LIST OF UPDATES ON DRGD FIRST EDITION, FEBRUARY 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	February 2014	Section A: General Overview	**Deletion of the following statement and addition of link to the related directive at 7. Use of Halal Logo** *Halal* logo may be used voluntarily on registered product label for the following categories, for both local and export market, provided that such products have been certified and approved *halal* by the Malaysia Department of Islamic Development (*Jabatan Kemajuan Islam Malaysia*, JAKIM): a) Non-scheduled poison, excluding ~~parenteral dosage form and~~ veterinary products; *Reference: Circular* (95)dlm.BPFK/PPP/01/03 Jld. 2; (6)dlm.BPFK/PPP/07/25. b) Health supplements; c) Natural products; and d) Cosmetics.	Directive No. 7 Year 2013: *Direktif perluasan logo halal kepada produk bukan racun berjadual bentuk parenteral*
2.	February 2014	Section D: Inspection & Licensing	**Addition of the following paragraph under 12. Inspection, Additional Information:** 2. Please refer (8)dlm.BPFK/PPP/07/25 Directive No. 2 Year 2014 for the requirement on Head of Production for pharmaceutical, radiopharmaceutical and veterinary product manufacturer.	Directive No. 2 Year 2014: *Keperluan Ahli Farmasi Berdaftar Memo from Centre for Compliance & Licensing (69)dlm.BPFK/30/06/1 Bhgn 6*

<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>3.</td><td>February 2014</td><td>Appendix 5: Guideline on Registration of Natural Products</td><td>Deletion of the following botanical name in List B: Botanicals which may be Adulterated with Aristolochic Acid

<u>Table 4:</u>

<table><tr><th>Botanical Name</th><th>Common or Other Names</th></tr><tr><td><s>Stephania tetrandra S. Moore</s>

Vladimiria souliei (Franch.) Ling</td><td><s>Fen fang ji , fang ji</s>
<s>Fang ji (root)</s>
<s>Han fang ji</s>
<s>Kanboi (Japanese)</s>
<s>Hanbanggi (Korean)</s>
<s>Fun-boui (Japanese)</s>

Sen-mokkou</td></tr></table></td><td>Drug Evaluation Committee Meeting No. 23/2013 & Memo from Section of Complementary Medicine (10)dlm.BPFK/PPP/06/17 Jld.40</td></tr>
<tr><td>4.</td><td>February 2014</td><td>Appendix 5: Guideline on Registration of Natural Products

Appendix 9: Labelling Requirements</td><td>Addition of the following warning statement under 2.7.2 and 9.2:

2.7.2 Specific Labelling Statements/ Warning & Precautions (Appendix 5):

For product contaning Tabebuia spp. (Pau d’arco), please state:

“As the use of Tabebuia spp. (Pau d’arco) may increase the tendency of bleeding, please consult your physician/</td><td>Drug Evaluation Committee Meeting No. 3/2014</td></tr>
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			pharmacist if you are on or intend to start using any other medicine and before you undergo any surgical/ dental procedure." (Memandangkan pengambilan Tabebuia spp. (Pau d'arco) boleh meningkatkan kemungkinan pendarahan, sila rujuk kepada doktor/ ahli farmasi sekiranya anda sedang atau akan menggunakan ubat lain dan sebelum prosedur pembedahan/ dental dijalankan) **9.2 Specific Labelling Requirements (Appendix 9)** The following warning statement shall be included on the labels of products containing Tabebuia spp. (Pau d'arco): "As the use of Tabebuia spp. (Pau d'arco) may increase the tendency of bleeding, please consult your physician/ pharmacist if you are on or intend to start using any other medicine and before you undergo any surgical/ dental procedure." (Memandangkan pengambilan Tabebuia spp. (Pau d'arco) boleh meningkatkan kemungkinan pendarahan, sila rujuk kepada doktor/ ahli farmasi sekiranya anda sedang atau akan menggunakan ubat lain dan sebelum prosedur pembedahan/ dental dijalankan)	

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5.	February 2014	Appendix 8: List of Permitted, Prohibited and Restricted Substances	**Under 8.1.1 List of Prohibited Active Ingredients and Combinations:** **Addition** of Gamma-Aminobutyric Acid (GABA) as a prohibited active ingredient.	Drug Evaluation Committee Meeting No. 3/2014
6.	February 2014	Appendix 9: Labelling Requirements	**Amendment of the following paragraph at 9.1.3:** **9.1.3 CONSUMER MEDICATION INFORMATION LEAFLET (RiMUP) ~~PATIENT INFORMATION LEAFLET~~** **Consumer Medication Information Leaflet ~~Patient Information Leaflet (PIL)~~** or in *Bahasa Malaysia* known as *Risalah Maklumat Ubat untuk Pengguna (RiMUP),* is compulsory for products which are self-administered by patients, including: a) Scheduled poisons (Category A); b) Over-the-Counter, OTC products (Category X); c) Herbal products; and health supplements with high claims (disease risk reduction). For details, please refer to: i) *Direktif Penguatkuasaan Keperluan Mengemukakan Risalah Maklumat Ubat untuk Pengguna (RiMUP) Bil. 5 Tahun 2011* Bil (15) dlm BPFK/PPP/01/03 Jld 1 ii) *Garispanduan Pelaksanaan Risalah Maklumat Ubat untuk Pengguna (RiMUP)*	Memo from Centre for Post Registration (38)dlm.BPFK/PPP/17/FV/14

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			The draft copy of the RiMUP ~~PIL~~ in both English and *Bahasa Malaysia* shall be submitted for evaluation. ***Note:*** *RiMUP ~~PIL~~ is not compulsory to be distributed with the product but will be uploaded onto NPCB website as reference for ~~patients or~~ consumers or healthcare professionals.* *For OTC Products, if the product is intended to be sold without a PI or RiMUP ~~PIL~~, the information required to be included in the PI or RiMUP ~~PIL~~ shall be printed on the unit outer-carton of the product. However, submission of the RiMUP softcopy is compulsory as mentioned above.*	