Government of the People`s Republic of Bangladesh
Ministry of Health and Family Welfare
Public Health Section

No-MOH&FW/DS(PH)/2007/36 Date: 28 February, 2007

Dr. Elil Renganathan
Executive Secretary
WHO's Secretariat on Public Health, Innovation and Intellectual Property
World Health Organization
20, avenue Appia
1211 Geneva 27
Switzerland

Dear Dr. Renganathan

Please accept the attached as the official submission of the Ministry of Health and Family Welfare of the Government of the People`s Republic of Bangladesh regarding the working documents of WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).

We appreciate your attention to this submission and look forward to participating in the IGWG process in the future. Thank you for this opportunity to submit these comments and we wish you good luck in this important mission.

Sincerely,

28/02/07

Dr. Shamim Ara Begum
Deputy Secretary
Ministry Of Health & family Welfare

Attached: Bangladesh submission (3 pages)

Submission by the Ministry of Health and Family Welfare
of the
People's Republic of Bangladesh
to the
WHO's Intergovernmental Working Group
on Public Health, Innovation and Intellectual Property Rights

February 28, 2007

The People's Republic of Bangladesh makes this submission in response to the invitation from the Director-General of the World Health Organization (WHO) to submit comments regarding the working documents of WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). We welcome this opportunity to provide the input of Bangladesh, one of the world's 50 Least Developed Countries (LDCs), one of the few developing countries on track to meet certain Millennium Development Goals, and a country with a fast-growing, world-class generic pharmaceutical sector.

General Comments

Bangladesh believes it is critical that at every stage of this process the IGWG makes it a top priority to engage and incorporate the input of developing countries, as its mission is to address primarily Type II and Type III diseases, those disproportionately affecting developing countries. Toward this end and with all due appreciation to the IGWG for its efforts thus far, we believe that in order for all Member States to have a genuine opportunity to submit and revise proposals and consider and respond to others, more time is needed. Bangladesh recommends seeking an extension of one year for the IGWG's work, postponing its delivery of the global strategy and plan of action until the Sixty-second WHA in early 2009.

Such an extended period will allow stakeholders time to meet regionally regarding priority-setting for Type II and Type III diseases and to help the IGWG "propose clear objectives and priorities for R&D," as required under WHA 59.24. Such priority setting will be of great assistance to all Members States, private foundations, and other actors in appropriately allocating resources and should not be rushed. More time will also enable Member States to examine several important new proposals, including multi-lateral or regional patent pools, prize funds and a global medical research and development (R&D) treaty, and we encourage the IGWG to schedule meetings to specifically examine these substantive proposals.

While we were unable to send a delegation to the first meeting of the IGWG in December 2006, upon reviewing the IGWG's report of this meeting we were very pleased with the contributions made by the other delegations from the SEARO region, including especially Thailand and India, and we would like to associate ourselves with their excellent contributions.

Capacity Building and Technology Transfer

Bangladesh recommends paying special attention to the capacity building "areas for action" identified in Subparagraphs 4(c), 5(b), 5(c), 5(d), and 5(f) of the "Elements of a plan of action" (A/PHI/IGWG/1/5, Annex 1) ("the Plan of Action document"). These areas point the way toward increased investment in research and development in developing countries that will have a lasting, positive impact on their innovative capacity. For example, though Bangladesh is presently a low prevalence country for HIV/AIDS, we remain vulnerable and must be proactive. Bangladesh's research institutions and burgeoning pharmaceutical sector are well poised to absorb knowledge and new technologies from the developed world, and have the potential to serve as a manufacturing center of generic versions of anti-retrovirals (ARVs) for HIV/AIDS for domestic use and for all LDCs. Therefore, we recommend that Subparagraph 5(f) is focused and perhaps amended to ensure that developed countries invest resources, share technology and engage in capacity building projects for research and production of ARVs within LDCs.

Further, Bangladesh may be unique among LDCs in its exceptional innovative research capacity, as home to world class scientific research and capacity building institutions, such as the *International Centre for Diarrhoeal Disease Research, Bangladesh* (ICDDR,B), the *National Institute of Preventive & Social Medicine*, the *Bangladesh Institute for Research on Diabetes, Endocrine and Metabolic Disorders*, the *Institute of Epidemiology, Disease Control and Research*, and the *Bangladesh Medical Research Council.* Since the knowledge and research capacity of such institutions offer particular value for other LDCs, we recommend intensifying LDC-LDC partnerships and networks, and promoting special incentives under Subparagraph 4(b) and Paragraph 5 of the Plan of Action document for LDC-LDC technology transfer and capacity building, as a distinct subset of South-South collaboration.

Access to Existing Medicines - Beyond TRIPS Flexibilities

One fundamental component of the IGWG's mission is to make recommendations for increasing access to existing medicines, vaccines and other technologies. Private incentives for financing innovation in medicine have until now been linked to high prices for medicines, whereby innovation is rewarded and future innovation is financed by the end user of the patented product. As the Commission on Intellectual Property, Innovation and Public Health recognized in its final report, while this may work relatively well for wealthy countries, it simply will not work in LDCs or other countries where consumers are not able to pay such prices and could create significant barriers to access to medicines in Bangladesh beginning in 2016.

In addressing this issue, it is necessary for the IGWG to go beyond reiterating existing TRIPS flexibilities. We encourage the IGWG to make specific recommendations regarding more effective and sustainable mechanisms for increasing access to existing medicines. Measures to increase voluntary patent licensing initiatives (such as the recent launch of "Baby Zinc" in Bangladesh) and non-voluntary licensing to generic drug manufactures would ensure that a competitive global market exists for generic products of acceptable quality. Multi-lateral or regional patent pools have the potential to prevent developing countries from having to contend individually with the pressures typically targeted at countries using TRIPS flexibilities, and should be examined.

Bangladesh recommends that, in addition to seeking other opportunities to incorporate these comments in its final global strategy and plan of action, the IGWG put special emphasis on Subparagraph 5(e) of the Plan of Action document, and that its scope is expanded to include downstream as well as upstream usage of technologies.

Innovation in Future Medicines

Creating new mechanisms for increasing access to existing medicines will only succeed if equal attention is paid to stimulating and rewarding investment in innovation. Therefore, another critical component of the IGWG's work includes proposing new obligations on governments to support public sector R&D and to provide effective incentives for private innovation for Type II and Type III diseases. Two new systems have been proposed to address these issues and they deserve serious consideration.

Prize Fund Model

We note with great interest a shift in the global policy discussion, away from the status quo of TRIPS-compliant patent regimes for medicines and toward new models for rewarding innovation, such as prize funds. The prize fund model separates the incentives for innovation from the prices of medicines. Innovation would be rewarded directly from nationally, regionally or globally managed prize funds based on improvements in health care outcomes, while ensuring low prices for medical innovations from generic competition immediately upon market entry. Funding for such prize funds could come from any number of instruments, such as a UNITAID-style airline tax, taxes on currency transactions, or direct contributions by governments.

The prize fund model has been introduced in U.S. legislation and favorably discussed by a number of prominent economists and health experts, including Tim Hubbard of the Wellcome Trust, James Love of

the Consumer Project on Technology, and Nobel prize-winning economist Joseph Stiglitz of Columbia University. We urge the IGWG to fully explore it and make specific recommendations on it to the WHA.

Bangladesh recommends that, in addition to seeking other opportunities to incorporate these comments in its final global strategy and plan of action, the IGWG add the following text to Subparagraph 6(c) of the Plan of Action document: ", such as the prize fund model".

Global Medical R&D Treaty

We were particularly pleased that the SEARO and EMRO regions officially supported consideration of the proposed global treaty on medical R&D at the December 2006 IGWG meeting, and we join them in calling for its formal consideration. This proposal, first submitted to the WHO in 2005 by 162 leading medical researchers, NGOs, parliamentarians, government officials, and other stakeholders, presents a potentially historic opportunity for countries to simultaneously pursue their moral obligations to ensure access to medicines, while meeting appropriate obligations for investments in medical R&D for Type II & Type III diseases. Such a treaty warrants examination as an alternative to the existing WTO requirement that all member countries become TRIPS-compliant for medicines.

Bangladesh recognizes that any system of sustainable financing for priority medical R&D will cost money. We believe that everyone should participate in funding priority R&D, as appropriate. Under the proposed treaty, funding obligations could be tied to any number of macroeconomic indicators. While mandatory treaty obligations might not be achievable immediately, the IGWG should consider recommending incentives based on non-binding, voluntary standards for investment. As a nation required to become TRIPS-compliant by 2016, one possible incentive of particular interest to Bangladesh would be to reward countries that met such standards with lower patent requirements than those mandated by TRIPS.

We recommend that, in addition to seeking other opportunities to incorporate these comments in its final global strategy and plan of action, the IGWG provide sufficient resources and time for Member States to meaningfully consider and provide recommendations regarding the treaty proposal mentioned in Subparagraph 3(i) of the Plan of Action document.

Bangladesh is confident that given an extended time period and more opportunities to meet with other Member States, we will be able to provide more specific and helpful input to the IGWG in its effort to provide the WHA a global strategy and plan of action. We appreciate your consideration of these comments and look forward to participating in this important process.