LIST OF UPDATES FOR GUIDANCE NOTES FOR ACTIVE PHARMACEUTICAL INGREDIENT (API) INFORMATION (PART II S) FOR PRODUCT REGISTRATION APPLICATION VIA QUEST SYSTEM, VERSION 6.1, JULY 2022

No.	Version	Description of Updates	Effective date
1	Version 1.0	Initial Publication	April 2018
	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
2	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
3	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

4	Version 4.1	Change of Administrative Procedure for Section S Revision for products not containing Anti-Infective APIs. Appendix 4- Addition of Glycine and Olive Oil as examples of Atypical API	Feb 2020
5	Version 5.0	Appendix 4- Addition of Magnesium Sulphate, Medium Chain Triglyceride, Potassium Dihydrogen Phosphate and Sodium Lactate as examples of Atypical API Addition of Part F: Product Registration Application Referencing to a Drug Master File (DMF) Previously Submitted to NPRA	June 2020
6	Version 6.0	Rearrangement of topics title. Topics which are incorporated in updated DRGD (Third edition, Jan 2021) are removed from this Guidance Notes. Addition of Part D: Mode of Submission for Drug Master Files (DMFs) Addition of Part E: Product Registration Application Referencing to WHO Prequalified APIs Updating of Appendix I: Addition of WHO PQ requirements Updating of Appendix IV: Addition of Cetylpyridinium Chloride, Mannitol and Malic Acid as examples of Atypical API Editorial changes: - DRGD Appendix 6 changed to DRGD Appendix 11 - Change of label of Appendixes of Guidance Notes from 1, 2, 3, 4 & 5 to I, II, III, IV & V	March 2021

7	Version 6.1	Updating of Appendix IV: Addition of Lysine Hydrochloride, Taurine, Histidine Hydrochloride Monohydrate, Potassium Acetate, Sodium Dihydrogen Phosphate Dihydrate, Fish Oil (Rich in Omega-3-Acids) & Magnesium Acetate as examples of Atypical API.	July 2022