

19 May 2015

**Statement to the 68th World Health Assembly   
on agenda item 17.3 Substandard/spurious/falsely-labelled/falsified/counterfeit medical products.**

Thank you, Chair, for thisopportunity to address the distinguished members of the World Health Assembly on behalf of MMI, PHM and TWN.

The term SSFFC MP originally seen as an interim arrangement has continued in use for more than 5 years. The term “counterfeit”, which legally refers to specific trademark violations conflates issues of poor-quality medicines (a clear global public health problem), with IP enforcement issues. We call upon the MS to shed the trade and IP enforcement considerations which constitute the core interests of the pharmaceutical Industry, and work on the core public health issues which are the mechanisms and processes that guarantee access to affordable medicines with quality and safety. The obtuse usage of SSFFC clouds discussions regarding medicines with compromised quality, safety and efficacy. We urge MS to undertake a work program with an objective to finalise more useful terminology.

While the traceability of medicines is necessary for the recall of substandard medicines, the current defense of in-transit seizures of generic medicines, notwithstanding that they are “in compliance with the regulatory requirements of the country of export and the country of final destination” is an attack on access to legitimate generic medicines. The MSM should make it absolutely clear that in transit seizures of generic medicines clearly belongs on the list of actions, activities and behaviours which lie outside the mandate of the MSM, and has no justification in terms of defending standards of quality, safety and efficacy.

WHO’s budget crisis has impacted badly on the Organization’s support for development and effective functioning of national and regional drug regulatory agencies. The freeze on assessed contributions must be lifted if WHO is to fulfill its mandate, including ensuring access to safe and effective medicines, appropriately used.

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