

Exploratory Process on the Future of the Medical Devices

Potential themes for further reflection at the European level and Issues identified by the Members

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A- Introduction to the Process

Background

The medical devices industry constitutes a key sector for healthcare. It is one of the most dynamic sectors, improving and saving lives every day by providing innovative solutions for diagnosis, prevention and treatment. The medical devices industry is also a major employer in Europe. However these companies face challenges of national, European and international dimensions that may have an impact on their innovation capacity and their competitiveness. These difficulties might have consequences on the health of European citizens.

An **Exploratory Process on the future of the medical devices sector** has been put in place over the second semester of 2009 to map the existing public health and industrial challenges in the sector and investigate possible topics of reflection at the European level. This process provided industry, users and consumers of medical devices with an opportunity to share existing challenges.

Objective

The objective of the Exploratory Process on the future of the medical devices sector was to gather at the end of the process an **overview of existing public health and industrial challenges, to identify current dynamics of the sector and highlight key topics of interest at the European level** which resulted in a set of **suggested themes of potential further reflection** adopted by the Members of the Exploratory Process.

Deliverables

The Exploratory Process on the future of the medical devices sector was **an opportunity for the Commission to work together with key stakeholders** of the sector. All interested parties gathered in a common platform in order to jointly reflect on the main public health and industrial challenges for the medical devices sector.

The **sharing of experience and points of view** between the participants of the Exploratory Process constituted an important deliverable of the process and lead to the building of **shared knowledge** on the sector, **mutual trust** and **common understanding** on challenges.

The Exploratory Process offered the occasion **to map current public health and industrial challenges** in the sector and to **identify items for further reflection at European level**. Indeed, a concrete deliverable is represented by the list of issues identified by actors in areas such as (1) future challenges and opportunities for public health and medical technologies developments, (2) balance between the patients' needs and financial sustainability and (3) competitiveness and innovation of the medical devices industry.

Finally, the exploratory process on the future of the medical devices sector initiated a **momentum among stakeholders** that might result in **further reflection at the European level**.

Membership

The Exploratory Process was chaired by the Commission services which also provided for the secretariat.

The Membership represented both private and public health interests with the involvement of the following stakeholders¹:

- **EUCOMED** : Trade association representing the medical technology industry
- **EDMA** : European Diagnostic Manufacturers Association
- **COCIR** : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- **EUROM I** : European Optical Industry committee
- **EUROM VI** : European Industrial Federation committee on Medical Technology
- **EHIMA** : European Hearing Instrument Manufacturers Association
- **EUROMCONTACT** : European contact lens and lens care industry's association
- **FIDE** : The Federation of the European Dental Industry
- **CPME** : The Standing Committee of European Doctors
- **UEMS** : European Union of Medical Specialists
- **ESC** : European Society of Cardiology
- **EFORT** : The European Federation of National Association of Orthopaedics and Traumatology
- **ESR** : European Society of Radiology
- **HOPE** : The European Hospital and Healthcare Federation
- **EPF** : The European Patient's Forum
- **BEUC** : The European Consumers' Organisation
- **ESIP** : The European Social Insurance Platform
- **AIM** : Association Internationale de la Mutualité
- **PGEU** : Pharmaceutical Group of the European Union
- **EFCC** : European Federation of Clinical Chemistry and Laboratory Medicine
- **CED** : Council of European Dentists
- **EAHP**: European Association of Hospital Pharmacists

Experts were also invited to contribute on their personal capacities according to their field of expertise.

Working methods and structure

In order to steer the process in a given way, the **heads of the stakeholders organizations** involved were invited twice, to open and to close the Exploratory Process.

The Exploratory Process was organized around **two discussion sessions** with representatives of the involved stakeholders organizations and experts. In addition to a plenary session, the participants were invited to explore more in depth challenges covered within three distinct work streams.

¹ The European Federation of Nurses Associations (EFN) was invited to take part to the process but decided to withdraw after the first meeting.

- **Future challenges and opportunities for public health and medical technologies developments**
This work stream provided the overarching high level framework for the discussions. It considered the future challenges for the public health systems and how the medical devices industry could respond to them, with a particular focus on emerging needs (e.g. developing a shared understanding of future healthcare goals), increasing expectations (e.g. overcoming health inequalities), societal changes (e.g. ageing society) and the emergence of new medical technologies (e.g. potential of the e-health technologies).
- **Balance between the patients' needs and financial sustainability**
This work stream covered all the challenges of access to medical devices for the European citizen. These included issues such as how to measure appropriately the value of medical devices, how to enhance better access of patients to medical devices looking at the different factors including pricing and reimbursement policies. Challenges of the purchasing systems and payment mechanisms have been looked at in that context.
- **Competitiveness and Innovation of the medical devices industry**
This work stream investigated what are the global innovation and competitiveness challenges faced by the medical devices industry, including aspects of R&D, emerging technologies and green economy. It also covered aspects linked to the position of Europe in the world, both in the field of trade and regulatory cooperation. Finally, challenges specific for SMEs have been looked at as well.

The terms of reference of the Exploratory Process and the **mandates** of the work streams were agreed by all in order to frame the discussions. In addition, a webpage² was created for the public to access to key documents.

Timeframe

The **opening meeting** on 2nd October 2009 has been organised as a kick-off with the head of the stakeholder's organizations involved in the Exploratory Process. Each organisation has been invited to adopt the terms of reference of the Exploratory Process and the mandates of the work streams and to nominate experts for each work stream.

Considering the limited timeframe, the Exploratory Process was organised around two discussion sessions during which experts explored the challenges covered within the three distinct work streams.

The first discussion session took place on the 9th and the 10th of November 2009. During the first meeting of each of the work streams, participants were invited to identify the topics to be discussed among them and to have a first exchange of possible suggestions for a future European reflection on medical devices.

The second discussion session took place on the 21st and the 22nd of January 2010. The **second meeting of each work stream** was organised in order to (1) present the issues identified, (2) discuss among the experts of potential theme of further reflection and (3) endorse the issues identified and the preliminary themes of further reflection within each

² See http://ec.europa.eu/enterprise/sectors/medical-devices/competitiveness/exploratory-process/index_en.htm

works streams. During the last day, the **plenary session** was organised for the head of organizations to adopt the final suggestions for a future European reflection on medical devices.

B- Potential themes for further reflection at the European level

The Members of the Exploratory Process identified the following issues as needing further consideration at the European level:

- 1. Promoting innovation for the benefit of patients, healthcare professionals, industry and society**
 - a. Develop tools and mechanisms to evaluate the impact of innovation
 - b. Promote common and innovation-oriented criteria, collection of data and predictability for market and patient access (HTA, reimbursement, procurement mechanisms and smart regulation)
 - c. Reduce barriers to interaction and involvement of patients, healthcare professionals and providers, users, payers and industry in innovation and decision-making processes for access to patients
 - d. Develop a shared understanding of future education, new skills, curricula and training needs for innovative products and services in the medical devices sector.

- 2. Supporting the competitiveness of the EU medical devices sector (*e.g.* research & development, clusters, intellectual property, regulatory and trade aspects) with particular emphasis on creating a favourable environment and practical support for SMEs**

- 3. Developing a EU vision on the contribution of medical devices to new patient-centred models for healthcare delivery and health promotion and management, including transparency and better information to patients**

C- Issues identified by the Members of the Exploratory Process on the future of medical devices sector

The Members of the Exploratory Process strongly endorsed the need for a clear political vision of the role of the medical device sector in the health of citizens and the economy. The group agreed that the European Union should act to make Europe the global leader for Medical Devices by promoting innovation, efficiency and sustainable health outcomes. A strong medical device sector in Europe will play a central role in supporting the broader EU aspiration that citizens live a longer and healthier life.

1. Public health challenges

The Members of the Exploratory Process identified several **societal changes** in the EU that might impact the sustainability of healthcare systems in the future: **demographic pressures** (e.g. ageing of population, low birth-rate, etc.), **increased outside-family care provision and private payment, possible lack of healthcare professionals, need to reduce inequalities**, etc. This will require also addressing various **clinical challenges** including **communicable, chronic and lifestyle diseases** (e.g. addictions, nutrition, metabolic diseases representing 60% of the disease burden in Europe). One other major point to address will be the necessity to further improve the **quality of care**, and for example, to identify and implement clinical guidelines with the aim of reducing the existing and wide variation in guidelines for clinical practices in different Member States.

The **increasing prevalence of age and life-style related chronic diseases, coupled with medical progress that has transformed many previously fatal diseases into chronic conditions** will not only increase the financial pressure on healthcare systems, but also drive the need to change the current delivery models. National systems face the challenge of addressing **increasing needs** from European patients and citizens while coping with **increasing resource constraints**. In that context, the difficulty for Member states to deal both with resources constraints and with an increasing recourse to Medical devices was identified as a major issue. To cope with these constraints, there is a need to focus on prevention and to further develop the **“Efficiency-based Medicine”**. In this context, the Members of the Exploratory Process highlighted that the timely uptake of innovative technologies that improve the efficiency and quality of public health management programmes around patient safety and productivity of healthcare systems should be further considered. It was noted that it is also necessary to further improve the development and use of clinical, economical and societal evidence for medical devices. This evidence should increase the use of **appropriate screening and early-diagnosis programmes** to both improve **patient outcomes** and **drive efficiency**. The development of **"Efficiency-based Medicine"** will imply a steady evolution of the healthcare mode through early diagnosis and accurate treatment, ambulatory care, use of telemedicine and e-health, minimally-invasive surgery, health management, broadening the type of professionals involved with the use of technologies in healthcare settings. In this context, **patient empowerment** will become a critical factor for increasing compliance, decision-making, self-care and self-management of chronic diseases by patients.

Holistic approaches

A major issue for further reflection at the European level, identified by the Members of the Exploratory Process, is the need **to promote a paradigm shift in the healthcare policies**. Focusing on the formula "from health to wealth", the participants jointly underlined the necessity to adopt a **holistic approach** and therefore to shift from the "treatment vs. prevention" debate towards new models for healthcare delivery and health maintenance—prevention, early/accurate diagnosis and effective treatment. A holistic approach is required in order to help moving from a treatment-based health system to a **comprehensive, patient-centred, disease management approach** and ultimately to an appropriate health management throughout an individual's entire life.

Scope and role of Medical Devices (MD) sector³

To this end, the **overall visibility of the medical devices' contributions** in the economy and in healthcare should be strengthened. On one side, the EU next to the USA is the largest global market for medical devices. A prosperous industry also supports a broader EU vision of promoting growth and jobs as indicated in the 2020 European agenda. Furthermore, there remains a need to raise awareness regarding the contribution of medical devices to better health and quality of life.

Public health policies

The Members of the Exploratory Process reiterated the need to focus on **patient needs and patient-centred approaches in the healthcare systems**. They also drew attention to the **absence of clarity and visibility with regard to public health policies and strategies**. It was pointed out that there is sometimes a lack of focus and funding for the implementation of priority programmes and a **lack of harmonisation on best practices and guidelines between Member States**. The stakeholders stressed the need for medium- and long-term strategic planning in addition to short-term tactical planning in healthcare policies. The stakeholders noted that innovative technologies when introducing cost effective innovation can be a solution to healthcare problems.

Involvement, education and training of the different actors

The Members of the Exploratory Process shared the view that **the role of all actors needs to be acknowledged**. The development of new skills and professional curricula need to complement the innovation-cycle of the medical devices sector, to fully leveraging its potential. Moreover, it was noted that it is necessary to **further adapt training and skills for healthcare professionals** to the appropriate and effective use of new technologies. Bridging competences needed for medical devices (*e.g.* engineers, scientists) might be reached through **education and interaction platforms** between technology, patients and healthcare professionals (doctors, nurses, etc.). It will be necessary for all stakeholders to develop a shared understanding of future education needs in order to achieve better coordination between Member States. Finally, healthcare professionals should also be involved in pre-market evaluation and post market surveillance.

Patient Safety & Quality of Care

The Members of the Exploratory Process acknowledged that patient safety is a critical component of the quality of healthcare. Patients can be injured by or be exposed to adverse events and their **safety** be compromised while being treated. In addition, this has proved to be very **costly for healthcare systems** It was highlighted that the appropriate use of medical

³ Medical devices are those defined by Directives 90/385/EEC, 93/42/EEC and 98/79/EC,

technologies can contribute effectively to improving patient safety and controlling costs, for example healthcare associated infections, and also improve the quality of care to the individual. The exchange of information on best practice and on technologies improving patient safety and hence the quality of care should be enhanced.

Fight against counterfeit medical devices

Counterfeiting was recognized by all participants as an important issue which puts patient safety at risk. The **supply-chain in the distribution** of medical devices being not regulated, participants highlighted a risk that counterfeit medical devices enter the distribution chain more easily.

2. Encompassing innovation

The Members of the Exploratory Process reflected on the innovation and competitiveness challenges faced by the medical devices sector, identifying several areas for further reflection at European level.

The Members recognised that the sector was by itself very complex due to the **broad diversity of the products types, outcomes and lifecycles**. A shared vision within the Exploratory Process was that the **concept of “innovation”** should be considered in a broader sense, including products, services, processes, financing and the constructive engagement of key stakeholders. **Innovation and research should target public health's, patients' and consumers' needs as well as demographic trends**. Furthermore the design process should be adapted to the context in which the medical device is used.

Further reflection should be developed at European level on items such as R&D policies and intellectual property rights which can **affect the development of innovative products**. It was noted that a true EU wide patent providing the same level of protection across the EU would be beneficial.

Innovative technologies/products

Realising the positive impact of innovative technology, like e-Health, on healthcare systems is crucial. It is necessary to put in place mechanisms to ensure a robust evaluation and rapid access to market for innovative products and services with added value. But the Members of the Exploratory Process highlighted the absence of a **clear strategy for innovation** while the current fragmented approach to the uptake of innovation in the EU acts as a barrier and disincentive. This is particularly the case when medical devices incorporate technology from other existing, or novel, branches of science and technology. New developments in other sectors, both adjacent and more distant to the medical device sector, are an important source of innovation for the medical device sector. It was therefore highlighted that the dissemination of **valuable developments in other sectors** into the medical device sector should be facilitated.

With regard to **eHealth**, even though a lot has been done at EU level to promote the use of eHealth in order to improve the efficiency, productivity and quality of healthcare systems, there are still many obstacles to its development and implementation: *e.g.* no single-market, lack of consolidated governance, discrepancies between Member States in pricing, financing and reimbursement, lack of trust, acceptance and confidence, privacy concerns among stakeholders. The development of the European eHealth governance initiative is welcome.

The need to address the issue of interoperability, reliability, privacy and the need to address issues related to the organisation of the healthcare system were also pointed out by participants. The Members stressed the need to create the tools to evaluate the efficiency gains brought by eHealth.

The stakeholders stressed that the **added value to patients and health care systems of innovative technologies should be highlighted further and that all aspects of innovation** – e.g. medical, ethical, social, environmental and economic – **should be acknowledged**. For instance, **personalized healthcare** must be considered in terms of efficacy and safety of treatment. It is an approach which capitalizes on increased understanding of the differences between individuals, the molecular basis of disease and of how patients respond to targeted therapies.

Involvement for innovation

The Members of the Exploratory Process recognised that innovation is not sufficiently driven by patients', users' and consumers' needs. It was highlighted that more attention should be paid to the **organisational aspects of innovation** to systematize and facilitate the innovation process, for instance through **multidisciplinary partnerships including patients and users**. Members of the Process also stressed the fact that healthcare professionals, carers and patients should receive training and objective information on how an innovative technology may influence the whole treatment pathway and can improve quality and efficiency of care. Healthcare professionals should also be involved in training and provision of objective information to patients.

Procurement procedures and reimbursement

Some Members of the Exploratory Process noted that the implementation of procurement procedures do not always incentivise cost effective innovation. The procedures put in place tend to be rather **volume supply and price oriented** rather than value or outcomes driven, and the societal perspective is sometimes ignored. Moreover, the duration of the supply contracts can inhibit competition by keeping some actors out of the market, limiting the introduction of new products and therefore innovation in the sector. In addition, the Members of the Process pointed out that there is a new tendency to establish **centralised tenders** with increased size (e.g. purchasing consortia) which may reduce competition and may block the uptake of innovation. In particular, it could have severe effects on the viability of SMEs and stifle their innovation capacity.

However, when applied taking into consideration the improved patient's outcomes and the full benefits of innovation, procurement procedures and the relevant criteria can be used to improve the quality of healthcare delivery.

The **reimbursement/ funding systems** have also been identified as affecting positively or negatively innovation dynamics. Most Members consider that when reimbursement/funding systems are based on existing technology only, they create a barrier to developing and adopting new and more innovative technologies.

Research and development

Aspects linked to research and development were also discussed, and particular attention has been given to identifying the industrial drivers that contribute to the development of innovative technologies. The Members of the Exploratory Process noted the need for a more **enhanced R&D support at EU level**, combined with a clearer and simplified structure and

better access to funding. In particular, it was pointed out that SMEs should benefit from increased incentives for innovation aims. The Members also recognized the importance of **medical devices, and associated services, as well as the coordinated development at European level of technological and/or disease focused clusters**, in order to boost innovation.

3. Value of and access to medical devices

The Members of the Process recognised that access to medical devices is a **multi factorial challenge**, dealt within different ways in Member States and with different needs according to the type of medical devices. All stakeholders recognised that access is not the same between and within Member States. This situation, combined with the legal possibility of cross-border healthcare delivery, may lead to patients increasingly choosing in which Member State they wish to be treated.

Market Availability

The primary challenge for access to medical devices is the **availability on the market** of safe, innovative, useful and affordable products. Timing to market was raised as an important aspect. Items such as duration to obtain the CE marking and the impact of the regulatory framework for a product to be available on the market were raised as important issues. The Members of the Exploratory Process noted the importance of ensuring international regulatory coordination/harmonisation and of leveraging the European regulatory framework in order to ensure confidence in the EU system both within and outside the EU. The Members also noted that the EU could take a stronger role in leading the move towards greater global harmonisation of regulations for market access through the GHTF⁴.

Measuring value of medical devices technologies

Another issue for further reflection identified by the Members of the Exploratory Process was the lack of **European vision in relation to the measurement of value of medical devices**, and, in particular, the differences in the use of health technology assessment systems (HTA) within and between the Member States.

The Members of the Exploratory Process agreed that, if used appropriately, **health technology assessment** can be a useful tool for the decision makers to better ensure a fair access to medical interventions making the best use of scarce resources. HTA is indeed necessary in order to have an independent analysis of effectiveness⁵ or when possible relative effectiveness, long-term outcomes and cost effectiveness of new medical devices and to reassess value of technologies and healthcare services. The HTA objective is broad: to serve patients with the research of best value and best practices. The need to **understand and better balance both clinical value and societal value was indeed recognised**. However, the common understanding was that the use of HTA as a tool for decision making on access is hindered by the **variability in the application of key principles of HTA**. Also, there were concerns that HTA might be used as a cost-containment tool only.

⁴ Global Harmonization Task Force

⁵ As defined by the Pharmaceutical Forum, Effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice and Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice. <http://ec.europa.eu/pharmaforum/>

It was explained that the assessment of the value of a medical device often lacks a **holistic approach** as it does not always consider the **whole clinical pathway** and the **full life-time of a product** when it is justified (problem of silo-budgeting). It is a challenge to take into account the **impact of the different and variable clinical applications** of relative importance of the same medical device. Other aspects such as **non-monetary improvements linked to societal aspects** (e.g. quality of life, reduced hospital stay for patients, social inclusion, etc.) are rarely considered. Finally, **implications for the healthcare systems and organisations** when introducing a new medical device (changes of practices, reorganisation of services; costs, terms and conditions of financing..) are not enough addressed in the assessments.

In addition, Members believe that the **innovative element of a product** is not always appropriately captured in HTA methodologies nor the **value proposition** always clearly described by the applicant. Members also underlined the importance of respective processes **appropriately designed according to the type of product or the intervention** being assessed and to the timing of the assessment. It was noted that the methodologies, and **the evidence requirements, for the HTA processes are more easily applied to pharmaceuticals** and do not always sufficiently consider the specificities of medical devices (e.g. importance of learning curve of healthcare professionals for the effective use of a product) and diagnosis.

The need to **develop, deliver and use guidelines for good HTA practice** including transparency and stakeholder participation also in order to **ensure predictability for all actors** was underlined by the Members. Finally, the Members of the Exploratory Process drew the attention towards the fact that **requirements for clinical evidence** in order to obtain CE marking are **not designed for HTA purposes**. Thereafter, Members underlined the importance of **developing standardised, predictable and common criteria for HTA methods appropriately designed for medical devices**. The Members acknowledged that assessments of the cost effectiveness and budget impact are the responsibility of Member States.

Inclusion of medical devices within the scope of the national health insurance systems and funding systems

Inclusion of medical devices within the scope of the national health insurance systems and funding schemes for medical devices differ significantly across Europe. Nevertheless, both valuation and **healthcare coverage are crucial for the access to medical devices**. In addition to the difficulties encountered in the valuation of medical devices, reimbursement⁶ procedures represent a crucial step for patient's access. Indeed, while the CE marking process might allow for a rapid placing of some innovative product on the market in Europe, one has to keep in mind that in terms of access to patient the process of pricing and reimbursement is of primary importance. It was noted that decisions about reimbursement are too often taken on the basis of short term considerations (such as silo-budgeting) and do not reflect the need for new models for healthcare delivery.

Members of the Exploratory Process noted that there are **no common procedures and criteria** for inclusion of medical devices within the scope of the national health insurance

⁶ By Reimbursement we mean inclusion of medical devices within the scope of the national health insurance systems.

systems. Members noted the importance for reimbursement decision making (1) to be based on proven added value, *i.e.* proven benefits (as for instance clinical studies) and expected long term patient outcomes, (2) to consider an adequate timeframe for the innovation path, (3) to recognise sufficiently prevention and (4) to avoid those decisions to be based on silo-budget considerations.

Members of the Exploratory Process noted that reimbursement decision making is **not always designed to stimulate innovation**. This is due to the fact that the reimbursement decisions are not necessarily based on value, *i.e.* do not always recognize the entire care process and long-term patient outcomes. The duration of the decision making process can be inadequate for the rapid **innovation cycle of medical devices** and the **benefits for prevention are not sufficiently recognised**. Moreover, there are few common assessment criteria to evaluate if and when a product, which is still in R&D pipeline, will be reimbursed in order to enhance predictability.

It was also underlined by some Members of the Exploratory Process that the **reimbursement decisions might not be always aligned to medical guidelines** *i.e.* performance indicators and guidelines issued by medical societies influencing clinical practices.

Public procurement

Another issue identified by the Members to the Exploratory Process was that of **public procurement** which can impact on patient access.

Given the importance of public procurements for suppliers to enter some national or regional public health markets, the shared view was that the **implementation of the tendering processes** is a crucial challenging factor affecting access to medical devices. Furthermore, some Members noted that decisions made within many public procurement procedures do not fully consider **the value of a technology**, as for instance outcomes of HTA evaluations are not always the decisive criteria. In addition, public procurement procedures tend to **reinforce the effect of silo-budgeting** which fails to recognise the value of new medical products across the patient pathway. It was also highlighted that increasingly centralised and aggregated procurement procedures can act to restrict access to innovative technologies and treatments.

Late payments

Late payments might, over the longer-term, delay patient's access by putting financial pressure on healthcare providers and restricting the number of medical devices suppliers in the market. The main resulting effects of late payments are the **distortion of competition** and the unsolved issues of interests which ultimately can lead to bankruptcy of businesses, especially for SMEs. This is why EU regulation aims at combating late payment between businesses or between businesses and public authorities.

Generation of data

The Members of the Exploratory Process noted that a better understanding and use of **appropriate methodologies for generation of clinical and patient-reported outcome data** is lacking. Members indeed noted that there is a need to find appropriate mechanisms to generate real-life information about product performance. For instance, it was mentioned that registers may be a tool to monitor the use of medical devices and to collect such data. However, problems such as (1) accessibility of data including post marketing studies, (2) funding of data collection projects, (3) inadequate multiplication and incompatibility of

registers, (4) inappropriate use of data, (5) misinterpretation of outcomes, and (6) lack of commonly shared methodological guidelines for making registers relevant sources of clinical data were identified.

Information to patients and clinical practices

The Members of the Exploratory Process recognised that information to patients was another policy impacting access to medical devices. It was agreed that further reflection at the European level should be carried out regarding the importance of quality information to patients and consumers on medical devices and its impact on the choice of medical devices and related clinical practices. The stakeholders noted that the **patients and the consumer want and should be more involved in decisions** regarding their own health and that there is a need for **further high quality, non promotional, unbiased, comparative and validated information** on safety, efficacy, clinical validity, utility, implications on daily life, clinical follow up, HTA outcomes, product availability and costs.

4. Industrial challenges

The Members of the Exploratory Process identified the main industrial challenges in the medical devices sector. The Members of the Process underlined the **importance of SMEs** in the medical devices sector and the fact that the sector depends on a healthy stream of SMEs to develop new ideas and create new technologies. They also noted the need to develop incentives to drive and reward investment in **green technology**.

Global context for research investments

In the current international economic context, there is a need to acknowledge the impact of the financial crisis on **the potential return on investments** and on **venture capital resources** which might have implications on innovation. The Members of the Exploratory Process emphasised that financing for investment in innovation is too limited in Europe, indeed, the research efforts are fragmented and uncoordinated and **the access to finance and business support skills are not widely spread**. The importance of technology transfer and exploitation within the EU of the results from publicly funded science and medical research was also noted.

Financial challenges

The need for **better protection against late payments** was recognized by the participants. Late payments keep certain players out of the market and this is particularly true for SMEs. Moreover, SMEs face challenges in the area of procurement procedures due to the **complexity of the procedures**, the increased focus on product price, the little consideration of complementary services, and the length and the wide scope of the whole procedures. The possibilities for SMEs to enter the market are often restricted. Finally, stakeholders recognised the **difference of tax systems** for healthcare products where VAT levels happen to be higher for medical devices than for pharmaceuticals in some Member States.

Industrial environment

The Members to the Exploratory Process recognized the need to **ensure assistance for SMEs** in order for them to have a **broader knowledge** on the regulatory framework, access to funding, etc. With regard to the European regulatory framework in the field of medical devices, the Members of the Exploratory Process noted issues such as the lack of guidance, including for new products, in particular when medical devices incorporate technology from

other existing, or novel, branches of science and technology, and the lack of regulation of the medical devices supply chain (including internet sale). Better training on and promotion of EU system, as well as learning about other regulatory systems (export markets) were raised as important issues. The Members to the Exploratory Process underlined also the **increasing global competition**, in particular from India and China.

Regulatory framework

Some Members of the Exploratory Process noted that **the current EU regulatory system provides European patients with timely access** to good and up-to-date medical technology. However, the group recognised that there is room for improvement in order to continue to ensure patient safety and the functioning of the internal market are achieved, whilst not strangling industry's ability to thrive. This is particularly true for **post-market surveillance and vigilance activities, especially as new distribution channels allow for easy access to counterfeit and non-compliant products**. Last but not least, according to some Members of the Exploratory Process, the integration in the regulatory framework of requirements from other sectors impacting medical devices, *e.g.* environmental, would be welcome.

5. Stakeholder involvement, transparency and predictability

Involvement in decisions on access

Another issue identified by the Members of the Exploratory Process was the **lack of some stakeholders** (*e.g.* healthcare professionals, patients, industry) involvement in discussions on access to healthcare technology. For example, stakeholders might not always be enough involved in the HTA process where they could provide a useful input given that they can explain their own perspective on the value of the medical device. The final decisions will remain those of the responsible authority.

Patient empowerment

It was underlined by the Members of the Exploratory Process that **patient empowerment** is necessary to optimise treatment concordance, clinical decision-making, self-care and self-management of chronic diseases. More should be done in order to improve communication and trust between healthcare professionals, patients, payers, consumers and industry. In addition, the Members of the Exploratory Process emphasised the necessity to involve **patients, users, consumers and healthcare professionals in the early stage** of the design process of medical devices to ensure that the devices will meet real needs and expectations of patients, users, consumers and healthcare professionals.

Transparency

The necessity to improve transparency on the regulatory framework for medical devices, including on the **post-marketing and vigilance systems**, were also issues identified. Members also raised the issue of **access to restricted databases** held by the public authorities and **availability of comparative information** to support individual decision making.

Finally, Members agreed on the necessity to examine ways to increase transparency in pricing and reimbursement decisions by public authorities as well as ways to promote transparency of prices of medical devices that are consumer goods.

Governance in the evaluation and decision making processes

The evaluation process often does not include **all key elements for good governance** such as transparency, predictability, participation of stakeholders, full disclosure of conflicts of interests for all those involved in the HTA processes, independent evaluations and/or appeal processes.