LIST OF UPDATES FOR GUIDANCE NOTES FOR ACTIVE PHARMACEUTICAL INGREDIENT (API) INFORMATION (PART II S) FOR QUEST3+ PRODUCT REGISTRATION APPLICATION, VERSION 4.1, DEC 2019

No.	Version	Description of Updates	Effective date
1	Version 1.0	Initial Publication	April 2018
2	Version 2.0	Addition of Part C - Regulatory Control of API for Product Registered Before the Implementation of Directive on Regulatory Control of API in Malaysia	July 2018
3	Version 3.0	Change of Part D to Part E for Good Manufacturing Practice Compliance Evidence for Manufacturers Involved. Addition of Part D - Regulatory Control of Atypical APIs Addition of Appendix 4 - List of Atypical Active Pharmaceutical Ingredient (API) Addition of Appendix 5 - Summary of Required Documents for Atypical Active Pharmaceutical Ingredient (AAPI) Information	October 2019
4	Version 4.0	Change of name from “Center of Product Registration” to “Centre of Product and Cosmetic Evaluation” Submission to API Section changed to submission to Head of New Drug Product Section* / Head of Generic Medicines Section* (*refer to product category) Template of Cover Letter for DMF submission is available on NPRA website Upon payment, submission of CD copy to “Center of Product Registration” or “Center of Quality Control” are no longer required.	December 2019

	Version 4.1	Change of Administrative Procedure for Section S Revision for products not containing Anti-Infective APIs. Addition of Glycine and Olive Oil as examples of Atypical API	