126th WHO Executive Board: The Expert Working Group on R&D financing

18-19 January 2010

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EVENT MEMO

Overview

On Monday 18 January 2010, Members of the Board were presented with the Executive Summary from the report of the Expert Working Group (EWG) on Research & Development financing; the committee charged with evaluating alternate financing mechanisms for research & development (R&D).

The report is the product of a controversial process that has suffered from a number of alleged leaks, from both the EWG itself and the pharmaceutical industry, who appear to have had access to the EWG conclusions even before the document had been officially published.[1]

As well as doubts about the transparency of the EWG process, the report's conclusions have disappointed many Member States and nongovernmental (NGO) stakeholders by adhering staunchly to the status quo on innovation, which depends heavily on the existing intellectual property and R&D system.

Initial criticisms of the EWG report and its process

After the initial presentation by the Chair of EWG, Sir George Alleyne, on Monday afternoon, India and Brazil made strong statements expressing their dissatisfacton with the analysis and recommendations of the report.

India gave the first response, stating that the conclusions fell short of the decisive plan in the GSPA (Global Strategy and Plan of Action on intellectual property, innovation and public health) and that the WHO should play a greater role in assisting developing countries to use the TRIPS (World Trade Organization Agreement on Trade-related Aspects of Intellectual Property) flexibilities that allow for States to prioritise public health above commercial IP interests. Brazil's statement reiterated the point that "medicines cannot be treated like other products" and that there was a lack of linkage between the report and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA).

These interventions marked the end of the day's discussions and the agenda item was carried over to Tuesday morning for further interventions from EB members, other WHO Member States and NGOs.

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[1]The Lancet. Editorial: Drug development for neglected diseases: pharma's influence. 15 December 2009. DOI:10.1016/S0140-6736(09)62123-1. http://download.thelancet.com/flatcontentassets/pdfs/S0140673609621231.pdf

Response from the WHO Director-General

In response to the previous day's criticism that only the Executive Summary in English had been made available to EB members for them to consider for approval, Director-General (D-G) Dr. Margaret Chan opened the Tuesday morning session with an apology to the Board for confusion surrounding the document. Dr. Chan told members that the Executive Summary would no longer be put forward for approval at this session of the EB, and that more time would be allowed for members to review the full report, which would be translated into all six official languages. She instead suggested that it be discussed at the World Health Assembly (WHA) in May.

Comments from Executive Board Members

The summary report attracted criticism, even from within the ranks of the EWG,[2] and during the discussions on Monday and Tuesday, WHO members from India, Brazil, Bangladesh, Uganda (on behalf of the forty-six Africa nations), Bolivia, and Thailand all voiced less than enthusiastic responses to the analysis and recommendations in the report.

Main criticisms

The interventions outlined similar concerns, noting that the report marginalised the role of technology transfer in improving access to medicine; neglected to discuss the delinking of R&D costs from the price of medicines; and that the analysis was not based on the conclusions on IP and public health contained in WHA resolution 6121. Many countries also reiterated the obligation for States to protect the public health of their citizens and the human right to "the enjoyment of the highest attainable standard of health". Bolivia and India called for the Special Rapporteur on the right to health, Anand Grover, to address the WHA this year, to present valuable insights from his report, presented to the Human Rights Council in March last year.

In a follow-up to their earlier statements, Brazil and India made a proposal to have an inter-sessional, open-ended consultation on the full report at government level, before discussing it at the WHA. The idea of the consultation was supported by Bangladesh, Uganda (on behalf of the 46 African countries), Thailand, Chile, Paraguay, Indonesia and Bolivia, who also proposed the inclusion of interested parties in the consultation.

Bangladesh made an intervention in the Tuesday session, supporting the Brazil and India proposal, and expressing their concern about the process and the conclusions of the EWG's Executive Summary. With regards to the conclusions and dismissal of some of the proposals on prize funds, submitted in part by Bangladesh, they asked that the EWG clarify their rejection of the prize fund proposal, stating that they "would like to have the benefit of understanding how the EWG arrived at this conclusion". Their statement also referred to the omission of a reference to the R&D treaty, which was submitted as a proposal by Bangladesh, Brazil and Bolivia.

Thailand expressed their disappointment with the working process of the EWG. They commented on the timeliness of the report, stating that the WHA Resolution had clearly defined the mandate of the EWG, which required (in the roadmap established two years ago) that the full report be presented to the EB, not just an Executive Summary. The Thai representative also stated that they were unhappy with the transparency of the process and called on the D-G and EB Chairman to instigate an investigation into allegations of the leak of the report.

[2] Cecilia López Montaño, Member of the WHO Expert Working Group on R&D Financing. Open letter to the WHO Executive Board. 15 January 2010. http://keionline.org/node/756

Uganda emphasised access to technology as a core priority in the Quick Start Programme of the GSPA implementation. They also requested that the D-G convene a high-level consultative meeting with the Directors-General of the WTO and the World Intellectual Property Organization, donor countries, and other stakeholders to find possible sources of financing for the Quick Start programme.

Aside from substantive short-comings, serious concerns about the transparency and integrity of the process were raised several times by Member States, referring to allegations that some confidential EWG draft documents were leaked to the international pharmaceutical industry association, IFPMA. These allegations have been widely reported and were the subject of an editorial in the Lancet.[3]

Further comments from Member States

Statements from the Japanese and Canadian EB delegations presented an intermediate position on the EWG report. Both countries stressed the need to prioritise access, the important role of the GSPA in the process, but did not express any critique of the report itself.

The United States representative expressed ambivalence toward India and Brazil's proposal for an open-ended consultation on the full report. They were concerned that the number of consultations that might be requested between now and the WHA in May could place an undue financial and time burden on some Member States and the WHO secretariat.

Hungary's statement on behalf of European Union Member States, commented on the efforts towards the implementation of the GSPA and did not express criticism of the report or the process. The statement recognised the usefulness of a consultation but saw the place for it 'within the context of the WHA', and proposed that it be held just before the WHA.

NGO statements from Médecins Sans Frontières and HAI Global

Médecins Sans Frontières (MSF) and HAI Global both presented statements to the Executive Board in their capacity as NGOs with official relations with the WHO. Both statements echoed some of the concerns raised by Bangadesh, Brazil, India, Thailand and Uganda.

MSF's intervention outlined several areas of concern about the EWG report and process, the first being that the Executive Summary did not build on conclusions of the CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health) report and the GSPA, particularly with regard to proposals on de-linking the cost of R&D from the price of medicines. They also noted that the report appeared to endorse role of IP in research, against the findings of the CIPIH report; the criteria used to evaluate proposals was not modified following input from the public consultation and that the recommendations favoured existing organisations and companies involved in R&D. MSF also touched on the alleged pharmaceutical industry access to the EWG and called for a review of the EWG findings to assess the compatibility with elements contained in the GSPA.

HAI's intervention noted a number of short-comings in the conclusions and process of the Expert Working Group. The Executive Summary "fell short of many expectations with regard to truly original financing mechanisms that can respond to public health needs in developing countries". We also reiterated the findings of the CIPIH report and GSPA, which established that "the current

[3] The Lancet. Drug development for neglected diseases: pharma's influence. DOI:10.1016/S0140-6736(09)62123-1.

system of innovation incentives...based on various forms of IP protection...has failed to meet the needs of developing countries." The statement also discussed the omission of the proposal for a Biomedical R&D treaty and referred back to previous concerns expressed by Member States and NGOs about the process by which the EWG report has been produced.

Dr. Chan's response to comments

Dr. Chan addressed the issue of transparency and the allegations that documents were leaked by taking a tough line. She stated, "I take it extremely seriously...I have started an investigation. However, she maintained that criticisms about these allegations should not be accepted until there was evidence that the group of experts were being influenced, but committed to waiving the diplomatic immunity of all staff to help her investigation.

Agreement on an open consultation on the full report

On Tuesday afternoon, a significant amount of time was spent on finalising a date and general format for an open consultation that was agreeable to all EB Members. Having noted a general consensus among EB members to hold a consultation on the final EWG report, the EB Chairman, Dr. Zaramba asked for proposals on a suitable time to conduct the consultation. Whilst the Indian and Brazilian delegates asked for the consultation to be held sometime in advance of the WHA to allow sufficient time for all views to be discussed, the United States, Japan, and Hungary (on behalf of the EU) all requested that it be held as close to the WHA as possible. They expressed concern that smaller, developing country governments may not have the resources to attend a consultation in Geneva in addition to the WHA. Both the suggestion of Chile for an early web based consultation, and the idea of a one day consultation, were adopted as a solution to the divergent proposals. Dr. Chan and Dr. Zaramba opted for a one day consultation to be held on Thursday 13 May, five days before the opening of the WHA this year. The extent to which this consultation will be conducted in the public domain, and the degree by which comments will be invited from all stakeholders, remains to be seen.

Conclusions

The debate around the EWG report proved to be a contentious agenda item that, in the end, was discussed over two days and provoked numerous responses. The main points of criticism surrounding the report were the general diversion away from the conclusions on IP and public health contained in WHA resolution 6121 and the CIPIH report, and concerns about the transparency and integrity of the EWG process. Other concerns were related to notable omissions on: the role of technology transfer in improving access to medicine; the de-linking of R&D costs from the price of medicines; the report's compatibility with the human right to health.

The debate brought to light significant differences in the positions of some Member States and the discussions about the next steps for the report were influenced heavily by these divergent points of view. The agreement to hold a consultation prior to the next World Health Assembly was reached grudgingly, and it is clear that the discussion about the EWG and the implementation of the Global Strategy and Plan of Action is far from settled.

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