



The Case for Europe as a Leader in Research and Innovation for Global Healthⁱ

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Summary

Europe is well placed to take a lead role in developing global health research and innovation. This paper explores the potential and makes recommendations for Europe's role in research and innovation to improve global health. It highlights the need for coherence between Horizon 2020 and other key EU policies, including that on the EU's role in global health, and the potential for global health research to play an instrumental role in achieving *Europe 2020* goals of growth, innovation and social inclusion.

- The EU should ensure coherence between its agendas for development, research and health and a well coordinated approach to the execution of the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*. This should include coherent application of European policies, programmes and science diplomacy efforts in addressing the recommendations of the WHO Consultative Expert Working Group on Research and Development (CEWG), including the question of a Research and Development Convention.
- Recommendations for research mechanisms and strategies to develop Europe's role in and to advance global health research and innovation include;
 - Special mechanisms to promote and support research that is cross-sectoral and interdisciplinary, involving both technological and social innovation;
 - Special mechanisms to ensure continued fair, equitable and needs-oriented collaboration with LMICs, including joint priority and agenda setting, management, exploitation of results.
 - Research that acknowledges the 'right to health' and European values in health such as equity, universality and access;
 - Innovation stimuli which take into account the special characteristics of health technologies and products, such as long lead times, high intensity of investments, high attrition rates, and the lack market incentives for investing in medicines for poor populations.
 - Previous experience has shown the gains to be achieved from global, collaborative health research and that some innovations can only occur on a regional/international level;
 - The large and complex character of many global health challenges makes them particularly suited to a 'grand challenges' approach to developing global health, which involves cross-sectoral research conducted by multinational consortia within and beyond the EU.

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1. Introduction

1.1 Background

Research, development and innovation

Efforts to promote European economic growth and competitiveness and ensure a stable, prosperous future for the citizens of the European Union (EU) are central to **'Europe 2020'** – the EU's growth strategy for the coming decade.^{1,2,3,4} Three key drivers for growth will be implemented through concrete actions at EU and national levels: **smart growth, sustainable growth, and inclusive growth**. To meet the Europe 2020 targets, the European Commission (EC) proposes a series of **flagship initiatives**, one of which is the **'Innovation Union'** - re-focussing research and development (R&D) and innovation policy on major challenges, while closing the gap between science and the market to turn inventions into products.^{5,6}

The EU's 7th Framework Programme for Research and Technological Development 2007-2013 (FP7) has a total budget of over €50 billion. The world's largest single research programme, FP7 includes € 6.1 billion for health. FP7 will be succeeded in 2014 by **Horizon 2020: Framework Programme for Research and Innovation**, which incorporates the current Competitiveness and Innovation Framework Programme and European Institute of Innovation and Technology to create coherence along the whole innovation chain.⁶ Horizon 2020 will run from 2014 to 2020, with a proposed budget of €87.7 billion budget. It will focus on strengthening science, innovative industry and technology and tackling societal challenges, whilst creating jobs and growth in Europe.

The role of health

Good health is fundamental to the objectives of Europe 2020, the Innovation Union and Horizon 2020:

- **Health is wealth...**

Good health is essential for a healthy economy^{7,8} – **'a powerful argument for European governments to invest in the health of their populations, not only because better health is a desirable objective in its own right, but also because it is an important determinant of economic growth and competitiveness'**.⁹

- **... and poor health is a drain on wealth...**

- EU countries have ageing populations. As noted by the EC's DG for Economic and Financial Affairs, the EU will require its citizens to work longer and will need to lower the incidence of chronic diseases which reduce healthy working years and which greatly increase the costs of health care in old age.¹⁰
- Health disparities within and between member countries are large and constitute one of the most profound areas of inequity in the EU. Use of effective measures to tackle health inequities means ensuring that a country's health system is not falling short of its performance potential.¹¹
- Costs of prescription medicines are continuously rising. In the last couple of decades the increases have outpaced other categories of health care spending and are projected to continue to exceed the growth rates for hospital care and other professional services throughout the present decade.¹²
- The health workforce accounts for >8% of GDP and c. 10% of the EU's total active workforce, including physicians, nurses, pharmacists, administrative and supportive staff, researchers, teachers and trainees.¹³

- **... demanding more research and innovation for health and health equity (Box 1)**

More effective disease prevention and health promotion are vital – and so are better, cheaper ways of producing drugs, vaccines and diagnostics and more effective ways of delivering health information, products, processes and services to users.^{14,15,16,17,18} In addition, we need not only affordable and accessible products and services, but also well organised and accessible health systems in low- and middle-income countries (LMICs) in order to improve global health.

The imperative to reach the highest attainable standard of health for all people, enshrined in the global recognition of health as a human right,¹⁹ demands explicit attention to uncovering and eliminating health inequities. Research has multiple roles to play in detecting health inequities, understanding their causes and developing solutions.^{20,21,22} Moreover, research itself must be rigorously constructed to ensure that it is free of biases in conceptualisation, methodology or

interpretation that could lead to increasing disadvantage for groups based on factors such as ability, ethnicity, gender, geographic location, poverty or social position.²³

Box 1 The health research and innovation system

Research for health is research in any discipline or combination of disciplines to understand the impact on health of policies, programmes, processes, actions or events originating in any sector – including, but not limited to the health sector itself and encompassing biological, economic, environmental, political, social and other determinants of health; assist in developing interventions to help prevent or mitigate that impact; and contribute to the achievement of health equity and better health for all. (Ref 14)

Innovation for health and health equity is an initiative in any sector or combination of sectors that takes up novel ideas, inventions or processes and applies them to achieving improved health and greater health equity. It has been stressed that a combination of **social and technological innovation** is essential and the importance of social innovation (involving new ways to manage people, processes, and information) to the Europe 2020 agenda has been highlighted. (Refs15-17)

The global health research and innovation system encompasses all of these activities and requires the development of a comprehensive systems perspective to guide efforts to achieve greater effectiveness, efficiency and impact and respond to innovation failures in science, the market, or public health, as an essential element of reducing health inequities. (Ref 18)

1.2 The importance of global health

Global health recognizes the interdependent relationship between health status within and across countries and policy and legal instruments across diverse sectors, so constituting a distinct field requiring special attention.^{24,25}

- As many of the determinants and new challenges for health are global and complex in nature, action on health must transcend national boundaries. The definition of global health²⁵ as *‘health issues which transcend national boundaries and governments’* includes a range of health challenges operating across the EU, beyond those that can be dealt with nationally, e.g. health security, social determinants and non-communicable diseases.
- The background paper to the World Conference on the Social Determinants of Health has emphasised that due to the *‘interconnectedness of the modern world, national action on social determinants is not sufficient. International organizations, nongovernmental agencies, and bilateral cooperation partners need to align their efforts on social determinants broadly with those of national governments’*.²⁶
- Conceptualized beyond a ‘global burden of disease’ approach, global health *‘emphasises the social, environmental, and economic contexts in which health, disease, and healthcare interventions are embedded’*.²⁷
- The process of globalisation has created not only threats to health but also many new opportunities that require global frameworks. For example, globalisation has provided significant opportunities for sharing and exchanging knowledge through networks in global research and innovation.

2. The case for explicit EU engagement in research and innovation for global health

Previous experience has shown the gains to be achieved from global, collaborative health research and that some innovations can only occur on a regional/international level.

Justification for attention by the EU to research and innovation for global health includes:

- Recognition of health as a human right and promotion of human rights and European values;
- Consistency with EU commitments to global health, including global solidarity,^{28,29} Millennium Development Goals (MDGs - some of which are health specific and others health-determining),³⁰ equity²² and development;³¹
- Benefits to the EU and the world accruing from addressing global health needs and inequities in terms of early control of pandemics, but also through promotion of social cohesion and responsibility;

- Fostering innovative models for fair and empowering partnerships with low and middle income countries. Good examples of models include the European and Developing Countries Clinical Trial Partnership (EDCTP)³² and the Bamako Call to Action on Research for Health³³;
- Adding value to previous investments in joint R&D and capacity building (e.g. the FP7 funded Call for Africa (Health) (€39 million) capacity building projects, the EDCTP and the SICAs – see 2.2)

In many European economies, health is the largest industry and is a growing industry. Europe thus has a unique opportunity to take a more prominent role in moving global health research and innovation forward. Support for commercialisation to turn research into products (including medicine and food products) and technological and social innovations, supported by systems and innovative distribution models, will greatly benefit Europe and LMICs. A significant increase in investment for global health is necessary to ensure that Europe is not left behind in terms of global health research and innovation in these areas. Europe also has played a prominent role in research capacity building in developing countries for global health (see 2.2 below).

2.1 Recognition of health as a human right and promotion of human rights and European values

The fundamental right to health is affirmed in the UN Declaration of Human Rights,³⁴ the WHO Constitution,³⁵ the International Covenant on Economic, Social and Political Rights,³⁶ and the Declaration of Alma-Ata.³⁷ The EU is founded on ‘*the values of respect for human dignity, liberty, democracy, equality, the rule of law and respect for human rights.*’ Respect for human rights is also enshrined in the Council of Europe’s *Convention for the Protection of Human Rights and Fundamental Freedoms*.³⁸ Human rights and health are also interlinked such that the achievement of many human rights, such as social and political rights and freedoms, is dependent upon a good state of physical and mental health.³⁹ Conversely, achievement of the ‘right to health’ is also dependent upon other rights being achieved, e.g. the right to an adequate standard of living.

The EU cannot credibly sustain human rights within and beyond its borders without explicitly addressing the range of important global health issues discussed in this paper – especially those concerned with equity, access to health services, social determinants of health and effective governance for global health.

Given the shared nature of global health threats and global public goods, global health is a leading field in which Europe can demonstrate and develop its shared values of solidarity, equity, universality and human rights, among the citizens of its own Member States and Associated Countries along with those in other countries. Some EU Member States have experience to share globally when it comes to human rights and health initiatives (e.g. the UK government’s Human Rights in Healthcare framework⁴⁰).

2.2 Consistency with International and EU commitments to global health

Global health has gained increasing prominence through various international forums such as the World Economic Forum (e.g. the Global Health Advisory Board, chronic disease and global health activities, and data collection and management activities), UN Summits (e.g. 2001 HIV/AIDS Summit, 2011 UN Summit on Non-Communicable Diseases) and G-20 and G-8 which committed to promoting research in support of Global Health in L’Aquila in 2009.⁴¹

Policy commitments to global health have been made through the EU and through EU Member States’ support of international resolutions. They typically require both coherence across a range of sectors and visible action, often in collaboration with international partners. Since many of the global health challenges are testing the limits of current knowledge and tools, research is a vital component of effective response.

One of the European Commission’s guiding principles for global health is ‘*action to make the impact of research more equitable - joint agenda and priority setting for global health research*’.⁴² One of the sub-areas of the FP7 framework is international public health and health research focused on health

policy, systems and services and reproductive and maternal and child health.⁴³ Research to serve the health-related MDGs is a mandate of this framework. Global research partnerships which have developed research capacity building and global health outcomes have thus been part of previous research frameworks. These and other initiatives for global health include:

- The Call for Africa ('Better Health for Africa') in FP7 (emanating from the EU-Africa Strategic Partnership) which commenced in 2009 and focused on translating research for human health, international public health and health systems and specific topics of malaria control, infectious agents and cancer, human resources for health, maternal and newborn health, capacity building for research and migrants' health.⁴⁴
- The FP7 Specific International Cooperation Actions (SICAs) which developed research capacity in LMICs and research collaboration based around themes, e.g. health, food, agriculture and fisheries, environment and socioeconomic themes.⁴⁵
- The Health Research Programme also funded the European and Developing Countries Clinical Trials Partnership (EDCTP). The EDCTP was established in 2003 and funded by 16 European countries and the EC. Its main objective is to support the clinical development of new drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis, while also improving the overall environment for carrying out clinical trial activities in Africa.³²
- Capacity building also occurs through the Marie Curie International Research Staff Exchange Scheme,⁴⁶ which involves the short-term exchange of researcher between EU/associated countries and 'third countries,' most of which are LMICs.
- The Food Security Thematic Programme of the Development Cooperation Instrument,⁴⁷ which provided € 130 million over 4 years to the Consultative Group on International Agricultural Research (CGIAR).

Key examples of related policy documents include:

The Lisbon Treaty

The Treaty⁴⁸ states that the EU will '*support, coordinate or supplement the actions of member states*' in a number of areas including '*protection and improvement of human health*'. It defines Europe '*as an actor on the global stage*' and aims for greater EU visibility and policy coherence in policy development and external policy relations. This necessitates explicit linkages between Horizon 2020 and the EU policies on development and global health.

EC Communication: The EU's Role in Global Health

The Communication²¹ recognises that global health '*is about worldwide improvement of health, reduction of disparities, and protection against global health threats. Addressing global health requires coherence of all internal and external policies and actions based on agreed principles*'. It is based upon an understanding of the social determinants, and argues that '*public health policies need to go beyond the national level and require strong global institutions and coordinated efforts*'. A key aspect of the Communication is a repeated stress on the multi-sectoral nature of the challenges and the research and capacity building needed to address them, stating:

- Progress on the MDGs has been undermined by unbalanced and fragmented attention to health. Special attention needs to be paid by a multi-sectoral approach.
- It is essential that research priorities are geared to making the biggest impact on public health. Access and innovation need to be addressed simultaneously, as highlighted in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.⁴⁹ One requirement is for multi-disciplinary research capacity at national level.
- The EU should address the multi-sector nature of health and its close links to gender, nutrition, water, sanitation, environmental quality and education in all relevant policy dialogues.
- On security concerns and global health threats, the EU must pay closer attention to the concept of 'one world, one health'. This promotes 12 'Manhattan Principles' that emphasise the global and multi-sectoral nature of infectious disease challenges and the need to '*better understand the relationships between health and ecosystem integrity to succeed in improving prospects for a healthier planet*.'⁵⁰
- The EU should build up a **collective expertise on capacity in global health** analysis and policy dialogue.

- The Communication calls for a set of specific actions on research, which are further amplified in the accompanying Commission Staff Working Document (Box 2).⁵¹

Europe 2020

The strategy states³ that the EU is a global player and that it needs to take its international responsibilities seriously. It has been developing partnership with LMICs to eradicate poverty, promote growth and fulfil the MDGs. Europe 2020 highlights the need for a research agenda focusing on health challenges, and the need to ‘*combat poverty and social exclusion and reduce health inequalities*’ and promote access to health care.

Health in All Policies

The demand for an approach to health that requires attention to policy across a range of sectors (such as planning and development, industry, trade and commerce, environment, finance, agriculture, housing, public works, education, culture and communications)⁵² derives its legitimacy from the Ottawa Charter for Health Promotion,⁵³ from a deepening understanding of the multitude of factors acting as determinants of health^{54,55} and from the EU’s own charter,³⁴ which stipulates that ‘a high level of health protection shall be ensured in the definition and implementation of all Union policies and activities’.

Health in all Policies ‘*is a horizontal, complementary policy-related strategy contributing to improved population health. The core is to examine determinants of health that can be altered to improve health but are mainly controlled by the policies of sectors other than health*’.⁵⁶ It was pursued in the 2006 Finnish presidency of the EU⁴² and is a central principle of the European Health Strategy.⁵⁷ A specific focus on mental health in ‘mental health in all policies’ approaches have also been recommended.⁵⁸

Box 2 The EU Role in Global Health

Communication - Section 4.4. Research and evidence based dialogue and action (Ref 24)

- The EU should coordinate more effectively research on global health in order to address the highly fragmented landscape and identify shared global priorities for health research. It should promote effective and fair financing of **research that benefits the health of all people**.
- The EU Research Framework Programs should continue to give priority to actions which tackle global health challenges. These actions should be based on joint priority setting processes, equitable partnerships and safeguard access to the knowledge generated.
- The EU should strengthen and balance the **complete health research process** of innovation, implementation, access, monitoring and evaluation. Such research should provide effective input for health policies, improve health service provision, and include mechanisms for partner countries to build and sustain their national research capacity.
- The EU should enhance its current work²⁷ with relevant national and international bodies such as WHO, the OECD and the Health Metrics Network, to improve health information systems and the collection of comparable **data and statistics** to allow benchmarking and inform global, European and national policies. The EU should promote the use of ICT, including eHealth.
- All global normative action on the safety of food, feed, products, pharmaceuticals, and medical devices must be evidence-based. The EU should promote the dissemination of information on hazards and risks in these areas.

Staff Working Document: European research and knowledge for global health (Ref 42)

- The document emphasises the shared European values of universality, access to good-quality care, equity and solidarity.
- Control/eradication of communicable diseases is a clear example of a global public good benefitting everyone, in poorer and richer countries alike and in present and future generations. Global collaboration could improve health equity.
- EU Framework Programme: European added-value and mutual interest supports an international science and technology policy that has two interdependent objectives:
 - to support and promote European competitiveness by means of strategic research partnerships with non-EU countries, including highly industrialised and emerging economies, by engaging the best scientists to work in and with Europe; and
 - to address specific problems that non-EU countries face or of a global nature, on the basis of mutual interest and mutual benefit.
- The critical area of improving health systems performance is recognised, stressing the need for health policy and systems research, health care services research.

WHO has been tasked⁵⁹ to ‘*work closely with partner agencies in the multilateral system on appropriate measures that address the social determinants of health... and to advocate inclusion of this topic high on global development and research agendas*’; and to ‘*support research on effective policies and interventions to improve health by addressing the social determinants of health that also serve to*

strengthen research capacities and collaborations'. Institutional mechanisms for working with other sectors are required to achieve these aims.⁶⁰

Implications for the research and innovation agenda: The acknowledgement of the broad-ranging nature of determinants of health creates a need for:

- structuring research that is interdisciplinary, that crosses sectoral boundaries and that is conceived, organized, reported and has its results applied in ways that stand outside the normal frameworks of conventional single-discipline research. Interdisciplinary research, such as that enquiring into the health impacts of various categories of health determinants in different sectors, faces a number of professional, organizational, and cultural obstacles⁶¹ and requires special mechanisms to foster collaborative action;
- organizing an innovation environment that bridges sectors and that encompasses social as well as technological aspects of innovation.

Development policies and assistance

Europe is the world's largest donor for development assistance⁶². The EU's development policies, encapsulated in the 'European development consensus',⁶³ have the overarching objective of eradicating poverty in the context of sustainable development and rest on the central pillars of achieving the MDGs⁶⁴ and adhering to the Paris Declaration on Aid Effectiveness and Accra Agenda for Action.⁶⁵

- The EU has committed to policy coherence in 12 policy areas to accelerate progress towards the MDGs, including research and innovation.⁶⁶ The latest biennial report⁶⁷ notes that research policy provides a good example of positive synergies created between different policies, contributing decisively to development through financing research projects in the health, food security, social sciences and humanities areas. It stresses the need for a 'whole-of-Union' approach and notes that the evolving global financial crisis underlines the importance of development-oriented support in the areas of research and technology. Recognizing the need for action beyond 2015, the FP7 work programme for 2012 includes a call for proposals to set a new, post-2015 MDG agenda – to include paving the way towards an improved system for global health innovation.⁶⁸
- The *EU Strategy for Action on the Crisis in Human Resources for Health in Developing Countries* recognizes one obstacle to achieving the MDGs is the dearth of health workers and sets out a range of EU actions for the training and retention of health workers in LMICs.⁶⁹ One is 'Identifying opportunities to strengthen research capacity,' to include supporting research networks and partnerships such as the EDCTP, which is effectively building clinical trials capacity (see Section 2.2).
- The EU also supports the *International Health Partnership Plus (IHP+)*, within which capacity development for LMICs is a key strategy, along with mobilising donor agencies around country-initiated health strategies and plans.⁷⁰
- Through both its individual member states and collective action, the EU has a major role to play in the execution of the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* which was negotiated by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.⁷¹ This will require coherent EU approaches on a range of development, research and global health agendas. In an important further step following adoption of the *Global Strategy*, in 2011 WHO established a Consultative Expert Working Group on Research and Development (CEWG) to examine mechanisms for financing and coordination.⁷² Based on its work to date, it seems likely that the CEWG will recommend that international negotiations are undertaken to establish an R&D Convention.⁷³ The EU can make a substantial contribution to this process, both through the coordinated operations of its development, research and global health agendas and through the application of its capacities in science diplomacy (see Section 2.3.5 below).

Horizon 2020 must therefore be framed in a way that addresses the development aspects of research and innovation in relation to global health and the health aspects of the MDGs. Application of science and technology is indispensable to achieving the MDGs⁷⁴ and Horizon 2020 will need to encompass research and innovation that can accommodate the post-2015 global agenda for health and development. Key elements of the ***research and innovation agenda to support development goals*** are:

- **Within the EU:** Funding collaborative research and innovation on new or improved methods for the diagnosis, prevention and treatment of infectious diseases and for non-communicable diseases (NCDs) that pose a significant threat to health in LMICs. While infectious diseases have been specifically targeted in the MDGs, *‘multiple studies demonstrate a continuing and significant disconnect between aid and the burden of health conditions, including maternal mortality and malaria, and the disability adjusted life years measure.’*⁷⁵ Little attention has been paid to NCDs in LMICs, although NCDs have now overtaken infectious diseases as the main causes of morbidity and mortality in LMICs.⁷⁶ With 70-86% of deaths in Europe now being attributed to NCDs, comparative studies of chronic disease management programmes across countries are providing one important approach to finding effective and affordable solutions.⁷⁷ The growing levels of NCDs in LMICs – expected by 2030 to account for three quarters of the disease burden in LMICs, have been described as a ‘chronic emergency’ by the World Bank,⁷⁸ which has argued *‘the case for elevating the challenge as a priority item to address on the agenda of decision-makers’*. Research to address issues such as obesity, food security and surveillance, mental health (and associated disability), and developing local research capacity and civil society engagement in these initiatives are required.⁷⁹ Furthermore, Public Health Genomics (PHG) is a field of growing importance as it contributes to the better understanding and prevention of growing global health problems, including obesity or mental health.⁸⁰
- **Through collaborations between the EU and external actors:** Funding collaborative research involving institutions in EU member states, other HICs and LMICs on new or improved methods for the diagnosis, prevention and treatment of infectious diseases and NCDs that pose a significant threat to health in LMICs. The new UN General Assembly *Political declaration of the High-level meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases*⁸¹ now provides a framework for action and research on NCDs.
- **As a component of empowerment:** Supporting LMICs to build national capacities for research and innovation policy development and management, including in all key areas of research and innovation for health:
 - Supporting LMICs to enhance their capacities to conduct research to tackle major health challenges and improve population health - including achieving the specific MDG targets and also such fields as research on NCDs and the very neglected but critical field of health policy and systems research.
 - Supporting LMICs, nationally or regionally, to meet their aspirations for establishing the activities necessary for drug discovery⁸² and production.⁸³ This will include not only clinical trials capacity (e.g. the EU-supported EDCTP³²) but also establishing national or regional capacities for drug innovation and for pharmaceutical production and regulatory agencies and laboratories that can license products and can also conduct high quality local monitoring of the quality of pharmaceuticals in order to deal with the severe problems associated with substandard and counterfeit drugs that are widely in circulation.⁸⁴
 - Supporting LMICs on research into innovative health financing and creating accessible and equitable health systems, to reduce the burden of health costs for citizens of LMICs and improve health outcomes.⁸⁵

2.3 Benefits to the EU itself of addressing global health needs and inequities

2.3.1 Innovation Union

The EC Communication on the Innovation Union⁸⁶ recognizes the critical importance for the EU of: (1) strengthening its ability to drive innovation in products, services, business and social processes and models and (2) successfully tackling major societal challenges, such as climate change, energy and resource scarcity, health and ageing and social exclusion. Among the ***weaknesses identified*** that the Innovation Union aims to tackle are:

- Under-investment in the EU’s knowledge foundation. Other countries, like the US and Japan, are out-investing the EU, and China is rapidly catching up.
- The need to adopt a much more strategic approach to innovation. An approach whereby:
 - Innovation (including ‘social innovation’) is the overarching policy objective,
 - A medium to longer-term perspective is taken,

- EU and national/regional policies are closely aligned and mutually reinforcing,
- New products are addressing priority health needs and are accessible to those in need,
- International collaboration is based on the principles of fairness and mutuality, and
- The highest political level sets a strategic agenda; regularly monitors progress; tackles delays.

The EU has recently endorsed EC proposals to launch a European innovation partnership on active and healthy ageing, the first flagship initiative under Innovation Union (see below). It must be recognised that innovation per se is not an end in itself, but needs to contribute to improving health and reducing inequalities.

Some of the concrete actions that the Innovation Union proposes to achieve its goals are summarised in Box 3.

Box 3 Some concrete actions proposed to achieve the Innovation Union goals

- Protecting and stepping up the investments in education, R&D, innovation and ICTs. For the EU itself, this must include sticking to the target of raising expenditure on R&D to 3% of GDP by 2020.
- EU and national research & innovation systems need to be better linked with each other and their performance improved.
- We need to get more innovation out of our research. Cooperation between the worlds of science and the world of business must be enhanced, obstacles removed and incentives put in place.
- Remaining barriers for entrepreneurs to bring "ideas to market" must be removed: better access to finance, particularly for SMEs, affordable Intellectual Property Rights, smarter and more ambitious regulation and targets, faster setting of interoperable standards and strategic use of our massive procurement budgets. As an immediate step, agreement should be reached on the EU patent before the end of the year.
- European Innovation Partnerships should be launched to accelerate research, development and market deployment of innovations to tackle major societal challenges, pool expertise and resources and boost the competitiveness of EU industry, starting with the area of healthy ageing.
- Strengths in design and creativity must be better exploited. We must champion social innovation, develop a better understanding of public sector innovation, identify and give visibility to successful initiatives, and benchmark progress.
- We need to work better with our international partners. That means opening access to our R&D programmes, while ensuring comparable conditions abroad.
- A key concern of the EU is progressing international cooperation with third countries to develop global approaches, address societal challenges and move towards a level playing field by, for example, removing barriers to access.

Communication from the Commission (Ref 86)

Innovation in healthcare technologies

There are very few industrial segments whose growth will target the priorities of Europe 2020 and the Innovation Union as effectively as healthcare.^{6,87} ***The health research and innovation system provides wealth:***

- Healthcare technologies promote growth, create wealth and attract investment. They encompass a range of areas including pharmaceutical drugs, vaccines and diagnostics; medical devices, surgical instrumentation, orthopaedics, prosthetics, advanced wound-care, health information technologies, telemedicine, eHealth, mHealth, medical imaging, medical and surgical robotics, and laboratory facilities for a range of R&D and process activities including clinical trials, medical diagnosis and screening, life sciences, toxicology, genetics, drug delivery, medical engineering, information technology, chemical and biochemical analysis.
- The European medical technology industry invests some €3.8bn in R&D and employs 435,000 people, making a major impact upon Europe's economy. The healthcare technology venture capital market is the second largest sector behind the information and telecommunications sector. Around 24% of all European deals are invested into healthcare technology.⁷⁰ Small- and medium-size enterprises (SMEs) comprise the majority (80%) of companies in the medical technology industry. The Lund Declaration under the Swedish presidency of the EU advocated European leadership in research and called for a focus on grand challenges of our time with the involvement of SMEs.⁸⁸ It emphasised the importance of Europe taking a global lead in the development of enabling technologies (including biotechnology). Eucomed (which represents the medical technology industry in Europe) has noted that key barriers to growth in emerging markets include lack of consistent application of EU regulation and lack of easy access to research and development funding.⁸⁹
- The pharmaceutical industry has been one of the major innovative industries in Europe and responsible for a large fraction of economic activity. For example, it is the biggest sector investor in

R&D in the UK, accounting for c. 25% of total investment by business, valued at £3.3bn. In 2007 the UK had the third-highest share of global pharmaceutical R&D expenditure of any nation, with 9% of the total, behind the USA (49%) and Japan (15%). The UK has the largest pharmaceutical R&D expenditure of any European nation (23% of the total), followed by France (20%), Germany (19%), and Switzerland (11%).⁹⁰ Opportunities in emerging pharmaceutical market such as Brazil, China, India and the Russian Federation are growing rapidly.⁹¹

But the healthcare industry in general and the pharmaceutical industry in particular provide an example *par excellence* of where the EU is presently losing ground and where an explicit, coherent and comprehensive effort is required if Europe is to sustain its historical leading role. ***The pharmaceutical industry is now in crisis globally and the European component is in serious decline.*** Globally, the industry now relies heavily on sales from an aging portfolio of drugs, whilst the proportion of total sales from newer drugs has dropped. There has been a steep decline in the number of new molecular entities registered in the last decade, both in terms of absolute numbers and as a proportion of research spending.^{92,93} A combination of factors, including costs of labour and shifting balances between regulation and innovation stimuli, have led to movement of the industry away from Europe and towards the USA and emerging markets^{94,95} driving companies to invest in emerging economies like India.⁹⁶

Concerted effort within the EU will be essential if it is to retain and revitalise this important sector of its innovation portfolio. This will need to recognise the special features of drug development that distinguish it from other areas of innovation, including: the long development lead times (up to 10-15 years) and extremely high costs (hundreds of millions of Euros) and high attrition rates, making this a much less attractive area for venture capital and requiring public support at a number of stages of the basic science, drug discovery and development processes; the lack of capacity of SMEs to take products all the way from bench to bedside – as a result of which they tend to get absorbed by large pharmaceutical companies as soon as they have a promising candidate drug, which repeatedly stifles the building of sustainable SME innovation capacity; and the need to develop reward systems that balance returns on investment against access and affordability issues. Consequently, specific measures are required to address this critical area of innovation in the EU. Horizon 2020 should build on the important experience of FP7 in opening access of funding to SMEs for drug development. As recently observed by one SME, ‘EC money could help companies carry their research to higher stages of value without depending on private markets’.⁹⁷ The field of public health genomics can also provide examples for innovative business models in health care systems at European and global levels.^{98,99}

Furthermore with public intervention, a crucial reform of pharmaceutical innovation can be engineered: re-orientating it towards developing products that are intrinsically cheaper and more cost-effective. This will benefit health and health systems globally, enable the EU to re-position itself as a leader in the field and help facilitate health access and products for the ‘bottom billion’. For example, a cheaper ‘polypill’ could be developed, making the treatment of NCDs more accessible in both HICs and LMICs. There are many systems and environmental drivers associated with the food industry contributing to the obesity pandemic.¹⁰⁰ However, the food industry also provides good examples of innovative strategies being used to promote nutritional products for the bottom billion (e.g. Box 4).¹⁰¹ In addition, EU Flagship projects such as IT Future of Medicine (ITFoM)¹⁰² using innovative technologies can serve as a blueprint for the future of medicine and health care.

Box 4 Food industry: Challenges and Opportunities

Important factors in the global obesity pandemic, an issue now prominent across LMICs as well as HICs, include system drivers such as the pursuit of high growth and promotion of consumption, along with environmental drivers such as the food industry’s effectively marketed, easily accessible, energy dense foods (Ref 100).

Conversely, the company Grameen Danone Foods has developed ‘social business’ in Bangladesh to tackle malnutrition (provide yogurt to poor populations, contributing to MDG 1 on Nutrition) and providing jobs to many locals, i.e. micro-farmers’ milk is used for production and the food distribution system used is ‘door to door’ sales. Similarly, Nestlé Peru has used innovative and inclusive business strategies by developing a food distribution model in order to access new markets in Lima, whilst at the same time developing employment for local women.

World Business Council for Sustainable Development (Ref 101)

Social innovation has been defined by the EU as ‘*innovations that are social in both their ends and their means...new ideas (products, services and models) that simultaneously meet social needs (more effectively than alternatives) and create new social relationships or collaborations. They are innovations that are not only good for society but also enhance society’s capacity to act.*’¹⁰³

Some key aspects of social innovation that need to be addressed by Horizon 2020 are:

- **Social exclusion and health:** One of the five main targets for Europe 2020 requires that at least 20 million fewer people are in or at risk of poverty and social exclusion.¹⁰⁴ Social innovation policies and strategies to tackle these problems are highlighted. The Renewed Social Agenda aims to ensure that all EU policies promote opportunities, access and solidarity (screening new initiatives for social and employment impacts).¹⁰⁵

Since poor health is a major cause of poverty and social exclusion, research to understand and address the major causes of ill-health is indispensable. Health itself is not an area of EU competence and Europe 2020 includes a set of national targets covering many areas.¹⁰⁶ However, given that health is major element of the Framework programmes, there is clearly a need for **a research agenda which addresses the determinants of health in relation to the causes of poverty and social exclusion.**

Taking account of the nature of many of the issues that need to be addressed (e.g. ageing, NCDs, substance abuse, nutrition and diet, transport, work, environment), two elements are essential to the **research and innovation agenda on poverty and social exclusion:**

- The research must be **interdisciplinary** and cross sectoral boundaries: often taking as its starting point an examination of health impacts of policies, actions and conditions that originate outside the health sector and which influence behaviour and lifestyle;
 - Fostering **social** innovations to promote and sustain good health must be central to developing solutions.
- **Migration and health:** With increasing migration across and into Europe have come new challenges for health, equity and social inclusion.¹⁰⁷ The physical and psychological health of migrants may be affected by a number of factors, including their social and economic circumstances, health history and access to health care prior to arrival in the new country, skills in the language of the new country, along with the circumstances surrounding the migration.¹⁰⁸ Migrants, refugees and asylum seekers, whose numbers have recently accelerated due to conflict in home countries, are at greater risk for poverty, unemployment and subsequently social exclusion.¹⁰⁹ Access to secure employment and treatment within employment roles is an important issue for migrant populations. Recently Navi Pillay, the United Nations High Commissioner for Human Rights, has made a call for the ratification of the International Convention on the protection of the rights of all migrant workers and members of their families.¹¹⁰ ‘Better integration of migrant workers in the workforce’ is a goal of Europe 2020. It has also been recognised³ that ‘*Europe needs to make full use of its labour potential to face the challenges of an ageing population and rising global competition*’. Fields such as ageing, community care and health care are critical avenues for migrant employment development, social innovation and research. Provision of education, training and language skills will be key to developments in the aged care workforce¹¹¹ and other areas. As migration is a cross country issue, there are many potential benefits of research collaboration in this field.
- **Ageing, the health care system and informal care:** Population ageing is a global trend creating many challenges, including increased levels of chronic disease and conditions,¹¹² increased health and care costs, increasing rates of disability¹¹³ and high levels of informal carers. Costs may be exacerbated by over-medication and unnecessary operations occurring in particular regions of Europe.¹¹⁴ It has been predicted that spending on long term aged care in OECD nations will double or even triple by 2050.¹¹¹ Informal carers also share the burden of care and contribute to GDP e.g. it has been estimated that informal care has the same economic value as high-end residential aged care.¹¹⁵ Carers are also more likely to be unemployed or in part-time paid work than average, and experiencing poverty and health problems, including mental health problems.¹¹¹ The European Innovation Partnerships includes ‘technologies to allow older people to live independently and be active in society’. There are many potential benefits of developing low cost, low tech solutions applicable in settings with few resources – e.g. IT and other communication technologies (e.g. eHealth, mHealth), are important innovations in the context of an ageing society.

Examples include online and telemedicine services, e.g. the UK's NHS Direct and NHS 24 providing telephone and online health services, with service goals including reduced hospital admissions, reducing delays in hospital discharge and increasing levels of care provided in the home.¹¹⁶ Research into such technologies, their access and acceptability and strategies to support their use by older people and informal carers is one area for development.

Ageing is a field where technological and social innovation must go hand-in-hand. The aim of the European innovation partnership on active and healthy ageing is to 'enable EU citizens to lead healthy, active and independent lives while they age, as well as improve the sustainability and efficiency of social welfare and healthcare systems'.¹¹⁷ The strategy has a research component, 'where possible resulting in new medicines for the elderly, new treatments or diagnostic tools, new institutional or organisational approaches and new solutions allowing for a better quality of life for the elderly'.¹¹⁷ These resources must be accessible and affordable as inconsistent availability of services (e.g. in the diagnostic industry) is evident across Europe. A 'roadmap for ageing research' (launched 18th Oct 2011) has recently been developed through the UK-led, European funded Futurage project, which has identified priorities for ageing research across the next 10-15 years.¹¹⁸

Some recommendations for ageing research include supporting strategies to promote healthy ageing policies, including early screening through health assessments, 'ageing in place',¹¹⁹ research to support informal carers, research to support quality of life (including defining QOL measures) and quality of care in residential and home care settings to prevent elder abuse, research to explore chronic disease management and health care systems¹²⁰ and long term care insurance policies (such as those available in Japan)¹²¹ and other strategies to promote older people's access to health, residential and community care. The provision of and research into services such as multi-disciplinary care and medication review is also required (e.g. Australia's Drug and Therapeutic Information Services (DATIS) is a good example, evaluated by its National Prescribing Service¹²²). It should be noted that research focusing on chronic disease management for older people undertaken in LMICs needs to move away from donor driven and vertical programmes and focus more on primary health care in health system responses.¹²⁰

Research with a health promotion focus may include research into strategies to promote older people's (over 50s) skills and access to the paid workforce as well as flexible employment arrangements, research into lifelong learning approaches (e.g. University Of The Third Age¹²³), research into effective physical activity initiatives and research on strategies to reduce loneliness and social isolation, including intergenerational projects which build bridges across generations (e.g. Intergenerational Playgroups,¹²⁴ performing and visual arts, radio initiatives or oral history projects).

- **Disability:** Around 10% of the world's population have a disability (80% are living in LMICs).¹²⁵ Disability is strongly associated with social disadvantage and a social gradient of disability.¹²⁶ People with disabilities have much lower rates of labour force participation and higher rates of unemployment (up to 80%)^{127,128} compared to the general population. Economic losses from excluding people with disabilities from the workplace in LMICs amount to 3-7% of GDP.¹²⁹ More research into social innovations to enable people with disability to function independently or be supported within living and working environments are required (e.g. disability access housing/home modifications, supported/supportive housing and employment models where required, web accessibility), especially due to the strong association between ageing and disability. Due to the social nature of disability, participatory action research is particularly recommended in this field. A good example of an organisation which works with government, business leaders and people with disabilities to develop disability inclusive business is Kanchi,¹³⁰ an Irish NGO, which promotes the 'business case for disability.' This includes strategies such as 'access to markets' (e.g. inclusive design to access markets for people with disabilities), 'access to talent' and 'retention of staff' (equal opportunity policies and the employment and inclusion of people with disabilities) and 'reputation management.'
- **Mental health:** Mental health is particularly overlooked, although it affects more than a third of Europeans¹³¹ and is a major contributor to the burden of disease worldwide. Psychosocial factors can affect physical health, just as poor physical health, functional limitations and disability can affect psychological health. The link between mental health and other physical health problems is often misunderstood, such as the relationship between compliance for HIV and tuberculosis treatment and the treatment of depression.¹³²

Many countries do not have a stand-alone budget or indicators for mental health funding and outcomes¹³³ It has been argued that ‘even if policy decisions are to be based on mortality alone, mental illnesses should be considered a priority because mortality both from suicide and from premature death from physical disease among person with mental illnesses is similar to the global mortality associated with malaria and HIV’.¹³⁴

The Global Challenges in Global Mental Health forum has recently developed 25 priorities for research in global mental health, with future breakthroughs ‘likely to depend on discoveries in genomics and neuroscience, in tandem with exploration of the role of socio-cultural and environmental contexts’¹³⁵ Given the shortage of specialists in this area, research is warranted into effective and efficient service delivery models and models of care which consider assessment and treatment in primary care. Such cost-efficient models could also have implications for poorer regions in Europe. Economics-related research into the role of mental health in development is required, and LMICs are likely to be dependent on HICs for such research.¹³³ Social innovation and models that go beyond a medical model and are better linked to the social development sector are also required. Mental health promotion and prevention activities particularly require cross-sectoral strategies including areas such as health, education, criminal justice, social services and employment,⁵⁸ and housing.

- **Violence and conflict mitigation:** According to WHO, violence accounts for 1.5 million deaths per year, with 80% of deaths occurring as a result of suicide and homicide, and 90% of deaths from violence occurring in LMICs.¹³⁶ Violence and suicide have become important causes of death for young people in the latter half of the 20th century, especially for young men in all regions of the world.¹³⁷ War is the eighth leading cause of death for young males (10-24yrs) across all regions.¹³⁸ Improvements in the mortality rates of young people aged 10-24 years have been half that of children 1-9 years of age. Traffic accidents (14% of young males), violence (12% of young males) and suicide (6% of young people) are prominent causes of death in young people aged 10-24 years, particularly amongst young men in LMICs.¹³⁸ For these reasons, it has been recommended that ‘*future global health targets should include the causes of death in people aged 10-24 years, and should extend beyond HIV infection and maternal mortality to include injury and mental health*’.¹³⁷ In addition, interpersonal violence (physical, sexual, emotional) against women and children is a significant public health problem with the potential to cause current and intergenerational health problems, particularly drug and alcohol and mental health problems. Research in conflict settings and strategies to mitigate violence (including interpersonal violence) and conflict is required, along with research on the relationships between violence, injury and mental health. It has also been noted that cause of death statistics are frequently inaccurate in LMICs, and in terms of research there is a greater need to support monitoring mechanisms and the development of civil registries and quality of certification.¹³⁹
- **Maternal Child and Newborn/Infant Health:** In 2010 the G8 leaders committed to the Muskoka initiative,¹⁴⁰ furthering MDG goals 4 and 5 on maternal, infant and child health. The G8 leaders at Deauville (2011) reaffirmed their commitments to achieving the health related MDGs, including on maternal health and reducing child mortality and sexual and reproductive health.¹⁴¹ Maternal, child and newborn health should be an ongoing priority for development support and research with LICs. The *Information and Accountability Commission on Women’s and Children’s Health* was established to support efforts in this area. Again, the report of this Commission observed problems with reporting systems within LICs: of the 49 lowest income countries, only 23 had conducted one national health account in the previous 5 years, 8 had a statistical report with district data online, and only 2 had coverage of death registration at over 50% of deaths.¹⁴²

2.3.2 Health security

Whereas security was traditionally seen as related to freedom from armed conflict and other forms of organized violence, **human security**¹⁴³ *sees the proper focus for security as the individual rather than only the state*. It is broadly defined in terms of *secure access to a range of essential human needs, including food, water, shelter, freedom from violence, opportunity to sustain good health and obtain treatment for ill-health; and conditions that minimise the adverse effects of natural and man-made disasters*.^{144,145} In this people-centred view, human security is necessary for national, regional and global stability¹⁴⁶ and the concept converges with that of human development on a common view that

economic growth is insufficient on its own and that areas such as health, education, technology, the environment, and employment should not be neglected. As an important part of people's well-being, human security is therefore an objective of development: both perspectives are people-centred, multidimensional and consider poverty and inequality as the root causes of individual vulnerability.¹⁴⁷

International¹⁴⁸ and global¹⁴⁹ aspects of *health security* form an important, evolving¹⁵⁰ component of the overall human security picture.

Health security threats from infectious diseases

The Oslo Declaration¹⁵¹ emphasised the need for preparedness to identify health risks and threats, and global mechanisms to ensure informed and coordinated global responses. Recent global threats to health (e.g. SARS virus, Avian influenza H5N1), have provided the imperative for Europe to develop its capacity to meet incoming health and health security challenges, prevent problems from developing at the source, prevent the migration of infectious diseases, and support countries' capacities to adhere to the International Health Regulations.

There are also new global challenges for infectious diseases. A recent research review has shown that, due to migration and weak economies in regions of Europe, 'neglected tropical diseases' (a range of parasitic infections as well as bacterial, fungal and viral infections) that are common in Africa and Asia are appearing more often in Europe.¹⁵² The study recommends increased policy commitments to determine the prevalence and incidence of these neglected infections in Europe, along with R&D for new control tools. In the case of pulmonary TB and the pertussis respiratory infection, research into new antibiotics is required to address drug resistant forms. It appears that protection from pertussis vaccine may be decreasing over time.^{153,154} Researchers have proposed the possible negative impact of climate change, and specifically rising sea levels, on vector-borne infectious diseases.¹⁵⁵ Research at the level of vectors is also required following the recent appearance of vectors in Europe due to migration. The reappearance of malaria in Italy and other European countries has led to a focus on new treatments¹⁵⁶ and genetic research on mosquitoes which do not produce sperm.¹⁵⁷

The health and economic impacts of rapidly emerging infectious diseases with pandemic potential, such as SARS^{158,159} (Box 5) and avian influenza, as well as re-emerging diseases such as multi-drug resistant TB and antimicrobial resistance,¹⁶⁰ have highlighted the *critical importance of global attention to this area*. In particular:

- There is a need to develop Europe's capacity to meet emerging challenges and prevent migration of infectious diseases.
- It is vital to prevent problems from developing at the source by building scientific capacities in areas such as surveillance, diagnosis, containment, vaccination and treatment in LMICs - which are often the countries of origin or of onward transmission – and establishing long-term collaborations that create trust and facilitate rapid, coordinated action.
- Capacity building in LMICs for surveillance/response systems (investigation disease and control), and global data and collection systems is another area for research development. At a briefing to the World Health Assembly, Dr Margaret Chan declared that investment in health information systems was largely lacking and appealed for more support in this area which would serve countries well in the longer term.¹⁶¹

Box 5 Severe Acute Respiratory Syndrome (SARS): lessons from a new disease

The fourth lesson concerns international collaboration: the world's scientists, clinicians and public health experts are willing to set aside academic competition and work together for the public health good when the situation so requires. International collaboration greatly advanced understanding of the science of SARS. One month after the laboratory network was established, participating scientists collectively announced conclusive identification of the SARS virus; complete sequencing of its RNA followed shortly afterwards. The network of clinical experts provided a platform for comparison of patient management strategies to indicate to the world which treatments and strategies were effective. In addition, the epidemiology network confirmed the modes of transmission of SARS and began the long-term collaboration needed to understand clearly the clinical spectrum of disease, including its case fatality ratio, while also providing the information needed to regularly reassess and adjust the case definition.

World Health Report (Ref 158)

There are very large economic as well as health benefits accruing from successfully dealing with infectious disease challenges...

- In the 1960s, there were c. 10-15 million cases of smallpox and 1.5-2 million deaths from the disease each year across more than 50 countries, costing their economies at least US\$1 billion per year. Eradication of smallpox and cessation of the need for surveillance, containment and global vaccination has brought massive economic benefits to every country. It is calculated that the largest donor, the USA, saves the total of all its contributions to smallpox eradication every 26 days by not having to vaccinate or treat the disease.¹⁶²
- It is estimated that the global initiative to eradicate polio could provide net benefits of at least US\$40-50 billion if transmission of wild polioviruses is interrupted within the next few years.¹⁶³
- The costs of anti-retroviral drugs (ARVs) for the treatment of people with HIV/AIDS fell from more than US\$10,000 per year in the 1990s to less than US\$100 per year by 2008, as a result of innovative work by Indian pharmaceutical companies. This made possible, with support from the international donor community, wide access to ARVs by people with HIV/AIDS in resource-poor countries.¹⁶⁴ It has also demonstrated the potential of generics for massively lowering the costs of drugs globally.

... while the potential economic and health costs of failure to tackle infectious disease challenges quickly and efficiently are enormous:

- Estimates of economic losses from the Influenza A H1N1 outbreaks in 2009 range from 0.5% to 1.5% of GDP in affected countries¹⁶⁵ and are typical of impacts seen in other cases such as SARS. For the rest of the world, fear of a pandemic leads to emergency measures being taken at both individual and national levels – many of which may be inappropriate in the absence of adequate scientific data and lack of prevention and treatment options of proven effectiveness – causing massive and avoidable economic losses.¹⁶⁶
- Multi-drug resistant and extremely drug resistant forms of TB present a growing health and economic problem worldwide. Research by the World Bank has emphasised that the economic benefits of effective control programmes will far outweigh the costs of these programmes.¹⁶⁷ It is clear that much more rapidly acting treatment regimes are needed as well as better approaches to diagnosis and case management.¹⁶⁸
- Antimicrobial resistance to drugs, resulting from evolutionary changes (often exacerbated by the inappropriate use of antibiotics) has become a very serious worldwide problem at a time when there has been falling investment in the development of new antibiotics.^{169,170}
- The May 2011 outbreak of enterohemorrhagic *E. coli* food poisoning linked to an organic farm in Germany resulted in about 4000 cases in several European and North American countries and over 40 deaths. Russia banned the import of all fresh vegetables from the EU for a period of time, highlighting how quickly a public health security issue can become a major economic problem.¹⁷¹

Health security threats from disasters

Natural or man-made disasters can also have sudden and large consequences for both health and economies. These two are often inter-related, with the immediate and longer-term health impacts of physical disasters causing massive economic loss and slowing the pace of economic recovery; and with the economic disruption caused by physical damage to land, buildings and infrastructure and the consequent loss of livelihoods and amenities adversely affecting short-term health recovery and long-term physical and mental health. While the causes, character and predictability of the natural and man-made events are highly variable, they nevertheless share a number of ***common features that define a research agenda*** that is designed to underpin:

- ***risk assessment*** – including health impacts and emergency health needs for different kinds of events;
- ***early warning*** – including, where relevant, devising, testing and implementing health surveillance and reporting systems that can pick up early signs of developing disasters, such as the health consequences of biological, radiological or chemical releases, heat waves;
- ***disaster management*** – including establishing appropriate items of medical and nutritional supplies to be stockpiling and distributed and the training and maintenance of emergency health response teams; and
- ***recovery*** – including developing methods to treat the immediate consequences of trauma and injury and to deal with the longer-term physical, mental and psycho-social sequelae.

Implications for the research and innovation agenda

The *research agenda for health security* must operate coherently and consistently across three arenas:

- ***Within the EU:***
 - Funding research and innovation on new or improved methods for the diagnosis, prevention and treatment of infectious diseases that pose a significant threat to public health in the EU;
 - Enhancing capacities at the pan-European level for surveillance, diagnosis and laboratory support for case management and for the collection, sharing, pooling and analysis of relevant data.
- ***Through collaborations between the EU and external countries and agencies:***
 - Funding collaborative research involving institutions in the EU, other HICs and LMICs on reducing pathogen induction and disease vectors and creating better methods for prevention, diagnosis and treatment of infectious diseases posing significant threats to public health globally.
 - Building capacities in LMICs for these research activities and for surveillance, diagnosis and laboratory support for case management and for the containment of pathogens.
 - Contributing to enhancing global mechanisms for surveillance and early warning of emerging pandemic threats and global response mechanisms – including research and innovation capacities for rapidly developing new diagnostics, drugs and vaccines.
- ***As a component of development:***
 - Supporting governments and institutions in LMICs to build national capacities for surveillance, diagnosis and laboratory support for case management of infectious diseases and for the recognition and safe handling, containment and shipment of pathogens.
 - Working with WHO and OECD and surveillance/response systems and global data collection systems and collaborating to develop databases and online information and resource tools.

Research and innovation for health security warrants specific attention in Europe because special measures are needed to ensure effective action in this field and the potential costs of neglect, both in health and economic terms, are massive.

2.3.3 Economics, trade and health equity

Health equity and economic development

Whilst the health of a country's population is essential for the health of its economy, economic growth does not necessarily translate to the same level of improvements in health. The EU has recently highlighted that *'the long-held belief that economic growth creates employment and wealth that goes on to alleviate poverty has been disproved by recent events'* leading to a greater need for social innovation.⁸²

Horizon 2020 was one of the key strategic priorities¹⁷² during Poland's presidency of the EU in the second half of 2011. A recent EU-funded Polish study highlighted major gaps in health equity, especially concerning the ten new EU member states in Central and Eastern Europe.¹⁷³ Poland pledged to move forward on reducing health inequalities within the EU and Poland's Minister of Health¹⁷⁴ emphasized the need for continued improvements in public health as crucial for building human capital and achieving economic progress. Poland's call for 'Solidarity for Health' in the EU, which many member states joined, requires action at national levels and also at the EU level. Elements of the agenda set out by Poland that are relevant to Horizon 2020 include requirements for:

- health impact assessments
- development of new indicators to take into account the impact of social factors on health
- creation of standardized methods for the assessment of health status and for data interpretation and comparison
- joint actions to exchange experiences about closing the health gaps in specific countries and between societal groups, and also with regard to institutional solutions which contribute to improving the health of societies.
- strengthening health literacy to support people in improving their own health through enhanced knowledge.
- building additional capacities for public health

A key priority in the Agenda for Action arising from the authoritative *Lancet* Series on Trade and Health is to strengthen evidence on trade and health links, supporting the development of research, research capacity and indicators in this field.¹⁷⁵

‘Corporate social responsibility’ and ‘shared value’ approaches

Raising ‘corporate social responsibility’ (CSR) amongst the business community to ensure long term employee and consumer trust’ is one objective of Europe 2020. Examples of CSR initiatives in the health field include Areva in Niger, who are tackling HIV/AIDS through a public private partnership.¹⁷⁶ and Chirano Gold Mines Integrated Malaria Control Program in Western Ghana.¹⁷⁷ One identified danger of CSR activities is that they are seen as ‘sideline’ activities not central to the core business of an organisation and it is often difficult to engage the private sector in global health partnerships.¹⁷⁸ It has been argued that we must go beyond the concept of traditional CSR and embrace the concept of ‘shared value’ defined as ‘policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates’. There is a clear need to research and better understand such initiatives to determine their impact upon health and equity, along with their sustainability.¹⁷⁹

Global health governance and accountability, the role of civil society, service user and carers

Governance challenges, international health stakeholders and public-private partnerships: Corporate donations, private foundations and public private partnerships have led to a significant increase in funding for global health initiatives in recent years.¹⁸⁰ With the increasing range of actors within global health, another area for capacity building is global health governance research. United Nations Development Programme (UNDP) principles for good governance include legitimacy and voice, direction and strategic vision, performance (responsiveness, effectiveness and efficiency), accountability and fairness (equity).¹⁸¹

Poor governance has been identified as one problem area needing attention,^{128,182} particularly in relation to progress on the social determinants of health.²⁶ One review of governance practices in global public-private partnerships has identified representation, transparency and accountability as three key issues for governance.¹⁷⁸ Clarity regarding transparency in decision-making, processes to ensure democratic participation and representation, coherence across policy areas (and coherent representation), clear outcomes and indicators and monitoring and accountability mechanisms are required. Global health governance to achieve action on the social determinants of health and NCDs also requires action and research on intersectoral policy and action and policies and practices that promote equity in health systems.²⁶

In particular, the UNDP principles for good governance of ‘legitimacy and voice’ and ‘fairness’ correspond with UN Universal Declaration of Human Rights Principles, particularly the participation of groups that have faced discriminatory practices.¹⁸¹ An important aspect of governance is thus democratic processes, ensuring participation and clarifying roles that different actors play within policy processes. Research into effective processes to ensure increased user involvement and empowerment in planning, decision-making, implementation and monitoring and accountability mechanisms for global health governance is required, e.g. platforms for engagement and participation (including non-government and private sector participation) and accountability mechanisms. Action research into effective strategies for global health governance and involvement of civil society organisations, local health service users (and carers) and ensuring their feedback and evaluation in research is also important for research and capacity building, in particular for research undertaken with LMICs.

Accountability strategies: Health impact assessments: The Oslo Declaration notes that ‘*health-impact assessments of all foreign, trade, and defence policies would do much to advance the cause of health across governments*’.¹⁵¹ Haber¹⁸³ suggests that a useful tool for building equity into priorities for planning and measuring outcomes is ‘Health Equity Impact Assessment’. Specific evaluation and impact assessments to determine the impact of health, educational and social policies on people with disabilities have also been recommended.¹⁸⁴

2.3.4 Capacity building in the health workforce and research

Health training, competencies, research and social accountability

Capacity building in the global health workforce is necessary and will lead to potential benefits for Europe.

- One Europe 2020 flagship initiative is ‘youth on the move’, an objective being ‘to explore ways of promoting entrepreneurship through mobility programmes for young professionals.’ One strategy would be practice-based research exchange programmes for young health professionals going to LMICs (and vice versa).
- The Commission on Education of Health Professionals for the 21st Century¹⁸⁵ found a dearth of research on the effectiveness of health professional education. They state that ‘sharing learning by supporting metrics, evaluation and research should be strengthened to build up the knowledge base about which innovations work under which circumstances’. They also recommend a **systems approach to training and research** in order to follow an education-care-research continuum, whilst acknowledging the need for capacity building in LMICs in academic systems. Educational systems should be guided by the determinants of health and should include ‘social accountability’ (to ensure health services address the priorities of the community) and measure competencies and research into meeting them.¹⁸⁶ In addition, the Commission considered the shortage of health professionals in LMICs and the need for ‘scaling up’ health organisations within low income countries..
- The international diffusion of new knowledge and ‘best practices’ is one of the key forces of scaling up – a goal now more readily achieved through low-cost methods available through the internet.¹⁸⁷
- A recent European forum by Norad on global health and AIDS has also highlighted the ‘*need to invest in health services research and in mechanisms for research utilisation. The goal is **translation of learning into policy**. Sustained and further developed **systematic reviews** are essential in this respect*’.¹⁸⁸
- The Association of Schools of Public Health in the European Region (ASPHER) has established various initiatives to strengthen the many facets of workforce capacities.¹⁸⁹ These activities play an important role for the effective and sustainable development of the health workforce in Europe.

2.3.5 Health as foreign policy and diplomacy

Global health challenges have increasingly manifested themselves as problems in foreign policy and international affairs in the last decade, as evidenced, for example, by their periodic appearance in high-level meetings of the UN^{190,191} and G8¹⁹² and by the formation of a Foreign Ministers group¹⁹³ specifically to address them. The Oslo Declaration¹⁰² of seven foreign ministers from across Europe, South America, South Africa and Asia agreed to work towards prioritising health in foreign policy and trade issues, asserting that, ‘*in a globalised and interdependent world, the state of global health has a profound impact on all nations – developed and developing*’. Foreign policy actions in security, trade, conflict, crisis, environment, and human rights have a strong bearing on whether we can achieve national as well as global health security. Often a public health threat in one country requires a concerted response with many foreign policy makers working together. The important role of research was highlighted at the 2010 UN General Assembly debate on ‘Global Health and Foreign Policy’,¹⁹⁴ when the EU stated ‘we should continue to enhance our collective understanding of how health outcomes are affected by different aspects of foreign policy’.¹⁹⁵

Health is intertwined with the three key global agendas of security, economic policy and social justice. Foreign policy and health can interact in the following ways:¹⁹⁶ (1) foreign policy endangering health when diplomacy breaks down or when trade considerations trump health; (2) health used as a foreign policy instrument in order to achieve other goals; (3) health as an integral part of foreign policy; and (4) foreign policy promoting health goals. It has been noted¹⁹⁷ that ‘*research in this area aims to develop policy options for reducing the collective vulnerability to health threats by addressing their politically and economically sensitive determinants. It also examines the political and economic effects of disease threats and efforts to combat them*’.

It has been said that ‘better global health promotes stability and growth, which can deter the spread of extremism, ease pressure for migration, reduce the need for humanitarian and development assistance

and create opportunities for stronger political alliances and economic relations'.¹⁹⁸ Global health diplomacy is a potential source of 'soft power' (or building upon 'common interests and values to attract, persuade and influence')¹⁹⁹ enabling the development of trust between countries.

Creating links between health and other related policy areas in order to ultimately impact upon global health is a key objective. It has been argued that in order to fulfil the expectations of global health diplomacy and build links between health and foreign policy, professional development to create improved skills, understanding and resources are required across both areas; specifically, systematic development of specific skills amongst foreign diplomats or global health professionals are necessary, including technical expertise, legal knowledge and diplomatic skills, along with expansion in countries' overseas workforces.¹ In some areas, specific knowledge and skills may be required, such as in the case of previous WHO negotiations regarding virus sharing, where knowledge of vaccine production, epidemiology, intellectual property rights and the context of emerging economies was called upon.¹⁹⁸ Non-government organisations also increasingly play a role in global health diplomacy.²⁰⁰ For example, during the development and negotiation of the Framework Convention on Tobacco Control (FCTC), five key areas for NGOs included monitoring, lobbying, offering technical expertise, brokering information and fostering inclusion. NGOs helped to facilitate the role of developing countries in diplomacy processes.²⁰⁰

Science diplomacy

Science diplomacy refers to the role of science, technology and innovation in informing foreign policy (science in diplomacy), developing international science cooperation (diplomacy for science) and improving international relations (science for diplomacy).²⁰¹ Science diplomacy has a crucial role in facilitating international science cooperation and influencing foreign policy and governance for global health. Global science diplomacy is necessary in order to address many important health-related challenges including pandemic threats, food insecurity, poverty, climate change and energy issues. The EU has made a commitment to science diplomacy through a number of global research projects, many of which are global health projects.²⁰² Developments in science diplomacy, including developing human resources for science diplomacy in foreign offices (science attachés in embassies²⁰¹) and international organisations, international research and knowledge and data and resource sharing, will contribute to innovative and common solutions to global health challenges (Box 6). One recommendation for developing science diplomacy in the area of global health is through the development of regional and international collaborative research centres in order to support intergovernmental panels with the aim of progressing global health (see section 3). In any initiatives in science diplomacy, interdisciplinary collaboration is crucial, particularly with the social sciences;²⁰¹ see the example (Box 6) of multidisciplinary research to tackle dengue fever in Asia.²⁰³

Box 6 Science as a global endeavour

Science is a truly global endeavour with scientists sharing their knowledge with their colleagues around the world. Most health and bio-medical challenges are borderless and if research is to help meet those challenges, an international approach is essential.

M. Geoghegan-Quinn, EU Commissioner for Research, Innovation and Science (Ref 202, p3)

Multi-disciplinary, international research to combat dengue fever

One multidisciplinary research project with the aim of controlling dengue fever in Asia focused on **eco-bio-social strategies** for dengue vector control. The research was conducted by the Special Programme for Research and Training in Tropical Diseases (TDR) and Canada's Ecosystems and Human Health Program of the International Development Research Centre (IDRC), and involved entomologists, epidemiologists and social scientists, along with academic institutions, communities, local governments and non-government organisations. Following a mapping exercise across six countries, site specific interventions were introduced which included 'innovative biological, chemical, mechanical and environmental vector control technologies, or a combination of these tools' (Ref 203).

2.4 Debating the case for EU leadership in research and innovation for global health

Global Health Europe conducted a symposium on ‘**The case for Europe as a leader in research and innovation for global health**’ at the 2011 World Health Summit in Berlin. A number of presentations were made, including by co-authors of this paper and representatives of the EC Directorate-General for Research and the European Federation of Pharmaceutical Industries and Associations. An earlier version of the present paper was distributed at the symposium and feedback invited. A report on the main discussions and the key conclusions of the symposium has been published (Box 7).²⁰⁴

Box 7 Key messages from the symposium on ‘The case for Europe as a leader in research and innovation for global health’, World Health Summit in Berlin, 25 October 2011

Strengthening research and innovation for global health (*‘health issues which transcend national boundaries and governments’*) is central to meeting the EU’s commitments to tackle a range of global health challenges (including addressing deep health inequities within and beyond Europe; and achieving the Millennium Development Goals); and enabling the EU to achieve its goals for economic growth and prosperity.

Recommendations include ensuring that Horizon 2020 will give explicit attention to:

- Programmes that tackle major challenges, such as noncommunicable diseases, antimicrobial resistance, pandemics and ageing and that encompass health promotion and disease prevention as well as diagnosis and treatment.
- Special mechanisms to promote and support research that is cross-sectoral and interdisciplinary, involving both technological and social innovation.
- Research that acknowledges the ‘right to health’ and European values in health such as equity, solidarity, and access to health care.
- Recognition that attention to global health is a matter of ‘enlightened self interest’ for the EU.
- Sustaining coherence and momentum in areas where the EU has already made major commitments (e.g. in relation to health-in-all-policies, development policies), or major investments (e.g. capacity building for research and development in low- and middle-income countries, research on the social determinants of health).
- Ensuring the inclusion of stakeholders in priority setting research agendas.
- Innovation stimuli which take into account the special needs of pharmaceutical development (which include long lead times, high intensity of investments, high attrition rates, and balancing the factors that support innovative small- and medium-size enterprises and large pharmaceutical companies).
- A ‘grand challenges’ approach to developing global health, which involves cross-sectoral research conducted by multinational consortia within and beyond the EU. Several mechanisms were highlighted, including flagship research programmes and establishing ‘Networks of Excellence’ and EU ‘Global Health Chairs’.
- Utilisation of ‘reverse innovation’, i.e. high-countries learning from low- and middle-income countries.
- Better definition and measurement of the impact of research, development and innovation.

S. Battams, Global Health Europe (Ref 204)

3. Conclusions and Recommendations for Research and Innovation

This paper has argued that European commitment to research and innovation for global health needs to be addressed through Horizon 2020 and that this will benefit Europe in a range of ways. Key reasons for European investment in this field are:

- Combating effectively the major health challenges in European and global level, including the rising tide of non-communicable diseases and the widening health equity gap;
- Strengthening the EU’s economy through support for a key but challenged area of European innovation;
- Providing competitive advantage for European industry and research (bearing in mind the need for balance with access issues for LICs and the importance of the Doha Declaration);
- Improving health for Europeans and globally, with consequent positive effects on health systems, employment and global health security;
- Sustaining EU credibility with regard to commitments made across a range of EU policies, including those on health, economic growth, social inclusion and development;
- Promoting European goals and values in health;
- Facilitating global health and science diplomacy, knowledge sharing and common solutions to problems.

Throughout this paper it is repeatedly emphasised that research and innovation for global health has a number of special features that require specific attention, beyond the factors that would be dealt with

generically in a broadly framed policy on research and innovation. There are important implications of this set of characteristics for the framing of Horizon 2020:

- The specific needs of research and innovation for global health should be addressed explicitly;
- Special mechanisms are needed to promote and support research that is cross-sectoral and interdisciplinary, involving both technological and social innovation;
- Special mechanisms are needed to promote and support research collaboration with LMICs, including capacity building;
- Innovation stimuli must take account of the special needs of pharmaceutical development, including long lead times, high intensity of investments, high attrition rates, complex registration processes and the danger of repeatedly eliminating innovative SMEs as they are absorbed by large pharmaceutical companies;
- Previous experience has shown the gains to be achieved from global, collaborative health research and that some innovations can only occur on a regional/international level.

The section below outlines some specific initiatives through which the policy goals in research and innovation for global health can be pursued effectively.

Recommended Strategies to Progress Research and Innovation for Global Health

1. Policy directives

In the elaboration and implementation of Horizon 2020, clear policy statements should establish global health as a priority; recognise its special characteristics and define areas for priority attention across such domains as pharmaceutical and social innovation, health security and development.

2. Interdisciplinary and cross sectoral research

The special challenges of interdisciplinary and cross sectoral research need to be recognised and mechanisms instituted that create an enabling environment and promote such research, including funding and review mechanisms.

3. Focus on health and equity research

The WHO Commission on Social Determinants of Health called for strengthening research to improve health equity. Recent suggestions²⁰⁵ on priority areas for research on equity and health include:

- ‘global factors and processes that affect health equity;
- structures and processes differentially affecting people’s chances to be healthy in a given society;
- health system factors that affect health equity;
- policies and interventions to reduce health inequity.

4. European Grand Challenges in Global Health

In line with the Lund Declaration⁷¹ a programme of European Grand Challenges should be established to develop collaborative global health research tackling major health challenges, which should be open to ‘bottom-up’ identification of challenges and approaches to solutions. Models include Canada’s Grand Challenges in Global Health programme,²⁰⁶ funded by the Bill and Melinda Gates Foundation.²⁰⁷ This programme is a family of grants which focus on addressing 14 key grand challenges (with a focus on infectious diseases and infections).²⁰⁸

Another example of a ‘grand challenges’ approach is the US Grand Challenges in Global Mental Health Initiative, which has focused on developing research priorities for neuropsychiatric disorders including ‘depression, anxiety disorders, schizophrenia, bipolar disorders, alcohol and drug use disorders, mental disorders of childhood, migraines, dementias, and epilepsy.’²⁰⁹ This initiative is led by the U.S. National Institute of Mental Health and the Global Alliance for Chronic Disease, in partnership with the Wellcome Trust, the McLaughlin-Rotman Centre for Global Health, and the London School of Hygiene and Tropical Medicine.²⁰⁹ The process included a Scientific Advisory Board establishing the scope and questions for global mental health, with a Delphi Panel then refining priorities for research.²¹⁰ The priority setting process also developed a network of research funders.²¹¹

A European Grand Challenges in Global Health programme would build upon these initiatives and provide important opportunities for partnerships between the EU, the private sector and foundations; and for creating consortia that include academic and private sector actors, including multinationals and SMEs. They can be built around multi-sectoral and multi-disciplinary teams, with partners from

across fields such as engineering, business, statistics and the social, chemical and biological sciences. A European approach should not necessarily specify specific topics, but promote an inclusive, fair, needs driven and transparent process of priority setting for research.

5. *European Global Health Chairs*

These provide the opportunity to promote research in a hitherto under-resourced field. The Canadian Global Public Health chairs provide a possible model: funded by the Canadian Chair Programme (2000 research professorships in all), they attract outstanding researchers who are world leaders in their field, and whose research corresponds with the strategic research plan of the host university. Renewable chairs are available for either seven (university receives \$200,000 annually) or for five years (university receives \$100,000 annually). Chairs are also eligible for infrastructure funding from Canada Foundation for Innovation. Nominations are peer reviewed through a ‘College of Reviewers,’ with involvement from a Steering Committee in the review process.

6. *Collaborative global health research centres*

European involvement in global health research could be advanced through the development of collaborative research centres for global health which have strong links to a global health policy forum. Models to draw upon include the German Collaborative Research Centres and Australian Research Council’s Centres of Excellence (which facilitate cross disciplinary research across institutes, departments and faculties and with external organisations).

The Center for Global Health Research in Toronto is an example of a research collaboration which conducts studies in LMICs. It is an independent, non-profit NGO funded through a public-private partnership which includes the Canadian Institutes of Health Research, the US National Institutes of Health, the Bill and Melinda Gates Foundation, St. Michael’s Hospital and the University of Toronto.

7. *Capacity building initiatives with LMICs, including the involvement of civil society, and ‘people’s initiatives’*

Global health research and innovation initiatives should continue to to develop research capacity within LMICs and across LMICs/HICs. There are already some examples^{46,47,212,213,214,215,216} where this is occurring (see Box 7). One way to develop research capacity in LMICs and ensure that research is relevant and appropriately meeting the needs of local populations, is through the involvement of civil society. The analysis of the responses² to the Green Paper¹ on Horizon 2020 acknowledged the need for citizens and civil society to be involved in the research process through a range of strategies such as citizens’ juries and participatory research projects.

Box 8 Examples of capacity building initiatives

The EU funded SICA⁴⁵ projects and EDCTP³² projects are good examples of capacity building for research initiatives with LICs. The EDCTP has supported more than 50 clinical trials in Sub-Saharan Africa, but a significant result of the overall project has been the support for capacity building for clinical research in Africa

A programme currently funded by the Netherlands government aims to stimulate health policy and systems research and build research capacities by funding competitive, peer-reviewed project of high quality involving collaborations between researchers in the Netherlands and LMICs.²¹²

Further examples of collaboration/capacity building initiatives are ‘twinning programmes’ where several sub-Saharan African medical training centres have partnered with other universities for training and mutual exchange (e.g. Ibadan in Nigeria and the University of London (Ref 213), the Makerere schools in Uganda and John Hopkins University. (Ref 214)

Attention has focused recently on the way in which ‘People’s Initiatives’ are implemented, that is, research which is self-organised, self-funded and self-managed, using indigenous knowledge. (Ref 215)

The Ethox Centre in the UK has established a research network with the Wellcome-KEMRI Unit in Kenya which focuses on the ethics of collaborative global health research and the way in which such research is manifested in local communities. (Ref 216)

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