OPPI, IDMA come out with contrasting views on definition of counterfeit drugs

January 14, 2009 Pharmabiz, Ramesh Shankar, Mumbai

While the government and the industry thrashed out a semblance of consensus on India's viewpoint on the definition of counterfeit drugs that will be presented at the WHO executive board meeting later this month, two major industry associations in the country, OPPI and IDMA, took a totally contrasting view on this controversial issue.

While the OPPI wholeheartedly supported the WHO initiative, saying "The proposed WHO-IMPACT definition is a step in the right direction and we remain aligned to the changes that are being proposed by WHO-IMPACT," the IDMA opposed it tooth and nail saying that "….we earnestly urge the government to oppose the IMPACT definition as it stands today. Both the original definition as well as the one arrived at Bonn (25-26 Nov 2008) are totally unacceptable being against the developing countries and the generic industry. They seem to be part of MNC's IPR enforcement agenda through back door."

The IDMA further pleaded with the authorities that instead of confining itself to health hazard aspect of counterfeit drug problems, IMPACT is trying to expand the definition of counterfeit to include IPR and other (so called) violations. "We are unable to accept this approach because the criminality aspect or 'mens rea' associated with health issues do not apply in cases of IPRs or regulatory matters. IPR issues are commercial matters and regulatory matters are administrative matters unconnected with public health crimes. Therefore, they have to be dealt with accordingly. We feel that such expanded meaning will hurt the broad public interest; generic industry and its legitimate international trade. That will also be against the objectives of WHO and WTO," the IDMA said.

Meanwhile, the OPPI pointed out that "Section 17b of the Drugs and Cosmetics Act gives a fairly exhaustive and well thought through definition of 'spurious' drugs that is much broader than what is being proposed by WHO-IMPACT or for that matter what is being debated at various forums here. A careful reading of the proviso provides us an insight into the mindset of the lawmakers who had worked to encompass the various angles that any unscrupulous element could adopt while peddling spurious/counterfeit drugs. This definition is aimed at taking adequate measures to protect the interests of the patients, industry and the public at large."

http://www.pharmabiz.com/article/detnews.asp?articleid=47839&sectionid