GUIDELINE HISTORY

No.	Guideline	Description of Amendment	Effective date
1.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS First Edition – 15th Mac 2017	Initial Publication	1st July 2018 (extended until 1st July 2019)
2.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Second Edition – 1st April 2019	I. Removal of 5.3 Fees Imposed By CAB II. Additional of Appendix 5: Endorsement Letter Application Flow Chart For Ancillary Medical Device Component	1st April 2019
3.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Second Edition – 20th June 2019	Additional of : • 6.1 Changes/ Variation To Particulars Of A Registered Drug-Medical Device Combination Product • Appendix 6: Change To Ancillary Medical Device Components • Appendix 7: List Of Relevant References	20th June 2019

No.	Guideline	Description of Amendment	Effective date
4.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Second Edition – 19th December 2019	I. Additional '*No processing fees will be charged until further notice' at 5.1 Fees Imposed By NPRA II. Updates on: • Appendix 3: Application Form For Endorsement Letter Of Ancillary Component For The Registration Of Combination Product • Appendix 4: Application Form For Approval Letter Of Change/ Variation Application For Ancillary Components For Combination Products • Appendix 7: List Of Relevant References	19th December 2019
5.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Third Edition – 15th September 2020	I. Additional of "iv. Natural products and Health Supplement products. " at 1.3 Definition Of Combination Product Products that are excluded from the term combination product and will be regulated separately. II. Updates of Appendix 3	15th September 2020
6.	GUIDELINE FOR REGISTRATION OF DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Forth Edition – 6th October 2021	Additional of: • 7.0 Post-Marketing Activities: Management Of Incident Involving Registered Combination Product By The Industry • Appendix 7: Relevant Post-Marketing Activities Form	1st July 2022

No.	Guideline	Description of Amendment	Effective date
7.	GUIDELINE FOR DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS - ENDORSEMENT LETTER APPLICATION - ADVERSE DRUG REACTION AND INCIDENT REPORTING Fifth Edition – 3rd January 2023	Updates of: • Name of the guideline, Preamble, Glossary • 2.0 Registration Process Of Combination Product • 4.0 Timeline For Registration Of Combination Product: Evaluaton timeline by NPRA • 7.0 Adverse Drug Reaction and Incident Reporting • Appendix 1: Ancillary Medical Device Dossier Requirement For Drug-Medical Device Combination Product • Appendix 2: Ancillary Drug Dossier Requirement For Medical Device-Drug Combination Product • Appendix 3: Application Form For Endorsement Letter Of Ancillary Component For The Registration Of Combination Product • Appendix 6: Change To Ancillary Medical Device Components • Appendix 8: List Of Relevant References • Appendix 7: Incident Reporting Form for Combination Product	3rd January 2023
8.	GUIDELINE FOR DRUG-MEDICAL DEVICE AND MEDICAL DEVICE-DRUG COMBINATION PRODUCTS Fifth Edition – 3rd January 2023	Deletions of Bank Draft payment method. Addition of BayarNow payment method to Drug-Medical Device Combination Product Application for Endorsement Letter. **Amendments were done at page 19 and 54.*	17th Oct 2024