

## Scoping Paper for Horizon 2020 Societal Challenge 'Health, demographic change and well-being'

### Important Notice: Working Document

This paper is a working document. It is sent to the Programme Committee for the Horizon 2020 Specific Programme for discussion in the context of the preparation of the Horizon 2020 Work Programme 2016-2017. As such, information and descriptions of activities indicated in this document may not appear in the adopted Work Programme 2016-2017, and likewise, new elements may be introduced.

### 1. Context

This scoping paper for the Horizon 2020 Societal Challenge 'health, demographic change and well-being' has been developed mainly on the basis of the Report of the Health Advisory Group (AG)<sup>1</sup>. This AG report has been submitted to a targeted stakeholders' consultation from 20 August to 20 September 2014. A series of additional consultations, reports from conferences and workshops, foresight exercises, as well as more specific action plans and roadmaps were also taken into account for drafting this document.

The headline goal of the Health Societal Challenge is better health for all. Its main policy objectives are to improve health and well-being outcomes, to promote healthy and active ageing, to promote market growth, job creation, and EU as a global leader in the health area.

The challenges to this goal derive from the ageing of European population and lifestyle patterns, which, if not actively managed through a life-course approach, will increase the burden of chronic diseases on individuals, on existing health and care systems and on society. This will also result in increase of public expenditure coupled with labour force and productivity losses. The Health Societal Challenge aims at delivering **evidence-based outcomes**, resulting from scientific research data, ICT solutions and good practices in interventions improving efficiency and quality of health and care systems. Activities supported under this Societal Challenge therefore offer a unique opportunity to improve the quality of life of EU citizens, to position EU as a central player in the global context and to stimulate the high quality of European research and innovation (R&I) and industrial competitiveness by mobilising relevant European R&I performers, both public and private.

The Health Societal Challenge exemplifies the new approach of Horizon 2020 in that the right instruments are used to support investigators to solve the challenges linked to health, demographic change and well-being, across the entire research and innovation chain. It mobilises stakeholders, from academic, SME, large industry, regulators, to patients and national/regional/local authorities, in order to deliver new intervention and healthcare strategies. In addition, this Societal Challenge integrates the principle of responsible research and innovation in all its activities, including ethic, as well as social sciences and humanities whenever relevant.

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<sup>1</sup> See <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2942&NewSearch=1&NewSearch=1>

**Personalising health and care** was the approach followed in the Work Programme 2014-2015 for addressing those challenges and opportunities. By providing the right prediction, prevention, diagnosis or treatment strategy to the right person at the right time, personalising health and care holds the potential to improve health status of the population, individual well-being, adherence to treatment, and if properly implemented downstream, contain healthcare spending at Member State level. A total of 34 topics were opened in 2014-2015 as well as 16 additional topics for 'Co-ordination activities'.

The main **lesson learned** from the 2014 call is a strong mobilisation and participation of the scientific community, industry and demand side actors in particular in areas such as diseases determinants and risk factors, *in vitro* diagnostic tools and technologies, new therapies for chronic non-communicable diseases, ageing well and self-management of health and disease (citizen engagement and mhealth). The specific SME instrument also resulted in the engagement of numerous SMEs working on biomarkers validation in the first phase of the instrument. Finally, stakeholders, including Member States, showed readiness for coordination of global and national efforts in the healthy ageing and in important diseases specific areas. This confirms a high demand for innovation in personalised health care and for addressing problems of the ageing population, such as chronic diseases. The new applications of existing and new technologies and evidence-based results to be generated constitute opportunities for prevention measures, promotion of mental well-being and social inclusion, and more efficient health and care systems.

## 2. Strategic orientations for 2016-2017

The overall strategic orientation for the Health Work Programme 2016-2017 will be '**promoting healthy ageing and personalised healthcare**'. It directly links with what has been successfully initiated in the years 2014-2015 and is in line with the recommendation of the AG report. Compared to the strategic programming 2014-2015, a stronger accent will be put on life-long health, including ageing. Under this overall strategic orientation, the challenges to be addressed and the solutions to be delivered are the following:

Challenge	Opportunities/solutions
<i>The burden of diseases, including associated co-morbidity conditions (major causes of disability, loss of function, ill-health, health-related retirement and premature death)</i>	Earlier and more effective prevention, diagnosis and treatments strategies. Better prevention and assessment is particularly important as it can largely contribute to keep population healthy, preserve quality of life and reduce healthcare costs
<i>The ageing population which will further increase the burden of diseases, of frail and dependent people</i>	Strategies and innovation supporting more active and healthy ageing
<i>The rising of health and social care costs due to lifestyle and the ageing population</i>	Strategies for organising health and care systems in a more efficient and sustainable way, capitalising on technological development, new organisational models, independent living and fully exploiting advances of modern medicine and of digital

	solutions
<i>The decrease of research and innovation productivity in the health-related industry</i>	Conditions and strategies for stimulating and exploiting the potential of technology and entrepreneurship in health care business

**Action to address those challenges is more acute than ever and is needed now.** Chronic diseases in Europe are the major cause of premature death representing 87% of all deaths, ill-health and work-preventing disability. Antimicrobial resistance (AMR) is another global challenge, responsible for 25,000 deaths each year and costing over EUR 1.5 billion in healthcare expenses and productivity losses. In addition, the number of EU residents aged 65 and over is expected to increase dramatically over the next 50 years, from 92 million in 2013 to 148 million in 2060. With the prevalence of chronic diseases like diabetes or dementia increasing with age, EU health systems will be challenged. Public spending on health already accounts for more than 7% of GDP in the EU. By 2060 public expenditure on acute health care and long-term care is expected to increase significantly to 8.5 and 9.1% of GDP, respectively. As an example, annual costs of brain diseases (e.g. Alzheimer's disease, depression) were estimated in 2010 to EUR 800 billion and of cancer to EUR 126 billion. Finally, the poverty-related diseases, HIV/AIDS, tuberculosis and malaria together account for 41% of the 1.5 billion disability-adjusted life years worldwide, and for 8 % of these in Europe, making health a real global challenge.

On that basis, the **priorities** identified for 2016-2017 under the Health Societal Challenge will be part of a comprehensive strategy covering the whole innovation cycle:

- **Innovative approaches for healthy ageing and personalised healthcare.** The objectives are to deliver earlier, accurate prevention, diagnosis and treatment of diseases, to contribute to well-being (from early development to old age), to maintain healthy working lives and efficient and sustainable health and care systems. In line with the recommendations of the AG report, possible areas to be included for 2016-2017 are: *"Ageing: from early development to the elderly"*, *"Understanding diseases, mechanisms, systems medicine, diagnostics, including environment and health"*, *"Population health and health promotion & sustainable health and care systems"*, *"Infectious diseases"* and *"ICT for health"*. It should be noted that personalising health and care is a long-term approach that may involve major changes in the existing paradigms in health and care and for which further support for evidence building is still needed.
- **Exploiting the potential of technology and entrepreneurship in health and care business.** This specific priority will be articulated along:
  - (i) Public-Private Partnership where the **Innovate Medicines Initiative 2 (IMI2)**<sup>2</sup> brings together the relevant stakeholders to drive the development of better and safer medicines and other interventions in an open innovation ecosystem. Areas to be included in IMI2 calls for 2016-2017 will be based on the IMI2 Strategic Research

<sup>2</sup> IMI2, AAL2 and EDCTP2 are self-standing initiatives. Their topics will be determined and approved by their respective Board and are not detailed in this document.

Agenda<sup>3</sup> where personalising health and care is considered by the European healthcare industry as an important competitiveness tool.

(ii) The **Active and Assisted Living Joint Programme (AAL2)**<sup>2</sup> which will complement the activities addressing active and healthy ageing by supporting projects close to the market and which can help industry and in particular SMEs to bring new ICT based products and services to the European market<sup>4</sup>.

(iii) Stimulation of innovation, investments and growth in SMEs, for which the specific SME instrument will be used.

(iv) Stimulation of innovative procurement for eHealth and integrated care services, using 'pre-commercial procurement' and 'public procurement of innovative solutions' instruments taking into account a systems view and the need to address complex organisational structures and interactions among people (recipients of care, care-givers, and others).

– **Fostering European and global coordination in health and disease research**, through:

(i) Public-Public Partnerships: calls to be opened under the **European and Developing Countries Clinical Trials Partnership 2 (EDCTP2)**<sup>2</sup> will address clinical trials, diagnostics and delivery optimisation for poverty-related and neglected infectious diseases<sup>5</sup>;

(ii) Cooperation with third countries, in particular the US: the **Programme-level co-operations** which are crucial for implementing common objectives, delivering common guidelines and best practices, e.g. in the area of rare diseases (IRDIRC); the implementation of **GLOPID-R**, the multi-funder initiative for the Global Research Collaboration for Infectious Diseases Preparedness; as well as activities for cooperation on ICT-related programmes (with WHO in m-health and non-communicable diseases; with US in interoperability and standards, and in improving IT skills and eHealth workforce; with Japan in ICT for active ageing).

'Promoting healthy ageing and personalised healthcare' will support the following **health research policy objectives**: (i) translating science to benefit citizens; (ii) improve health and well-being outcomes; (iii) promote healthy and active ageing; (iv) support efficient and sustainable health and care systems; (v) support the development and uptake of digital solutions for health and ageing well; (vi) promote market growth and job creation in the health area; (vii) promote EU as a global leader in the health area.

It will also support the **new planned policy initiative** on '*Getting personalised health care: European Strategy for Developing Personalised Medicine*', aiming at accelerating the

<sup>3</sup> <http://www.imi.europa.eu/content/imi-2#SRA>

<sup>4</sup> <http://www.aaliance2.eu/>

<sup>5</sup> [http://www.edctp.org/fileadmin/documents/Towards\\_EDCTP\\_II/Strategic\\_Business\\_Plan\\_for\\_EDCTP2\\_-\\_May\\_2012.pdf](http://www.edctp.org/fileadmin/documents/Towards_EDCTP_II/Strategic_Business_Plan_for_EDCTP2_-_May_2012.pdf)

development of 'personalised health, care and well-being' by developing a comprehensive strategy covering the whole innovation cycle. This policy initiative should make Europe's key players, disciplines and research data to link up and work much better together. This will include particular efforts to standardise and harmonise data from across the EU ('Big Data'), define and use best practices, educate, communicate activities, and turn new knowledge faster into medical applications. It should lead to sustained public funding and support, intensive cooperation between different disciplines and countries, pooling of data and know-how from across Europe, and internationally acknowledged standards and regulatory frameworks.

'Promoting healthy ageing and personalised healthcare' has the potential to drive new and faster development processes and products, providing European health-related industries (including SMEs) with a competitive edge that can secure growth and jobs. Europe has a strong competitive position in this area that should be maintained, taking advantage among others of the 'Big Data' and of the results generated by the previous generation of public-public and public-private initiatives. In addition, health research stimulates and interacts with other industrial sectors, such as food, agriculture, chemical, nano-sciences or cosmetics. Finally, the continuous cooperation with third countries, in particular in large, structuring, multipartner initiatives is decisive to position Europe as a leader in the rapidly expanding global markets for health, ageing-well and well-being innovations.

Those health research policy objectives are therefore implementing the **Europe 2020 Strategy**, in particular the **Innovation Union** and the **Digital Agenda flagships**, as well as the **eHealth Action Plan**. They are also in line with the new **Commission's agenda priorities** on "a new boost for jobs, growth and investments", "a connected digital single market", and on "a stronger global player", as well as with the priorities on "a Union of jobs, growth and competitiveness", "a Union that empowers and protects all citizens" and "the Union as a strong global leader" highlighted in the **Strategic Agenda for the Union in times of change** (European Council of 26-27 June 2014). Furthermore, they present strong synergies with other EU policies such as ageing and health policies, ageing well and long term care strategy, EIT-KIC on Healthy and Active Ageing, Smart Specialisation and ESIF investments.

### 3. Translation into calls 2016-2017

The Work Programme 2016-2017 will include **one single CALL: 'Promoting healthy ageing and personalised healthcare'**.

This call will **support a coherent research and innovation programme** characterised by a high degree of inter-disciplinarity collaboration. This includes improved translation of new knowledge into medical applications and proof-of-concept examples demonstrating feasibility and value.

We will also follow-up on supporting our **international initiatives** through this call. We should continue addressing several healthcare items globally as well as positioning and maintaining EU as a global leader. This will be the case for the rare diseases (IRDIRC<sup>6</sup>, who has already generated 120 out of 200 new therapies planned for 2020), the epigenomic international consortiums (IHEC<sup>7</sup>), the Global Alliance for Chronic Diseases (GACD<sup>8</sup>), as

<sup>6</sup> <http://www.irdirc.org/>

<sup>7</sup> <http://www.ihec-epigenomes.org/>

well as several activities for cooperation on ICT-related programmes listed above. Those activities for supporting international initiatives will be included within the specific orientations listed below.

A key role will be devoted to **activities supporting SMEs** in this area. One area of potential interest is the cell technologies, e.g. for therapies or regenerative medicines. Another potential area relates to ICT products and services, based on open platforms, for ageing well.

Part of the objectives of this call will also be addressed through other instruments and initiatives, in particular IMI2, EDCTP2 and AAL JP2. These initiatives have their own governance framework as defined in their legal basis where the Commission will ensure the complementarity with relevant Horizon 2020 activities. It is to be noted that through flawless coordination, overlaps among the various activities results from the initiatives described will be avoided, and a strategic coordination and focus will be provided by the Commission services in charge.

The call on '**Promoting healthy ageing and personalised healthcare**' will include the following **main orientations**, in line with the recommendations proposed in the AG report:

### **1. Ageing: from early development to the elderly**

- This area will aim at understanding the ageing process, developing quantitative and qualitative markers and evaluation of ageing, as well as deciphering the conditions for (non)-healthy ageing (including co-morbidities, loss of function and frailty). It will provide new ICT based solutions in support of independent living and active ageing of older people. The area will include an ICT and biotechnological innovation dimension that is expected to preserve independence, and enhance social interaction, mobility, function and contribution to society, and quality of service provision. The social science and humanities dimension will be present through research on health, social and environmental systems. Taking a life course perspective, this area will target research examining which protective processes and adaptive systems make a difference in children's lives. In particular, research will consider variations in the expression of vulnerability for disorders across age and gender when designing prevention and implementing interventions. It will thus provide new breakthroughs in keeping people active, independent and functionally capable for longer, thereby reducing institutionalisation and improving well-being.
- The expected impact and innovation are: (i) enhance knowledge on the early development and ageing process; (ii) new biomarkers and behavioural markers of development and ageing and application of new technologies and treatments including regenerative medicine; (iii) breakthroughs, including in smart and digital solutions, for better living-environments and lifestyles, in particular to support older people and encourage retained function, encouraging active engagement, including new and adaptive models for service provision in and outside of the home; (iv) to assess how discovery and delivery research of pathways and interventions can lead to optimal development, increase resilience and mitigate the impact of biological, psychosocial and environmental risk factors.

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<sup>8</sup> <http://www.gacd.org/>

## **2. Translational research for molecular characterisation of diseases and patients for targeted prevention and therapy strategies, including aspects related to environment and health**

- In this area, research and innovation will firstly focus to establish a pipeline to support the development of personalized medicine and enhance prediction, prevention and therapy addressing chronic multifactorial diseases affecting large sections of the population, as well as rare diseases. Emphasis will be put on better characterisation of diseases and on patients' stratification in view of developing personalised preventative and therapeutic interventions. For this purpose, studies will focus on linking big data derived from relevant disciplines (e.g. omics, behavioural, clinical) with phenotypes and long-term outcome data, and by validation of biomarkers and diagnostics. This area will also support clinical studies for the development of preventive and therapeutic strategies, and comparative effectiveness research for targeted clinical management of diseases.
- The environment and health strand will address: (i) research and innovation on interactions between the environment and human health and wellbeing to build up the understanding of the influence of environmental exposures on health and diseases – as a building block for this, a coordinated European approach to human bio-monitoring will be supported; (ii) the use of “big data” for the purposes of surveillance, screening, and identification of high risk populations and causalities of diseases will be expanded, (iii) efficacy of policy and research and innovation actions in this area will be assessed.
- The expected impact and innovation will be (i) piloting and demonstrating personalised medicine in applications for promoting well-being, disease detection, prevention and treatment; (ii) demonstrating that the innovations bring health benefit and are cost-effective, as well as accessible to diverse populations; (iii) accelerating development and facilitating regulatory approval of innovative interventions; (iv) move towards sustainable and prevention-oriented health/public health/social care systems taking into account not only health but also the well-being of people, which would serve as important examples of best practice and as sources of innovation, (v) ensuring that knowledge from research on the interaction between the environment and human health is brought into decision making in interrelated policy areas to promote and sustain a healthy environment and thus contributing to social innovation.

## **3. Population health and health promotion & sustainable health and care systems**

- In the field of population health and health promotion, the development of innovative interventions, tools and personalised medicine approaches will aim at promoting health and wellbeing at individual and community level. Research will focus on the following areas: (i) mental disorders such as depression, anxiety, antisocial and/or addictive behaviour. The activities will focus on the development and validation of effective interventions and new health promotion & disease prevention strategies; (ii) regarding obesity, health and nutrition, in view of encouraging changes towards healthier food production, processing, consumption and lifestyle, activities will explore innovative approaches in the food value chain including consumer behaviour to ensure a positive impact on health and the environment. In this context, the Health Societal Challenge will be addressing public health and the Societal Challenge Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy the food value chain.

The expected impact is to obtain new knowledge on important population-based health problems and provide evidence on effective population based interventions.

- The area of sustainable health and care systems will capitalise on healthcare innovations, including personalised medicine approaches to transform health systems and to improve health outcomes. The following is proposed: (i) policy research addressing the uptake of existing research evidence for policy-making and on policy bottlenecks, and studying on how to move from a reactive health care system to implementing proactive and sustainable population health; (ii) implementation research for successful scaling-up of innovations, including patient engagement and empowerment; (iii) health economics research including cost benefit analysis of new health care interventions; (iv) research on integration of large and real time data sets in health systems management and performance assessment. This would include research on the integration of health and social services, and community-based delivery systems, their impact on care, sustainability and the health workforce.

The expected impact will be evidence on new approaches to integrate care across health and social sectors, models and approaches for responsive and efficient health systems, as well as facilitated deployment and public purchasing of proven innovative solutions for eHealth and integrated care services (innovative procurement).

#### **4. Infectious diseases**

- This section will target (i) vaccines research including into new vaccine platforms and/or improvement of existing ones e.g malaria, neglected infectious diseases and emerging diseases; (ii) therapeutics including anti-infectives (e.g. novel antibacterial and antiviral agents); (iii) understanding host-pathogen interactions, the sources and routes of exposure as well as mitigation measures taking a one health approach. This action is expected to be implemented in collaboration with the Societal Challenge Food security, sustainable agriculture and forestry, marine, maritime and inland water research, and the bioeconomy.
- The expected impact and innovation will be the creation and validation of new products essential for controlling infections. It should also result in assessing infectious diseases within the broader health context to determine which integrated approaches entail the most effective mix of curative and preventive strategies that can be deployed effectively in a given health and social system, meeting public acceptance and in line with public health policies and strategies.

#### **5. ICT for health**

- This area will target person-centred healthcare delivery, integrating health and social care, empowering the patient, and considering the environment and community setting of the individual. It will also address wellbeing and prevention to identify trends towards ill health and thereby strive to keep people away from unnecessary care and help them be proactive. New breakthroughs in controlling better the events and changes in public health or in the healthcare pathways (related to mhealth, big data, new and business models) or in drug management can be provided by modelling technologies, for example, in-silico trials. Innovation activities are needed in order to assess the existent ICT solutions ready to go to the users. It should develop the best solutions for integrating heterogeneous data sources,



and improve e-health/digital literacy of citizens for education, health promotion and their active participation in prevention and care.

- The expected impact and innovation will be: (i) establishing evidence for integration of ICT solutions in national health and care systems, building on current technological infrastructure through targeted applications and evaluation frameworks for assessment of their benefits; (ii) technological development and innovation to bridge the gap between raw technologies and business intelligence, amounting to a technologically enabled culture shift in healthcare but also in lifestyle promotion and wellbeing. Personalised *in silico* medicine will help prevention, well-being, functional re-education and early diagnosis.

## **6. Planned contributions from the Health Societal Challenge to activities and candidate Focus Areas in other Horizon 2020 parts**

- Contribution to the activities on 'Use of Big Data in health and care' (Leadership in Enabling and Industrial Technologies, the Information and Communication Technologies part (LEIT-ICT)), which may include early detection, management of co-morbidities, prevention, public health monitoring, fitness and well-being, treatment as well as in development of new innovative treatments.
- Contribution to the candidate Focus Area on 'Internet of Things' (LEIT-ICT). Activities may include large scale deployment of innovative services in intelligent environments for ageing well and with applications in the context of health.
- Contribution to the candidate Focus Area on 'Digital Security' (Societal Challenge Secure societies). Activities may include security against leakage, cybercrime and cyber-attacks of data storage and exchange; security and transfer of data to and from mhealth applications and for integrated health and social care services; secure techniques allowing structured operations on data, control of patient's own data, encryption and anonymisation.
- Contribution to activities on 'Empowering co-creation' (Societal Challenge Europe in a changing world – Inclusive, innovative and reflective societies) aiming at improving the e-health/digital literacy of citizens for enabling their active participation in the management of their health and wellbeing.