Consultation on "Elements of a global strategy and plan of action"  
(A/PHI/IGWG/1/5)

Comments by the European Union

28/02/2007

Dear Dr. Renganathan,

On behalf of the EU and its 27 member states the German EU presidency has the honour to deliver the following comments on the document prepared by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. The comments of the EU on the document entitled "Progress to date in the Intergovernmental Working Group" (document A/PHI/IGWG/1/5) refer to Annex 1, just as asked for in the letter of 12 January 2007, and are to be considered additional to the comments made earlier by the EU.

In the EU statement to the Executive Board (delivered by Portugal), we already underlined the importance of a well prepared process on the IGWG. As we pointed out in this statement we look forward to receiving adequate background information on each of the eight elements of the plan of action in a timely manner. In addition to this we would suggest a reflection on the following questions:
- which are the impediments at national and international level to synergize and increase public and private investments for R&D for neglected diseases?
- to what extent can this be attributed to national and/or international policies?
- what is needed and can be done in a realistic way to improve policy coherence at national and international level?
- what guidance and support is needed at national and international level to make this happen?
- which are the key players?

Furthermore we have some comments on the annexes which we hereby transmit.
A. EU comments on Elements of a Plan of Action (PoA)

1. General comments

As a general comment, the action plan should focus more on health needs and health policy priorities, in particular in points 1, 2, 4, 5, 6 and 7.

a) Actors and Mandates

It is of utmost importance that the PoA sticks to the WHO mandate and respects the mandate of and work carried out in other international organisations, such as WTO and WIPO.

Therefore we would like to add to the 1st sentence of the PoA "Further to discussion... in respect of the elements of a plan of Action, in relation to the mandate of WHO".

Where the PoA refers to the mandate of other organizations (WIPO, WTO or other international fora), this needs to be clarified as well (4, 5, 6) and this on top of the "generic" reference in Paragraph 10.

It needs to be clarified which actions address which actors. Sometimes the PoA refers to WHO, sometimes to Member States and sometimes (7.k) the PoA seems to refer to the private sector. The PoA should suggest or propose lead responsibilities which can be discussed. This would be helpful for example for the areas for action on section 2 below.

Some drafting suggestions:

Para 1:
- Add: identifying and (prioritizing research and development needs) (Bullet 1)
- Promoting add: and supporting (research) (Bullet 2)
- Transfer of technology add: and know how for innovative capacity (Bullet 4)
- Establishing monitoring and reporting systems, add: including peer review (Bullet 8)

b) Background information

The EU also reiterates the need for background information on the state of play, the feasibility and the impact of suggested actions, e.g.:
- 2.e: accessibility of compound libraries
- 3.d: how will this possible forum relate to existing structures (in case the Global Health Research Forum)
- 3.g: consider legislation relating to the form of research exemption
- 3.j: methods on open source etc.
- 5.e: promotion of patent pools
- 6.b, d, h transfer of technology: inventory of mechanisms which already exist to promote and facilitate technology transfer
- 6.i: who should focus? WHO? Member States?

You will find further requests for clarification along with the comments provided herewith.

c) Focus and Terminology

On a general level, we consider document A/PHI/IGWG/1/5, written on the basis of the first session of the intergovernmental working group (IGWG), as a good working record. In our view the document could be improved by being more focused and by using more precise expressions (e.g. “management” of intellectual property, paragraph 6. Also the definitions should be in line with work already done or being carried out in other international fora (WIPO, WTO in particular). It will be important for the PoA to set out clearly the funding implications of its proposed actions, to prioritise within each set of actions as well as to set out clear and time-bound responsibilities for taking them forward.

The proposed action plan should clarify and be explicit:

- where the proposed focus of action is on particular needs of developing countries, and
- where the emphasis is on more general measures

in order to enhance the Member States’ awareness of the kind of commitments they make.

Prior to further discussions we need among others clarification or agreed definitions for the following terms:
2. Identifying and prioritizing research and development needs

The EU welcomes the fact that the focus of the document is on health and R&D. Hence, the positive contribution of IPR on R&D should be underlined (and WHO’s role in monitoring the impact of IPR on access to healthcare).

We would like to emphasize the operational paragraph 4.4. of the resolution 59.24 stating that reporting on R&D should focus on public health needs and priorities, identification of gaps and needs in relation to pharmaceuticals. Tasks of identifying and prioritizing R&D needs should be separated from further commitments on global support to R&D.

Also the stress put “on diseases that disproportionately affect developing countries” fits with the mandate given in resolution WHA59.24. The many other paragraphs in this action plan that deal more generally with “public health needs in developing countries”
should be amended in the same spirit, notably paragraphs 2.d and 3-chapeau (p. 4), 3e, all of points 4 (p. 5-7) and 5(e).

Some drafting suggestions:
c. **add**: based on appropriate and regular needs assessments
c. 1st sentence: set research priorities, including health-systems… **add**: and rational use of medicines

new para f. set up and finance public health libraries with full access (at least for PH professionals and students)

2nd sentence: A significant improvement… to drive research on new… **add**: and existing products.

3. Promoting research and development

A drafting suggestion:
c. and h. … **add**: using systematic reviews and needs assessment

4. Building and improving innovative capacity

A drafting suggestion:
f. recognize, … **add**: investigate, evaluate, … develop and promote traditional medicines.. **add**: within an evidence-based framework.

5. Transfer of technology

As the document points out, there are already some initiatives and mechanisms in this area. A comprehensive preliminary inventory of existing mechanisms in advance of the next IGWG session would be very helpful.

A drafting suggestion:
Transfer of technology… **add**: "for innovative capacity" through North-South and South-South collaboration… **add**: "and through institutional cooperation"
d. The EU would be interested in getting an evaluation of transfer on health-related technology and presentation of best-practices by the developed countries.

6. Management of intellectual property

The EU feels that the action point "Management of intellectual property" (and to a lesser extent the action point "Transfer of Technology") runs roughly parallel with WTO and WIPO's work within the Provisional Committee on Proposals related to a WIPO Development Agenda (PCDA). Within this committee the following key areas have been identified:

- Technical Assistance and capacity building
- Norm-setting, flexibilities, public policy and public domain
- Technology transfer, ICT technology and access to knowledge
- Assessments, evaluation and impact studies
- Institutional matters including mandate and governance

It is important that WIPO, WHO and WTO/TRIPS cooperate closely, and WHO’s role in monitoring the impact of IPR on access to healthcare is recognized, in order to ensure that these two ambitious initiatives do not run counterproductive to one another. In doing so we ensure that innovative incentives for R&D are in accordance with international intellectual property framework. In order to better monitor and coordinate international action in this area, a joint database showing activities undertaken by WHO, WTO and WIPO in the field of Intellectual Property linked to health issues (training and workshops for implementation of TRIPS flexibilities for example), would be very helpful. This matrix could be updated regularly and indicates in which areas training activities or further work are needed. It would be consistent and complementary to the current monitoring, within the WTO, of the Doha declaration on TRIPS and public health.

b. add: that would serve health needs and priorities of developing countries.

d. It needs to be clarified for what type of information and users the mentioned databases are meant.

f. replace "incorporate" with "impose"
h. the original recommendation did not include references to harmonization. We would prefer to promote exchange of information and enhance dialogue between national regulatory authorities for medicines and health products and intellectual property offices.

i. see comments in part 1(a)

7. Improving delivery and access

Sustainable financing of health systems and mechanisms to promote and regulate rational use of drugs are key points for further action. Therefore we support the approach taken in this chapter. Still we feel that the wording is confusing on some accounts:

- the chapeau mentions several important aspects of drug policies that curiously do not appear within the areas for action, namely “health-delivery infrastructure”, “financing the purchase of medicines and vaccines through insurance” and “mechanisms to regulate the quality, safety and efficacy of medicines and other products”.
- action point (m) overcompresses the CIPIH recommendation 4.10: important to flag up developing country government responsibilities for investing in their own healthcare systems.
- conversely, paragraph 7.i and 7.j deal with issues that come better under “management” of intellectual property and should therefore be transferred to paragraph 6.

i. add: in order to respect the Doha declaration on TRIP's and public health. In the implementation phase the WTO decision must be carefully followed and no extra constraints added that might hamper the use.

The possibilities of the Bolar exception to accelerate the entrance of generic drugs to the market should be further explored.

Some drafting suggestions:
- in the preambular part "appropriate use" should be changed to "rational use"
- replace a. and b. with the following text taking into account both areas of action:

Enhance technical support to national regulatory and procurement capacities of
developing countries, including quality assurance, and ensuring timely entry of safe, effective and cost-efficient products responding to health policy priorities. Existing products.

- c. Replace the text with: ensure that new products are evaluated, approved and used in a context of rational drug policies especially in resource poor settings. Appropriate assessment of costs and benefits should be made in order to address the problem.

- c. an evaluation is important to make sure that measures are efficient. Are there other ways to underline the importance of evaluation and knowledge-based decisions on a more overarching level of the document?

- d. add: and existing products in a context of rational use of drugs and broader preventive and public health measures.

- h. devise ways to curb counterfeiting… add: and the production and distribution of substandard medicines and technologies.

- h. the issue of counterfeit is being addressed by the EU enforcement strategy and other international initiatives. In order to improve the access and distribution, we would prefer the emphasis according to the original recommendation, which stated that the emphasis should be on production and distribution of substandard medicines and technologies.

- k. should avoid the wording "lower middle-income developing countries" in this provision.

- m. replace with para 4.10 of CIPIH report language and needs of developing countries.

- m. add… "solely" after "access to drugs cannot…"

- n. what is meant by "monitor the supply and distribution chain?" Who is supposed to monitor and for what purpose? Member States should ensure that taxes and tariffs are applied in a manner which does not negatively influence equity in access to pharmaceuticals.

- add new para o. Strengthen WHO’s work on pricing of pharmaceuticals and look closer at variation of pricing of pharmaceuticals and mechanisms that Member States can use at national level to lower prices, including the use of generic drugs.

The EU would further suggest to draft a provision to tackle the problem of re-exports.
8. **Ensuring sustainable financing mechanisms**

Some drafting suggestions:
- b. add: through a transparent process, encouraging competition and taking account of comparative advantage
- add new para f. reinforce use of generic drugs while Monitoring & Evaluation system for drugs utilization in use
- d. add: …and diseases and concerns where current treatment options are limited or might be compromised, in coordination with existing programmes and initiatives securing sustainable financing for such research.
- e. add: “purchase and advance marketing schemes”

9. **Establishing monitoring and reporting systems**

Generally
- Monitoring and reporting systems should include all aspects covered in the PoA and not only trade related aspects.
- It is important that WHO collaborates with other relevant organizations, such as WTO, UNCTAD, UNESCO and WIPO in order to ensure better understanding of health issues and appropriate scope for future work.

- a. Who will monitor this? Evaluation is important but we must also bear in mind that many other factors than TRIPs and the Doha declaration have consequences on innovation and access to medicines.

Generally for the whole draft PoA:
For the sake of reader-friendliness we would suggest to copy the whole text of the CIPIIH recommendations the PoA is referring to into the draft PoA (e.g. as a footnote).