OPEN Letter to the Chairperson of WHO Working Group on Substandard

Date: 24 October 2011

Source: KEIonline.org

We the undersigned would like to highlight some key concerns and recommendations for the consideration of the Working Group in its upcoming session on 25-28th October 2011.

We are of the view that the upcoming meeting is an opportunity for Member states to reenergise WHO's work-programme on medicines particularly in refocusing WHO's attention to facilitate availability of quality, safe and efficacious medicine at an affordable price and on building regulatory capacity of developing countries. We believe that these are critical pillars to tackling the proliferation of medical products of compromised quality, safety and efficacy (QSE).

Thus we are deeply concerned with the lack of human and financial resources allocated to WHO's programme on medicines. Secretariat's paper (A/SSFFC/WG/2/2) highlights budgetary constraints, the worrying dependence of WHO's work program on QSE on extra budgetary resources and the risk of loss of independence, adversely affecting the capacity to address priorities set by member States. This situation has crippled the ability of WHO to show leadership from a public health perspective. It has also enabled other entities (e.g. Interpol, World Customs Organization (WCO) to appropriate a public health matter and to instead advance an agenda on enforcement of intellectual property.

*As such we urgently call on WHO member states to restore WHO's independence and to reassert its leadership by ensuring that WHO's medicines programme receives the funds it needs particularly from WHO's regular budget to fulfil its responsibilities to Member States. *

One of the important objectives of the Working Group is to bring clarity with regard to the terminologies and definitions pertaining to medical products with compromised QSE.

On this matter, several of the undersigned organizations have on previous occasions highlighted concerns with WHO's continued use of the term 'Counterfeit' to also refer to medical products of compromised QSE.

The term 'Counterfeit' is defined by the WTO-TRIPS Agreement as referring to a specific category of trademark violation[1] <#_ftn1> and in some legislation to all other intellectual property (IP) violations as well. Against this background WHO's use of the term 'Counterfeit' to refer to compromised medical products would result in confusion and also offer a convenient route for proponents of an extended IP agenda to press for inappropriate IP enforcement standards in developing countries under the false premise that such standards will deliver quality assured pharmaceuticals to the people.

The Secretariat has also recently agreed that the term 'counterfeit' is 'perceived as associated with intellectual property rights' rather than with 'public health'.[2] <#_ftn2> *Thus we urge Member States to agree in the upcoming Working Group to the discontinue using the term 'counterfeit' to refer to medical products of compromised QSE. *

Further from a public health perspective, circulation of any medical product of compromised QSE is problematic and therefore needs to be withdrawn from the market. Thus WHO should focus on tackling all aspects of medical products of compromised QSE and should not limit itself to only dealing with a select category of compromised products to the exclusion of others. Moreover *determination of what terminologies should be used is a process deliberated and guided by Member states. It is not a decision to be taken alone by technical committees of WHO.

On WHO's relationship with IMPACT, we reiterate that WHO should disassociated itself from IMPACT. Significant concerns have been raised about participation in IMPACT's activities especially the central role played by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in IMPACT's activities, the lack of transparency surrounding IMPACT's activities, and lack of accountability as IMPACT has operated outside the purview of WHO member states.[3] <#_ftn3>

Concerns have also been raised about IMPACT's link to entities (e.g. OECD, MNCs, WCO, Interpol) which are very much engaged on matters pertaining to IP enforcement under the banner of 'anti-counterfeiting activities. This further raises concern about conflicts of interests, about which WHO by its own admission, has taken no measures to address.[4] <#_ftn4> It is also particularly noteworthy that IMPACT has been identified as an initiative involved in IP enforcement[5] <#_ftn5>.

Another key concern pertains to outputs of IMPACT particularly its Principles & Elements for National Legislation Against Counterfeit Medical Products which includes a call for addressing counterfeit medical products *inter alia* by establishing or enhancing intellectual property legislation; contains provisions that could result in TRIPS plus implementation as well as non-tariff barriers for trade in medical products which could undermine access to affordable medicines, become entry barriers for generic industries particularly of developing countries and affect use of flexibilities such as parallel importation of good quality medicines. These elements also promote measures that have led to seizures/detainment of good quality pharmaceuticals in transit at European ports on request of MNCs on suspicion of IP violations, which resulted in delayed treatment for developing country patients.[6] <#_ftn6>

Noting these concerns and the wide recognition that IMPACT lacks credibility and legitimacy, we strongly urge WHO Member States to agree that WHO disassociates itself from IMPACT and to stop hosting IMPACT's website or rely on the documents produced by IMPACT as a basis for its work on QSE.

***We also strongly urge the Working Group to** reorient WHO's programme towards addressing the real causes and solutions to medical products with compromised QSE in particular focusing its attention to dealing with high prices of pharmaceuticals, ensuring timely availability of affordable pharmaceuticals, as well as strengthening the capacity drug regulatory authorities. *

We understand that proposals on various mechanisms including multi-stakeholder and coordination mechanism may be considered by the Working Group. We caution against these mechanisms particularly as WHO's work on QSE must be driven by its Member states and not by other organizations or entities. Further we are also concerned about WHO's cooperation with other organizations such as Interpol and the World Customs

Organization particularly as these organizations are known to continue using ‘counterfeit’ to refer to medical products of compromised QSE and promote IP enforcement.

*We stress that any mechanism that is developed should be intergovernmental in nature, open to all member states and to observers in official relations, with decision-making powers remaining with WHO Member states. Member States should work to empower and guide WHO’s work on QSE particularly in enhancing its ability to take specific measures to facilitate availability of quality affordable medicines and to build regulatory capacity. *

Keywords: Letter / WHO / Substandard