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

HAI Europe welcomes the opportunity to respond to the Commission's Public Consultation on the European Research Area (ERA) Framework.

Executive Agency for Health and Consumers

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Civil Society as a research body

As correctly highlighted by the Consultation background document, researchers in Europe currently face numerous barriers that impede the realization of their research potential, preventing the EU from becoming an effective single market for knowledge, research and innovation. Whilst HAI Europe supports the need to overcome these existing barriers, we also would like to highlight the shortcoming in the European Commission's conception of research which is confined to traditional researchers who work for institutes, universities and industry. It is in our view that civil-society also plays an important role in EU funded research and innovation, not solely as a recipient of research results, but also as a driver. Only by breaking down the current educational, mobility, demographic and employment barriers to researcher, and, at the same time, including civil society organisations (CSOs) into the Commission's definition of researchers will it be possible to complete an European Research Area (ERA).

HAI Europe represents more than 100 individual and organisational members, many whom receive funding from the EU to conduct research. Individual members have been sponsored through the FP7 Science in Society programme to execute the project European Patient Organisations in Knowledge Society. Moreover, the HAI Europe Secretariat receives an operating grant from the EU in the framework of the Health programme, a portion of which has funded research into: experiences of consumer and patient involvement in pharmacovigilance activities (2009); the impact of European trade agreements on access to medicines in Peru & Colombia (2009); financial disclosure and transparency of European patient & consumer organisations (2010).The aforementioned EU-funded research activities, undertaken by the HAI Europe Secretariat and its network, underline the clear role that the not-for-profit sector plays in advancing research and innovation.

It is therefore imperative that the ERA promotes forms of cooperation between civil society and research centres, and encourages the exchange of knowledge. Not only should the ERA enable CSOs to participate in research programmes, but it should also allow civil society to help set the EU research agenda. The EU's traditional view of civil society as only recipients of research needs to be redefined to include the important role CSOs play in study design, data collection and interpretation, as well as drivers of change stemming from research outcomes. CSOs' unique view as lay experts and their proximity to end users yield valuable insight to identify research gaps and address needs that may otherwise be overlooked by conventional research. In general, research that involves or is driven by CSOs improves the quality and the relevance of the research outputs.

Nonetheless, there are currently a number of barriers to CSOs involvement in research production. These challenges are, among others:

- Lack of sufficient financial support and available time;
- lack of information on the opportunities and ways to get involved.

Dissemination, transfer and use of research results

Horizon 2020 emphasizes "raising levels of excellence" as one of its major objectives, as well as improving the EU's performance compared to the USA. At the same time, the EU identifies that a fee-for-access (to data) approach impedes the speed of scientific progress and innovation. Therefore, in order to realise its own goals, the EU should consider non-payment methods to disseminate information and data.

The exploitation of research results is key to encouraging further research and innovation, thus Open Access to publications is vital. An Open Access Pilot was launched under FP7 to encourage open access to publications. Nonetheless, today it appears that only 10-20% of research articles and data are actually available for free online. Furthermore, where this publicly available material can be found on the web is rather vague.

In order to stimulate the use of research results through open access the EU first needs to have a comprehensive database identifying the outcomes of EU funded research. Simply publicly posting the data or conclusions on the internet is insufficient, and in some cases, counterproductive to a clear understanding of what knowledge EU funds have produced. The EU should adopt a systematic and clear approach that collects and provides public access to the results of EU funded research. The existence of such a database should be clearly publicised. A transparent, clearly organised database which brings together extensive publication and data derived from EU funded research will underline the EU's scientific and technological advances, thereby attracting further talent and investment.

Nonetheless, it is important to underline that promoting scientific and technological advances under the ERA goes hand in hand with ensuring that these developments, in fact, yield the highest social benefit. Therefore, HAI Europe believes that open access to results should go further than simply granting free online access to research publications and data. The rules which govern the transfer of public knowledge derived from EU funded research need to foresee commercialisation of research results at affordable prices. This is especially relevant in the biomedical fields where the current intellectual property (IP) framework which governs the research and innovation models fails to generate the highest social benefit out of research funded with European taxpayers' money. The concept of Socially Responsible Licensing[1] (SRL) aims to contribute to solving this issue.

Currently, in the biomedical field, public research institutions patent their discoveries and license their knowledge to pharmaceutical companies for further development. Here, all rights over further product development are given up by the research institution and limited to that specific licensee, normally a recognised pharmaceutical company or a small or medium enterprise (SMEs). The public research institution can no longer ensure that their knowledge is used to the benefit of global health and everyone has access to essential medicines. Furthermore, the licensee enjoys a monopoly over this knowledge and can sell the final product, be it a therapy, a medicine, a diagnostic or a vaccine, at a price of its choice due to a lack of generic competition. As a result, while some European taxpayers end up footing the bill twice (first by funding the initial research and subsequently by over-paying for a biomedical product), others

[1] Also known as Equitable Access Licensing, Humanitarian Licensing

simply cannot access some of these essential biomedical products because they have to pay for it out-of-pocket due to lower reimbursement coverage by health insurances (this is namely the case in eastern EU member states) or no insurance at all (as is the case in developing countries).

Under SRL, grant beneficiaries (in the biomedical field) would only be awarded research and innovation funds by the European Commission on the condition that the contractor accepts specific obligations regarding the exploitation and dissemination of results. The contracting authorities shall enjoy at minimum royalty-free access rights to the results for their own use as well as the right to grant, or require the participating contractors to grant, non-exclusive licenses to third parties to exploit the results under fair and reasonable conditions without any right to sub-license. These provisions would encourage research and innovation in the field of neglected diseases, reduce over-priced technology by promoting competition (and thus further innovation). SRL is also relevant to advancing the international dimension of the ERA as this would ensure access to knowledge globally.

Today, the concept of SRL is already successfully applied by numerous universities in the USA, promoted by the Universities Allied for Essential Medicines (UAEM). Prominent research institutions, including Harvard, Yale, University of Pennsylvania, Brown, Boston University and Oregon Health & Science University, have adopted this concept and signed on to the Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies (SPS) created in 2009. Specifically, 73% of exclusive, biomedical relevant licenses negotiated by Harvard University's Office of Technology Development included global access provisions in the past fiscal year. The University of British Columbia has partnered with a private Canadian company under a global access license to develop a new oral formulation of the antifungal treatment Amphotericin B. UC Berkeley is collaborating with the Gates Foundation and private sector partners to develop mass-production systems for an innovative malaria treatment (semisynthetic artemisinin) under global access terms.

While no such statement has been publicly endorsed by public research institutions in the EU, it is important to note that Oxford University, University of Manchester, University of Edinburgh, University of Dundee and Charité - Universitätsmedizin Berlin each adopted their own specific socially responsible licensing policies. The European Commission could therefore perhaps draw on the experience of these institutions in order to also effectively implement the SRL concept.

To conclude, HAI Europe wishes to underline that while improving knowledge transfer in order to develop new services and products is important, ensuring that those in need of these services and products, such as new medical therapy and technology, actually have access to these is essential. Only by including this form of social responsibility will the ERA serve its purpose of improving EU research performance.