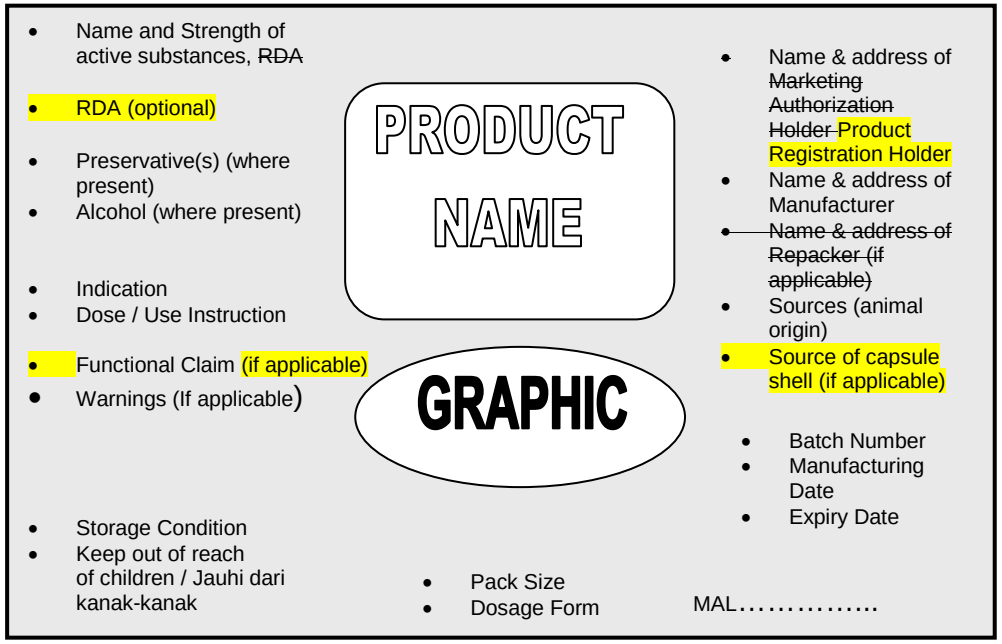
# LIST OF UPDATES ON DRGD FIRST EDITION, JUN 2014

<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>1.</td><td>Jun 2014</td><td>Appendix 4</td><td>

**1. Addition of symbol of asterisk (*) for Assay under Testing Parameters of Stability Study for each type of dosage form (Table 12):**

a) Assay *

**2. Amendments of Standard Labelling for Health Supplements under Section D: LABELLING REQUIREMENTS**




</td><td>Drug Evaluation Committee Meeting No. 9/2014<br><br>Memo from Section Complementary: (30)dlm. BPFK/ PPP/ 06/17 Jld.45</td></tr>
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| 2. | Jun 2014 | Appendix 9 | **Amendment of the following parameter under 9.1.1 LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER AND OUTER CARTON**<br>a) No. 17 To declare source of ingredients derived from animal origin (active and excipient) including starting materials and gelatin ~~(capsule shell)~~<br>b) No.18 To declare the source of capsule shell (if applicable)<br>c) No 19. Recommended daily allowance (RDA) for vitamins/ mineral preparations used as dietary supplements (optional)<br><br>**Addition of the following note under 9.1.1 LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER AND OUTER CARTON**<br>Declaration of nutrition information per serving (for example energy, carbohydrate, protein and fat) is not permitted in a health supplement product label. | Drug Evaluation Committee Meeting No. 9/2014<br><br>Memo from Section Complementary: (30)dlm. BPFK/ PPP/ 06/17 Jld.45 |
| 3. | Jun 2014 | Section C: Quality Control | **Addition note for Microbial Contamination test, Table VIII, 9.2 Specific Requirements:**<br>*Note:<br>Products are not allowed to send for gamma radiation treatment for the control of microbial contamination. Please refer to this circular for details:<br>Aktiviti Pendedahan Produk Berdaftar kepada Sinar Gamma | Circular (54)dlm.BPFK/02/5/1.3, 16 Apr 2006:<br>*Aktiviti Pendedahan Produk Berdaftar kepada Sinar Gamma* |

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<tr><td>4</td><td>Jun 2014</td><td>Section B Product Registration Proses</td><td>Amendment at 8.1.7 Variants:<br><br>~~A maximum of five (5)~~ variants to the registered product may be considered for the following dosage forms:</td><td>Drug Evaluation Committee Meeting No. 10/2014</td></tr>
<tr><td>5</td><td>Jun 2014</td><td>Appendix 13</td><td>Amendment of the following:<br><br>a) Supporting documents required for change of manufacturing site (COS) application<br><br>~~*Note: Existing COS Type I conditions (change within the same entity, change of location and transfering back to own manufacturing premise) for pharmaceutical products will still follow the requirement in Table (b) until 30 June 2014.~~<br><br>b) ~~*~~ Supporting documents required for Type I change of manufacturing site (COS) application for natural products ~~& existing COS Type I conditions for pharmaceutical products~~<br><br><table><tr><th>No.</th><th>Documents to be submitted</th></tr><tr><td>9.</td><td>Letter of commitment to submit stability data~~,~~ and certificate of analysis ~~and process validation report (where applicable)~~ after approval of site change.</td></tr></table></td><td>Circular (7)dlm.BPFK/PPP/01/03 Jld. 3: Kebenaran pertukaran tapak pengilang ke pengilang kontrak tempatan melalui prosedur pertukaran tapak pengilang dan meminda dokumen sokongan bagi pertukaran tapak pengilang jenis I</td></tr>
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| | | | 11. Letter of commitment to submit comparative dissolution profile between the proposed and current site for oral solid dosage forms that are entitled for "biowaiver".<br><br>*For further information, please refer circular:*<br><br>(31) dlm. BPFK/PPP/01/03<br><br>*OR*<br><br>Letter of commitment to submit report of bioavailability and bioequivalence studies for generic products.<br><br>*OR*<br><br>Letter of commitment to submit comparative dissolution profile between the proposed and current site for oral solid dosage forms for innovator products, if applicable.<br><br>*(Please Refer to ASEAN Guidelines and list of products requiring BA and BE study).* | |

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<td>Jun 2014</td>
<td>Appendix 9</td>
<td>
<u>9.2 Specific Labelling Requirements</u><br><br>
Addition of specific labelling requirements under <u>Table 2: List of Substances which Requires Specific Labelling Requirements</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>17.</td><td>ARTESUNATE</td><td>Please refer to MEFLOQUINE for products containing Mefloquine in combination with other active ingredients (mefloquine/artesunate)</td></tr>
<tr><td>44</td><td>CYPROTERONE ACETATE WITH ETHINYLESTRADIOL IN COMBINATION</td><td>• Indication<br>• Dosage and method of administration<br>• Undesirable effects</td></tr>
<tr><td>55</td><td>ETHINYLESTRADIOL</td><td>Please refer to CYPROTERONE ACETATE WITH ETHINYLESTRADIOL IN COMBINATION for products containing cyproterone acetate 2mg with ethinylestradiol 0.035mg in combination.</td></tr>
<tr><td>90.</td><td>MEFLOQUINE</td><td>• Special warnings and precautions for use<br>• Postmarketing adverse event</td></tr>
<tr><td>108</td><td>ONDANSETRON</td><td>Dosage and administration</td></tr>
</table>
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<td>Circular (14)dlm.BPFK/PPP/01/03 Jld.3: Pengemaskinian sisip bungkusan semua produk oral mengandungi kombinasi cyproterone acetate 2mg dan ethinylestradiol 0.035mg dengan memperketatkan indikasi dan mengukuhkan amaran berkaitan risiko thromboembolism<br><br>Circular (13)dlm.BPFK/PPP/01/03 Jld.3: Pengemaskinian sisip bungkusan semua produk antimalaria yang mengandungi mefloquine (termasuk produk kombinasi) dengan maklumat keselamatan berkaitan kesan advers pada sistem saraf (neurologik) yang berpanjangan dan gangguan penglihatan<br><br>Circular (13)dlm.BPFK/PPP/01/03 Jld.3: Pengemaskinian sisip bungkusan semua produk injeksi yang mengandungi ondansetron dengan maklumat keselamatan baru berkaitan dose dan kesan advers pemanjangan tempoh QT jantung yang boleh mengakibatkan “Torsade de pointes” (arrhythmia jantung yang mengancam nyawa)</td>
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