

## List of countries considered as Stringent Regulatory Authorities (SRA) from 1<sup>st</sup> July 2009.

The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA) as per the Global Fund Quality Assurance Policy for Pharmaceutical Products from July 1, 2009. For details on ICH, please look at [www.ich.org](http://www.ich.org). Please find below the list of countries which are members, observers and associates of ICH.

### MEMBERS:

- **European Union member States** (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom)
- **Japan**
- **United States**

**OBSERVERS:** European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada (as may be updated from time to time).

**ASSOCIATES** through mutual recognition agreements: **Australia, Norway, Iceland and Liechtenstein** (as may be updated from time to time).

For medicines used exclusively outside the ICH region, positive opinions or tentative approval under any of the following three special regulatory schemes are recognized as **stringent approval**:

- **Article 58 of European Union Regulation (EC) No. 726/2004**
- **Canada S.C. 2004, c. 23 (Bill C-9) procedure**
- **United States FDA tentative approval** (for antiretrovirals under the PEPFAR programme)