IGWG: Norwegian comments to Draft Plan of Action

Reference is made to C.L. 9.2007, where Member States are invited to submit additional comments and suggestions to the doc. A/PHI/IGWG/1/5;

Norway considers the follow-up process of the CIPIIH report to be important. We recognize the need to elaborate further the results of the IGWG meeting in December 2006 and look forward to receive a working document, based on input from Member States and relevant stakeholder, by July 2007. We want to contribute to the July 2007 document by submitting comments to the draft Plan of action (A/PHI/IGWG/1/5).

Relevance of the proposed action points
Norway considers all the proposed action points reflected in the draft action plan to be relevant to the follow-up and implementation of the recommendations from the CIPIIH report. The action plan needs, however, to reflect which actors the recommendations should be directed to. In going through and suggesting changes to the recommendations, we will therefore propose possible actors (WHO, i.e. director general, member states (all or specifically addressing developed or developing countries), private sector, other JN agencies and NGOs) responsible for follow-up of the recommendations.

Comments and input to action points, and identification of actors responsible for follow-up

2. Prioritizing research and development needs:
   - a: responsibility for follow-up of this action point should be directed to WHO, in
collaboration with the Global Forum for Health Research (GFHR)
- b: we suggest this point to be rephrased as follows: "identify research priorities for both type II and III diseases". Responsibility for follow-up of this action point should be directed to WHO in collaboration with GFHR. However, it is important to involve the views of Member states in the process
- c: responsibility for follow-up of this action point should be directed to Member states. However, it is important that WHO develops and provides the methods and tools needed to support Member states in this effort
- d: we suggest that the action point be rephrased as follows: "conduct research appropriate for resource-poor settings and research on technologically......" Responsibility for follow-up of this action point should be directed to Member states and the private sector

3. Promoting research and development:
- a: responsibility for follow-up of this action point should be directed to Member states
- b: responsibility for follow-up of this action point should be directed to Member states and the private sector
- c: we suggest that this paragraph be rephrased as follows: "Provide support for a national health research system and research programmes through......" Responsibility for follow-up of this action point should be directed to Member states. WHO should have a supporting role
- d: responsibility for follow-up of this action point should be directed to WHO. It should be considered to collaborate with GFHR since this is an existing forum
- e/f: responsibility for follow-up of this action point should be directed to Member states and the private sector
- g: responsibility for follow-up of this action point should be directed to Member states
- h/i: responsibility for follow-up of this action point should be directed to WHO
- j: there is a need for clarification concerning the kind of arrangements/systems in question, whether it should be of a voluntary nature or not and who the action point should be directed to. We suggest adding the following: "... of open source, open access, including both open access to research data and open access publication, and collaborative issues".

4. Building and improving innovative capacity
- a, b and c: responsibility for follow-up of this action point should be directed to Member states
- d: it is important that pharmaco vigilance is part of the strengthening of product regulatory capacity in developing countries. Pharmaco vigilance should be included as follows: "...standards, clinical-trials capacity and pharmaco vigilance systems.". Responsibility for follow-up of this action point should be directed to Member states, but WHO should be responsible for coordinating the efforts
- e/f: responsibility for follow-up of this action point should be directed to Member states, but WHO should be responsible for coordinating the efforts.

5. Transfer of technology:
- a/b: responsibility for follow-up of these action points should be directed to WHO and WTO.
- c: responsibility for follow-up of this action point should be directed to Member states and the private sector.
- d: responsibility for follow-up of this action point should be directed to Member states.
- e: since patent pools will be a voluntary arrangement for the patent holders involved, we question whether it is necessary to consider any further intellectual property implications of such a proposal. Responsibility for follow-up of these action points should be directed to WHO and WIPO.
- f: responsibility for follow-up of this action point should be directed to Member states and the private sector.

6. Management of intellectual property and exploration/promotion of other incentive schemes:
- we feel that an extension of the title for this section, i.e. including other incentive schemes, is warranted.
- a: responsibility for follow-up of this action point should be directed to Member states. It is important that the WHO, upon request by developing countries, provides support to them in this process. This should be the subject of a separate action point.
- b: we do not think that the term promote is appropriate here and suggest that it should be omitted, i.e.: "... frameworks to manage intellectual property". Responsibility for follow-up of this action point should be directed to Member states.
- c: the following should be added at the end: "...incl. price rewards and value-based pricing of drugs". Responsibility for follow-up of this action point should be directed to Member states and WHO.
- d/e: responsibility for follow-up of this action point should respect current division of work between WIPO and WHO and call for cooperation between them, particularly to improve dissemination and updating of information.
- g: the wording should be corrected to reflect accurately res. WHA 57/14, "to take into account in bilateral trade agreements the flexibilities ...". Furthermore the footnote should be corrected: Resolution WHA57/14, paragraph 2(6). Responsibility for follow-up of these action points should be directed to Member states.
- h: responsibility for follow-up of this action point should be directed to Member states.
- i: it is not clear to us what sort of recommendation is suggested and to whom it is directed. This should be clarified.
7. Improving delivery and access:
   - a: responsibility for follow-up of this action point should be directed to the WHO and Member states
   - b: we think this is an important action point. However, accelerated processes underscore the need for proper pharmacovigilance systems. We would therefore like to add: "...with potential utility and strengthen capacity to monitor the safety of products, with special emphasis on products first introduced in developing countries". Responsibility for follow-up of this action point should be directed to Member states
   - c: responsibility for follow-up of this action point should be directed to private sector
   - d/e: responsibility for follow-up of these action points should be directed to Member states
   - f: responsibility for follow-up of this action point should be directed to Member states and the private sector
   - g: responsibility for follow-up of this action point should be directed to Member states
   - h: we are not sure whether this action point should be prioritised in this plan. If it should stay in, we suggest this point to be rephrased as follows: "devise ways to address public health aspects of counterfeiting.....". Responsibility for follow-up of this action point should be directed to Member states
   - i: responsibility for follow-up of this action point should be directed to Member states
   - j: we see the need to encourage use of generics when applicable as a way of reducing the cost of medicines. A successful measure introduced in Norway has been the so-called "replacement lists" mandating pharmacies to substitute prescribed brand-name drugs with approved generics, without consulting the medical doctor who issued the prescription. Hence we suggest the following rewording of this action point: "..... such as the "early working" exception, measures for generic substitution, and more generally policies that support ...." Responsibility for follow-up of this action point should be directed to Member states
   - k: there is a need for enhanced sharing of information and for monitoring when it comes to pricing policies and prices. WHO has an important role to play in this regard. The recommendation should be addressed to the private sector
   - l: we suggest the following rephrasing of the action point: "continue to monitor price of treatment for communicable diseases...." The action point should be directed to WHO
   - m: responsibility for follow-up of this action point should be directed to Member states
   - n: we suggest this point to be rephrased as follows: "consider to remove tariffs and taxes on drugs, medical devices and diagnostics and monitor....." Responsibility for follow-up of this action point should be directed to Member states

8. Ensuring sustainable financing mechanisms
   - a: responsibility for follow-up of this action point should be directed to WHO
- b, c: responsibility for follow-up of this action point should be directed to Member states
- d: responsibility for follow-up of this action point should be directed to WHO
- e: we suggest that the action point be reworded as in d) above: "...devise forms of advance-purchase schemes or utilize existing ones which may....". Responsibility for follow-up should be directed to Member States

9. Establishing monitoring and reporting systems
- a-e: responsibility for follow-up of all action points under this item should be directed to WHO

Intersessional work
Reference is made to the discussions at the EB 120 in January this year, where the Secretariat put forward a plan for intersessional work to be carried out before the next IGWG in October later this year. Norway supports the plan put forward by the Secretariat, including possible informal consultations during the period of the WHA60 in May. As far as the voluntary reporting of implementation of recommendations in a public database is concerned, we are in the process of going through the recommendations and plan to provide updated information to such a database. Please make sure again in this database who should report on the implementation of different recommendations, i.e. member states, private companies etc.

Yours sincerely,

[Signature]

[Name]
Director General

[Signature]

[Name]
Head of Delegation to the IGWG