

LIST OF UPDATES ON DRGD FIRST EDITION, NOVEMBER 2013

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	November 2013	Section E: Post-Registration Process	<p>Addition of link to the following circular under 14. Maintenance of Registration</p> <p>(5)dIm.BPFK/PPP/01/03</p>	<p>Circular (5)dIm.BPFK/PPP/01/03 Jld. 3, 14 August 2013: <i>Lanjutan Tarikh Kuatkuasa Untuk Memenuhi Keperluan Data Kajian Stabiliti Dalam Zon IV B Bagi Produk Farmaseutikal Berdaftar</i></p>
2.	November 2013	Section E: Post Registration Process	<p>Replacement of this statement at 16.4.2 VERIFICATION PROCESS:</p> <p>“For new indication which has been registered in European Countries (United Kingdom, Sweden and/or France) and one of the other Authority’s reference countries (United States of America, Australia, Canada, Japan and Switzerland).” (deleted)</p> <p>With the following:</p> <p>“For new indication which has been registered by <u>any two</u> reference country’s authorities (United Kingdom, Sweden, France, United States of America, Australia, Canada, Japan, Switzerland and EMA).” (replacement)</p>	<p>Pharmacy Regulatory Policy Meeting No. 3/2013</p>

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3.	November 2013	Appendix 2: Requirements For Product Registration	<p>Addition of the following paragraph under B) BIOEQUIVALENCE (BE) STUDY:</p> <p>Note: The two above directives shall be read in conjunction with the supplementary circular that further explains the procedure for evaluation of BE centre inspection reports in line with the requirement of accreditation of BE Centres. (Reference: Circular dated 12 September 2013; Bil(6)dIm.BPFIK/PPP/01/03 Jld 3.)</p>	<p>Memo from Section of Generic Medicine (15)dIm.BPFIK/PPP/06/17 Jilid 37</p> <p>&</p> <p>Circular (6)dIm.BPFIK/PPP/01/03 Jld. 3</p>
4.	November 2013	<p>Appendix 4: Guideline on Registration of Health Supplements;</p> <p>Appendix 5: Guideline on Registration of Natural Products;</p> <p>Appendix 9: Labelling Requirements.</p>	<p>Amendment of the following paragraph under labelling requirement of Appendix 4 and Appendix 5 as well as Table 1 in Appendix 9:</p> <p>To declare source of ingredients derived from animal origin (active and excipient) including starting materials and gelatine (capsule shell), including gelatin (active, excipient, and/or capsule shell)</p>	<p>Drug Evaluation Committee Meeting No. No. 17/2013</p>

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5.	November 2013	Appendix 5: Guideline on Registration of Natural Products	<p>a) Addition of the following allowance limit at 2.2 Excipient:</p> <p>LIST OF RESTRICTED EXCIPIENTS:</p> <table border="1"> <thead> <tr> <th>Specific Excipient</th> <th>Limits (Not allowed)</th> </tr> </thead> <tbody> <tr> <td>1. Menthol</td> <td>- Oral (>10mg/day) - External (>10%)</td> </tr> </tbody> </table> <p>b) Addition of the following paragraph at 2.4 PRODUCT NAME and amendment in Table 7 Non-Permissible Product Names:</p> <p>“For products in which the product name is the name of active ingredient or the product name is a common name, e.g. <i>Kapsul Kacip Fatimah</i>; <i>Misal Kucing Tea</i>; <i>Ortosiphon Capsule</i>; <i>Herbal Rub</i>; <i>Natural Herb Capsule</i>, a brand name shall be added to the product name, in order to differentiate and identify this specific product.”</p> <p><i>Note: Please refer amendment in Table 7 Non-Permissible Product Names in Attachment.</i></p>	Specific Excipient	Limits (Not allowed)	1. Menthol	- Oral (>10mg/day) - External (>10%)	Memo from Section of Complementary Medicine (56)dIm.BPFK/PPP/06/17
Specific Excipient	Limits (Not allowed)							
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6.	November 2013	Appendix 5: Guideline on Registration of Natural Products	<p>c) Amendment of the following statements (addition as highlighted with yellow) under 2.7.4 Prohibited Visual/ Graphics/ Statement On Packaging Material (Label, Box, Package Insert Or Patient Information Leaflet)</p> <table border="1"> <thead> <tr> <th>No.</th> <th>Subject Matter</th> <th>Example(s)</th> <th>Notes</th> </tr> </thead> <tbody> <tr> <td>10.</td> <td>Introduction/ description of founder/ manufacturer i.e. elaboration on the identity of the founder or manufacturer</td> <td>Manufacturer ABC is a GMP certified manufacturer and has manufactured many products. Founder Dr. ABC is a world renowned surgeon.</td> <td>Prohibited on product label</td> </tr> </tbody> </table>		No.	Subject Matter	Example(s)	Notes	10.	Introduction/ description of founder/ manufacturer i.e. elaboration on the identity of the founder or manufacturer	Manufacturer ABC is a GMP certified manufacturer and has manufactured many products. Founder Dr. ABC is a world renowned surgeon.	Prohibited on product label	
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7.	November 2013	Appendix 9: Labelling Requirements	<p>Addition of the word ‘parenteral’ in the following statement under 9.2 Specific Labelling Requirements, No. 20 – Benzyl Alcohol:</p> <p>The following <u>statement</u> shall be <u>included on label and in package insert</u> of parenteral products containing benzyl alcohol:</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age.</p> <p>Not to be used in neonates.</p> </div>	Pharmacy Regulatory Policy Meeting No. 3/2013

Attachment:

* Addition of information as per highlighted in yellow.

No.	Non-Permissible Product Names	Example
1.	Prohibited use of disease names as stated in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983)	Example : Diabetes, Asthma, Cancer
2.	Prohibited use of a single active ingredient as a product name in products containing more than one active ingredient unless product name contains words such as 'Plus, Compound, Complex, Herbanika	Example : Tongkat Ali Capsule ---- But product contains tongkat ali, ginseng, ect.
3.	Prohibited use of superlative - Names which indicates superiority inefficacy	Example : Power/ Kuasa, Superior, Pure, Mustajab, Safe, Healthy/ Sihat, Penawar/ Shifa, VIP, Good, Heal/ Sembuh, Premium, Mustajab, Men/ Women/ Children Complete, Men/ Women/ Children Enriched, Paradise/ Syurga, Menawan
4.	Prohibited use of spelling of words which may cause confusion Words which involve names of/part thereof: i) 20 disease names prohibited in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983) ii) Other Diseases without scientific proof evidence of efficacy/ prescription medication to treat diseases/ parameters that indicate certain diseases (e.g. insulin, glucose) iii) Prohibited indication (e.g. to detoxify body)	Example : a) Go Out = GOUT (label) b) UTix = Urinary Tract Infection c) Diabecine = Diabetes d) Metformon = Metformin e) Insuprem = Insulin f) Glucosey = Glucose g) DetoxB = Detox body

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5.	<p>Prohibited use of names which may cause ambiguity Ambiguous product name</p>	<p>Example: B For Energy?</p>
6.	<p>Prohibited use of names which may be offensive or indecent</p>	<p>Example: SENXBIG=SEnXBIG(label) Sexy, Enjoy, Paradise, Heavenly, Blue boy, Casanova, Desire (<i>Dezire</i>), <i>Sensual</i> (<i>Xenxual</i>), <i>Asmara</i>, <i>Syok</i></p>
7.	<p>Prohibited use of product names which are incoherent with the approved indication Name containing a product claim whereas product is indicated for more than the approved indication</p>	<p>Example: Cough Syrup X= Approved indication for cough, dizziness, flu and itch</p>
8.	<p>Prohibited use of product names which has elements of ludicrous belief Statements referring to ancient believe/ negative spirits/ supernatural power</p>	<p>Example: Words such as miracle, magic, magical, miraculous, saintly, heavenly</p>
9.	<p>Prohibited use of product names similar to the existing approved product names Product names similar to the spelling and pronunciation of words of the existing product names</p>	<p>Example: Tenormin vs Tenormine vs Tenormy Re-Liv vs Re-Lif</p>
10.	<p>Prohibited use of product names which may cause ambiguity in the nature of product (drug/ food/ beverage) Product names similar to a food/ beverage product</p>	<p>Example: Juice, Health drink, Beverage, Kooky</p>
11.	<p>Prohibited use of product names which represents professional advice or opinion or referring to the profession</p>	<p>Example: Dr Sunny, Dr Noortier Rooibose Tea, Professor, Herbalist, Doctor</p>

No.	Non-Permissible Product Names	Example
12.	Prohibited use of product names which represent weight loss/ slimming properties	Example: Slim, Langsing, Trim, Trimnfit, Sleen, Kurus, Susut perut
13.	Prohibited use of product names referring to any religious content	Example: Maksum, Mahmudah, Arifbillah
14.	Name of internal organ	Example: Liver, Brain, Kidney, etc.
15.	Prohibited use of abbreviation as a product name	Example: TVB, PLQ
16.	Other prohibited product names	Example: Minda, IQ, Smart, Genius, Ultra Mega, Detox

Note:

The Authority reserves the right to disallow any other words or phrases for product names which in its opinion is misleading, improper or not factual.