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Response to the Second Public Consultation of the Expert Working Group on Research and Development Financing

This response has been prepared by Health Action International (HAI). HAI is a non-profit, global network of consumers, public health interest NGOs, health care professionals, academics, media and individuals with over 25 years experience in representing the voice of civil society, especially 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 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.

Overall remarks

HAI welcomes the opportunity to contribute to this important consultation initiative, which is to be commended.

The documents made available for this public consultation do not acknowledge/refer to important items which were included in the 2006 Commission on Intellectual Property Rights, Innovation and Public Health report, or in the World Health Assembly resolution 61.21. They should be included as a significant contribution to the proposals.

Any sustainable systems of finance for medical R&D, including both sources of funding and possible incentive mechanisms proposals stemming from the EWG, should:

- be transparent and cost effective
- be ambitious enough to address real needs for innovation
- include government funding
- be inclusive, when possible, of open licensing of inventions and other IPR in developing country markets

- encourage or require open access to data, material and knowledge
- foster the transfer to and development of technology in developing countries
- base financing decisions on identified access requirements
- promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development (R&D) from the price of health products
- when possible, ensure a sustainable and competitive supply of products from generic producers in developing countries
- enshrine accountability to governments, users and the democratic process.

Criteria

Access - While considerable attention has been paid to structural criteria related to financial mechanism and its acceptability, one fundamental aspect has been overlooked within the evaluation norms being proposed, namely that there is no mention of any access criteria against which the products being developed would be measured. Ensuring that essential medicines are accessible and affordable to those that need them is of paramount importance and therefore all the financing mechanisms should be assessed as to their potential contribution to access and the extent to which they address real health needs.

Defining priorities – The evaluation criteria should include provisions which accommodate the possibility for states to direct R&D according to their own public health priorities and the therapeutic needs of their country.

Interaction, Acceptability, Experience - It is important to recognise that creative financing models should not be penalised or excluded, and financing mechanisms should not be limited to well-know and established models. On the contrary, the added value of this exercise should be to facilitate new approaches and ideas, in spite of some risk to investors, because the dividend to global health would be unparalleled. By extension, a proposal should not be evaluated purely on compatibility with other proposals, but rather on a case-by-case basis. The degree of acceptability by stakeholders should also not be taken into account, as a subjective pre-judgment. A selection based on subsequent acceptance is not legitimate. The evaluation should, in all cases, be based on objective criteria and conducted without bias.

Accountability - Under this criterion aspects such as social responsibility and openness should also be included. Proposals which encourage knowledge sharing and open access should be stimulated and appropriately rewarded.

Conflicts of Interest - We have concerns in that the pharmaceutical industry, Product Development Partnerships (PDPs) and academic and other non-profit research institutions will all be applicants or recipients of new money for medical R&D. As such, there will be incentives and opportunities to skew EWG outcomes to favour their institutional mandate. The EWG needs to recognise these conflicts of interest, which are

not adequately addressed in the proposed evaluation criteria and adopt concrete provisions to manage the risks they present.

Usefulness of the criteria – The usefulness of the evaluation criteria will be dependent of the principles applied when aggregating or weighing the findings. As this information is not provided, it is impossible to comment on the overall usefulness of the approach.

Ambiguity of the criteria – The rating of the criteria is dependent on their interpretation. In several cases, the headings do not seem to match the description being provided and therefore forestall any a proper classification. This is particularly the case for the suitability, efficiency, automaticity, governance and cost criteria.

Inventory

The inventory does not mention the proposals of:

- UNITAID patent pool
- Open licensing and /or equitable licensing for publicly funded research. For a list of publications see www.med4all.org
- Biomedical R&D treaty as proposed in the Bangladesh, Barbados, Bolivia and Suriname submission to the first web-based public hearing of the EWG.

Other remarks – Reading list

Spelling Correction: Where it reads Abraham, John; Read Tim; "Trading risks for markets: the international harmonisation of Pharmaceuticals regulation"; 2001", it should read Abraham, John; Reed, Tim; "Trading risks for markets: the international harmonisation of Pharmaceuticals regulation"; 2001"