Clarification with Respect to a Stringent Regulatory Organization as Applicable to the Stringent Regulatory Authority (SRA) Guideline

The recent reforms at ICH, formerly the International Conference on Harmonisation and currently the International Council for Harmonisation, prompted the WHO Prequalification Team: medicines to reconsider the definition of a stringent regulatory authority (SRA) as applicable to WHO's Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities ("SRA guideline") (Technical Report Series, No. 986, 2014, Annex 5). The definition of an SRA is rephrased as follows.

A regulatory authority that is:

a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or

b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or

c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.