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IFPMA defends involvement of IMPACT on counterfeit issue

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Even as the debate got hotter over the issue of counterfeits with NGOs objecting to World Health Organisation's role and India taking the dispute of drug seizures to the World Trade Organisation, the International Federation on Pharmaceutical Manufacturers and Associations (IFPMA) chose to defend WHO and IMPACT.

However, IFPMA sought to delink patent and counterfeit clause, in line with Indian claims. "A medicine that is authorized for marketing by one regulatory authority but not by another should not be regarded as counterfeit on these grounds alone in the latter's territory," the IFPMA said, in its ten principles on the counterfeit medicines.

"Counterfeit medicines threaten the full spectrum of legitimate medicines. They can be falsified versions of patented medicines, generic medicines or over-the-counter medicines and exist in all therapeutic areas (even traditional medicine). They range from medicines with no active ingredients to those with dangerous adulterations," according to one of the principles.

Patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents. Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the fraudulent production of falsified versions of genuine approved medicines. All sub-standards are not counterfeits. A medicine which is approved and legally manufactured, but does not meet all quality criteria, is substandard and may pose a significant health risk, but should not be regarded as counterfeit. However, all counterfeits are, by their nature, at high risk of being substandard, said the IFPMA.

"Government regulatory and enforcement authorities must be fully vested with the proper power and adequately resourced to fight counterfeits. While the incidence of counterfeit medicines occurs in both developed and developing countries, the problem is more prevalent in countries where regulatory oversight and enforcement are weak. Stopping the international trade in counterfeit medicines is vital. Countries should be encouraged to adopt border measures that will stop trade in medicines that do not contain the ingredients that they purport to contain," the federation said.

It also defended the IMPACT, which according to it, is the sole global initiative launched by regulators to specifically focus on combating counterfeiting of medical products and hence it should be supported. IMPACT brings together the expertise of medicines' regulatory agencies, enforcement agencies, healthcare providers and the private sector in a unique global platform. "As the leader on global health matters, and particularly with respect to threats to public health in developing countries, the World Health Organization has a key role to play. The WHO is currently the home of the IMPACT secretariat," it said.

Besides a host of NGOs raising concern on the topic and the role of WHO and IMPACT, the debate has also escalated after India and Brazil filed requests for consultations with the European Union and the Netherlands over the seizure of generics medicines in transit through Europe. This is the first step towards a dispute settlement case, and if issues cannot be resolved via consultations then formation of a dispute settlement panel could be requested in the coming months