ANNEX A

List of Reference Drug Regulatory Agencies (RDRAs)*

1. Therapeutic Goods Administration (TGA) – Australia
2. Federal Agency for Medicines and Health Products (FAMHP) – Belgium
3. Health Canada (HC) - Canada
4. European Medicines Agency (EMA) - European Union
5. French National Agency for Medicines and Health Products Safety (ANSM) - France
6. Federal Institute for Drugs and Medical Devices (BfARM) – Germany
7. Paul-Ehrlich-Institut (PEI) – Germany
8. Italian Medicines Agency (AIFA) – Italy
9. Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
10. Medicines Evaluation Board (MEB) – Netherlands
11. Health Sciences Authority (HSA) – Singapore
12. Swiss Agency for Therapeutic Products (Swissmedic) - Switzerland
13. Medicines and Healthcare Products Regulatory Agency (MHRA) - United Kingdom
14. US Food and Drug Administration (USFDA) – United States of America

Note: The list may be updated at any time as determined by FDA.

* *Selection criteria include the founding members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), WHO Listed Authorities (WLAs) for medicines and vaccines, and other regional and national regulatory authorities performing or operating at maturity level 4.*