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IPA calls for amendment to D&C Act to exclude IPR issues from Sec 17

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Indian Pharmaceutical Alliance (IPA) has called for more clarity in the definitions of counterfeit and spurious drugs and necessary amendment to the Drugs and Cosmetics Act accordingly, if the country wants to deal tougher with the instances like recent seizure of fake drugs with 'made in India' labels in Nigeria but produced and exported from China.

In a recent meeting jointly held by different departments including health, pharma and commerce on the issue, the IPA has suggested that the terms of counterfeit and spurious be defined separately and the IPR related issues (e.g misbranded) should be removed from Section 17 of the Drugs and Cosmetic Act.

IPA secretary general D G Shah, at the meeting, also called for preparing a directory of Schedule M compliant units in the country and providing it to all the Indian missions abroad and foreign mission in the country. "On a pilot basis, entrust Pharmexcil with the task of monitoring imports of pharmaceuticals from three key markets having local capabilities (Nigeria, Ghana and Kenya). The Pharmexcil may subscribe to appropriate data base, analyse both imports and exports and identify use of `made in India' in appropriate consignments," he said.

He also urged the government to collect more information on the misuse of 'made in India' label. "We also need to assess how much of it is made in and outside India and identify the potential sites outside India. Government should be a key player in sourcing this information," he added.

IPA also took strong exception to the report of the International Policy Network (IPN) which was circulated to the associations by the Department of Pharma, as it raised several doubts. The report clubbed both counterfeit and spurious drugs under 'fake drugs'. The report also quoted various estimates of `fake' drugs but did not disclose the source of its data, the IPA pointed out.

"Among the various actions listed in the report, its emphasis is on enforcement and protection of IPRs (a favourite course of action of MNCs) which are aimed at clubbing legitimate generics with counterfeit medicines. The absence of data analysis also makes it impossible to evaluate effectiveness of suggested remedial measures and its relevance to the ground reality. In the absence of unit of measure (like volume, value, number of consignments) it is not possible to relate to the size of the market. It is therefore futile to give undue respectability to IPN report," the IPA said.