LIST OF UPDATES ON DRGD FIRST EDITION, JANUARY 2013, REVISED JANUARY 2016

<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>January 2016</td><td>APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS</td><td>Amendment at Subappendix 2.4 : Product Name.

Addition of content for point (j) & (k) ;
(j) The name of the active ingredient is not allowed to be used as brand name.
(k) The name of active ingredient combined with product indication is not allowed to be used as product name.
(l) Product names which are not permitted to be registered are as specified in Table 7 below:</td><td>Drug Evaluation Committee Meeting No. 20/2014 & 18/2015</td></tr>
<tr><td>2.</td><td>January 2016</td><td>APPENDIX 9: LABELING REQUIREMENTS</td><td>Amendment at Subappendix 9.2: Specific Labeling Requirement.
Table 2 : List of substances which requires specific labeling requirement.

Addition of new substance at No. 101 : Natural occurring berberine alkaloids in plants other than genus Berberis.

<table><tr><th>No.</th><th>Substances</th></tr><tr><td>103.</td><td>MUCOLYTIC AGENT</td></tr></table></td><td>Circular: Bil.(22)dlm.BPFK/PPP/06/12 Jld.26. Kawalan produk mengandungi bahan aktif yang mempunyai berberine secara semulajadi.</td></tr>
</table>

<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></td><td></td><td></td><td><table>
<tr><td>104.</td><td>NATURAL OCCURING BERBERINE ALKALOIDS IN PLANTS OTHER THAN GENUS BERBERIS (E.G. HYDRATIS CANADENSIS, COPTIS CHINENSIS, FIBRAUREA CHLOROLEUCA ETC)</td></tr>
<tr><td>105.</td><td>NEVIRAPINE</td></tr>
</table></td><td></td></tr>
<tr><td>3.</td><td>January 2016</td><td>APPENDIX 9: LABELING REQUIREMENTS</td><td>Amendment at Subappendix 9.2: Specific Labeling Requirement.
Table 3 : Details of specific labeling requirement

Addition of new warning statements for traditional products containing natural occurring berberine alkaloid in plants other than genus Berberis.<table>
<tr><th>No.</th><th>SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)</th></tr>
<tr><td>104.</td><td>NATURAL OCCURING BERBERINE ALKALOIDS IN PLANTS OTHER THAN GENUS BERBERIS (E.G. HYDRATIS CANADENSIS, COPTIS CHINENSIS, FIBRAUREA CHLOROLEUCA ETC)

The following warning shall be included in the label of the product:</td></tr>
</table></td><td>Circular: Bil.(22)dlm.BPFK/PPP/06/12 Jld.26.
Kawalan produk mengandungi bahan aktif yang mempunyai berberine secara semulajadi.</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			Warning: **1. Not to be taken by babies, children under 12 years of age, pregnant women or lactating mothers.** **2. 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 or** **- If you are using paclitaxel, cyclosporin or other chemotherapeutic agents.**	

<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>4.</td><td>January 2016</td><td>APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS</td><td>Amendment at Subappendix 2.7.4 : Prohibited visual/ graphics/ statement on packaging material (Label, box, package insert or consumer medication information leaflet)

Table 12 :

Deletion of item (5) in the table:
<table><tr><th>No.</th><th>Subject Matter</th><th>Example(s)</th><th>Notes</th></tr><tr><td>~~5~~</td><td>~~Photograph of product pioneer~~</td><td></td><td>~~Not allowed~~</td></tr></table>
Amendment of wording for item (17) in the table
<table><tr><th>No.</th><th>Subject Matter</th><th>Example(s)</th><th>Notes</th></tr><tr><td>17.</td><td>~~Sex symbol~~ Gender symbol (male or female)</td><td>(♀ and/or ♂)</td><td>Prohibited on product label</td></tr></table></td><td>Drug Evaluation Committee Meeting No. 20/2015</td></tr>
<tr><td>5.</td><td>January 2016</td><td>APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS</td><td>Amendment at Subappendix 2.7.4 : Prohibited visual/graphic/ statement on packaging material (Label, box, package insert or consumer medication information leaflet)

Table 12 :

Addition of following keynote at the end of Table 12:
New :
- The list is not to be exhaustive and will be reviewed from</td><td>Drug Evaluation Committee Meeting No. 20/2015</td></tr>
</table>

<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></td><td></td><td></td><td>time to time.
- The Authority reserves the right to disallow any other words, phrases or graphic for product label which is in its opinion is misleading, improper or not factual.</td><td></td></tr>
<tr><td>6.</td><td>January 2016</td><td>APPENDIX 4: GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS</td><td>Amendment at Section D : Labeling Requirement
Table 13 : Prohibited visual/graphics on label.

Amendment involved in item (15) in the table
<table><tr><th>No.</th><th>Subject Matter</th><th>Example(s)</th><th>Notes</th></tr><tr><td>17.</td><td><s>Sex symbol</s> Gender symbol (male or female)</td><td>(♀ and/or ♂)</td><td>Prohibited on product label</td></tr></table></td><td>Drug Evaluation Committee Meeting No. 20/2015</td></tr>
<tr><td>7.</td><td>January 2016</td><td>APPENDIX 4: GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS</td><td>Amendment at Section D : Labeling requirement
Table 13 : Prohibited visual/graphics on label.

<u>Addition</u> of following points in the existing Table 13:
<table><tr><th>No.</th><th>Issues</th><th>Example</th><th>Note</th></tr><tr><td>20.</td><td>Photograph of celebrities</td><td>Example
- Artiste, sports person(s), politician</td><td>Prohibited on product label</td></tr></table></td><td>Drug Evaluation Committee Meeting No. 20/2015</td></tr>
</table>

<table>
<tr><th rowspan="2">NO.</th><th rowspan="2">REVISION</th><th colspan="4">UPDATES</th><th rowspan="2">REFERENCE</th></tr>
<tr><th>SECTION/ APPENDIX</th><th colspan="3">DETAILS</th></tr>
<tr><td></td><td></td><td></td><td colspan="3"><table>
<tr><td>21.</td><td>Statement on sugars</td><td>Example
- This product contains no sugar
- This product contains no added sugar</td><td>The statement is allowed on product label provided the product contains no fructose, glucose, sucrose, or other kind of sugars with a potential to affect diabetics are not included in the formulation</td></tr>
<tr><td>22.</td><td>Negative statement</td><td>Example
- No gluten, yeast etc</td><td>Prohibited on product label</td></tr>
<tr><td>23</td><td>Other statements</td><td>Example :
- This product is blended with premium quality
- Certified chemical residue free</td><td>Prohibited on product label</td></tr>
</table></td><td></td></tr>
</table>

<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>8.</td><td>January 2016</td><td>APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS</td><td>Amendment at Table 10: List of prohibited ingredients in pregnancy

Table 10 : Addition of 9 ingredients as listed below;

<table>
<tr><th>No.</th><th>Name of herbs</th><th>Common name</th></tr>
<tr><td>1.</td><td>Glycyrrhiza glabra/ Glycyrrhiza uralensis</td><td>Licorice</td></tr>
<tr><td>2.</td><td>Aloe barbadensis</td><td>Aloe vera</td></tr>
<tr><td>3.</td><td>Epimedium grandiflorum</td><td>Horny goat weed</td></tr>
<tr><td>4.</td><td>Hyssopus officinalis</td><td>Hissopo</td></tr>
<tr><td>5.</td><td>Nigella sativa</td><td>Black seed/ black cumin</td></tr>
<tr><td>6.</td><td>Calomelas</td><td>Qing fen</td></tr>
<tr><td>7.</td><td>Croton tiglium</td><td>Ba dou</td></tr>
<tr><td>8.</td><td>Whitmania pigra Whitman, Hirudo nipponica Whitman, Whitmania acranulata Whitman (Hirudo)</td><td>Shui Zhi</td></tr>
</table></td><td>Drug Evaluation Committee Meeting No. 20/2015</td></tr>
</table>

<table>
<tr><th>NO.</th><th>REVISION</th><th colspan="2">UPDATES</th><th>REFERENCE</th></tr>
<tr><th></th><th></th><th>SECTION/ APPENDIX</th><th>DETAILS</th><th></th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>9.</td><td>Moschus berezovskii Flerov, Moschus sifanicus Przewalski, Moschus moschferus Linnaeus (Moschus)</td><td>She xiang / musk</td></tr>
</table>
Addition of Statement at the bottom of table 10 and table 11.:
‘Note: The list is not to be exhaustive and will be reviewed from time to time’.
</td><td></td></tr>
<tr><td>9.</td><td>January 2016</td><td>APPENDIX 9.2 : SPECIFIC LABELLING REQUIREMENTS</td><td>
Amendment of the following under Appendix 9.2 <u>SPECIFIC LABELLING REQUIREMENTS</u>
The following statement shall be included in the <u>package insert</u> of product that contains Montelukast:
ADVERSE EFFECTS:
<u>Postmarketing Experience</u>
Blood and lymphatic system disorders : thrombocytopenia
</td><td>Circular : (31)dlm.bpfk/ppp/07/25 ;

Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 6 Tahun 2015 :

Direktif Untuk Semua Produk Yang Mengandungi Montelukast : Pengemaskinian Sisip Bungkusan Dengan</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
				Maklumat Kesan Advers Berkaitan *Thrombocytopenia*
10.	January 2016	**APPENDIX 9.2 : SPECIFIC LABELLING REQUIREMENTS**	**Amendment of the following under Appendix 9.2 <u>SPECIFIC LABELLING REQUIREMENTS</u>** The following statement shall be included in the <u>package insert</u> of product that contains Diclofenac Sodium: **<u>DOSAGE AND ADMINISTRATION</u>** **DOSAGE** As a general recommendation, the dose should be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see section WARNINGS AND PRECAUTIONS). **ESTABLISHED CARDIOVASCULAR DISEASE OR SIGNIFICANT CARDIOVASCULAR RISK FACTORS** Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes melilitus and smoking) should be treated	**Circular :** (30)dlm.bpfk/ppp/07/25 ; Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 7 Tahun 2015 : Direktif Untuk Semua Produk Yang Mengandungi Diclofenac (Formulasi sistemik) : Pengemaskinian Sisip Bungkusan Dengan MaklumatKeselamatan Berkaitan Kesan Advers Kardiovaskular

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			with diclofenac only after careful consideration and only at doses ≤100 mg daily if treated for more than 4 weeks (see section WARNINGS AND PRECAUTIONS). **CONTRAINDICATIONS** Severe cardiac failure (see section WARNINGS AND PRECAUTIONS). **WARNINGS AND PRECAUTIONS** **CARDIOVASCULAR EFFECTS** Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, maybe associated with an increased risk of serious cardiovascular thrombotic events (including myocardial infarction and stroke). Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes melilitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≤100 mg daily when treatment continues for more than 4 weeks.	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continues for more than 4 weeks. Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event. **ADVERSE DRUG REACTIONS** **CARDIAC DISORDERS** Uncommon*: Myocardial infarction, cardiac failure, palpitations, chest pain. * The frequency reflects data from long-term treatment with a high dose (150 mg/day). **DESCRIPTION OF SELECTED ADVERSE DRUG REACTIONS** **Arteriothrombotic events** Meta-analysis and pharmacoepidemiological data point towards an	

NO.	REVISION	UPDATES		REFERENCE
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			increased risk of arteriothrombotic events (for example myocardial infarction) associated with the use of diclofenac, particularly at a high dose (150 mg daily) and during long-term treatment (see section WARNINGS AND PRECAUTIONS).	
11.	January 2016	**APPENDIX 9.2 : SPECIFIC LABELLING REQUIREMENTS**	**Addition of the following under Appendix 9.2 <u>SPECIFIC LABELLING REQUIREMENTS</u>** The following statement shall be included in the <u>package insert</u> of product that contains Azithromycin: ***Special Warnings and Precautions for Use*** ***<u>Hypersensitivity</u>*** *As with erythromycin and other macrolides, rare serious allergic reactions, including angioedema and anaphylaxis (rarely fatal), dermatologic reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (rarely fatal), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported. Some of these reactions with azithromycin have resulted in recurrent symptoms and required a longer period of observation and treatment.* *If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.*	**Circular :** (34)dlm.bpfk/ppp/07/25 ; Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 3 Tahun 2016 : Direktif Untuk Semua Produk Yang Mengandungi Azithromycin (Formulasi Sistemik) : Pengemaskinian Sisip Bungkusan Dengan Maklumat Keselamatan Berkaitan Kesan Advers QT *Prolongation* dan *Drug Reaction With Eosinophilia And Systemic Symptoms* (DRESS)

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			<u>Prolongation of the QT interval</u> *Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in treatment with macrolides, including azithromycin (see section 4.8). Prescribers should consider the risk of QT prolongation, which can be fatal, when weighing the risks and benefits of azithromycin for at-risk groups including:* • *Patients with congenital or documented QT prolongation* • *Patients currently receiving treatment with other active substances known to prolong QT interval, such as antiarrhythmics of Classes IA and III, antipsychotic agents, antidepressants, and fluoroquinolones* • *Patients with electrolyte disturbance, particularly in cases of hypokalemia and hypomagnesemia* • *Patients with clinically relevant bradycardia, cardiac arrhythmia or cardiac insufficiency* • *Elderly patients: elderly patients may be more susceptible to drug-associated effects on the QT interval* ***Adverse Drug Reactions*** ***Post-marketing experience:*** *<u>Cardiac Disorders</u>: Palpitations and arrhythmias including ventricular tachycardia have been reported. There have been rare reports of QT prolongation and torsades de pointes (see **Special Warnings and Precautions for Use)**.* *<u>Skin and Subcutaneous Tissue Disorders</u>: Allergic reactions*	

NO.	REVISION	UPDATES		REFERENCE
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			including pruritus, rash, photosensitivity, edema, urticaria, and angioedema. Rarely, serious cutaneous adverse reactions including erythema multiforme, SJS, TEN and DRESS have been reported.	
12.	January 2016	**SECTION A: GENERAL OVERVIEW,** **SUBSECTION 1.4 MEDICAL DEVICE –DRUG – COSMETIC INTERPHASE PRODUCTS**	**Addition of the following statement under Subsection 1.4.1 : Introduction** Combination products include: i) A product comprised of two or more regulated components, i.e., drug/ device, biological/ device, or drug/ device/ biological, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; ii) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products.	MDDCI Steering Committee Meeting No. 02/2014
13.	January 2016	**SECTION A: GENERAL OVERVIEW,** **SUBSECTION 1.4 MEDICAL DEVICE –DRUG – COSMETIC INTERPHASE PRODUCTS**	**Amendment of the following statement under Subsection 1.4.2 : Classification Criteria** b) The primary mode of action/ the principal mechanism of action by which the claimed effect or purpose of the product is achieved; i) Drug is based on pharmacological, immunological or metabolic action in/ on the body. ii) Medical device is not based on these function as mentioned in para (i) above. ~~is based on function by physical means,~~	MDDCI Steering Committee Meeting No. 01/2015

<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></td><td></td><td></td><td>~~e.g. mechanical action, creation of a physical barrier or replacement or support of organ or body function;~~</td><td></td></tr>
<tr><td>14.</td><td>January 2016</td><td>SECTION A: GENERAL OVERVIEW,

SUBSECTION 1.4 MEDICAL DEVICE – DRUG – COSMETIC INTERPHASE PRODUCTS</td><td>Addition of the following statement under Table III: Summary of Medical Device-Drug-Cosmetic Interphase (MDDCI) Products and Combination Products Classification Decision
<table>
<tr><th>No</th><th>Product</th><th>Intended Purpose/ Indication and Mode of Action</th><th>Category</th><th>Custodian Agency</th></tr>
<tr><td>1.</td><td><u>Collagen Hemostatic Agents</u> (fibrillar or soft, pliable pad/sponge or loose fibres)</td><td>A sterile, bioabsorbable device derived from animal collagen (e.g., bovine or porcine collagen) designed to produce a rapid haemostasis through platelet activation/aggregation (which initiates the haemostatic cascade leading to a fibrin clot) during a surgical procedure. It is</td><td>MEDICAL DEVICE</td><td>MDA</td></tr>
</table></td><td>MDDCI Steering Committee Meeting No. 01/2015 & 02/2015</td></tr>
</table>

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
					applied directly to the wound where it remains to be absorbed by the body; it is not dedicated to a specific anatomy/application and does not contain an antimicrobial agent			
			2.	**Enteral Feeding Kit** *(containing Iodine Pack drug)*	A collection of sterile devices that includes tubing and other materials intended to administer nutrient liquids directly into the stomach, duodenum, or jejunum of a patient by means of gravity or an enteral pump.	**Device-Drug combination product regulated as MEDICAL DEVICE**	**MDA**	
			3.	***Fluoride dental preparations***	A liquid substance used for the protection of	**MEDICAL DEVICE**	**MDA**	

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
					pulpal tissue and to provide a marginal seal to newly placed amalgam restorations. A thin coating of this solution is applied over the tooth's surfaces before placement of restorations. It is used as a protective agent for the tooth against constituents of restorative materials. After application, this device cannot be reused.			
			4.	**In vivo diagnostic agents**	As Diagnostic Test Kit consist of drug and analyser	**DRUG-DEVICE combination product regulated as DRUG** **NOTE:**The device component	**NPCB**	

NO.	REVISION	UPDATES						REFERENCE
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						will be regulated on a case to case basis.		
					As diagnostic analyser only (without drug)	**MEDICAL DEVICE**	**MDA**	
			5.	**Nasal inhaler**	A hand-held device designed to administer substances directly into the nares of a patient, to serve as a barrier against external influences by formation of a moisturizing film on the nasal mucosa.	**MEDICAL DEVICE**	**MDA**	
			6.	**Oral care products Artificial Saliva / Saliva Substitute/ Replacement**	Solutions used to mimic and replace/substitute normal saliva in the symptomatic treatment of dry	**MEDICAL DEVICE**	**MDA**	

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
					mouth (xerostomia). Generally contain viscosity-increasing agents, such as mucins or cellulose derivatives such as carmellose as well as electrolytes, including fluoride. They seldom relieve symptoms for more than 1 or 2 hours and does not stimulate saliva production.			
			7.	**Peeling/Exfoliator Products** (eg. Products containing glycolic acid and salicylic acid)	To improve skin texture due to unaesthetic skin appearance caused by pigmentation, post acne scars, photo damage, etc. **NOTE :** The ingredient	**COSMETIC**	**NPCB**	

NO.	REVISION	UPDATES						REFERENCE
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					and intended use should comply with the Guidelines for Control of Cosmetic Products in Malaysia.			
			8.	**Wound care product:** **i.Comprising a matrix** (eg. dressing, gauze, swabstick, plaster, sponge)	To provide a protective layer/barrier to the wound and prevent microbial penetration and create healing environment. It may incorporate an ancillary medicinal substance eg. antimicrobial/ antiseptic agent.	**MEDICAL DEVICE**	**MDA**	
			9.	**Wound care product:** ***v.Deep cavity wounds dressing for application to a surgical wound***	To use as the wound covering material for deep body cavity to reduce the adhesion of surrounding tissues by applying to the surgical area	**MEDICAL DEVICE**	**MDA**	

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
			10.	**Wound care product:** ***vi.Intravascular catheter securement device containing antimicrobial/antiseptic agent (e.g. chlorohexidine gluconate, CHG)***	An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin. The antimicrobial agent provides ancillary antimicrobial activity to reduce skin colonization and catheter colonization, supress regrowth of microorganism's, and reduce catheter-related bloodstream infections (CRBSI) in patients with	**DEVICE-DRUG combination product regulated as MEDICAL DEVICE**	**MDA**	

<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></td><td></td><td></td><td><table><tr><td></td><td></td><td>central venous or arterial catheters.</td><td></td><td></td></tr></table></td><td></td></tr>
<tr><td>15.</td><td>January 2016</td><td>SECTION A: GENERAL OVERVIEW,

SUBSECTION 1.4 MEDICAL DEVICE – DRUG – COSMETIC INTERPHASE PRODUCTS</td><td>Addition of Guidance for the Classification of Medical Device-Drug-Cosmetic Interphase (MDDCI) Products</td><td>MDDCI Steering Committee Meeting No. 01/2015</td></tr>
<tr><td>16.</td><td>January 2016</td><td>SECTION A: GENERAL OVERVIEW,

SUBSECTION 1.3 FOOD – DRUG INTERPHASE PRODUCTS</td><td>Amendment at Subsection 1.3.6 : Negative List for Food

Addition of ingredient Simmondsia Chinensis (Jojoba) at Table 2 : Negative List for Food
<table><tr><th>Ingredient</th><th>Common or Other Name</th></tr><tr><td>Scilla sinensis</td><td></td></tr><tr><td>Simmondsia Chinesis</td><td>Jojoba</td></tr><tr><td>Sophora tomentosa</td><td>Sea coast Laburnum, Silver</td></tr></table></td><td>FDI Committee Meeting No. 01/2015</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			Bush	
17.	January 2016	**SECTION A: GENERAL OVERVIEW,** **SUBSECTION 1.3 FOOD – DRUG INTERPHASE PRODUCTS**	**Amendment at Subsection 1.3.4 : Additional Notes** **Addition of Statement No. 7 as below;** 5. Food products shall not have name/ brand name with the word of 'stem cell'. 6. Products containing only ingredient(s) such as roselle, jasmine, rose, chamomile, chrysanthemum flower, ginger (rhizome), vanilla(stem), mint leaf, lemon peel and cinnamon bark (with/without C*amelia sinensis*) will be regulated by FSQD. 7. Fruit ingredients that are not commonly consumed as food in Malaysia will be considered as active ingredient.	FDI Committee Meeting No. 02/2015
18.	January 2016	**APPENDIX 4 : GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS**	**Amendment at Checklist of Dossier Requirement For Health Supplement** **Table 15:** Checklist for general/ nutritional and medium claim • Deletion of following statement under point A3 : ~~- Source of capsule shell~~ ~~- BSE/ TSE free certificate if capsule from animal source from competent authority~~ ~~- Letter to rectify the source of gelatin from the product manufacturer~~ Deleted statements as above will be replaced by ;	Drug Evaluation Committee Meeting No. 14/2015

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			'Letter to verify the source of gelatin used' • Deletion of following statement under point B1.2 : ~~- BSE/TSE free certificate if active ingredient from animal source~~	
19.	January 2016	**APPENDIX 4 : GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS**	**Amendment at Section B : Product Formula – Example of stability data** - Deletion of requirement for testing at the time point of month-15 and month-21. - Additional testing time point for month-36 (Product with shelf life of 3 years). - Additional of 'NA' for heavy metal testing from month-3 until month-36.	Drug Evaluation Committee Meeting No. 14/2015
20.	January 2016	**APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS**	**Amendment at Section 2.6 : Stability Data - Example of Stability Data** - Additional of 'NA' for heavy metal testing from month-3 until month-36.	Drug Evaluation Committee Meeting No. 14/2015

<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>21.</td><td>January 2016</td><td>APPENDIX 4: GUIDELINE ON REGISTRATION OF HEALTH SUPPLEMENTS</td><td>Amendment at Section B : Example of In Process Quality Control
- Deletion of point no. 4 and no. 5 i.e. testing done for microbiology and heavy metal at the final stage of the manufacturing process.</td><td>Drug Evaluation Committee Meeting No. 14/2015</td></tr>
<tr><td>22.</td><td>January 2016</td><td>APPENDIX 9:
LABELING REQUIREMENTS</td><td>Addition of new substance <u>Boswellia serrata</u> at Section 9.2: Specific labeling requirement. Table 2 : List of substances which requires specific labeling requirement
<table><tr><th>No.</th><th>Substances</th></tr><tr><td>23.</td><td>BLACK COHOSH (CIMICIFUGA RACEMOSA)</td></tr><tr><td>24.</td><td>BOSWELLIA SERRATA (FOR HEALTH SUPPLEMENT PRODUCTS ONLY)</td></tr><tr><td>25.</td><td>BROMAZEPAM</td></tr><tr><td></td><td></td></tr></table></td><td>Drug Evaluation Committee Meeting No. 14//2015</td></tr>
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<tr><td>23.</td><td></td><td>APPENDIX 9:

LABELING REQUIREMENTS</td><td>Addition of warning statements for new substance <u>Boswellia serrata</u> at Section 9.2: Specific labeling requirement. Table 3
Details of specific labeling requirement

<table>
<tr><th>No.</th><th>SPECIFIC LABELLING REQUIREMENTS (SUBSTANCE SPECIFIC)</th></tr>
<tr><td>24.</td><td>BOSWELLIA SERRATA

The following statement shall be included on label and package inserts of health supplement products containing Boswellia serrata:

WARNING:

Please consult your doctor/pharmacist before using this product if you are on other medicines.</td></tr>
</table>
</td><td>Drug Evaluation Committee Meeting No. 14//2015</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
24.	January 2016	**APPENDIX 7: SPECIAL CONDITIONS FOR REGISTRATION FOR A PARTICULAR PRODUCT OR GROUP OF PRODUCTS**	**Addition of following statement for special conditions for registration for a particular product or group of products:** **8. PARACETAMOL INTRAVENOUS INJECTION** a) Products containing paracetamol in the form of intravenous injection are restricted for hospital use only.	Drug Evaluation Committee Meeting No. 02/2016
25.	January 2016	**ABBREVIATIONS AND ACRONYMS**	**Amendment of following statement :** API Active Pharmaceutical Ingredient (Interchangeable with drug substance or active substance). ~~The term API Manufacturer is interchangeable with DMF Holder~~.	-
26.	January 2016	**ABBREVIATIONS AND ACRONYMS**	**Amendment of following statement :** CEP Certificate of Suitability ~~(For Guideline on Registration of API,~~ CEP is referring to Certificate of Suitability of European Pharmacopoeia monographs issued by the EDQM)	-

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
27.	January 2016	**APPENDIX 6 : GUIDELINE ON REGULATORY CONTROL OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)**	**General information updates on the whole Appendix 6.**	-
28.	January 2016	**APPENDIX 9 : LABELLING REQUIREMENTS**	**Amendment of the information regarding Specific Labelling Requirements for products containing Ondansetron** Updates on 'Chemotherapy and Radiotherapy Induced Nausea and Vomiting (CINV and RINV)	Innovator product; Zofran™ Injection package insert (June 2014 version)
29.	January 2016	**SECTION E: POST-REGISTRATION PROCESS**	**Amendment at Subsection 14. Maintenance of Registration** Any form of appeal **shall not be considered** if re-registration application is not submitted before the expiry date of a product registration since reminder letter is issued 3 months prior to the expiry date. A new registration application shall be submitted if applicant wish to continue to market the product. The application for product re-registration shall only be submitted when all of the requirements for product for re-registration have	-

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			been complied with. Failure to do so shall result in the re-registration application being rejected by the Authority. The requirements for product re-registration as per stated in the following circulars shall be complied with before the submission of re-registration application: a) (10) dlm.BPFK/PPP/01/03 Jilid 1 b) (27) dlm.BPFK/PPP/07/25 c) (7) dlm.BPFK/PPP/07/25 d) (11) dlm.BPFK/PPP/01/03 Jld 3	