NAMIBIA MEDICINES REGULATORY COUNCIL

REGULATORY AUTHORITIES (RAs) AND ORGANISATIONS THAT NMRC ALIGNS WITH:

A. FOR REGISTRATION PURPOSES (Council may first track the registration of products registered by the following regulatory authorities)

1. WHO via the WHO Collaborative Registration Procedure only.
2. United States Food and Drug Administration (USA)
3. Therapeutic Goods Administration (Australia)
4. Health Canada (Canada)
5. Ministry of Health, Labour and Welfare (Japan)
6. European Medicines Agency (EMA).
7. Medicines and Healthcare products Regulatory Agency and Veterinary Medicines Directorate (UK)
8. National Agency for Medicines and Health Products Safety (France)
9. Federal Institute for Drugs and Medical Devices (Germany)
10. Health Products Regulatory Authority (Ireland)
11. Swedish Medical Products Agency
12. National Authority of Medicines and Health Products (Portugal)
13. Medicines Evaluation Board (The Netherlands)
14. Federal Agency for Medicines and Health Products (Belgium)
15. New Zealand Medicines and Medical Devices Safety Authority

16. Danish Medicines Agency (Denmark)
17. Finnish Medicines Agency (Finland)
18. Spanish Agency for Medicine and Health Products (Spain)
19. National Medicines Institute (Poland)
20. Icelandic Medicines Agency (Iceland)
21. Norwegian Medicines Agency (Norway)
22. Department of Pharmaceutical (Liechtenstein)
23. Swissmedic (Switzerland)
24. South African Health Products Regulatory Authority (RSA)
25. Medicines Control Authority of Zimbabwe (Zimbabwe)
26. Zazibona collaborative procedure

B. FOR GMP INSPECTION PURPOSES (Council may approve or accept a valid GMP compliance certificate or inspection report issue by the following regulatory authorities)

1. All the regulatory authorities and organizations stated under A above
2. Regulatory authorities that participate in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/s) before 25 October 2008.

Effective date: 21 February 2019

REGISTRAR OF MEDICINES

REGISTRAR OF MEDICINES
REPUBLIC OF NAMIBIA