REGULATORY AUTHORITIES (RAs) AND ORGANISATIONS RECOGNISED BY NMRC

MINISTRY OF HEALTH AND SOCIAL SERVICES

NAMIBIA MEDICINES REGULATORY COUNCIL

A. FOR REGISTRATION, POST REGISTRATION AMENDMENT/VARIATION AND SECTION 27 AUHTORIZATION PURPOSES:

Council may fast track the registration and/or review of post registration amendments of products registered/approved by the National Regulatory Authority (NRA) of the following Countries and other regulatory bodies:

1. African Vaccines Regulatory Forum (AVAREF)
2. African Medicines Regulatory Harmonisation (AMRH) within AUDA-NEPAD
3. WHO via the WHO Collaborative Registration Procedure
4. European Medicines Agency (EMA)
5. Australia
6. Austria
7. Belgium
8. Bulgaria
9. Canada
10. Croatia
11. Cyprus

12. Czech Republic

13. Denmark

14. Estonia

15. Finland

16. France

17. Germany

18. Greece

19. Hungary

20. Iceland

21. Ireland

22. Italy

23. Japan

24. Republic of Korea

25. Latvia

26. Liechtenstein

27. Lithuania

28. Luxembourg

29. Malta

30. Netherlands

31. Norway

32. Poland

33. Portugal

34. Romania

35. Saudi Arabia

36. Singapore

37. Slovakia

38. Slovenia

39. South Africa

40. Spain

41. Sweden

42. Switzerland

43. United Kingdom

44. United States of America

45. Zazibona Collaborative Procedure

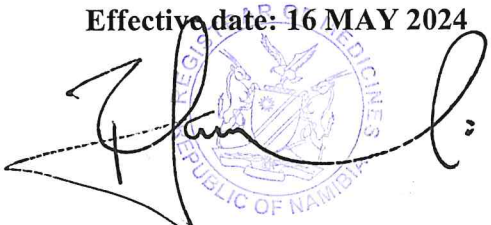
46. Zimbabwe

B. FOR GMP INSPECTION PURPOSES

Council may approve or accept a valid GMP compliance certificate or inspection report issue by the following regulatoryauthorities:

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: 16 MAY 2024



REGISTRAR OF MEDICINES