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European research and knowledge for global health

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The EU Role in Global Health

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Contents

Introduction

This paper, accompanying the Communication on the EU Role in Global Health,[1] describes the valuable input that research can offer for improving global health. The factors enabling and impeding innovation targeted on health for all are described along with the EU's current role and position. Overall, the aim is to outline how the EU could contribute to strengthening the knowledge base on public health and to technological improvements to support development of health services around the world that are based on the shared European values of universality, access to good-quality care, equity and solidarity.

1. Context

Innovation in health sciences has made a major contribution to improving longevity and quality of life in Europe and beyond. However, innovation can only make a meaningful contribution to public health if it can be put to the benefit of the entire population. It is not enough for new treatments or medical products to be effective and safe. They also have to be acceptable, affordable and accessible. Access issues therefore need to be built into the research process at an early stage.

Knowledge can generally be considered a 'public good' that is underprovided in perfect markets as there is no direct link between the costs of production and the benefits of consumption. In order to benefit fully from medical research, public intervention is necessary. This can take the form either of public subsidies for research (e.g. grants) or of a regulatory framework that allows the private sector to reap the benefits of its research and development efforts with the aid of exclusive marketing rights (e.g. intellectual property rights — IPR).

Under its Research Framework Programmes, the EU has been supporting research across the entire innovation cycle: from the discovery of potential healthcare products using basic research, development of new products by means of pre-clinical and clinical research and the delivery of new products and treatments as a result of public health and health services research.

The European Commission views IPR as a key element in promoting innovation and underlines the need for high-quality patents granted by efficient and affordable procedures and giving all stakeholders the legal certainty they need.[2] However, gaps in the innovation process have emerged. First, despite increasing investment in research and development (R&D), pharmaceutical companies are not refilling the product pipeline effectively. Consequently, the number of novel medicines reaching the market is decreasing. Second, IPR provide big incentives to develop new medicines and medical technologies. However, these incentives are much less effective when patients are either too few or too poor. Third, there is an enormous gap between what is available and known to maximise the quality of healthcare and what is being delivered in practice.

It is therefore essential that:

- research priorities are geared to making the biggest impact on public health (see section 2.1);

[1] COM(2010) xxx of xx.xx.2010.

[2] Commission Communication 'Enhancing the patent system in Europe', COM(2007) 165 final.

- public research funding and regulation of medical innovations are coherent and aligned with those priorities (see section 2.2);
- the needs of the populations currently underserved by medical innovation, the poor and those with rare diseases or conditions are adequately addressed (see section 3).

1.1. Knowledge as a public good for health

Economic input in human well-being is classified as either a public or a private good. Most goods are private in nature. They cannot be consumed again (they are rival) and their consumption can be withheld until payment is made (they are excludable). Private goods are best provided by the market mechanisms of supply and demand. By contrast, public goods are not diminished by use (non-rival) and are available to all (non-excludable). A classical example is a lighthouse, whose benefits are available to all ships all the time. Public goods are underprovided in free markets, as there is no natural incentive to produce them. Therefore the state has a role to play in order to secure the collectively optimum level of public goods, either by providing them directly or by ensuring that they are produced by private companies. That is not to say that no knowledge would be produced without intervention by the state. However, there would be much less.

Knowledge is considered a public good, even if it is embodied in a tangible good (e.g. a drug). Public policy is therefore crucial to ensure that knowledge is acquired, either by subsidising research directly (see section 2.2.2) or by providing effective incentives for private engagement in research (see section 2.2.1). The forms of incentive and amount of direct subsidies differ widely from country to country, even within the European Union. However, increasing attention has been being paid to intervention at European and global level to coordinate and optimise generation of knowledge relevant to health for all.

1.1.1. Global public goods for health

The concept of 'global public good' (GPG) is an extension of the economic theory described above. GPG is defined as 'a good which it is rational, from the perspective of a group of nations collectively, to produce for universal consumption, and for which it is irrational to exclude an individual nation from consuming, irrespective of whether that nation contributes to its financing'.[3] The concept is limited to collective action at global level that is (also) in the donor countries' self-interest. Even though the concept calls for 'collective action', this does not mean that all collective action that is worthwhile actually produces a GPG. The main issue raised by provision of public goods at global level is how to manage collective action effectively in the absence of a 'government' that could provide or finance the public goods.[4] Control (possibly eradication) of communicable diseases is one clear example of a GPG. It would benefit everyone, in poorer and richer countries alike and in present and future generations. Industrialised countries cannot provide the GPG 'communicable disease control' by policy measures of their own but depend on the cooperation of countries around the world. This became apparent in the recent H1N1 pandemic. Since successful cooperation depends on

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[3] Woodward, D., Smith, R.D.: 'Global Public Goods for Health: concepts and issues'. In 'Global Public Goods for Health: a health economic and public health perspective', Chapter 1, edited by Smith, R.D., Beaglehole, R., Woodward, D. and Drager, N., Oxford University Press, 2003.

[4] Sandler, T: 'Global and Regional Public Goods: A Prognosis for Collective Action', Fiscal Studies 1998, 19:221-247.

sharing the costs and net benefits fairly, such global collaboration could improve health equity.[5]

Research and development to generate medical knowledge is another example of a public good that is inherently global in nature. Medical knowledge includes diagnosis, prevention and cure of diseases, understanding health risks and the effectiveness of health delivery systems and traditional medicine. However, the end-use of knowledge, particularly when it is embodied in a product or service, is predominantly excludable and rival and, therefore, a private good. The GPG aspects of R&D and the fact that they are lacking in fields that would benefit poor countries call for collective action at global level in this area.[6]

1.2. Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

The debate on the contribution that innovation in public health can make to improving human health in developing countries led to establishment of the *Commission on Intellectual Property Rights, Innovation and Public Health* by the World Health Assembly (WHA) in 2003.[7] This Commission concluded that IPR provide big incentives to develop new medicines and medical technologies. However, those rights are not an effective incentive when patients are either too few (e.g. sufferers of rare diseases) or too poor. New approaches to incentives, financial mechanisms and coordination of stakeholders are necessary to address the very different issues when either no product exists to address specific health needs of the poor or existing medical products are not accessible and affordable for poor communities. The WHA adopted Resolution WHA 59.24 on Public Health, Innovation, Essential Health Research and IPR: Towards a Global Strategy and Plan of Action. Among other proposals, the resolution requested the Director-General of the World Health Organisation (WHO) to establish an inter-governmental working group open to all interested Member States to develop a global strategy and plan of action with the aim, *inter alia*, of securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development and estimating funding needs in this area. After extensive and lengthy discussions and negotiations in the Intergovernmental Group, the WHA adopted the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* in 2008.[8] This strategy is designed to promote a new approach to innovation and access to medicines which would encourage needs-driven rather than market-driven research to target diseases that disproportionately affect people in developing countries.

1.3. EU Framework Programme

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5 Kaul, I. and Faust, M.: 'Global public goods and health: taking the agenda forward', Bulletin of the World Health Organisation, 2001, 79: 869–874.

6 Smith, R.D. and MacKellar, L.: 'Global public goods and the global health agenda: problems, priorities and potential', Globalisation and Health, 2007, 3:9.

7 Resolution WHA56.27: Increasing Access to Essential Medicines, fifty-sixth World Health Assembly, Geneva, 19–28 May 2003, World Health Organisation.

8 Resolution WHA61.21: Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, sixty-first World Health Assembly, Geneva, 19–24 May 2008, World Health Organisation.

The main instrument for implementing the EU's research policy is the *Framework Programme of the European Community for research, technological development and demonstration activities*. The EU has been financing research on the basis of multiannual Framework Programmes since 1984. The current Seventh Framework Programme (FP7) runs from 2007 to 2013.[9] Within FP7 the specific programme with the highest budget is 'Cooperation' (€32.413 billion for 2007-2013), which supports health research (the Health Theme has a budget of €6.1 billion, the ICT (eHealth) Theme an additional €450 million, which is relatively small when compared with the actual needs and the level of funding provided by other public or private international funding agencies).

The objective of FP7 is to strengthen industrial competitiveness and to meet the research needs of other Community policies, including health, thereby contributing to creating a knowledge-based society, building on a European Research Area and complementing activities at national and regional levels. It promotes excellence in scientific and technological research, development and demonstration activities.

The specific programme on 'Cooperation'[10] provides support for transnational cooperation across the European Union and beyond to address social, economic, public health, environmental and industrial challenges. The overarching aim is to contribute to sustainable development in the context of promoting research, the primary purpose of which is to increase knowledge at the highest level of excellence.

International cooperation offering European added-value and of mutual interest supports an international science and technology (S&T) 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.

International cooperation is implemented in each thematic area and across themes by means of:

• Greater participation by researchers and research institutions from all countries, with particular emphasis on encouraging non-EU participation in identified areas of mutual interest.

• Specific cooperation targeted on non-EU countries in cases of mutual interest in cooperating on particular topics selected on the basis of their scientific and technological level and needs. Identification of specific needs and priorities is closely linked to relevant bilateral cooperation agreements and ongoing multilateral and bi-regional dialogues between the EU and these countries or groups of countries. Priorities are based on the particular needs, potential and level of economic development in the region or country. To this end, a *Strategic European Framework for International Science and Technology Cooperation*[11] has been developed with

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9 Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).

10 Council Decision 2006/971/EC of 19 December 2006 concerning the specific programme 'Cooperation' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013).

11 Communication from the Commission to the Council and the European Parliament, COM(2008) 588 final of 4 September 2008.

the main objective of contributing to global sustainable development and fostering Europe's scientific and technological excellence.

This framework aims to contribute to the free circulation of knowledge — 'the EU's fifth freedom' — at global level. More specifically, it is designed to: strengthen coordination of Member States' and EU-funded action with the aim of reinforcing strategic S&T cooperation and information society dialogues with partners worldwide; generate additional synergies between public authorities, industry and civil society to make EU action in these policy fields more efficient; facilitate access to knowledge, resources and markets worldwide; have a positive influence on the global science and technology agenda by pooling resources to build up critical mass and by underlining democratic values in the global information society, in particular freedom of expression and the right of access to information; improve the conditions under which international research is conducted and promote the European model of convergence to make information society policies more effective; make it easier for Europe's researchers and universities to work with the best scientists and research infrastructure in the world; and strengthen the global position of European industry in electronic communications and other advanced technologies.

2. Action to make the impact of research more equitable

2.1. Joint agenda and priority-setting for global health research

In the last two decades, resources for health research and innovation have increased considerably — more than five-fold since 1986 to more than €160 billion per year worldwide[12] — coinciding with increasing interest shown by new players (philanthropists, public-private partnerships and product development partnerships[13]). The private for-profit sector accounts for 51% of this amount, the public sector for 41% and the private not-for-profit sector for 8%. These positive developments have led to diversification but also fragmentation of research funding, raising the issues of critical mass, thematic overlap and the accountability and transparency of the individual bodies and organisations funding research relevant to global health.

2.1.1. EU level

The EU has adopted a common vision for the European Research Area in 2020.[14] The aim is to create strong added value by fostering healthy Europe-wide scientific competition while ensuring the appropriate level of cooperation and coordination. Research priorities are identified and agreed within the EU in the light of the Framework Programmes, the basis on which all research-related EU action is financed. Most of the research funding is managed by adopting annual work programmes (WP). Each WP is drafted by the Commission, based on the research priorities of all its departments dealing with health and input from an advisory board of about 20 outstanding scientists in the field. Each WP has to be discussed and agreed by the Programme Committee that brings together representatives from every EU Member

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12 Global Forum for Health Research: 'Monitoring financial flows for health research 2008', Washington DC, 2009.

13 In May 2009, the Commission 'Progress report on the implementation of the European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)' reaffirmed the pivotal role played by product development partnerships (SEC(2009) 748 final).

14 Council conclusions on a '2020 Vision for the European Research Area', 2 December 2008.

State (and 10 non-EU countries), most of which are represented by the ministry responsible for research. This coordination is a formal and lengthy process but can take into account the views of various stakeholders (policy-makers, health professionals, scientists, patients, etc.) at both European and national levels.

For international coordination of research beyond Europe, a range of different mechanisms for consultations and joint priority-setting have evolved under the Framework Programmes. In FP6, regional dialogue mainly took the form of joint coordination schemes, such as the Common Area of Higher Education for countries in the European Union, Latin America and the Caribbean region (ALCUE). Specific action was initiated with countries that have bilateral science and technology agreements with the Commission. In FP7 these arrangements have developed into INCO-Nets[15] at regional level and BILAT[16] action at bilateral level wherever there is a science and technology agreement. These fora cover a broad range of themes and are complemented by more theme-specific coordination on 'Health' topics, for example on migrant health, poverty-related diseases and capacity-building for health research.

The 'Health' theme of the specific programme on 'Cooperation' under FP7 provides a mandate for international cooperation in the context of the millennium development goals. Priority areas, formulated by bi-regional dialogues in non-EU countries, regions and international fora and adapted to local needs or with the aid of partnerships, include health policy research, health systems and healthcare service research, maternal and child health, reproductive health, control and surveillance of neglected communicable diseases and emerging unforeseen policy needs in the regions concerned. In a two-way process combining active participation in major conferences discussing the global agenda for research on health (such as the Global Forum and Ministerial Summits (Mexico 2004 and Bamako 2008)) with specific scientific conferences (for example, the biannual Congresses on Tropical Medicine and International Health last held in Verona, Italy, in September 2009), the Commission is contributing to further development of this agenda in the light of the FP, taking up new ideas and approaches in the work programmes for FP7.

2.1.2. Global level

The Commission is promoting and operating within international frameworks for dialogue and agenda-setting based on its concepts of mutual benefit, equitable partnership and global agreements, such as the millennium development goals. Most prominently, the Commission is closely engaged with the WHO and its aligned programmes, such as the Tropical Disease Research Programme, the World Alliance for Patient Safety and the annual conferences of the Global Forum for Health Research.

World Health Organisation

The Commission interacts with the WHO in several ways on health research. It sits in as an observer at meetings of the Advisory Committee for Health Research (ACHR) set up in 1959 to support the WHO in its constitutional role of promoting and coordinating research relating

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15 The purpose of an INCO-NET is to bring policy-makers and stakeholders from a given region or group of countries together with the EU partners to establish a dialogue to identify S&T priorities of mutual benefit and interest, define the broad lines of cooperation policy and take specific action to promote and contribute to participation by the targeted regions or countries in the Framework Programme.

16 BILAT projects support coordination to enhance and develop S&T partnerships. They are restricted to non-EU countries which have signed, or are in the process of signing, an S&T cooperation agreement with the EC.

to international health work, acting in close cooperation with external institutions pursing common goals and with the scientific community at large. The WHO Regional Office for Europe also has an Advisory Committee for Health Research, in which the Commission has likewise participated as an observer. The Commission is also represented on the WHO World Alliance for Patient Safety Research Council, whose aim is to facilitate research into patient safety and encourage the spread of research results throughout healthcare systems globally, by contributing to building up the evidence necessary for developing new solutions and for applying known solutions to patient safety more effectively. Furthermore, in a more strategic context, the Commission participated in a high-level consultation launched by Director-General Chan in June 2008 on 'scaling up research and learning for health'.

Global Strategy and Plan of Action

In its capacity as a regional economic integration organisation, the Commission has also played a proactive and constructive role in the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights. In this connection, the European Commission and the WHO have signed agreements on preparatory action with a view to implementing elements 3 and 4 of the Global Strategy and Plan of Action.[17,18] These agreements were made possible by preparatory action adopted by the European Parliament in 2008 and 2009 in response to the concern in the domains of research and development about poverty-related, tropical and neglected diseases and improving access to medicines in developing countries by pharmaceutical-related technology transfers and local production.

At the same time, the Commission coordinates with other major funders of health research at global level, such as the Heads of International Research Organisations (HIROs), the Gates Foundation, the National Institutes of Health (NIH) and the Wellcome Trust, in order to increase synergies and complementarity. Building on its rich experience on agenda- and priority-setting with international partner countries, the Commission supports moves by low- and middle-income countries to identify opportunities for research under FP7.

2.2. Better generation of knowledge relevant to global health

Research and development needs and contexts should be based on the priorities identified above. It is therefore necessary to align the incentives and public subsidies for meaningful research on these priorities.

It is beyond the scope of this document to enter into a detailed discussion of how the regulatory framework for pharmaceutical innovation can help to address the challenge of pharmaceutical companies refilling the product pipeline, particularly as, despite increasing investment in R&D, the number of novel medicines reaching the market has been decreasing.[19] Instead, it will concentrate on how global health equity can be achieved, so that populations underserved by scientific progress can benefit in an equitable way.

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17 Decision C(2008) 8124 of 15 December 2008 approving the financing of a pilot project and two preparatory actions in the field of human and social development under budget items 21 05 01 05, 21 05 01 06 and 21 05 01 07 of the general budget of the European Communities.

18 Decision C(2009) 10024 of 18 December 2009 approving the financing of two preparatory actions in the field of human and social development under budget items 21 05 01 06 and 21 05 01 07 of the general budget of the European Union.

19 Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report, COM(2009) 351 of 8 July 2009.

2.2.1. Better regulation; building on the experience with orphan drugs

Rare diseases are diseases with particularly low prevalence. The European Union considers diseases rare when they affect not more than 5 per 10 000 persons. Between 5 000 and 8 000 distinct rare diseases have been identified today, affecting between 6% and 8% of the population in the course of their lives. In other words, although the prevalence of each individual rare disease is low, the total number of people affected by one rare disease or another in the EU lies between 27 and 36 million. Most of them suffer from diseases affecting not more than one in 100 000 people. These patients are particularly isolated and vulnerable.

Because of the low prevalence of rare diseases, their specific nature and the high total number of people affected, the EU calls for a global approach based on special combined efforts to prevent significant morbidity or avoidable premature mortality and to improve the quality of life and socio-economic potential of sufferers.[20] The EU has been taking a coordinated approach to address the issues regarding innovation targeted on rare diseases. First, the EU adopted the Orphan Medicinal Products Regulation[21] which defines the criteria for designation as 'orphan' in the EU and offers a range of incentives for R&D (e.g. 10-year market exclusivity, protocol assistance and access to the centralised procedure for marketing authorisation) to encourage research, development and marketing of medicines to treat, prevent or diagnose rare diseases. The Regulation is part of a broader strategy[22] for addressing rare diseases which is backed up, for example, by the particular attention paid to rare diseases within the Framework Programme. Similar regulations have been introduced in the USA, Japan and Australia.

Although the orphan drug legislation is particularly relevant to developed countries, it could be redesigned for products to combat neglected diseases[23] in developing countries as well. The 'pull' factor that such legislation could generate will, however, remain limited as long as the markets for such products remain small. Global coordination of similar regulatory instruments would considerably add to their impact.

2.2.2. Direct subsidies for research to improve global health equity

Twenty years ago, the *Commission on Health Research for Development* found that only 5% of the total funds were spent on research addressing the problems facing developing countries, which were bearing 93% of the global burden of disease. It called for an increase in international support for health research, setting targets of 2% of national health expenditure and 5% of international official development assistance (ODA) for more effective coordination and compliance with the principles of 'essential national health research' (ENHR) addressing ownership, participation and the pertinence of health research (the 'Alma-Ata of health research').[24]

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20 Council Recommendation on action in the field of rare diseases, 5 June 2009, 2008/0218 (CNS).

21 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

22 Communication from the Commission on 'Rare Diseases: Europe's challenges', COM(2008) 679 final.

23 'Neglected diseases' are a group of tropical infections which are especially endemic in low-income populations in developing regions of Africa, Asia and the Americas. Different organisations define this group of diseases differently.

24 Commission on Health Research for Development: 'Health research, essential link to equity in development', Oxford University Press, 1990.

As regards the levels of health research in developing countries, very few countries have made progress towards the 2% target. The *'90/10' gap* — with under 10% of the world's biomedical research funds allocated to addressing problems behind 90% of the world's disease burden — remains a challenge, as concluded at the 2008 Global Ministerial Forum on Research for Health in Bamako.[25] On the positive side, investment in research and development targeted on poverty-related diseases has increased significantly in recent years, partly as a result of more active private-sector and catalyst initiatives such as public-private partnerships (PPPs) and product development partnerships (PDPs). Overall, there is still a 90/10 gap, while health disparities between and within countries are widening. North-South research partnerships must be designed in equitable fashion and funding needs to be sustained beyond the often short-term investment in a research project.

Further investment in research remains necessary, but the results must reach low-income countries as well. Local ownership, training and retention of human resources for research are crucial.

Research supported under the EU Framework Programme

Global health research features prominently in the EU Framework Programmes in different ways, whether in the field of international public health and health systems, poverty-related diseases, or neglected infectious diseases research. The programme is focusing strongly on supporting the research necessary to achieve the health-related millennium development goals (MDG).

Specific International Cooperation Actions: SICAs

One of the objectives of EU international cooperation on health research in connection with the MDGs is to address specific problems that non-EU countries face or problems with a global dimension. In this area, *Specific International Cooperation Actions* (SICAs) can address particular needs of developing and emerging economies, by means of dedicated cooperative activities. SICAs are restricted to non-associated non-EU countries and respond to their mutual interest in cooperating on particular topics selected on the basis of their scientific and technological level and needs. Identification of specific needs and priorities is closely linked to relevant bilateral cooperation agreements and ongoing multilateral and bi-regional dialogues between the EU and these countries or groups of countries and international fora or in the context of the MDGs. Priorities are based on the particular needs, potential and level of economic development in the region or country and may include domains stated in the specific programme on 'Cooperation', namely health policy research, health systems and health services research including ICT for health (eHealth), maternal and child health, reproductive health, control and surveillance of neglected communicable diseases and emerging unforeseen policy needs in the regions concerned.

Furthermore, the 'Health' theme in general is particularly important, as it provides for research at global level to tackle anti-microbial resistance, HIV/AIDS, malaria, tuberculosis and emerging epidemics, including support for the European and Developing Countries Clinical Trials Partnership (EDCTP) in response to its achievements and future needs.

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[25] Global Ministerial Forum on Research for Health: 'The Bamako Call to Action on Research for Health', Bamako, Mali, 17-19 November 2008.

International public health and health systems

The focus of research relating to international public health and health systems has direct relevance to the international dimension of the public health policy of the European Union by contributing to health protection, prevention and promotion, while at the same time generating new knowledge relevant to health, social, environmental and economic issues. Taking cross-sectoral and multi-disciplinary approaches, this research contributes to initiatives such as the millennium development goals (MDG), the Ministerial declarations on global health research[26] and the European policy coherence framework for development, with particular emphasis on attaining the health MDGs, including child, maternal and reproductive health. Such research also contributes to building the evidence base on health workforce management and international migration. The plan is to focus a new strategic health research agenda on better health systems performance and more effective preventive public health interventions and providing input for future EU development cooperation. This is reflected in the fourth call for proposals which included, in particular, a special call on Africa. Under the international cooperation (INCO) in the Sixth Framework Programme (2002-2006), some €34 million was provided to support 20 projects on health financing, access to healthcare, quality management, health migration and reproductive health. A comprehensive review, covering 43 FP5 and FP6 health systems research projects, confirmed the significant impact and contribution to building solid North-South partnerships[27]. Furthermore, under the FP6 scientific support for policy activity, an additional €14 million went to research on SARS.

ICT for health actions have supported FP7 collaboration between the EU and Latin America in the areas of patient safety, transfer of technology, and alert and decision support systems based on grid capabilities. The focus of this collaboration is on optimising the use of biomedical data and computing resources.

HIV/AIDS

In the Sixth Framework Programme (FP6), the European Commission funded 41 projects on HIV/AIDS, with a total EU contribution of more than €123 million. In particular, support was given to research on (a) therapeutic approaches (drugs, RNA interference, therapeutic vaccines based on apoptotic T cells and others) with an EU contribution of €52 million; (b) vaccines (mucosal vaccines, vaccines targeting dendritic cells and DNA vaccines, new antigen design and delivery systems) with an EU contribution of €49 million; (c) microbicides (design of new molecules and use of anti-retroviral drugs to inhibit HIV replication in vaginal mucosa) with an EU contribution of €22 million; and (d) studies on cohorts of HIV-infected adults and children to investigate insurgence of resistance to marketed anti-HIV drugs and mother-to-child virus transmission. Many of the translational research projects in FP6 included phase I clinical trials. In the Seventh Framework Programme (FP7), 14 projects had been funded by December 2009 with a total EU

[26] Call to Action on Research for Health from the Global Ministerial Forum on Research for Health, Bamako, Mali, 17-19 November 2008; Conclusions of the Council and the Representatives of the Governments of the Member States meeting within the Council on 'Policy Coherence for Development', 20 November 2007; Statement from the Ministerial Summit on Health Research, Mexico, 16-20 November 2004.

[27] North South Partnership for Health Systems Research – 20 years of experience of European Commission support. http://ec.europa.eu/research/iscp/pdf/n_s_partnership_health_report.pdf

contribution of about €70 million, of which €32 million went to vaccines, €12 million to microbicides, €22.5 million to treatment and about €5 million to basic research and training. These 14 projects covered: study of vaccines, inducing broadly-reactive neutralising antibodies; a platform to support harmonisation of vaccine adjuvant testing; mucosal and transcutaneous vaccines and translational vaccine research (allocating funds for phase I and IIa clinical trials); drug discovery and pre-clinical development; and paediatric formulations of drugs.

Malaria

Under FP6, 17 malaria research projects were granted support totalling €64 million. These include three large structural projects that have become cornerstones of the European Research Area in this field: (a) a strong basic research network (NoE) on malaria, (b) an integrated project to develop new antimalarial drugs and (c) the European Malaria Vaccine Development Association, an integrated project that builds on the European Malaria Vaccine Initiative (EMVI) initiated under FP4 and part-funded by Member States. In this way, a critical mass of European malaria research was built up. As a result, the EU is now in a position to participate in the relevant global coordination of malaria research. Under FP7, construction of an ERA in the field of malaria research needs to be consolidated where major structural malaria projects are already under way and extended where gaps remain in certain subareas (e.g. vector research). Under FP7, malaria research is being supported across the four specific programmes with a total of €76 million granted up to December 2009. Seventeen projects on this subject are in progress under the 'Health' theme of the 'Cooperation' programme, two more under the 'Capacities' programme, three under the 'Ideas' programme and ten applications under the 'People' programme. The main areas funded by the EU from 2007 to 2009 were basic research (€24 million), vector control research (€17 million), vaccine development (€11 million), drugs (€8 million) and diagnostics research (€2 million).

Tuberculosis

Many of the research projects supported by the EU on tuberculosis (TB) aim to address the mechanisms of pathogenesis and the delicate balance between humans and the pathogen. However, only translational research can lead to real applications. The BCG vaccination is not as effective at controlling TB as hoped and the spread of antimicrobial resistance has rendered most current drugs ineffective against some TB strains. Large-scale translational projects have proved useful for bridging the gap between discovery and application and even larger initiatives can be expected in the future.

Research of relevance to TB has been supported throughout the Framework Programmes, albeit sporadically in the early FPs. Under FP5 (1998-2002), the EU took a more dedicated approach to this area, with funding of €30 million. The projects funded covered a wide range of activities, from basic research, e.g. on mucosal immunology, structural and functional genomics, host-parasite relationships and population studies, to applied research for vaccine development, drugs and diagnostics. In FP6 (2002-2006), TB research was stepped up with a budget of €68 million, shifting the focus to translational research, particularly in three integrated projects (with an EU contribution of €11 to 17 million each) addressing vaccine development, drug development and mucosal vaccines. In the first three years of FP7, up to December 2009, the EU provided funding of €56 million for TB research, including large-scale projects on clinical management of TB drug resistance and on the development of new

vaccines against TB. Despite the scientific progress made in this area, it is still necessary to continue funding a multitude of scientific approaches to TB control, including basic, translational and clinical research and clinical trials. Further coordination and alignment within Europe, with global organisations and, most of all, with the countries where TB is endemic is crucial.[28]

Neglected infectious diseases

In the area of neglected infectious diseases (NIDs), the Seventh Framework Programme is building on the advances made in previous FPs that provided €70 million to 55 research projects on NIDs from 1998 to 2006 — the majority involving African research groups. Scientific and technological cooperation between the EU and developing countries began in 1982 with three successive Science and Technology for Development Programmes. Then 1984 saw the launch of international scientific cooperation based on bilateral agreements between the EU and non-EU countries. FP4 (1994-1998) introduced the INCO (INternational COoperation) programme, which became one of the few international funding instruments focusing on research to control neglected infectious diseases. Twenty-seven INCO projects on NIDs received total funding of some €45 million under FP6 for 2002-2006. INCO health projects have global scope, with 46 partner countries taking part. They have helped link up public authorities, NGOs and other interested parties, spreading best practice. Such projects have covered a range of relatively little-known diseases, including leishmaniasis, schistosomiasis, lymphatic filariasis, onchocerciasis, trypanosomiasis, dengue and haemorrhagic fever, echinococcosis, buruli ulcer and other childhood infections. Work included vector control, vaccines and development of innovations like traps for tsetse flies and solar-powered disinfection of drinking water.[29]

FP7 is focusing more on applying new modern research methods and technologies to develop new medicines and prophylactics against these diseases. The aim is to establish an integrated approach to development of preventive, therapeutic and control tools based on collaboration between European and international partners, including researchers from countries where these diseases are endemic. Activities in this area include, to give just a few examples, parasitic diseases caused by trypanosomatidae species (e.g. trypanosomiasis, Chagas disease and leishmaniasis), bacterial diseases such as Buruli ulcer, leprosy and trachoma, helminth diseases such as schistosomiasis, filariasis and other neglected infectious diseases such as infantile diarrhoea. Projects are addressing both preclinical and early clinical activities, along with the particular health conditions and health needs of countries where these diseases are endemic. An integrated multidisciplinary approach, including significant participation by partners from areas where these diseases are endemic and, where relevant, industry, is strongly encouraged, including, where applicable, technology transfer, training activities and human capacity-building.

European and Developing Countries Clinical Trials Partnership (EDCTP)

[28] Lang, H., Quaglio, G.L. and Olesen, O.F.: 'Tuberculosis research in the European Union: Past achievements and future challenges'. Tuberculosis (2010) Vol. 90.1: 1-6.

[29] For further details see: 'Final Report International Conference on Neglected Infectious Diseases', Brussels 8-9 November 2006: http://ec.europa.eu/research/health/infectious-diseases/neglected-diseases/pdf/nid-conference-final-report052007_en.pdf.

The European and Developing Countries Clinical Trials Partnership was set up in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases — HIV/AIDS, malaria and tuberculosis.[30] Fourteen EU Member States together with Norway and Switzerland have pledged €200 million for this partnership, which will be matched by €200 million from the EU Framework Programme. Essentially, EDCTP provides a platform for conducting clinical trials with a particular focus on phases II and III and developing the capacity required in sub-Saharan countries. Clinical trials are an essential step to assess the viability and suitability of drugs, vaccines and microbicides. Trials occur late in the development of products, when their safety and efficacy in human beings are tested. They are expensive and require high standards of regulations and ethics in the countries concerned. Clinical trials can be a bottleneck if there is not enough financial support or capacity. EDCTP aims to bridge these gaps.

EDCTP supports multicentre projects which combine clinical trials, capacity-building and networking. The aim of integrating these three activities is to ensure that the capacity developed is used to conduct the clinical trials successfully and sustainably. Besides successful outcomes, this also makes sure that the capacity developed is used optimally and retained, thus securing sustainability. The networking component facilitates north-south technology transfer and south-south mentorship, allowing dissemination of the capacity developed and building up critical mass. In addition, the partnership supports Africa's capacity for ethical reviews, regulatory frameworks and clinical trials registration for health research. Such support includes grants to establish and strengthen institutional and national ethics committees and enable them to become functional and independent. Support is also provided for strengthening and harmonising national regulatory authorities and to improve registration of clinical trials in Africa by means of the recently established Pan-African Clinical Trials Registry. EDCTP also supports various types of training on ethics and regulatory frameworks and is mapping the ethics and regulatory capacity in Africa.

There is generally a wide disparity between research capacity and regulatory and ethics oversight for conducting clinical trials in Africa. This divide is likely to widen considering the traditional ways of awarding grants in which excellence is rewarded at the expense of under-developed capacity in less-endowed centres. This problem is compounded by channelling support through traditional ties between northern and southern institutions that usually favour advanced centres. To mitigate this, EDCTP has established regional networks of excellence for conducting clinical trials. They are divided into Central, Eastern, Southern and Western African regions and bring together institutions with varying but complementary capacity which work in synergy to conduct clinical trials and provide training, south-south mentorship and capacity-building in Africa. EDCTP unites the 14 participating EU Member States plus Norway and Switzerland with sub-Saharan African countries. The partnership helps EU Member States to integrate and coordinate their own national research and development programmes and form partnerships with their African counterparts.

After a slow and cumbersome start-up phase, when EDCTP had to set up its own guidelines, regulations and governance structure and to explore ways of working under new and untried conditions, EDCTP has now established a credible governance and administrative structure that includes robust and transparent peer review, a solid accounting and auditing system, an independent

[30] Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States.

advisory structure for scientific and strategic matters and an efficient secretariat.[31] To date, EDCTP has funded 168 projects valued at over €300 million and involving 135 institutions from 28 sub-Saharan countries, 72 institutions from 17 European countries and 51 other partners — non-profit organisations and private-sector partners. In all, EDCTP is funding 51 clinical trials — 23 on HIV/AIDS, 17 on tuberculosis and 11 on malaria. African researchers make up 68% of the coordinators of EDCTP projects.

EDCTP is currently operating under a no-cost extension until September 2010. As required by the Decision setting up EDCTP, in June 2009 the Commission initiated an independent external evaluation of its activities over the period 2003-2008. Based on this external review and a thorough internal impact assessment, the Commission will decide if, and on which basis, it will propose to renew EDCTP beyond 2010. This might involve broadening the scope either geographically (beyond sub-Saharan Africa to other countries where diseases are endemic) or in terms of the diseases addressed (to neglected diseases) and types of clinical trials supported (to phases I and IV).

Innovative Medicines Initiative

The EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have established a new, non-profit body, the Innovative Medicines Initiative (IMI) joint undertaking (JU).[32] This pan-European collaboration brings together large biopharmaceutical companies, small and medium-sized enterprises (SME), patients' organisations, academics, hospitals and public authorities. The initiative aims to speed up discovery and development of better medicines by clearing bottlenecks in the drug development process by taking a coordinated approach and supporting pre-competitive pharmaceutical research and development. It also aims at increasing the research investment in the biopharmaceutical sector in the EU by pooling resources and fostering collaboration between the public and private sectors. It focuses on creating better methods and tools that will improve the drug development process, rather than on developing specific new medicines.

The IMI JU has a mandate to award research grants to European public-private joint ventures conducting innovative research projects that focus on implementing the recommendations made in the IMI research agenda. Funding for such research is provided in equal measure from the EU Framework Programme and members of the EFPIA. The total IMI budget for the period 2008-2017 is €2 billion (€1 billion from the EU in cash and €1 billion in-kind contribution from industry). The first call for proposals was published in April 2008. A total of 134 proposals were submitted, of which 15 were selected to receive €246 million. The first call focused on non-communicable diseases that are particularly prevalent in Europe. The second, published in November 2009, includes diagnostics for tuberculosis and pneumonia, which place a particularly heavy disease burden on low-income countries.

The IMI research agenda was established under the leadership of industry following intensive consultations with a broad range of stakeholders from across Europe. It identifies the principal bottlenecks in biopharmaceutical R&D and makes recommendations to overcome them focusing on four areas:

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[31] Communication from the Commission on the Progress Report on the 'European and Developing Countries Clinical Trials Partnership' Programme, COM(2008) 688 final.

[32] Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines.

- Predicting safety: this addresses bottlenecks in accurately evaluating the safety of a compound during the pre-clinical phase of the development process, but also has an impact on the later phases of clinical development.
- Predicting efficacy: this addresses bottlenecks in the ability to predict how a drug will interact in humans and how it might produce a change in function.
- Knowledge management: this underpinning theme addresses more effective use of information and data for predicting safety and efficacy.
- Education and training: this second underpinning theme closes existing training gaps in the drug development process.

Precompetitive research platforms like IMI are expected considerably to improve the efficiency of research and development. Public co-funding of such platforms is justified by the fact that the findings of such research will be available to many developers rather than being the property of just one company. Due to the public nature of such research findings, important basic research would otherwise be underprovided. Advances achieved by precompetitive research platforms will be useful for developing a range of medical products in that particular medical area, but might not be for different diseases. If they are to have a great impact on global health, such platforms would therefore have to focus on the specific needs of developing countries, the diseases that are most prevalent, and where pharmaceutical innovation is particularly needed.

Other innovative means of financing

Identification of medical knowledge as a global public good for health that needs effective public policies and additional funding to make it accessible to all has triggered a comprehensive debate at global level on better ways to coordinate and finance research and development that is also relevant to developing countries. The discussions at global level are shaped by the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (see section 1.2) which stresses that further sustainable funding is essential to support the long-term efforts required to meet the health needs of developing countries. The WHO subsequently set up an expert working group that examined current financing and coordination of research and development and proposals for new and innovative sources of financing to stimulate research and development relevant to developing countries. Its report will be discussed by the World Health Assembly in May 2010.[33] In any event, effective mechanisms to fund research must be further explored, such as product development partnerships (PDP), public-private partnerships (PPP) or funding trials in developing countries, such as EDCTP. The impact of regulation (e.g. patents, priority review vouchers or orphan drugs regulation) needs to be continuously evaluated.

2.3. Equitable access to knowledge and implementation of results

Whether science can help to improve health at global level depends not only on whether relevant research will in fact be undertaken, but also on whether the resultant knowledge, once produced, can be translated into evidence-based services or products that improve public health in an equitable manner. Policy-makers and researchers must make continuous efforts to transmit research findings and translate them into evidence-based decisions. Evidence-based

[33] Report by the World Health Organisation Expert Working Group on Research and Development Financing, World Health Organisation, Geneva.

policies can only be grounded in country-led research and learning that can be backed up by global support. This requires domestic leadership and sustained investment in local capacity-building for analysis and learning, robust systems for monitoring and evaluation and better direct access for country-based researchers to funding opportunities. This will make it possible to design and manage health systems that offer universal and equitable access with the necessary inputs (financing, human resources, supplies, information technology, governance, etc.) that are based on the best evidence available and respond to local needs and realities. The inadequate access to medical innovations in developing countries is caused partly by a sometimes defunct health system, a key 'access good' as a functioning health system is necessary to deliver the 'public good' of knowledge and the products and services produced from that knowledge.

2.3.1. Open access

Science is a collaborative process and openness is fundamental to advance knowledge. Access to health research publications is an essential requirement for securing the chain of communication from the researcher to the front-line health worker. There is global inequity in access to published health literature by research communities in developing countries. Rising costs of subscriptions and permission barriers imposed by publishers have barred access to the extent that local health research and healthcare have been weakened.[34] If research requires public subsidies — as it would be underprovided otherwise — due to its nature as a public good, then the results of the research should become a public good as well. As part of its Seventh Framework Programme (FP7), the European Commission is conducting a pilot project to provide open access to peer-reviewed research articles within a specified period. This initiative covers approximately 20 % of all the projects funded under the FP7 budget and includes health research.[35]

2.3.2. Local capacity

Effective and evidenced-based health policy making requires considerable expertise and multidisciplinary research capacity at national level. The EU instruments described above provide strong support for developing local scientific capacity. The considerable but very different support offered by development assistance and the Framework Programme makes it difficult for national research policy and health policy-makers to create sustainable programmes. Official development assistance often gives priority to primary, secondary and vocational education, which is key to ensuring employability. In addition, the EU strategy for Africa of 2005[36] emphasises the importance of cooperation with Africa in higher education to build high quality tertiary capacity by means of networking, mobility of students and scholars, and institutional support and innovation. There are now opportunities for collaboration between higher education institutions under the education programmes Erasmus Mundus Programme[37], Edulink[38], and the Mwalimu Julius Nyerere programme[39]. The FP7 special call

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34 Yamey, G.: 'Excluding the poor from accessing biomedical literature: a rights violation that impedes global health', Health and Human Rights 2008:10.

35 Commission Decision C(2008) 4408 final, 20.8.2008.

36 COM (2005) 489

37 Decision 1298/2008/EC, 16 December 2008. http://eacea.ec.europa.eu/erasmus_mundus/

38 http://www.acp-edulink.eu/

39 http://ec.europa.eu/development/policies/9interventionareas/humandev/humandeveduc5_en.cfm

on Africa[40] paid particular attention to research capacity building and training. Howver, competitive research calls are looking for scientific excellence, which can be difficult to build up and sustain without considerable external funding. Coherent EU action could provide more effective support for developing countries to create and retain scientific expertise by helping to strengthen institutions that build capacity in health and health sciences and supporting national innovation systems to develop treatments and health systems that are suitable and appropriate for the national setting.

International scientific cooperation is possible and fruitful only if sufficient scientific expertise is available in the partner country to enable bilateral learning. The benefits of regional cooperation on research have been realised in the EU and supported by the Framework Programme. The EU would be best placed to provide assistance for establishing regional or south-south partnerships for research. One promising example set up with the support of the EU is the African Network for Drugs and Diagnostics Innovation (ANDI). Its task is to promote and sustain African-led innovation in health products that addresses African public health needs by putting together research networks and building capacity to support human and economic development.[17] [18] [41]

2.3.3. Translation of knowledge into clinical care provision (implementation research)

To optimise healthcare delivery, it is necessary to understand not only how to design the most effective intervention, but also the best way to ensure that it is delivered effectively and applied in clinical practice. Building up this knowledge base with the aid of implementation research is imperative in order to get the best return on decades of investment in biomedical research. All relevant knowledge available, including indigenous and traditional knowledge, should be tapped to improve health and health systems.

Most researchers who propose to develop and test disease control methods either explicitly or implicitly intend to promote efficacious intervention either amongst the broader population from which the sample for the efficacy study was drawn or in the public health or clinical practice settings in which the method was originally tested. For many years, health researchers tended to assume that a method found efficacious in clinical or community-based trials would be easily transmitted to the field. Evidence suggests that this has not been the case. Moreover, little is known about effective approaches to overcome barriers to adoption of evidence-based intervention.

Recent literature has underscored the importance of understanding the multiple factors that influence whether public health or clinical practice communities will use a given method. The EU Framework Programme is funding research on implementation addressing the degree to which health intervention can fit into real-world public health and clinical service systems.

2.3.4. Translation of knowledge into policies (health services research)

Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organisational structures and processes, health technologies

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[40] Call for proposals FP7-AFRICA-2010 published on 30 July 2009 with a deadline of 14.1.2010. Successful projects are expected to start beginning of 2011.

[41] http://andi.tropika.net/

and personal behaviour affect access to healthcare, the quality and cost of healthcare and, ultimately, individuals' health and well-being. Although the Member States are responsible for organising them, health systems in the European Union are all based on the shared values of universality, solidarity and equitable access to quality healthcare. The EU Framework Programme supports cross-border collaboration to establish the evidence-base by means of comparative health systems research that can then be used by national decision-makers when they reform their health system. This knowledge is necessary in order truly to learn from successes and failures in healthcare delivery in other countries, be they in Europe or beyond. That is why this form of research collaboration may include partners from developing countries and regularly target issues particularly relevant to developing countries' health systems in specific international cooperation activities.

3. Conclusions

The European Union can play a key role in addressing the weaknesses that are currently preventing realisation of the full and equitable benefits that research can offer for global health. The EU institutions and the existing structures and instruments at European level offer great potential for coordinating the European response to the challenges of knowledge for global health. The instruments and policies described above could enhance the EU response proposed in the Communication in the following ways:

In order to coordinate more effectively EU research for global health that benefits the health of all people, the existing strong institutional links in the EU could serve to define a common EU position on the research priorities, the distribution of research between various entities, sectors and geographical areas, and the financing of research and development. Global coordination of these issues will not be realistic without a strong European voice and common position. The EU in general and the European Commission in particular are well represented in the many global initiatives aiming — so far unsuccessfully — to coordinate research and development at global level.

The EU Research Framework Programmes should be based on joint priority setting processes, equitable partnerships and safeguard access to the knowledge generated. The focus on collaborative international research consortia in the 'Cooperation' programme, addressing research topics that are often beyond the remit of national research consortia alone, could be harnessed to foster sustainable global collaboration on health research. Building on the existing research collaboration on poverty-related diseases and expertise in comparative health systems research, the European expertise in research on non-communicable diseases could be an additional driver for international scientific cooperation on global health. The impact of the innovative partnership instruments that the EU has established with the private sector (IMI JU) and developing countries (EDCTP) will be evaluated, as required by the decisions establishing them. Making these initiatives more effective will provide the EU with powerful and innovative tools to support generation of new knowledge relevant to global health and also to build in the need for equitable access to innovative products and treatments embedding that new knowledge. The IMI Joint Undertaking should continue to include pre-competitive research that is relevant to diseases with an impact on global health. EDCTP has the potential not only to support the crucial but expensive clinical trials that are necessary to develop drugs or medical devices relevant to health in Africa but also to extend the partnership and joint learning to other diseases and other developing countries.

The EU should strengthen and balance the complete health research process of innovation, implementation, access, monitoring and evaluation; and inform health policies, including the

development of national research capacities. Implementation of new knowledge and equitable access to innovative products and treatments needs to be built into the entire innovation process in order to provide meaningful results for global health. This implies evaluating and addressing the impact of IPR on global health. The EU is one of the key actors in discussions on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. In the case of research on rare diseases, not only collaboration on pre-clinical and clinical research seems pertinent, but also closer international collaboration on regulating the market for rare or other neglected diseases, in order to create effective incentives that reward development of new treatments and diagnostics for them by the private sector. To deliver innovative medical products and treatments effectively to the people in need, even more research is necessary both on take-up and dissemination of new knowledge and on health services including the supporting IT tools to provide the evidence-base for national decision-makers when they build or reform their health systems so that they can provide services effectively to the population that needs them. As knowledge for health is a powerful global public good and the health system is an important access good, it is in the interest of the EU to build capacity in both health and health research in developing countries and to invest in sustainable structures to support this capacity-building. Coordination between the various instruments that the EU has at its disposal, particularly the European Development Fund (EDF) and the Framework Programme for Research, will create synergies that will considerably increase the impact of EU action in these fields.

The EU should work with relevant national and international bodies such as the WHO, OECD and the Health Metrics network to improve health information systems and the collection of comparable data and statistics to enable benchmarking and inform global and national policies. The EU should equally promote the use of ICT for health (eHealth). Decisions in managing health care or health care systems should be based on the best information available. EHealth solutions offer great potential for improving health service provision. A meaningful analysis of health systems requires data that is comparable with other health systems. Coordination of the national health information systems in the EU has improved the comparability of such data and consequently its value for decision makers in the Member States. Closer global coordination of health information systems would reduce the burden of the different reporting requirements and enhance the opportunities for joint learning. Reliable and comparable health statistics at global level are an important cornerstone of effective and equitable global policies for health.