

Annex A

List of Reference Drug Regulatory Agency (RDRA)*

1. European Medicines Agency (EMA) - European Union
2. Health Canada (HC) - Canada
3. Medicines and Healthcare Products Regulatory Agency (MHRA) - United Kingdom
4. Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
5. Therapeutic Goods Administration (TGA) - Australia
6. US Food and Drug Administration (USFDA) – United States of America

*The list may be updated at any point in time as determined by FDA.