

Innovation in Healthcare: from Research to Market

30 – 31 March 2011

**Flagey, Place Saint-Croix,
Brussels 1050**

Conference report

The following report is a summary of the discussions and the presentations held at the “Innovation in Healthcare: From Research to Market” jointly organised by the Health Directorate of DG Research and Innovation, in collaboration with DG Enterprise and Industry and DG Health and Consumers, on 30-31 March 2011, in Brussels.

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EXECUTIVE SUMMARY

Innovation in Healthcare is of crucial importance to Europe. Key European goals as set out in the Europe 2020 strategy and relating to economic growth and development, European competitiveness, job creation, healthcare, and quality of life, all hinge on continued and increasing innovation in healthcare in Europe.

Yet there are increasing challenges and obstacles to innovation in healthcare in Europe, and these must be addressed. Fostering innovation in healthcare is a particularly difficult process due to the escalating costs, long product development cycles, protracted regulatory approval, the structural inertia of healthcare systems and the peculiar nature of healthcare markets (e.g. private consumers and public payers). This often represents a "valley of death" for innovative Small and Medium Sized Enterprises (SMEs). Many of these challenges are inherent to the sector, and can only be addressed through the development of new, better, more efficient and innovative models. Others are common to many sectors such as counter-productive policies, market failures, or inadequate funding cycles. All require solutions.

The 2011 Innovation in Healthcare conference is the second in a series of broad, European stakeholders meetings launched by DG RTD in 2010 with the support of DG ENTR, and driven forward in a broader programme in the 2011 edition, in cooperation with DG Sanco, to address issues and challenges to innovation in healthcare in Europe.

The programme was conceived bringing together the key stakeholders, namely high-level policymakers, industry representatives, patient groups, researchers and regulators, along with experts in the fields of venture capital, technology transfer and academia.

Outcomes of the 2011 conference, the recommendations and proposals are summarised in this report aimed to be reviewed and taken into account in policy discussions within the European Commission and for future shaping of European policy and research funding.

Key findings and recommendations

General:

- Healthcare innovations that do not reach patients are a waste of time, expertise, and resources.
- Innovation is not just about technology and new products, but also about people, management of expectations and improving organisational efficiency.
- A change in mindset is required towards more risk sharing by all stakeholders around researchers and entrepreneurs (e.g. regulatory authorities, flexibility of rules of funding agencies, etc.) in recognition of diversity of context to make innovation happen.

- Move to cooperative multi-actor approach and evidence + value based systems matching supply with market demand and patient need.
- EU has strengths in world-class research excellence and a tradition of working in consortia, but needs to focus more on sustainability, viability, and international Public Private Partnerships (PPP) cooperation.
- Innovation in healthcare has a unique potential, not only as a potentially powerful driver of socio-economic development, economic growth and high-value jobs, but in terms of reducing healthcare costs and increasing quality of care to patients.
- Calls for doubling research budget (of FP7), more flexibility in rules, more bottom-up calls, continued focus on simplification especially for SMEs and small universities, more help with co-funding issues, towards a trust- and outcome-based system of funding, and continued focus on internationalisation.
- This is a timely conference, in relation to the Innovation Union, new instruments like European Innovation Partnerships (EIP), the mid-term review of FP7 and CIP in order to define future funding instruments and position research/innovation as a key pillar in EU policies and budget.

Patients & access to medicines:

- Innovation is not a goal in itself — the goal is to improve healthcare, both in terms of benefits to patients and of economic sustainability, including industrial competitiveness.
- Funding which focuses primarily on pushing technology beyond the state-of-the-art misses the point that patients do not care about what is scientifically sexy, they care about what will provide them benefit in terms of life expectancy and quality of life.
- Patients' groups and venture philanthropy are playing an extremely important role in financing R&D into cures for specific diseases in the US.
- Europe is far behind in terms of venture philanthropy – European support is needed to foster this key ingredient for alternative sources of funding.
- The main risk for venture capital is that the burden of regulatory approval is too high and the prospects too remote. Patients' groups can play an important role helping move projects closer to approval and advocating with the regulatory agencies as to an appropriate balance of risk and benefit.
- Patients' groups can play an important role, but they must become more involved, and do more than just make demands. They must educate themselves, propose ideas, facilitate the process, and source funding. There are phenomenal best practices to follow.
- Meeting societal needs has to be part of research programmes, including those that industry invests in.

Economics & competitiveness:

- Roughly one tenth of the EU's GDP is spent on healthcare.

- Healthcare employed more than 6.9% of European workers in 2006, i.e. 15.1 million people.
- The pharmaceutical industry alone generated €137 billion in sales at ex-factory price in 2007. The medical device industry represented €72.6bn in 2007. 80% of these companies are SMEs.
- The pharmaceutical and the medical device industries show a trade surplus of €34.8bn.
- Markets are global – where fast growing competitors are making massive investments into healthcare R&D and industry.
- Innovation is the key to economic growth, labour productivity, and public health.
- Innovation is key to European competitiveness.
- Investment in multi-factor productivity (MFP) & intangible capital account for between two thirds and three quarters of growth from innovation.
- Innovation has been the force behind the competitive advantage of developed economies. As developed economies, we have no alternative but to grow through innovation, innovation must be our route forward out of the crisis.
- Europe cannot do this alone. The challenge is to develop competitiveness through new partnerships.

Framework programmes:

- There was almost universal consensus that the Framework Programmes have improved significantly, but it was emphasised that further evolution and simplification are required.
- Only 5-10% of FP projects led to a product or service on the market, yet 51% of SMEs involved in FPs declare commercial returns on these projects. Real SME involvement (not symbolic or secondary) provides the best chance for eventual use of results and commercialisation. SME involvement must be increased.
- Innovation does not happen in silos. Stop the ‘silo-thinking’ in funding programmes. The focus should be on what it takes to get the desired outcomes, not on specific disciplines.
- Increase the focus on funding Proof of Concept with separate lines of funding for early stage (pre-FP) PoC, and for pre-commercial development and clinical trials.
- If projects aimed at developing new medicines are to be financed, for any chance of success the evaluators must be people who understand industry product development and trials, not academics.
- Europe is losing promising projects because they cannot be re-funded under current FP programmes and there is a shortage of private sector capital. There is need for continuity of funding through human Proof-of-Concept.
- Not all funding should be for collaborative research. It is often not appropriate. Initiate at least some lines of funding available to single companies or universities for a given project. This is crucial if the goal is to actually get new medicines or technologies onto the market and benefitting patients.

- Cut funding early for unsuccessful programmes and use it to extend successful programmes.
- More joint international funding.

Technology transfer & innovation market:

- Technology Transfer capacities remain generally weak in Europe. There are few tech transfer officers with both a scientific and business background and a successful track record of licensing and bringing healthcare products to market. Those who do have these qualifications are in high demand, and universities and institutes must compete with pharma and biotech companies to recruit and retain them. European initiatives are needed to support the following:
 1. recruitment and retention of professionals with the right expertise and qualifications;
 2. training and capacity building of current tech transfer officers to develop expertise, industry and market understanding, and key networks and relationships with their finance and industry counterparts;
 3. secondments and exchanges between industry and technology transfer offices;
 4. funding of IP funds or pools for universities and research institutes;
 5. building on, and increase of current EIF technology transfer funding.

Finance:

- Access to finance remains perhaps the most significant obstacle to innovation in healthcare in Europe. Measures are needed to encourage limited partners (LPs, institutional investors in VC funds) to invest in healthcare venture capital in Europe, and for professional venture capital investors to raise and manage new funds in Europe and invest in European companies and projects. This means ensuring a strong source of European funding, and not further discouraging investment in innovation in healthcare by taxing long term, value creating expert investors who help build Europe's companies as if they were the same as speculative traders, hedge funds or commercial private equity breaking up assets to achieve fast returns.
- Europe should learn from alternative sources of funding like the Wellcome Trust, and the many more models of foundations and patients groups which provide R&D funding for specific therapies in the US.

Regulatory, HTA, pricing & reimbursement:

- The fragmentation of HTA, pricing and reimbursement throughout the EU Member States was raised by various panels and speakers as a major hurdle and inefficiency in the European market which makes Europe much less competitive than it should be and hinders through cost and delay the introduction of beneficial new therapies, diagnostics and devices across Europe. A need for the improvement of the European context was stressed.

- Regulatory clinical trial design was seen as not being particularly well suited to the needs of specific patient groups, and not at all suited to personalised medicine. A need was stressed to set different criteria for clinical trials and the size and selection of patient cohorts to be more relevant for stratified medicine, as well as a trials and approvals process for truly individualised medicines.
- If we want to see the development of personalised medicine and the benefits it offers, we need to frame value and reward for innovation in personalised medicine, including regulatory approval, HTA, pricing, and reimbursement.
- Diagnostics are key to ensuring efficient expenditure and to personalised medicine. The current limitations on the number and cost of diagnostic tests by national payers to control costs are counterproductive and will result in much greater expense over time. Diagnostics must be properly valued and reimbursed if we are to get to an effective, efficient and affordable healthcare system.
- ‘Stop treating tomorrow’s needs with yesterday’s models’- need for improved evidence based decision making (e.g. use of (mini) HTAs).
- Focus more on prevention, as it is more cost effective.
- HTA should not be different for personalised medicine, but the question is how we define HTA. If you raise efficacy by targeting the population, it should be considered more efficacious.
- Improving the system at all levels (multi-stakeholder approach with active participation, e.g. of patients) in a coherent way is key to ‘Innovation for Sustainability’: there is no alternative with the ageing population, rising costs of healthcare system and severe budget constraints.

BACKGROUND AND RATIONALE

In light of the continuing financial crisis and the massive impact this was having on the biotechnology sector, especially SMEs, the first edition of this conference in 2010 focused primarily on the challenges of healthcare innovation from the perspective of SMEs, focusing understandably on access to finance to bridge the “Valley of Death” faced by many excellent European biopharma and medtech start-ups. It also put the spotlight on the challenges, best practices and opportunities for improvement in technology transfer, public-private R&D collaborations, European fragmentation, and European funding for R&D. Many of the proposals in 2010 were echoed and re-emphasised at the 2011 conference.

Yet the 2011 conference took a much broader approach, and dealt also with equally crucial issues such as access to healthcare and innovative medicines, Healthcare Technology Assessment, pricing and reimbursement, alternative sources of funding, and fostering entrepreneurship and innovation. The set of outcomes was therefore much broader, yet what was exceptionally noteworthy was the fact that in so many different sessions, with different topics and different stakeholder groups represented, so many of the recommendations were very similar. There are again, as in 2010, and number of recurring obstacles, challenges, weaknesses and threats identified, and similar solutions were proposed by a very broad range of stakeholders from patients’ groups, to CEOs, to technology transfer directors, to investors, to industry executives, to non-profit directors, to economists.

Scope of this document

The following report is a summary of the discussions and presentations during the event.

This report does not endeavour to provide a word for word record or minutes of the meeting, but rather to summarise the key points discussed, to extract the key issues raised and challenges highlighted, and in particular to focus on the recommendations of the expert panels and on solutions proposed. In short, this report is intended to capture and crystallise the key outcomes of the meeting, the recommendations and proposals made so that these may be reviewed and taken into account in policy discussions within the European Commission and for future shaping of European policy and research funding.

Method

The method has been loosely based on the application of a basic SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis applied to the various discussions, and then to the overall conclusions and outcomes. As the purpose of this initiative is to generate a clear picture of the major obstacles to innovation in healthcare in Europe, provision of world-class healthcare to Europeans, and the development of a strong and competitive bio-economy in Europe, the primary emphasis was placed on weaknesses (or obstacles, challenges), threats, and opportunities to build on best practices, and to implement changes and solutions.

Moderators of each session were briefed in advance that a primary goal of each session in the programme was to draw out the opinions, experiences and insights of each of the assembled panels of stakeholders and experts, and to specifically ask them to identify their key problems, challenges and obstacles to innovation in healthcare in Europe as related to the topic of their session and their area of expertise, and more importantly the proposals and solutions for improvements. Sessions were further enriched by debate with the audience.

Official opening and keynote session

Robert-Jan SMITS, Director-General DG Research & Innovation

Mr. Smits opened the first plenary session to set the scene by giving an overview of the objectives of this conference and insight into the context from the perspective of the European Commission. We are fortunate to hear contributions from the Commissioners of DG Sanco, DG Enterprise and from DG Research & Innovation.

Last year's conference focused more on the participation of SMEs in the FP7 and barriers and challenges they experience in bringing products to the market. Fostering innovation in healthcare is a particularly difficult, expensive and long process that includes clinical evaluation and regulatory approval. It takes between € 0.5-1 billion over a period of 10-15, sometimes 20 years, to develop an idea into a viable, marketable and profitable pharmaceutical product. There are a lot of pre-requisites and conditions to ensure good knowledge creation and transfer that will lead to innovation for the benefit of patients and the economy. Several recommendations were made in the 2010 conference report. Since then the Commission has taken a number of steps in line with those recommendations, important additional measures are currently in preparation. Measures for simplification of the framework programme have for example been taken, progress on the EU patent is finally happening and the innovation policy is resulting in funding for research that is more aligned with innovation. One example is the new innovation partnership for active and healthy ageing. The three aims are to remove bottlenecks preventing ideas from reaching the market, to make Europe a world-class research performer and to address the grand challenges across the EU in partnership.

These conferences are important to involve all stakeholders in following up on progress made; therefore the discussion will focus on the *strengths, weaknesses, opportunities and threats* (SWOT) analysis and recommendations for improvement.

This year there was more attention to the whole value chain from Research to Market, to ensure that research results are brought to the market, and that the lack of venture capital in Europe is addressed. Attention was also given to how the healthcare system works and copes with new delivery models. Many stakeholders are involved in the healthcare system and therefore academia, European industry, policy makers as well as patient associations were represented in this conference. Sessions covered knowledge creation, fostering entrepreneurship, knowledge transfer and innovation funding. In addition to case studies, attention was given to a multifaceted approach to rethink the entire healthcare system to make it more sustainable, affordable and accessible.

The outcome from this conference will be used, together with the input gathered through the open consultation on the Green paper entitled 'From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation funding', to design the proposals for the next generation of EU funding schemes that will be presented by the Commission to Council and Parliament before the end of 2011. The objectives are to position Research & Innovation as a key pillar in this EU Budget.

Miklós SZÓCSKA, Minister of State for Health, Hungarian Presidency of the Council of the European Union

"Health sector modernisation and innovation from the governmental perspective"

His presentation started out with the statement: "we have a paradox: we need to become more efficient within the limits of financial constraints, but the only option is to invest in innovation of the system". There is a need to do more for accessible prevention systems, to change our research culture, and change access to interventions for patients across Europe. These are challenges for Hungary's six-month EU Presidency this year. Secondly, we need to address professional pathways; we already lose 15% of our best brains. The challenge is to use our existing labour force more efficiently: this is fundamental to having a sustainable healthcare system. Thirdly, we need to improve our regulatory bodies, the struggle with bureaucracy and how we evaluate our projects. In other words: again a need for systemic innovation. Fourthly, changes in the reimbursement system are needed. The right incentives need to be put in place to bring products to the market faster. Fifth, there is a need for active partnerships with patient organisations, nurses and other professionals in the sector. Finally, the full cost of research needs to be recognised, especially in the new member states, where the research funding supplied is often less than the full costs. This would help provide the incentives needed to stop the brain drain from these countries.

MEP Maria Da Graça CARVALHO, ITRE member and Rapporteur for simplifying the implementation of framework programmes

Mrs. CARVALHO provided an overview of the future of the different European Research and Innovation programmes. This is a particularly crucial moment for us all as the Parliament, the Council and the Commission are in the process of conducting the mid-term review of the FP7. They have also already started working on the FP8 and on the future EU budget, post-2013.

First she focused on the simplification process. The EC has made considerable progress in this area recently. Problems have grown in scope over the years, especially for SMEs and small universities, as the complexity and size of budgets has increased. She recommends moving away from a cost-based to a more trust-based approach: simplifying the monitoring of the financial aspects and reinforcing the (peer) review of technical and scientific processes and outcomes.

Secondly, she flagged the importance of the mid-term review of FP7 and proposed major guidelines for FP8. FP7 was designed before the financial crisis and with over 50% of the budgets still available some priorities may now need to be reconsidered. Perhaps we need thematic programmes that are more market oriented, more bottom-up approaches relevant to SMEs, and themes closer to the grand challenges (energy, environment, people & ageing society/healthcare, industry competitiveness in a global world). For FP8, she would see five principles: trust-based funding, linking frontier to applied research and demonstration/valorisation/innovation activities, simplified instruments, more coordination with structural funds for research capacity building, and finally enhanced international cooperation. The programme could be organised around three broad pillars: science-driven (e.g. cooperation projects and mobility), industry-

driven (JTIs, SME programmes) and policy-driven activities (CSAs and other cooperation programmes addressing great societal challenges).

The third part of the talk dealt with the present and future budgetary aspects and the need for increased funding for the EU Research and Innovation programmes. She made a recommendation that the budget should be doubled in FP8, as European research is chronically underfunded.

Alastair KENT: Chairman, European Platform for Patients' Organizations, Science and Industry (EPPOSI)

“A Multi-Stakeholder Approach to Sustainable Innovation in Health Care”

Sustainability in healthcare needs to be multi-stakeholder driven. Innovation is not axiomatically a “good thing.” To be “good” innovation must address objectives valued by society. Healthcare innovations that do not reach patients are a waste of time, expertise, and resources.

In the area of healthcare we cannot afford a shotgun approach where we shoot off in all directions based on our own agendas, we need to identify the priorities and secure consensus across the different stakeholder groups. Ultimately it is citizens' money that is being spent, not just national and European public funds, but also the investment of private money. If there is no thought as to how that money is going to deliver benefits, people will not want to make that investment.

The frameworks for research and innovation must be proportionate and appropriate to the problem. Policies should be consistent over time and between products.

Consistency is required in all steps of the process, from first approach to marketing authorisation, from clinical benefit and HTA to pricing and reimbursement and from workforce capacity building to infrastructure to political will. For FP7 and FP8, simplification is really needed. FP7 promised simplification and ended up worse than FP6. We need a regulatory framework that is proportionate and appropriate and properly weights benefits (to patients, to society) and risks. It must be consistent over time and between products so that "goal-posts" do not move just as you think you are reaching the target in terms of bringing a product to the market. This kills innovation, and kills SMEs.

We need to stop treating tomorrow's healthcare needs with yesterday's models. There is much talk of innovative medicines, personal medicine, and gene therapy, but the regulatory model of large-scale double-blind clinical trials may no longer be appropriate for certain medicines even if the patients were all from the same phenotype.

We must remember that entrepreneurship is not the sole preserve of SMEs. It is multi-faceted and requires input from all stakeholders (academia, clinicians, patients, planners, politicians, and industry).

Reaching the goal requires public support, patient engagement, and flexibility. Not all innovations look the same, and not all innovations are as good as they appeared at the start of the process. The first "out of the box" is not necessarily the best "out of the box". It may be beneficial to patients and therefore should be approved but it can

continue to be improved through incremental innovation. Incremental innovation is therefore highly valuable and must be incentivised. The right policies must therefore be flexible and recognise this.

Guy LEBEAU, chairman of the European Medical Technology Industry Association, EUCOMED

EUCOMED represents 25 national associations plus 58 corporate members of the medical technology industry in Europe. This is a very diverse sector with 22,500 companies of which the majority are SMEs, nearly half a million employees and a combined annual turnover greater than €95 billion. Mr. Lebeau presented the innovation challenges in the medical technology sector and the role that Europe can play to stimulate health research activities. Innovation in this sector focuses on improving healthy quality of life, improving efficiency of healthcare systems, addressing overburdened healthcare professionals and enhancing their technical competence. Innovations can be realised with a more value driven and market oriented focus, so that regulations and costs are less important as barriers to change. The key is to find the right balance and create smart systems, not only to improve the quality of people's lives but also the changes needed to help build new models of healthcare delivery. EU initiatives like the Entrepreneurship and Innovation Programme and Innovation Union strategy play an important role there to stimulate multi-stakeholder collaborations.

Alexandre Delacoux, Executive Director, European Biopharmaceuticals Enterprises (EBE)

"Challenges & key success factors for the biopharma industry in Europe"

Innovation is needed to address fundamentally unmet medical needs and for investment into patient care, improving the quality and efficiency of European healthcare systems, nurturing Europe as an attractive territory for added value industrial and R&D investments, and leveraging technological and scientific advancements.

We should recognise that innovation in biopharma has not met expectations. R&D spend continues to increase but the number of innovative medicines is still dropping. This is partly a result of an unrelenting selection process and very long development cycles, but delayed access to treatment, in the form of delays from authorisation to market access, have compounded the problem.

It is therefore critical to encourage innovation, and European programmes are important because they seek to address research bottlenecks. The financial crisis has worsened the financing of innovative SMEs. There remains a major lack of start-up capital, the number of VCs is decreasing, and in some countries biotech SMEs raised no biotech money at all in 2010. This problem must be addressed.

The regulatory framework is evolving, but a better balance and relationship is required between the European Medicines Agency (EMA) and Health Technology Assessment (HTA). Europe needs to accelerate market access in the 27 Member States in order to improve patients' access to innovative medicines. Improvements are needed in both patent and data protection, which are key to our industry.

- Industry's role is in bringing new, targeted products to market and actively working with research institutions.
- The EMA's role is in ensuring heightened safety, efficacy and quality.
- Government's role is to fund innovation and clarify the role of HTAs.

We need to work together to find how these three elements combine to provide the right framework for innovation in healthcare products in Europe.

Iain GILLESPIE, Head of the Science and Technology Policy Division, Organisation for Economic Cooperation and Development (OECD)

“Innovation in Healthcare – the Economic Case and Some Current Challenges and Opportunities”

Markets are not just about making something available; in healthcare they are about getting the right new innovative medicines onto markets, available to patients and making them well.

Global markets – there are new, fast-growing markets in the world, we all know who they are. No one is trying to develop a medicine just for Europe, or just for the USA. They are targeting multiple markets. A growing world population will reach eight billion by 2050 with low growth, or twelve billion if rates remain high. Challenges will include major infectious diseases but also chronic disease epidemics worldwide.

Innovation is the key to growth in economies and labour productivity. It is key to productivity growth. It is key to public health. And it is key to continuing European competitiveness and leadership. As a measure, Multi-Factor Productivity (MFP) is not perfect but is the best estimate we have of innovative behaviour. Investment in MFP and intangible capital account for between two thirds and three quarters of growth from innovation, and therefore cannot be ignored. Innovation matters. It directly impacts economic growth and development, employment, GDP, etc. It has been the main advantage of the developed economies. And therefore it must be our route forward out of the crisis. As advanced economies we have no alternative but to innovate.

Productivity in pharmaceuticals is in trouble, the cost of bringing a New Chemical Entity (NCE) to market is enormous and rising. The financing of R&D is also changing over time. Proportionately there has been a very big rise in industry funding as the government share has declined over the years, but the financial crisis has had a strong negative impact on the availability of venture capital. Private funding is therefore not available to the extent that it once was, and as a result much innovation is even more highly reliant on public sector science and funding. The vast majority of patents cited in related fields are public sector funded. Therefore investment in public sector R&D matters, if anything, *more* than it did 10 or 20 years ago, and further investment is needed.

Yet we need to understand that innovation is not always what we – or policymakers – tend to think of it. It is not in silos. It is about convergence and bringing different sciences together, but funding is not granted that way. So, for Framework Programmes, please get us out of these silos. The innovation cycle is an interactive circle of components, but that is not the way it works in funding, which still follows a linear format of discovery, development, delivery, and diffusion, rather than engaging in a virtuous innovation cycle. Canada's policy efforts (Industry Canada and Health Canada)

are a good example of moving away from a linear model, and while it still only goes one way and needs to go two ways, it is a significant improvement that can be looked to as a model to be improved upon.

IMI is a good model of multi-actor involvement and looking across the different actors in innovation. But it needs to go beyond the pre-competitive stage. Matching supply and demand and getting the value proposition right will be at the root of success.

- Partnership is key. Risk must be shared.
- New governance approaches are emerging but need to be evaluated and steered.
- Should policy be set by regulators? Or should regulators be guided by policy?
- A collective approach to evaluation and dealing with new technologies, new issues, new demands and challenges is needed.
- Cooperation in science is increasing; it is a much more global enterprise than ever before. More patents are with foreign co-inventors globally, except China where the percentage of patents with foreign co-investors is dropping.
- China is the big rising power in R&D spend, accounting for 30% of the increase in R&D spend globally in 1996-2001 vs. 2001-2006 came from China.
- Europe – we still do not have a single European patent. I am speechless!
- Developing collaborative networks and markets, IP exchanges, patent pools, drug development platforms, brokering services, and networks, etc. will all be crucial ingredients.
- Europe cannot do this alone. Talent is becoming increasingly global, so is research, and innovation. Markets already are. The trick will be to develop competitiveness through new partnerships.

Panel Discussion

In response to a question with regard to the comment about regulators setting policy or responding to policy, it was explained that this was not meant as a controversial point, but as a plea for a collective approach to evaluation and dealing with new technologies, new issues, new demands and challenges. There is also the question of how does one change the classic clinical trial to make it more relevant. Singapore is probably the country that is most innovative in terms of getting new products out to the market by selecting small but more relevant patient cohorts. However, this is policy-led – it is part of innovation and healthcare policy; it was not started by regulatory agencies.

Other panellists commented on examples of good practices where regulators have taken a lead, such as the Orphan Medicinal Products designation. Yet they emphasised that the regulators would not have been comfortable going out onto thin ice and being innovative if they did not know that European policy makers were behind them.

Additional funding for international cooperation was endorsed, but the need to go much further and be much more strategic in international collaboration was highlighted.

Europe needs to create a framework where there is a coherent expectation of sharing and results. Advanced therapies have often been developed by academic groups that do not understand the hurdles that face them, so there needs to be a framework for increasing understanding of the appropriate development path to meet regulatory or HTA expectations.

The medical device industry in Europe may well be very flexible and close to the market, and can adapt, but only if it has the discussion about product definition early on. It is in a strong position globally, but this lead will be lost if not proactively built upon and protected.

The current fragmented approach of approving innovation and then trying to figure out how to pay for it is at the root of current problems. Europe needs to get to a more integrated, strategic framework for determining the concept of value for approvals and reimbursement. Member States will not likely lead in this regard. It will be up to the EC to come up with a framework for determining value in a systematic way and get to a more strategic and harmonised approach. It is not just about increasing spending; it is also about stopping spending on things that do not work.

Session A1: Accelerating Knowledge Creation

Chairs:

Ruxandra DRAGHIA-AKLI, Director, DG Research & Innovation

Nathalie MOLL, Secretary General, EuropaBIO

Panel:

Tine BRYAN STENSBØL, Divisional Director, Lundbeck

Björn EKSTRÖM, President & CEO, Olink

Andras DINNYES, Director, Biotalentum

Marco D'ANGELANTONIO, CEO, Health Information Management

The aim of this session:

This session was to give insight into how the various instruments (such as FP7, CIP, Cohesion funds) can enhance innovation and how resources and expertise can be pooled better. The objectives of the Commission are to build on lessons learned, to broaden the SME participation, to increase EU competitiveness and to increase impact in society. Examples of new partnership models are the EDCTP (joint programming with the member states), IMI (joint funding with industry), new European Innovation Partnerships (healthy aging), etc.

Two key challenges in these new partnerships remain long-term financing (coordinate support from European Investment Bank?) and reaching the agreement on how to handle Intellectual Property Rights. For example, for many SMEs IP is a core issue while their interests are not always aligned with those of academia. In the Eurostars programme the funding rules differ per country resulting in uncertainty about whether all partners in a consortium will be funded. For the coordination of a project 'size of the coordinator and track record' do matter, making it very difficult for a young SME to lead a project, even though they might be more efficient than an academic partner. Other challenges are recognised at the level of liabilities, ethics and above all securing subsequent financing: generally projects have a short life span, while product development takes many years.

Strengths:

- ★ Public funding comes without the strict requirement of return on investment that venture capitalists have, is good as seed money, and is the only transnational source of funding for high risk innovation.
- ★ Networks are important, across disciplines and countries, facilitate learning from each other, access science, access infrastructures & information & future markets through partnerships.
- ★ Public funding programmes improve cohesion and understanding between cultures.
- ★ Ensure tax payers' money actually gets invested in R&D.
- ★ Brings together academia, big and small industry.
- ★ Ensures emphasis on interaction of the stakeholders of the entire value chain.
- ★ Provides diversity in programmes and in funding instruments.

Weaknesses:

- ★ Co-financing is difficult for early stage SMEs.
- ★ Time to contract is too long.
- ★ Covering the entire life cycle from R&D to market requires multiple submissions to different funding instruments.
- ★ Different rules apply for different funding instruments.
- ★ SMEs and academics within consortia find it hard to agree on IPR.
- ★ Sometimes financial rules are in conflict with local accounting rules, post-ex audits contradicting general project officer recommendations.
- ★ Length and costs of negotiation up to the contract with the Commission.
- ★ Submission cost and complexity can deter newcomers.

Opportunities:

- ★ Expectations/curiosity regarding European Innovation Partnerships. Would they complete with or coordinate the other EU programmes?
- ★ Public consultation on future funding programmes.
- ★ More bottom-up approach from applicants for the definition of the topics.
- ★ Calls that are relatively undefined in content/generic title and published several times a year.
- ★ Possibility to renegotiate budgets and timelines for successful projects.
- ★ Opportunity to build on the synergies that are created.

Threats:

- ★ Rigidity of contractual framework could limit innovation because new avenues cannot be pursued/explored.
- ★ Risk taking too limited (young start-ups are excluded because of need for co-funding).
- ★ If project size becomes too big, SMEs cannot be (financial) coordinators as defined by current financial regulations.
- ★ Threat of national VAT rules changing (e.g. EU funds no longer tax deductible).
- ★ Limitation of international contribution in programmes such as IMI.
- ★ Elimination of additional cost model.

Recommendations:

1. Flexible project time with flexible partnerships that can change during the course of time from innovation to product filing.
2. Shorten time-to-contract and lighten monitoring and improve performance of external agencies (REA etc.).
3. Create two-stage submissions to reduce paper-work.
4. Increase transparency of evaluation system and outcomes.
5. Create a system to allow very young high-potential academic groups or start-ups to access funding.
6. Clarify accounting rules and requirements and maintain them.
7. Improve electronic reporting systems to avoid bugs.
8. Regularly monitor outcomes and consider ending the funding when the outcomes do not meet minimum standards or expectations and use recovered money to extend highly successful projects.
9. Create joint international funds e.g. EU with US, China, etc.
10. Implement the EU Patent.

Session A2: Fostering Entrepreneurship

Chairs:

Peter DROELL, Head of Unit Policy Development for Industrial Innovation, DG Enterprise and Industry

Frank HEEMSKERK, CEO, Research & Innovation Management Services

Panel:

Nevenka KREGAR, Director Educell

Julianna LISZIEWICZ, President & CEO, Genetic Immunity

Ernö DUDA, Director, President Hungarian Biotechnology Association & CEO Solvo Biotech

Onno VAN DE STOLPE, CEO, Galapagos

The aim of this session:

This session was to discuss challenges and barriers from the perspectives of small biotech companies, via a mature publicly listed biotech company to regional initiatives that can help foster entrepreneurship in Europe. Beyond the challenge of finding money, what other barriers do you face and how did you go about them? Discussion revolved around elements critical to growth, challenges to grow beyond the initial stages, challenges at level of management skills to make the right decisions at the right time, etc. Challenges discussed included changes in legislation or regulatory rules that greatly affect product development plans, unrealistic expectations from investors, need for more flexibility in rules from authorities (change in mindset), the need for flexibility to change business models according to change in the market needs, etc. But also suggestions to use some of the unique benefits of working in new member states within the EU, to fight the brain drain there, the need to enlarge the talent pool with business expertise, etc.

Strengths:

- ★ There is an excellent science and technology base in Europe.
- ★ Strong/new business models are present with leadership that pays attention to achieving social and economic sustainability.

- ★ Funding programmes like FP7 with a tradition of open cooperation with the world, with experience to benefit from cultural diversity.
- ★ FP7 favours working in consortia, helping to achieve critical mass and provides access to external assets.

Weaknesses:

- ★ European success stories not always sufficiently visible in the world.
- ★ Europe needs more serial entrepreneurs: need to retain them and support their longer term involvement with new enterprises.
- ★ Pool of experienced entrepreneurs and managers with business skills is small in Europe.
- ★ Need for more and effective industry-academia collaborations.
- ★ More awareness of IPR and knowledge transfer.
- ★ Matching successful public R&D funding with venture capital investments (“is VC money a blessing or a curse?”).
- ★ Need more focus on the value proposition.
- ★ Limitations to entry into national markets.

Opportunities:

- ★ Allow rules to adapt to current paradigm shifts in therapies, diagnostics and product types.
- ★ Encourage state administration and regulatory administration to act as support environment to the companies, provision of clear instructions to meet their programme requirements.
- ★ Make better use of the specific advantages in the New Member states.

Threats:

- ★ Risk-averse behaviour with many stakeholders.
- ★ Decreasing public R&D funds.
- ★ Uncertainty in regulatory environment in relation to long-term strategic decisions in the companies (need for more consistency in interpretation across types of products and countries).
- ★ Ownership changes in companies with a short-term focus (e.g. only financially-driven changes).

Recommendations:

1. Longer-term scope for public funding is needed to enable strategic follow-through funding that goes beyond the lifetime of a single project.
2. More stability and predictability of regulatory rules.
3. Consider assessing funding proposals taking the qualities of (young) enterprises more into account, not decisions based on their track record only, which favours merely established companies.
4. “Size matters”: help SMEs to achieve sufficient critical mass to achieve impact
5. “Management matters”: help young companies to strengthen their management teams.
6. “Flexibility of rules matters” and “Context matters”: a more risk-sharing attitude, by all stakeholders (including public funding and regulatory authorities) around a young growing company would help the tremendously.
7. Fostering entrepreneurship is not just about money, but it is all about people, management and organisation.

Session B1: Alternative financing sources for innovation in healthcare

Chairs:

Giulia DEL BRENNNA, Head of Unit, Food and Healthcare Industries, Biotechnology, DG Enterprise and Industry, European Commission

Emmanuel CHANTELOT, Director European Government Relations and Public Policy, Shire

Panel:

Gerd ZETTLMEISSL, CEO, Intercell

Margaret ANDERSON, Executive Director, FasterCures

Daniel NELKI, Head of Legal and Operations, Wellcome Trust

The aim of this session:

The objective of this session was to review and discuss alternative financing sources for innovation in healthcare. Building on the discussion of access to capital at the 2010 meeting, this session's goal was to review and highlight other useful sources of funding for innovation in healthcare and to provide a broader picture of the overall landscape of potential sources of finance, as well as to propose ways to build on existing sources and to provide new sources of funding for innovation. The panel started with an overview of the technology transfer process and the approach of the Wellcome Trust to funding innovation in healthcare, with a focus on using various innovation funding tools to bridge the gap and bring healthcare innovations to the market. Highlighted tools included grant funds to very early stage research, translational funds for projects and research programmes, venture funds for start-up companies, and institutional funds for the development process. Also highlighted were various models through which a charitable foundation like the Wellcome Trust can collaborate with industry and government. Taking a closer look at a specific example, the session reviewed the case of Intercell, now a well-established and growing biotech company, and looked at their development and financing history as well as use of both traditional and less traditional collaborations and funding mechanisms from the public and private sectors. Following the presentation of the FasterCures programmes in the USA. The discussion then turned to the role of venture philanthropy (VP). The point was made that patients pay the price for stalled progress. Everything that happens in the medical research centre needs to happen with patients in mind, and we must all remember that even if we are not patients now, at some point we all will be. 15 years is simply too long to wait for a new cure. In the current system, the development of new cures not only takes too long, but is far too expensive. And the rate of new medical approvals is declining. In the meantime, the explosive growth in chronic disease has led to massive treatment costs, meaning the longer the development of new cures takes, the more money will be driven into management of symptoms rather than into researching and developing new cures and therapies. The overall situation is, from this perspective, unacceptable for either patients or society as a whole.

The powerful roles of a number of patients' organisations were highlighted, including the Multiple Myeloma Foundation, the Michael J. Fox Foundation, the Prostate Cancer Foundation, and the Cystic Fibrosis Foundation. Looking at the important roles played by such foundations in particular through VP, and seeking to increase the number and role of patients' organisations taking an active role in funding and supporting research, FasterCures advocates that the roles of Patients' Groups and VP should be in de-risking

the research so that pharma will get involved, and giving regulators a patient perspective with regard to risk-benefit analysis. This has led, for example, the FDA to reassess an application with a new understanding of what 25% increased lung function means to a Cystic Fibrosis patient. Patients Groups and VP can also develop pre-clinical tools, support research translation, fund mechanisms that bring industry into the equation, manage academic science, provide access to patient communities and scientific expertise, advocate with the regulatory agencies, and help bridge the funding gap.

Strengths:

- ★ There is an existing dialogue in Europe on the need to address access to finance and the funding “Valley of Death” faced by SMEs.
- ★ There is a strong network of European and national funding.
- ★ Many European companies have already accessed various forms of “alternative” finance, such as Public-Private Partnerships and engagements with non-profit organisations, government agencies etc.
- ★ There are many active patients’ groups in Europe.
- ★ Foundations like the Wellcome Trust play a valuable role and serve as a best practice model for emulation.
- ★ Patients groups in the US are demonstrating the extremely valuable role that they can play as a source of finance through venture philanthropy.

Weaknesses:

- ★ There is a severe shortage of biotech VC in Europe.
- ★ The prospects are not yet improving, in fact they are getting worse.
- ★ Other than the Wellcome Trust, there are few examples of large European foundations active in providing funding for translational medicine, bridging the gap between research and industry, or active as venture philanthropy organisations funding the development of new product candidates.
- ★ European funding schemes do not adequately take into account how to co-invest or co-fund venture philanthropy or patient group supported programmes.
- ★ Europe is far behind in this regard.

Opportunities:

- ★ Many European government agencies are becoming more pro-active.
- ★ There is more and more support for Public-Private Partnerships and this can make a real difference if this momentum is properly harnessed and PPP properly fostered and encouraged.
- ★ Europe has a strong basis of patients’ organisations who can lead in this regard if large donors can be identified and if European supports can be put in place.
- ★ Patients’ organisations in Europe are already active in advocacy and engaging with regulators to ensure a sensible balance of risk and benefit. Many are also offering expertise in clinical trials and patient recruitment. They are well placed to do more with the right support.
- ★ The severe shortage of institutional investors for VC means European VCs should be even more open than US VCs (who are very positive) to the prospect of working or co-investing with venture philanthropy organisations.
- ★ There are concrete examples from major foundations which can be learned from and emulated.

- ★ The emerging models in the US and the lessons from FasterCures and various successful foundations can be taken as case studies and models and localised for Europe.
- ★ There are real opportunities for Europe to learn from best practices such as the new NIH models which allow for PPP co-financing of innovative projects and companies by the NIH together with VC and VP.

Threats:

- ★ The main threats are of complacency and inaction. Europe is on its way to losing its venture capital sector. If real action is not taken both to halt this loss, and to develop new and alternative source of funding, there will be an insurmountable gap between fundamental research and the point at which industry can take over. Europe will lose its ability to finance innovation in healthcare.

Recommendations:

1. PPPs and VP should be further developed in Europe (possible incentives at national and European level).
2. Ways of encouraging the combination of VP, VC and public funding should be explored.
3. Public funding initiatives need to take into account the importance of collaborating with VP, VC and industry.
4. Successful international ventures like FastForward could be looked at as models.
5. Patients' groups should be more involved in the financing process (awareness raising and advocacy).

Session B2: How much will it cost/how much will we pay? Pricing and reimbursement

Chairs:

Giulia DEL BRENNA, Head of Unit, Food and Healthcare Industries, Biotechnology, DG Enterprise and Industry, European Commission

Andrea RAPPAGLIOSI, Co-chair HTA Task Force, European Federation of Pharmaceutical Industries and Associations, Vice President, GlaxoSmithKline

Panel:

Angela BRAND, Director, European Centre for Public Health Genomics (ECPHG), University of Maastricht

Pietro FOLINO GALLO, Director of Medicines Utilisation and Expenditure and HTA, Italian Medicines Agency

Thomas BOLS, Vice President Corporate Health Policy and Market Access, Merck Serono

Bernhard GIBIS, Director, National Association of Statutory Health Insurance Physicians Germany

Ludovic LACAINE, Director of Healthcare, EuropaBio

John R. RIDGE, Director, Reimbursement and Health Economics, Roche Tissue Diagnostics

The aim of this session:

The objectives of this session were to understand the different challenges facing, and presented by, pricing and reimbursement for the biopharma and diagnostic sectors in Europe as regard to the development of personalised medicine applications. Participants examined both the current weaknesses and challenges, and the emerging trends and developments which will have to be addressed. We are no longer in the age of the human genome project; we are in the age of the personal genome project based, among other factors, on a better understanding of disease mechanisms at molecular level. Are we ready to translate research into market? The current paradigm is the identification and management of symptoms. The new paradigm is to pre-empt disease in order to lower costs and improve quality of life (QoL). For personalised medicine to become a reality, medicine will become more precise. This requires diagnostics. This requires proper valuation and reimbursement of innovation. At the same time, the national pricing and reimbursement authorities have an obligation to ensure that everyone has access to the best quality healthcare and to ensure that costs are controlled to maintain the viability and efficiency of the healthcare systems.

Strengths:

- ★ A strong European research base.
- ★ The genome revolution and a leading European position in personalised medicine.
- ★ From common complex diseases to multiple rare diseases.
- ★ From diseases to diseasomes.
- ★ From risk factors to risk pattern.
- ★ From clinical utility to personal utility.

Weaknesses:

- ★ Present structures are adapted to one-size-fits-all – which has never been the case with medicines and is becoming less so. About 75% of cancer patients in the US do not respond to any given therapy – we do not yet know in advance who the responders are.
- ★ Diagnostics can help determine this, but diagnostics are not properly valued or reimbursed.
- ★ Neither is prevention, so resources go to treating preventable chronic disease rather than new therapies.
- ★ Smaller population and high development costs and no incremental price premium.
- ★ Payers are hesitant to embrace personalised medicine with no immediate benefits and increased costs.
- ★ Diagnostics, which help identify responders and target treatments and save costs, do not receive value/outcome-based pricing.
- ★ Variations in pricing and reimbursement across and within countries in Europe.
- ★ Substantial investments needed to raise awareness among physicians about personalised medicine applications and their benefits.
- ★ With current policies there is no clear business case for industry as to how they will recuperate the massive investments required for personalised medicine.

Opportunities:

- ★ Achieving better health outcomes.

- ★ Reducing trial and error approach.
- ★ Reduced adverse reactions.
- ★ Better allocation of healthcare resources.
- ★ Reconfiguring drugs to treat specific populations.
- ★ Optimised research and development costs.
- ★ Earlier market launch for new medicines.
- ★ Better differentiation of medicines.
- ★ Improved patient compliance.
- ★ Learning from best practices in HTA and negotiated entry schemes such as cost sharing, and payment by results.

Threats:

- ★ Doing nothing.
- ★ Applying the systems of the past to the treatments of the future.
- ★ Not properly considering the higher efficacy levels of personalised medicine.
- ★ Not moving to value/outcome pricing for diagnostics (which will cost far more in the long run than properly reimbursing diagnostics).
- ★ Pricing and reimbursement for personalised medicine and or diagnostics by experts using traditional pharma models which do not apply properly.

Recommendations:

1. The coexistence of a centralised procedure for marketing authorisation together with a great number of national (sometimes regional) pricing and reimbursement systems was seen by many as an obstacle to access and innovation. Since the latter is a matter of national competence, a possible solution would be greater coordination of health technology assessment (HTA) at European level.
2. HTA models should be adapted taking into account the need for specific expertise (pharmaceuticals and diagnostics assessments require different expertise).
3. When determining the value of the personalised therapy contributions of both, drug and diagnostic should be assessed.
4. Adapted pricing and reimbursement systems/managed entry models should be considered.
5. Awareness-raising among patients, health care professionals and competent authorities is needed.
6. European co-ordination is important for all of the above in order to avoid further inequalities in patient access.

John DALLI, Commissioner for Health and Consumer Policy, European Commission

Europe needs innovation in health, to provide better healthcare, to more people, in an efficient manner, in the long term. We need to use innovation to make healthcare systems deliver more, and in a sustainable manner. Innovation is not an end in itself; it is a means to serve patients and to drive the economy. We live in times of economic crisis and fiscal austerity, while at the same time the burden of chronic diseases is increasing as Europe's ageing population grows. This increases costs at a time when the healthcare workforce is shrinking. Each person deserves equal quality healthcare regardless of where he or she lives and what he or she earns. So how do we deliver

more healthcare with fewer health professionals and limited resources? Innovation – rather than spending more we need to spend better on new models of healthcare which provide better care while keeping down costs and maintaining efficiency and sustainability. We need to look beyond just new products and look at the whole value chain, from insurance systems to hospitals and care givers.

E-health is an example. It can give patients access to the best medical expertise from their own homes, and help physicians and leading experts monitor patients from a distance. This needs to be exploited across Europe, but health systems are not interoperable. They need to be inter-operable within hospitals, and towns, but also across borders. The new directive on Patients Rights in Cross Border Healthcare guarantees patients access to healthcare across borders and incentivises healthcare authorities to work together and ensure interoperability.

To provide high quality healthcare, we need a strong innovative pharmaceutical and medical devices industry. Our policy here needs to strike a delicate balance between maintaining high quality products, while ensuring access and containing costs. The pharmaceutical industry in Europe is on the leading edge of innovation and technology. One of its latest developments is personalised medicine which recognises that the best treatment varies according to the patient.

When we introduce new technologies, we need clear evidence that the investments made will pay off. We need to know that the benefits over existing technologies in terms of efficacy and safety will outweigh the costs. HTA has proved to be a valuable tool for decision makers in considering taking up new therapies or phasing out old technologies. The EC is fostering cooperation in this area at the European level.

We need more than technology, we need to change mindsets and ensure innovation in the way we think, and in how we design hospitals. Innovation must be in management, organisation, financial planning and control, coordination between services, economies of scale, rethinking the different tasks of healthcare services, as well as innovative ways to make healthcare systems more efficient. Innovation can enable our health systems to thrive under pressure and respond to the needs and expectations of Europeans, and helps provide quality healthcare for each and every European. Each and every citizen should have access to high quality care, regardless of where he or she earns or lives.

Antonio TAJANI, Vice-President of the European Commission, responsible for Industry and Entrepreneurship

A Thriving Healthcare Sector is an Engine for Economic Growth and Employment

The new 2020 Strategy aims at turning the EU into a smart, sustainable and inclusive economy delivering high levels of employment, productivity and social cohesion. To reach these objectives, the healthcare sector is a key area which deserves the attention of European and national decision makers.

- Roughly one tenth of the EU's gross domestic product (GDP) is spent on healthcare.
- Healthcare employed more than 6.9% of European workers in 2006, i.e. 15.1 million people.

- The sector is regarded as non-cyclical and stable, and growth rates are high.
- The pharmaceutical industry alone generated €137 billion in sales at ex-factory price in 2007.
- The medical device industry represented €72.6bn in 2007. 80% of these companies are SMEs.
- With regard to our trade balance the pharmaceutical and the medical device industries shows an excess of €34.8bn.

The contribution at an economic level is clear.

What can be done to realise the full potential for Europe and its citizens? We have to be innovative. But innovative in a holistic sense, i.e. dealing with new ways of thinking, with inventions and discoveries and the useful and innovative application of the knowledge created. We must consider not only products and technology development but also services, access to innovative financing models, new ways towards autonomous patient care and also focus on prevention. The EC is therefore taking a "Joint Undertaking" approach of three Directorates-General which cover the whole value chain of the healthcare sector: research and knowledge creation, technology transfer, access to finance, and market access and uptake (namely pricing/reimbursement).

Innovation is not an end in itself, but a means to an end. I am fully committed to promoting innovation and to create a stable and predictable environment for innovations by

- making further progress towards the single and sustainable market,
- taking on the opportunities and challenges of globalisation and,
- making industry responsible and deliver for European patients.

Innovation needs to be accessible and affordable. Patients have a right to benefit from innovation. Someone has to pay for innovation. The difficulties in public finances have been exacerbated by the economic crisis.

The EC is taking the following initiatives to support an accessible and affordable innovation process in the healthcare sector

- Process on Corporate Responsibility in the field of pharmaceuticals: This initiative aims at facilitating discussions on ethics and transparency, and access to medicines in Europe and in developing countries. We need a balance between national authorities on access to treatment on the one hand, and reward and incentive for innovation on the other.
- The Transparency Directive (89/105/EEC): Pricing and reimbursement policies fall within the responsibility of the Member States. There is no room for harmonising pricing and reimbursement systems in Europe and the Commission cannot interfere with the substance of national pricing and reimbursement decisions. However we are seeking to ensure the transparency of national procedures and the elimination of unjustified obstacles to trade in order to ensure timely access to medicines.
- The international dimension: The EU-based pharmaceutical industry has to cope with the challenges of the global economy. The Commission is engaged in ensuring a level playing field for European enterprises. Europe is also committed to alleviating the difficult situation facing many people in developing countries, in particular with regard to access to medicines.

Session A3: Innovative Knowledge TransferChairs:

Audrey GOOSEN, Policy Officer, Knowledge Transfer: University-Industry Relations, Innovation Policy DG Research and Innovation, European Commission

Christian SUOJANEN, Head of Life Sciences, Valor Management S.A. and Co-Chairman, Tech Transfer Summit

Panel:

Tony HICKSON, Managing Director, Technology transfer, Imperial Innovations

Lilian WIKSTRÖM, CEO, Karolinska Institutet Holding AB

Rudy DEKEYSER, Managing Director, VIB Transfer

Patrick TRICOLI, Scouting & Partnering International, Sanofi Aventis

Piyush UNALKAT, Principal, Transaction Relationship Management (Technology Transfer), European Investment Fund

The aim of this session:

This session assembled a number of Managing Directors of top technology transfer programmes at leading universities, a big pharma licensing and business development executive, and an EIF funding manager working on investment into life sciences, VC and technology transfer funds. The goal of the session was to address the strengths and weaknesses of technology transfer in Europe, and identify opportunities for further development as well as threats to be dealt with. Organised as a moderated round-table discussion, the entire session was devoted to the issues and there were no presentations. Technology transfer was not narrowly defined, but was taken as the entire process of bringing world-class research from the lab onto the market to the patient in the form of safe and effective innovative medicines and technologies.

Strengths:

- ★ Europe's strength is in its research, which is world-class.
- ★ There are some real best practices, some gold standards of technology transfer at key universities and institutes.
- ★ European funding is also an asset.

Weaknesses:

- ★ The lack of truly skilled and appropriate Technology Transfer Officers (TTOs) in Europe. There are very few with a scientific background, industry experience, a track record, and a real understanding of the market.
- ★ Small tech transfer teams across Europe are facing an enormous task trying to learn entire industries and make all of the relevant contacts, often within multiple industry sectors (not just life sciences, pharma or medtech).
- ★ Much greater capacity is therefore needed in terms of human resources.
- ★ There is a lack of seed funding in Europe. Seed funding (pre-FP stage) for early PoC, and seed funding for pre-commercial development.
- ★ There is a lack of IP funding in Europe.
- ★ Collaborative funding may be at the heart of the European idea, but it is often not appropriate when the goal is to develop product candidates with the hope of

bringing them to the market and benefitting patients. Collaborative funding is not well suited for IP management, it adds exponential degrees of complexity to all negotiations and makes it much harder to secure VC or industry funding, to do licensing or R&D collaboration deals, or otherwise commercialise the results. Simply put, collaborative funding can act against the goals of bringing innovative healthcare therapies and technologies to the market and getting them to patients. There must be alternatives.

Opportunities:

- ★ The potential of European research to provide real benefit to patients and society is enormous, in terms of healthcare, benefit to patients, economic growth, and job creation.
- ★ The European Funding programmes are not ideal, but they are an excellent basis from which to develop new programmes and launch them at a European level, rather than incrementally at a national level.
- ★ The EIF's activities in funding technology transfer can be built upon.
- ★ Successful European programmes from other sectors can be emulated (see recommendations).

Threats:

- ★ Once again, doing nothing, complacency and inertia are the main risks. The status quo is not that bad, but it is not where we need to be and it is not going to get Europe where we need to go. If Europe is to ensure innovation in healthcare, remain competitive in a global world, meet the Lisbon goals, and develop a knowledge-based economy, we must take action.

Recommendations:

1. EC grants or other supports to recruit, train and retain really qualified people into Technology Transfer.
2. Programmes to build competence. Not just more of the same licensing programmes, but developing real sector knowledge, industry expertise, and relevant networks and contacts (and not just between regions or TTOs). For example, programmes to second key tech transfer officers to industry or to biotech companies, and vice versa.
3. Network and relationship building within the life sciences. There is a need for TTOs to understand not just the industry, but also all of the key stakeholders and their objectives, and the individuals themselves.
4. Funding of IP funds or pools for universities and research institutes.
5. Build on and increase current EIF technology transfer funding.
6. Increase European funding of research and especially development (translational medicine, Proof of Concept, Clinical Trials) in FP7 and FP8. There should be separate lines of funding for early stage PoC, perhaps pre-FP funding, and also for pre-commercial development and clinical trials, but these must be properly evaluated by people who understand commercial development and trials for product candidates, not just research.
7. Simplification of EC funding. There has been significant improvement but it needs to go further. The way evaluations are done, and the criteria used, needs to be adjusted if we are to meet the goals of SME participation and funding R&D that can lead to real product candidates with a significant chance of reaching the market.

8. Initiate at least some lines of funding available to single companies or universities for a given project, when appropriate. Europe is losing some of its most promising programmes because they cannot be funded under current FP programmes and there is such a shortage of private sector capital. These need funding to human PoC, and in some cases the best way to get the desired results, or the only way, is through funding of single company or university projects.

Session A4: From idea to market: evidence from case studies

Chairs:

Stéphane HOGAN, Head of Unit, Horizontal Aspects, Health, DG Research and Innovation, European Commission

Mike WARD, Editor, Scrip Intelligence, Informa Group

Panel:

Joël JEAN-MAIRET, Managing Partner, Ysios Capital Partners

Cécile THARAUD, CEO, Inserm transfer, Vice-President, Association of European Science and Technology Transfer Professionals (ASTP)

Torbjörn KRONANDER, CEO Sectra

Jacques VISEUR, Managing Director, Eurotop Cooperation Partner

The aim of this session:

This session reviewed a number of practical cases where innovative healthcare research has been successfully brought to market, or is nearing market entry in Europe, and is or will soon be providing benefit to patients. What are the lessons that can be drawn from these success stories? What were the most important challenges they faced or continue to face, and how did they overcome these or will they overcome them? What are their recommendations for policy changes and new European initiatives to help develop a more innovative culture and to foster innovation in healthcare in Europe? The panellists included a leading European biotech entrepreneur who is now a key venture capital investor, the Managing Director of a key European technology transfer office at a leading research agency, the CEO of a successful medical technology company built from the ground up based on academic research, and a sector specialist reviewing data on SMEs which have successfully commercialised the outcomes of their FP projects.

Strengths:

- ★ Aside from Europe's strength in research, and several best practices (which are not all still in place) from individual Member States, there were few references to strengths. The view of the panel is that yes, Europe has excellent research, and yes, there have been some success stories, but these have been too few and too far between, and there are many obstacles which need to be addressed urgently.
- ★ Technology transfer has made exceptional progress in Europe over the past five years, but still has a long way to go.

Weaknesses:

- ★ Far too few FP projects have resulted in products or services on the market (5-10%). This is likely due to the focus on "innovation" rather than product development suited to the pharma industry and real medical needs.

- ★ Most European universities and institutes (and biotech companies) have almost no budget or capacity for IP litigation. Much potential value is therefore lost due to a lack of financial resources.
- ★ The nearly complete fragmentation of European HTA, Pricing and Reimbursement is a catastrophe for European biotech companies. The extra costs and the unwarranted delays with no single appeals process pose an enormous hurdle in terms of additional costs and delays to the introduction of innovative new medicines and technologies in Europe.
- ★ Lack of seed capital.
- ★ Lack of venture capital, there is still a dearth of venture capital in Europe.
- ★ Lack of serial entrepreneurs, lack of entrepreneurial culture, and lack of experienced serial entrepreneurs to act as mentors and help guide new biotech entrepreneurs.

Opportunities:

- ★ While only 5-10% of FP projects have resulted in licenses or products on the market, 51% of SMEs surveyed by Kappa Health declare commercial returns on their FP project results. Increasing SME involvement in FP projects, in key roles, will lead to an increased chance of use of results and innovative new medicines and technologies on the market and benefitting patients.
- ★ There are opportunities to address many of the current challenges with programmes similar to those used in other sectors (see recommendations).
- ★ Stronger collaboration between research universities and top MBA schools could have a significant impact. This is already happening, but at far too timid a rate. It needs to be fostered and accelerated.
- ★ HTA and reimbursement harmonisation would remove a massive hurdle to innovation and access to new medicines and medical technologies.
- ★ There is an opportunity to stop sabotaging Europe's own Lisbon (and Europe 2020) objectives by recognising that venture capital consists of small, specialised and high value-adding funds which are crucial to the process of innovation in healthcare, and stop treating venture capital like large private equity and hedge funds.

Threats:

- ★ The situation is not at risk of not advancing, it is in the process of getting worse. The choice is to act now, or to allow one of Europe's key sectors, one which is central to the Europe 2020 strategy, to erode further and perhaps to the point where it cannot be revived.
- ★ The best research and the best entrepreneurs will migrate to the best environments. So the loss of talent will mean loss of access to drugs, and government and payers will lose control over cost of drugs and our own healthcare, which will also ultimately lead to a loss of capital as investors will invest where they will make the best returns, especially when they are treated punitively in Europe *vis-à-vis* other markets.

Recommendations:

1. Proposals include stronger collaborations between Europe's top research universities and institutes, and its leading MBA schools.
2. European funds for an IP insurance pool or fund to protect the IP generated at Europe's universities and institutes.

3. Foster seed capital by encouraging angel investments through tax incentives.
4. Further EIF funding for European Venture Capital, and treatment of VC which does not sabotage the European objectives for innovation in healthcare.
5. Harmonised HTA, pricing and reimbursement.
6. European Reimbursement Code.
7. Single, European, and speedy appeals process to overrule blocking by one individual when the evidence is clear.
8. Action to protect the current strong position of Europe's medical technology sector.
9. Foster entrepreneurship starting in secondary school.
10. Replicate at a European level the Swiss model of providing senior industry, entrepreneur and VC coaches to promising young company CEOs to help them learn from experience and insight.
11. Rather than taking risks, government should enable companies to take risk, provide funding for the healthcare system and hospitals to purchase from companies. It creates good companies. It allows them to grow rather than just selling out to a larger company, and allows hospitals to borrow risk funds to buy from companies.
12. Europe should provide for greater free movement of human capital through harmonisation of taxation of options etc. Many countries' policies actively discourage entrepreneurship.
13. Build on existing SMEs, and involve entrepreneurs in shaping future policies.
14. Support IP creation; establish trans-national networks for IP.
15. Support programmes to develop business acumen among graduate and postgraduate students.
16. Support more market focused research, not just early stage research.
17. Support public health and orphan disease areas.
18. Focus on the challenges presented by fragmentation of IP, HTA, pricing and reimbursement in Europe.

Sessions: B3 and B4: A multifaceted approach to Innovation in Healthcare

Chairs:

Andrzej RYS, DG Health and Consumers

Philippe JACON, European Diagnostic Manufacturers Association

Panel:

Panos KANAVOS, Director Health and Social Policy, London School of Economics

Jean-Jacques ZAMBROWSKI, hospital physician and Prof Health Economics
Descartes University Paris

Anders OLAUSON, President, European Patients Forum

Maria IGLESIA-GOMEZ, member, Steering Group Healthy Ageing

Simon VRHUNEC, Director, University Medical Center Ljubljana

John WILKINSON, Chief Executive, EUCOMED

Stefan NARDI-HIEBL, Head, Healthcare Consulting Siemens

Anne-Kristine DYRVIG, Coordinator, Odense University Hospital

The aim of these sessions:

This double session focused on the various perspectives and stakeholders involved in improving the healthcare system. The first half analysed issues in a hospital setting (general economic challenges, challenges from the professional and from patient perspectives) and how new types of partnerships (such as the EIP for healthy ageing) may be able to improve things.

The second half concentrated more on actual cases to highlight what could be done from a hospital viewpoint, the medical industry perspective and at the level of improving internal organisation and decision-making on the basis of technology assessments.

Strengths:

- ★ A healthy Europe is a wealthy Europe: our systems address equity; which is a necessary basis for wealth and growth.
- ★ Europe has a large, varied and innovative medical technologies industry.
- ★ Europe in a global context.
- ★ Good examples exist on how the system can change - but we need to do more!

Weaknesses:

- ★ Too strongly focussed on disease management.
- ★ Insufficient contact between the supply and demand side (e.g. hospitals and industry).
- ★ Health systems not good enough on implementation.
- ★ Insufficient efforts put into the optimal use of diagnostics (interoperability needed).
- ★ Inertia (inability to adapt to change quickly).
 - Multiple actors lead to complex decision-making and implementation.
- ★ Health systems are not good enough on disinvestment decisions.
 - Rigid financing systems.
 - Regulations.

Opportunities:

- ★ System development key to innovation: Technology is an enabler.
- ★ Address managing lifestyles instead of diseases; put prevention at the core of health policies.
- ★ Seek efficient use of resources.
- ★ Increase flexibility of health systems.
- ★ Better link health and social care services.
- ★ Well implemented, e-Health tools may increase productivity and reduce the burden on scarce health personnel resources.
- ★ Involving hospital staff in uptake decisions (e.g. through mini-HTA) increases the use of evidence-based medicine in changing hospital practice.

Threats:

- ★ Resource constraints:
 - Economic outlook.
 - Resource competition (social services etc.).
 - Lack of qualified workforce.
- ★ Silo structures among actors and services.

★ Demography:

- Increased demand (quantity/quality).
- Changed needs for health services.
- Decrease in number of health professionals.

Recommendations:

1. European health services will need major re-engineering, including better integration.
2. Addressing effectiveness: use Health Technology Assessments properly.
3. Ensure that evidence leads to implementation of new policies.
4. Change in mindset.
5. Better collection of data to move towards evidence- and efficiency-based medicine.
6. Sharing best practice within Europe – and going beyond.
7. Measures should enable better interaction between European health systems.
8. Reducing health inequalities should be an objective of introducing innovation.
9. Adopt a 360 degree model for setting the patient in the centre of healthcare innovation.

CLOSING REMARKS & KEYNOTE: MÁIRE GEORGHEGAN-QUINN, COMMISSIONER FOR RESEARCH, INNOVATION & SCIENCE, EUROPEAN COMMISSION

In her closing speech the Commissioner of Research, Innovation and Science thanked everyone for the efforts in organising this conference in order to have an open dialogue among the various stakeholders with the aim for identifying the strengths and weaknesses in the system. Good health concerns us all and is vital for an active, creative and vibrant economy. Therefore it is important to suggest new approaches and solutions, some of which may be adopted and taken up in the larger framework of the Innovation Union programme as a centrepiece in Europe's 2020 Strategy. The Innovation Union aims to link all elements along the innovation value chain to ensure a smooth path between laboratory and market. SMEs have a key role in this. Although the FP7 and CIP funding programmes, in which SMEs are highly encouraged to participate, already have a significant impact on the development of the European Research Area in the health sector, this conference provided valuable input on how they can be improved even further to develop a genuine knowledge market.

Other key elements, by stimulating multidisciplinary initiatives to address the complexity of developing new therapies and scaling up new healthcare solutions, are the European public-private initiatives such as the Innovative Medicines Initiative and the new 'European Innovation Partnership' for Active and Healthy Ageing. This latter pilot partnership has three main goals: to enable older people to lead healthy, active and independent lives; to improve the sustainability and efficiency of social and health care systems; and, because the Innovation Union is also about growth and jobs, to boost the competitiveness of the markets and businesses for innovative products and services. In addition, since last year's conference, progress has been made at other levels too: for example the EU patent.

This year's conference also provided food for thought on how to improve knowledge transfer and entrepreneurship. Building on our excellent science base in Europe, there is a need to remove the barriers that prevent bright discoveries from reaching the market in the form of innovative products and services. This requires effective partnerships between academia and industry, better access to finance and less bureaucracy, but also more flexibility in mobility between the two sectors. Through the Innovation Group of Commissioners closer cooperation is being stimulated between the various DGs and also with the European Investment Bank (to improve access to finance with various instruments). Investments in the "right" products need to be stimulated to strengthen a closer link with market needs and demand.

We all share the goal of ensuring the sustainability of European health systems, which are facing new opportunities and challenges with more expensive and innovative treatments coming on-stream, and with them, higher public expectations. And all of this against a backdrop of tightened public finances. Therefore solutions must go beyond investing in new technologies; innovation is also about finding ways to improve the functioning of our healthcare systems and changing mindset of people and organisations. All stakeholders, governments, policymakers and service providers, have to strike a delicate balance together between delivering high quality and accessible healthcare, while containing costs and putting patients first.