

LIST OF UPDATES ON DRGD FIRST EDITION, JULY 2013

NO.	REVISION	UPDATES		REFERENCE				
		SECTION/ APPENDIX	DETAILS					
1.	July 2013	Appendix 5: Guideline on Registration of Natural Products	<p>a) Addition of the following information in Table 7 Product Names Which Are Not Permitted To Be Registered:</p> <table border="1"> <thead> <tr> <th>Non-Permissible Product Names</th> <th>Example</th> </tr> </thead> <tbody> <tr> <td>Name of internal organ</td> <td>Example: Liver, Brain, Kidney, etc.</td> </tr> </tbody> </table> <p>b) Addition of the following information (as highlighted in yellow) under 2.5.3 Quality Testing For Specific Ingredient:</p> <p>ii) For products containing Red Yeast Rice (<i>Monascus purpureus</i>), applicants shall provide certificates of analysis (for both raw material and finished product) showing the Monacolin-K content. The percentage of Monacolin-K shall not exceed 1% and the Monacolin-K consumed shall not exceed 10 mg per day.</p>	Non-Permissible Product Names	Example	Name of internal organ	Example: Liver, Brain, Kidney, etc.	<p>Memo from Sub-Section of Complementary Medicine (1)dIm.BPFK/PPP/06/17 Jilid 35</p> <p>Drug Evaluation Committee Meeting No. 12/2013 [c] For products containing Psyllium/ Plantago (Seed/ Husk)]</p>
Non-Permissible Product Names	Example							
Name of internal organ	Example: Liver, Brain, Kidney, etc.							

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			<p>c) Addition of the following information (as highlighted in yellow) under 2.7.2 Specific Labelling Statements/ Warning & Precautions:</p> <ul style="list-style-type: none"> • For products containing Senna Leaf (Cassia spp.) – fruit/ pod/ semen and leaf and Rhubarb/ Radix et Rhizoma Rhei/ Rheum Palmatum/ Rheum Officinale – root part, please state: <ul style="list-style-type: none"> - “Do not use when abdominal pain, nausea or vomiting is present.” - “Frequent or prolonged use of this preparation may result in dependence towards the product and ‘imbalanced electrolytes’.” - “Please consult a healthcare practitioner for use beyond 7 days.” • For products containing Psyllium/ Plantago (Seed/ Husk), please state: <ul style="list-style-type: none"> - “If the constipation does not resolve within 3 days or if abdominal pain occurs or in case of any irregularity of faeces, the use of psyllium should be discontinued and medical advice must be sought.” - “Please consume a large amount of fluid/ water when taking this product.” 	

NO.	REVISION	UPDATES		REFERENCE				
		SECTION/ APPENDIX	DETAILS					
2.	July 2013	Appendix 8: List of Permitted, Prohibited and Restricted Substances	<p>Amendment on Cyclamates under 8.2 List of Prohibited and Restricted Excipients:</p> <ul style="list-style-type: none"> - Deleted from 8.2.1 List of Prohibited Excipients. - Added in 8.2.2 List of Restricted Excipients as follows: <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>Excipients</th> <th>Restrictions</th> </tr> </thead> <tbody> <tr> <td>Cyclamates</td> <td>Limited to not more than 1.5mg/kg body weight/day</td> </tr> </tbody> </table>	Excipients	Restrictions	Cyclamates	Limited to not more than 1.5mg/kg body weight/day	Drug Evaluation Committee Meeting No. No. 12/2013, 25 June 2013 & Memo from Sub-Section of Complementary Medicine (55)d/m.BPFK/PPP/06/17 Jilid 34
Excipients	Restrictions							
Cyclamates	Limited to not more than 1.5mg/kg body weight/day							