

**Statement to the 67<sup>th</sup> World Health Assembly  
on agenda item 15.6 on Regulatory system strengthening  
delivered by Susana Barria**

Thank you, Chair, for the opportunity provided to MMI and PHM.

We express our concern on WHO's participation in the 'International Conference on Harmonisation', a *de facto* standard setting body set up by the transnational pharmaceutical industry to serve their business interests. The ICH compromises the neutrality of the process of setting regulatory norms and standards. It seeks to raise the bar on acceptable manufacturing standards, and to globalise these. However, higher standards, beyond a point, do not add to medicines quality and public health outcomes. It adds to costs of manufacturing and is a barrier to entry of generics in L&MICs.

We urge member states to ask for the disengagement of WHO from ICH and for the exclusion of the ICH from WHO's Expert Committee meetings.

We urge member states to call on WHO to address the issue of unethical clinical trials in L&MICs by developing a global mechanism for registration of clinical trials. In many L&MICs, non-transparent procedures make it impossible to obtain accurate information about clinical trials. A global mechanism, under the aegis of WHO, should monitor all ethical issues regarding clinical trials, especially in L&MICs.

An increasing number of top selling drugs and those in the R&D pipeline are biotherapeutic products. Resolution EB 134.R19 provides a framework for regulating the marketing approval of such products. However, provision in OP1(2) would require monitoring the reference biotherapeutic products before starting the evaluation of a biosimilar. This would severely restrict market entry of low cost biosimilars and goes much beyond the WHO Expert Committee on Biological Standardization guidelines of 2009 [[here](#)].

We call upon WHO to build its own capacity to provide guidance on regulation of biologics and biosimilars. This guidance should include help in scaling up the use and local production of biosimilars in L&MICs.

Thank you.

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