particular, there is a fear that if the number of NBs for certain types of products were to be reduced, the approval procedure would slow down.

Besides, there is a common belief that excellence is likely to happen through the natural development of competences thanks to competition among NBs rather than by means of an administrative decision.



**C1-12) How do you rate the level of support that companies receive from the notified bodies?**

The large majority of the respondents appear to be satisfied with the level of support received from NBs (70%). However, it is reported that support differs considerably from one NB to another.

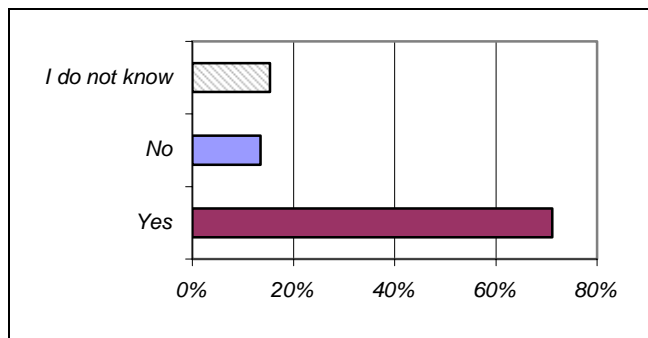


**C1-13) Do you see any opportunities for further improvement of the performance of the notified bodies?**

The majority of the respondents think that there are opportunities for further improvement of the performance of the notified bodies (71%).

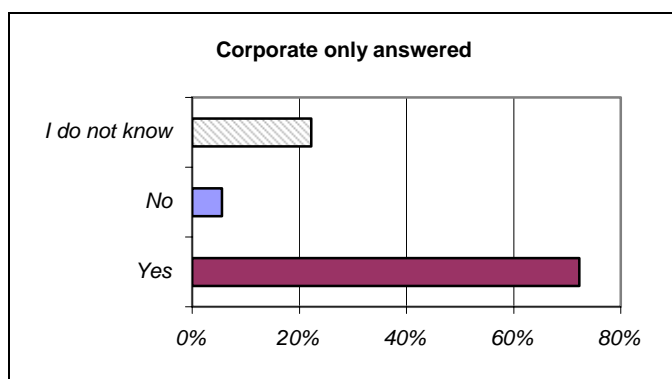
Some suggestions:

- More specialization by reducing the area of competence;
- Surveillance of NBs at EU level could lead to better harmonisation to counter the current inconsistency;
- Better development of relations and dialogue between notified bodies themselves on one hand and research centres and companies on the other hand;
- Investment in human resources and training;
- More speedy reviews or the introduction of fixed review times;
- More transparency of reviews.



**C1-14) As far as the assessment of the competences and the designation of the notified bodies are concerned, member states use their own evaluation criteria (in the framework of European provisions). Does this system generate significant differences between notified bodies in different countries?**

72% of the respondents consider that the current system for the assessment of the competences and the designation of the NBs does generate significant differences between NBs in different countries. The expertise of the NBs and the efficiency varies from country to country and even within the same country (e.g. Germany).



**C1-15) As far as the control and sanctions of the notified bodies is concerned, member states use their own methodology (in the framework of European provisions). Does this system generate significant differences between notified bodies in different countries?**

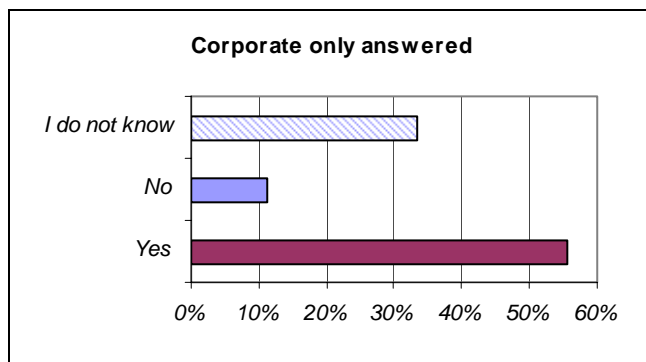
56% of the respondents consider that the current system for control and sanctions of the NBs does generate significant differences between NBs in different countries.

The differences concern:

- Competencies of the NBs;
- NBs' working procedure;
- NBs' risk management strategy.

Some suggestions have been put forward:

- Harmonisation of audit procedures to improve consistency;
- More visibility and transparency on action taken by member states. Some procedures could be made public (e.g. warning letters from authorities to NBs, guidelines for local competent authorities).



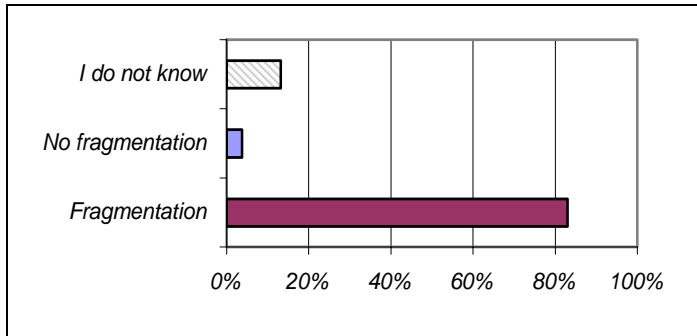
**C1-16) Transposition of directives into national legislations can bring about differences between countries. How do you rate the current level of fragmentation of the medical technology market due to different national legislations?**

83% of the respondents consider that the transposition of directives into national legislation can bring about a certain level of fragmentation of the European Medical Technology market.

The fragmentation concerns:

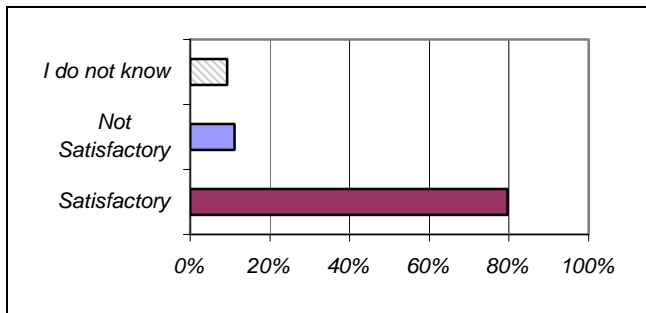
- Reporting criteria and timing (e.g. timeline for vigilance reporting varying from 48 hours to 30 days depending on national law);
- Clinical investigation (e.g. time to get ethical committee approvals);
- Notification of the placing on the market;

Particular problems are reported in France (due to inclusion of medical devices under the Clinical Trial Directive meant for pharmaceuticals), Spain, the UK, Hungary and Romania.



**C1-17) How do you evaluate the help provided by the system of harmonised standards to your business?**

The vast majority of the respondents evaluate positively the help provided to their business by the system of harmonised standards (80 %).

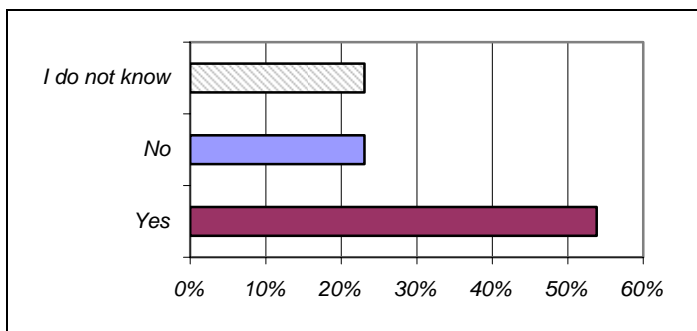


**C1-18) Do you see any opportunities for further improvements to the system of harmonised standards mentioned in the previous question?**

According to 54% of our sample, there are opportunities for further improvements to the system of harmonised standards.

A number of suggestions are put forward:

- Shortening the timeline for approval at CEN and Commission level;
- More participation of the competent national authorities;
- More adoption of global standards;
- Evolution of harmonised standards in line with the evolution of technology;
- Better coordination between the various standardisation bodies.



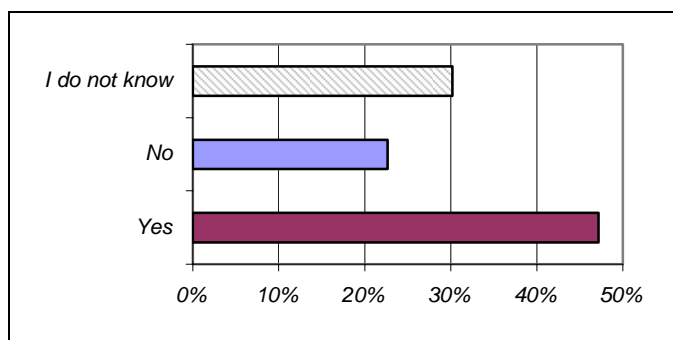
**C1-19) Member states' surveillance authorities monitor products placed on their market to ensure compliance with the provisions of their national legislation. Does this system generate significant differences between market surveillance in different countries?**

The larger group of respondents (47%) consider that the current system for market surveillance does generate significant differences between countries.

The differences concern:

- Amount of information to be provided to national authorities;
- Timeline for notification of product complaints issues.

Germany (where significant differences are reported also at regional level), France and UK are mentioned as the most active countries in terms of market surveillance.

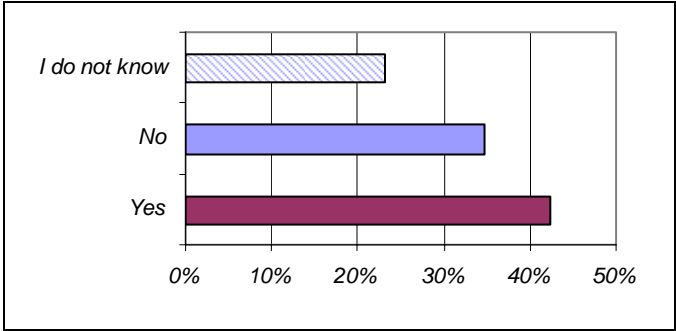


**C1-21) Do you see any opportunities for improving the market vigilance without increasing the administrative burden for companies?**

42% of the respondents think that there are opportunities for improving the market vigilance without increasing the administrative burden for companies.

Some suggestions are put forward:

- More electronic communications between competent authorities (CAs) and manufacturers and between CAs in the member states;
- Better rationale for additional information request;
- Distinction between expected or foreseen (or “routine”) complaints and unexpected ones;
- Regular reporting frequency rather than case-by-case;
- Enhancing MEDDEV 2.12.1;
- Harmonisation of reporting timelines;
- General acceptance of documents in English;
- Harmonised vigilance system;



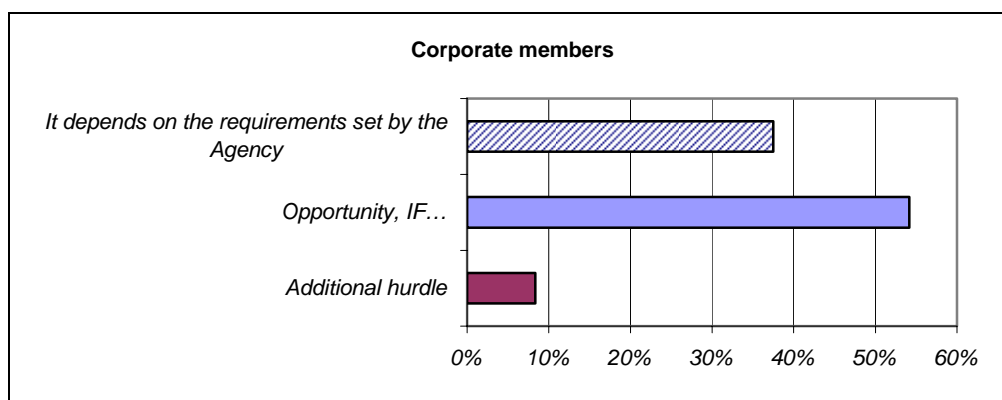
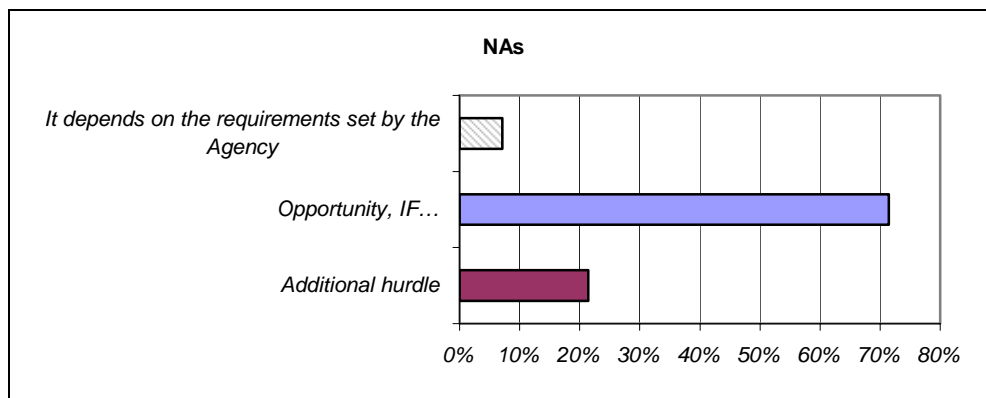
## 6.2 Health Technology Assessment

Only a small proportion of respondents are currently required to go through the HTA process. Moreover, an unusually high number of respondents replied “I do not know.” We believe that these respondents have not yet experienced the HTA process. Keeping this in mind, we did not include “I do not know” answers in our analysis.

### C1-22) Do you consider HTA as an additional hurdle or as an opportunity for bringing new technologies on the market?

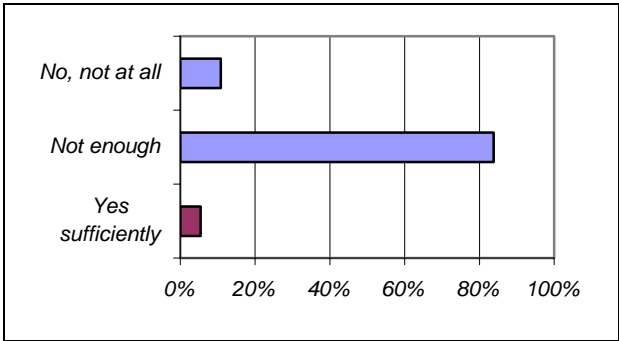
Both NAs and corporate members consider that HTA can be an opportunity in bringing new technologies to the market and in showing the real value of good medical devices provided that:

- The process is transparent and objective;
- The specific characteristics of the devices are taken into consideration (especially in the case of innovative devices)
- All stakeholders are involved;
- The timeliness and quality of the assessment is assured.



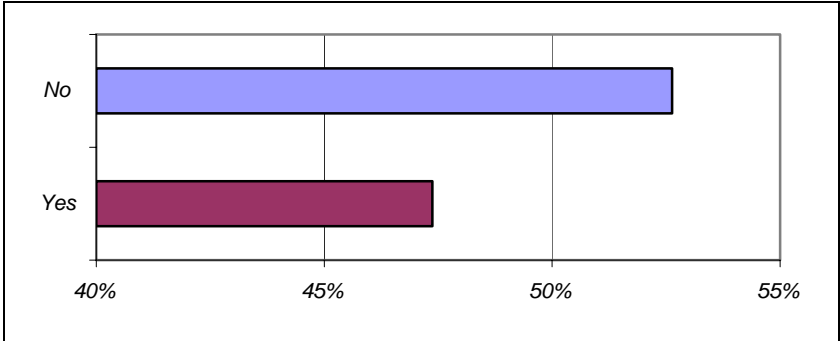
### C1-23) Do you think that the medical technology industry is sufficiently involved in the design of HTA procedures in Europe?

The large majority of the respondents (84%) think that the medical technology industry is not represented enough in the ongoing HTA process, mainly because it is viewed as “source of bias” by some HTA agencies.



**C1-24) In the European Countries where HTA is in place, is the level of the clinical evidence required reasonable for the scope of the assessment?**

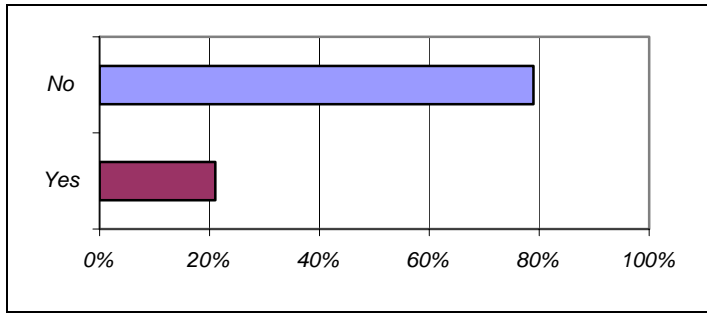
It emerges that the industry does not agree with what is generally requested by HTA Agencies as clinical evidence. One point of contention is the request of HTA agencies for randomised control trials (RCTs) even when other types of studies would be more appropriate and relevant for the decision-maker vis-à-vis a given technology.



**C1-25) In the European countries where HTA is in place, is the economic evidence required reasonable for the scope of the assessment?**

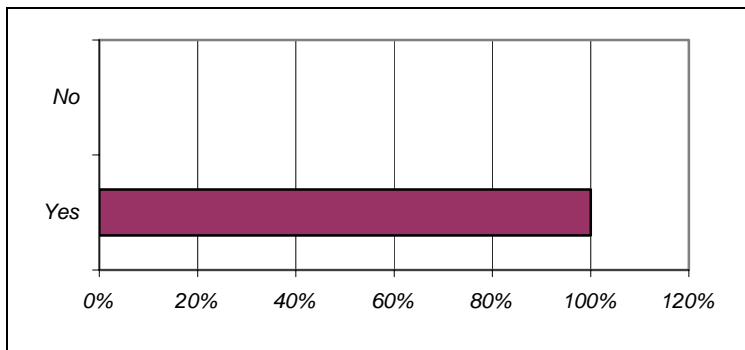
Respondents seemed to feel that the economic evidence requested for HTA is not seen as reasonable by the industry, especially in the following cases:

- Timing of assessment does not allow for calculating true economic value since costs and benefits will accrue over time;
- Economic evaluation analyses are often very costly (e.g. because of the various methodologies used in the different countries).



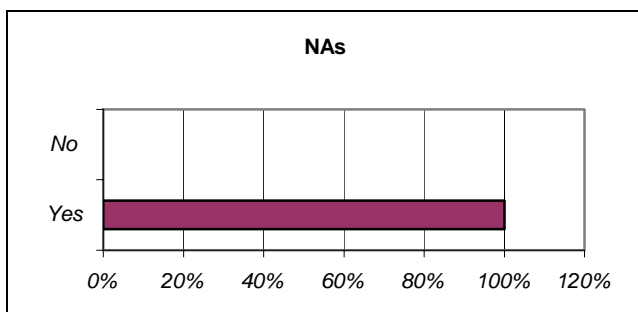
**C1-26) In Countries with mandatory HTA, does the duration of the assessment by the HTA agencies excessively delay the launch of the products?**

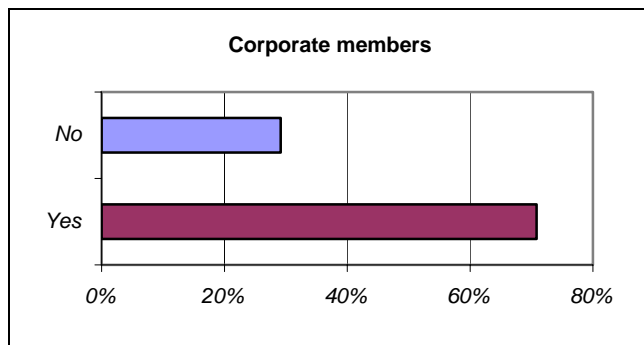
100% of respondents said that HTA delays the market introduction of technological innovation. In the comments, this is tempered by the recognition that there are differences between the European countries.



**C1-27) Does/Did HTA requirements influence human resources budget (e.g. recruiting of HTA specialists) by incurring additional (avoidable) personnel costs?**

It clearly emerges that the industry considers HTA as an additional - even though not avoidable - personnel cost which needs to be considered in its overall cost and profitability calculations.

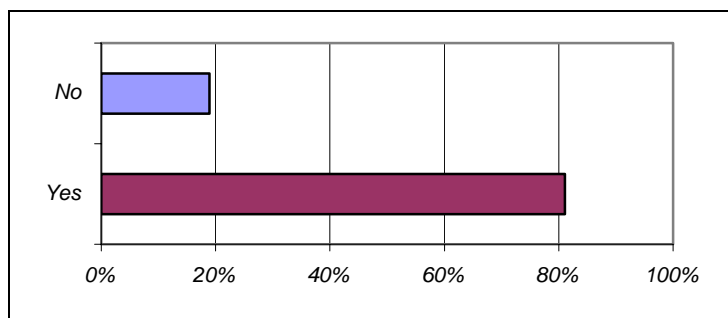




**C1-28) Do HTA, and health economics arguments in general (e.g. cost-effectiveness analysis), affect costs in terms of additional training/education to be provided to company staff, physicians and/or customers?**

The large majority of respondents (81%) report that HTA and health economic requests incur additional training costs for the company or for the national association.

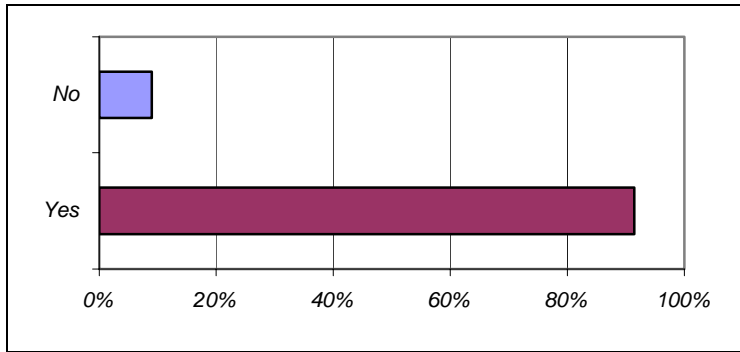
From the comments, it also emerges that this is an additional cost for the industry though it seems to be rather new and several companies do not know how to consider it (e.g. investment cost).



**C1-29) Do HTA, and health economics arguments in general (e.g. cost-effectiveness analysis), affect your company's [NA: your member companies'] administrative costs (e.g. "economic dossier" filing fees, filing follow-up, and consultant costs, etc.)?**

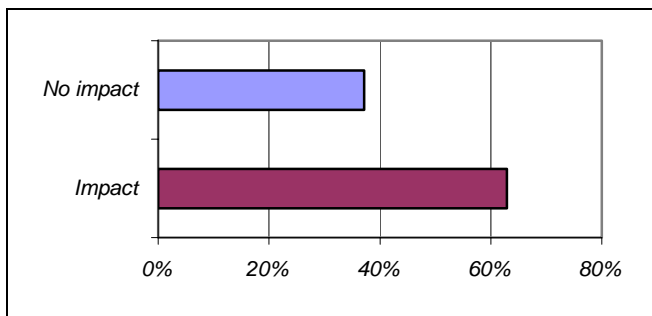
The large majority of respondents (91%) report being affected by additional administrative costs incurred because of HTA and health economic requirements.

These additional costs are however not seen as avoidable but as necessary to show the value of medical devices.



**C1-30) A number of European initiatives have been taken in the HTA Area (e.g. EUR-ASSESS, EUnetHTA) and a tendency for National Agencies to converge has been observed (e.g. German HTA Institute IQWiG, NICE in the UK and the Haute Autorité de Santé in France). So far, have these initiatives made any impact on your company' [NA: on your member companies] (E.g. easier access to information, greater clarity in HTA requirements, etc.)?**

The larger group of respondents (63%) consider the international and European projects as having a potential impact on the business but it is too early to say how this impact will look. Nevertheless, it emerges from the comments that the current impact is modest when compared to the impact that national initiatives have on the medical technology market. HTA is still mainly a national/local issue.



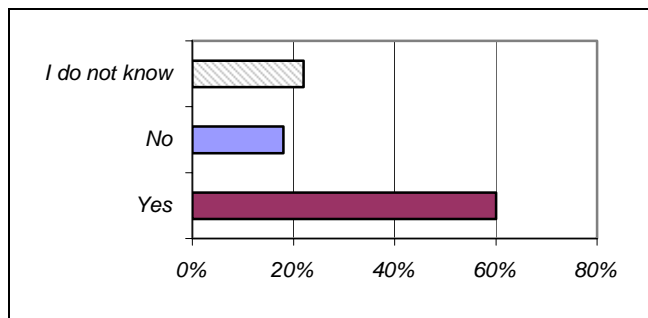
### 6.3 Funding and Reimbursement

#### **C1-33) Did the implementation of DRG-systems in some of the bigger European countries affect the amount of reimbursement for products?**

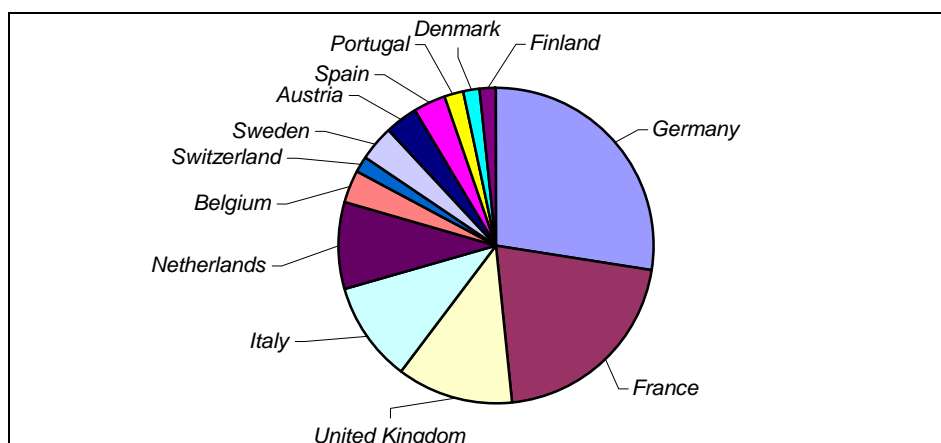
The majority of the respondents (60%) consider that the implementation of DRG-systems in some of the bigger European countries affects the level of reimbursement of products.

It emerges from the comments that the amount of reimbursement is affected by:

- the transition period; ,
- how DRGs are calculated; and
- the existence of an effective mechanism to introduce innovation (e.g. pass-through payment, exclusion list, etc...).

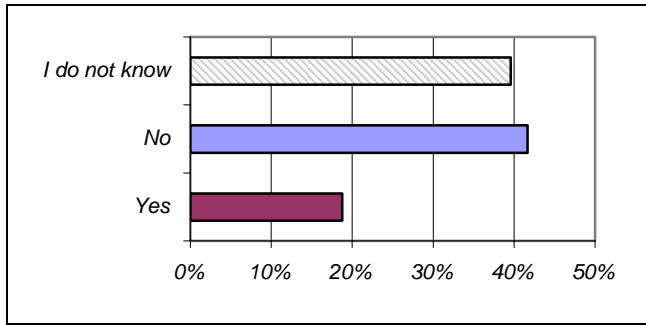


The pie chart shows the countries where the implementation of DRG-systems has affected the reimbursement the most. France and Germany are the countries where the pressure is the highest, followed by the UK and Italy.



#### **C1-34) Do the DRG-systems, in the larger European countries, provide you with a sufficiently sound mechanism to introduce higher-level technologies?**

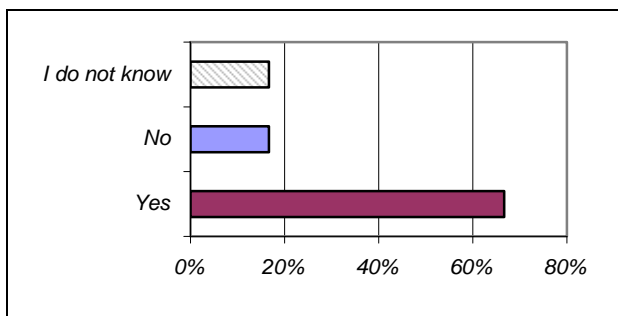
The largest group of respondents (42%) think that DRG-systems do not provide sufficiently sound mechanisms to introduce higher-level technologies.



**C1-35) Did the implementation of DRG-systems in some of the larger European countries exert price pressure on products?**

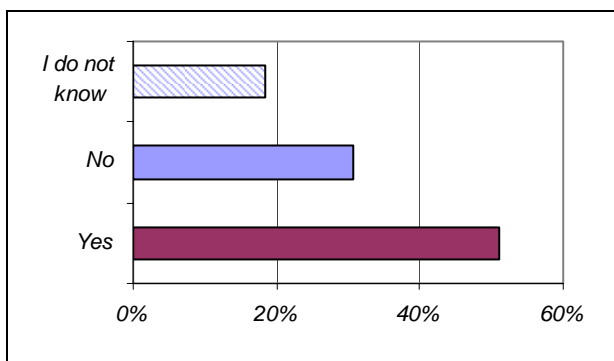
Clearly, the vast majority of respondents (67%) report being affected by the implementation of DRG-systems in terms of increased price pressure.

One interesting related point, mentioned by the commentators, and that will be further investigated later in this survey (Chapter 6.4) is the growing tendency for hospitals to issue tenders for a number of important technologies, often using price as the sole criterion for choice.



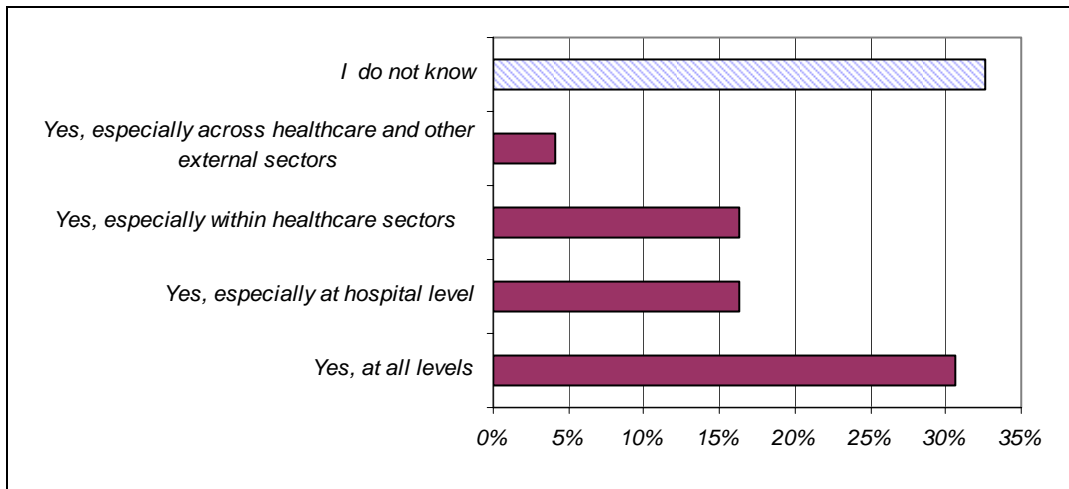
**C1-36) Does/Did the implementation of DRG-systems influence human resources budgets (e.g. recruiting of DRG specialists) incurring additional (avoidable) personnel costs?**

The majority of respondents (51%) report being impacted in terms of additional personnel costs by the implementation of DRG-systems.



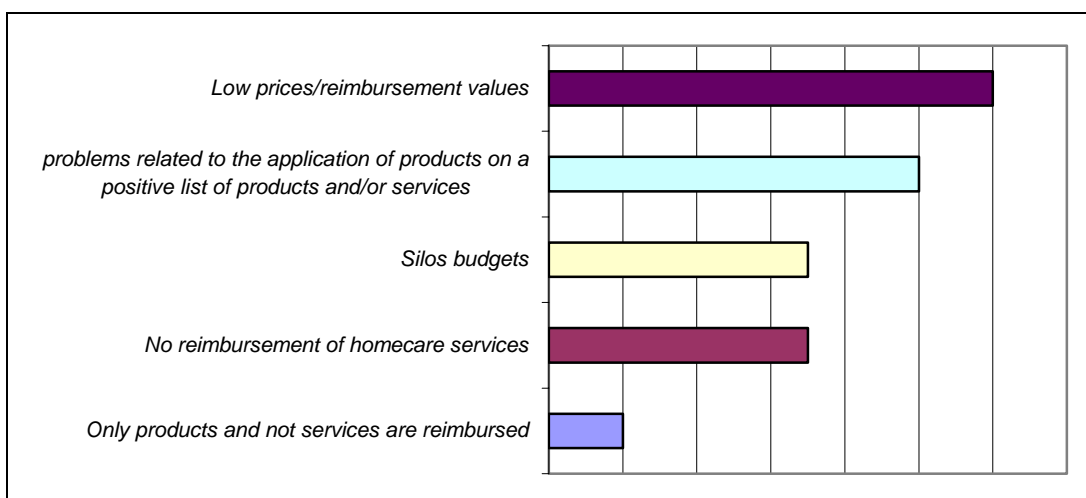
**C1-37) Silo mentality is an attitude that prevents the rational allocation of scarce resources. Silo budgeting is generally present at three levels: at hospitals, within healthcare sectors and across healthcare and other external sectors (e.g. social services). Do you think that this silo mentality has a negative impact on the competitiveness of companies?**

It clearly emerges that the respondents think that the silo mentality has a negative impact on industry competitiveness.



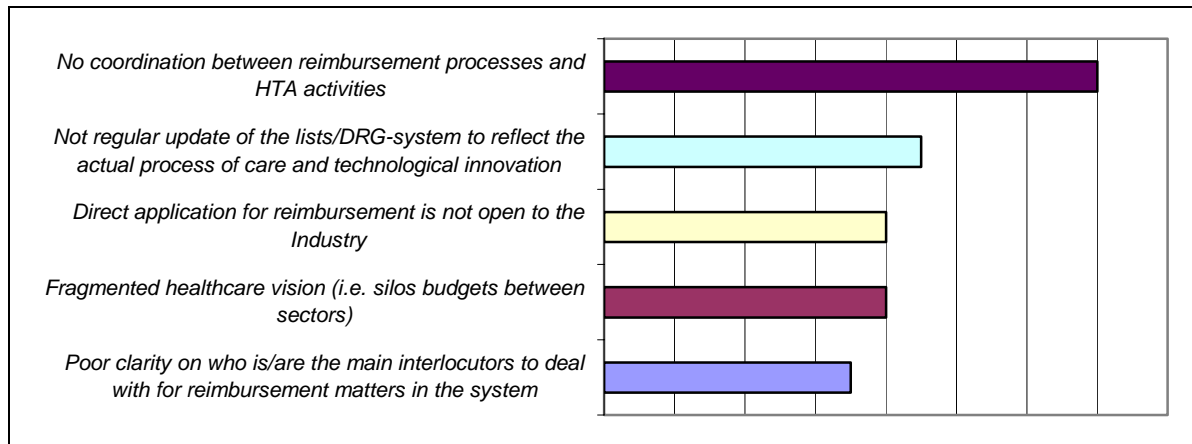
**C1-38) What are the main hurdles for your company [NA: for your member companies] as far as the reimbursement rules of outpatient and homecare are concerned?**

As far as the reimbursement rules of outpatient and homecare are concerned, the main hurdle is perceived to be the “low price/reimbursement values” followed by the “problems related to the application of products on a positive list of products and/or services.” The rank is based on a weighted comparison of the preferences, which were expressed on a rating scale from 1 to 5.



**C1-39) What are the main hurdles, in particular those common to certain European countries, to be overcome as far as reimbursement matters are concerned?**

As far as reimbursement matters in general are concerned, the main hurdle is perceived to be “no coordination between reimbursement process and HTA activities” followed by the “[lack of] regular update of the list/DRG-system to reflect the actual process of care and the technological innovation.” The ranking is based on a weighted comparison of the preferences, which were expressed on a rating scale from 1 to 5.

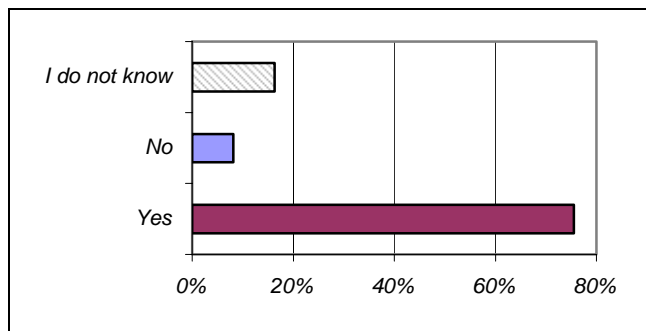


## 6.4 Public Procurement

**C1-40) Do the new public procurement directive 2004/17/EC and 2004/18/EC affect your business environment?**

The vast majority of respondents (76%) felt that they are affected by the new public procurement directives 2004/17/EC and 2004/18/EC.

Examples of those effects are more stringent and costly processes, where one sees on one side a concentration of purchasing powers and on the other a focus on price only (rather than including quality and value criteria, existing under the new directive (i.e. Most Economically Advantageous Tender, MEAT)).

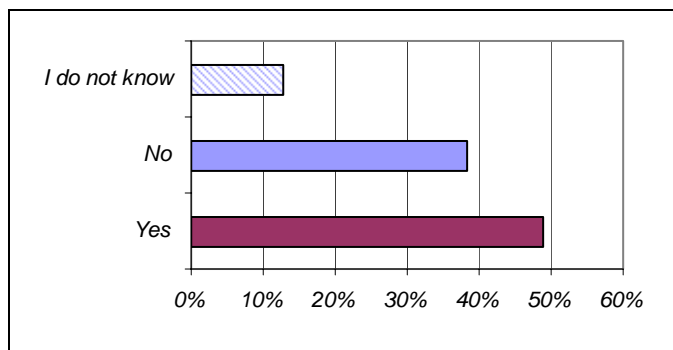


**C1-41) Centralised purchasing activities and purchasing cooperatives of healthcare service providers or/and service buyers are appearing everywhere**

**in Europe. Are these developments affecting your business in terms of loss of market share?**

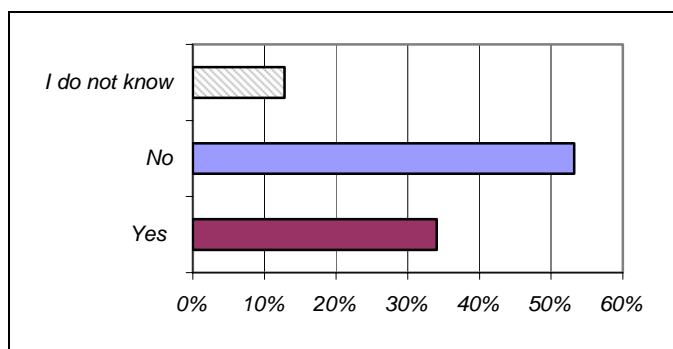
According to a plurality of respondents (46%), centralised purchasing activities are affecting business in terms of loss of market share.

From the comments, it emerges that the trend towards centralised purchasing distorts the market and competition, because the winner of the tender may get a market monopoly for up to five years, and other companies not winning may be forced to leave the national or regional market. This might also lead to shortages and difficulties in supply of products as well as services related to the products.



**C1-42) Have centralised purchasing developments discouraged your company from pursuing technological innovation and research activities?**

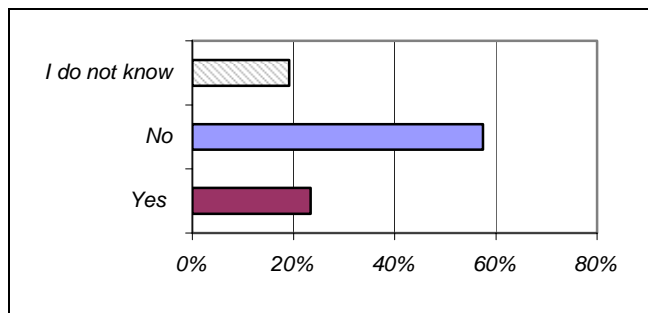
Despite the fact that the majority (53% of the sample) reports not being discouraged, 34% of the respondents are discouraged from pursuing technological innovation and this trend is likely to increase in the future, given the recent developments towards more centralisation in most of the European countries.



**C1-43) Have these developments discouraged new investments (e.g. mergers and acquisitions)?**

Centralised purchasing does not seem so far to have major direct impact on new investment (e.g. mergers and acquisitions) for the majority of the respondents.

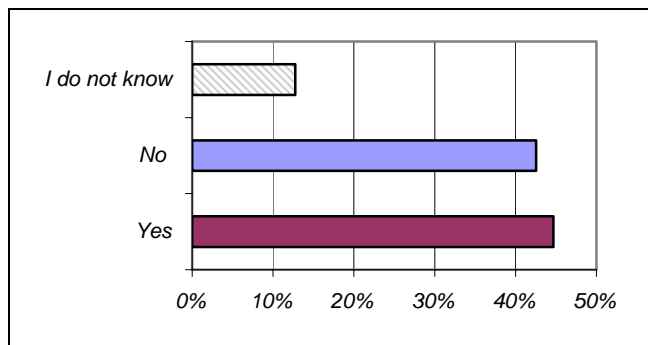
However, based on the 22% of respondents who answered yes, we can say that if these developments are pushed further, reduction of revenues would then result in more reduction of investments on new projects.



**C1-44) Have these developments discouraged your company [NA: your member companies] from increasing the workforce?**

Despite the fact that the respondents split almost evenly in this respect, all the comments mention that there is a logical correlation between decline in the investments in workforce when there is a decrease of revenues coming from the price pressure from hospitals and buying groups. These comments can be explained by the fact, also mentioned by the comments that the dynamics of the workforce is directly affected by the very nature of the tender: if you win you maintain/employ, if you lose you have to let people go (depending on the scale of the tender)

The first people being affected by the cuts are the sales and marketing staff. The training and technical support staff will have to be re-considered as value-added services may disappear in a commoditised selection system.



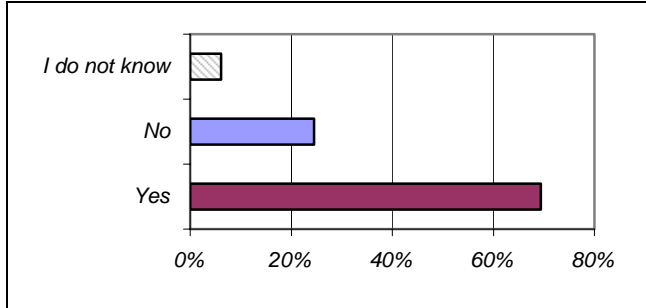
**C1-45) Does this new procurement environment affect marketing and sales strategies (e.g. fewer participations in tenders)?**

Based on the high number of respondents answering “yes” in this question (69%), we can conclude that companies adjust their sales and marketing strategies based on the market developments. The use of public procurement can distort the markets, which disproportionately affects SMEs, representing ± 80% of the industry.

From the analysis of the comments, it is worth reporting the following points:

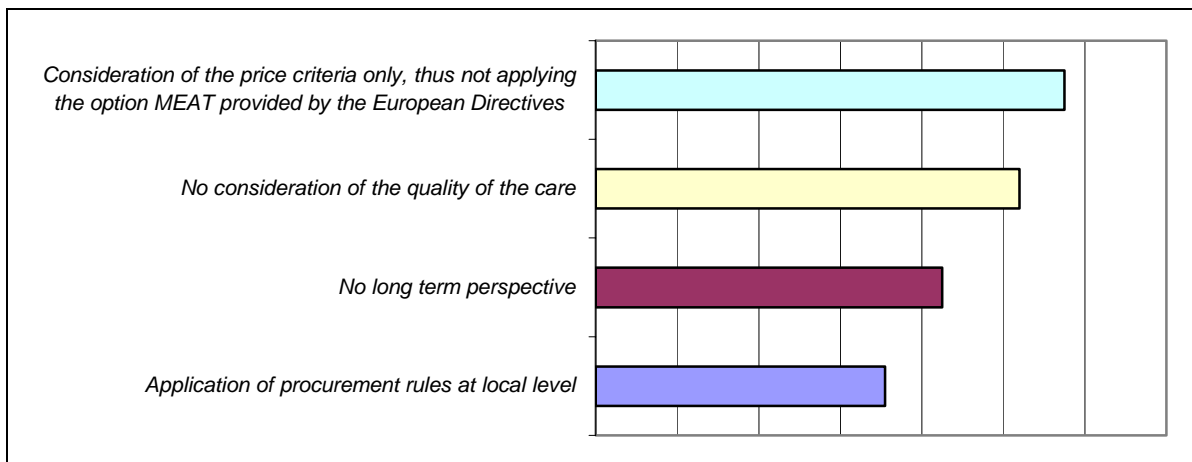
- It is becoming necessary to set-up of teams including legal advisors to deal with more complex tenders;
- As more and more procurement decisions are being made by non-clinicians, new marketing methods will have to be developed;

- Hospitals tend to invite only some companies for price negotiation, leaving others outside;
- Slower adoption process due to an increasing number of potential influencing stakeholders in the new procurement process brings a substantial delay in the decision-making process to adopt new technologies.



**C1-46) What are the main hurdles to be overcome as far as public procurement matters are concerned?**

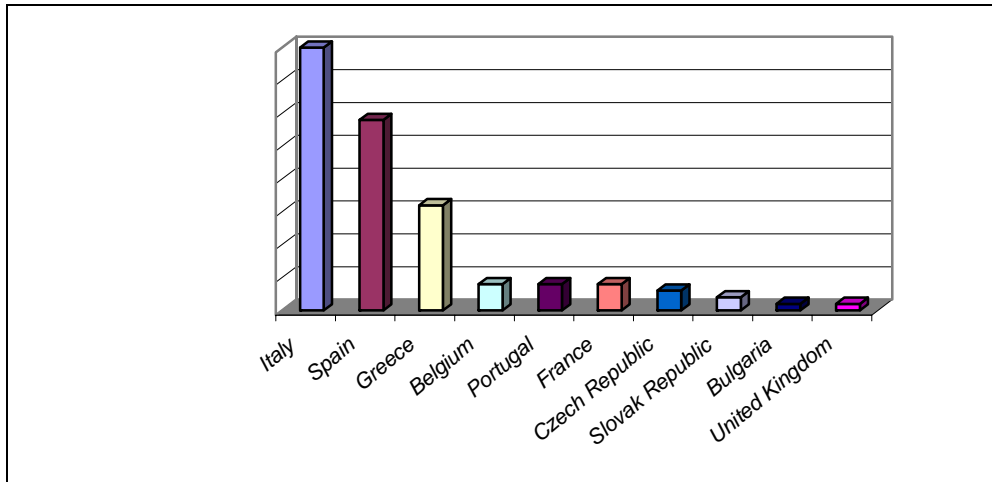
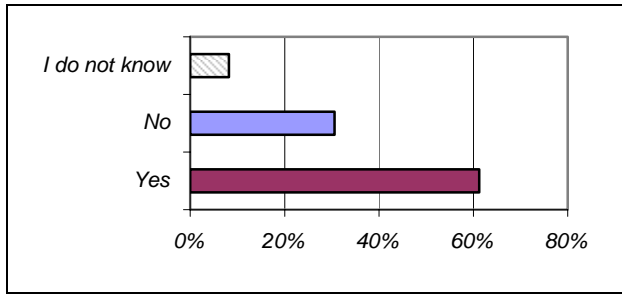
As far as public procurement matters in general are concerned, the main hurdle is perceived to be the “consideration of the price criteria only thus not applying the option MEAT provided by the European Directives” followed by the “[lack of] consideration of the quality of the care”. The ranking is based on a weighted comparison of the preferences, which were expressed on a rating scale from 1 to 4.



## 6.5 Late Payments

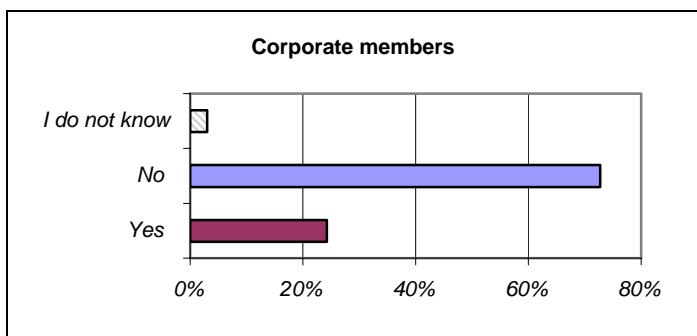
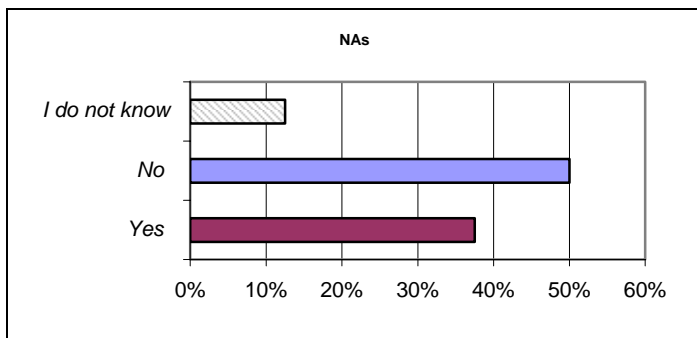
**C1-47) Is the ability to stay in business threatened by late payments depriving the business cycle of necessary cash flow?**

For 61% of the respondents, the ability to stay in business is threatened by late payments depriving the business cycle of necessary cash flow. From the analysis of the comments, the countries most often referred to are Italy, Spain and Greece as well as some central European countries.



**C1-48) Is the rate of intensity of innovation affected by late payments?**

Companies with global presence are less exposed to country risk factors and can finance operations and innovation in one country thanks to revenue and payments from other countries. When the size of the company gets smaller and the country risk exposure gets higher, late payments may impact the rate of innovation. Respondents report that small companies are particularly penalised by late payments.



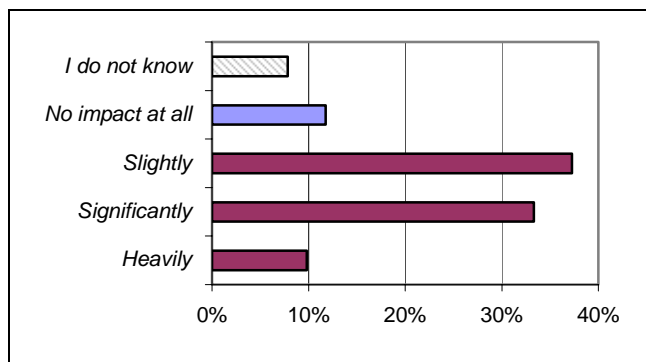
**C1-49) To what extent does a country's payments culture affect ability/willingness to do business Europe wide?**

Country's payments culture clearly affect the ability/willingness to do business Europe wide (37% slightly, 33% significantly, 10% heavily).

SMEs are particularly affected by late payments and can be "forced" to abstain from doing business in some countries, segments or areas due to commercial risk that is too high.

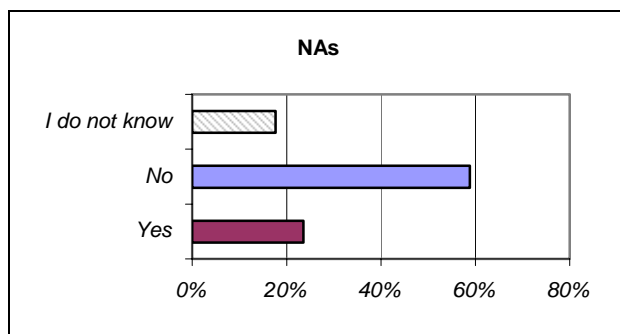
Global companies certainly consider this factor when taking decisions about investing earlier in one country than another.

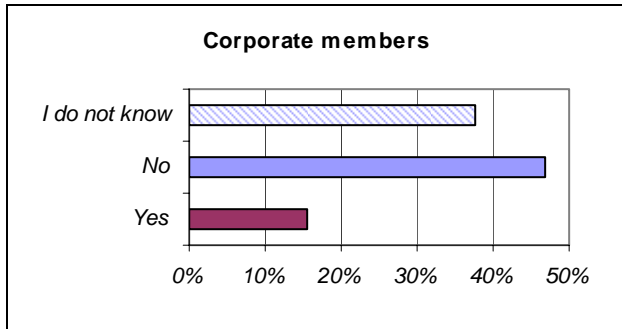
As a general remark, it should be pointed out that late payments affect the ability to generate cash flow that could be invested in other value-creating activities such as R&D, training, etc.



**C1-50) Have you observed any improvement of the overall situation since Directive 2000/35/EC entered into force in August 2002?**

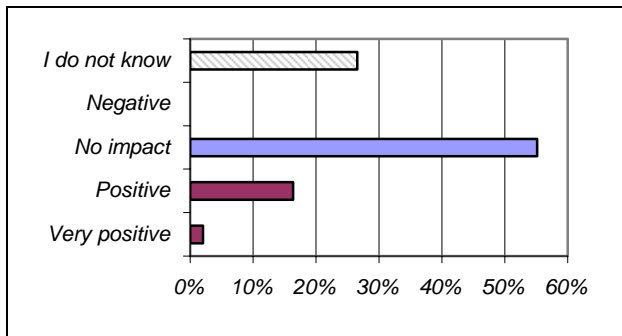
For both NAs and corporate members, a plurality of respondents has not observed any improvement in the overall situation since Directive 2000/35/EC entered into force.





**C1-51) How do you evaluate the impact on your company [NA: your member companies] of the transposition of the Directive 2000/35/EC into national legislations?**

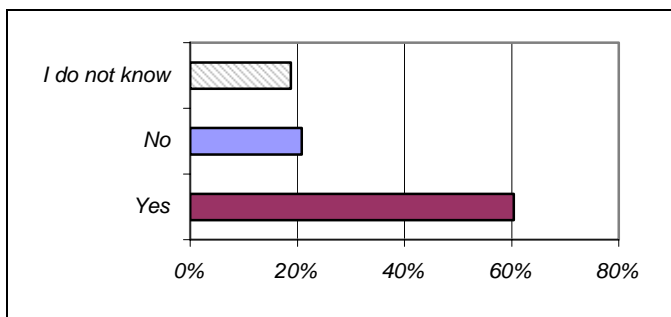
The transposition of the Directive 2000/35/EC does not seem to have brought significant improvements for the majority of the respondents (55%), which suggests that member states are neither complying with nor enforcing the directives.



**C1-52) Do you see any measure that could be taken at European or national level to reduce the delay of payments in your sector?**

The majority of the respondents think that there are measures that could be taken at European or national level to reduce the delay in payment for the medical technology sector (60%).

The main suggestion put forward is that the Commission should take the lead in ensuring that the Late Payments Directive is appropriately applied in the member states.





## 7. External Trade

This section is made up of 22 questions on different topics relevant to external trade in the medical technology sector (e.g. global harmonisation, labelling and packaging, low cost/low quality products, authorities' support, etc.).

On average, 52 respondents participated in this section of which:

- 35 corporate members;
- 17 NAs.

For five questions, only corporate members answered.

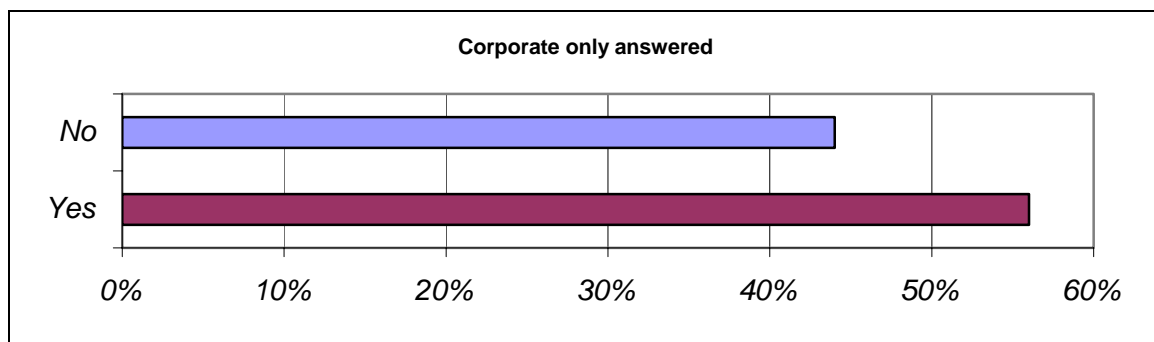
Only a small proportion of respondents are currently involved in external trade. Moreover, an unusually high number of respondents replied "I do not know." We believe that these respondents are not involved in external trade. Keeping this in mind, we did not include "I do not know" answers in our analysis.

**C2-1) When trying to export for the first time to a non-European Country, have you experienced any particular obstacle/barrier that made it difficult or even discouraged from starting the operation?**

Many companies have experienced obstacles when trying to export for the first time to a non-European Country (56%).

Obstacles are most frequently reported in Japan, China, India, Brazil, Turkey and the Russian Federation and include:

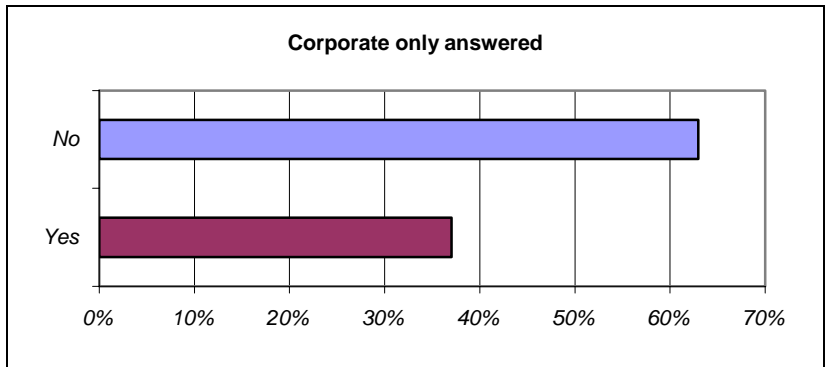
- Local Authorization;
- Late payments;
- Copyrights.



**C2-2) The purpose of the GHTF is to encourage world-wide convergence in regulatory practices. Have you observed any significant harmonisation over the last 10 years?**

A large portion of respondents report not having observed greater harmonisation over the last 10 years (63%).

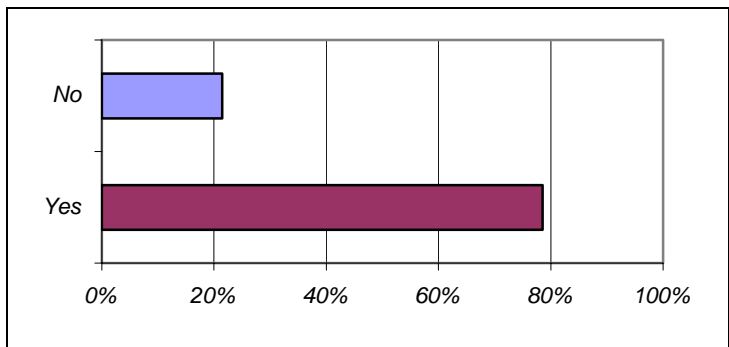
However, from the analysis of the comments, there emerge some examples of successful harmonisation with Australia, the US, Canada, Japan, New Zealand and India.



**C2-3) Do you see any opportunities for international harmonisation that would help sales into new markets/or expanding in already well-established markets?**

The large majority of the respondents (79%) think that there are opportunities for international harmonisation that would help external trade. Some suggestions are:

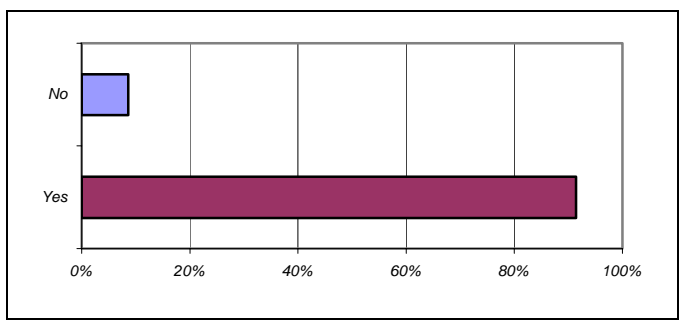
- Mutual recognition of country-specific marketing authorizations;
- Better recognition of international standards.



**C2-4) Do you consider the EU/US MRA beneficial for your business?**

The large majority of respondents (63%) consider the EU/US Mutual Recognition Agreement (MRA) beneficial for their business.

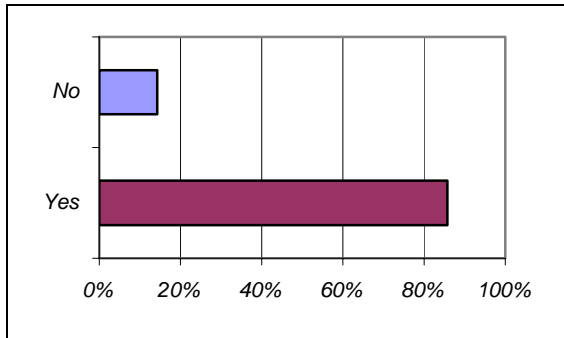
As the MRA has not yet entered into force, the benefits are most likely to be expected (e.g. stimulating closer collaboration between authorities, similar quality system requirements).



**C2-5) Would you like the EU to pursue the possibility for MRA with other non-European Key-Regions/Countries?**

The vast majority of the respondents (86%) would like the EU to pursue the possibility of MRAs with other non-European key regions/countries. It emerges that the priority countries for the medical technology industry are:

- China;
- Japan.

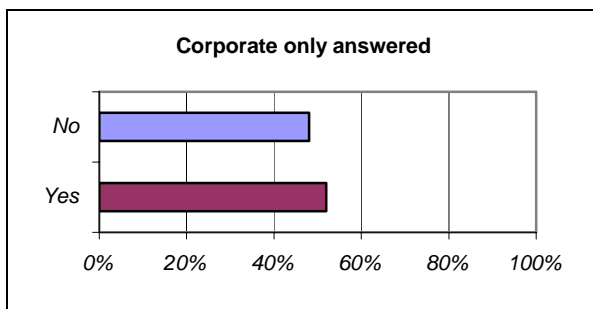


**C2-8) Have you experienced any particular problem with the customs clearance formalities in some non-European countries?**

A majority of respondents (52%) report having experienced problems with customs clearance formalities in some non-European countries. 48% report not having experienced any particular problem.

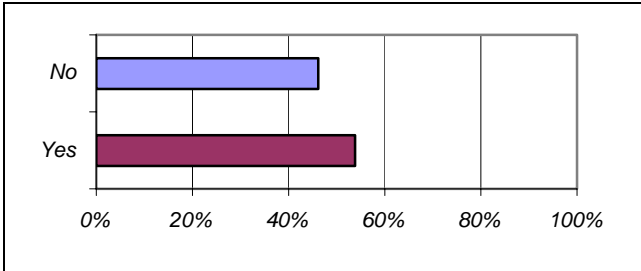
The assessment of the comments brought up some significant examples:

- China:
  - customs declaration;
  - quota issues;
  - differing procedures and requirements by province or trade zone.
- Brazil:
  - cumbersome bureaucratic procedures.
- India:
  - new pharma-like regulatory regime (although this is not a customs matter)



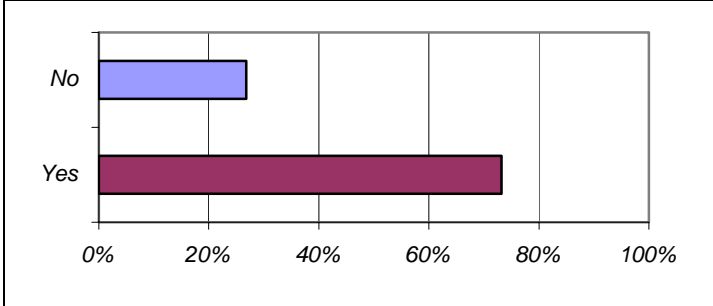
**C2-9) Have you experienced any problems with labelling and/or packaging requirements in some non-European Countries?**

Problems with labelling and/or packaging requirements in some non-European countries have been experienced by 54% of the respondents. The most frequent problems (such as local languages requirements) are reported in China, the Russian Federation, Japan, India, Korea and Turkey.



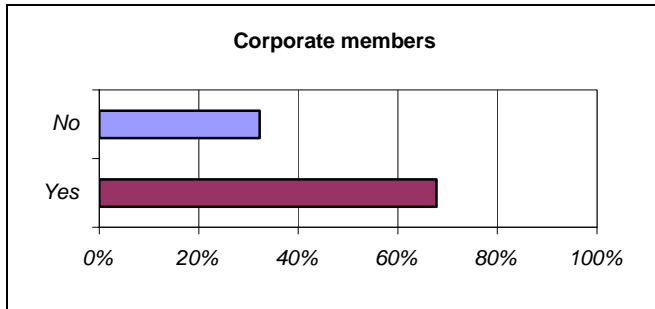
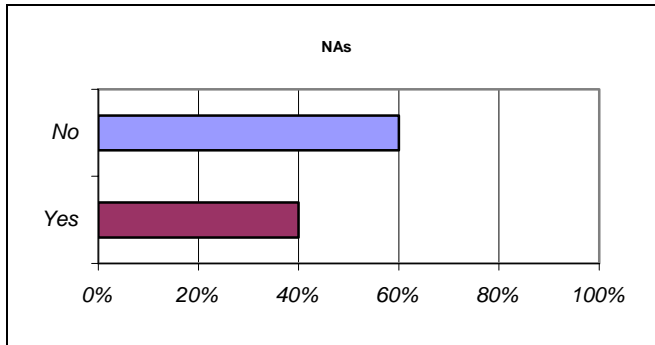
**C2-10) Do you think, in general, that the current level of paperwork requirements (e.g. translation into different languages) in some non-European countries may cause excessive costs and therefore represent a barrier to international trade?**

The large majority of respondents (73%) think that the current level of paperwork requirements in some non-European Countries may cause excessive costs and therefore represent a barrier to international trade.



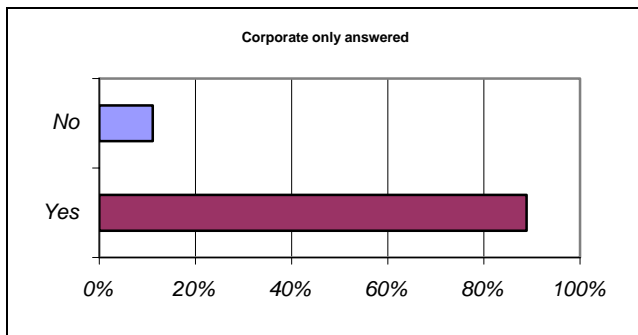
**C2-11) Are you [NA: your member companies] able to easily access reliable information on regulatory requirements needed to sell products in non-European Countries?**

National associations' member companies are not able to easily access reliable information on regulatory requirements in non-European Countries (60%). As far as corporate members are concerned, the access to this kind of information does not seem to be difficult for the majority of respondents (68%).



**C2-12) Are you able to easily access reliable information on potential distributors in non-European Countries?**

For the vast majority of the corporate members (89%), the access to reliable information on potential distributors in non-European countries does not seem to be difficult.



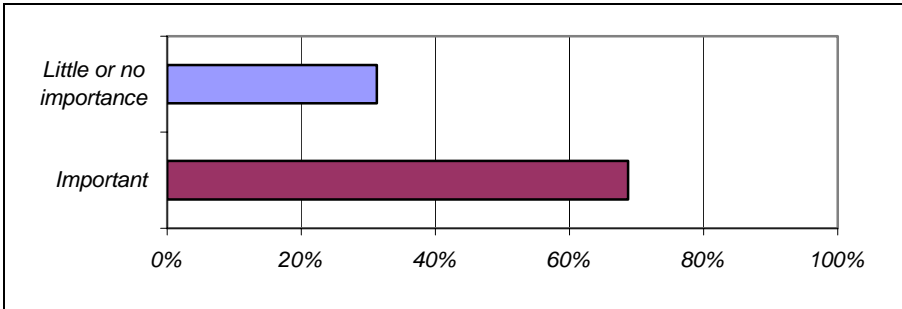
**C2-13) How do you evaluate the importance of actively participating in the activities of local industry associations in non-European countries?**

According to 80% of the respondents, active participation in the activities of local industry associations in non-European countries is “important”.

The main reasons mentioned are:

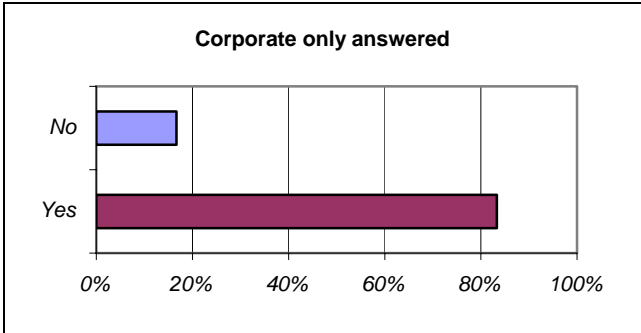
- Easier access to reliable local information (distributors list, regulatory aspects, market analysis, etc.);
- Opportunity to have contact with potential partners;
- Possibility to influence future approaches to regulation.

However, obstacles do exist. In particular, active participation requires resources and sometimes companies just cannot afford to be part of such associations. This is particularly the case of SMEs, as reported by national associations.



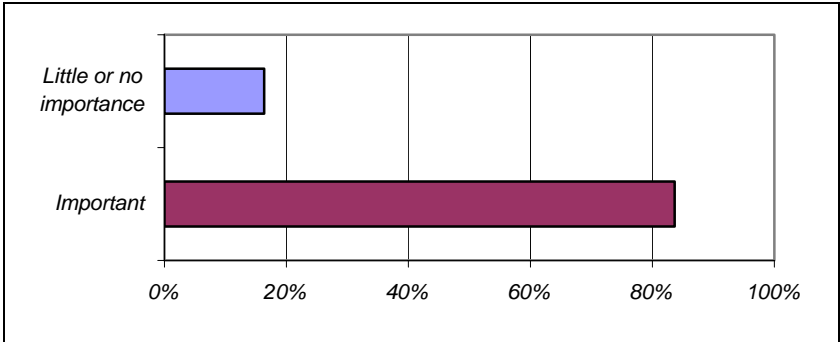
**C2-14) Is your company able to actively participate in the activities of the local Industry Associations in non-European Countries?**

The majority of corporate members report being able to actively participate in the activities of the local industry associations in non-European countries (83%).



**C2-15) How do you evaluate the importance of being supported by public authorities promoting international trade (such as the Department of Commerce in the USA)?**

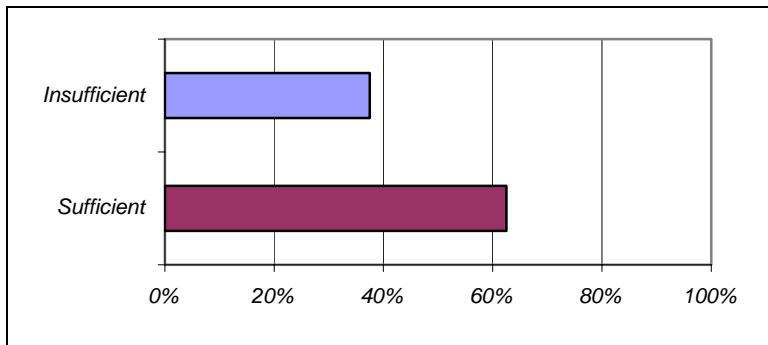
According to the vast majority of respondents (84%), being supported by public authorities promoting international trade is "important".



**C2-16) In general, how do you evaluate the current support of European countries' public authorities in the promotion of international trade?**

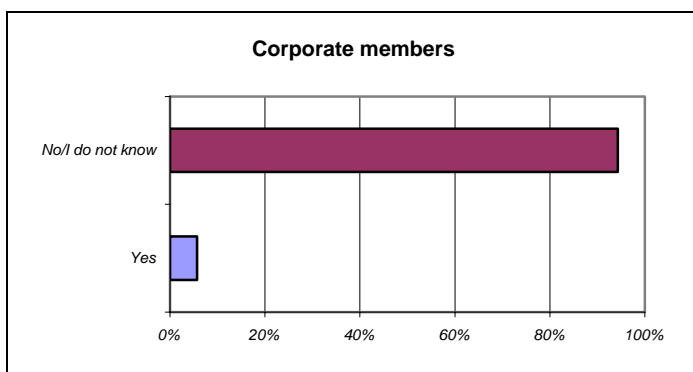
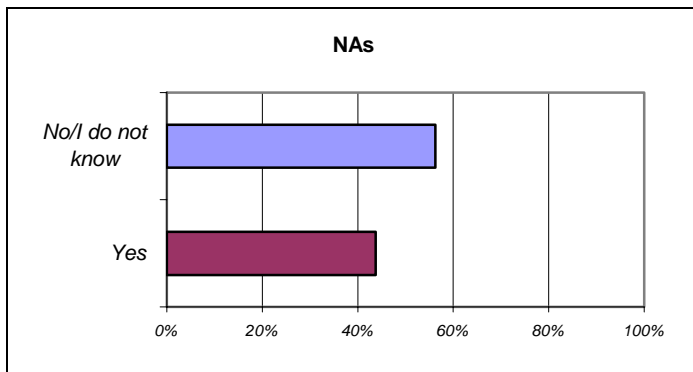
As far as the evaluation of the current support of European countries' public authorities in the promotion of international trade is concerned, 38% consider it to be "insufficient" whereas 63% appear to be satisfied with it.

From the analysis of the comments, it emerges that the countries where the public authorities' support is the best are Germany, the UK and France, respectively.



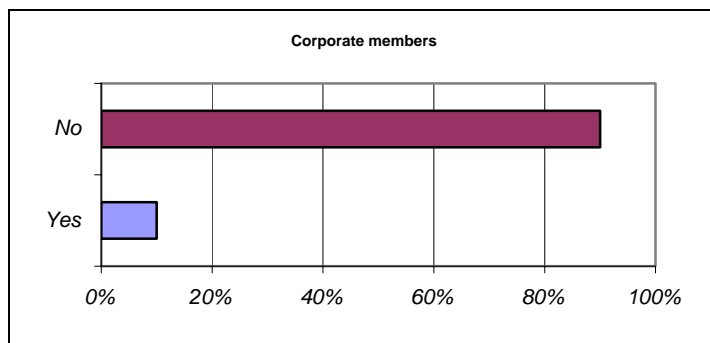
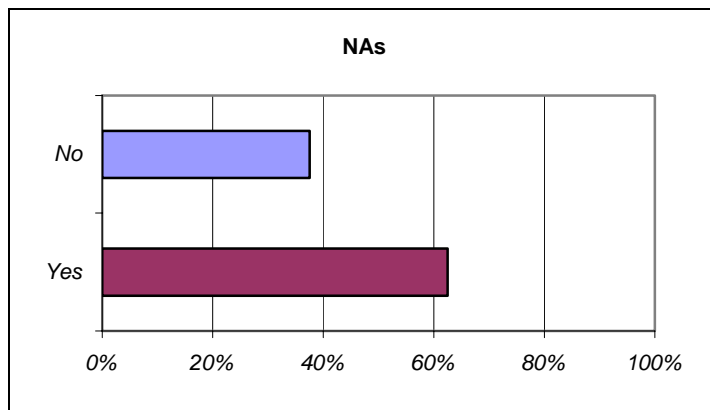
**C2-17) Are you aware of any public incentive aimed at facilitating access to non-European Countries?**

As far as public incentive aimed at facilitating access to non-European Countries are concerned, many NAs appear to be aware of these opportunities (44% of NAs against 56%) whilst corporate members do not seem to be aware of such incentives (94% of corporate members are not aware against 6% that are).



**C2-18) Does your company [NA: your member companies] benefit from any public incentive designed to help trade in non-European Countries?**

The tendency that emerged in the previous question is confirmed: NAs believe that their members benefit from public incentives designed to help trade in non-European countries (63% of NAs answered “yes” against 37% who answered “no”) whereas corporate members do not feel that they benefit from such incentives (10% of corporate members answered “yes” against 90% who answered “no”).



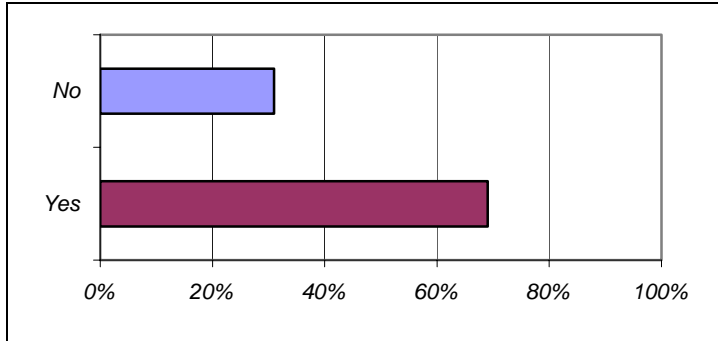
**C2-19) Are you suffering competition from "low cost" products imported from some non-European countries?**

69% of respondents report being negatively affected by “low cost” products imported from some non-European countries.

From the analysis of the comments it emerges that the top-3 countries of origin are:

- China (by far the most mentioned):
  - Technical aids;
  - Single use products;
  - Rehabilitation products;
  - Disposables, syringes, dressings, surgical gloves, etc.;
  - Wound dressing;
  - Simple medical devices;
  - Breast implants;
- India:
  - Single use products;
  - Disposable, syringes, dressings, surgical gloves, etc.;
  - Single use catheters and surgical blades;
  - Intraocular lenses (IOLs);

- Other countries in the Asia/Pacific area:
  - Single use products;
  - Syringes;
  - Intraocular lenses (IOLs);
  - Breast implants.

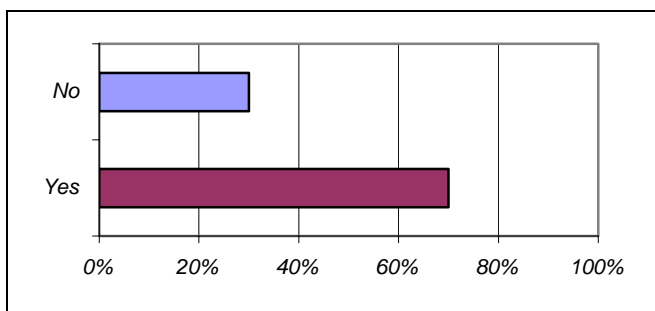


**C2-20) Are you suffering competition from "low quality" products imported from some non-European countries?**

70% of respondents report being negatively affected by "low quality" products imported from some non-European countries.

From the analysis of the comments it emerges that the major concerns regard:

- China (by far the most mentioned):
  - Single use products;
  - Rehabilitation products;
  - Disposables, syringes, dressings, surgical gloves, etc.;
  - Wound care;
  - Intraocular lenses (IOLs);
- Other countries in the Asia/Pacific area:
  - Single use products;
  - Intraocular lenses (IOLs);
  - Single use surgical instruments;
  - Soft contact lenses and soft coloured contact lenses.

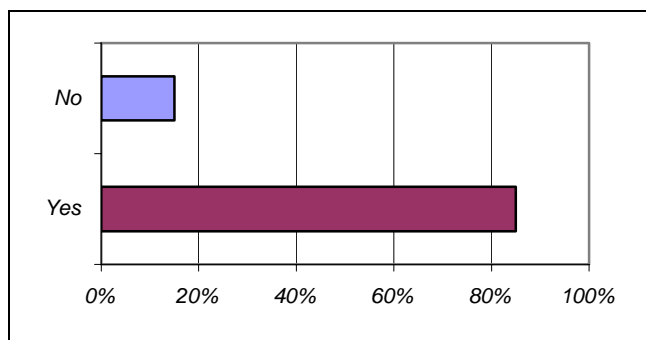


**C2-21) Do you foresee, over the next 5 years, serious problems due to competition from "low cost/low quality" products imported from some non-European countries?**

85% of respondents foresee, over the next 5 years, serious problems due to competition from “low cost/low quality” products imported from some non-European countries.

From the analysis of the comments it emerges that the major concerns regard:

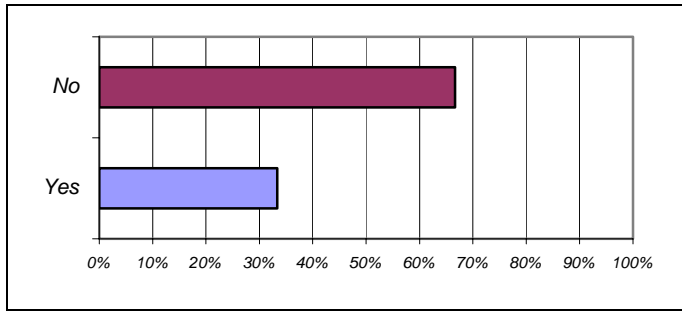
- China:
  - Technical aids;
  - Single use products;
  - Disposables, syringes, dressings, surgical gloves, etc.;
  - Wound dressings;
  - Simple medical devices;
  - Breast implants;
  - Medical electronics;
  - Pacemakers;
  - Stents;
  - Hospital equipment;
  - Compression stockings;
  - Spinal surgery products;
  - Lancets;
  - Facial fillers;
- India:
  - Single use products;
  - Disposables, syringes, dressings, surgical gloves, etc.;
  - Dressings;
  - Hospital equipment;
  - Stents.



**C2-22) Have you experienced any situation of counterfeited products imported from non-European countries?**

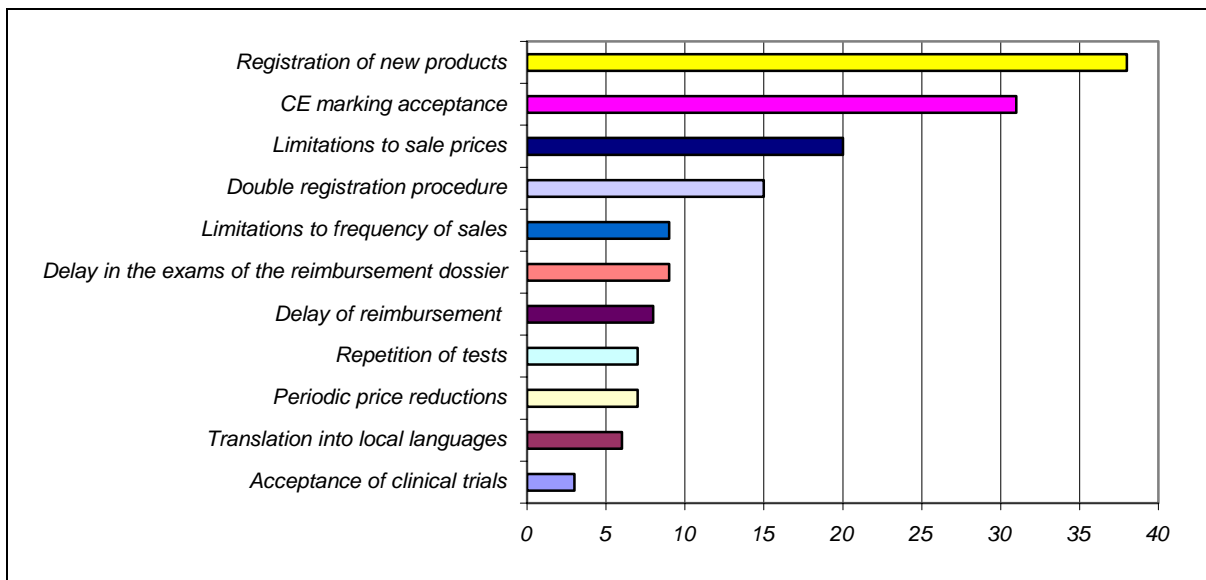
Despite the fact that the majority of respondents have not experienced any situation of counterfeited products imported from non-European countries (67%), some cases are reported to have involved goods from China, and other Asia/Pacific countries. Products commonly counterfeited include:

- China:
  - Disposables, syringes, dressings, surgical gloves, etc.;
  - Simple medical devices;
  - Wheelchairs;
- Other countries in the Asia-Pacific area:
  - Breast Implants.



**C2-23/24) Top items that prevent companies' growth in one or more non-European Countries.**

Regarding the obstacles that prevent companies' growth in non-European countries, the main hurdle is perceived to be the "registration of new products" followed by the "CE marking acceptance" and the "limitations to sales prices". The ranking is based on the total frequency of the preferences, which were expressed on a rating scale from 1 to 5 out of list of 11 potential barriers.



## 8. R&D and Innovation

This section is made of 30 questions on different topics affecting R&D investments and innovation rate (e.g. educational system, medical professionals' attitude, intellectual property rights, etc.).

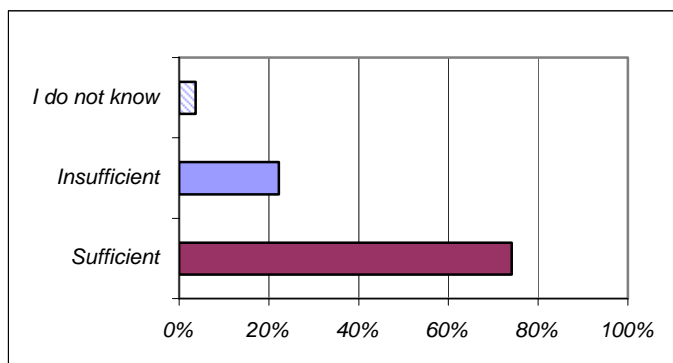
On average, 53 respondents participated in this section of which:

- 36 corporate members;
- 17 NAs.

### C3-1) How do you rate the ability of the European educational system to prepare candidates for employment in the medical technology industry?

As the graph below clearly shows, the vast majority of the respondents (74%) consider the ability of the European educational system to prepare adequate employees at least sufficient. Only 22% of the sample replied that it is "insufficient".

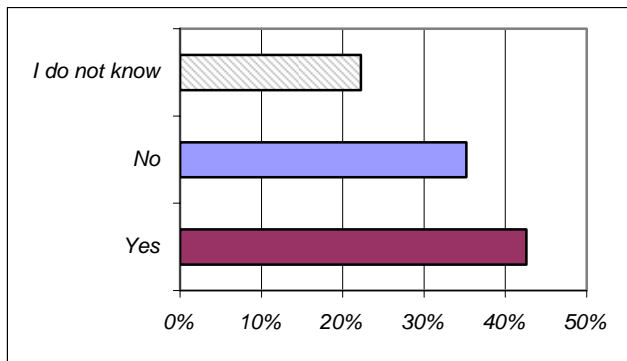
The analysis of the respondents' comments highlighted that the offer of university courses is generally considered ample and diverse; however there seems to be lack of specialised education for the medical technology industry, which must therefore depend on other specialities (e.g. pharmaceuticals).



### C3-2) Do you think there is a particular lack of skilled personnel in some key technical disciplines (e.g. biomedicine, biochemical, bioengineering, nanotechnology, material science, etc.)?

A plurality of respondents (43%) believes that there is indeed a particular lack of skilled personnel in some key technical disciplines whereas 35% of the sample does not see major problems on this issue.

From the analysis of the comments it emerges that young people seem to be less attracted by technical studies and professions and the reason could be found in lower salary expectations as compared to business disciplines.

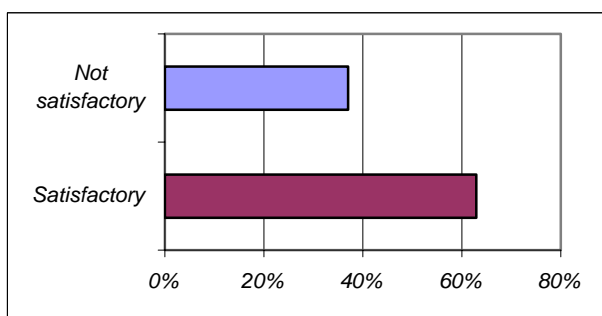


**C3-3) How do you rate the ability of the European educational system in preparing medical professionals for work in the development of new products?**

As far as the medical professional's education is concerned, the majority of the respondents (63%) consider the current European educational system to be "satisfactory" whilst 37% replied that it is "not satisfactory".

Criticisms/suggestions that were found in the comments and that are generally common to both groups of respondents are:

- Medical professionals tend to get interested in development of new technologies after they have qualified or even only after medical practice;
- The use of technology should be part of the medical training which is at the moment focused on diseases only;
- Professionals/doctors in hospitals have limited time to get involved in other duties outside the patients -- they must "process" patients;
- Professional education provided by the industry plays a big role; in fact, it is vital to the system.

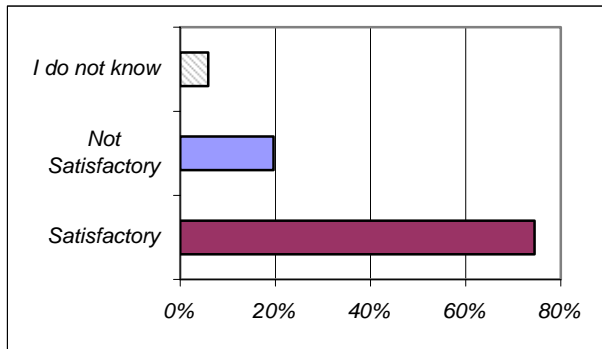


**C3-4) How do you rate the general level of receptivity of medical professionals to new procedures and products?**

When it comes to the level of receptivity of medical professionals to new procedures and products, a large majority of the respondents (74%) consider it "satisfactory" whereas only 20% of the sample considers it "not satisfactory".

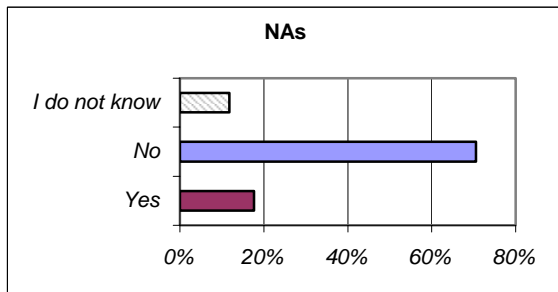
Most of the comments collected highlight the feeling that the level of receptivity always depends on the individual medical professionals. However, in general, the level of intellectual openness of medical professionals to new products is considered to be satisfactory. Some cases of low level of receptivity are mentioned with regards to:

- Cardiac surgery;
- Homecare technologies;
- Preventative medicine in general versus treatment.

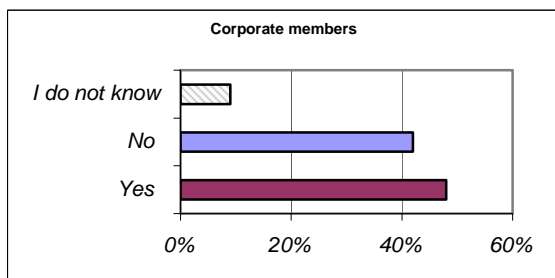


**C3-5) Do you think that medical professionals in the public sector have different levels of receptivity to new procedures and products than those in the private sector?**

On this particular topic, there emerges a different perspective according to the type of respondent. In particular, for the NAs, 71% do not seem to think that medical professionals working in the public sector have different level of receptivity to new procedures and products than those in the private sector, versus 18% that do.

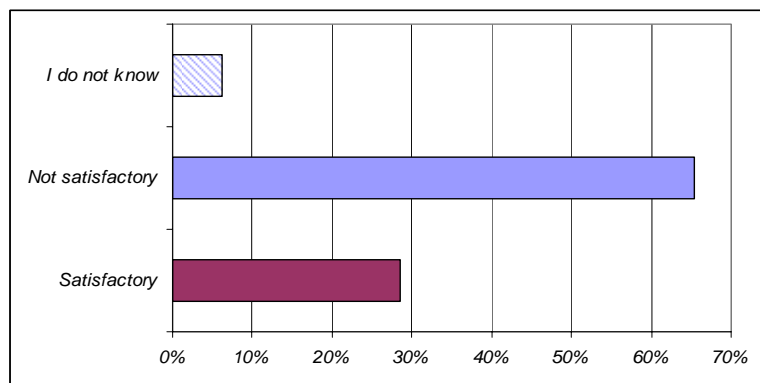


On the contrary, among the corporate members a plurality of respondents (53%) thinks that there is indeed a different level of receptivity in the public sector. Medical professionals in the public sector are seen to be less receptive, which many respondents attributed to budgetary constraints.



**C3-6) How do you rate the general level of receptivity of healthcare administrators to new procedures and products?**

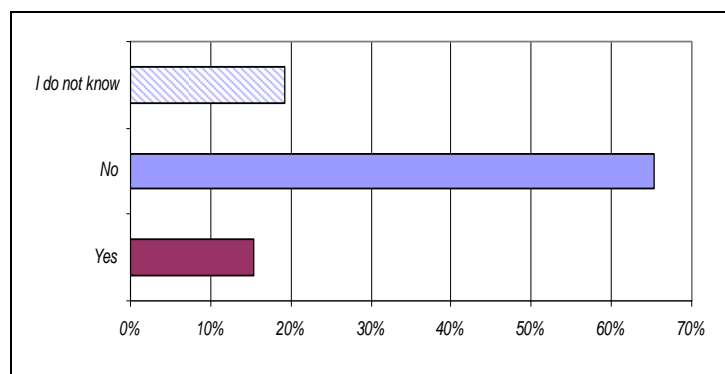
The level of receptivity of healthcare administrators is generally reported to be “not satisfactory” (65%). Most comments collected denounce the cost containment attitude which shifts the focus away from patient benefit. Budgets being the main concern, silo mentality and short-term perspective are seen as the main determinants which prevent new product adoption, even though they may prove to be economically convenient in the long-term.



**C3-7) Do you think that medical professionals have the right incentives to encourage them to use the best treatment and/or the best technology?**

65% of the respondents believe that medical professionals do not have the right incentives to encourage them to use the best treatment/technology whereas only 15% of the sample considers the incentives correct.

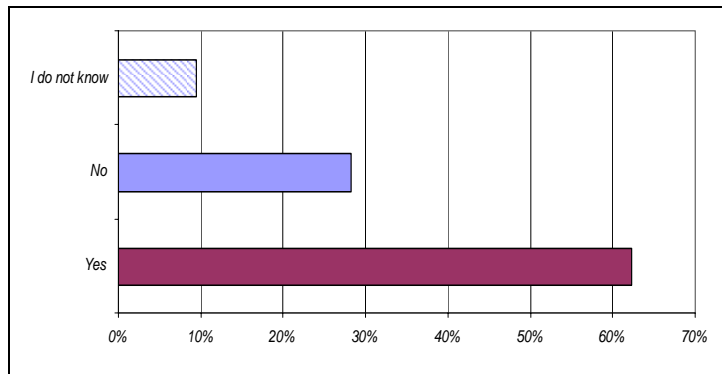
The main hurdle to the adoption of such treatment/technology seems again to be the budgetary constraints. There is a tension in the system between doctors (concerned by patient care) and administrators (concerned by cost containment); in this system, the budgetary incentive overrides the incentive to deliver the best possible treatment.



**C3-8) Do you believe that particular remuneration schemes (e.g. public vs. private, fixed salary vs. performance-based salary) for medical professionals may have an impact on their willingness to adopt new procedure and products?**

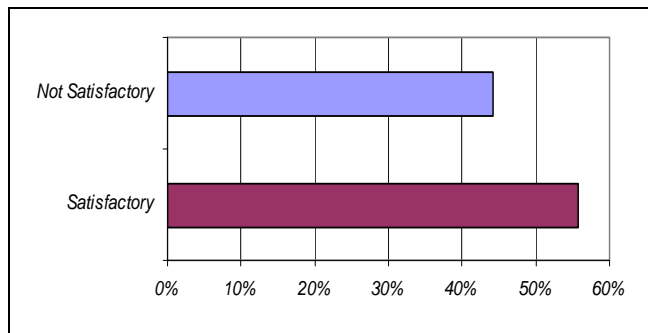
The large majority of the respondents (62%) consider that performance-based salary for medical professionals may be a driver for the adoption of new products. On the contrary, 28% of the respondents do not think that the salary scheme could have an impact on their willingness to adopt new procedures and products.

The analysis of the comments brings up the issue of having the performances based on the right measures (e.g. long term patient outcomes).



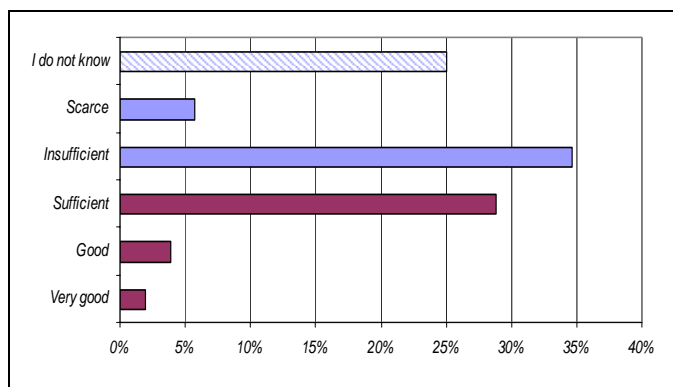
**C3-9) How do you evaluate the conditions of the European research environment, infrastructure and facilities for the development of new products?**

The respondents are split between those who are satisfied with the current conditions of the European research environment (56%) and those who are not (44%)  
 Those who give a positive opinion refer to good clusters and centres of excellence whilst those who give a negative opinion denounce lack of funding for R&D and fragmentation (e.g. 25 patent offices, scattered expertise).



**C3-10) How do you rate the level of multi-disciplinary collaboration between the major European research institutions involved in medical technology?**

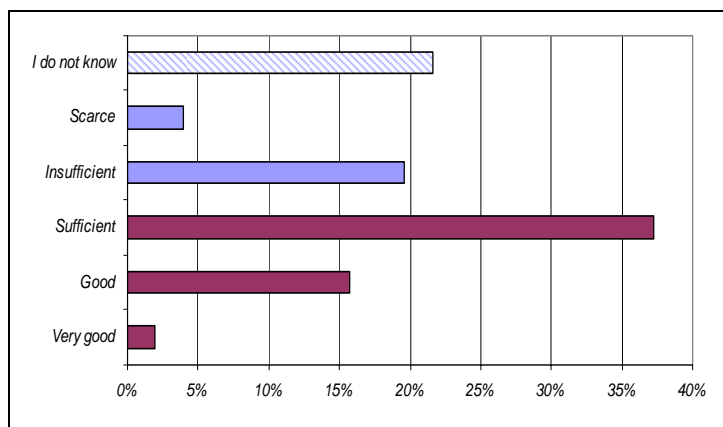
Only a few respondents consider level of multi-disciplinarity very good or good. Both those who believe that the level is sufficient (29%) and those considering this level insufficient or scarce (41%) agree that there appears to be a positive trend towards multi-disciplinary collaboration (both between universities working in clusters and between universities and industry).  
 Innovation and business development groups inside universities in the UK were cited as an example.



**C3-11) How do you evaluate the overall conditions under which clinical effectiveness studies are organised (e.g. logistics, professionals' attitude, patient willingness, regulatory requirements, etc)?**

Despite the fact that the majority of the respondents consider the overall conditions for clinical effectiveness studies to be at least sufficient, the analysis of the comments show that there is a real concern about the current trend:

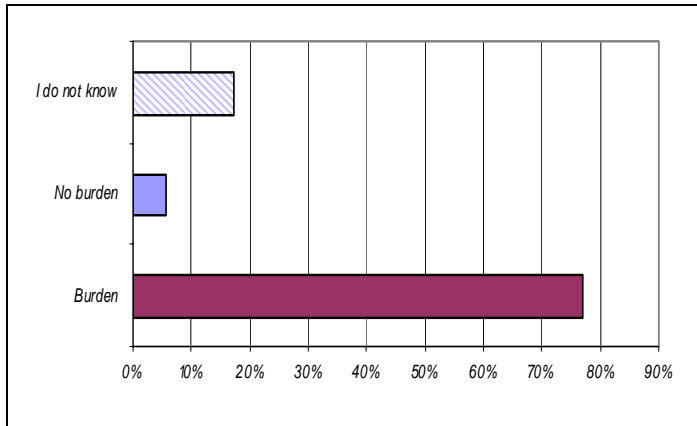
- Procedures are becoming slower;
- Costs are rising;
- Reviews and control requirements are adding up;
- Privacy protection rules are becoming excessive;
- Country and hospital specific rules additional to European ones.



**C3-12) How do you rate the level of administrative burden companies have to support in order to patent a new product and obtain protection in Europe?**

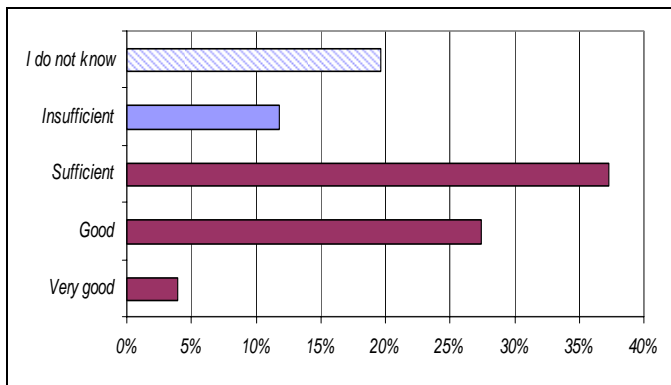
The vast majority of the respondents denounce an excessive administrative burden concerning the patent procedure in Europe (77%). In particular:

- Multiple filings;
- The procedure is time consuming;
- Maintenance is expensive;
- If the procedure becomes more expensive and lengthy, the patent life extension should be envisaged.



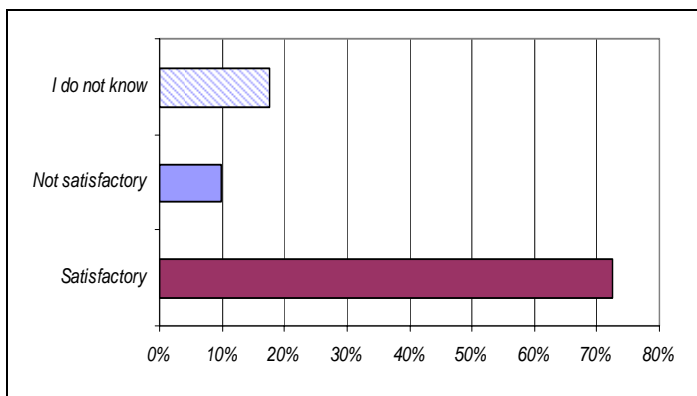
**C3-13) How do you rate the level of protection provided by the current European patent system?**

The level of protection is generally considered to be satisfactory. 37% of the respondents answered that it is “sufficient”, 27% “good” and 4% “very good”. The analysis of the comments shows that, whilst the application of the law in most European countries is reported to be good and the performance of the European Patent Office is satisfactory, the problems seem to lie in the protection of the European patents outside Europe.



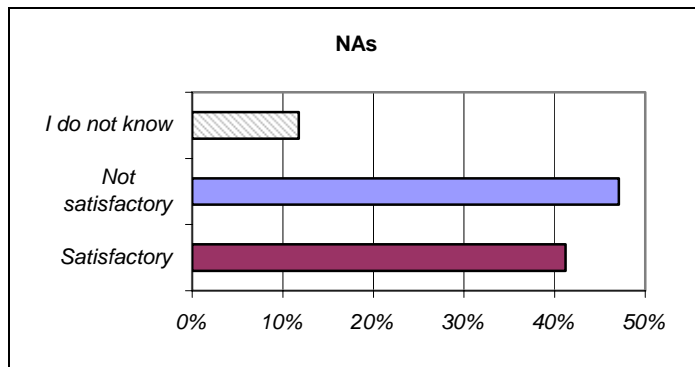
**C3-14) How do you rate the level of access to information about patents in Europe?**

The level of access to information about patents in Europe is reported to be satisfactory by the vast majority of the respondents (72%).

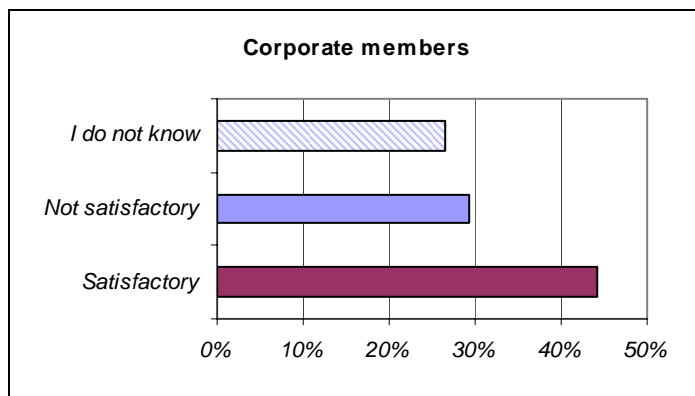


**C3-15) How do you rate the level of access to information on national public financial incentives for R&D and innovation?**

On this particular topic, there emerges a different perspective according to the type of respondent. In particular, for the NAs, 47% consider the level of access to information on national public incentives for R&D and innovation “not satisfactory”, against 41% who consider it satisfactory.

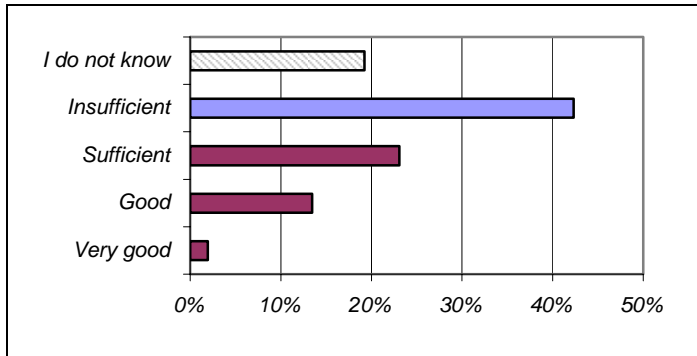


On the contrary, among the corporate members 44% of the respondents versus 29% think that the level of information is “satisfactory”.



**C3-16) How do you rate the level of access to information on European public financial incentives for R&D and innovation?**

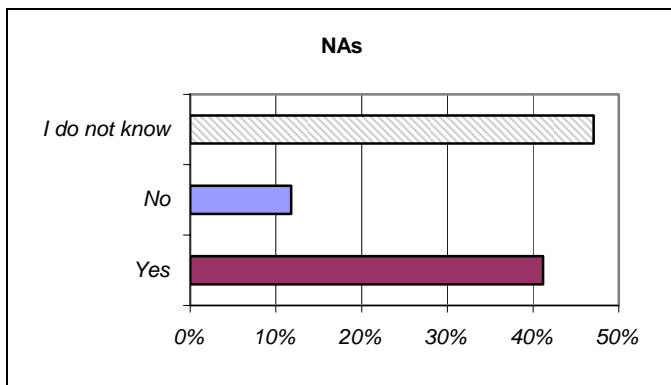
As far as the information on European public incentives is concerned, a plurality of respondents (42%) considers the level of access “insufficient”. Only a few respondents seem to be fully satisfied with it (very good 2%, good 13%). From the analysis of the comments, it emerges that it is commonly considered hard to directly access correct and complete information and the recourse to specialists seems to be the most viable -- though costly -- option.



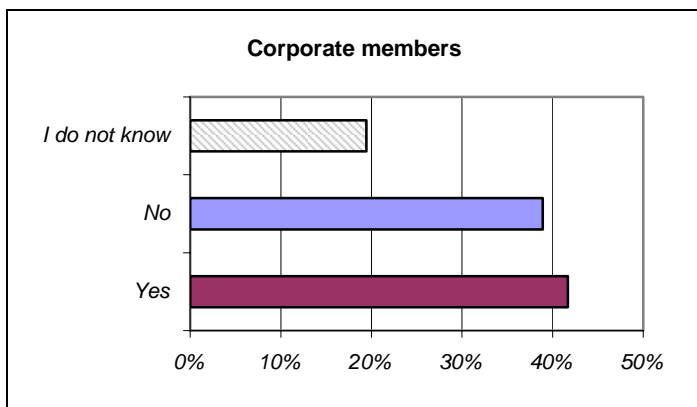
**C3-17) Does/did your company [NA: your member's companies] benefit from public financial incentives for R&D and innovation?**

The answers provided by the NAs to the question about the actual use of public financial incentives for R&D and Innovation show that:

- Almost half of the NAs do not know whether their members benefit from such type of incentives;
- Among the NAs who have this information, the majority (41% of the sample) report having members who actually benefit from financial incentives for R&D and innovation.



Despite the fact that a plurality report having benefited from financial incentives for R&D and innovation (42%), a significant number of corporate members do not report having had such experience (39%).

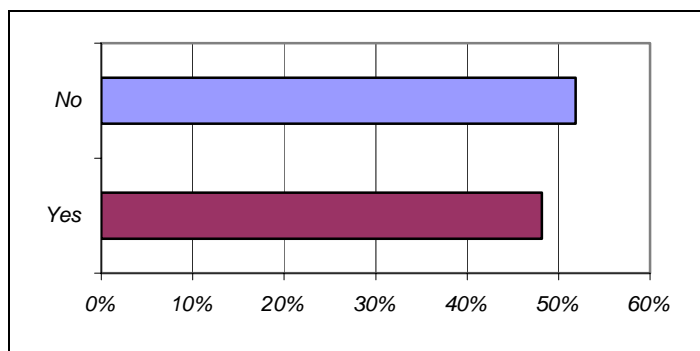


**C3-18) Do the public financial incentives in place for R&D and innovation focus on the correct priorities and therefore match your needs?**

Among those who have an opinion about that, the answers are split almost evenly between “yes” and “no”.

However, from the analysis of the comments a number of points emerge:

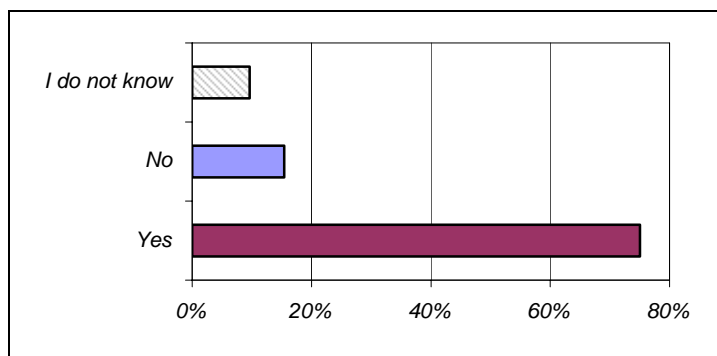
- Medical technology is not directly targeted enough (though the Seventh Framework Program of the European Commission will be more interesting for the industry thanks to technology platforms);
- Application procedures are reported to be very cumbersome;
- For big companies the financial incentives in places seem to be too tiny and spread to affect investment decisions. Fewer but much more significant amounts could have more effect.



**C3-19) Is your company [NA: your member's companies] able to successfully manage and benefit from collaboration between industry and universities?**

The vast majority of the respondents report being able to successfully manage and benefit from collaboration between industry and universities (75%).

Although the US is reported to be still far ahead in this respect, the European medical technology industry reports successful collaborations with universities.

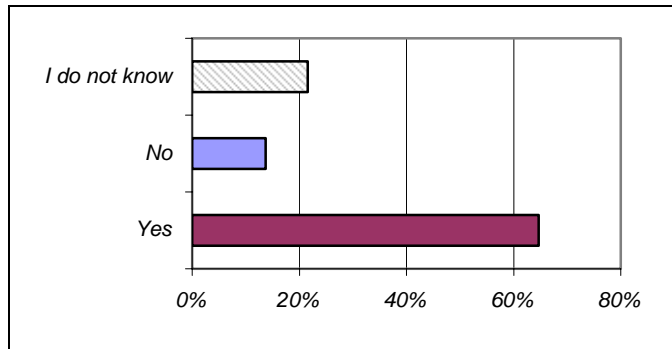


**C3-20) Do you think that the career scheme of academic researchers is overly focused on scientific publications and not sufficiently directed to acquiring business experience and the development of new products (spin offs, start-ups, etc.)?**

A large majority of the respondents consider the career scheme of academic researchers overly focused on scientific publications and not sufficiently directed to acquiring business experience towards the development of new products (65%).

It was suggested by respondents that the career scheme of academic researchers should include more business-related measures as a way to orient their research and help academic-commercial linkage.

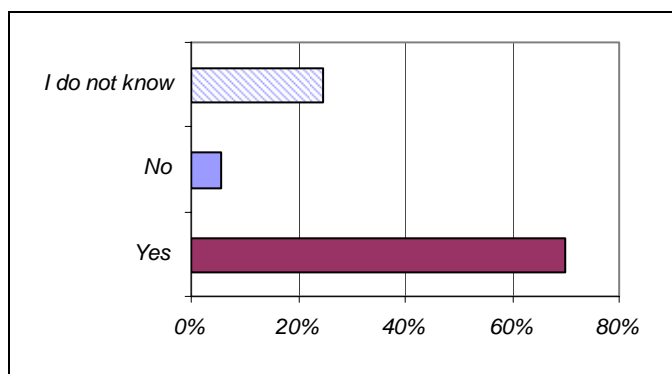
The US is reported to be far ahead in terms of licensing and start ups.



**C3-21) Do you believe that business incubators can help turn ideas into products?**

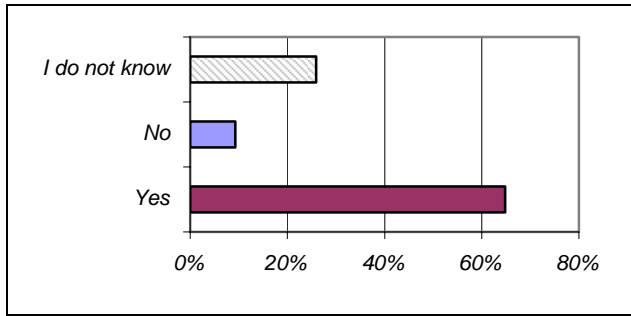
There appears to be a common belief that business incubators can help turn ideas into products (70%). A number of points are put forward:

- Professional support and low cost infrastructure is what early stage companies need;
- Their success highly depends on how the incubators are organised and managed;
- Again, the US is reported to be far ahead in this respect.



**C3-22) Do you believe that Europe is suffering from a lack of Innovation clusters?**

There appears to be also a common belief that Europe is suffering from a lack of innovation clusters (65%). In particular, even though some clusters have been created in some countries and regions, Europe is reported to be lagging behind the US in this respect.

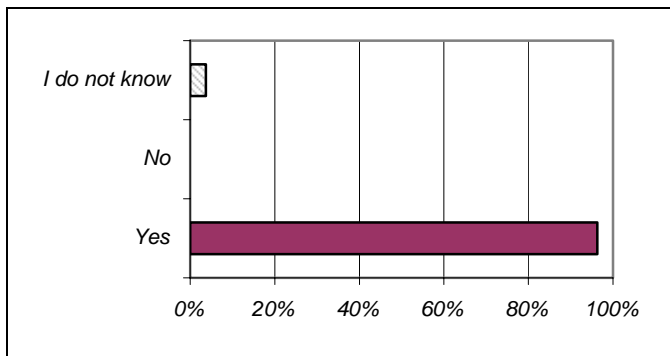


**C3-23) Do you believe that Europe and US differ in terms of attitude towards business risk and business failure?**

There is almost unanimity around the issue of the different attitude towards business risk and business failure in Europe and the US. 96% of the respondents acknowledge this phenomenon.

Two main factors seem to drive this gap:

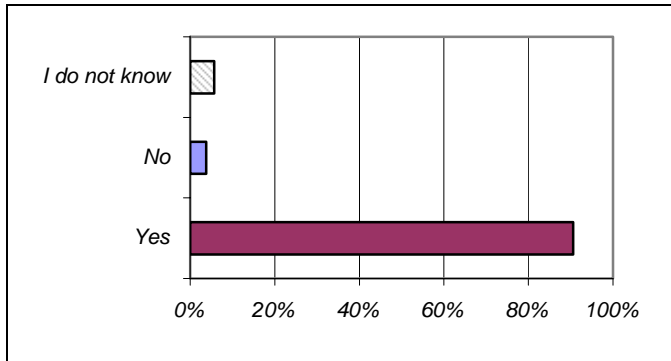
- Risk averse attitude as a cultural aspect;
- Lack of venture capital.



**C3-24) In the last few years an increasing number of mergers and acquisitions have been observed in the medical technology industry. Do you think that this will be a permanent trend?**

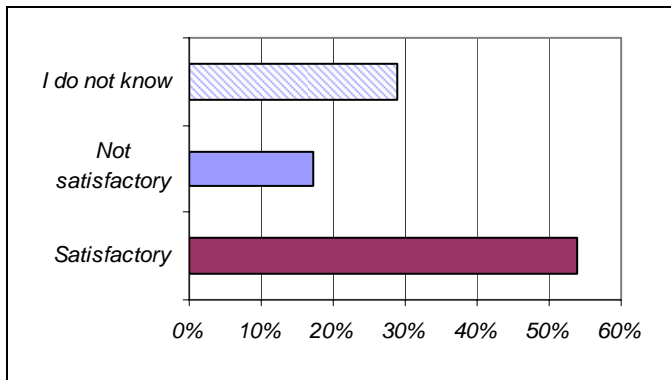
91% of the respondents think that the current trend of increasing number of mergers and acquisitions in the Medical Technology Industry will continue.

Cost containment and rationalization in the healthcare sector (HTA, purchasing groups) are expected to lead to an increase in the average size of companies to face these challenges. Moreover, major companies are currently sustaining their growth by taking over successful innovative companies.



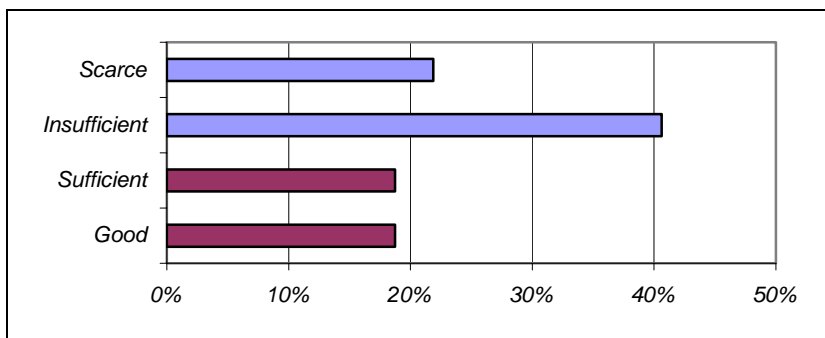
**C3-25) How do you rate the level of access to information related to potential investors (banks, venture capitalists, etc.)?**

Access to information is generally reported to be satisfactory (54% against 17%). From the analysis of the comments, it seems that the focus should be on the willingness of investors in Europe to invest early.



**C3-26) How do you rate the availability, in Europe, of bank credit for R&D?**

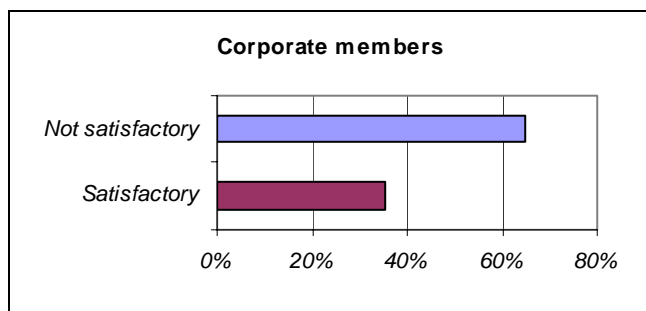
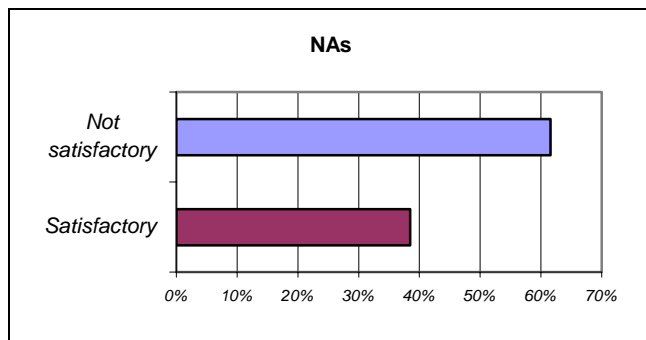
A plurality of respondents appears to believe that the availability of bank credit for R&D is insufficient. From the comments to this question it emerges that banks are perceived to look for a quick and sure return on investment and do not understand the medical technology business.



**C3-27) How do you rate the availability, in Europe, of seed capital investment (here defined as capital ranging from 0.5 to 1 million euros)?**

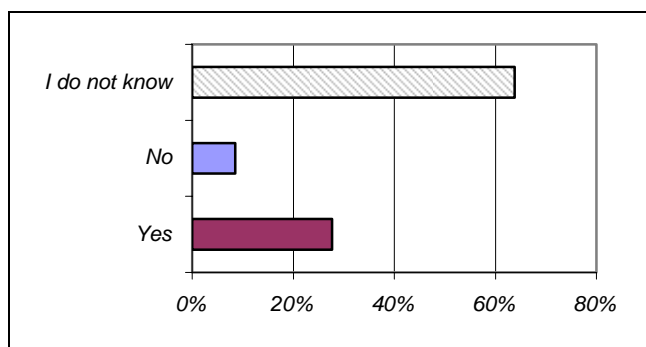
A negative opinion seems to prevail in this respect: availability of seed capital in Europe is not enough.

The analysis of the comments shows that respondents believe that venture capitalists are less interested in medical technology than in the pharmaceutical sector because the volume are lower and the return may be lower.



**C3-28) In Europe, is there a lack of post-seed capital (amounts between seed capital and venture capital) that could hamper technology uptake by depriving the development process of the necessary resources?**

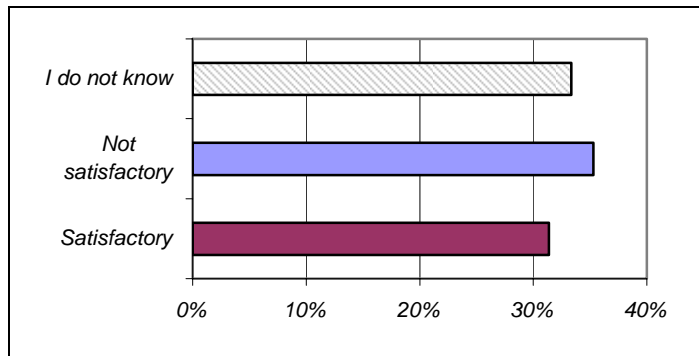
More than three times as many respondents felt that there is a lack of post-seed capital available for businesses in Europe. A number of them noted a particular lack of this sort of "intermediate" investment.



**C3-29) How do you rate the level of understanding of the specificities of the medical technology field among potential investors (e.g. venture capitalist, bank, buyout operations)?**

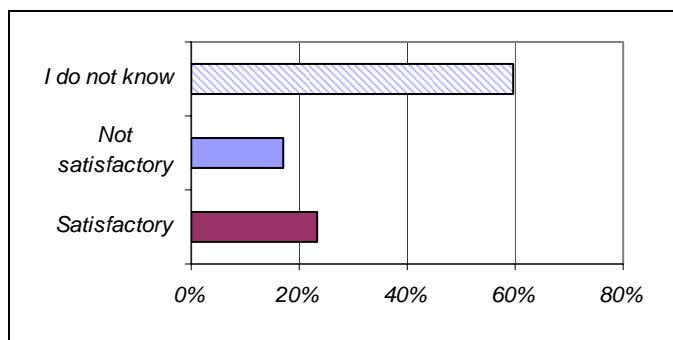
The prevailing opinion is that the level of understanding of the medical technology sector among potential investors is not satisfactory (35%). From the analysis of the comments it emerges that:

- There is often confusion with the pharmaceutical sector;
- There are only a few specialists who understand the medical technology sector.



**C3-30) How do you rate the level of protection of the inventor's rights vis-à-vis the interest of the investor during the development phase (e.g. "anti-dilution protection" as often applied in the US)?**

Respondents are split on whether inventors' rights are satisfactorily protected. They note that "good investors" keep inventors incentivised and that recent legal changes have helped, but that investors still tend to take an overly large equity stake.



## **Conclusions**

The results of this survey represent the collective voice of the European medical technology industry. It clearly shows that there are many limiters to the European medical technology's competitiveness and innovativeness vis-à-vis its overseas competitors. By highlighting the determinants of competitiveness and innovativeness, one can see which of them need to be monitored and acted upon to improve the current situation. Based on the results of the survey, Eucomed recommends that the European Commission take the following steps to improve the competitiveness of the European medical technology industry.

### ***European Market Access***

#### **CE Marking**

- Coordinated campaign to highlight the meaning and value of the CE marking
- Clearer classification systems, especially for borderline products
- Effective participation of industry in shaping of the regulatory framework of CE marking
- Stronger approval timelines for the CE marking process

#### **Notified Bodies (NBs)**

- Single European database for registration procedures, surveillance and adverse events reporting
- Increased employment of specialists for new and emerging technologies
- Increased promotion of Centres of Excellence for conformity assessment of emerging technologies
- Better harmonisation of procedures and requirements among notified bodies, especially
  - Standardisation of data and documents provided
  - Increased use of IT in NBs
- More transparency of approval procedures, and speedier reviews and fixed timelines for NB approval
- Ensuring that revised Medical Devices Directive and the New Approach sets criteria to avoid detrimental variation among NBs
- Generalised acceptance of documents by NBs in English

#### **Health Technology Assessment (HTA)**

- More involvement of industry in the development and operation of HTA systems
- Transparency of HTA process and methods used by authorities
- Assurance that new technologies are assessed by clinicians with appropriate experience
- More careful examination of requirements for clinical and economic evidence

- Harmonisation of HTA systems across Europe

Please refer to [Eucomed's HTA Position Paper](#) for more specific recommendations

## **Funding and Reimbursement**

- Ensure that DRG tariffs are kept up-to-date based on reliable data
- Provide mechanisms for incorporation of new technologies
- Better coordination between reimbursement processes and HTA activities
- Elimination of silo budgets and mentality

## **Public Procurement**

- Ensure competition among purchasers to avoid monopoly-purchaser situations
- Require tenders to consider factors beyond simply cost, especially quality of care (e.g. MEAT)
- Streamline tender processes, especially for the sake of SMEs
- Limit the size of tenders to avoid putting companies in a “make or break” situation. As the medical technology industry employs more than 435,000 people across Europe, companies that fail as a result of lost tenders can lead to high levels of unemployment
- Ensure that all companies are given the opportunity to participate in tenders, especially SMEs

## **Late Payments**

- Ensure that Directive 2000/35/EC is fully transposed in to national law and enforced by member states
- Monitor closely member state payment behaviour and provide punitive recourse against those who are consistently late with payments

## ***External Trade***

- Promote GHTF, both as it currently exists and for future development
- Pursue mutual recognition of regulatory processes as a means to facilitate external trade
- Promote harmonised international standards so as to avoid duplicative administrative processes, especially translation in to multiple languages
- Create and publicize public support programs for international trade
- Strengthen regulations against the import of low-quality or counterfeit products from abroad

## ***R&D and Innovation***

- Promote education in fields where specialists are lacking (e.g. biomedicine, biochemistry, bioengineering, nanotechnology, material science)
- Promote earlier involvement of medical students in technology
- Provide means for active physicians to participate in the development of technology
- Offer incentives for the active use of new technologies in medicine, especially in the public sector
- Create systems which require administrators to consider factors other than short-term cost
- Streamline patent system at member state and European levels
- Promote collaboration between the industry and universities, through research clusters, business incubators, especially ensuring connections among regions
- Increase R&D funding for medical technology, meaning public funding, bank credit (perhaps through a special development bank), and seed capital
- Promote the development of business skills for academic researchers

## Glossary

*DRG – Diagnosis Related Group*: a means for reimbursing healthcare providers on a fixed scale according to the diagnosis of the patient

*Eudamed*: an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission's Enterprise and Industry Directorate General and the Competent Authorities in the European Union member states<sup>4</sup>

*EUnetHTA - European network for Health Technology Assessment*: a network which aims to connect public national/regional HTA agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by the Member States<sup>5</sup>

*EUR-ASSESS*: a project undertaken by the various European HTA agencies and programs to improve coordination in several areas of HTA

*GHTF – Global Harmonisation Task Force*: a group of representatives of national medical devices regulatory authorities and representatives of industry, which aims to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade<sup>6</sup>

*HTA – Health Technology Assessment*: the collective name given to a number of activities applying systematic methods of scientific inquiry to the evaluation and use of new or existing healthcare technologies. The evaluation can focus on all impacts of a particular healthcare technology, including its clinical, ethical, social, legal and economic implications

*Micro-enterprise*: for the purposes of this survey, a company which has fewer than 10 employees and/or less than €2 million in annual turnover and/or less than €2 million on the balance sheet

*MEAT – Most Economically Advantageous Tender*: a tender in which the winner is selected based on a number of weighted criteria extending beyond cost

*MEDDEV*: collectively, the guidelines relating to medical devices directives

*MRA – Mutual Recognition Agreement*: an agreement by which two countries (or groupings of countries) agree to recognise one another's certifications, reports and conformity markings

*MDD – Medical Devices Directive*: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

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<sup>4</sup> <http://ec.europa.eu/idabc/en/document/2256/580>

<sup>5</sup> [http://www.eunetha.net/About\\_EUnetHTA/](http://www.eunetha.net/About_EUnetHTA/)

<sup>6</sup> <http://www.ghtf.org/information/information.htm>

*NBOG – Notified Bodies Operations Group*: a group which aims to improve the overall performance of notified bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation and control<sup>7</sup>

*RCT – Randomised Control Trial*: a type of trial where patients are allocated to various treatments at random to ensure statistically equivalent groups so as to eliminate the effect of confounding variables and biases

*Silo Budgeting*: a system of budgeting where funds are allocated to finite programs without regard to other programs

*SME – Small or Medium-sized Enterprise*: for the purposes of this survey, a company with fewer than 250 employees

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<sup>7</sup> [http://ec.europa.eu/enterprise/medical\\_devices/nb/nbog\\_report\\_2003.pdf](http://ec.europa.eu/enterprise/medical_devices/nb/nbog_report_2003.pdf)



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