

Annex 1: List of Countries Considered to Have Stringent Regulatory Authorities

A **stringent regulatory authority (SRA)** is a national regulatory authority or institution which is considered by the Medicines Control Agency (MCA) to be competent and trusted through application of stringent standards for quality, safety, and efficacy in its process of regulatory review of medicines and related products for marketing authorization (registration).

The following countries are considered by MCA to have Stringent Regulatory Authorities (SRAs):

No	Country
1	Australia
2	Austria
3	Belgium
4	Bulgaria
5	Canada
6	Croatia
7	Cyprus
8	Czech Republic
9	Denmark
10	Estonia
11	Finland
12	France
13	Germany
14	Greece
15	Hungary
16	Iceland
17	Ireland
18	Italy
19	Japan
20	Latvia
21	Liechtenstein
22	Lithuania
23	Luxembourg
24	Malta
25	Netherlands
26	Norway

27	Poland
28	Portugal
29	Republic of Korea
30	Romania
31	Russia
32	Slovakia
33	Slovenia
34	Spain
35	Sweden
36	Switzerland
37	Turkey
38	United Kingdom
39	United States of America