HAI EUROPE RESPONSE

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This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI advocates for access to essential treatments that satisfy the priority health care needs of a population.
- HAI Europe promotes better access to medicines by advocating for EU trade policies that are coherent with the EU's commitments on health and development; by campaigning for changes to the EU's internal market laws that hamper access to medicines in Europe; by advancing EU actions on the exploration of new models of medical innovation.
- HAI Europe is committed to ensuring the rational use of medicines through greater controls on medicines promotion, independent medicines information, greater patient involvement in the reporting of adverse drug reactions so that harmful or ineffective medicines are identified more quickly, thereby reducing the threat to public health.
- HAI Europe advocates for the highest levels of transparency, independence and accountability in all aspects of pharmaceutical policy and regulation, as well as the wider participation of patients and consumers in decisions that will affect their health and wellbeing.

Summary

The structure of the consultation did not allow for comprehensive responses that addressed our overarching perspective on the approach taken in the Green Paper. The following response reflects the suggestions and concerns put forward from our network and, where possible, reference has been made to specific questions.

Executive Agency for Health and Consumers

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Weak reference to healthy ageing and omission of global health challenges

Despite the importance of a healthy population as a fundamental condition for achieving the EU's 2020 Strategy, health has been given very little space in the Green Paper. Preventing a decline in public health standards is fundamental to achieving the goals set out in EU 2020. It is also disappointing that so soon after the Global Health Council Conclusions, EU leadership on meeting global health challenges, in particular through research and innovation, should have been so thoroughly overlooked in this report.

Health as a societal challenge: medical innovation

HAI welcomes the emphasis on societal challenges, but regrets the lack of references to health in the Green paper especially as much attention is given to health and healthy ageing in the Innovation Union Communication and its European Innovation Partnerships pilot. Challenges such as demographic ageing, and consequent increases in chronic disease burdens, cannot be met by continuing to focus only on innovation that benefits economic growth. The next Common Strategic Framework (CSF) must also dedicate resources to innovation that helps to overcome societal challenges, of which health is an important element.

Medical innovation is a prime example of how a business model has become divorced from the societal needs that it was intended to address. The race for profit and market share has become less and less aligned with the public interests of citizens and public health budgets.

The current model of biomedical innovation carries problematic incentives and does not promote needs-driven or accessible innovation. The Council Conclusions on Global Health in May called for the exploration of mechanisms for needs-driven research and development (R&D) that dissociate the high cost of R&D from the price of medical products. This principle also needs to be supported and explored by the EU in the next CSF.

Civil society participation in research

There is a lack of attention paid to the knowledge base of civil society in research and, in particular, research in the field of health. Civil society organisations are in an ideal position to provide first-hand knowledge of the most pressing research needs. Furthermore, civil society contributions take more of a public interest perspective than that of commercial bodies as they are driven by public needs rather than by profitability. Strengthening the partnership between civil society and academic institutions can enhance the efficiency of health research; ensures research resources are directed efficiently; and supports dissemination of research knowledge to inform follow-on innovation.

RECOMMENDATIONS

Link research and innovation funding more closely with policy objectives (Questions 4.1: 2& 7)

At present, we suffer from a lack of needs-driven medical innovation and a crisis in global access to essential medicines. The Green Paper notes that we are living through a period "of severely constrained budgets" and that "the most needs to be made out of every euro". This has

never been more true than for the European model of publicly-funded healthcare systems, and this is explicitly acknowledged in the Communication on the Innovation Union.[1] In the EU, and around the world, governments are unable to meet the growing cost of healthcare, of which medicines represent a significant portion. Price cuts of patented medicines by various EU Member States in recent years are a testament to the lack of sustainability of the current innovation model, not only for developing countries, but also here in Europe.

> *To respond to health needs at home, and in facing global health challenges, the EU should explore new models of affordable and socially useful medical innovation. The medical research and innovation funding in the new CSF for EU Research and Innovation Funding should be designed in a way that supports the policy needs of governments facing untenable healthcare bills, and fulfils existing EU commitments to tackling global health challenges.*

Create EU policy coherence on intellectual property (IP) versus Innovation & Access (Question 4.4: 26)

The Green Paper considers IP rights for research and innovation to be "decisive for efficient exploitation and technology transfer". However, it also goes on to call for "access to and rapid dissemination of scientific results", which seems entirely incoherent with its stance on data exclusivity and rising standards of exclusivity rights that have the opposite effect of stifling cooperative research, and restricting space for technology transfer and knowledge exchange in the interests of more efficient research and innovation.

> *This incoherence should be addressed by the Commission, and IP policy must be brought in line with the goals of "greater international cooperation" and "access to and rapid dissemination of scientific results". The recent review of IP enforcement policy may place an additional burden on cooperation, by fostering a protectionist and timid research environment that operates in the shadow of heavy IP enforcement. DG Research should take a strong position against IP enforcement policy that interferes with the goal of supporting European research and innovation.*

Increase open and fair competition to benefit positive societal impact

Both in the Green Paper and in the Innovation Union Communication, there is an acknowledgement of the value and necessity of strong competition policy. HAI Europe whole-heartedly endorses this conclusion, especially with regard to the pharmaceutical sector. We note the outcomes of the Commission's pharmaceutical sector inquiry by DG Competition; the efforts made to follow up the pharmaceutical sector inquiry; and we support attempts to prevent unjustified interventions by originator companies in marketing authorisation processes, pricing and reimbursement decisions, and problematic 'pay-for-delay' settlements.

> *The EU should act on the lessons learned from the Pharmaceutical Sector Inquiry, and incorporate both safe-guards and incentives to encourage open and fair competition for outputs from publicly-funded European research in the design of the next Common Strategic Framework.*

[1] The goal to "improve the sustainability and efficiency of our social and healthcare systems" features in the Innovation Union Communication (2010). SEC (2010) 1161. Annex II.

Measure societal impact for medicines according to public health benefits (Questions: 4.1: 7 & 4.2: 13&14)

The Communication on the EU role in Global Health, published in March 2010, outlines an important condition of medical research that applies both in and outside Europe: that new medicines and treatments must be "affordable and accessible" in order to have a wide societal impact.[2] The same EU Commission Communication notes the essentiality of ensuring "that research priorities are geared to making the biggest impact on public health" and that "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".

> *We wholeheartedly endorse these conclusions that place public health where it belongs: at the centre of medical research. DG Research should ensure that incentives for medical research in the new CSF reflect these core principles, and that research outputs, successful outcomes, and societal impact are measured in terms of public health benefits.*

Fulfil EU Commitments to exploring alternative innovation models (4.2)

These commitments include: the management of intellectual property rights to meet European and global public health needs; mechanisms to increase the sharing and access to scientific knowledge and data and the collaboration among researchers; the exploration of R&D funding with incentives that de-link the cost of R&D from the price of products.

In its Global Health Council Conclusions 2010, the EU acknowledged the need for, and committed itself to, further exploration of innovation models that dissociate the cost of R&D from the price of medical products.[3] The EU Innovation Union Communication also calls for innovative approaches which have societal benefit. This followed from the 2008 World Health Assembly where Member States, including EU Member States, passed resolution WHA61.21 on a 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (GSPA). The strategy encouraged Member States to develop new models of biomedical innovation in order to ensure both increased access to medicines and innovation.[4]

> *This consultation process on the Green Paper offers the EU an opportunity to follow upon the implementation of the recommendations in the GSPA and show concrete, leadership such as specific references to open source methods in innovation and the publishing of research data, and an increased use of technology transfer to promote access. What is needed now is practical action in EU policy and budget decisions to support the commitments made in internal and multilateral fora. One example could be the integration of issues arising from the WHO Consultative Expert Working Group on Research and Development, such as the importance of incorporating access provisions into the early stages of the research process.*

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[2] "It is not enough for new interventions or medical products to be effective and safe; they also have to be acceptable, affordable, and accessible so they can be put to benefit the entire population." In the Communication on the EU role in Global Health. SEC (2010)380. SEC (2010)381. SEC (2010)382. Section 3 - A Stronger EU Vision, Voice and Action.
The EU Council Conclusions on the EU role in Global Health. May 2010. Conclusion 18.d also support access and commit the EU to "ensuring that EU public investments in health research secure access to the knowledge and tools generated as a global public good and help generate socially essential medical products at affordable prices, to be used through rational use."

[3] EU Council Conclusions on the EU role in Global Health. May 2010. Conclusion 18. c

[4] The WHO Consultative Expert Working Group on Research and Development (CEWG) is one element of GSPA implementation, and the Commission and in particular DG Research should align EU research and innovation efforts with the aims and strategies of the CEWG.

SPECIFIC INITIATIVES FOR THE EU COMMON STRATEGIC FRAMEWORK

1. **Equitable licensing:** Ensure access to publicly funded research: Work towards making non-exclusive licensing a standard in the next CSF

2. **New models of innovation:** Explore new models of innovation through pilots and feasibility studies, with particular consideration for innovation inducement prizes that reward health impact

1. Equitable Licensing (Question 4.2: 20)

The Value of Public Research: Health and Medicines

Every year governments invest billions of euros in scientific research. Publicly funded research is a key element in the R&D of medicines, vaccines and diagnostics." On average, more than 40% of spending for health R&D is coming from tax payers,[5] in the area of neglected tropical diseases it is around 61 %,[6] and in the research for a HIV vaccine the public contribution it is 86 %.[7] Indeed, of 86 Nobel winners in medicine in the previous 30 years, 80 come from academia, while only 6 come from industrial activities (ref UAEM in footnotes).

Public funds for Public Good

License agreements between public institutions and private companies offer the possibility of re-emphasizing the social responsibility of science.

Equitable Licensing' is a concept to create the highest possible social benefit for publicly funded research. If the results are licensed to a private company, the contract includes a set of conditions with the aim of achieving a low product price, a high accessibility and – if possible – an access concept. Non-exclusive licensing could be the standard model. Equitable Licensing is already in use in the United States by several universities and by the National Institutes of Health. The model is accepted by pharmaceutical companies at least in the area of infectious diseases.

Even though at this point the EC might be happy to see any innovation and patenting coming out of its funding at all, (partly) publicly funded biomedical innovation should not grant exclusive rights to the company or institute involved. Where biomedical end products are involved DG Research should make equitable licensing the CSF the standard. There are many different forms of non-exclusive licensing that would be useful and fair to have in the Framework program.

Several elements from the Equitable licensing principles are directly applicable to the EU research context and the goals set out in the Green Paper, the Global Health Council Conclusions, and the Innovation Union. We propose that similar conditions are included in the *General Conditions of Grant Agreement* under the next CSF to ensure that public funds really

[5] Monitoring Financial Flows for Health Research. Global Forum for Health Research 2008. http://www.globalforumhealth.org/layout/set/print/Media-Publications/Publications/Monitoring-Financial-Flows-for-Health-Research-2009-Behind-the-Global-Numbers
[6] Mary Moran et al. G-Finder: Neglected Disease Research & Development: New Times, New Trends. Sydney 2009
[7] Advancing the Science in a Time of Fiscal Constraint: Funding For HIV Prevention Technologies in 2009. www.hivresourcetracking.org

do yield public good. These principles are especially relevant in the context of R&D for medical products and technologies.[8] Below we give an overview of relevant examples;

Equitable licensing principles on assignment of rights:

- *Preferably no transfer of ownership of the patent right to industrial partners.*
- *Preferably no agreements on exclusive licenses.*
- *The public research institution reserves the right to terminate the license if the patent is not used in the public interest as defined.*

Equitable licensing principles covering the influence on utilisation:

- *In case of public third party financing by politically accountable government bodies, the state reserves the right of use.*
- *A concept about use, future exploitation and access will be agreed.*
- *The current status of use will be discussed at regular meetings. Nonappearance at scheduled meetings will be considered a reason for termination.*

Ensuring availability in developing countries:

- *The end products must be made available at a reasonable price. The concept includes access for developing countries as a target, and defines the steps how to reach this goal (access commitments).*
- *The products must be cheaper in developing countries than in developed countries (differential pricing); they should be offered to poor countries at production costs with minimum profit.*
- *Obligation to enable competition in poorer countries, e.g. by open licenses for the production in these or for these countries. This corresponds to the global market structure: exclusive license for developed countries, non-exclusive license for developing countries.*

HAI suggests for the Commission to integrate the principles of equitable licensing into the new research framework as much as possible.

2. New models of innovation (Question: 4.2: 19)

The current model of innovation relies heavily on intellectual property protection which entails monopolies and high prices. High prices are deemed necessary to pay for innovation. However, there are alternative models of research and development that will break the link between the cost of R&D and the price of the end product, thereby supporting affordability and access. These models would benefit patients and healthcare systems both in Europe and outside of Europe. The Commission has the mandate and, through mentioned EU commitments, the obligation to explore these models. Furthermore, the EU is well positioned to explore these models, and take the global lead in innovation.

[8] The Med4all paper, Medical Research: Science in the Public Interest (2009) also recognises the value of equitable licensing for other technologies, "equitable licensing models do not have to be restricted to medical products. They can also be helpful in herbal research for food supply, in providing low-priced communication technology for poor countries, or for technologies for independent energy supply." http://www.med4all.org/fileadmin/med/pdf/med4all_englisch_final.pdf

Innovation inducement prizes represent such an incentive system. Monetary prizes can provide incentives to induce R&D into new medicines, while ensuring widespread access. Rewards would not be tied to the exclusive rights to sell products and monopoly prices, rather, innovators would be awarded money: large monetary "prizes" tied to the actual impact of the invention on improvements in healthcare outcomes that successful products actually deliver. This would bring about that rewards are based on improvements to health outcomes.[9] Prizes can be designed to provide incentives to innovate and support increased sharing and access to knowledge. If used widely, this incentive scheme would eliminate high prices for medicines, creating a market based on affordable (generic) manufacture of medicines.[10] There are several far developed proposals that target very specific R&D and access needs.

The Commission has some experience with prizes yet not in the biomedical field. Innovation inducement prizes have been widely discussed in many forums and deserve exploration to address European and global health challenges. HAI would encourage the Commission to engage in pilots and feasibility studies regarding innovation inducement prizes. There are several developed disease-specific proposals that could be considered.[11]

[9] Prizes would also reduce incentives for heavy promotion and marketing of medicines, leading to irrational use.
[10] http://www.cklawreview.com/wp-content/uploads/vol82no3/Love.pdf
[11] http://www.keionline.org/prizes