The meeting was chaired by Ruxandra Draghia-Akli, Director for Health Research, and Liselotte Hoejgaard, Chair of the FP7 Health Theme Advisory Group.

Mrs Draghia welcomed the participants and presented the main lines of Horizon 2020 as well as preliminary ideas related to the considered Grand Challenge on Health, Demographic Change and Wellbeing, and, together with Prof. Eero Vuorio, presented the outcome of the Impact Assessment exercise for EU-funded Health research prepared in view of Horizon 2020. The latter was mainly performed through a) the works of an independent expert group chaired by Prof. Vuorio, and b) a survey of the FP6 and FP7 Health research project participants.

This exercise concludes that EU Health Research proves very successful in terms of integration of EU research teams into networks, of generation of results, publications, patents, support for small and medium enterprises (SME) and jobs creation. But it also highlight that EU research suffers from two major weaknesses: lack of funding for medical research compared to the US and Asia competitors, in relative and absolute terms, and limited alignment of medical research funding and priority-setting within he EC and between the EC and national programmes: the EU health research landscape remains very fragmented.

The participants were invited to provide their views on the challenges to be tackled by EU research and innovation, with the following set of questions provided to guide the debate:

1. What are the grand challenges and how can they be broken down into meaningful components?
2. How can research and innovation contribute to meeting these challenges?
3. What are the priorities for the EU level, and how should this relate to activities by Member States?
4. Over the next years, what will be the new and emerging research areas, technologies and innovations that should be supported?
5. How can we ensure the link between research and innovation and that results of projects are fully utilised?

The aim of this exercise being to consult a representative sample of the communities involved in this grand challenge, the summary below attempts to reflect, in a consolidated way, the ideas and view expressed during the workshop. It thus represents a snapshot of ideas presented. The views expressed may not reflect a consensus - as some were contested - and some views may be conflicting with others. Some of the challenges mentioned may be more relevant to other EU or national policies. The opinions expressed were recorded by the Commission services, but this does not represent an endorsement by the Commission.
I. Environment and health, nutrition and health

Main challenges identified

- **Prevention strategies** are needed that integrate detection and social determinants.
- **Prevention in paediatric nutrition needs integration.** Industry should be involved.
- **Moving from general to specific: pedagogy, behaviour and accessibility:** How does population risk transfer to the individual? We need to look at the individual as well as at large populations. A lot is known about nutrition and environment, but people are still obese and have lung disease. Evidence needs to be formatted so that it can convince the consumer/patient and lead him/her to act as his/her own health co-producer. Since health-lifestyle issues now belong to the challenge, and since people make decision by themselves, research into behavioural aspects is needed, especially with the elderly. Also, access to information and education on lifestyle issues should be suited to the patients' physical and mental capacities. Interaction with social scientist is currently missing and will help maturing the field to face this challenge.
- **The challenge of health information management.** How to implement research results in clinical (or general) practice. How can clinical/GP information flow back? There are enormous gaps in the distillation process from data in the databanks and biobanks to useful info. Data mining techniques are needed that will translate clinically useful research data into meaningful information for the doctor. At this stage, gaps exist between ICT capacity and medical information, an example being medical records, which are currently non structured, in different formats, hard to use in research.
- **Maintaining the link to policy-making for environment.** To govern the matrix [health-relevant area theme x policy advice], leadership is needed. Health research is quite fragmented, but an EU Council of Health Research and Innovation is much needed to provide this lead.
- **Integration/combination and timeline.** Longitudinal toxicological studies are needed, especially since one is subject to a whole panel of exposures from conception to end of life: Radio-frequencies, chemicals, endocrine disrupters, social and professional environment ("exposomics"). Models integrating exposure to all external elements are needed, that will later feed into personalised medicine. Another form of integration will be achieved by moving from the fragmented approach “what is the role of chemical x, y in disease?” to "what are the determinants of disease z"?
- **Investigating the effects of climate change.** Climate change causes the spreading of pathogens to EU areas that were previously untouched, but also leads to social instability and migration. Diseases spread in this context. Therefore, prospective studies are needed.

Other observations:

- **Integration of Environment and Health issues in the grand challenge** is welcome, especially with regard to their relevance to public health issues/research. Contribution from this field will ensure better integration of crossover issues, notably regarding the multiplicity of determinants.
- **Suggested areas for research, including emerging ones:** prenatal exposure; indoor, social and occupational environment (this issue is not under the purview of this challenge); gene-environment interaction.
The Chair's conclusions

A strong evidence base is required for effective health promotion and disease prevention, as well as for providing the relevant evidence for evidence-based regulation. There is a need for comprehensive health indicators for the EU, and for the long-term support and study of cohorts, which will provide evidence for, amongst others, the interplay between socio-economics, environment, behaviour and genetics, and health and disease. Integrated research approaches incorporating the "static " (genome-based - molecular-level) data and "dynamic" (environmental and nutrition) factors into useful predictive models as a base for creating personalised approaches to treatment of lifestyle-determined chronic diseases should be encouraged.

II. Understanding human development and ageing

Main Challenges

- **Strategies for healthy ageing.** Human development starts at pre-conception. Studies have to consider phases when individuals are particularly sensitive to exposure. Prevention strategies should be developed for pregnancy and foetal life. Human development obviously is better studied in life phases when human undergo changes: infancy, adolescence and older age [starting at 50].

- **Exploiting research opportunities offered by increased longevity.** Thanks to increased longevity, many people get older with a chronic disease, and develop new symptoms. New conditions become relatively common at old age, that are rare with younger patients (e. g. lung fibrosis). Older people and of their health status are very heterogeneous. Ageing of different organs and tissues that constitute an individual is different. These elements can teach us a lot, on the diseases, on epigenetic mechanisms, and on the ageing process as such.

- **Tackling growing complexities about maintaining health as we get older.** Multi-morbidity and the effects of poly-pharmacy are fields where knowledge must expand.

- **Understanding the complexity of human being from a holistic point of view,** including the physical, mental and health-related social dimension. Research should integrate these three perspectives. Many diseases have also many co-determinants and their contribution to health production needs investigation. Some benefits can also be envisaged by moving from disease model into a functional perspective.

- **Personalised medicine can help.** Chronic diseases are associated with ageing, but you don’t have to be obese to get diabetes, cardio-vascular disease or cancer. Understanding the interaction between lifestyle and genome, identification of relevant biomarkers will help to define tailored therapeutic/coping strategies. Large observational studies will also be key to achieve this aim.

- **Research is needed into health promotion strategies.** How do we help elders to adhere to treatment and recommendations? How do we educate them? How can we prescribe to ensure compliance in terms of behaviour and lifestyle?

- **Cognitive functions of the elderly are** a potential additional constraint for health strategies (for instance for compliance). The role of environmental and nutritional factors on these functions deserves studies.

- **Deploying efficient strategies and best practices.** Progress in health related areas is different in EU countries. Roadmaps need to be defined to implement the knowledge to contribute to increase healthy life expectancy everywhere.
Other observations

• Basic versus applied? For basic research that does not need intensive collaboration networks, ERC might be the way to go. Fundamental research under this challenge should be funded where cooperation is needed, and an European added value is demonstrated. A typical example area of collaboration in fundamental research is that of systems biology/virtual physiological human project.

• The dilemma of appropriate time scale on delivery: Prenatal life effect into ageing is a very long term effect. Very long longitudinal studies are needed, but also short-term research that will rapidly transfer into the health care systems in the EU that need them.

The Chair's conclusions

Further investments into collaborative fundamental research (mechanisms of ageing processes in combination, identification and validation of new biomarkers and understanding of patterns of age-related chronic diseases, in the context of co-morbidities) are urgently needed.

Understanding human development and ageing needs a holistic approach which takes into account their physical, mental and health-related social dimension. This will allow furthering our understanding on the biology of these processes, the relationship between environment, behaviour and genetics and their impact on health and disease presentation as well as the approaches for diseases prevention.

III. Mechanisms of disease and new taxonomies

Main challenges identified:

• Redefining diseases and developing strategies to face their complexity and heterogeneity. For many diseases, we have no clear idea on what the disease actually is, and what mechanisms underlie it. Multi-layer characterization is needed, including the molecular level, phenotype, aetiology, pathogenesis, influencing factors such as mental condition ("only happy rats don't get cancer"), genetic susceptibility, chemical, nutritional and social exposure, etc. Within all these, a lot of unmet needs will be identified. Also, with this in mind, a continuum between healthy state and disease should be considered as opposed to the healthy vs. non-healthy perception.

• Gain efficacy through tailored personalized –or at least stratified- medicine. Conversion of genetic variability into medical, biological information and the resulting patient stratification offers potential major benefits in terms of efficacy. These endeavours need major networking all over the EU.

• Understanding the overlap and relationship between diseases. Co-morbidity, effects of polypharmacy. Large integrative projects integrating -omics with well-characterised clinical data are needed. Systems medicine may provide concepts and tools to then promote the integration. The above multi-factorial dimension will also need to be taken into account. All relevant stakeholders have to be involved.

• Tackling fragmentation: standardisation, harmonization and interoperability of generated clinical data, widespread access to registers, databases and bio-banks. For monitoring of drug adverse effect, for consolidation, meta-analysis, common standards require involvement from the relevant scientific communities to have themselves defining their standard interoperability. Sharing data, pooling samples also need a legal and ethical framework. A CERN-like EU House of Medicine could also be a place for debate and definition of standards.
Other observations

- **The EU added-value** is in the many different populations, many different environments, many different strategies potentially already tried and tested, and in the large enough pool to extract signals, to detect effects and to analyse and interpret the large amounts of genotypic/phenotypic data gathered.

- **Keeping patients at the centre.** The approach chosen needs to take into account aspects such as psychology, behavioural aspects, patient's education and willingness, as well as the ethical dimension. Individuals should become empowered to improve and manage their health status, including through the application and application-driven research in information and communication technologies.

- **Time frame: long-term studies and shorter-term responses.** A balance has to be found between the volume of upstream or longer-term studies (cohorts, observational studies) and shorter-termed ones that may have a rapid impact on innovation: on some specific occasions, fast, simple, practical solutions may be more effective than investing into developing knowledge of underlying mechanisms of disease.

- **Multi-disciplinarity is needed,** for example, stakeholders in systems biology projects and those involved in ICT-projects should come together or those working in systems biology and clinicians to transfer the knowledge into systems medicine approaches, and combine their expertise in view of their long-term targets.

The Chair's conclusions

EU-wide, coordinated approach to identify and implement common standards on generation, sharing and interpretation of clinical data contributing to the redefining and better understanding of complex diseases is needed. Better understanding of the mechanisms of disease and as part of this, better classifying diseases, by using the existing and new approaches, such as stratification, in an integrated way is a major challenge for biomedical research. In this session, the discussion showed emphatically that continuing to work at the European level will be essential in order to capitalise on progress to date, to encourage new breakthroughs and to get research results to clinic and market. Europe is in a very strong competitive position in this field, but cannot afford to be complacent. The scale and complexity of the scientific challenges demand a strengthened cooperative approach to biomedical research and innovation, building on the successes of European research up till now. Participants at the meeting emphasised that data standardisation and harmonisation, database interoperability and easy access to such resources are absolutely essential: the only realistic way of achieving such goals is through actions at the European level. Similarly, the multi-factorial origin and nature of disease, and the increasingly experienced phenomenon of diseases co-morbidity, and the related issue of "poly-pharmacy", will only be better understood through highly multidisciplinary research. In many cases, this can done only at the European level, whether through lack of expertise and resources, or through lack of sufficient numbers of cases, such as for rare diseases, in individual countries. At the policy level, a CERN-like House of Medicine was proposed as a way of promoting, for example, common data standards. Synergies with ESFRI-supported related infrastructural activities (such as BBMRI – biobanking, ELIXIR – bioinformatics or ECRIN – clinical trials) should be strengthened.
IV. Detection and treatment

Main challenges identified:

- **Europe needs a prevention/prophylaxis approach for chronic diseases, not only drugs.** The "vaccines approach" can be used as a model for tackling non-communicable disease: once the bug is well-characterised, one can consider using the paradigm to tackle the diseases. Defining early biomarkers of disease development will help with prevention.

- **Integrating all detection, diagnostic and prediction strategies and all different markers** (in a broad sense, including imaging), is needed to better understand the processes that lead to the condition. In order to understand disease and disease processes, the aim should be to identify early biomarkers of disease, to develop and test screening methodologies and programmes, and promoting innovative technologies or developing existing ones, with a view to bring significant benefit in terms of disease outcomes through earlier and more accurate diagnosis.

- **Supporting personalised/stratified medicine.** This includes two 'forecast elements', risk profiling (via biomarkers of susceptibility to diseases) and predictability (how will one respond to treatment).

- **Integrating data in health technology assessments (HTA) and prevention.** There is a need for a strong unified European effort on research on cost-effectiveness. A lot of the HTA generated needs integration. Also, prevention, screening and vaccination policies are very diverse in the EU, and needs further integration (try travelling with a cat in the EU...)

- **Supporting observational studies** which can show effectiveness of new solutions, by correlating the outcome with impacts on patients.

Other observations

- **Involving all key stakeholders** will ensure the taking-up of innovative research results into daily practice: research needs involvement of daily practitioners, nurses and other medical professions, as well as tools to educate them cheaply. Patients, regulatory agencies, health care systems authorities need to be on board when relevant.

- **Long translational research projects would need to be have inbuilt** stop/go steps, with effectiveness, comparative efficiency and cost-efficiency as key performance indicator.

The Chair's conclusions

A new holistic viewpoint for disease development should be developed where longitudinal, observational and epidemiological studies combined with stratified clinical trials with innovative biomarkers would lead to a better meta-analysis of disease understanding and disease progression. The goal should be to significantly improve disease outcomes or prevention of disease. The integration of different strategies and approaches and the interoperability of different data sets and results will be a key for increasing the efficiency and effectiveness of disease management. A paradigm shift to personalized interventions has to be prepared by this new research programme.
V. Optimising healthcare (HC) and health systems

Main challenges identified:

- **Informing and empowering the patient.** Patients need to be involved and empowered as 'co-workers' and 'co-planners' of their health, to increase their confidence and trust and thus ensure better compliance. This implies health promotion interventions, improving health literacy in schools and working environments, as well as somewhat shifting focus from the disease to the patient/individual. Patient should be made aware of what is available with respect to treatment, but also of the risks of excessive self-medication and lifestyle drugs (e.g. Viagra). EU metrics are needed to identify patient expectation of the health care (HC) systems, as well as tools to find out to what these HC systems deliver on these expectations.

- **Moving to more disruptive/innovative technologies,** which could be low-cost, more user friendly, more patient-friendly, (e.g. for screening and early detection).

- **Deploying models of alignment, using the rare diseases example.** Patients suffering from rare diseases are scattered all over Europe, but some countries could take charge of some given diseases. Centres of expertise with specific diseases could to be established, then linked and networked. The principle can be then expanded and adjusted to other fields.

- **Pluri-disciplinarity.** To optimize the care of the elderly, action on welfare is needed, which also entails ethical and legal aspects. Integration of heath care models with social care models is necessary, which required common work by DGs SANCO, EMPL, RTD, JUST.

- **Health economics for identification of best practices.** "How can we get the new research into the health systems without blowing them up?" A "sentinel" system is needed to judge ex-post, if an intervention works in a Member State (MS), and if other MS should follow suit.

- **EU needs common metrics/indicators and information tools and systems for their assessment of HC systems, unified common terminology** (what is meant by health, by innovation, by treatment…); **harmonization** (of protocols, of questionnaires, of health indicators, of tools for planning and resources allocation).

- **Standardisation, integration, meta-analysis of epidemiological studies is needed** to fulfilling EU's health care full potential. Inclusion criteria need EU harmonization. Data collection needs European indicators, for example when possible to shorten clinical trial time. All clinical resources available could then contribute their information.

- **Exploiting longitudinal studies of large cohorts.** We need to understand development of conditions and define quality index of care and key variables to be followed and understood. For diabetes, for instance, associated diseases must be followed, and their links to treatment investigated.

Other observations

- **Research priorities mentioned:** Take into account the FP7 Heath Services Research into European Policy and Practice (HSREPP) roadmap project on health services research; mental health; early promotion; screening (not only neo-natal, but at all ages); primary prevention - not only genetics; studying the impact of legislation; prospective studies (new and future developments and legislation resulting from these will have an impact on health, e.g., policy that impacts water quality that, in turn, impacts health); issues of equal access (gender, religion, age… ).
The Chair's conclusions

An increasing disease and disability burden in the context of increasing patient expectation, increasingly costly technologies, an aging population and increased migration will place unsustainable demands on our healthcare sector. Efforts are required to improve decision making in prevention and treatment provision, to identify and support the dissemination of best practice in the healthcare sector, to support the update of technological and organisational innovations and to enhance health promotion and prevention efforts. There is a need for actions which facilitate the involvement of the individual in solutions for personalised disease and disability management.

VI. ICT in health

Main challenges identified:

- **Providing ICT for patient empowerment.** Research in ICT tools to empower individuals to improve self management of diseases and lifestyle, supporting also disease prevention. Involving the individuals as co-producers and planners of health. Need research also in behavioural models for patient empowerment.

- **Providing ICT for personalised and integrated care.** ICT for better patient services and better communication between patients-doctors. Research needed on knowledge infrastructures and ICT services for integrated health, social and self-care. Need for developing protocols, guidelines and governance of these services.

- **In-silico medicine.** Need for research to combine computational biology and physiology-based modelling resulting in simulations used for disease prediction, evolution and medical treatment. Model based simulation could be investigated to support clinical trials, predictability of treatment response and speeding up individualisation of clinical guidelines.

- **ICT platforms supporting model based simulation.** For effective modelling and simulation, ICT platforms should support the sharing of data and models. The platforms will allow the use of the knowledge to stratify the patients and optimise treatments.

- **Providing ICT solutions to leverage innovative healthcare processes.** ICT tools are needed to guide the process from research to innovation. Innovative processes should distil clinical research into healthcare systems. New actors like social networks should appear in these innovative processes.

- **Translation of ICT research into clinical practice.** Innovation potential of disruptive technologies (e.g. for screening and early detection) needs to be harnessed. HTA and implementers should be embedded better in innovation projects/initiatives. Better integration of health and health related social services. Flagship projects of adequate duration (even 10 years) to encompass all elements in the innovation chain.

Other observations:

- **Interoperable health information infrastructures.** A common framework should be considered to allow the communities to develop their standards and share their data. Interoperability of data and harmonized access to relevant databases are required.

- **ICT tools can support randomised clinical trials** via support to observational studies and the use of databases and electronic health records as data sources in clinical trials.

- **Common model for research in health and social care.** Health and social care together should develop a model for research making sure that data are comparable.

- **Electronic Identification.** The need to be able to identify the patients, doctors and other actors in health was also stressed.
The Chair's conclusions.

ICT in health is to mobilise the advanced or applied research as well as innovation. As regards the first there is a need to both push the boundaries of the digital technologies as well as to combine several technologies, enabled by high-performant computation and networking (in patient empowerment with behavioural modelling and social networks; in *in silico* and personalised medicine; in simulation for diagnosis and treatment). At the same time, health and wellbeing being information-based, the integrating potential of digital information platform needs to be advanced, which requires multi-stakeholder cooperation in innovation (e.g. on common specifications and protocols, interoperability, where policy will play a significant role) but also in more advanced research e.g. into knowledge infrastructures for chronic disease management or personalised health pathways.

VII. Assisted and Independent living

Main challenges identified:

- **Providing ICT solutions for improving functioning and well being** by using advances in ICT to improve physical, cognitive and emotional capacity of people facing functional limitations as well keeping them active for as long as possible.
- **Providing ICT solutions to underpin innovation** in social care systems, as well as supporting formal and informal carers.
- **Providing ICT solutions for age friendly living and work environments.** New research is needed to provide effective ICT solutions for age friendly living environments in urban or rural areas or sustaining participation in the work place.

Other observations:

- **Making innovative and appropriate technologies for ageing well affordable, accessible and attractive.** New approaches should be explored to call for devices and solutions from industry at affordable prices, accessible and with improved design.
- **Multi-disciplinary research across behavioural, gerontology and digital science** is required in order to develop attractive solutions for assisted living.
- **Build on a broad approach to well-being and active ageing,** taking into account additional issues such as cost-effectiveness, ethics, design and usability for user acceptance, thereby avoiding stigmatisation.
- **Ethical aspects should be addressed as an integral part** of the research.
- **Develop new understanding, methodologies and indicators for assessment of impact** across a holistic perspective on health; quality of life, well-being and happiness.
- **Broader calls allowing for multidisciplinary approaches are needed.** If appropriate, projects should last at least 5 year to enable longer time working in multidisciplinary teams. Evaluation should be built into different phases - evaluate model projects, have a continuum of projects with evaluation in between.
- **EU support should be provided to support all necessary stages including long term, applied and translational research, innovation and large scale uptake of results.**
- **Work should build on active cooperation and partnership with Member States, regions and other key stakeholders.**
The Chair's conclusions

For quality of life and wellbeing of elderly and persons with disabilities, this field has to pursue unity of research i.e. combining the necessary research disciplines around the wellbeing, autonomy, care, participation and other needs of the user. An integrated perspective on life and work when ageing combining technology and non-technology (e.g. social and organisational) aspects to address health and non-health aspects can provide meaningful and ethically responsible solutions. Research and innovation would address the complex interplay of ageing user – technology – environment. Digital technologies, computation, simulation, networking are to be enablers for information acquisition (e.g. in the elderly living space), knowledge sharing, and driver for providing components to independent/assisted living and active ageing solutions, converging with other technologies and sciences. Research can also be driven directly by the challenging user requirements of those with functional limitations, such as extreme usability and robustness. As economies of scale, the global dimension business opportunities and policy requirements are of key importance, large scale research and innovation should take a multi-stakeholder approach.

VIII. Preparedness and emerging epidemics

Main challenges identified:

- **Preparedness is needed.** While it is the case now that through ECDC, many elements are already in place, more coordinated strategies are required at EU level, and the EU must play its part in global efforts. Guidelines and consensus among stakeholders, common instruments and protocols are needed, as well as coordination among relevant centres. Development and maintaining surveillance and early warning networks, the modelling of epidemics (including emerging epidemics, also of zoonotic origin) are needed and more models developed that can speed up the development of new vaccines in emergencies, combined with pre-pandemic vaccination strategies. Plans for training for medical staff, organisational workflows, communication to contain "panic" and strategies for civil protection must be prepared and tested through simulation.

- **Involving the citizen and appropriately spreading information.** Health literacy and competence of the citizens will help them make the right decision. General practitioners must also be appropriately informed. The information gap between different MS should be bridged.

- **Including the animal/ecological dimension for preparedness.** This implies monitoring epidemics in animals; studying animal pathogens that risk jumping to humans and investigating this transfer; understanding how change in ecology/climate may provoke changes and epidemics and transfer to humans.

- **Readiness to develop research on the spot.** Establishing a quick response system, encompassing quick financial backing and organisation of experts' groups with pre-identified expert (which implies the mapping of available expertise).

- **Tackling antibiotics resistance:** Tackling antibiotics resistance: the development of new compounds and treatment concepts to fight resistance is needed as well as understanding mechanisms and dynamics of resistance, together with support for the rational and refined use of existing antibiotics, including the "one health" approach.

Other observations
• **Research priorities mentioned:** Confinement; transmission mechanisms (human to human, animal to human) notably via modelling; understanding the response of host to pathogens; immunity; safety studies; investigating epidemics as adverse effect of vaccines; behavioural aspects into spreading infections (e.g., HIV); study difference of immunogeneticity depending on the strains; cohorts and longitudinal studies (notably to investigate chronic effects of acute situations).

**The Chair's conclusions**

There is a need for the development and maintenance of surveillance and early warning networks, for the modelling of epidemics, including emerging epidemics, and in the context of climate and pathogen changes, also of zoonotic origin as well as to ensure adequate communication with the public in pandemic response as well as in combating antimicrobial resistance.

**IX. Health infrastructures including info-structures**

**Main challenges identified:**

• **Prioritising and unlocking funding for ESFRI-identified health infrastructures.** Where does the EU go from here, now that a priority list has been established, including relatively cheap infrastructures for health (as compared to, e.g., physics), but with little funding at this stage?

• **Ensuring sustainability of existing infrastructures and, post-project, maintenance, storage, accessibility and update of generated data.** "Everybody wants data. No one wants to pay for maintaining, storing and sharing it!" Institutional funding by major funder/users? A fund? Originally built-in mechanisms? Dedicating 1% of all project overhead costs to it? Fees?

• **Free? Cheap? Open? Access to EU-funded infrastructures.** Must the researcher/taxpayer pay twice for data or sample, the generation of which he has already contributed to? Should there be minimum requirements for access?

• **Mobilising structural funds.** Development of new infrastructures and access to locally existing ones are an opportunity for EU-12.

• **Exploring ways and means to launch and co-finance infrastructures via (or in the context of) public private-partnerships (PPPs).**

• **Providing an umbrella to nationally-developed infrastructures** to ensure standardization.

**Other observations**

• **Proposed infra- and info-structures, including virtual ones.** Epidemiological surveillance systems; repositories for health and nutrition surveys and other data collection, IT structures for data meta analysis; clinical trials networks.

**The Chair's conclusions**

The two main challenges revolve around the question of funding: funding for the setting-up of infrastructures that have been identified as a priority in the field of health by ESFRI and funding to ensure the sustainability of current infrastructures once the initial grant is exhausted, and more generally, of the wealth of data generated by projects, to ensure its complete exploitation.
X. SMEs and public private partnerships

Main challenges identified:

• **Changing academic perception of PPPs.** IPR issues and non-involvement of academia in the priority-setting, but also prejudices, have caused reluctance from some academics to get involved in IMI calls, though there are major benefits, sometimes less direct, sometimes longer-termed, to be expected from PPPs. Apart from solving common problems through the concept of "open innovation", collaboration will trigger further partnerships, bilateral or larger. In this respect PPPs are "incubators of change of minds" that can contribute to instilling an entrepreneurship culture.

• **Creating a SME-friendly landscape in terms of research and innovation.** SMEs have to be easy partners to find, they should face a really simplified administrative environment, be invited early in the setting-up of the projects, enjoy support in terms of regulatory affairs, enjoy EU instruments that will help them bridge funding gaps, with timelines suited to the innovation cycle, and find easier access to investors.

• **Tailoring the instrument for innovation.** Innovation is not a linear process. Depending on the stakeholders involved in the field, different types of collaborations, of instruments may be required.

Other observations

• **PPPs offer potential for consolidation/maintenance/availability of databases and registries**

• **Non-profit research exists!** Its potential contribution to innovation taken in a broad sense, such as triggering changes in public policy, must also be appropriately acknowledged and channelled.

The Chair's conclusions

Research-intensive SMEs need a simpler administrative environment, EU instruments tailored to their needs, often shorter and more downstream than standard FP7-funded projects, as well as further support to find partners and investors.

The myth should be dispelled that Public-Private Partnerships are only for the benefit of large companies. In addition to funding for their teams, academic partners will also develop exchanges and links with industrial partners and plant the seeds for further fruitful collaborations.

XI. International initiatives

Main challenges identified:

• **Being a leader in more large international partnerships.** EDCTP is a good example of successful partnership that also proves that such initiatives can take time to become effective. Participation in large world health research consortia should be encouraged further, but EU should be prepared to take the lead, and to launch some of these. Articulation with initiative of other international institutions, such as WHO, should also be considered.

• **A Joint Programming in International Cooperation for health research?** Each country has its international cooperation policy, to which scientific collaboration contributes. Promoting a better alignment between national funding could improve value for money by avoiding fragmentation.

• **Investing in the capacity building of the South.** ("Just taking their samples/cohorts is not enough"). South-South partnerships should also be encouraged.
• **Opening more to the North?** There is debate on flexibility of involving the whole world *versus* protecting European financial interests. But if the EU wants to leverage major expertise from outside *to solve its problems*, outside forces need to be attracted via funding. "European competitiveness cannot be generated by Europe alone". Exchange of people may stimulate brain gain, and can only positive and fruitful. The international rare diseases consortium illustrates this.

• **Looking East.** The EU still offers a difference of landscape and riches. Some forms of partnership have to be developed to ensure benefits from a better contribution of some EU 12 countries. The arsenal of past measures can be screened. Roadmaps may be part of the solution, as well as membership of international organizations.

**Other observations**

• **Axes mentioned for international collaboration:** Involving China, South-east Asia or Mexico for flu-related preparedness issues; expanding academia-driven multicentre clinical trials; investigating the health effect of migrations; developing links with Brazil (currently far behind US, Russia, India and China in terms of research collaborations with EU).

**The Chair’s conclusions**

Fostering strategic collaboration with particular geographic regions worldwide is required. Supporting long-term research and innovation collaboration in commonly identified priority areas between the EU and other geographical regions creating the "win – win" situation for both partners. International Cooperation under this grand challenge should reflect a delicate balance of competition, collaboration and solidarity.

**XII. Policy priorities to transfer knowledge into innovation and scalable innovation actions**

**Main challenges identified:**

• **Managing the cultural shift from research to research and innovation.** There is a need for instruments to help translate research into products and services. There is also a need to promote an entrepreneurship culture within the academic community, make it sensitive to and better trained, early, on- IPR issues; to break prejudices and misconceptions of many researchers regarding the motivations of industry and the role that they can play in projects (SMEs can contribute to new ideas, new discoveries, not only develop and sell products) … and the other way round.

• **Early training in - and substantial support for - technology transfer.** More education and training is needed on innovation, IPR and technology transfer, especially for the younger researchers. They should be introduced in curricula or possibly required in the context of Marie Curie fellowships. Research institutions should acknowledge the potential/vocation of research investigators for technology transfer and provide time and support for developing business plan, creating start-ups.

• **Funding follow-up of projects with high innovation potential through staged-projects.** Long projects (5 years and possibly more) that aim at eventually producing a validated technology or idea could be designed by stages with a precise milestone where the Commission decides, based on innovation-related criteria, whether or not funding should continue, with possibly new partners being involved for the innovation phase. Such integrated funding would reduce timescales to evidence.

• **Continuous support for successful research, innovation and deployment** by properly designed instruments and funding mechanisms, including leveraging the use of other
financial instruments such as Structural Funds, European Investment Bank instruments, project bonds and public procurement.

- **Simplification: A one-stop shop and other measures.** Whether for research, innovation or both, applicants must find a single entry point, as single programme under this particular grand challenge. Real simplification is needed, not just nominal one. In addition of support for SMEs is welcome, but it can also be of help to facilitate the involvement of other possible stakeholders, like NGOs or technology transfer agencies.

- **Health economics and/or insurances on board.** If we want insurance systems (through their reimbursement schemes) to become innovation-friendly, project have to provide evidence that the new technology will reduce the cost for society, even if only in the long term. Having insurances representative on board from the onset might prove a significant advantage in the long term.

- **The "extended audience":** New technologies will be taken-up if they respond to a need, acknowledged by the patients and/or the relevant medical professions. Upstream involvement of these categories is crucial, together with that of regulatory authorities.

**Other elements identified**

- **The need for a unified EU patent (and simple EU patent system to go with).**
- **More value/weight could be given to patenting** (compared to publishing) when ministries are evaluating their laboratories and institutions, or for tenure.
- **Exploiting multi-disciplinarity.** It is interesting to have mathematicians, physicists on board, talking to clinicians and biologists. Expertise from apparently remote areas can be crucial ("Some ordinary differential equation can help solving some behavioural questions"). In the same logic, shying away for the "logic of silos" will also reveal the potential effect on health and health care of more remote policy areas (transport, employment) and the need to give due consideration to health effects when legislating in these areas. Researchers need training to develop skills in multiple relevant disciplines such as health, social science, technology, gerontology

- **Research and policy-making.** There is a need, at MS level, notably the EU12, for better information exchange between research and health ministries. The contribution of health research results for policy making must be better acknowledged and reinforced.

**The Chair’s conclusions**

Tackling misconceptions of researchers about innovation, start-ups, patenting and financial expectations, including returns on investment from one’s own research requires early education of science students.

The Horizon 2020 instruments need to better encompass innovation aspects, either through EU-funded extensions of the most promising completed projects, shorter, downstream projects suited to innovating SMEs and mechanisms for unlocking further investments. Acceptability is essential, both in terms of cost-benefits for the health systems, and for the main relevant stakeholders (medical professions, patients, regulatory authorities).
Conclusion - Main features emerging from the debate

- **The European Research Area of health research is far from complete.** National infra- and info-structures and protocols, data collections need common tools, common indicators, harmonisation, alignment, integration; and sustainable repositories. As long as this fragmentation continues, hampered information flow will prevent the full exploitation of the wealth of experience, of critical mass and of diversity in the EU, and the identification and taking up of best practices.

- **Implementing innovation requires a "mind-set" change of all stakeholders involved, notably in academia.** More and better information on innovative approaches, strengthening of trust between "providers and users" as well as education and training of healthcare practitioners enabling the wider application of innovation.

- **Better targeted instruments for specific needs have to be developed** including the involvement of a broader range of stakeholders. New scientific disciplines need to be integrated in a more holistic way in order to develop new medical interventions for specific age related groups which are also more cost efficient and patient friendly. Sustainable funding support over a longer period along the innovation chain should be considered which will provide a faster uptake of products and services. Innovative funding schemes need to be developed, also to exploit the full potential of health related infrastructures. Targeted Public Private Partnerships with clear common strategic research objectives based on the lessons learned from previous experience should be established for different parts of the innovation chain.

- **Innovation requires acceptability of the technology developed.** Taking-up a new technology implies early empowerment of individuals and early involvement of health professionals, including regulatory authorities and insurances, targeted health systems research and the standardisation of indicators and information tools.

- **Empowerment of individuals** implies defining health promotion strategies incorporating findings from a variety of research including behavioural studies.

- **Together with a feasibility study, a health cost-benefit analysis** must accompany each innovation-driven project. **Innovation is not bound to always be expensive:** "frugal innovation", disruptive technologies, may prove low-cost or more cost-beneficial.

- **Flexible approaches in terms of time scale and funding adapted to the objectives:** both shorter projects for SMEs, but also very long term for longitudinal studies of large cohorts should be supported. **Long translational research projects or projects bringing concepts to pre-market phases would need to be have built in stop/go steps,** with effectiveness, comparative efficiency, cost-efficiency as key performance indicators. Funding schemes should be flexible regarding the upper funding ceilings adapted to individual situations best ensuring the critical mass to achieve the maximal impact of the funded actions.

- **Real simplification has to be offered,** especially to SMEs.

- **Multi-disciplinarity will be essential** and may be facilitated by establishing a "one-stop shop" for research related to the health, demographic change and wellbeing challenge.

These reflections will feed into the preparation of the forthcoming Commission proposal for the Horizon 2020 Common Strategic Framework for Research and Innovation.

O. Le Dour