LIST OF UPDATES ON DRGD FIRST EDITION JANUARY 2013, REVISED JULY 2015

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	July 2015	Section A : General Overview.	**Amendment at Subsection 5.1.4 : Registration of Orphan Product** 2. For all categories of products namely **new chemical entities/new drugs**, **biologics and generics (including Non-Scheduled Poison product)**: i. Application for registration that being submitted to National Pharmaceutical Control Bureau (NPCB) will only be accepted/ considered after the products have been designated as orphan products. ~~by the Pharmacy Practice and Development Division, Pharmaceutical Services Division, Ministry of Health, Malaysia.~~	-
2.	July 2015	Appendix 5 : Guidelines on Registration of Natural Products	**Amendment at Subappendix 2.7 : LABELLING REQUIREMENT;** **Subappendix 2.7.3 : CAUTIONARY STATEMENT FOR PRODUCTS SPECIALLY USED IN WOMEN** However, for products containing any ingredients as listed in the following lists, i.e. List of Prohibited Ingredients in Pregnancy and List	-

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			of Restricted Ingredients in Pregnancy, the following cautionary statement shall be stated in the product label: i) Prohibited Ingredients in Pregnancy: **"Contraindicated in pregnant women. Insufficient reliable data in breastfeeding women"** ii) Restricted Ingredients in Pregnancy: **"To be used with caution in pregnancy. Insufficient reliable data in breastfeeding women"**	
3.	July 2015	Section E : Post registration Process	**Amendment at Subsection 14 : MAINTENANCE OF REGISTRATION** **Addition of the following Subsections;** **a) Subsection 14.1 : Re-registration Application** **b) Subsection 14.2 : Re-registration Processing Fee**	-

<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>4.</td><td>July 2015</td><td>APPENDIX 9 : Labelling Requirement</td><td>Amendment at Subappendix 9.2 : SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)

Addition of information on specific labelling requirements for products containing DOMPERIDONE and link to related circular.

<table>
<tr><th>NO.</th><th>SUBSTANCES</th><th>ADDITION OF INFORMATION</th></tr>
<tr><td>112.</td><td>DOMPERIDONE</td><td>i) WARNINGS
ii) THERAPEUTIC INDICATIONS
iii) DOSAGE AND ADMINISTRATION
iv) CONTRAINDICATIONS
v) WARNINGS AND PRECAUTIONS
vi) ADVERSE REACTIONS</td></tr>
</table></td><td>Reference Directive : (28)dlm.bpfk/ppp/ 07/25 ;

Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 4 Tahun 2015 : Direktif Untuk Semua Produk Domperidone Untuk Mengehadkan Penggunaan Berikutan Risiko Kesan Advers Jantung</td></tr>
</table>

<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>5.</td>
<td>July 2015</td>
<td>APPENDIX 9 : Labelling Requirement</td>
<td>
Amendment at Subappendix 9.2 : SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)

Addition of information on specific labelling requirements for products containing PARACETAMOL (including combination product) and link to related circular.
<table>
<tr><th>NO.</th><th>SUBSTANCES</th><th>ADDITION OF INFORMATION</th></tr>
<tr><td>112.</td><td>PARACETAMOL</td><td>i) WARNINGS
ii) ADVERSE EFFECT/UNDESIRABLE EFFECT</td></tr>
<tr><td>113.</td><td>PARACETAMOL WITH CAFFEINE IN COMBINATION</td><td>i) WARNINGS
ii) ADVERSE EFFECT/UNDESIRABLE EFFECT</td></tr>
</table>
</td>
<td>Reference Directive : (29)dlm.bpfk/ppp/ 07/25 ;

Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 5 Tahun 2015 : Direktif Untuk Produk Yang Mengandungi Paracetamol, Termasuk Produk Kombinasi : Pengemaskinian Label, Sisip Bungkusan, Dan Risalah Maklumat Ubat Untuk Pengguna (RiMUP) Dengan Amaran Berkaitan Kesan Advers Serius Pada Kulit</td>
</tr>
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NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
6.	July 2015	SECTION A : General Overview.	**Amendment at Subsection 5.2.5 APPLICATION FOR A CONVENIENT PACK** **5.2.5 APPLICATION FOR A CONVENIENT PACK** a) Refers to products which are packed together in a single packaging unit for convenience of the consumers, such as a Confinement Set or *Set Jamu Bersalin*. b) Shall consist of registered products only. ~~c) Applicable to health supplements and natural products only.~~ The convenient pack is applicable for registered products in the categories of; i) Health supplements. ii) Natural products. Or registered products from both categories (i) and (ii) iii) Non-Scheduled Poison (OTC) (Only between OTC products with Abridge Evaluation category) d) Application for a convenient pack shall be made via the variation process.	-

<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>7.</td><td>July 2015</td><td>SECTION B : Product Registration Process</td><td>
Amendment at Subsection 8.1.2 METHOD OF EVALUATION; Table VI : Products containing Glucosamine, Chondroitin and Methylsulphonylmethane (MSM)

Amendment of information on remarks for products containing Glucosamine and link to related circular.
<table>
<tr><th>No.</th><th colspan="2">Product</th><th>Remark</th></tr>
<tr><td rowspan="2">1.</td><td rowspan="2">Products containing Glucosamine</td><td>As single active ingredient</td><td><s>As combination with other supplement ingredients are NOT allowed to be registered</s></td></tr>
<tr><td>As combination with Chondroitin and/ or MSM</td><td>Products containing glucosamine in combination with other health supplement ingredients are only allowed to be registered for therapeutic purposes and NOT allowed to be registered as Health Supplement Product.</td></tr>
</table>
</td><td>Reference Circular : Bil. (20) dlm.BPFK/PPP/01/ 03 : Produk yang mengandungi Glucosamine, Chondroitin dan Methylsulfonylmethane (MSM)</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
8.	July 2015	APPENDIX 9 : Labelling Requirement	**Addition of Subappendix 9.1.4 : PRODUCT NAME** **Addition of information and reference table on guidance for constructing product names and list of non-permissible words/ sentences for product names.**	-
9.	July 2015	APPENDIX 9 : Labelling Requirement	**Addition of Subappendix 9.1.5 : PROHIBITED VISUAL/ GRAPHIC/ STATEMENT** **Addition of information and reference table on prohibited visual/ graphic/ statements that are not permitted to be used on product labels.**	-