LIST OF UPDATES ON DRGD FIRST EDITION, SEPTEMBER 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	September 2014	Section A: General Overview	**5. Type of Application** **5.1 Registration of Products** **5.1.3 Registration of Product for Export Only (FEO)** **Amendment of the following:** d) For a registered product intended ~~to be exported~~ for exportation as well as to be sold in Malaysia: • New application for registration for export only will ~~is~~ NOT be required ~~necessary~~ if there is no change in the formulation ~~or~~ and appearance of the registered product. • ~~In this case,~~ A CPP will be issued to the applicant for the registered product, together with an explanation/ declaration letter of any difference(s) to the importing country (e.g. a product exported with a different product name), upon application. e) For a registered product, now intended to be for export only and no longer for sale in Malaysia: • Application for registration as a FEO product is required. • The existing registration number (i.e. MAL number) will remain the same but with the addition of the administrative code E (For Export Only)	Drug Evaluation Committee Meeting No. 14/2014

<table>
<tr>
<td>2.</td>
<td>September 2014</td>
<td>Appendix 5</td>
<td>
Addition of the following under <u>2.4 PRODUCT NAME:</u>

e) Product names which are not permitted to be registered are as specified in Table 7 below:
<table>
<tr><th>No.</th><th>Non-Permissible Product Names</th><th>Example</th></tr>
<tr><td>3.</td><td>Prohibited use of superlative - Names which indicates superiority in efficacy</td><td>Example :

Power/ Kuasa, Superior, Pure, Mustajab, Safe, Healthy/ Sihat, Penawar/ Shifa, VIP, Good, Heal/ Sembuh, Premium, Mustajab, Men/ Women/ Children Complete, Men/ Women/ Children Enriched, Paradise/ Syurga, Menawan, Booster</td></tr>
</table>
</td>
<td>Drug Evaluation Committee Meeting No. 17/2014</td>
</tr>
<tr>
<td>3.</td>
<td>September 2014</td>
<td>Appendix 5</td>
<td>
Amendment of the following under <u>2.7 Labelling Requirement</u>

2.7 Labelling requirement
<table>
<tr><th>No.</th><th>Items</th><th>Immediate Label</th><th>Outer Label</th><th>Package Insert</th><th>Blister Pack</th></tr>
<tr><td>21.</td><td>Security Label (Hologram)</td><td>√</td><td>√ #</td><td></td><td></td></tr>
</table>
In case of a product without an ~~no~~ outer carton, the security label shall be applied ~~to~~ onto the immediate label. The security label shall however not be applied onto the outer shrink wrap of the ~~a~~ product.
</td>
<td>Directive No. 2 Year 2013 (1)dlm.BPFK/PPP/07/25, 4 Apr 2013: Direktif Pelaksanaan dan Pengendalian Label Keselamatan</td>
</tr>
</table>

<table>
<tr>
<td>4.</td>
<td>September 2014</td>
<td>Appendix 9</td>
<td>
<u>9.2 Specific Labelling Requirements</u>

Addition of specific labelling requirements under <u>Table 2: List of Substances which Requires Specific Labelling</u> and <u>Table 3: Details of Specific Labelling Requirements</u> as below:
<table>
<tr><th>NO.</th><th>SUBSTANCES</th><th>ADDITION INFORMATION</th></tr>
<tr><td>89.</td><td>LOVASTATIN</td><td>i) Contraindications
ii) Dosage and Administration
iii) Warnings and Precautions
iv) Interactions</td></tr>
</table>
</td>
<td>Circular (13)dlm.BPFK/PPP/07/25 : Direktif untuk mengehadkan penggunaan produk yang mengandungi Lovastatin dengan kontraindikasi dan had dos yang baru untuk mengurangkan risiko kecederaan otot</td>
</tr>
</table>

<table>
<tr>
<td>5.</td>
<td>September 2014</td>
<td>Appendix 9</td>
<td>
Amendment of the following under <u>9.1 GENERAL LABELLING REQUIREMENTS</u>

<u>9.1.1 LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER AND OUTER CARTON</u>

<u>TABLE 1</u>

<table>
<tr><th>No.</th><th>Parameters</th><th>Outer Carton (Unit Carton)</th><th>Immediate Labels</th><th>Blister/ Strips</th></tr>
<tr><td>23.</td><td>Security Label (Hologram)</td><td>✓ #</td><td>~~✓*~~</td><td>NA</td></tr>
</table>
i. In case of a product without an ~~no~~ outer carton, the security label shall be applied ~~to~~ onto the immediate label. The security label shall however not be applied onto the outer shrink wrap of the ~~a~~ product.

ii. Exemption will be for small labels (i.e. volume of 5ml or less) ~~used for~~ such as for ampoules/ cartridge, vials, eye drops, ear drops, and nose drops.
</td>
<td>Directive No. 2 Year 2013 (1)dlm.BPFK/PPP/07/25, 4 Apr 2013: Direktif Pelaksanaan dan Pengendalian Label Keselamatan</td>
</tr>
<tr>
<td>6.</td>
<td>September 2014</td>
<td>Appendix 9</td>
<td>
Amendment of the following under <u>9.1 GENERAL LABELLING REQUIREMENTS</u> as below:

<u>Table 3: Details of Specific Labelling Requirements</u>

<table>
<tr><th>NO</th><th>SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)</th></tr>
<tr><td>16.</td><td>ARIPIPRAZOLE

Please refer to ~~DOPAMINERGIC INGREDIENT~~ ANTIPSYCHOTIC AGENTS</td></tr>
</table>
</td>
<td>Circular (14)dlm.BPFK/02/5/1.3: Keputusan Mesyuarat PBKD-Keluaran yang mengandungi bahan aktif Dopaminergik: Tambahan amaran berkaitan dengan ‘Sudden Sleep Onset’</td>
</tr>
</table>

<table>
<tr>
<td>7.</td>
<td>September 2014</td>
<td>Appendix 9</td>
<td>Removal of Loratadine from Table 2: List of Substances Which Requires Specific Labelling Requirments and Table 3: Details of Specific Labelling Requirements under <u>9.2 SPECIFIC LABELLING REQUIREMENTS</u> as below:
<table>
<tr><th>NO.</th><th>SPECIFIC LABELLING REQUIREMTNS

(SUBSTANCE SPECIFIC)</th></tr>
<tr><td>88.</td><td><s>LORATADINE</s>

<s>The following <u>boxed warning</u> shall be <u>included in the package inserts</u> of products containing Loratadine:</s>

<s>WARNING</s>

<s>Drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received macrolide antibiotics, ketoconazole, cimetidine, ranitidine, or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.</s></td></tr>
</table>
</td>
<td>Memo from Center for Post-Registration of Products (12)dlm.BPFK/17/FV/14 Jld 49, 17 Sept 2014

Circular (12)dlm.BPFK/PASCA/6A : Pekeliling untuk makluman pembatalan keperluan pelabelan spesifik bagi produk yang mengandungi loratadine</td>
</tr>
</table>

8.	September 2014	Appendix 11	**Addition of the following under <u>11.2.1 STEP 1: PRODUCT VALIDATION :</u>** **<u>[1] Product Name:</u>** • The generic name cannot be used alone as product name but in combination with another name other than generic name.	Pharmacy Regulatory Policy Meeting No. 2/2014, 3/2014