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India successfully thwarted Ã¢â?¬Å?HarmonizationÃ¢â?¬?

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India has successfully thwarted Big Pharma's attempt to influence norm-setting for medicines in the resolution passed recently at the World Health Assembly in Geneva. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), is pharma industry initiative.

The ISH initiative, harmonization of technical requirements for registrations of pharmaceuticals for human use by developing appropriate norms and standards taking into account the standards created by existing regional and international initiatives in the resolution was protested by India and several other countries. Such references dropped before the resolution on regulatory system strengthening for medical products was adopted.

"The WHO guidelines are advisory in nature. But if a resolution is adopted, it becomes binding on the member countries. We cannot be party to a resolution where the language is not clear. What exactly do you mean by convergence or harmonization of regulation? Who will harmonize with whom? The needs of different countries are different," said R K Jain, additional secretary in the health ministry. He, along with V G Somani of Central Drug Standards Control Organization (CDSCO), negotiated on India's behalf.

Civil society organizations working for greater access to medicines are pleased with the Indian initiative. According to them, "harmonization", in this context, was just a euphemism for setting of industry-led standards which favour the interests of transnational pharmaceutical corporations and their push to weaken competition from generic medicines.

Civil society groups like Medicus Mundi and the People's Health Movement had in their letter to WHO pointed out that while ICH sought to raise the bar on acceptable manufacturing standards and to globalize these, higher standards, beyond a point, did not add to the quality of the medicines or public health outcomes. "It adds to the cost of manufacturing and is a barrier to the entry of generics," stated the letter.

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