LIST OF UPDATES ON DRGD FIRST EDITION, MAY 2013

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	May 2013	Section A: General Overview; 6. General Conditions for Registration of Drug Products under the Control of Drugs and Cosmetics Regulations 1984	**Addition of link to specific circulars/ directives pertaining security label (hologram) as per listed below at 6.4 Product Authentication:** a) "Circulars and directives pertaining to security label (hologram): i) Bil (32) dlm BPFK/02/5/1.3 ii) Bil (36) dlm BPFK/02/5/1.3 iii) Bil (62) dlm BPFK/02/5/1.3 iv) (88)dlm.BPFK/PPP/01/03 Jilid 2 v) (1)dlm.BPFK/PPP/07/25 Jld. 1"	Circulars and directive as linked; latest directive (1)dlm.BPFK/PPP/07/25, 4 April 2013: *Pelaksanaan dan Pengendalian Label Keselamatan*

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2.	May 2013	Section B: Product Registration Process	**Addition of the following paragraph at 8.1.6 Second or Third Source:** "A second source product, excluding biologic products, may differ for the following aspects: a) equipments/ machines; b) minor manufacturing process (e.g. blending time, number of sub-parts); c) batch size; d) packaging materials, thickness of same packaging materials, pack sizes; *(Note: Use of different packaging material shall be supported with stability study report.)* e) manufacturer of API; and f) source of excipients. **EXCEPT** differences in shape, embossment and thickness of tablet, in order to avoid change in product identity and subsequently causing confusion. The manufacturer shall declare with support of manufacturing validation process data that there is no change in formulation, specification of active ingredient(s) and excipient(s), and finished product for the second source product compared to the first source. For pharmaceutical product, no third source is allowed for same product unless in emergency situation such as outbreak of infectious disease."	Pharmacy Regulatory Policy Meeting No. 1/2013

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3.	May 2013	Section C: Quality Control	**Replacement of this statement at 11. Guideline for the Submission of Product Samples for Laboratory Testing:** "The sample shall be submitted to the Centre for Quality Control within 14 days after the payment has been confirmed. Application for product registration shall be rejected by the Authority if the sample is not submitted within 30 days from the date of confirmed payment." **(deleted)** **With the following:** "The applicant is given a period of **14 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." **(replacement)**	Pharmacy Regulatory Policy Meeting No. 1/2013
4.	May 2013	Section E: Post-Registration Process	i) **Addition of the following paragraph and link at 14. Maintenance of Registration:** "For pharmaceutical products which were submitted for registration before 2009, applicants shall ensure that stability study for the products at zone IV B has been conducted and granted variation approval before submission of registration renewal application. Please refer circular (1)dlm.BPFK/PPP/01/03Jld.3, 5 April 2013 for more information."	Circular (1)dlm.BPFK/PPP/01/03 Jld. 3, 5 April 2013: *Keperluan Data Kajian Stabiliti Dalam Zon IV B Bagi Produk Farmaseutikal Berdaftar*

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5.	May 2013	Section E: Post-Registration Process	**ii) Amendment of the following paragraph and addition of link at 17.2 POST-MARKET SURVEILLANCE** a) It is the prime responsibility of the holder to ensure products marketed are in accordance to the standards and requirements of the Authority. ~~Samples of products registered by the Authority may be taken and tested for compliance with official or pharmacopoeia standards or specifications agreed by the manufacturer~~; b) ~~Samples of products~~ Registered products ~~by the Authority~~ may be ~~taken~~ sampled and tested for compliance with official or pharmacopoeia standards or specifications agreed by the manufacturer. Labels and package inserts of the samples will also be checked to ensure compliance to the requirements as approved. c) The Authority will take necessary action on products which do not conform to the standards/ specifications and requirements in the form of warnings or recalls. ~~If a sample fails to meet adequate specifications, the product registration holder will be issued a warning. Unless the failure is serious enough to justify recall of the product,~~ The product registration holder has up to thirty (30) days to identify the ~~source/~~ cause of ~~quality~~ defect and actions to be taken for ~~to~~ improvement ~~quality~~. **17.2.1 PRODUCT COMPLAINTS** a) The product registration holder should notify the NPCB ~~Director of Pharmaceutical Services~~ of any product quality	Memo from Center for Post Registration of Product Bil (87)dlm.BPFK/17/SV/21.16, 10 May 2013

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			related problems (with registered products) that the holder is aware of; b) It is also the responsibility of the prescribers, ~~the~~ pharmacists, as well as all other health professionals who come into contact with the drug to report to NPCB by using the NPCB complaint form i.e. BPFK 419 / BPFK 418.4 together with complaint sample (if any). c) All complaints received will be investigated by the NPCB as well as product registration holder/ manufacturer. It is the responsibility of the company to determine the appropriate corrective and preventive action. Guidelines on Good Distribution Practice, Chapter 9. **17.2.2 PRODUCT RECALLS** a) The decision for recall~~s~~ of ~~defective or unsafe~~ a product~~s~~ shall be made when there is or may cause potential risk to the user of the products. Recalls may be done voluntarily by the product registration holder or as directed ~~are instituted~~ by the ~~Authority, supported by the~~ Director of Pharmaceutical Services Division, Ministry of Health Malaysia; b) The product registration holder is responsible for conducting recalls of defective or unsafe products. No recall should take place without first consulting/ informing the Authority. ~~Director of Pharmaceutical Services~~. Guidelines on Good Distribution Practice, Chapter 10.	

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6.	May 2013	Appendix 4: Guideline on Registration of Health Supplement	**Replacement of this statement at 4.1.4 Exclusion as Health Supplement:** "(iii) Any human part or substance derived from any part of the human body;" **(deleted)** **With the following:** "iii) Any cells, tissues, organs or any substance derived from the human body;" **(replacement)**	Pharmacy Regulatory Policy Meeting No. 1/2013
7.	May 2013	Appendix 4: Guideline on Registration of Health Supplements; Appendix 5: Guideline on Registration of Natural Products; Appendix 9: Labelling Requirements.	**Addition of the following paragraph as "#" at column Outer Carton for Security Label (Hologram):** "In case of no outer carton, the security label shall be applied to the immediate labels. The security label shall not be applied onto outer shrink wrap of a product."	NPCB Dialogue with MOPI, PhAMA and MAPS on DRGD & Pharmacy Regulatory Policy Meeting No. 1/2013

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8.	May 2013	Appendix 8: List of Permitted, Prohibited and Restricted Substances	**a) Amendment of the following at 8.1.2 List of Restricted Active Ingredients and Combinations:** **i) Camphor** - Existing: Oral; External (Analgesic >3%, Counter Irritant >11%) - **Amendment: Oral; External (>11%)** **ii) Menthol** - Existing: Analgesic: > 1.0%; Counter Irritant: >16% - **Amendment: External Preparations >16%** **b) Addition of the following substance in 8.1.1 (a) List of Prohibited Active Ingredients:** 1,3-dimethylamylamine (DMAA)	Pharmacy Regulatory Policy Meeting No. 1/2013
9.	May 2013	Appendix 9: Labelling Requirements	**Amendment of the following requirement at 9.1.2 Proposed Package Insert:** "Package insert (PI) is required for products containing scheduled poison and for **injectable** OTC products. PI may also be submitted for **other** OTC products. The draft copy of the PI shall be submitted for evaluation."	Drug Evaluation Committee Meeting No. 7/2013

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10.	May 2013	a) Appendix 11: Guideline On Filling The Online Application Form For Product Registration Via Quest System b) Two locations as follow: Appendix 4: Guideline on Registration of Health Supplements, 4.5 Product Name; Appendix 5: Guideline on Registration of Natural Products, 2.4 Product Name.	**a) Amendment of the following at 11.2.1 Step 1: Product Validation, [1] Product Name:** • "Product name shall not imply the following: a. Tricky, ~~confusion~~ confusive and against the law; b. ~~Scandal~~ Scandalous and offensive; c. ~~Prejudice~~ Prejudicial; d. ~~Well known~~ Notorious; e. * ~~The name which may sound like or had been used for a product that has been revoked due to safety concerns~~; f. * ~~Any other name which deemed inappropriate by the Authority.~~" * **Note:** "e" and "f" above is amended as follows: • "Any product name which is the same or similar either in writing/ pronunciation, with the product name of an adulterated product or a product that has been revoked due to safety concerns is prohibited." • "If a product name is found similar to another registered product or any other name which deemed inappropriate by the Authority, NPCB reserves the rights to request for the change of the product name." **b) Addition of the following paragraph at these two locations:** "Any product name which is the same or similar either in writing/ pronunciation, with the product name of an adulterated product is prohibited."	Drug Evaluation Committee Meeting No. 7/2013 & No. 8/2013

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11.	May 2013	Section E: Post-Registration Process	**Addition of link to the directive and amendment of procedure at 16.3 Change of Product Registration Holder**	Directive No. 4 Year 2013 *(2)dlm.BPFK/PPP/07/25, 3 Jun 2013: Direktif Untuk Meminda Prosedur Pertukaran Pemegang Pendaftaran*