Conference report

The following report is a summary of the discussions and the presentations held during the conference Innovation in Healthcare without borders, on 16-17 April 2012, in Brussels. This report does not endeavor to provide a word for word record or minutes of the meeting, but rather to summarize the key points discussed, to extract the key issues raised and challenges highlighted.

The conference has been organized by the European Commission, more precisely by the Health Directorate of DG Research and Innovation, in collaboration with DG Enterprise and Industry, DG Health and Consumers, with DG for Regional Policy and DG Development and Cooperation.

The conference program has been developed in consultation with a number of experts mainly representatives of the major European health associations (patients, industry and hospital) and relevant stakeholders.

Report prepared by:

Frank Heemskerk, CEO, Research & Innovation Management Services bvba (RIMS).
Teresa Cunha, CEO, MTConsulting SA
Ludovica Serafini, responsible for SMEs & Innovation at the European Commission, DG RTD, Health Directorate
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background Rationale</td>
<td>3</td>
</tr>
<tr>
<td>Scope of this document and Method</td>
<td>3</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>4</td>
</tr>
<tr>
<td>Key findings and recommendations</td>
<td>4</td>
</tr>
<tr>
<td>Plenary sessions</td>
<td>6</td>
</tr>
<tr>
<td>Session A1: Beyond borders for business skills in healthcare</td>
<td>11</td>
</tr>
<tr>
<td>Session A2: Beyond borders in knowledge transfer: raising standards and capacities</td>
<td>12</td>
</tr>
<tr>
<td>Session B1: Health inequalities within EU – the case in new EU member states</td>
<td>14</td>
</tr>
<tr>
<td>Session B2: Bridging the border among decision makers</td>
<td>16</td>
</tr>
<tr>
<td>Programme &amp; Session Review Day 2</td>
<td>18</td>
</tr>
<tr>
<td>Keynote Session</td>
<td>18</td>
</tr>
<tr>
<td>Session A3: EU Research and Innovation funding, a tool to remove borders within the EU and beyond</td>
<td>19</td>
</tr>
<tr>
<td>Session A4: Removing boundaries an access to finance: New approaches, new models</td>
<td>20</td>
</tr>
<tr>
<td>Session B3: Improving access to medicines in Africa, where do the solutions lie: at home or abroad?</td>
<td>22</td>
</tr>
<tr>
<td>Session B4 – Bridging borders to build capacity globally: case study African countries</td>
<td>24</td>
</tr>
<tr>
<td>Keynote Session</td>
<td>26</td>
</tr>
<tr>
<td>Session B5: The global report for research priorities on infectious diseases of poverty</td>
<td>27</td>
</tr>
</tbody>
</table>
BACKGROUND RATIONALE


The rationale for these conferences is the fact that fostering innovation in healthcare is a particularly difficult, expensive and long process that includes clinical evaluation and regulatory approval. It takes on average > €1 billion, over a period of 10-15 years, to develop an idea into a viable, marketable and profitable pharmaceutical product for the ultimate benefit of patients and the economy. Fostering innovation in healthcare thus requires a multi-stakeholder approach to reach agreement and move forward. As in 2010 and 2011, the 2012 event aimed to do just that.

Consequently, responding to the needs of the sector, the 2012 Conference sessions developed two tracks:

- "Removing borders in the health supply chain" assessing achievements and remaining barriers;
- "Overcoming barriers to equality and solidarity" exploring new challenges within the EU and beyond (with focus on Africa as a case study).

The conference program has been developed in consultation with a number of experts mainly representatives of the major European health associations (patients, industry and hospital) and stakeholders, namely European Federation of Pharmaceutical Industries and Associations (EFPIA), European Biopharmaceutical Enterprises (EBE), European Association for Bioindustries (EuropaBio), European Medical Technology Association (EUCOMED), European Diagnostic Manufacturers Association (EDMA), European Hospital and Healthcare Federation (HOPE), European Patients Forum (EPF), Council of European Bioregions (CEBR), Association of European Science and Technology Transfer Professionals (ASTP), Tech Transfer Summit (TTS Ltd), International Venture Club and European Venture Contest, Research & Innovation Management Services (RIMS), the Organization for Economic Co-operation and Development (OECD), World Health Organization (WHO).

SCOPE OF THIS DOCUMENT

The following report is a summary of the discussions and presentations during the event. This report does not endeavor to provide a word for word record or minutes of the meeting, but rather to summarize 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 crystallize 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 upon 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 program 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 audience participation.
EXECUTIVE SUMMARY

KEY FINDINGS AND RECOMMENDATIONS

General
- An overall recommendation about how to enhance innovation in healthcare, coming from several different sessions and discussions, was the need for more coherence in planning and for connecting the different policies and decision making processes across sectors (e.g. upstream co-operation between clinicians, patients, government, SMEs and pharmaceutical companies when addressing cost reduction and procurement rules or reimbursement policies and models or for the development of policies for innovative technologies...).
- We need to enforce an integrated programming, taking into account influences from all sectors relevant to healthcare. This could be made tangible in (e.g.) a better use of structural funds to leverage the investments in R&D and innovation as a driver for improvement in competitiveness and for addressing health inequalities.
- In international cooperation there are a number of great opportunities for Europe to address common health related problems and to build local capacity developing for example new drugs or diagnostics specifically designed for the African reality. Many of the weaknesses relate to lack of coordination across sectors and current use of limited public initiatives where new models of partnerships may be more effective (such as EDCTP and ANDI).
- There is a need to involve all key stakeholders (e.g. from patients and clinicians to hospitals, regulatory bodies, to those responsible for reimbursements) to interact much earlier in the R&D phase, avoiding problems at later stages in the innovation chain, for example resulting in the development of products inappropriate for the hospital setting or for the patient. In the sessions related to specific solutions for developing countries, emerged the need for innovative partnerships and early stakeholder involvement in the various stages of product development.
- Developing better indicators to measure successful outcomes would be a great help for policy makers. Given the current limitations on financial resources, this would help guiding decisions on where investments could have the biggest impact.

Skills & capacity
- Europe still lacks business skills in emerging companies. This is an important bottleneck in developing new technologies, securing funding and delivering professional partnerships. SMEs often have difficulties to find the right expert(s) and partners to take the company from early stages forward to growth and expansion.
- In the European Technology Transfer Offices (TTOs) there are not enough skilled, experienced professionals with real industry practice. Academia and TTOs often fail to recognize downstream risks. It is fundamental to have professionals with expertise and understanding of the healthcare sector, market and of key stakeholders' needs.
- The challenges must be faced concretely. It is not enough to educate people theoretically on how to deal for example with drug development, but skill-building is required in practice.
- "Big pharma" is starting to recognize the value available outside of its own structure, namely in academia and SMEs, as well as the importance of involving the patient as early as possible in the product development process. There should be an increased number of large companies extending their skills through partnerships with SMEs.
- Collaborative projects should further enforce integration throughout the whole value chain, making it compulsory, in order to magnify the effectiveness of knowledge and skills transfer (e.g. bring clinicians and students into pharma and SMEs; venture capital and pharma into academic labs; TTOs into pharma and vice-versa...).
EU funding

- Funding for high risk projects should be reinforced as is lacking.
- Commercialization of research outcome will have a stronger prioritization in future projects. This should be mirrored in the selection process for EU funded projects. More experts with this kind of knowledge should be included as evaluators.
- Safety concerns are constantly increasing for both drugs and medical devices, which should be reflected in the funding programs.
- Collaborative research projects remain effective and important to enforce academia-industry collaboration. Inclusion of SMEs in the consortia is very important, however should not be mandatory.
- It is recommended to amend the financial regulation so that single entities (especially SMEs) can be funded in Horizon 2020, in particular for the SBIR-like instrument.
- Horizon 2020 should continue to promote Public-Private Partnerships like IMI, as they leverage industrial investment back in fields where big pharma and VC money is not available but where there is a clear medical need (example: IMI calls on antimicrobial resistance and development of new antibiotics).
- For a real and integrated implementation of European research and innovation policies more coherence in the different funding programs and calls is needed. We need to harmonize who funds what, where and at which stage, both at EU level (framework programs, Structural Funds, ERA-NETs) as well as by national agencies (R&D/Innovation and Development Aid agencies). The "Active and Healthy Ageing Partnership" seems a valuable approach to integrated programming.

Finance

- From financial actors’ perspective, the average return of venture capital (VC) in Europe has been disappointing. Europe's VC industry should be strengthened and more private investment and alternative private financing models should be introduced.
- The key ingredients for VC investment are available: we develop good science in Europe and there has been a culture shift about patenting. Now filing a patent is well perceived by scientists and it has become more a routine.
- We are starting to find repeat entrepreneurs in Europe. We have VCs who operate across borders. We have big European pharma companies in Europe and they collaborate with VCs.
- The problem for VC is more downstream: "Pharma" is the only exit option for VCs in Europe since there is no NASDAQ and the different European stock exchanges do not have critical mass.
- There are new good financial models emerging in some countries. The classic VC model will endure, but new VC-like models are already emerging: philanthropic foundations and crowdsourcing are ways to address and bridge the early-stage funding gap. European funding schemes do not address properly co-investment with venture philanthropy associations, and Europe lags behind in this regard. Patient’s groups should be more involved in the financing process.
- The profile of the health sector needs to be raised further, with increased awareness and advocacy to bring more sources and types of investors into the sector.
- Within the context of Healthcare innovation, one must keep in perspective that for the amount of cash required, the local initiatives and the Business Angels community are not able to deliver. The “big money” is with the institutional investors: limited partners (LPs). We need to have more funds of funds, reactivate the process of LPs and fuel this money to VC. The European Investment Bank could help to leverage the investment of the LPs with specific financial instruments (e.g. guaranties).
OPENING AND KEYNOTE SESSION (PROVIDING THE CONFERENCE SET-UP THROUGH POLICY-MAKERS’ AND MAIN ASSOCIATIONS REPRESENTATIVES’ SPEECHES).

Ruxandra DRAGHIA-AKLI, Director, Directorate Health, DG Research and Innovation, European Commission

Mrs Draghia-Akli opened the third edition of the Innovation in Healthcare conference welcoming the participants and introducing the conference and the speakers.

The 2012 event, "Innovation in Healthcare without Borders", analyzed how to create a borderless research and innovation landscape and how to reduce healthcare inequalities both within Europe and globally.

The Commission will feed the conclusions into the relevant policy making activities, in particular for the implementation of Horizon 2020, the next Framework Program for research and innovation.

The problem-solving oriented approach and structure of the previous editions is maintained. As in previous years, top speakers were brought together to generate debate enriched by audience contribution. During each parallel session the moderators draw conclusions and performed a ‘SWOT’ analysis, highlighting the strengths, weaknesses, opportunities and threats arising from the discussion.

The opening plenary did set the scene for the event, providing an overview from a variety of stakeholders.

Máire GEOGHEGAN-QUINN, Commissioner for Research, Innovation and Science, European Commission

The Commissioner started by welcoming participants to the conference. She highlighted how this year event is an excellent example of the multidisciplinary approach needed to foster greater innovation in healthcare - having been co-organized by no fewer than five Directorates General of the European Commission, working closely with major industrial and patient associations.

The last three years Innovation in Healthcare conferences have been an excellent forum for debate between key stakeholders, contributing to the identification of the key priorities. The conclusions from the previous two events have been taken up in both Innovation Union and in the European Commission’s proposal for Horizon 2020 (for example with the development of a SBIR like instrument for SMEs and a greater focus on the entire innovation chain).

Horizon 2020 is Commission’s 80 billion Euro proposal for the incoming European research and innovation program. The radical changes compared to the 7th Framework Program aim to simplify funding, provide seamless support from research to innovation and to enhance excellent science, tackle societal challenges, and strengthen the competitiveness of European industry and SMEs. The proposal is under negotiation with the European Parliament and Council in a process that will occupy much of the next two years.

This year’s conference provides the opportunity to discuss health investments in those newer Member States where health inequalities are a particular problem and how structural funds can contribute to transformational changes in healthcare by boosting innovation to build more effective, accessible and equal health systems.

Health problems are of course not only an issue for Europe. The global health challenges that we face are immense – but through effective co-operation with developing countries we can bring benefits to everyone.

This year’s conference also focuses on Africa and Health Innovation. So far under the Health theme in FP7, 190 African participant organizations have received 53 million Euro of funding. In addition to this, the European Commission continues to support the European and Developing Countries Clinical Trials Partnership (EDCTP), which brings European and African research efforts together to combat HIV / AIDS, malaria and tuberculosis.

Finally, the European Commission has – together with the World Health Organization – been instrumental in establishing "A.N.D.I.", the African Network for Drugs and Diagnostics Innovation.
A.N.D.I. will promote and sustain African-led product R&D innovation through the discovery, development and delivery of affordable new tools.

Two sessions in the conference are of particular interest in this respect: they explore how African and European partners can work together to generate pharmaceutical and diagnostic innovation respectively.

The Commissioner then announced the "Prize Competition for the development of a novel alternative to cold-chain technologies for vaccine formulation, preservation and transportation". The European Commission will offer a prize of 2 million Euro for the solution to a problem which causes unnecessary loss of life, and considerable suffering: immunization in many regions of the world is difficult, if not impossible, because of the need to maintain vaccines at controlled temperatures.

Patricia REILLY, member of the Cabinet of the Commissioner Máire Geoghegan-Quinn

Mrs Reilly provided details on the prize announced by Commissioner Máire Geoghegan-Quinn, which aims to encourage inventors to overcome one of the biggest barriers to distribution of vaccines in tropical and developing countries: the need to keep them at a cool and stable temperature.

The World Health Organization estimates that half of all supplied vaccine doses are wasted, mostly due to an inadequate "cold chain" to protect them before use. This cold chain also increases costs and logistical difficulties meaning that vaccination programs in the developing world face real barriers to success.

There is the expectation that this prize will induce innovative solutions to address weaknesses in the current cold-chain approach, and pave the way for better access to vaccines for all. It is very important to note that in contrast with many types of grant based funding, this prize does not prescribe the approaches to be taken.

The prize will be awarded with the help of a judging panel of experts. The winner of the prize will need to show that the solution has the potential for a significant impact on global health. He or she will also need to provide data which demonstrate that the solution retains the full effectiveness and safety characteristics of the vaccine under field conditions. The idea which demonstrates the greatest likely impact along with the greatest range of protection against the variability of field conditions and with the greatest likelihood of being implemented at reasonable cost will be declared the winner.

Derek HANEKOM, Deputy Minister of Science and Technology Dept of South Africa

Mr Hanekom started his presentation by stating that South Africa enjoys a long standing science and technology partnership with the EU, and is among the top 5 international countries benefiting from it. Health research receives the highest amount.

Public Health challenges are intrinsically related to poverty and development, emphasizing the need of tackling the poverty challenges simultaneously with the health challenges.

Of the global population infected by HIV - AIDS, almost 2/3 live in sub-Saharan Africa. In South Africa alone there are 5.6 Million people who are HIV positive (more than the population of Finland…). This is a very serious challenge. Life expectancy was 61.5 in 1991 and was down to 50 in 2006. The biggest cause of this decline was HIV-AIDS.

To address the topic of “Partnership opportunities with African countries”, Mr Hanekom referred to the notion, that: “Every country has something to offer (natural, geographic, knowledge advantageous, etc)”. There is a biodiversity abundance which can be sustainably exploited in health. Traditional medicines offer a great opportunity also; its use in South Africa is huge: this sector employs around 133 000 people, and over 72% of black South African population consume traditional medicines.

Additionally, the burden of diseases offers an "opportunity" by way of necessity. For example, South Africa has now the biggest antiretroviral program in the world, with 1.5 million patients currently receiving antiretroviral (ARV) treatment, and it is growing. These 1.5 million patients on ARV treatment are in it for life. Referring to the fact that “prevention is better than cure!” Mr Hanekom, emphasized that the search of a vaccine against HIV-AIDS should not be abandoned, despite all difficulties.

South Africa needs to reduce its dependence on import, in particular the local pharmaceutical sector should be strengthened. He mentioned "A.N.D.I.,” the African Network for Drugs and Diagnostics Innovation, as an example of a successful program receiving valuable support from the EC.
He finalized his presentation by inviting the participants to South Africa in November 2012 for the launch of the 2nd phase of the European Developing Countries Clinical Trials Partnership.

**António CORREIA DE CAMPOS, Member of the European Parliament**

Mr Correia de Campos has twice been Minister of Health in Portugal and is Vice-President of the panel for the Assessment of Scientific and Technological Policy Options for the European Parliament (STOA). In his presentation he highlighted the importance of the National Healthcare Systems (NHS) as one of the most important welfare achievements in the European social model. However, the financial foundations of healthcare systems are under stress. Increased government deficits and austerity measures make it impossible for a continued growth in Healthcare related expenditure. On the other hand, healthcare spending continues to be driven by growing patient expectations and increased healthcare demand maintained by an aging population and by a switch from acute illness to a prevalence of chronic conditions and also due to less healthy modern society lifestyles. Preserving the universal healthcare model will require improved system efficiency, the optimization of resources & facilities, more dynamic and adaptable Health systems. This is already an ongoing effort in many Member States and financial pressures will lead to the temptation to rationalize Healthcare provision and to the consolidation of Healthcare delivery facilities as a mean to contain costs. On the other hand, part of the necessary adaptation needs to be provided by development and deployment of innovative technologies that enable new and more efficient health services, new medical interventions and better health outcomes. Research & development promoting technological development is an important enhancer of continued economic growth and its potential is acknowledged by the EU, which is pooling resources to support Innovation. Horizon 2020 is under discussion. The size of the program, its higher focus on innovation and its drive to coordinate efforts with the Member States and with the private sector is certainly unprecedented.

This conference comes at a time where concerns about sustainability of health systems increase pressure to ensure efficient spending. To refocus innovation on more beneficial health outcomes may in itself be a cornerstone change for the industry. Dominance of chronic diseases will certainly force a change in incentives structure for innovators but also to treatments that enable patients to return to an active and productive life. We may witness a shift in focus from diseases treatment to health promotion-disease prevention, and even further to the development of secondary prevention. With health systems having difficulties to continue accommodating the growth of health expenditures, innovative technologies will be subjected to increased scrutiny and health technology assessment (HTA) will have a more prominent role in determining healthcare resource allocation in the future. While HTA is a valuable and necessary instrument for decision making, it is important that it does not represent an unnecessary burden for companies facing a diversity of national requirements for HTA and approval mechanisms. The recent EU legislation on cross-border healthcare will certainly prove to be useful in this regard.

**Roland PFLEGER, Vice-Chairman, European Medical Technology Industry Association (Eucomed)**

Innovation is vital to making ever more efficient and cost-effective technologies available to Europe's citizens. These solutions reduce suffering, allow for earlier diagnosis and enable ever less invasive treatments. Therefore, it is key to maintain an innovation-friendly environment.

Whereas twenty years ago healthcare was about progress, new treatments and making life easier, nowadays, the discussion centres around the "cost of healthcare". When thinking about future healthcare models, one of the key issues now debated by the industry is how to involve the patient more into the healthcare equation.

As an industry, we need to inform patients about the benefits and possible consequences of our technologies. This will empower them to make informed decisions.

Additionally, all healthcare stakeholders need to start looking at the entire care pathway, for instance when assessing the value of novel technologies. In its "Contract for a Healthy Future", Eucomed outlines the medical technology industry's 5-year strategy for keeping healthcare systems sustainable. The Contract stresses the need for considering not only clinical value of new technologies, but also their social, economic as well as financial benefits. The medical technology industry recognises that it can no longer continue on the familiar path of innovation without marrying cost-effectiveness with
improved clinical outcomes. Industry is ready and committed to play its part, and calls upon the other stakeholders to do the same.

Nathalie MOLL, Secretary General, EuropaBio

Mrs Moll gave a policy overview and vision of the Biotech and Pharmaceutical industry in Europe. The pharmaceutical industry is still one of the leading high technology industries in Europe, amounting to 18.9% of total worldwide business in R&D expenditure and 3.5% of the total EU manufacturing added value. Healthcare systems are going through unprecedented changes. On the R&D side, due to the increase in R&D expenditure we see the number of innovative medicines dropping and overall pipeline decreasing. The industry is adapting through increasing in-licensing and through working in collaboration with SMEs to minimize in-house R&D costs. The regulatory requirements are increasing substantially the product development costs on R&D driven pharmaceutical companies. Many innovative companies are adopting mitigating strategies, meaning they are no longer looking for new solutions, which are expensive, but turning towards biosimilars.

There is a change in the environment all the way from R&D to approval, and in the pricing and reimbursement. On average, the time it took to develop a product in 2003 was more or less 11.8 years. Now is 13.4 years. That adds 2 years for the patient to get the product. The same applies on average clinical development times: in 2000 it was 5 years, while in 2008 it was 8 years. The constraints and the requirements to ensure that the products are safe have to be balanced with the need to get the products to the patients in time.

Member states have also started to introduce hurdles after the authorization of products, when deciding on pricing and reimbursement. With the objective to speed up access to medicines for patients, there are currently discussions about the revision of the transparency directive to streamline and reduce the duration of national decisions on pricing and reimbursement of medicines.

What can we do as an Industry? The traditional pharmaceutical development model is not sustainable and we are moving towards personalized medicine, a considerably different model. We need to continue to innovate. We need to offer value for money. Corporate social responsibility is also important. We need to communicate the value of innovation.

Also Member States need to play a role to help innovation, embracing innovative treatments, understanding them without cutting costs prior to considering their impact, fostering as appropriate a competitive and innovative industry in Europe for the ultimate benefit of the patient.

Mariagrazia PIZZA, Senior Project Leader, Novartis Vaccines & Diagnostics, Siena, Italy

Mrs Pizza started with an evolutionary perspective of vaccines R&D.

All empirically discovered vaccines were found in Europe. Still Europe has a leading role in vaccines research, representing 2/3 of global R&D in the sector. 90% of vaccine production is held in Europe with only 1/3 of the market in Europe.

The new technologies (Systems Biology, Human Immunology, Co-Clinical...) will have an impact in a faster development of vaccines, in particular on the discovery phase. The critical step is now the clinical development. As phase I and phase III clinical trials are performed sequentially, they are much longer. What we envisage and wish for 2020 is a substantial decrease of the clinical development time through new tools, new mentality and approach making possible to run phase I and phase II clinical trials in parallel, with a low number of subjects, through the use of systems biology.

New vaccines should also address the current needs of society. Due to the increased life expectancy, adults and elderly people represent today the main targets. The development of vaccines for emerging infections and special populations like travelers, HIV infected and those in poverty are also a novelty.

Vaccines against poverty are a major challenge. Infectious diseases, in addition to causing morbidity and mortality, are a major contributor to poverty. Novartis has engaged in a Public-Private Partnership in developing countries, addressing the gaps to develop effective and affordable vaccines for neglected infectious diseases through Novartis Vaccines Institute for Global Health (NVGH).

Anders OLAUSON, President, European Patients’ Forum

Mr. Olauson started by raising the question: “How to foster innovation and its adoption in healthcare in an equitable and sustainable way?”
Patients can play a key role in providing answers to these questions and help us overcome the remaining barriers to maximize gains from healthcare innovations.

The issue at stake is “how can innovation provide the right answers and solutions to overcome the trade-off between cost-containment and quality and access to healthcare?” It is important to bear in mind that different stakeholders have different needs and expectations of a given innovation. For health organizations the intended benefit in innovation can be measured as enhanced efficiency of operations and cost, increased productivity, and quality improvement. From a patient’s point of view, benefits are: improved quality of life, satisfaction with healthcare, reduced suffering and harm due to illness.

Patients’ needs are at the very core of healthcare innovation. One of the conclusions of last year’s conference was that healthcare innovations not reaching patients are a waste of time, expertise, and resources. Building on that, we can now say that innovation not reaching the patient is not only wasteful, but is not innovation at all.

For innovation to fully generate its intended benefit it is paramount to have the “patients” involvement! This plays a crucial role in helping to understand not only what the real needs of patients are, but also, what the benefits and opportunities of Health innovation are, and whether these are perceived as such by the patients.

Innovation in healthcare is, however, an area where the patient has traditionally not been involved. Where there is involvement, this takes place too late when processes and services have been already developed in order to “convince” patients rather than engage with them.

It is true that involving patients in health innovation is sometimes a complex and a costly process. This holds particularly true in e-Health and pharmaceutical innovation. Evidence, however, shows that the costs of involving patients outweigh the costs of not doing it. The key issue remains how to ensure the effective involvement of patients in healthcare innovation. There is work to be done to create the necessary conditions for patient involvement, in particular in regards to health literacy and patient’s empowerment. A remarkable step forward in this area is the ‘European Patients’ Academy on Therapeutic Innovation (EUPATI), a patient’s academy funded by IMI.

Plenary Q&A session

A representative from the transatlantic consumer dialogue made reference to the WHO expert group on R&D treaty, which presented a proposal on new innovation models based on the concept of a) openness; b) new innovation models and c) de-linkage of the cost of research and development (R&D) from the price of medicines (collaborative burden sharing), and asked how would a public program like Horizon 2020 allow for such openness and what concrete measures would be taken in the EU.

The panel emphasized that the EU puts a lot of emphasis on transparency. The EU programs are built on open consultation and the results are publicly shared. But it is also essential to assure and stimulate European competitiveness and valorization of research results. Patricia Reilly highlighted that there is no real conflict between the current “push for open access” and patenting or other forms of commercial exploitation in the proposals for Horizon 2020. In fact, the commitment to open access is really unprecedented, both regarding data and results, while at the same time protecting the IP that allows innovative companies to actually make up the difference that we need. A combination of sensible open access policy with a sophisticated approach to cooperation between the private sector and public funding is very much the way the Commission intends to put forward.

A second question regarded the fact that “Innovation in Healthcare without Borders” needs international cooperation with developing countries and the participant inquired about related strategies and instruments the EU is considering in H2020.

The panel answered that, in general terms FP7 calls for proposals are open to international cooperation.

With Horizon 2020 the EU will continue that level of openness, access and availability across borders. In Health, the Commission is fully committed to continue supporting partnerships such as EDCTP, working very diligently with the Member States to enlarge the scope of this initiative, to include, for instance, additional phases of clinical trials, from phase I until post-marketing studies, and not only
focusing on phase II and phase III, as well as including other neglected infectious diseases. The conference next November in Cape-Town will signal the next phase of EDCTP.

The Commission supports also an initiative on rare diseases with partners from all over the globe to mobilize a large consortium of funders, with the goal to bring forward by 2020, 200 new therapies for rare diseases and the diagnostic means for most rare diseases (25 entities so far have committed).

SESSION A1: BEYOND BORDERS FOR BUSINESS SKILLS IN HEALTHCARE

Moderators:
Stéphane Hogan, Head of Horizontal Aspects Unit, Health Directorate, DG Research and Innovation, European Commission
Claire Skentelbery, Network Manager of the Council of European BioRegions (CEBR)

Panel:
Paul Trenerry, Senior Vice President, Scinovo, Platform Technology and Science, GlaxoSmithKline, UK
Lene Foss, Professor, Tromsø University Business School, Norway
Eric M. Wielhouwer, CEO Syntecnos, The Netherlands

The aim of the session: To explore the Human resources perspective and the skills required to grow a company and develop innovative ideas through the value chain and ultimately bring value to the patient.

The emphasis of the discussion was put on how Europe is making use of existing talent and how it could fill the gaps that remain, focusing on the Healthcare Innovation value chain.

The session assembled the point of view of industry, Big Pharma and SME, Academia and from the EC. Each stakeholder presented their experience and cases and were asked to comment on the lessons learned: what had worked, which were the most important challenges and the key issues in transferring knowledge from different stages (and worlds) in the healthcare innovation chain. What had been experienced in skills and programs with concrete economic impact?

The discussion highlighted the cooperation between Academia, SMEs and Industry and the fact that the real issue is no longer “what skills”, but rather new and effective models to transfer and acquire skills that go mostly through direct and genuine interaction, as opposed to training.

The main outcome of the discussion was that direct integration is the most effective way to transfer knowledge and skills across worlds.

Strengths:

- There are already significant skills throughout the healthcare innovation value chain.
- There are bright spots in ‘up-skilling’ where impact has been significant in delivering economic value.
- Skills transfer is best when there is direct integration between worlds (academia, industry, clinical setting, patients…).

Weaknesses:

- Skills remaining in silo. Little crossover among “worlds”. Insufficient cross-world training, or introduction to regulatory understanding for research students. University research does not yield significant knowledge transfer between different “worlds” and facilitate up-skilling.
- Larger mindsets are needed in several key places and support agencies, e.g. TTO, the value placed on IP and when it should be recouped, at what stage in the value chain. In Europe there is a move to recouping IP as early as possible, which impacts negatively as it does not achieve its full potential.
– Little chance of highly specialized individuals becoming broader practitioners.
– The former are impacting negatively on return on investment.

**Opportunities:**
– Everything is available in Europe – no ‘new’ skills are missing!
– Opportunity to change the approach to skills development away from external teaching about different elements of healthcare business delivery, and instead towards the integration of different elements directly.
– Building of Trust through direct relationships and partnerships between worlds (academia, industry, clinical, finance…)

**Threats:**
– A main threat remains and that is inaction! Delivering and making things happen is essential.
– Inadequate assessment criteria. Too much monitoring on a narrow number of criteria. There is a need for solid and externally assessment criteria for direct skills integration and exchange.
– There is still increased pressure in each “world” to deliver in “silo criteria”, which makes integration harder e.g. requirement to publish and getting to the next milestone.

**Recommendations**
1. Foster direct integration of people between worlds e.g. clinicians in R&D units of companies; students in SMEs, big business or venture capital; pharma into academic labs; TTOs into industry; academics into business…
2. Promote placements, entrepreneurs in residence, staff exchanges, mentors, student movement and new board members – throughout the value chain.
3. Make integration compulsory in collaborative projects. Training is important but not a ‘cure all’, so must be complemented with integration models.
4. Ensure careful choice of assessment criteria, which allows skills integration to be addressed, and not only “silo criteria”.
5. Capture and retain talented ‘broad skilled’ people – not narrow specialists – as vehicles for technology development.
6. Networking and partnership-building to ensure barriers between worlds become more porous.
7. Increased role of alumni for success/failure understanding.
8. Work on culture and mindset more e.g. change the expectations for managing IP revenue from universities, change policy making outlooks and make sure they are integrated across the different worlds and development stages.
10. Ensure standards across Europe to limit variation in quality and support.
11. Encourage a landscape where SMEs are allowed to make mistakes.

**SESSION A2: BEYOND BORDERS IN KNOWLEDGE TRANSFER: RAISING STANDARDS AND CAPACITIES**

**MODERATORS:**
Patrick MCCUTCHEON, Policy Officer Knowledge transfer, industrial research monitoring, public procurement; Innovation Policy Unit, DG Research & Innovation, EC
Christian SUOJANEN, Head of Life Sciences, Valor Management S.A. (CH) & Co-Chairman, Tech Transfer Summit Initiative, TTS Ltd., UK
**PANEL:**

**Anders HAUGLAND**, President ASTP & Managing Director, Technology Transfer Office Bergen, Norway

**Mike JOHNSON**, Divisional Director, Corporate Partnerships, MRC Technologies, UK

**Katja ROSENKRANZ**, Senior Manager, Spinnovator, Germany

**Rob PINNOCK**, Scientific Liaison, Merck Sharpe & Dohme

**Michel MORANT**, Managing Director, University-Industry Liaison Office, University of Liege, & CEO of Gesval, TTO of University of Liege, Belgium

**The aim of the session:** Acknowledging the importance of having worldwide top class capabilities in Technology Transfer for Europe, this session explored the topic of how to develop efficient knowledge/technology transfer from academia to industry in Europe.

Building on the discussions of the 2011 meeting, the focus of this session was mostly on building human capacity, developing expertise through best practices, training and networking. The emphasis was on the generation of more healthcare sector specific industry knowledge, expertise and understanding among young tech transfer officers, building real collaborations and doing what it takes to get safe, effective new therapies & technologies to patients.

The session was organized as a moderated round-table discussion, with views from industry, managing directors of European technology transfer offices (TTOs) and technology transfer associations. There were no presentations and the speakers were invited to comment on what knowledge transfer meant to them and what other sort of training to TTOs should be embraced to assure that it can provide real benefits to patients down the chain. Technology transfer was defined as the entire process bringing world-class research from lab onto market to the patient.

**Strengths:**

- There is a core of experienced, skilled TTOs at leading Universities and Research Institutes in Europe.
- Existence of Association Training on basic skills & logistics.
- Existence of a system for certification of TT professionals.
- Willingness of industry & finance to contribute and be involved to improve the situation.
- Existing networking among the TTOs and with other stakeholders in the healthcare innovation value chain.

**Weaknesses:**

- Lack of enough skilled, experienced professionals with real industry practice. There are a few professionals, but not enough and they are in high demand. What is fundamental is to have expertise & understanding of the healthcare sector and market and of the needs of the key stakeholders.
- Most TTOs are relatively new, and have not had enough time to have experienced TT officers.
- Many TTOs are small and lack critical mass regarding technologies as well as TT officers.
- Existing networks need to be strengthened & reach the “smaller” & “newer” offices.

**Opportunities:**

- Current EC FP7 projects are about to be launched on Networking & Training
- Interest of industry & finance (VCs) to coach and work with TTOs to build the capacities.
- Build on existing stakeholder networks (TTOs, Industry, Finance, IP, Entrepreneur)
Threats:
- Again "doing nothing" and inertia are the main risks. TTO and innovation are not yielding the potential results.
- Fragmentation: duplicating of existing structures
- Training by non-experts without reference to sector/market and focus only on logistics. They are important but insufficient for the healthcare industry.
- Technology transfer metrics tend to measure activity, not impact.

Recommendations
1. Secure existing structures (networks, training, associations). Build on the existing capabilities.
2. Focus on developing healthcare/bio/Pharma/device, sector/market knowledge & understanding.
3. Network based training for TTOs, top TTOs imparting expertise & experience, best practices to younger TTOs.
4. Collaborations between stronger TTOs & smaller offices like charities, etc. (internship, secondment-based training).
5. Ensure TTO mobility and "virtual mobility": exchanges, internships, secondments; TTO – TTO, & TTO to industry (pharma, biotech, regulators), finance- VC. And make it bilateral!
6. Empower collaborative programs. Encourage broader and deeper collaborative programs between industry, academia, financial, etc.
7. Encourage an early level (informal) of interaction between TTOs and industry.
8. Public funding for protection of IP.
9. Creation of maturation funds (after Proof of Concept) for small TTOs.
10. Collaboration/Integration of TTO and the Research management offices. It is important to have the TTO involved in the decision process of the research grants and R&D fund management.

SESSION B1 – HEALTH INEQUALITIES WITHIN EU – THE CASE IN NEW EU MEMBER STATES

MODERATORS:
John WALSH, Deputy Head of Unit Thematic Coordination and Innovation, DG Regional Policy, European Commission
Carsten THIEL, Vice President, Amgen Europe, Board Member of European Biopharmaceutical Enterprises (EBE)

PANEL:
Andrea MADARASOVA GECKOVA, Kosice Institute for Society and Health, Slovak Republic
Marton MATKÓ, Managing Authority of Regional Operational Programs, National Development Agency, Hungary
Isabel DE LA MATA, Principal advisor with Special Interest in Public Health, DG Health and Consumers, European Commission

The aim of the session: "Overcoming barriers to equality and solidarity", exploring new challenges of health inequalities within the EU and beyond.

DG Regional Policy, aside to Cohesion policy, deals with many other policies as well (health, agriculture, research/ innovation). Each region receives its own focus (from building basic infrastructure to supporting smart specialization and sustainable growth). The development of sustainable/affordable high quality healthcare systems requires going beyond discussing at the level...
of investments. Challenges lie rather at the level of delays in market authorizations and health inequalities relate to poor nutrition, poverty and unemployment, low educational level and also availability of transport (to a clinical center) and discrimination/immigration policies. Regions at risk of declining healthcare often suffer from additional problems such as increased flow of poor immigrants (e.g. the Roma) with specific health problems (high infant mortality), while facing local discrimination.

It was recognized that there is an urgent need for better horizontal collaboration across various levels (see also discussion and recommendations in next session) to address these issues in a more coherent way.

Also, quality data collection was debated: although some people argued there is already an abundance of data, but not enough knowledge, others argued that better quality data and indicators for success should be made available. Assessments linked to results at level of improved quality of life and overcoming cultural inequalities (as above), rather than counting number of beds and buildings constructed, would be valuable.

In addition, the absorption capacity of various regions across Europe is not equal, with good examples (e.g. in Portugal, Spain) and regions where structural fund spending may not have led to sufficient impact because of choices made by local governments, who not necessarily are trained to understand the European framework thinking. The current ‘audited/cost-controlled project call’ approach therefore may be less effective in these Regions than a more holistic programming approach for funding (a successful example from Hungary was presented).

**Strengths:**
- a relatively wide understanding of the drivers of health inequalities and the metrics is available
- Innovation has been applied to tackle health inequalities (i.e. Hungary, Spain, Portugal)
- Growing experience with e-health
- Public private partnerships like Innovative Medicines Initiative between pharmaceutical industry association EFPIA and EU or the International Rare Diseases Research Consortium to foster research on rare diseases (with the objective to deliver 200 new therapies and diagnostics by 2020) or joint actions like the European Union Committee of Experts on Rare Diseases to support Orphan Drugs regulation in the EU

**Weaknesses:**
- Health policies/provision are fragmented, budgets vary with different capacities and approaches to funding (i.e. differences in intensity of reimbursement of drug treatments).
- Lack of consensus amongst health policy maker and stakeholders on transformational changes needed in national health systems.
- Learning from positive experiences have not yet been translated into general thinking about defining effectiveness of action.
- Need for more work on public health priorities.

**Opportunities:**
- We need more integrated approaches to address health inequalities (addressing awareness, changing behavior, socio-economic factors, health system changes)
- Strong will for further exploration of health inequalities, to align political, social & economic priorities at EU and MS levels
- The role of innovation in different forms
- High political value attached to health
- Continued work on flexibility of the Structural Fund system

**Threats:**
- Pressure on public financing – continuing unmet needs, cuts in existing provisions;
- Political danger of frustration in meeting expectations;
Medical innovation has not been applied to tackle inequalities
Staying in silos, failure to adapt integrated approaches

**Recommendations**
1. Comprehensive, integrated strategies to address health inequalities;
2. Targeted use of structural funds to support innovation and transformational change, especially in less developed MS and for socially excluded groups;
3. More transparency and a clear focus on contribution to health outcomes under the cohesion policy framework 2014-2020;
4. More work needed on more relevant indicators linked to purpose of intervention

**SESSION B2 – BRIDGING THE BORDERS AMONG DECISION MAKERS**

**Moderators:**
Jacqueline MINOR, Director, Consumer Policy Directorate, DG Health and Consumers, European Commission
Luciano CATTANI, Chief Executive, Eucomed

**Panel:**
Anna SAPINO, Head of the Service of Surgical Pathology, San Giovanni Battista Molinette Hospital and Professor of Pathological Anatomy and Histology, Medical School, University of Turin, Italy
Sharon HIGGINS, Director, Irish Medical Devices Association, Ireland
Daniel FORSLUND, Chief Strategy Officer, Health Care Development, Sweden’s Innovation Agency VINNOVA, Sweden
Nicola BEDLINGTON, Director, European Patients’ Forum

The aim of the session: This session was building on the previous session on inequalities, but rather addressing the need for more cross-sector co-operation between the various bodies and decision levels.

The panel presented their views each from their own perspective (the clinician, the patient, the SME and the government).

At the clinician level the difficulties of balancing the needs of the patient vs the needs of the hospital were highlighted.

The patient is often ignored or involved rather late (instead of at the idea stage) and there is sometimes a lack of commitment to address the potential impact on the lives of patients, which would have helped to judge risk factors and make better decisions. An example of a good communication platform (EUPATI model) was presented, which might be adopted (e.g.) for a better dialogue in the Medical devices R&D sector as well.

At the level of the SME, the challenge of reduction of costs in healthcare systems with rather conservative procurement rules and HTAs (not very open to adopt innovations) was discussed.

Also effective dissemination and sharing of good practice across Europe would help to create sufficient awareness of innovative solutions.

Government innovation agencies could have a key enabling role if they assist innovations more with their implementation phase (several good practices from Sweden were presented on facilitation at multiple levels: innovate procurement, promote challenge driven innovations, structured information throughout the healthcare system, leadership to create political ownership and proper management, verification and demonstration of impact in test beds to create the right arguments for large scale roll-out).
Strengths:
- Innovative environment with high adaption to technology
- Effective and efficient regulatory environment
- Scattered co-operation initiatives
- Scientific excellence
  - modern, service-minded organization
  - Well-educated staff, patients with e-skills, high expectations

Weaknesses:
- Very slow innovation uptake at national level
- Difficult procedures: purchasing, reimbursement, funding, venture capital, HTA
- Framework/ R&D - Funding Models
- Difficult access to international distribution channels, esp. for SMEs
- Uneasy access to information on new technologies
- Viscosity of change at Member State level
- Coherence in policy making

Opportunities:
- Mapping of disparities and needs
- Growing awareness at decision-making level
- Increasing will of collaboration between different stakeholders
- Active involvement of patients and patient organizations
- Cross-silo information to relevant stakeholders
- Central catalyst for multidisciplinary networking (EU & then MS)
- Dedicated funding
- Organized sharing of best practices

Threats:
- Innovation perceived as inflationary instead of efficiency generator
- Complex reimbursement models discourage uptake of innovations and novel technology commercialization
- Not fit for purpose reimbursement regulations
- Lack of holistic vision on benefits of innovation (silo thinking)

Recommendations
1. Build awareness and ownership for innovation at highest decision-making level and beyond healthcare only
2. Fund/ organize collaborative multi-stakeholder projects
3. Support patient involvement and empowerment
4. Build bridges across silos as per funding and know-how
5. Consider community care oriented innovation (new)
6. Create facilitated EU network for innovation (use of new social tools)
7. Organize central structure to gather stakeholders and Member States around best practices and knowledge sharing (Commission role?)
8. Member states have dedicated budget for breakthrough innovation, example to be followed
9. Design SME friendly, fit for purpose Regulations and HTA access processes
10. Survey top priority SME needs to allow market access to innovation
11. Simplify:
   a. Reimbursement decisions
   b. Purchasing procedures for innovative technologies

PROGRAMME & SESSION REVIEW DAY 2

KEYNOTE SESSION

Pedro ORTÚN, Director, Tourism, CSR, Consumer Goods and International Regulatory Agreements Directorate, DG Enterprise and Industry, European Commission

Vice-President Tajani launched in September 2010 the "Process on Corporate Responsibility in the Field of Pharmaceuticals". Under this initiative 3 platforms have been set up:

1. The first platform brings together all relevant stakeholders to openly discuss ethical and transparency principles and recommendations. The result of our efforts will be a European set of guiding principles governing the interactions between healthcare professionals and patients’ organizations, competent authorities and mainly the pharmaceutical industry.

2. At the platform on Access to Medicines in Europe, working groups focus on different aspects of access to medicines: the conditions which could increase the market uptake of biosimilars, the special situation at small markets, the experiences with managed entry contracts, the orphan medicines and over-the-counter products.

3. The third Platform on Access to Medicines in Developing Countries with a particular focus on Africa aims at reflecting on the contributions stakeholders can make by pooling/coordinating their resources and capabilities in this continent and more specifically in the sub-Saharan region. A first working group on patent information is focusing on the better access to the patent information needed for medicines which are of particular interest to developing countries. A second working group concentrates on local capacity building. In cooperation with the industry (European and African manufacturers), with international organizations like UNIDO, WHO and UNCTAD, wholesalers and patients’ organizations possibilities are explored to support capacity building for distribution channels, local production and clinical trials in Africa.

The core business of DG Enterprise and Industry is to boost innovation and competitiveness of the European industry as the pre-condition for sustainable and inclusive growth and job creation with a particular focus on SME. Hence, between 2014 and 2020, DG Enterprise will launch a 2.5 billion EUR funding instrument, called COSME (Programme for the Competitiveness of Enterprises and SMEs) which will continue beyond the current Competitiveness and Innovation Program (CIP).

Also, DG Enterprise and Industry will strengthen the Enterprise Europe Network under COSME within the new Multiannual Financial Framework. The EEN, with currently over 600 partner organisations in over 50 countries, is the world’s biggest business support network offering a wide range of services to the small and medium sized businesses.

These include, beyond information and advisory services on EU legislation, also commercial, technology and research partnering including high quality technology transfer and innovation services. The EEN is to play also an important role in the implementation of Horizon 2020.
SESSION A3 - EU RESEARCH AND INNOVATION FUNDING, A TOOL TO REMOVE BORDERS WITHIN THE EU AND BEYOND

M OdERATORS:
Ruxandra DRAGHIA AKLI, Director, Health Directorate, DG Research & Innovation
Richard BERGSTÖM, EFPIA Director General

P ANEL:
Henk STUNNENBERG, Radboud University, Nijmegen Medical Centre, The Netherlands
Morten ALBRECHTSEN, CEO, ENKAM, Denmark
Anne-Fabienne WEITSCH, CEO, Endocells, France

The aim of the session: On the basis of testimonials about FP7 Health and IMI, this session assessed how Horizon 2020 will respond to the needs of the healthcare sector to boost European Research Area and the competitiveness of EU industry.

The speakers were further invited to reflect and discuss on the existing “Borders”: Big vs. small companies, public vs. private, translational borders - from discovery to development and from science to patients - as well as the physical borders in the MS countries and beyond Europe.

EU funding plays an important role in removing borders for research and innovation and is a major driver of competitiveness and growth. How do current and new instruments enhance innovation? Europe still faces major challenges, which demand a closer look and action:

- Non-communicable diseases worldwide will cause an output loss of €35 trillion over the next two decades.
- There is an increasing pressure for costs cutting on European healthcare systems.
- The EU is not closing the persistent gap with global innovation leaders such as the US, Japan and South Korea.
- Biomedical companies are finding drug development in Europe economically challenging and companies are moving their operations from the region, mainly to Asia.

Horizon 2020 aims to tackle many of the challenges and reinforces the continuation of successful risk-sharing programs like IMI and EDCTP. It further addresses several of the recommendations which came out of the 2010 and 2011 innovation in healthcare conferences.

Strengths:
- Strong EU-based biomedical research
- Success of previous/on-going EU health programs (FP6 and FP7)
- Success of PPPs (public-public and public-private) initiatives, namely the IMI and EDCTP
- Continuous support from the EU with a budget of €80 Billion proposed for Horizon 2020

Weaknesses:
- Fragmentation and low coordination in major health research fields in Europe (e.g. cancer, brain diseases, dementia/ Alzheimer).
- Persistent lack of private funding and recent disinvestment due to the economic crisis.
- High-risk / high-return approaches insufficiently supported in the EU.

Opportunities:
- Various stakeholders already working in partnerships in Europe (public-public, public-private, academic, SME, patient organization, large industry etc.)
- New SBIR-like instrument addressing the “valley of death” in early stage funding for SMEs.
Overall, a budget increase (+46%) for European research and innovation funding in Horizon 2020.

Threats:
- Persistent Innovation gap vs. the United States and Asia (Japan, South Korea…) in health.
- Persistence of the economic crisis.
- Emergence of BRICs with research and innovation capacities moving there due to more favorable environments (funding, regulatory advantages, tax incentives etc.)

Recommendations
1. Amend the current financial regulation so that single entities (especially SMEs) can be funded in Horizon 2020, in particular for the SBIR-like instrument.
2. Pursue EU funded collaborative research associating key stakeholders in the health field.
3. Renew and make more flexible innovative partnership initiatives (IMI, EDCTP).
4. Continue involvement in international initiatives – scale and scope.

SESSION A4: REMOVING BOUNDARIES AN ACCESS TO FINANCE: NEW APPROACHES, NEW MODELS

MODERATORS:
Clara DE LA TORRE, Director Research & Innovation Directorate, DG Research & Innovation
William STEVENS, CEO, Europe Unlimited, Belgium

PANEL:
Tom SAYLOR, CEO, Arecor and Chair of the EuropaBio SME platform
Denis LUCQUIN, Sofinnova Partners, France
Livio SCALVINI, Intesa Sanpaolo S.p.A., Italy
Markus SCHILLO, Head ERP-EIF Dachfonds, European Investment Fund
Jimmy LIN, Rare Genomics Institute, USA
Mark Wilson, Director of collaborative management, GSK, UK

The aim of the session: Access to finance still remains one of the most significant obstacles to innovation in healthcare in Europe. How can we overcome this obstacle and move beyond current boundaries?

Panelists were invited to comment on a set of 4 questions:
1. Which are the factors that make it difficult for players in the health innovation chain to have a reasonable level of access to funding?
2. How can we attract private sector investment?
3. What are the prospects of financing healthcare? Alternative sources of funding?
4. How and should the EU address some of the bottlenecks?

Venture Capital (VC), a key source of knowledge and finance for the sector, has been suffering from very low returns and is expected to shrink dramatically.

The panel discussion revolved around Europe needs for new models and funds that adapt to its specificities. In order to mobilize investment, there must be returns.

The increased participation of Big Pharma as corporate investors and the willingness of VC and Pharma to cooperate effectively in order to strategically bring assets down the chain and new drugs to the patients was recognized as extremely positive. The discussion focused on early-stage research. Crowd sourcing funding and venture philanthropy were very effective in the US, and should be
embraced more in Europe. Ultimately, the sector requires high amounts of money, which Business Angels and national public initiatives addressing the early-stage funding gap are not able to deliver. Therefore we must find a way to bring institutional investors’ money back in the health sector to fuel VC, which remains a key stakeholder in the healthcare innovation value chain.

**Strengths:**
- Strong science and current existence of serial entrepreneurs.
- Cross border investment and cooperation.
- Growth of corporate interest (open innovation) & funding (corporate venture investment).
- New financing models are emerging.

**Weaknesses:**
- The track record of VC returns is poor…
- Fragmentation of markets, namely financial markets (fiscal union?).
- Importance of regulations beyond finance.
- Risk (equity needed vs. debt) as long-term.
- National stock markets lack critical mass, and offer no real exit solution to VCs.

**Opportunities:**
- Learn from efficient existing national incentives.
- More funds of funds – attract back big institutional investors.
- Potential of new financing models: crowd funding (i.e. patient groups), new co-investment schemes for Business Angels and philanthropy.
- Corporate venturing/innovation.

**Threats:**
- Quote: “VC will die”!
- “Not allowing (faster & cheaper) failure” in Europe.
- Quote: “Debt is a trap” for the typical Biotech company. There are companies with a beneficial combination of debt and equity investment, usually for small investment, and companies which are able to generate revenues in the short term. However, in the context of healthcare innovation, venture debt is dangerous and very expensive.

**Recommendations**
1. Improve framework conditions for both investors and entrepreneurs.
2. Mobilise institutional investors (Limited partners, as they are going out of the system, by increasing the attractiveness of VC e.g by offering new return-oriented initiatives or supporting the objectives of the institutional investors.
3. Put emphasis on equity rather than debt.
4. Consider the societal value of the companies.
5. Raise the profile of the sector, to raise awareness and advocacy which will impact positively in bringing investors into the sector.
SESSION B3 – IMPROVING ACCESS TO MEDICINES IN AFRICA, WHERE DO THE SOLUTIONS LIE: AT HOME OR ABROAD?

MEDIUMATORS:
Clive ONDARI, Coordinator, Department of Essential Medicines and Pharmaceutical Policies, WHO
Nathalie MOLL, Secretary General, EuropaBio

(SWOT and recommendations were reported in the final session by Salvatore D’ACUNTO, head of Unit F5, DG Enterprise and Industry, European Commission)

PANEL:
Olowo Martin OTEBA, Assistant Commissioner and Head of Pharmaceutical Unit, Ministry of Health, Uganda
Jürgen REINHARDT, Industrial Development Officer United Nations Industrial Development Organization (UNIDO)
Sandeep JUNEJA, Business Development Director, Medicines Patent Pool
Evan LEE, Vice President Global Health Programs & Access, Eli Lilly

The aim of the session: Cooperation with Africa is of strategic importance for Europe and improving access to medicine is a key element of a better healthcare system.

Issues that were discussed in this session included:

a) which medicines to select first,
b) how to deliver (who pays, equity vs solidarity),
c) sustainability (safety, efficacy, quality and affordability),
d) efficient use of resources (wasted and misused medicines, human capital, purchasing systems).

In spite of the fact that with so many variables these are complex issues to address in the heterogeneous context of Africa, some remarkable progress has been made (several examples were presented). In order to enable a paradigm shift in cooperation between Europe and Africa, new forms of equal partnerships with multiple stakeholders from both public and private sectors are needed - as opposed to mainly public sector or NGO driven initiatives in the past.

Professional facilitators experienced to work with industry can help to implement programs with a long term vision. Where these have a focus on knowledge transfer (local ownership, matchmaking, reducing barriers to access to IP) and sustainable capacity building (e.g. developing or upgrading capacity of local pharma manufacturing capacity, developing local expertise) they can create real leverage and attract investments.

Challenges remain at the level of fragmented expertise, regulatory standards, medicinal production capacity to follow the rapidly increasing needs and creation of viable markets.

Many questions arose and the audience engaged in an active discussion with the panel around how partnership were formed, and how transparency made a big difference about the changes happening in the landscape today as compared to a few years ago, when initiatives faced a low level of enthusiasm (especially from big players).

A testimony from Lilly clearly explained the benefits for a big pharmaceutical company: improvement of external corporate image and also of corporate responsibility internally (better motivation of staff), expansion of corporate responsibility globally (move away from US centered approach) and finally metrics going clearly beyond simple technology transfer with an investment of 135 M€ creation of cohesion in a previously fragmented market (in this case for MDR-TB) and having a direct impact on people’s health.
Strengths:
- Health is a priority that increasingly dominates in policy debates across the countries and an increased interest in local pharmaceutical production;
- Willing partners to support investments in health, with capacity and technological know-how;
- Shift from product donations to nurturing competitive local production and market for health activities;
- Move towards focused technology transfer and public private partnerships;
- Availability of key data and systems to track progress, e.g. improved core health indices at least partially (infant & child mortality rates);
- Mechanisms to address IP issues are now available.

Weaknesses:
- Limited distribution capacities to ensure uptake and rational use;
- Disaggregated demand and lack of information to support market decisions;
- Fragmentation in national and regional markets as well as in interventions aimed at supporting the sub-sector;
- Varying and limited capacity in medicines regulatory authorities;
- Limited access to technology and investment capital to expand local capacity to attain international standards;
- Method, philosophy and the politics around health investments;
- Continued limited capacity in human resources both on the technology side and the management side of the sector;
- Lack of easy access to patent information and licenses.

Opportunities:
- Increasing incentives for technology/know-how and IP transfer;
- Investment and business partnership matchmaking;
- Incentives for EU industry: visibility and new market opportunities;
- Increased global access programs to aggregate fragmented demand and create market opportunities;
- Global appreciation of the seamless health problems;
- Existence of a "patent pool".

Threats:
- Lack of sustainability due to diversity of methods, philosophy and the politics around health investments – philanthropy vs sustainable health investments;
- Quality concerns (substandard, counterfeit or falsified medicines);
- Entry of patent regimes that prohibit access to low cost high quality technologies;
- Unpredictability of funding for treatments of priority diseases;
- Reluctance or insufficient involvement from some partners.

Recommendations
1. Keep political momentum, with a focus on priorities and quick gains;
2. Support the implementation of African Union Pharmaceutical Manufacturing Plan for Africa via EU-AU B2B partnerships, joint ventures, technology transfer, etc.;
3. Strengthen national capacity including R&D and regulatory mechanisms;
4. Support review in the interim of WTO/TRIPS provisions in order to provide more time beyond 2016 for least-developed countries (LDC); support public health licensing to IP;

5. Support of development of priority medicines including specific target groups (children) and niche formulations for developing countries;

6. Support exchange of best practices such as the public private partnership Procela in Uganda that allows offers from donors to be matched, assessed and aligned with national strategies, WHO guidelines etc.;

7. Support mechanisms for information exchange and public health licensing.

SESSION B4 – BRIDGING BORDERS TO BUILD CAPACITY GLOBALLY: CASE STUDY AFRICAN COUNTRIES

MODERATORS:
Line MATTHIESSEN, Head of Unit Infectious Diseases and Public Health, DG Research & Innovation
Knut SEIFERT, South Africa Country Manager and Senior Vice President International Public Health Organizations Roche Diagnostics Division, South Africa

PANEL:
David HAIN, CEO, Hain Lifescience GmbH, Germany
Philippe JACON, CEO, FIND Diagnostics, Switzerland
Joseph L. MATHEW, Chair of HTAi Interest Sub-Group on Health Technology Assessment in Developing Countries, Chandigarh, India
Tsehaynesh Messele GIDAY, CEO, African Society for Laboratory Medicine, Addis Abeba, Ethiopia
Keertan DHEDA, Lung Infection and Immunity Unit, Department of Medicine & UCT Lung Institute, University of Cape Town, South Africa

The aim of the session: Open panel discussion, focused on the role of Point-of-Care (PoC) diagnostics and the challenges for implementing it in low- and middle-income countries.

Panelists were invited to address these issues and comment on a set of 4 questions, namely:

- How can new diagnostic tools be developed in collaboration with Africa?
- How can local capacity for diagnostic innovation be strengthened?
- Can health technology assessments contribute to informed decisions on the introduction of new diagnostics in resource-poor settings?
- Which stakeholders and commitments are needed to make better diagnostics tools available in healthcare systems in resource-poor settings?

A number of parameters was highlighted to which PoC diagnostics should adhere, including key features such as accuracy, accessibility and affordability.

The panel agreed that a ‘one model fits all’ would not work, as to diagnose the right patients, integration in local context and infrastructures (pro-active patient or sampling recruitment) procedures would be needed. As in the previous session, a lively debate with many questions from the audience developed.

Innovation should be stimulated by developing human capital, but also by the way in which partnerships are developed and above all in a paradigm shift in product development. It was suggested to issue specific EDCTP calls to take product development to proof-of-concept followed by subsequent calls to take proof-of-concept products into the market, both with mandatory participation of African partners right from the start. This would strengthen local capacity, train people, ensure acceptance and take-up mechanisms, while pushing for sustainable long term solutions that fit the local needs. Other suggestions (a multi-stakeholder platform for diagnostics with Africa, better internet...
access as a primary infrastructure challenge, KT) were put forward. Other challenges were discussed, like brain drain and the role of HTAs in the product development process, how to counter perception of lack of interest by SMEs in international partnerships with Africa. In the end, the discussion evolved around the theme: how to link the right product to the right patient without too many inequalities?

**Key conclusions:**

PoC is key to develop efficient healthcare systems in low- and middle-income countries

PoC need to be cost-effective and adapted to local needs.

Training of local healthcare workers is a requirement for introducing PoC diagnostics

**Strengths:**

- African research teams are better aware about local needs and obstacles (including logistic feasibility).
- African clinical research sites have recruitment infrastructures and expertise about the local population.
- African research teams can better identify efficient channels for dissemination of knowledge at local/regional level.
- Brokering between local partners (including distributors and technical support) and uptake into healthcare system.

**Weaknesses:**

- Africa has very good scientific capacity, but clearly lacks funding opportunities.
- Lack of capacity for quality control, quality assurance and monitoring of performance of PoCs
- Weak or fragmented regulatory and registration in African countries, absence of clear guidelines
- Many resource-limited countries do not have a system or capacity to evaluate new technologies.
- Health technology assessment (HTA) is lacking in most developing countries, but can play an important role

**Opportunities:**

- Many opportunities, but significant investments are often necessary to develop business to meet the local needs. It can be hard to find African partner companies
- Collaborative science is a good example of true partnerships between Africa and Europe, but it must be based on equal partnerships

**Threats:**

- Cultural barriers: It takes time to convince partners or even employees to follow a specific idea
- Insufficient infrastructure, political issues, security
- Lack of funding is a great hurdle for African scientists, and in particular to develop ideas from proof of concept to final prototype, and from final prototype to market.

**Recommendations (or opportunities) for EU/ EDCTP/ Horizon2020:**

1. More should be done to ensure that research is translated into product development and taken up in the healthcare system. EU could consider to finance co-operation between scientists from Europe and low/ middle-income countries on the whole innovation chain, from ideas and proof of concept to final prototype and market introduction, including regulatory aspects as well as health technology assessment.

2. Increased focus on training and local capacity building through local and regional networks.
3. Funding instruments should allow African scientists (including SME's) to take the lead in research projects, such as the EDCTP.

4. Simplification of EC application procedures – too complicated for SME's

**KEYNOTE SESSION**

**Robert-Jan SMITS**, Director General DG Research and Innovation, European Commission

As a wrap-up of the conference with a view on the future, Mr Smits presented some highlights and news on how Horizon 2020 is prepared with the input of all stakeholders. Several instruments and principles from FP7 will be continued, while new elements will be introduced. As Research and Innovation are brought together more closely, cooperation between academia and industry remains important (e.g. knowledge transfer, business skills for young researchers to start up enterprises). Also new approaches to Innovation, like the EIT model will be supported, as well as new PPPs (like IMI). On the other hand cooperative RTD projects will remain an important element together with networks.

The 5 main axes were further highlighted:

1. **radical simplification**
2. improved access to finance through a combination of debt and public equity financing for innovative projects
3. intensively encouraging SMEs to participate, who are essential to create jobs and economic growth
4. reduction of Health inequalities and access to healthcare services, in spite of the current financial constraints, through innovative solutions in the healthcare chain in all regions of Europe (e.g. through a better use of the Structural Funds)
5. coherent programs (like the European Innovation Partnership on Active and Healthy Ageing), linking funding to global healthcare objectives and to strengthen capacity in partnership countries (e.g. EDCTP-2).

**Elisabeth FERET**, Head of Unit Human and Society Development, DG Development and Cooperation, European Commission (replacing Kristian Schmidt)

Research & Innovation are fundamental to enable change in developing countries. Complementarity between research and development is of paramount importance.

The Communication and Council conclusion on EU role in Global Health Challenges of 2010 followed by the adoption of the new agenda for increasing the impact of EU development policy "Agenda for Change" in 2011 had main focus on Health, Education and Social protection for sustainable growth, while supporting local business development, critical for such growth.

The World Health Assembly resolution on Global Strategy on public health, innovation and intellectual property endorsed a six-years action plan to tackle non-communicable diseases and directed WHO to help countries in reaching higher coverage of immunization. The plan developed together with WHO and the Global Report for Research on Infectious Diseases of Poverty presented in the following session acts as a guide to identify targets and to develop win-win solutions.

IP and Trade issues need also to be addressed

R&D on infectious diseases of poverty in relation to WHO guidelines needs to be prioritized to develop and guide investment strategies.

**Marie-Paule KIENY**, Assistant Director General, Innovation, Information, Evidence and Research, World Health Organization

First she expressed her thanks to the European Commission for support to WHO to analyze the challenges in tropical infectious diseases related to poverty (see also presentation in next session B5) and help in the implementation of the global strategy and plan of action.
While it is recognized that poverty induces a higher disease burden, which in turn aggravates poverty, many other factors influence this vicious cycle (clean water, environment, education, employment, living/housing conditions…).

Lack of access to vaccines, due to gaps in the cold distribution chain is one of them. Therefore the launch of the vaccine prize was seen as a welcome new approach.

Also, due to the complexity of interacting issues it is clear that decisions purely based on the best clinical approach may not be effective. So far funding has focused too much on the link 1 disease = 1 approach. Instead also a paradigm shift in funding is needed towards problem oriented funding, and preferably also a global platform on healthcare funding in infectious diseases to decide where and how to invest to get a maximum effect with the limited resources we have available since the economic crisis.

SESSION B5 - THE GLOBAL REPORT FOR RESEARCH PRIORITIES ON INFECTIOUS DISEASES OF POVERTY

MODERATORS:
Garry ASLANYAN, Scientist, TDR, World Health Organization

PANEL:
Lenore MANDERSON, Professor, Monash University, Australia
Marie-Paule KIENY, Assistant Director General, Innovation, Information, Evidence and Research, World Health Organization
Hassan MSHINDA, Director General, COSTECH, Tanzania
Hannah AKUFFO, Head of Team, Swedish Development Cooperation Agency (SIDA) and Chair, ESSENCE on Health Research
Line MATTHIESSEN, Head of Unit Infectious Diseases and Public Health, DG Research & Innovation (replacing Ole OLESEN)

The aim of the session: Present the Global Report for Research on Infectious Diseases of Poverty (see www.who.tdr/int) and discuss the way forward.

Dr Kieny presented the new Report, how it was developed through a large high level expert group and which issues were addressed with an overview of its contents.

The research spans thematic areas, with a global overview, an overview of the R&D landscape and finally 5 levels to act. The Report further makes the following 5 Recommendations for Action:

1. Create a new national development indicator using the prevalence of infectious disease (is rather an index than one indicator, to be used by policy makers and funders)
2. Adopt a 'One Health, One World' paradigm for research (a call for a multidisciplinary approach)
3. Promote research ownership by disease endemic countries (create research ownership and measure success differently)
4. Foster a culture of innovation based on open access/open source and transfer of knowledge and know how, not just on IPR (e.g. patent pool, or the Fiocruz R&D platform for neglected diseases)
5. Monitor funding flows for research on infectious diseases of poverty with a new tool

Dr Kieny took the opportunity of the Conference to briefly present the report of an independent Consultative Expert Working Group: Financing and Coordination (CEWG), which had just been released on April 5 for consideration by the World Health Assembly in May 2012. Dr Kieny commented that three of the recommendations from the CEWG (below) were very similar to recommendations 3 to 5 offered by the new Report:
– R&D approaches with more open knowledge sharing
– Strengthening R&D capacity and technology transfer in developing countries
– A Global Health Observatory to monitor funding flows and the R&D pipeline for diseases affecting developing countries

The subsequent panel discussion evolved around the following issues:
– agreement that the report came at right moment in time to swing attention back to infectious diseases
– how to embed these recommendations into national government S&T strategy and investments
– how to encourage multidisciplinary R&D (although Mrs Mathiessen noted that this was part of the EU Framework program philosophy for a long time, so there is good practice to be shared). She also thanked for the report as it would be useful and timely to link to the Horizon 2020 planning. She noted that there is still a challenge in changing the mindset of researchers.
– how to strengthen the local R&D and human capacity (see also discussions in sessions B3+4).
– also: how to convince the developing countries to invest in Health R&D as well to encourage ownership and to facilitate take up? The need to explain national governments that investing in health R&D can have an economic impact as well.
– how to boost local production capacity and attract private investments (see also discussions in sessions B3+4)
– the role of various national funders to adapt their calls (e.g. SIDA) and of EDCTP-2 (e.g. to encourage more south-south partnerships)?

Questions from the audience addressed many other issues: the influence of social dimensions such as persistent perceptions in Africa that diseases do not have a biological cause, whether it was not better to break the poverty cycle with micro-finance, the role of WHO to help national government to set their priorities, how to translate/disseminate this report to other stakeholders, making a bridge to non-communicable diseases as well.