LIST OF UPDATES ON DRGD FIRST EDITION, DECEMBER 2013

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	December 2013	Section A: General Overview	**Addition of the following note at 5.1.3 Registration Of Product For Export Only (FEO):** ***Note:*** *The applicant must first register membership for QUEST system with NPCB and subsequently purchase a USB Token that contains a User Digital Certificate, from Digicert Sdn. Bhd. This is to enable the applicant to access the system for product updating once the application for registration is approved. For further detail, please refer Section A General Overview under 3.3 How To Apply.*	Drug Evaluation Committee Meeting No. 22/2013

<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>2.</td><td>December 2013</td><td>Section B: Product Registration Process</td><td>Amendment of timeline for Abridged Evaluation - Generics (Non-Scheduled Poison) in Table VII under 8.4.4 Timeline for Product Registration as follows:
<table>
<tr><th>(B)</th><th>Abridged Evaluation</th><th>*Duration (Inclusive screening process)</th></tr>
<tr><td>5.</td><td>Generics (Non-Scheduled Poison)

(Product categories as stated in Table V above)

a) Single active ingredient
b) Two (2) or more active ingredients</td><td><s>80 working days</s>

a) 116 working days
b) 136 working days</td></tr>
</table></td><td>Mesyuarat Jawatankuasa Kajian Semula Pengurusan (JKKSP) Bil. 2/2013</td></tr>
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NO.	REVISION	UPDATES		REFERENCE
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3.	December 2013	Appendix 5: Guideline on Registration of Natural Products	**Amendment of the following paragraph (addition as per highlighted in yellow) at 1.4.1 and 1.4.2 under 1.4 CLASSIFICATION OF SPECIFIC ACTIVE INGREDIENTS** **1.4.1 PRODUCTS CONTAINING CASSIA/ SENNA:** Products containing less than 0.5g of the crude drug or 20 mg sennoside (standardized preparation) shall be classified as traditional products and are restricted to only traditional claims. ~~are allowed make claims for general health only.~~ (*Reference: Micromedex)* **1.4.2 PRODUCTS CONTAINING PSYLLIUM HUSK/ PLANTAGO OVATA** Finished products containing psyllium husk as an active ingredient and with a total daily consumption of less than 3.5g per day ~~of this active ingredient in a single formulation and not in a pharmaceutical dosage form with specific dosage instructions will~~ shall be classified as a non-drug. However, daily doses ~~quantities~~ above this amount and up to 6.9 g will require this product to be registered ~~classified~~ under the ~~as a~~ traditional product category. ~~and will require registration before it can be marketed.~~ (Reference: Circular on 14 May 2010 - Bil (24) dlm.BPFK/PPP/07/11Jld 5)	Memo from Sub-Section of Complementary Medicine (56)dlm.BPFK/PPP/06/17