

Statement on agenda Item: 21.3 (H)

Regulatory system strengthening for medical products

This MMI statement is supported by PHM and TWN.

We take this opportunity to caution MS and the Secretariat on the Regulatory System Strengthening.

First, The RSS should not lead to regulatory barrier resulting in an adverse impact on the competition and availability of affordable medicines. Much of the norms and standards set by WHO on the pharmaceutical products are borrowed from ICH , a body pushes standards of originator companies and squeeze competition. There is an urgent need of independent and open review of WHO norms and standards.

Second, the current pre-qualification process is based on heightened standards and helps only big companies. The recent independent external review found out that the share of developing country manufactures has been flat since the start of the program.

Third, we would like to point out the misleading statement in the progress report, which states in Para 80 that WHO expert Committee approved the "biotherapeutics, including an update of the 2009 similar biotherapeutic products guideline". However, EB145/10 to be discussed in the upcoming EB states: " The Expert Committee recognized that the guidelines from 2009 remained valid and did not, therefore, require revision at this point.". We call upon the Secretariat to remove the misleading statement in Document A 72/59.

Total: 207 words

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