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Public Health, innovation, and intellectual property: global strategy and plan of action

Mr. President

India commends the Director General for making progress on the various components of the "Quick Start Programme". The mapping of global R&D activities would lead us to identification of research gaps and would help research priority setting. Standard setting for traditional medicines in the developing countries is also welcomed. India has a strong traditional medicine structure which has now been integrated with our National Flagship Programme, the National Rural Health Mission.

We would call for strengthening the WHO pre-qualification programme urgently and to place more HIV/AIDS and anti-tuberculosis drugs under the pre-qualified list. As of now, only 3 anti-tuberculosis drugs have been pre-qualified.

India welcomes the full report of the Expert Working Group on Research and Development Financing that was set up in the context of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, made available by WHO.

We have studied the report and find that the EWG report has failed to capture the variety of problems that are linked to IP. The problems emanate from curbing the flexibilities under the WTO's TRIPS Agreement and mandating TRIPS plus measures such as Data Exclusivity, patent term extensions, enhanced scope of border enforcement provisions, lower threshold for patentability leading to the problem of evergreening, etc. The developed countries are not only making their domestic IP laws TRIPS plus but are also forcing the developing countries to accept such measures through Free Trade Agreements or the financial aid route. An issue of grave concern is the draft Anti-Counterfeit Trade Agreement (ACTA) among the developed countries and some developing countries. It has provisions that would allow seizure of generic drugs in transit and thus make the trade in cheap but QSE generic drugs illegal and deny the patients an access to such drugs.

On the other hand despite the increase in the number of patent grants, products with new therapeutic value are not emerging. Other abuses of patent rights h

issues are not sufficiently captured in the EWG report and it only focuses on the role of IP as an incentive.

The Report mentions the problem of lack of access including access to knowledge, but it simply says that the solution then would be buying out patents and compulsory license. While buying out patents and creating patent pools could help meet the requirements of developing countries but unless there is promise of adequate financial grants from the developed countries for the same, purchasing of the patents is unlikely to be easy. It also states that growth of science and technology would be hampered if intellectual rights are not protected. While respect for IP is acceptable, the curbing of TRIPS flexibilities could impair the access of patients to competitively priced generic drugs. Unfortunately dealing with IP is not as simple as buying out the patents since the patent holder is either not willing to give up his patent or the cost of buying out the patent is prohibitive. Issuing compulsory license is also a challenge for developing countries particularly as result of the pressure asserted by developed countries to not issue such licenses. We also need to keep in view that despite the Doha Declaration on Public Health of 2001 leading to creation of a compulsory licensing system to export to needy countries that lack manufacturing capacity, the provision has been used just once in last around 7 years. Further neither buying out of patents or compulsory license resolves the problem of access to know-how linked to the patented invention.

On page 16 of the report, a frame work to identify missing incentive structures for the production and distribution of knowledge has been depicted in a form of a quadrant. As per quadrant 1, the EWG states that the challenge is one of demand when knowledge exists but it is predominantly relevant to poor countries. On this it may not just be the case of demand but also that the returns are not sufficiently big enough to attract the MNCs to invest in the knowledge. Thus in such a situation, IP would not be an appropriate incentive and other incentives need to be explored. As regards quadrant 2, the report states that when knowledge exists and the knowledge is applicable to poor and other countries, IP may pose a barrier in terms of access. There is also another problem which is not explicitly mentioned i.e. that the products that emerge are likely to be oriented towards the needs of developed countries and may not be appropriate for use in developing countries. Here again IP may be a barrier as it may prevent the use of existing knowledge to develop products suitable for developing country needs. The same analysis would apply to quadrant no. 3. However the EWG promotes the idea of tier pricing as a solution to access. It appears to ignore the better solution in improving generic competition. Some

able to deliver the knowledge required. To deal with this problem the EWG report runs through several options. Some of the options have been analysed under the section on funding allocation and the EWG has itself criticized some of the options discussed e.g. orphan drug legislation. In fact in relation to tax credits the EWG itself has stated in Annex 2 that such an option would not meet the agreed criteria. Nevertheless these options are still mentioned at pg 19. The EWG however concludes that Partnership for Product development (PDP) is the most promising approach. The report does not give much insight into why the EWG feels that PDPs are so successful. The report mentions several PDP initiatives but fails to elaborate on the successes of such PDPs in delivering products for diseases of developing countries.

The EWG report gives health impact scores to the proposals without actually detailing or providing evidence to back those scores. For instance the EWG states that the impact of FRIND was "good" but gives no evidence as to why it rated the proposal "good". For instance it does not give evidence of the extent to which FRIND would actually ensure competition, promote generic manufacturing and promote access to medicines to countries that need it.

It then leaves what should have been the most important part of the work of the EWG to future work when it states "in-depth analysis is needed to determine which of the mechanisms or combination of mechanisms described above is most suitable for providing reliable, long-term, centralized funding and to link the funding to the efficiency of the partnerships". The EWG having assessed the proposals should have proposed the so-called combination of mechanisms that would deliver for health. However it fails to do so. It is also interesting to note that the conclusion appears to be more concerned with "efficiency of the partnerships" than actual deliverables in terms of products and affordability.

While the EWG has established the importance of Precompetitive Research and Development Platforms in saving costs, it does not provide ideas or any analysis on how to increase investment in platforms for developing country targets and the investment design that would best serve the needs of developing countries.

Finally the EWG rightly states that access to products of Type 1 diseases remains unresolved. However its explanation for the urgency of a resolution is limited to

EWG does not feel the same urgency for other developing countries although these countries have vast populations that do not have access to medicines.

Comment on Annex 1 & Annex 2

The EWG claims that over 90 R&D proposals were compiled from various sources. These 90 R&D proposals and their sources should have been included as part of the EWG report. With regard to Annex 2 the EWG lists proposals that supposedly did not meet the agreed criteria. The manner of presentation has several shortcomings. Firstly no references are provided that would indicate the source of the proposal. Secondly there is no discussion or analysis on why the EWG concluded that these proposals did not meet the agreed criteria.

We therefore suggest an [illegible]
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