DRAFT Intervention on Agenda item No. 11.20 'Counterfeit medical products', 63rd WHA

[Under this agenda item the Secretariat has issued a Report on 'Counterfeit medical products' (A63/23 dt April 22, 2010) and an information document on IMPACT (A63/INF.DOC./3)]

At the outset, let me reiterate that India attaches the highest importance to access to affordable, quality, safe and efficacious medicines. It has been the effort of the Indian government to promote universal access to medicines and health for all as a part of our commitment to the Right to health as an integral part of Economic, Social and Cultural Rights. We support international cooperation to promote these objectives. We also support international efforts to fight against medical products which do not meet QSE standards. India also upholds the primacy of health over IPR issues as agreed in the Doha Declaration on TRIPS and Public Health.

2. My delegation has taken note of the Secretariat Report on 'Counterfeit medical products' (A63/23 dt April 22, 2010) but we continue to have several concerns regarding the use of the term 'counterfeit' in the work of WHO.

3. Our first concern is regarding the nomenclature of this agenda item "counterfeit medical products". If the intention of the WHO is to deal with the challenges to public health posed by medical products of compromise quality, safety and efficacy, the agenda item should be appropriately re-christened. We would like to recall the WHO Sectt Discussion Paper (2009) on Legal Aspects of Defining "Counterfeit Medicines". The Paper concludes that "given the very specific connotations that the term "counterfeit" carries in the context of intellectual property law, it may be counterproductive to define a "counterfeit medicine" as encompassing anything more than the narrow class of trademark infringement as contemplated in the TRIPS Agreement. Also, adopting an overbroad definition of counterfeit medicines has the potential to handcuff countries from utilizing flexibilities in the TRIPS Agreement that can improve access to safe, effective and affordable medicines. Elaborate discussions on this term have taken place in the past. We recall the suggestion by the Director General at the 62nd WHA to replace the use of the term 'counterfeit' with an appropriate term to describe medical products of compromised quality, safety and efficacy. It is time to work on the suggestion.

4. In India's view, the term 'counterfeit' is a juridical term and is linked to Intellectual Property Rights. India's understanding of the term is in line with the definition of 'counterfeit trademark goods' contained in the TRIPS Agreement (Art 51, footnote 14(a)). TRIPS, as a multilateral legal instrument, has been incorporated into the national legislations of the 153 WTO Members, including India. Therefore, any issue regarding the definition of 'counterfeits' can be dealt with only in the WTO which is the custodian of the TRIPS Agreement. WHO, with its public health mandate, should remain focused on QSE issues.

5. The Secretariat Report A63/23 acknowledges (para 5) that "no accurate data on the extent of the problem exists". The Report also mentions (para 4) the difficulties in compiling data pertaining to counterfeits. The dubious method of data collection by national authorities has been highlighted by Members in the past. Projected data has often conflated different terms

(counterfeits, substandard etc.) and given misleading proportions of the problem. In the absence of a clear understanding of the term, any statistical analysis is devoid of value.

6. Let me also refer to the survey carried out through the WHO circular letter of Nov 5, 2009 regarding Members' use of the term "counterfeit medicines and/or equivalent in national legislation". We expected an analysis of the Survey to be presented in this meeting. However, we note from the Secretariat Report A63/23 that an analysis of the feedback received from Members will be presented to the Expert Committee on Specifications for Pharmaceutical Preparations for further discussion. While we await DG's report to the next Executive Board meeting, the preliminary summary presented to the Member States at an open forum held in Geneva on 26 March 2010 leads us to certain obvious conclusions. For instance, it is clear the Members who responded use different terminologies including "counterfeits", "falsified", "illicit", "illegal", "unregistered", "unauthorized", "adulterated" etc. Clearly there is no consensus around the use of the term 'counterfeits'. Therefore, pursuing the issue of 'counterfeits', without a consensus on its use, is a non-starter. Members need to explore other alternatives to describe medical products that compromise QSE.

7. Another concern we have is on viewing QSE issues through the prism of IPRs and deliberately creating a confusion between QSE and IPR issues. The work of IMPACT on counterfeits is premised on this duplicity and is only furthering the work of the proponents of TRIPS+ IPR enforcement norms. We are concerned at efforts to extrapolate this QSE/IPR confusion to linking counterfeit medicines with generic medicines which are perfectly IPR compliant and form the back bone of public health programmes of developing country governments and those of civil society organizations like MSF, Clinton Foundation, Gates Foundation etc.. The world needs to draw lessons from the fallout of this deliberate confusion in the form of the numerous drug seizures of generic drug consignments at EU ports. The EU has justified the drug seizures on the ground of tackling sub standard/fake/spurious medicines but the actual impact has been denial of generic drug supplies to several developing countries including LDCs. Some of the countries directly affected by the seizures include [Brazil, Peru, Colombia, Ecuador, Mexico, Nigeria, Venezuela, and Vanuatu]. Besides impeding the efforts of the WHO in developing countries, the other adverse systemic impacts include (i) impeding the principle of universal access to medicines, (ii) increase in national public health budgets, (iii) creating obstacles to legitimate trade of generic medicines, (iv) constraining use of TRIPS flexibilities and, (v) impairing the efforts of civil society organisations engaged in providing medicines and improving public health in the least developed parts of the world.

8. Let me also share India's views regarding IMPACT. It is an established fact that IMPACT has neither been created on the basis of a decision of Member States nor have Member States approved its Terms of Reference. There is no intergovernmental oversight by any organ of the WHO of IMPACT's operations and work.We are concerned about its non-representative nature, lack of transparency, and the conflicts of interests arising out of the involvement of big pharma. The FAQs posted on the IMPACT website acknowledge that "to date, participation in task force meetings has not required any declaration of interests". There is considerable opacity regarding source of funding and decision making processes of IMPACT. Members will recall that it was largely for these reasons that a proposal to endorse the recommendations of IMPACT was

rejected in the 124th Executive Board meeting in Jan 2009. Given this background, we do not understand how IMPACT "has become the main conduit for WHO's work on counterfeit medicines" as mentioned in para 16 of the Secretariat Report A63/23. We wish to categorically mention that India cannot accept any IMPACT document becoming a WHO document without express consideration and approval in the WHO governing bodies. The Secretariat Report A63/23 claims (para 17) that two different web sites have been established for IMPACT and WHO's new anti-counterfeiting Programme. However we note that both are housed on the same website i.e http://www.who.int.

9. In our view, the work of IMPACT serve less the purpose of Public Health and more the purpose of IPR enforcement and Market Access for developed countries and the big pharmaceutical companies. It is not surprising that the G-8 Summit Declaration at Heiligendamm in 2007 endorsed the work of IMPACT in the context of IPR infringement and the economic losses due to counterfeiting and piracy. Clearly, IMPACT is regarded is an instrument of IPR policy and market access by some of the largest economies of the world. We consider IMPACT as one of the prongs of the multipronged TRIPS+ enforcement drive of some developed countries and originator pharmaceutical companies. The deleterious impact of TRIPS+ enforcement, including drug seizures, on access to medicines is clearly brought out in the Report of the Special Rapporteur on the Right of Everyone to Enjoy the Highest Level of Health submitted to the 11th Session of the Human Rights Council in June 2009.

10. It is our strong recommendation that WHO should continue its focus on its mandate on public health and play its role in strengthening national health surveillance systems and promoting access to medicines. Diversion into issues of IP enforcement will dilute WHO's work in its mandated areas. In this context and in the spirit of constructive engagement, SEARO has submitted a Resolution on 'MEASURES TO ENSURE ACCESS TO SAFE, EFFICACIOUS, QUALITY AND AFFORDABLE MEDICAL PRODUCTS' which situates the problem in the public health context and seeks WHO's support in strengthening the national drug regulatory authorities to ensure the availability of quality, safe and efficacious medical products.

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