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COMMISSION STAFF WORKING PAPER

Guidance paper for the steering group of the pilot European innovation partnership on active and healthy ageing

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1. INTRODUCTION

Europe - and the rest of the world - faces a number of challenges, which if not adequately addressed, will have a significant and detrimental effect on all of us. Yet dealing with the issues of ageing of the population, preventing and mitigating the effects of climate change, tackling increasingly scarce natural resources and the need to ensure the sustainable production of food for a fast-growing global population represent not only challenges but also opportunities for developing innovative solutions, for enhancing Europe's competitiveness and for new markets to emerge and expand.

Europe has strong innovation potential, and should have the ambition to become a leader in finding solutions to such challenges. However, in order to fully exploit its potential, Europe needs to overcome fragmentation, remove a range of obstacles which delay or even prevent breakthroughs from making it to the market, and more generally, needs to involve all key players across the innovation value chain – from researchers, businesses, policy makers and regulators to end users – to achieve common objectives.

For these reasons, in its Europe 2020 flagship initiative Innovation Union[1], the European Commission has introduced the concept of **European Innovation Partnerships (EIP)** to promote breakthroughs to address societal challenges and gain competitive advantage.

The concept will be tested with the launch of a **pilot EIP on active and healthy ageing**, which is a common and pressing challenge for all Member States. The European Council, the Council and the European Parliament have all welcomed and supported the launch and development of the pilot.

2. HEADLINE TARGET, OBJECTIVES AND CONTEXT - EIP ON ACTIVE AND HEALTHY AGEING

The objective of the active and healthy ageing partnership is **to add, by 2020, two healthy life years to the average healthy life span of European citizens**. In a broader sense, the partnership aims to **pursue a triple win for Europe**: improving the health status and quality of life of European citizens, with particular focus on older people[2]; supporting the long-term sustainability and efficiency of health and social care systems; and enhancing the competitiveness of EU industry through business and expansion of new markets.

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1 COM(2010) 546 final

2 According to the UN definition, older people by default are defined as those that reach the age that make them eligible for statutory and occupational retirement pensions. On this basis, even though there is no UN standard numerical criterion, the agreed cutoff is + 60-65 years to refer to older population.

Over the next 20 years, the number of Europeans aged over 65 is expected to rise by 45% from 85 million in 2008 to 123 million in 2030[3]. This continued increase in life expectancy is a major achievement of the recent past. However, at the same time it risks putting an additional strain on the economy, society and the sustainability of public finances.

Public and private healthcare spending in the EU already accounts for 8.3% of GDP (2008), and, by 2030, due to ageing, total public age-related expenditure[4] is expected to increase by 2.7% of GDP[5]. This increasing economic burden is compounded by a shrinking and often insufficiently skilled workforce in the care sector[6].

This is where innovation, in all its forms – spanning across technology, process and social innovation – is a crucial factor improving the well-being and health of citizens, ensuring sustainability, and enhancing Europe's global competitiveness and growth. Fostering innovation requires high investment outlays, however, if focused on the most effective and cost-efficient evidence based solutions, these can generate efficiency gains and increase care personnel productivity and their satisfaction from their work due to increased quality and better outcomes (such as the shift in care services from acute, reactive, and hospital-based, towards home-based, palliative, and pro-active care, underpinned by disease prevention, health promotion and healthy living and self-care).

This large scope for innovation and breakthroughs in health and ageing will enable a **new paradigm of ageing to emerge** whereby ageing is seen as an **opportunity and not as a burden**; a positive vision which values older people and their contribution to society; and where they are empowered to influence and benefit from innovation for active and healthy ageing.

3. ROLE AND ADDED VALUE OF THE PILOT EIP ON ACTIVE AND HEALTHY AGEING

Many tools and instruments exist at EU, national and regional level that aim to support innovation in active and healthy ageing[7]. However, despite this array of supporting actions and initiatives, too few innovations make it to market quickly enough and when they do their deployment tends to be limited to certain geographical areas. This is largely due to persistent ***barriers and bottlenecks*** which include:

- Health and care systems are often insufficiently flexible to rapidly adopt innovative solutions, due to their complexity, budgetary limitations and common values (universality, equity, accessibility to good quality care and affordability). Underpinned by these characteristics, care systems cannot solely rely on usual market mechanisms matching demand and supply.

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3 Europeans aged over 65 will almost double over the next 50 years - from 85 million in 2008 to 151 million in 2060 - Ageing Report 2009: http://ec.europa.eu/economy_finance/publications/publication14992_en.pdf

4 It is composed of expenses on healthcare, pensions, education, long term care, unemployment benefits.

5 Ibidem

6 COM(2008) 725 final: Green Paper on the European Workforce for Health

7 Instruments at EU level include: the Framework Programme, Ambient Assisted Living Joint Programme (AAL JP), Public Health Programme, Competitiveness and Innovation Framework Programme (CIP), Structural Funds, Joint Programming Initiative (JPI) on Neurodegenerative Diseases and proposed JPI "More Years, Better Lives", e-health Governance Initiative, Lead Market Initiative (LMI) for e-health.

- Lack of integration of care (within healthcare and between health and social care) slows down the penetration of innovation and the implementation of organisational change thus hindering market growth in the areas of healthcare.

- Legal rules and procedures, and reimbursement and certification schemes which vary significantly across Member States limit the scope for developing and deploying innovations on an EU-wide scale.

- There is a lack of EU-wide standards, and their effective use and application, which impedes interoperability of novel products and services.

- The interactions between demand (care providers, older people, carers) and supply (research, innovative industry and companies) are insufficient, meaning that innovations do not always match the real needs of end-users[8], carers do not always possess the right skills and qualifications or lack incentives to implement new solutions or processes, and citizens and patients are not sufficiently aware of innovative solutions and/or reluctant in accepting them.

- Evidence-based assessments of the effectiveness including cost and benefits of innovations are often either absent, fragmented or poorly assessed, or are not well communicated to healthcare actors and patients.

- There is a lack of continuity between research, pilot projects and the rolling-out and scaling up of innovation into the market due to inadequate and/or limited access to finance and/or missing financing instruments.

The results from the recent public consultation[9], organised to gather input from stakeholders, broadly confirm these barriers. In particular, older people, patients, academics and their representative organisations and SMEs highlight insufficient involvement of end-users in the innovation development process. Stakeholders also believe that public authorities are often reluctant to absorb new innovative solutions and that there is potential for creating important markets through joint procurements. This is echoed by larger companies who also raise the issue of complex, unclear or often unpredictable legal frameworks.

A number of stakeholders believe there is considerable scope for speeding up time-to-market, for example by fast-tracking assessment procedures, improving the involvement of older people in clinical trials and testing, through the harmonisation of regulatory requirements within the single market (such as measures to protect and use personal health data), the development of common health technology assessment methods, by targeted European standards for new devices and products, or by providing for reimbursement of innovative solutions by health insurance systems.

Many stakeholders, including Member States, agree that finding effective solutions and producing more tangible impacts, first and foremost, requires new ways of working together in a collaborative way, across borders, disciplines, sectors and institutions, setting common strategic directions and improving the coherence between different research and innovation mechanisms.

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8 End-users including consumers, patients/ older people and care takers

9 The public consultation was launched on 26 November 2010 and closed on 28 January 2011. Approximately 530 replies were submitted from a wide array of stakeholders.

This pilot partnership aims to respond to those issues. In order to achieve its objectives, it will **mobilise and link up stakeholders, EU institutions, national and regional authorities** in order to **facilitate new ways of working together across the entire innovation value chain. I**t will aim to optimise the coherence between, and the use and cost-effectiveness of, existing instruments. To align them and where necessary combine their resources.

In order to succeed, the partnership must be **politically-driven**. Building on expertise and a shared problem analysis, it must draw strength from **strong political leadership**, so as to break down deep-seated barriers and **bring all key actors together behind a shared vision**. A strong commitment and ownership on the part of all relevant stakeholders is therefore essential.

Consequently, the pilot EIP on active and healthy ageing is expected to bring added value by:

- **Joining up efforts** across the European Union by encouraging cooperation based on a shared vision and common targets, fostering synergies and avoiding overlap, to achieve results that respond better to citizens' needs.

- **Bridging the gaps** between public and private actions and instruments, by addressing the lack of support on innovation to considerably reduce time-to-market of research and innovation breakthroughs.

- **Facilitating scaling up of results** by reducing complexity, overcoming fragmentation and enabling different approaches to converge.

- **Improving the framework conditions** by removing bottlenecks and anticipating common regulatory and other needs for all stages of the innovation chain to achieve critical mass.

4. GUIDANCE OF THE HIGH-LEVEL STEERING GROUP

An important part of the pilot partnership's operation is the setting-up of **a high-level steering group** whose primary role is to **draw up a strategic implementation plan**, which is a focused document containing **a set of operational and actionable recommendations** addressed to the different stakeholder communities to achieve the partnership’s objectives. Given that reaching the target requires steps to be taken in time to produce impacts well before 2020, the steering group is particularly invited to identify concrete actions that can be delivered in the short term (‘early wins’). The group's members should also play a central role in driving the delivery of this plan through political and sectoral advocacy and in lending sustained, long-term commitment to unblocking existing barriers to innovation.

The high-level steering group will be **composed of 33 members** drawn from a wide variety of backgrounds and stakeholder communities who have an important role to play in delivering on the partnership's promises. The steering group members, who have been invited to participate in their personal capacity, should ensure a high-level advocacy for the partnership and individual commitment within their own means and remit. The names and affiliations of the members of the steering group are set out in Annex I.

The steering group will be **chaired** by **Vice-President for the Digital Agenda Neelie Kroes** and by the **Commissioner for Health and Consumers John Dalli**, and assisted by a secretariat provided by the Commission. The steering group members can be supported by

"Sherpas", for example, to prepare agendas. As necessary, the steering group may also draw on a stakeholder forum and request expert input from operational groups working on specific aspects of the partnership. Members of the steering group are indeed invited to solicit input and proposals from interested parties and networks to ensure that all views are taken into account. As part of its strategic implementation plan, the steering group is encouraged to develop its views **on the vision of ageing as an opportunity** and the structural changes this might imply.

In order to be effective, the EIP must be **result-oriented** (i.e. organised to achieve commonly agreed objectives), **'light' in terms of governance** and aim at overcoming barriers resulting from a traditional 'division of labour', be it across geographical borders or areas of competence.

5. ORGANISATION OF WORK OF THE HIGH LEVEL STEERING GROUP

In preparing its **strategic implementation plan**, the steering group's task is to **identify the priority action areas** drawing on the identified bottlenecks and results of the public consultation.

Features of a priority action area are:

(1) likely to make the greatest contribution to the objectives of the partnership;

(2) will benefit particularly from the partnership approach;

(3) likely to significantly contribute to overcoming the key bottlenecks and barriers;

(4) will facilitate innovation in an area where European industry has or may develop a competitive advantage.

The priority action areas can be updated in light of further deliberations, and as necessary Section 6 below provides indicative ideas for innovation in active and healthy ageing, to stimulate the reflection on the priority action areas.

The steering group is responsible for **identifying the key barriers and measures to overcome them**, targeting in particular those barriers whose removal can be expected to produce the utmost positive impacts. The steering group should **identify areas where greater interaction between suppliers and end-users would facilitate innovation** both in terms of quality of care and cost-efficiency. Furthermore, the steering group should **assess how the existing policies, instruments and programmes can better contribute to tackling the barriers**. In analysing opportunities for improvement, the steering group is invited to look outside the EU for inspiration on how to improve market access and exploit global opportunities for European companies.

On the basis of its analysis and taking account of stakeholders' contributions, the steering group should then seek to **identify the necessary commitments of all key stakeholders** – each acting in its own sphere and employing its own relevant instruments and resources – to work together to overcome the bottlenecks. This should lead to a set of **actionable recommendations in the strategic implementation plan**. These, among others, may include priorities for research and innovation in the area, more evidence based and cost-effective interventions, a better use of funding instruments, modifications to the legislative framework,

ways to better bring suppliers and end-users together and/or the setting up of joint procurement schemes. The aim is not to produce a detailed list of recommendations but focus on the **most critical commitments** that will have the greatest impact.

Finally, the steering group will need to identify, if necessary with the support of technical expertise, **clear and concrete milestones in the short, medium and longer term**. Achieving the objectives of the partnership requires a sustained effort to implement the strategic implementation plan and regular **monitoring of progress** on the basis of **a set of agreed targets and indicators**. The steering group will, therefore, also advise on the longer-term high-level steering and development of the vision for the implementation phase of this partnership.

6. INDICATIVE AREAS FOR REFLECTION

The Commission suggests that the steering group may particularly wish to look at the following three areas which can be expected to be of significant relevance for the partnership's objectives and in which there appears to be a particular **scope for innovation and breakthroughs**, including social innovation**.**

(1) Innovation in support of people's health and well-being – prevention, diagnosis and treatment

The first area concerns aspects of **ageing-related chronic diseases** (e.g. Alzheimer's, diabetes, musculoskeletal, cancer, Parkinson's).

Specific bottlenecks, barriers and gaps in this area include: little response to demand pull for innovation, scattered research across Member States, delays in authorisation procedures, insufficient exchange of good practices and guidelines, under-representation of older people in clinical trials.

The partnership could foster the development of innovative solutions to prevention, early diagnosis and screening, treatment, therapeutic and diagnostic technologies, medicines (including personalised medicine), clinical trials, health promotion, own health management and monitoring.

Sectors in this area include: health professional services, medical devices, pharmaceuticals, food, ICT and internet.

(2) Innovation in support of collaborative care systems and services for the older people

The second area concerns innovation in **social and health care systems** in order to promote and support more integrated and collaborative approach to care delivery, leading to accessibility, quality and financial sustainability.

Specific bottlenecks, barriers and gaps in this area include: mismatch of supply and demand, care structure rigidity to adapt to changing conditions, slow innovation of existing business models, incomplete skill-set of care providers or insufficient training of health care workforce.

The partnership could help identify conditions to promote innovative solutions for policies and business models to achieve more integrated and coordinated care systems for the older citizens based on continuum of care approach, extension of home care provision and self-care, large scale tailoring and deployment, long-term care (e.g. e-Health, ICT-enabled), training for health and social care workers (e.g. in geriatrics, gerontology), support services for informal carers and social innovation. Possibilities for fostered EU-wide cooperation on health technology assessment (HTA) could also be considered.

Sectors in this area include: health and social care professional services, medical devices, pharmaceuticals, e-health and ICT, telecommunications, business intelligence.

(3) Innovation in products and services for active and independent ageing

The third area concerns the **development and deployment of innovative products, devices and services**, including those enabled by ICT, that promote **independent and active lives**, as well as generate opportunities for businesses.

Specific bottlenecks, barriers and gaps in this area include: lack or ineffective interoperability and standards, fragmentation resulting from different legal, reimbursement and certification schemes, weak links between demand and supply (i.e. the use of public procurement).

The partnership could concentrate on improving and developing European or global standards so as to ensure better interoperability of innovative solutions for older people, more efficient and innovative use of public procurement schemes (inc. pre-commercial procurement), as well as greater involvement of users in the development of innovations from the outset of the process, including training on how to use the innovative solutions.

Sectors in this area include: social and health care, assistive technologies, mobility, food, medical devices sector, pharmaceuticals, telecommunications.

Addressing bottlenecks to innovation in the above areas could lead to **rapid success**, for example **by promoting**:

– more integrated and collaborative care for prevention and management of chronic diseases (including multiple chronic conditions), clinical practice guidelines and training for care professionals and carers serving older people;

– development and uptake of tele-monitoring systems and home-based care and self-care, which have the potential to increase the quality of life of older citizens and significantly reduce costs incurred in hospitalisation; as well as training for users of such innovative solutions and technologies;

– development and market introduction of fall prevention technologies, with potential major economic and quality of life savings;

– fostered competitiveness of the medical technology and pharmaceutical sectors, while ensuring a high level of patient safety, supported with robust evidence based (cost and benefit) assessments.

Priority action areas should comprise a limited number of targeted, ambitious but implementable actions. These actions should be very specific and focussed on deliverables.

Further detailed examples of issues that may be covered within and across priority action areas are contained in Annex II.

7. PROPOSED TIMETABLE

The first meeting of the high-level steering group has taken place in May 2011. The schedule of the subsequent meetings will be decided by the steering group in view of the timetable for preparing the strategic implementation plan. The strategic implementation plan should be finalised within 6 months from the start of the group's work, in principle, in autumn 2011.

The Commission will analyse the strategic implementation plan, and on this basis, in principle before the end of 2011, will present its views and proposals in a Communication to Council and Parliament for their political endorsement, following which implementation will begin. It will then be important to ensure that strong political support translates into fast-tracking of decision-making at all levels so that the benefits expected from the partnership for Europe, for its citizens and for its competitiveness can be harvested fully and rapidly.

In order to learn lessons from the pilot partnership for possible further partnerships, the Commission will present preliminary results of the work undertaken so far in the second half of 2011, focusing especially on the working of the governance arrangements. However, it should be noted that any further partnerships need to be organised to reflect the specificities of the particular area under consideration so that the governance of the pilot partnership does not prejudge the precise organisation of other possible partnerships. The Commission will prepare a further progress report on the pilot by the end of 2011.

Annex 1: Composition of the steering group

1. **The Rt. Hon. Zoltan Cséfalvay,** Minister of State, Hungary
2. **The Rt. Hon. Benoît Cerexhe,** Minister of Research, Belgium
3. **The Rt. Hon. Maciej Banach,** Undersecretary of State, Ministry of Science and Higher Education, Poland
4. **The Rt. Hon. Cristina Garmendia Mendizábal,** Minister of Science and Innovation, Spain
5. **The Rt. Hon. Annette Schavan,** German Minister for Education and Research, Chair: Joint Programming Initiative More Years, Better Lives
6. **The Rt. Hon. Leire Pajin,** Spain Minister of Health, Welfare and Gender Equality; Chair, e-Health Governance Initiative
7. **Member of European Parliament** – to be nominated
8. **Member of European Parliament** – to be nominated
9. **Member of European Parliament** – to be nominated
10. **Member of European Parliament** – to be nominated
11. **Ms Lena Gustafsson, President,** Ambient Assisted Living Joint Programme
12. **Mr Philippe Amouyel,** Chair, Joint Programming on Alzheimer and Neurodegenerative Diseases
13. **Mr Wolfram Kuschke,** Member of Parliament in North Rhine-Westphalia, Germany
14. **Mr Anke Boye,** Mayor of Odense, Denmark
15. **Mr Andrew Witty,** CEO GlaxoSmithKline
16. **Mr Emmanuel Faber,** CEO Danone Europe
17. **Mr Guy Lebeau,** CEO Johnson & Johnson Europe
18. **Mr Frans van Houten,** CEO Philips
19. **Mr Stephen Elop,** President and CEO Nokia
20. **Mr Gil Baldwin,** CEO Tunstall Healthcare Group
21. **Mr Vittorio Colao,** CEO Vodafone Group
22. **Ms Sharon Higgins,** Director, Irish Medical Device Association

23. **Ms Christine Dawson,** Director, European Social Insurance Platform

24. **Mr Anders Olauson,** President, European Patients' Forum

25. **Ms Anne-Sophie Parent,** Director, AGE Platform Europe

26. **Mr Alain Franco,** Secretary General-Vice President of the International Association of Gerontology and Geriatrics

27. **Ms Madeleine Starr,** Head of Policy Development, Carers U.K.

28. **Mr Konstanty Radziwill,** President, Standing Committee of European Doctors

29. **Mr Paul De Raeve,** Secretary-General, European Federation of Nurses Associations

30. **Ms Marianne Olsson,** Senior Advisor, County Council Sörmland, Sweden

31. **Mr Sergio Pecorelli,** President, Italian Medicines Agency, Italy

32. **Mr Jos Peeters,** Chairman, Capricorn Venture Capital

33. **Mr Joseph Bannister**, Chairman, Malta Financial Services Authority, Malta

Annex II: Examples

Example***: dementia disorders*** are highly prevalent, costly (estimated cost of €160 billion in EU-27 in 2008) and burdensome for both patients and caregivers. The likelihood of developing dementia in those aged 65+ roughly doubles every 5 years in Europe. The evidence on dementia treatments and solutions is still scarce and patchy, especially in the area of prevention and integrated care solutions. An opportunity would be to aggregate evidence for better guidance on treatments and decisions about prescription, referral, or placement.

Example: the ***medical technology*** sector is a sector with a high proportion of high-tech SMEs and a relatively rapid turnover of devices. However, its competitiveness is hampered by uncoordinated implementation of regulatory frameworks. Procurement criteria would benefit from focusing on health outcomes rather than price/volume. Besides, the variation in the application of key principles, methodologies and evidence requirements of health technology assessment (HTA) could be addressed. There is an opportunity for collaboration to address the inclusion of medical technologies in the scope of national health insurance systems. Another possibility would be to improve access to finance for SMEs.

Example: ***multiple chronic conditions*** such as heart failure, diabetes, depression, hypertension etc. are affecting 80% of people over 65, and often happen simultaneously. Tele-monitoring technologies together with careful health planning, patient follow-up, integrated health and social care, informal and self-care, enable hospital re-admissions to be reduced while care efficiency to be increased. There is, however, a need to overcome barriers such as lack of common guidelines for procurers and different authorities in social and healthcare. Also older people with multiple chronic conditions are still under-represented in clinical trials. Partnering those authorities and providing guidance and information on the commercial results of research and innovation programmes to procurers could help them with better planning, including using regional funding to scale up proven tele-monitoring approaches.

Example: ***evidence-base of cost-efficient interventions*** in the area of musculoskeletal conditions. These conditions comprise over 150 diseases and syndromes (e.g. osteoarthritis, osteoporosis), which are usually progressive and associated with pain. Musculoskeletal conditions are the major cause of physical disability across Europe and a major cause of work loss, disability pensions and early retirement, costing more than €240 billion per year. Despite similarity of problems, there are differences of care between Member States. An opportunity could be to facilitate cooperation on the use of Health Technology Assessment for evaluation of interventions. Capacity building could unlock Structural Funds for investments in imaging infrastructure, devices for treatment/prevention and training of care practitioners.

Example: ***falls are a serious risk for elderly*** - 1/3rd of people over 65 fall at least once per year, 1 in 8 patients are admitted to hospital due to a fall, many lose their independence, over 100,000 die annually and costs are at least €15 billion p.a. Many innovative solutions for fall prevention, such as balance monitoring devices, physical/cognitive training, or personal medication based on integrated health information, are not widely used in Europe. Impact could be enhanced by bringing together users, health providers, carers, industry and policy-makers, based on current fall prevention good practices across Europe. Joined-up public and private insurers and financiers could bridge the gap between investment and returns such as reduced hospitalisation. A platform of standardisation bodies, industry and users could define and promote the interoperability of devices, systems and protocols and standards take-up.

Example: ***horizontal framework conditions*** – Often innovations in active and healthy ageing do not progress beyond the pilot phase or testing ('valley of death'), get shelved, or at best stay confined to a small market. This holds for several of the domains in active and healthy ageing, especially where there is a public responsibility for care provision. An often-quoted reason is the lack of risk-based funding that allows for a longer-term assessment of return on investment and that can factor in the specificities of public-private cooperation and local needs. Overcoming these 'horizontal' innovation barriers could be facilitated by fostering new business models formation and joining up teams of active and healthy ageing financial experts, private and public investors, and social innovation funds.