LIST OF UPDATES ON DRGD FIRST EDITION, REVISED MARCH 2015

<table>
<tr><th rowspan="2">NO.</th><th rowspan="2">REVISION</th><th colspan="2">UPDATES</th><th rowspan="2">REFERENCE</th></tr>
<tr><th>SECTION/ APPENDIX</th><th>DETAILS</th></tr>
<tr><td>1.</td><td>March
2015</td><td>Section E: Post Registration Process</td><td>
Amendment at Subsection 16.1.2: Variation application for health supplements and natural products.

Mode of submission: Table XVI

<table>
<tr><th>No</th><th>Variation</th><th>QUEST 2 & QUEST 3 Products</th></tr>
<tr><td>1.</td><td>Type I</td><td rowspan="2">Applicant shall submit application for Variation Type I and/or Type II <u>manually</u> to the respective Sections in Center for Product Registration. For manual submission, applicant can download Form BPFK 416.4 from NPCB's website www.bpfk.gov.my .

Online submission for QUEST 2 products shall only proceed after all the documents are finalized through the correspondence email.

All updates for QUEST 3 products will be done by the NPCB IT department.</td></tr>
<tr><td>2.</td><td>Type II</td></tr>
</table>
</td><td>Circular Ref :

Bil (11)dlm.BPFK/ PPP/09/06

Date: 26th May 2014</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
2.	March 2015	Section A : General Overview	**Amendment and updating of the whole Subsection 1.3 : Food-Drug Interphase Products**	Circular ref : Bil (19)dlm.BPFK/ PPP/01/03 Jld.3) Date: 07 August 2014
3.	March 2015	Section C : Quality Control	**Amendment at Subsection 10 : GUIDELINE FOR THE SUBMISSION OF ANALYTICAL METHOD VALIDATION (AMV) DOCUMENTS.** **Addition of Japanese Pharmacopeia (JP) as one of the reference used for analytical method validation.** All the analytical validation done by the industry should be in accordance to ASEAN Guidelines for Analytical Procedures, ICH Technical Requirements for Registration of Pharmaceuticals for Human Use under Validation of Analytical Procedures: Text and Methodology Q2 (R1), British Pharmacopoeia (BP), United States Pharmacopeia (USP), or Japanese Pharmacopeia (JP).	Pharmacy Regulatory Policy Meeting No. 1/2015

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4.	March 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Amendment at Subappendix 1.4 : CLASSIFICATION FOR SPECIFIC ACTIVE INGREDIENTS.** **1.4.1 PRODUCTS CONTAINING CASSIA/ SENNA :** ~~Products containing~~ Finished products containing cassia/senna as an active ingredient with a daily dose of less than 0.5g of the crude drug or 20 mg sennoside (standardized preparation) shall be classified as traditional products and restricted to traditional claims. Active ingredient consumed more than this daily limit will be classified as pharmaceutical product, depending on the product formulation. ~~*(Reference: Micromedex)*~~	Memo from Section of Complementary Medicine : Ref (64)dlm.BPFK/ PPP/06/17 Jilid 56 Date : 11 March 2015
5.	March 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Updating of Subappendix 2.1.3 : PROHIBITED/ BANNED INGREDIENTS** **Table 1 : Botanicals (and botanical ingredients) containing scheduled poisons as listed under the Poisons Act 1952.** Updating of the information on Constituent(s) of concern for genus *Berberis*.	Memo from Section of Complementary Medicine : Ref (64)dlm.BPFK/ PPP/06/17 Jilid 56 Date : 11 March 2015

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6.	March 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Updating of Subappendix 2.1.3 : PROHIBITED/ BANNED INGREDIENTS** **Table 2 : Botanicals (& botanical ingredients) which are banned due to reported adverse event** Addition of active ingredient *Dioscorea hispida*, also known as Ubi Gadong which contains the constituent dioscorine and dioscorinine.	Memo from Section of Complementary Medicine : Ref (64)dlm.BPFK/ PPP/06/17 Jilid 56 Date : 11 March 2015
7.	March 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Updating of informations under Subappendix 2 : GENERAL REQUIREMENTS FOR REGISTRATION OF NATURAL PRODUCTS;** **Subappendix 2.3 : Indications** **Subappendix 2.4 : Product Name** **Subappendix 2.7.4 : Labelling Requirement**	Memo from Section of Complementary Medicine : Ref (64)dlm.BPFK/ PPP/06/17 Jilid 56 Date : 11 March 2015

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8.	March 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Addition of para 2.5.7 : Certificate of Analysis** Applicants will have to submit a certificate of analysis for each active ingredient used, which may be purchased from the supplier. This requirement is not applicable for raw materials that are processed in-house.	Memo from Section of Complementary Medicine : Ref (64)dlm.BPFK/ PPP/06/17 Jilid 56 Date : 11 March 2015