Agenda Item: 8.6 Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products

Statement

MMI would like to address this agenda item, this statement is supported by PHM and TWN.

We congratulate Member States for arriving at a consensus on the terminologies and working definitions that refer to quality compromised medical products. These new definitions put an end to the mistaken endeavour of conflating quality of medicines with alleged IP violations. This conflation has been systematically used to promote IP enforcement standards instead of pursuing a public health strategy to address the issue of medicines with compromised quality. We understand that as per the new decision WHO will stop using the term counterfeit to refer to medicines of compromised quality or those produced or marketed without license in a territory.

The new definition of falsified medical products excludes patents and other forms of IP infringements from the scope of the definition. Further, a medicine cannot be classified as falsified medicine simply because it is not registered in one country. This brings fresh approaches to address the issue from a public health perspective and to move away from the WHO-IFPMA definition of counterfeit medicines developed in 1992, which led to the conflation of IP and quality of medicines. The new definitions and terminologies proposed represent a course correction after two and half decades.

We call upon the Secretariat to reassess the threat of quality-compromised medicines in the light of new definitions. The Secretariat needs to take note of the definitions and to develop a public health oriented approach and to address the root causes for the circulation of substandard and falsified medical products. The Secretariat should rework on the study on socio economic impact of SSFFC medical products.

We also call upon the Secretariat and Member States to communicate the new definitions to other international organisations such as INTERPOL, WCO, UNODC etc. to stop conflating IP related issues with quality of medicines.