LIST OF UPDATES ON DRGD FIRST EDITION, AUGUST 2013

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	August 2013	Section A: General Overview	**a) Addition of the following information under 5.1.3 Registration Of Product For Export Only (FEO)** - Applications for registration of FEO products are processed based on abridged evaluation. - Applications shall be submitted by using an application form BPFK 438.1(for Generic Medicines/ Health Supplements) and BPFK 438.1 (T) (for Traditional Products).	Drug Evaluation Committee Meeting No. 14/2013
			b) Addition of the following information under 6. General Conditions For Registration Of Drug Products Under The Control Of Drugs And Cosmetics Regulations 1984, 6.1 Registration Number: Registration number appears as MALYYMM$$$$@##, e.g. MAL11070001ACERS: - MAL refers to “Malaysia” - YYMM refers respectively to year and month of registration by the Authority (e.g. 1107: July 2011); - $$$$ refers to a serial number for a product being registered (e.g. 0001);	Pharmacy Regulatory Policy Meeting No. 2/2013

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			- @ refers to category of product being registered i.e. A/ X/ N/ T/ H; and - ## refers to administrative code used by NPCB i.e. C/ E/ R/ S. - The symbols @ and ## refer to: a) A= Scheduled Poison b) X= Non-scheduled Poisons c) N= Health Supplements d) T= Natural Products/ Traditional Medicines e) H= Veterinary Products f) C= Contract Manufactured (the product is manufactured by a GMP certified contract manufacturer) g) E= For Export Only (FEO) (the product is to be sold for export only and not for sale in the local market) h) R= Repacked (the product is repacked by an approved GMP certified repacker) i) S= Second source (the product from a second source/ approved second manufacturer)	

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			c) Addition of the following information (as highlighted in yellow) under 1.3.2 Classification of FDI Products, a) Main Criteria, no. ii) and 1.3.3 Pictorial Guide to Classification of Food-Drug Interface Products: Substances or ingredients used for therapeutic purposes shall not be added to food: Glutathione, Hyaluronic Acid, Red Yeast Rice, Natto Extract, Placenta, Bile, GABA, Resveratrol And Glucosamine	Circular (4)dlm.BPFK/PPP/01/03 Jld. 3, 5 August 2013: *Keperluan Pendaftaran Produk Food-Drug Interface (FDI) yang mengandungi bahan aktif red yeast rice, natto extract, placenta, bile, glucosamine, hyaluronic acid, glutathione, GABA, resveratrol*

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2.	August 2013	Section B: Product Registration Process	**Amendment of the following paragraph (addition of information as highlighted in yellow) under 8.3.1 Screening of Application - Satisfactory:** Upon screening approval, the applicant is requested to proceed for payment and submission of hard copy documents (if applicable). Submission of hard copy documents: Please refer **Attachment**. For payment, applicant shall ~~print three (3) copies of payment voucher and~~ submit two (2) copies of printed payment voucher together with appropriate fees to the Finance Department, NPCB for payment confirmation. The applicant is advised to keep a copy of the payment voucher as reference. A product reference number shall be given to the application upon payment confirmation. ~~Applicant shall make~~ Payment has to be made within thirty (30) days from the date of approval for screening. The application form will be deleted from the system if payment has not been made within this stipulated time.	NPCB Dialogue with MOPI, PhAMA and MAPS on DRGD 2013

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3.	August 2013	Appendix 8: List of Permitted, Prohibited And Restricted Substances	**Addition of the following combination under b) Prohibited Combinations, 8.1.1 List Of Prohibited Active Ingredients And Combinations:** Topical Preparation Containing Combination of Antibiotic, Antifungal and Steroid	Pharmacy Regulatory Policy Meeting No. 2/2013
4.	August 2013	Appendix 9: Labelling Requirements	**a) Addition of the following information (as highlighted in yellow) under 9.1.1 Label (Mock-Up) For Immediate Container And Outer Carton** * Exempted for small labels (i.e. 5ml and less) ~~such as~~ used for ampoules/ cartridge, ~~and~~ vials, eye drops, ear drops, and nose drops.	Pharmacy Regulatory Policy Meeting No. 2/2013
			b) Addition of the following information under Additional Information, 9.1.1 Label (Mock-Up) For Immediate Container And Outer Carton: Use of QR code is permitted only for the purpose of monitoring inventory of the product, such as batch number, expiry date and manufacturing date, BUT NOT for linkage to any website. The addition of QR code on registered product labels without variation approval from NPCB can be considered only if that is the only proposed change to the currently approved labels.	

Attachment:

No.	Category of Product	Online Submission	Hard copy submission
1.	NDPs	All documents as required under Part I – IV	- A copy of CD and a copy of documents as required under Part I – IV; - Nine (9) copies of indexed folders containing proposed package insert and published clinical papers and/or in-house synopses; - A copy of CD and a copy of documents as required under Appendix 6, Table 1 (*for drug substance/ API*); - Further documentations may be requested from case-to-case as deemed necessary.
2.	Biologics	All documents as required under Part I – IV	Part I – IV including published clinical papers (6 sets – indexed, listing with summary/ abstracts of each paper)
3.	Generics (Scheduled Poison)	All documents	As requested e.g. big file size, unable to be submitted online
4.	Generics (Non-Scheduled Poison)	All documents	As requested e.g. big file size, unable to be submitted online
5.	Health Supplements	All documents	As requested e.g. big file size, unable to be submitted online
6.	Natural Products	All documents	All Sections (Section A-F) Ref.: Circular (103) dlm.BPFK/PPP/01/03Jilid 2