LIST OF UPDATES ON DRGD FIRST EDITION, REVISED NOVEMBER 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	NOVEMBER 2014	Section A : GENERAL OVERVIEW	**Amendment and addition of the following under : <u>Section 6. GENERAL CONDITIONS FOR REGISTRATION OF DRUG PRODUCTS UNDER THE CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984</u>** **6.3 LABELLING AND PACKAGING** **6.3.1 SHRINK WRAPPING** Shrink wrapping of multiple boxes of approved pack sizes are allowable provided the following conditions are met: a) This refers to multiple boxes of approved pack sizes of a single or multiple registered products which are shrink wrapped and marketed together for convenience of the consumers. b) This only applies to registered products from the Health Supplements, Natural Products/ Traditional Medicines and Non-scheduled Poisons category (category T, N and X). c) The shrink wrap does not come into contact with the dosage form. d) There are no qualitative or quantitative changes to the approved registered primary packaging and the outer packaging.	Drug Evaluation Committee Meeting No. 17/2014

NO.	REVISION	UPDATES		REFERENCE
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			e) There are no changes to the label contents of the product, and the label contents are not obscured. f) The shrink wrap used must be completely transparent and does not contain any stickers/ wordings/ graphics.	
2.	NOVEMBER 2014	Section A : GENERAL OVERVIEW	**Updating of content and table format for Medical Device-Drug-Cosmetic Interphase (MDDCI) Product Classification Decision.**	MDDCI Steering Committee Meeting No. 02/2014
3.	NOVEMBER 2014	Section A : GENERAL OVERVIEW	**Addition of the following under : <u>Section 6. GENERAL CONDITIONS FOR REGISTRATION OF DRUG PRODUCTS UNDER THE CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984.</u>** **6.1 REGISTRATION NUMBER** j) Y= Orphan products k) Z= Products listed under the National Essential Medicine List (NEML) for zero rated Government Services Tax (GST)	Drug Evaluation Committee Meeting No. 21/2014

<table>
<tr><th rowspan="2">NO.</th><th rowspan="2">REVISION</th><th colspan="2">UPDATES</th><th rowspan="2">REFERENCE</th></tr>
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<tr><td>4.</td><td>NOVEMBER 2014</td><td>APPENDIX 5</td><td>Addition of the following under <u>Section 2.7.2 SPECIFIC LABELLING STATEMENTS/ WARNING & PRECAUTIONS</u>
<table><tr><th>No</th><th>Substance</th><th>Specific Cautionary Statement</th></tr><tr><td>6</td><td>For pack size meant as samples, please state:</td><td>Sample not for sale</td></tr></table></td><td>Drug Evaluation Committee Meeting No. 17/2014</td></tr>
<tr><td>5.</td><td>NOVEMBER 2014</td><td>Appendix 5</td><td>Addition of the following under <u>2.7 LABELLING REQUIREMENT</u>

c) # In case the product has no outer carton, the security label shall be applied to the immediate label. The security label should in no way be applied onto the outer shrink wrap of a product.
d) Font size of the product name on the label, including alphabets and numbers, should be equal in size.
e) For a product containing 2 or more active ingredients, font size of each active ingredient must be of equal size and equal prominence.</td><td>Drug Evaluation Committee Meeting No. 17/2014</td></tr>
<tr><td>6.</td><td>NOVEMBER 2014</td><td>APPENDIX 9</td><td>Addition of the following under <u>9.2 : Specific Labelling Requirements</u>
Table 2 : : List of Substances Which Requires Specific Labelling Requirements</td><td>Pharmacy Regulatory Policy Meeting</td></tr>
</table>

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<table>
<tr><th>NO.</th><th>SUBSTANCES</th></tr>
<tr><td>21.</td><td>BENZYL ALCOHOL</td></tr>
<tr><td>22.</td><td>HERBAL CONTAINING NATURALLY OCCURRING BERBERINE (EXCEPT ALL SPP FROM GENUS BERBERIS WHICH IS BANNED)</td></tr>
<tr><td>23.</td><td>BLACK COHOSH (CIMICIFUGA RACEMOSA)</td></tr>
</table>
Table 3 : Details of Specific Labelling Requirements
<table>
<tr><th>NO.</th><th>SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)</th></tr>
<tr><td>22.</td><td>HERBAL CONTAINING NATURALLY OCCURRING BERBERINE (EXCEPT ALL SPP FROM GENUS BERBERIS WHICH IS BANNED)

The following statement shall be included on the label and in the package insert of products containing the berberine alkaloid:

WARNING

Not to be taken by babies, children under 12 years of age,</td></tr>
</table>
</td><td>No. 3/2014</td></tr>
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			pregnant women or lactating mothers. Consult your practitioner if you have conditions such as : -Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency -Haemolytic anemia -Glaucoma -Diabetes -High Blood Pressure -History of cardiovascular disease -If you are using Paclitaxel, Cyclosporin, or other chemotherapeutic agents.	
7.	NOVEMBER 2014	APPENDIX 9	**Addition of the following under : <u>SECTION 9.1 GENERAL LABELLING REQUIREMENTS</u>** **9.1.1 LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER AND OUTER CARTON** **<u>Additional Information</u>** **g)** The label of a registered product containing any Scheduled Poison shall not have colourful atrwork or graphics that can be misleading or will adversely influence caregivers'/patients'/children's perceptions of the appropriateness of the medication. **h)** Please refer to **Figure 1** as an example of a product label which in	Drug Evaluation Committee Meeting No. 15/2014

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<tr><td></td><td></td><td></td><td>accordance to the labelling requirements.</td><td></td></tr>
<tr><td>8.</td><td>NOVEMBER 2014</td><td>APPENDIX 12</td><td>Addition of the following under : <u>CONDITIONS AND SUPPORTING DOCUMENTS REQUIRED FOR AN APPLICATION OF VARIATION</u>

a) VARIATION TYPE I (MINOR VARIATION) :
<table>
<tr><th rowspan="2">NO.</th><th rowspan="2">VARIATION TYPE I

(MINOR VARIATION)</th><th colspan="2">AFFECTED FIELDS</th><th rowspan="2">SUPPORTING DOCUMENTS REQUIRED AND CONDITIONS APPLIED</th></tr>
<tr><th>FULL EVALUATION</th><th>ABRIDGED EVALUATION</th></tr>
<tr><td>7.</td><td>• Change in pack size of the drug product (Finished product), without change in primary packaging material.</td><td>• C
• D1
• D2
• D3
• E8 (if applicable)

• P7</td><td>• C
• D1
• D2
• D3
• F8 (if applicable)</td><td><u>CONDITIONS</u>

3. The new size is consistent with the dosage regimen and duration of use as approved in the package insert.</td></tr>
</table></td><td>Drug Evaluation Committee Meeting No. 17/2014</td></tr>
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				(including pack size meant as samples) • Change in the number or units (e.g. tablets, ampoules) in a pack. • Change in volume of non sterile preparations			*The sentence 'Sample not for sale' can be added in the product label without going through variation approval. <u>SUPPORTING DOCUMENTS</u> Revised drafts of the package insert and labeling incorporating the proposed variation (where applicable).	