10.3 SSFFC

Introduction

At the WHO’s Executive Board, member states were asked to note the report of the third meeting of the Member State mechanism on substandard/ spurious/ falsely labelled/ falsified/ counterfeit medical products, which met in Geneva from 29 to 31 October 2014.

Report of discussion

Use of term ‘Counterfeit’

Member state interventions served to highlight the persistent problem of including the term ‘counterfeit’ to define the problem of fake and substandard medicines. Some member states, like that of the intervention by Kuwait on behalf of EMRO, used this term in their interventions, asserting that ‘counterfeit’ medical products were a danger to health.

Nepal (on behalf of SEARO region) stated that the contestation over SSFFC and ‘counterfeit’ involved MNCs and reflected the conflation of IP with the issue of medicines quality.

Brazil reminded member states that the suspension of legitimate generic medicines in-transit was the catalyst for the creation of the member state mechanism, and that focus should be on public health and not the protection of knowledge (intellectual property). This was also emphasised by India. UNASUR (Uruguay) echoed these concerns and stated that safe medicines which meet regulations in origin and destination countries should not be seized in transit if they not a threat to public health. Uruguay highlighted the sovereignty of medical authorities to ensure safety. Brazil raised concerns regarding the handling of this issue outside the WHO, and India called on MS to maintain WHO leadership.

Iran, India and the Republic of Korea called for a clear definition of ‘counterfeit’, with Iran pointing out that in their country, counterfeits are defined as those medicines outside the drug distribution chain.

PHM took the opportunity to deliver a statement to the Board (hosted by MMI) which called on member states and WHO to drop the term counterfeit from the MSM.

Crime

Japan and Libya emphasised the need for regulation of supply channels, including informal channels like the internet. Libya framed SSFFC as a crime, and Russia referred to MEDICRIME in its intervention. India stated that there is a need to combat criminal networks.

Capacity

Kuwait on behalf of EMRO (and supported by Lebanon) called on MS to actively report to WHO suspected cases of SSFFC through WHO global surveillance.

MS in the African Union stated there is a need for huge investment and capacity building in the region to be able to implement the work plan.
Kuwait on behalf of EMRO stated that technical capacities and financial resources in the region are insufficient to meet the challenge of SSFFC. Lebanon called on WHO to provide technical assistance for surveillance and monitoring of SSFFC.

**Access to medicines**

Lebanon, Iran, India and UNASUR emphasised the need for accessibility and affordability of good quality medicines and the strengthening of health systems. India stated that local production and technology transfer was needed to improve access and thus reduce SFFFCC. Mexico suggested a study to investigate the links between access and safety of medicines. This was supported by Lebanon, who along with Iran, emphasised the need for strong regulatory authorities.

**Financing**

The US on behalf of Americas supported priority actions in the mechanism and urged that they be adequately funded.

South Africa called on MS to move forward on agreed upon items and reiterated the need for member states to work on financing. This was repeated by UNASUR (Uruguay), Mexico and Thailand, who raised concerns over the budget needed for implementation and asked the DG to present a reasonable budget. Nepal (SEARO) stated that the voluntary nature of financing for the work plan was problematic, in particular in light of the budget structure of the WHO, by which much of the budget is from voluntary contributions that are earmarked for specific areas. Nepal asserted that voluntary contributions may lead to donor distortions, and thus urged that funding for the work plan come from the regular budget (assessed contributions).

**Postpone evaluation**

In the report of the third meeting, the MSM decided to request the WHA to postpone the scheduled review of the MSM by one year. At the EB, member states recognised the importance of continuing the MSM and supported the request to postpone the evaluation of the mechanism until 2017.