LIST OF UPDATES ON DRGD FIRST EDITION, MAY 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	May 2014	Glossary	**Addition of the following terms:** **i) Bulk Product** A product that has completed all processing stages up to, but not including, final packaging. **ii) Contract Manufacturer** Any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations. (*as defined in Regulation 2, CDCR 1984*) **iii) Finished Product** A product that has undergone all stages of production and quality control, including packaging in its final container and labelling. **iv) Licensed Manufacturer** A person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer. (*as defined in Regulation 2, CDCR 1984*) **v) Repacker** Please refer *"Explanatory Notes for Repackers".* **vi) Explanatory Notes for Repackers**	Premises Inspection Evaluation Committee Meeting No. 4/2014, No. 5/2014 Drug Evaluation Committee Meeting No. 7/2014, No. 9/2014 Memos from Centre for Compliance & Licensing (42)dlm.BPFK/30/06/1 Bhgn 6 And (96) dlm.BPFK/30/06/1 Bhgn 6 *["Explanatory Notes for Repackers"]*

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2.	May 2014	Glossary	**Amendment of current terms as follow:** **i) ~~Manufacturing:~~** ~~The definition of 'manufacturing' includes:~~ Manufacture, in relation to any product includes – a) The making or assembling of the product; b) The enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container and; c) The carrying out of any process in the course of any of the foregoing activities. (*as defined in Regulation 2, CDCR 1984*) **ii) Manufacturer:** ~~A company that carries out at least one step of production as well as the final release of the finished product.~~ A person carrying out one or more of the steps specified in the definition of manufacture.	Premises Inspection Evaluation Committee Meeting No. 4/2014
3.	May 2014	Section A: General Overview	**Amendment of the following under 6.1 Registration Number:** R= Packed and/or repacked (the product is packed and/or repacked by an approved GMP certified packer and/or repacker)	Premises Inspection Evaluation Committee Meeting No. 5/2014

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4.	May 2014	Section B: Product Registration Proses	**Amendment of the following under 8.1.3 Requirements for Product Registration:** The implementation ~~has begun~~ began with voluntary submission for New Drug Products in April 2011 and was followed by; • Phase 1 - New Drug Products: ~~mandatory~~ January 2012 • Phase 2 - Generics (Scheduled Poison) ~~(to be determined):~~ July 2014 (by phases) • Phase 3 - Generics (Non-scheduled Poison): (to be determined)	Directive No. 3 Year 2011: *Direktif Pelaksanaan Kawalan Regulatori Bahan Aktif Farmaseutikal Di Malaysia* Directive No. 1 Year 2014: *Direktif Pelaksanaan Pengawalan Bahan Aktif Farmaseutikal bagi Produk Generic (Fasa II)*
5.	May 2014	Appendix 4 Appendix 5	a) Replacement of existing Table 14 under Appendix 4: Guideline on Registration of Health Supplements with the new table in accordance with BP 2012 *Appendix XVI D. Microbiological Quality of Non-sterile Pharmaceutical Preparations and Substances for Pharmaceutical Use - Table 5.1.5-1 – Acceptance criteria for microbiological quality of non-sterile dosage forms)* *b)* Replacement of existing Table 8 under Appendix 5: Guideline on Registration of Natural Products (2.5.7 Tests For Microbial Contamination) with the new table in accordance with BP 2012 (Appendix XVI G and Appendix	British Pharmacopoeia 2012 Memo from Centre for Quality Control: Bil(12)dlm.BPFKPKK/03/02KH 2

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			XVI D)	
6.	May 2014	Appendix 6	**a) Amendments of the following under 1. Introduction as below:** 1.3 The implementation ~~will begin~~ began with voluntary submission for New Drug Products ~~New Chemical Entities~~ in April 2011 and followed by; • ~~Phase 1 - New Chemical Entity (mandatory in Jan 2012)~~ • ~~Phase 2 - Scheduled Poison, (to be determined)~~ • ~~Phase 3 - Non-scheduled Poison (to be determined)~~ • Phase 1 - New Drug Products: January 2012 • Phase 2 - Scheduled Poison a. New Application (Generic Products):- i. Parenteral Dosage Forms : 1 July 2014 ii. Oral Dosage Forms : 1 July 2016 iii. Others : 1 July 2018 b. Registered Products:- (to be determined) *[Reference:* Directives dated 17 March 2011 Bil (12) dlm BPFK/PPP/01/03 Jld 1 and dated 16 January 2014 Bil	Directive No. 3 Year 2011: *Direktif Pelaksanaan Kawalan Regulatori Bahan Aktif Farmaseutikal Di Malaysia* Directive No. 1 Year 2014: *Direktif Pelaksanaan Pengawalan Bahan Aktif Farmaseutikal bagi Produk Generic (Fasa II)*

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		SECTION/ APPENDIX	DETAILS	
			(BPFK/PPP/07/25 (7) *]* • Phase 3 - Generic Products NOT containing Scheduled Poison (to be determined) **b) Rephrase accordingly at following parts:** • **1. Introduction** • **3. Scope** • **4. Procedure for Submission and Related Information** • **5. Option 1: Drug Master File (DMF)** • **6. Option 2: Certificates of Suitability (CEP)** • **7. Option 3: Full Details of "Part II – S ACTD" in the Product Dossier** • **References and Guidelines**	