LIST OF UPDATES ON DRGD FIRST EDITION, APRIL 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	April 2014	Section A: General Overview	**Addition of the following note under 5.1.2 Registration of Combination Pack (Combo Pack):** a) Refers to products which are packed together in combination for a therapeutic regimen such as for the treatment of *Helicobacter Pylori*, Hepatitis C, etc.). ***Note:*** *Products which are packed together in combination NOT FOR THERAPEUTIC REGIMEN but for convenience of the consumers (e.g. capsules of five health supplement products in a blister pack) will not be considered for registration as a combo pack.*	Pharmacy Regulatory Policy Meeting No. 1/2014
2.	April 2014	Section A; Section E; and Appendix 13	**Amendment under the following subject matters in accordance with the Malaysian Variation Guideline (MVG) April 2013 and circular (7)dlm.BPFK/PPP/01/03 Jld. 3:** a) 5.2.1 Variation (Section A: General Overview) b) 16.1 Variation (Section E: Post-Registration Process) c) 16.2 Change of Manufacturing Site (Section E: Post-Registration Process) d) Appendix 13: Supporting Documents Required for Change of Manufacturing Site (COS) Applications	Malaysian Variation Guideline (MVG) April 2013 & Circular (7)dlm.BPFK/PPP/01/03 Jld. 3: *Kebenaran pertukaran tapak pengilang ke pengilang kontrak tempatan melalui prosedur pertukaran tapak pengilang dan meminda dokumen sokongan bagi pertukaran tapak pengilang jenis I*

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3.	April 2014	Section B; and Section C	**Amendment for the following paragraphs:** **8.1.4 Conditions Applied on Product Registration (Section B: Product Registration Process)** d) Application shall be rejected if the applicant fails to submit required supplementary data/ information, or documentation ~~or samples~~ within six (6) months from the first correspondence date; ~~*(Reference: Circular Bil (08) dlm. BPFK/PPP/01/03)*~~ e) Applicant shall submit sample of natural product for laboratory testing to the Centre for Quality Control, NPCB within fourteen (14) working days from date of confirmed payment. Failure to do so within thirty (30) days from the date of the payment shall result in rejection of the application. **8.4.2 Correspondence (Section B: Product Registration Process)** Correspondence via the system shall be sent to the applicant if there is any clarification and further supplementary data/ information, documentation or samples pertaining to the application, if deemed necessary by the Authority. Application shall be rejected if the applicant fails to respond to the correspondence from NPCB to submit the required supplementary data/ information, or documentation ~~or samples~~ within six (6) months from the	Drug Evaluation Committee Meeting No. 7/2014

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			first correspondence date. (~~*Reference: Circular Bil (08) dlm. BPFK/PPP/01/03*~~) **11. Guideline for the Submission of Product Samples for Laboratory Testing (Section C: Quality Control)** The applicant is given a period of 14 working days from the date of confirmed payment to send samples for laboratory testing. If the samples are not submitted within the specified time frame, the product registration application shall be tabled to the Authority for rejection.	
4.	April 2014	Appendix 7: Special Conditions for Registration for a Particular Product or Group of Products	**Addition of the following restriction on usage for products containing ketoconazole (oral):** **KETOCONAZOLE** Products containing oral ketoconazole are restricted for hospital use only.	Directive No. 3 Year 2014, (9)dlm.BPFK/PPP/07/25: *Direktif untuk memperketatkan indikasi semua produk ketoconazole oral dan mengehadkan penggunaan di hospital sahaja berikutan risiko kesan advers hepatotoksisiti*

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5.	April 2014	Appendix 9: Labelling Requirements	**a) Addition of specific labelling requirement (restricted indication) for products containing oral ketoconazole under 9.2 Specific Labelling Requirements.**	Directive No. 3 Year 2014, (9)dlm.BPFK/PPP/07/25: *Direktif untuk memperketatkan indikasi semua produk ketoconazole oral dan mengehadkan penggunaan di hospital sahaja berikutan risiko kesan advers hepatotoksisiti*
6.	April 2014	Appendix 9: Labelling Requirements	**b) Addition of specific labelling requirement (restricted indication and duration of use) for products containing synthetic salmon calcitonin under 9.2 Specific Labelling Requirements.**	Directive No. 4 Year 2014, (10)dlm.BPFK/PPP/07/25: *Direktif untuk mengehadkan indikasi dan tempoh penggunaan produk yang mengandungi Calcitonin Salmon sintetik dalam bentuk injeksi dan Intranasal 'Nasal Spray' berikutan risiko kanser*

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7.	April 2014	Appendix 4; Appendix 5; and Appendix 9	**Rearrangement of labelling requirement for the following appendices:** a) Appendix 4: Guideline on Registration of Health Supplements b) Appendix 5: Guideline on Registration of Natural Products c) Appendix 9: Labelling Requirements	Drug Evaluation Committee Meeting No. 8/2014