LIST OF UPDATES ON DRGD FIRST EDITION, JULY 2014

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	July 2014	Section A: General Overview	**1) Additional subtopic 5.1.4 REGISTRATION OF ORPHAN PRODUCT under topic 5. TYPES OF APPLICATION** **2) Additional information under 6.1 REGISTRATION NUMBER as below:** Registration number appears as MALYYMM$$$$@##, e.g. MAL11070001ACERSY - ## refers to administrative code used by NPCB i.e. C/ E/ R/ S/ Y. - The symbols @ and ## refer to: a) A= Scheduled Poison b) X= Non-scheduled Poisons c) N= Health Supplements d) T= Natural Products/ Traditional Medicines e) H= Veterinary Products f) C= Contract Manufactured (the product is manufactured by a GMP certified contract manufacturer) g) E= For Export Only (FEO) (the product is to be sold for export only and not for sale in the local market) h) R= Packed and/or repacked (the product is packed and/or repacked by an approved GMP certified packer and/or repacker) i) S= Second source (the product from a second source/ approved second manufacturer) j) Y= Orphan products	Drug Control Authority Meeitng No. 275 Pharmacy Regulatory Policy Meeting No. 2/2014 Memo from Section Generic Medicine: (48)dlm. BPFK/ PPP/ 06/17 Jld.47

<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>2.</td><td>July 2014</td><td>Appendix 9</td><td>

9.2 Specific Labelling

Addition of specific labelling requirements under Table 2: List of Substances which Requires Specific Labelling and Table 3: Details of Specific Labelling as below:

<table>
<tr><th>NO.</th><th>SUBSTANCES</th><th>ADDITION INFORMATION</th></tr>
<tr><td>109</td><td>PALIPERIDONE</td><td>i) Warnings and Precautions
ii) Undesirable effects</td></tr>
<tr><td>130</td><td>RISPERIDONE</td><td>i) Warnings and Precautions
ii) Undesirable effects</td></tr>
<tr><td>138</td><td>SIMVASTATIN</td><td>i) Dosage and administration
ii) Contraindications
iii) Interactions</td></tr>
<tr><td>143</td><td>STRONTIUM RANELATE</td><td>i) Black box warning
ii) Indication
iii) Contraindications
iv) Special warnings and precautions for use
v) Undesirable effects</td></tr>
</table>

</td><td>Circular (16)dlm.BPFK/PPP/01/03 Jld.3: *Pekeliling tentang langkah-langkah pengurangan risiko bagi produk yang mengandungi Strontium Ranelate susulan risiko kesan advers kardiovaskular*

Circular (17)dlm.BPFK/PPP/01/03 Jld.3: *Pekeliling untuk mengemaskini sisip bungkusan semula produk yang mengandungi Risperidone atau Paliperidone dengan amaran berkaitan risiko Intraoperative Floppy Iris Syndrome (IFIS) pada pesakit yang menjalani pembedahan katarak*

Circular (18)dlm.BPFK/PPP/01/03 Jld.3: *Pekeliling untuk mengemaskini sisip bungkusan semua produk yang mengandungi simvastatin dengan memuatkan kontraindikasi dan had dos yang baru*</td></tr>
</table>