

Submission to the Consultative Expert Working Group (CEWG) on alternative financing

In June 2011 (HAI) Global, HAI Latin America and the Caribbean (AISLAC) and HAI Europe (HAI-E) made a submission to the Consultative Expert Working Group (CEWG) on alternative financing. For more information, see the submission below:

Submission to the Consultative Expert Working Group on Research and Development: Financing and coordination (CEWG). June 2011

This response has been prepared by Health Action International (HAI) Global, HAI Latin America and the Caribbean (AISLAC) and HAI Europe (HAI-E). HAI is a non-profit, global 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 voice is one of integrity and independence from commercial and political party interests; we engage in research and evidence-based advocacy.

- HAI promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

Health Action International welcomes the opportunity to make a submission to the Consultative Expert Working Group (CEWG) on alternative financing and would like to address identified cross cutting issues.

The CEWG is faced with a great responsibility, but a responsibility that also presents an extraordinary opportunity to change the face of Biomedical Research and Development(R&D) and as a consequence to change forever the health of the world's poor and neglected.

As such, the CEWG, should be very ambitious in its goals.

HAI would like to stress that it is of paramount importance to explore and support an international instrument to address the coordination, financing and norm setting for Biomedical R&D which is the only way a realistic structural change in R&D priority setting, focussed on needs-driven research can be achieved.

In the last thirty years there have been several initiatives investing in R&D for neglected diseases and improving the access to medicines for the poor. However, the focus of global biomedical R&D to a large extent remains on life-style and convenience medicines for the rich minority populations of the north, where there is a profitable market. This R&D framework is at the expense of the diseases that affect the majority population of the poor.¹ A structural change needs to be made and the global health and development community looks to WHO for leadership to promote such a shift, and to implement models for innovation that structurally change the way R&D is prioritised and incentivised.

Within this framework of global norm-setting, HAI insists the scope of diseases being tackled should not be limited and that recipient countries should be engaged in setting their own R&D needs. Moreover, in respect of financing and its allocation, HAI would like to draw attention to the importance of giving member states the opportunity to (partially) allocate their R&D contributions in their own countries, under the conditions and norms set by the international instrument.

Crucially, R&D initiatives should delink the cost of R&D from the price of the product by removing IP barriers. This will not only make new medicines more affordable, it will stimulate generic competition and ensure sustainable access. Removing IP barriers to entry into the market, will allow more players in developing economies to take part in the process of production and innovation. This is not only a desirable situation from the point of view of the right to development, but also the most effective way to ensure a sustainable supply of medicines. Generic competition has proven to be the most effective way to lower the price of medicines and ensure affordability.²

With respect to the coordination of R&D, sufficient consideration should be given to the adequate management of transparency and conflicts of interest as raised during 64th WHA by member states and NGOs.³ There must be a clear policy and systematic approach to transparency and interest declarations to ensure that those representing commercial interests are not part of policy and norm setting decision

making. In this respect, we emphasize the importance of evaluating the interests of pharmaceutical companies, vaccine manufacturers, other industries, and private donors who may have complex private interests.

4 HAI recommends that a thorough comparative analysis of the proposals submitted to the CEWG though important, is not enough. It is essential for the CEWG to also give specific **recommendations to member states on how to proceed with the exploration and implementation of the relevant proposals and instruments.** In this respect it would be useful to identify the next steps, the lead-stakeholders, and reasonable timelines. If the CEWG does not provide such a framework on the way forward, there is a risk the process will stall.

1 WHO (2006) 'WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health', Geneva. WHO(2004), The Global Medicines Situation, 2004,p 19

2 World Health Organisation and Health Action International (2006) 'Price, Availability, and Affordability: An International Comparison of Chronic Disease Medicines', p. 55.

3 <http://haieurope.org/wp-content/uploads/2011/05/24-May-2011-NGO-letter-on-Conflicts-of-Interest.pdf>

4 HAI supports a coordinated and comprehensive approach to handling personal conflicts of interest by:

i) Adopting a common definition of conflict of interest among relevant bodies ii) Instituting the mandatory declaration of the details regarding the activities of experts and decision makers in relation to any of the following: employment, strategic advisory roles, consultancy, representation, financial interests, ownership of a patent or product, researcher, employment or involvement at an institution receiving a grant or other funding. iii) Mandating the relevant bodies to publish all declaration of interest forms iv) Creating a procedure to identify and resolve any competing interest. In some cases, impartiality could be achieved by limiting the advisor's involvement in the decision making process.