



# Submissions to Section 1 - Draft Global Strategy and Plan of Action

**Submission by Health Action International Europe, September 2007**

Health Action International (HAI) welcomes the 2<sup>nd</sup> IGWG draft and is pleased to note that its previous comments have been included in the most recent draft. However, in general we consider the draft to be too broad, and that by attempting to cover every point so far discussed at IGWG the overall message is diluted. Therefore HAI recommends that instead it should focus on the main objectives of the IGWG process: promoting innovation and making sure that all people, especially the poor and marginalised, obtain access to the fruits of medical innovation.

This submission from HAI is the result of consultations with HAI members in Africa, Latin America and Asia-Pacific, because these regions are those who would benefit substantially from the IGWG plan of action. Nonetheless, in this submission we focus specifically on the responsibility of European governments.

## **Guiding principles**

All negotiations in respect to the Global Strategy and Plan of Action should focus on core guiding principles:

- The right of access to medicines for all people
- The right to health should be given a higher priority than commercial interests
- Because public health interests and commercial interests are often having conflicting aims, R&D should be coordinated by public institutions
- Since the pharmaceutical market fails to address people's needs in many public health care areas, R&D is a public responsibility

HAI calls upon national governments to consider these overall objectives as a minimum consensus.

Ultimately, access must be the main indicator for innovation success. Innovative medicines make no contribution to public health outcomes if the people they are intended to benefit are denied access to them.

Arising from these fundamental issues HAI identifies the following key points for the eight elements listed in the IGWG document.

### **Element 1: Priority setting**

- The Action Plan has to “reflect adequately the health needs of developing countries”<sup>1</sup>. Therefore it must not be limited to type II and III diseases but also include type I diseases which also significantly contribute to the overall disease burden in poor countries.

### **Element 2: Promoting R&D**

- The current situation is mainly characterised by a lack of commercial motivation on one hand and limited access to existing medicine by pharmaceutical company monopolies on the other. It shows that the IP model, relying on monopolies and high prices, does not cater for those diseases where the sick are either too poor or too few.
- Various enterprise models are needed to promote R&D. Interactions between public and private entities and advanced market commitments may work, but subsidies to pharmaceutical companies should not lead to new monopolies perpetuating existing problems. Maximum access to newly developed products must have the highest priority.
- Governments should promote non-profit R&D projects and support them with direct funding.
- R&D is a public responsibility. This should not mean the exclusion of industrial activities but it might lead to a discussion of who is taking leadership.
- Clinical trials need to be in the interest of public health and therefore should be funded by the public purse.
- The results of publicly funded R&D must remain in the public domain. The objective being to ensure maximum access to products resulting from public R&D. This will require:
  - \* open access to information: scientific papers resulting from public funding should be either published in open access journals or, if published in other journals, they should be made available from the PubMed database. This handling of scientific papers is already required by some funders (e.g. the Wellcome Trust<sup>2</sup>) and should be expanded to all kinds of public R&D.
  - \* IP protection of publicly funded R&D must not limit public health. Today most inventions made at public institutions are covered by patents, leading to monopolies and high prices. This excludes many people from the benefit of public R&D. If a drug is developed in a public institution, free licences should be given to developing countries. Such new models of open licencing already exist (e.g. Yale University), and should be applied widely and expanded.
- HAI calls for new incentive schemes<sup>3</sup>, promoting R&D by separating the price of new medicines from the R&D costs. If the costs for R&D are completely covered by public funding, new drugs can be produced as cheap generics without exclusive monopolies.

### **Element 3: Building and improving innovative capacity**

See element 2

- HAI is concerned about the inclusion of traditional knowledge (TK) in the Global Action Plan. IP issues related to TK are already discussed at other international fora

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<sup>1</sup> A/PHI/IGWG/2/2 p.4

<sup>2</sup> [http://www.wellcome.ac.uk/doc\\_WTD002766.html](http://www.wellcome.ac.uk/doc_WTD002766.html)

<sup>3</sup> this item is currently listed under element 5, but because this is more an issue of promoting R&D than protecting IP, we list it under element 2

like WIPO or the Convention on Biological Diversity. Therefore this discussion should be excluded from the IGWG process. HAI asks governments to increase their involvement in the discussions in the above-named relevant fora.

#### **Element 4: Transfer of technology**

- Increasing production capacity in developing countries is an important step for improving access to medicine. But HAI cannot agree to the use of the term “increasing of IP protection” in this context.

#### **Element 5 : Intellectual Property**

- Patent protection and monopolies leading to higher prices of medicines are limiting access and therefore contradict the principle of a human right to health. Evidence shows that the IP-based system does not fulfil its goal to foster innovation for diseases that affect predominantly the poor or for diseases with a limited number of patients.
- The pharmaceutical industry can and must be involved in the action plan to promote innovative R&D (see element 2), but the dogma of IPR must be marginalised. The pharmaceutical industry can provide a public health service by developing medicines with public funding, but new medicines arising from such projects must be considered public goods and should not be protected by any exclusive IP.
- Countries must retain the full right to implement TRIPS flexibilities.
- IP protection of publicly funded R&D must not limit public health outcomes. Therefore, open licencing for developing countries needs to be expanded.

#### **Element 6: Improving health systems**

The existence of adequately functioning health systems is a pre-condition for ensuring access to (innovative) medicines.

- HAI asks governments from developing countries to take responsibility for improving their national health systems.
- HAI asks governments from developed countries to facilitate health systems strengthening in developing countries by sustained funding and refraining from undermining activities such as recruiting health care staff.
- Governments are asked to remove all taxes on essential and life-saving medicines.
- Local production of drugs should follow GMP standards.
- HAI supports international action against substandard drugs
- Action must be taken at an international level to combat counterfeit drugs.

#### **Element 7 Financing mechanisms**

- The much-lauded new drug development cooperations for tropical diseases (“public private product development partnerships”) are mainly funded by philanthropic donors. This is unsustainable in the long run. If public health interests are not addressed by the conventional commercial market, there is a clear public responsibility for governments to fill the gap left by a failing market.
- There is a need for government commitments to funding mechanisms, including governments of developing countries. Clear targets should be set by IGWG.

**Element 8 monitoring systems**

- A central multistakeholder organization should be responsible for the implementation of the IGWG plan of action. HAI suggests this organization should be located at WHO.
- Civil Society has a valuable contribution to make to the implementation of the IGWG action plan. Therefore the participation of NGOs from all regions should be encouraged and funded.