SEARO INTERVENTION *(as delivered on 21 May, 2011)*

WHA-64, WHO, Geneva, 16-24 May, 2011
Agenda Item No 13.7 "Sub-standard / Spurious / Falsely-Labelled / Falsified / Counterfeit Medical Products"

Mr Chairman,

I make this statement on behalf of countries of the South East Asian Region.

Countries of the SEAR region wish to reiterate the importance they attach to access to quality, safe, efficacious and affordable medical products. The problems regarding access and affordability posed by high prices, weak drug regulatory infrastructure and other capacity constraints are further exacerbated by efforts from some quarters to promote **deliberate confusion between intellectual property considerations and quality related issues**. **In this context, the 63rd Session of the World Health Assembly held in May 2010 took a momentous decision - WHA 63(10) - to establish a Working Group of Member States on sub-standard / spurious / falsely-labelled / falsified / counterfeit medical products.** This corrected the anomalous implementation of the World Health Assembly Resolution WHA 41.16 of 1988 which failed to effectively address issues related to quality, safety and efficacy but instead strayed into the domain of intellectual property rights' enforcement.

02 Countries of the SEAR region have high hopes from the Decision WHA 63(10), which set up a Working Group of Member States to examine WHO's role in ensuring availability of quality, safe, efficacious (QSE) and affordable medical products as well as WHO's role in the prevention and control of medical products of compromised QSE. To ensure that WHO does not deviate from its public health mandate, the Decision also called into question the relationship between the WHO and IMPACT.

03 **SEAR countries commend the work of the Working Group under the stewardship of Ambassador Darlington Mwape of Zambia.** The meeting held between 28 February and 2 March this year provided the first steps in the right direction by clearly differentiating between public health and IPR issues. Progress has also been made regarding using the term "Sub-standard" separately from the other terms commonly used for compromised safety, efficacy, quality such as "spurious/falsely-labelled/falsified/counterfeit medical products". It is imperative that the Working Group continue its work. It is also pertinent to recall Director General Margaret Chan's remarks during the Working Group's meeting in February when she mentioned that this area has "has become clouded with confusion and controversy" and she correctly identified that the priority of WHO is to "protect populations from the harm caused by poor quality, unsafe medicines" and prioritised WHO's approach to include "strict regulatory control on the market, strict enforcement of quality standards and diligent pharmacovigilance". SEAR countries also endorse WHO's support "to promoting use of generic products through guidelines for conducting bio-equivalence studies, pre-qualification programmes" and other means.

04 Countries of SEAR region note with some relief that in response to the strident demands made by them and a large number of other developing countries, International Medical Products Anti-Counterfeiting Taskforce (**IMPACT) has shifted its office out of the WHO and relocated to Italy. We continue to hold the view that IMPACT has a predominant IPR agenda and has no mandate to be associated with the WHO in any way. The WHO should therefore, terminate any remaining links with IMPACT if it has to pursue its global public health mandate with undivided attention**. **We understand that such an action should not be procedurally difficult since IMPACT's creation or bringing it into the WHO was not based on the decision of WHO governing bodies but was taken by the WHO Secretariat.**

05 While being appreciative of the work of the Working Group on SSFFC, SEAR countries also wishes to sound **a few words of caution**. **We should not go down the path of defining or proposing terminologies since it has been with great effort that the term 'counterfeit' has been replaced by SSFFC in WHO's vocabulary.** We do not wish embark on another arduous exercise to replace 'counterfeits' with another contentious term which may not be understood uniformly by all Member States since Member States use different terminologies to identify medical products of compromised QSE. **We need to leave to national authorities the task of interpreting what QSE means in the context of their national standards and determining appropriate terminology rather than the WHO prescribing such terminology.**

06 **Another word of caution SEAR countries would like to sound is that discussions on IPR enforcement should remain outside the scope of our work relating to QSE issues.** The seizure of several generic drug consignments in recent years at EU ports, which led to denial to access to affordable generic medicines for vast populations of developing countries and LDCs, is not too distant in our memories**. We also wish to express our serious concern at the TRIPS+ IPR enforcement initiatives** being pushed through (i) multilateral fora, (ii) plurilateral agreements such as Anti Counterfeiting Trade Agreement (ACTA) and (iii) negotiation of IPR Chapters in RTAs. **These could create impediments to access to affordable medicines arising out of**

07 SEAR countries are convinced that the only way to deal with medical products of compromised QSE is to strengthen DRAs. The WHO has a crucial role to play in this effort. SEAR countries also wish to recall Article 1 of the WHO Constitution which states that "The objective of the WHO shall be the attainment by all peoples of the highest possible level of health". Member States have high expectations from the WHO, being the apex inter-governmental organization on public health, to continue playing its role in strengthening national health surveillance systems, drug regulatory authorities, promoting access to medicines and scrupulously distancing itself from IPR enforcement matters.

08 In conclusion, all 11 Member States of the SEAR call upon the World Health Assembly :

i. To **EXTEND the term of the Working Group on SSFFC** as recommended in para 20 of the Report of the Working Group (A64/16).

ii. To URGE the Working Group to **draw up a clear schedule for meetings** so as to conclude its work and report to 130th EB and to be considered by 65th WHA. SEAR countries strongly suggest that the next meeting should take place in next month, i.e. June 2011. Thereafter, if required, there should be at least three formal meetings between WHA-64 and WHA-65. Informal inter-sessional consultations of Member States and stakeholder consultations will also be necessary. Member States need to make up for the valuable nine months loss in constituting and convening the first meeting on the Working Group in February this year.

iii. To URGE Member States to deliberate in the Working Group the possible establishment of **a Member State driven mechanism within the WHO to deal with Quality Safety and Efficacy issues, including, strengthening national drug regulatory authorities.** Such a mechanism (i) should be drawn up in a transparent manner, (ii) should avoid conflicts of interests, (iii) should be Member State driven, and (iv) should have a clear mandate from the WHO governing bodies.

iv. To CALL UPON the **WHO Secretariat to start, or if work has already started, to continue its work on areas where convergence is reached by the Working Group** on SSFFC without losing any time.

v. Last but not the least, to INSTRUCT THE WHO SECRETARIAT to terminate ALL WHO relations with the IMPACT till the outcome of Working Group is finalised and its recommendations are endorsed by the 65th World Health Assembly. Such measures should include, interalia, removal of the WHO logo from IMPACT communications and their website.
