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

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
1.	July 2016	**APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCT**	**Additional of new statements on the Subappendix 2.7 : Labeling Requirement.** e) For a product containing 2 or more active ingredients, font size of each active ingredient that is highlighted on the inner/ outer carton must be of equal size and equal prominence (Note: this is not referring to the product name, but the statement made on the label).Justification for highlighting certain ingredients only on the product name / label must be provided and subject to approval by the Evaluation Committee. f) Please ensure all requirements as specified below are stated on the labels and package inserts: • State the weight per dosage form • State the quantity/ content of active ingredients per dosage form • For products in liquid form (syrup), content of active ingredients shall be stated as follows: “Each ____ml (per dosage) product contains extract of the following ingredients” Herb X = ___mg	Policy Meeting No. 01/2016

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			Herb Y = ___mg Check and correct all spelling/ grammar and translations g) For products meant for traditional practitioner/ physician use, please state its primary use by the related traditional physician/ practitioner on the label. For example: 'For Chinese Physician Use Only' OR 'For Ayurvedic Practitioner Use Only'.	
2.	July 2016	**APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCT**	**Newly added Subappendix 2.8 : Particulars of Packing** • The maximum pack size allowed for all dosage forms is based on the daily dosing for a quantity not exceeding six (6) months usage. • Packing particulars to the listing of packing as follow: C1: Pack size and fill details by weight, or volume or quantity. C2: Container type C3: Barcode/ serial number (optional) C4: Recommended distributor's price (optional) C5: Recommended retail price (optional) • Measuring spoon/ device must be provided for all products	Policy Meeting 01/2016 & 02/2016

<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></td><td></td><td></td><td>in bulk powder form unless it is for physician use only.</td><td></td></tr>
<tr><td>3.</td><td>July 2016</td><td>APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCT</td><td>
Shifting of berberis from Subappendix 2.1.3 : Prohibited/ Banned Ingredients Table 1: Botanicals (and botanical ingredients) containing scheduled poisons as listed under the Poisons Act 1952 to Subappendix 2.1.3 : Prohibited/ Banned Ingredients Table 2: Botanicals (& botanical ingredients) which are banned due to reported adverse event.

Table 1: Botanicals (and botanical ingredients) containing scheduled poisons as listed under the Poisons Act 1952
<table>
<tr><th>Genus</th><th>Species</th><th>Common/local name</th><th>Part of plant prohibited (whole plant unless otherwise specified)</th><th>Constituent(s) of concern</th></tr>
<tr><td>~~Berbe~~</td><td>~~All speci~~</td><td></td><td></td><td>~~Berberine~~
~~*Other herbs containing naturally-occuring berberine are allowed to be~~</td></tr>
</table>
</td><td>Policy Meeting 01/2016</td></tr>
</table>

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<tr><th>NO.</th><th>REVISION</th><th colspan="2">UPDATES</th><th>REFERENCE</th></tr>
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<tr><td></td><td></td><td></td><td>
<table>
<tr><td>~~ris~~</td><td>~~es~~</td><td></td><td></td><td>~~registered with specific labeling requirement.~~
~~Please refer to Appendix~~ 9

~~Notes: Only prohibited for oral preparation.~~</td></tr>
</table>
Table 2: Botanicals (& botanical ingredients) which are banned due to reported adverse event.
<table>
<tr><th>Genus</th><th>Species</th><th>Common/local name</th><th>Part of plant prohibited (whole plant unless otherwise specified)</th><th>Reason for prohibition</th></tr>
</table>
</td><td></td></tr>
</table>

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
			Berberis	All species			Contain berberine which able to displace bilirubin from albumin. This alkaloid also showing adverse effect on the cardiovascular system and have uterine stimulating effect. *Other herbs containing naturally-occurring berberine are allowed to be registered with specific labeling requirements. **Please refer to Appendix 9**	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			<table><tr><td></td><td></td><td></td><td></td><td>Notes: Only prohibited for oral preparation.</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>4.</td><td>July 2016</td><td>SECTION 16.2.3 TYPES OF MANUFACTURING SITE CHANGES (COS) TABLE XVII, ITEM NUMBER (5)</td><td>Additional statement (iv) under the column of description
<table>
<tr><th>No.</th><th colspan="2">Type of COS</th><th>Description</th></tr>
<tr><td>5.</td><td>Type V</td><td>Change of manufacturing site in crisis situation</td><td>i) Change of location of the site of manufacture that is deemed necessary due to certain circumstances such as natural disasters, closure or suspension of premise (revocation of manufacturing license), bankruptcy and matters related to breach of product quality, safety and efficacy ONLY.

ii) Prior to submission of Type V COS, approval letter issued by the</td></tr>
</table></td><td>Drug Evaluation Committee Meeting No. 6/2016</td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			secretariat of the Authority shall be obtained. iii) Application for Type V COS must be made within **three (3) months** from the date of the crisis. iv) Type V COS applications for natural products and health supplements are only applicable for local manufacturers.”	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
5.	July 2016	**SECTION 8.1.6 SECOND OR THIRD SOURCE**	**Addition of expedited pathway for Biologic application second source.** ~~For biologics, a third source may be considered if justified.~~ A second source product is defined as a product which is the same as product from the first source in all aspect, except for the site of manufacture. Similarly to Biologics,an application for a new product from a second source may be considered by the Authority but with justification. A third source may be also be considered if justified The manufacturer shall declare with support of manufacturing validation process data that there is no change in formulation, specification of active ingredient(s) and excipient(s), and finished product for the second source product compared to the first source. There is no difference in product identity and presentation, to avoid confusion. Biologics are highly sensitive to manufacturing condition. Therefore if any of the conditions outlined are not fulfilled, the application is automatically considered as new application. a) The following application procedures apply: **Second or third source for biologic products**	Policy Meeting 01/2016

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
				Conditions	**All** the following **conditions are fulfilled:** 1. The proposed facility is approved for manufacturing activities for the same company/sponsor 2. No change in the composition, manufacturing process and drug substance & drug product specifications 3. No change in the container/closure system 4. The same validated manufacturing process is used 5. The newly introduced product is in	Conditions 1. to 6. are **not fulfilled**		

NO.	REVISION	UPDATES					REFERENCE
		SECTION/ APPENDIX	DETAILS				
					the same family of product(s) or therapeutic classification as the one of those already approved at the site and uses the same filling process/equipment 6. Only one Final Release Site		
				Supporting data	1. GMP certification 2. Updated relevant sections in ACTD Part II (P) 3. Confirmation that information on the drug product has not changed as a result of the submission (e.g. other than	1. A complete product dossier specific to the new drug product manufacturing site can be made available (ACTD Parts I, II; ACTD Parts III, IV can refer to the first source product registered with DCA) 2. Manufacturer's declaration of no change in formulation, specification of active ingredient(s) and	

NO.	REVISION	UPDATES					REFERENCE
		SECTION/ APPENDIX	DETAILS				
					change in facility) or revised information of the drug product, if any of the attributes have changed 4. Name, address and responsibility of the proposed production facility involved in manufacturing and testing 5. Process validation and/or evaluation studies (e.g. equipment qualification, media fills, as appropriate), to demonstrate comparability between both current and proposed	excipient(s), and finished product for the second source compared to the first source 3. Quality comparability data (manufacturing process validation data, batch analyses, stability) 4. Real-time stability data to support proposed shelf-life (no extrapolation allowed by *ICH Q5C: Stability Testing of Biotechnological/Biological Products)*	

NO.	REVISION	UPDATES						REFERENCE	
		SECTION/ APPENDIX	DETAILS						
					manufacturing sites 6. Process validation study reports. The data should include transport between sites, if relevant. 7. Description of the batches and summary of results as quantitative data, in a comparative tabular format, for at least 3 consecutive commercial scale batches of the approved and proposed drug product, to demonstrate comparability between both current and proposed manufacturing				

NO.	REVISION	UPDATES					REFERENCE	
		SECTION/ APPENDIX	DETAILS					
					sites 8. Summary of stability testing and results (e.g. studies conducted, protocols used, results obtained), to demonstrate comparability between both current and proposed manufacturing sites 9. Stability test results from: accelerated testing (usually a minimum of 3 months) or, preferably, forced degradation studies under appropriate time and temperature conditions for the product;			

NO.	REVISION	UPDATES						REFERENCE	
		SECTION/ APPENDIX	DETAILS						
					and 3 months of real time testing at time of submission (6 months real time testing data at time of registration approval) on three commercial scale batches of the drug product manufactured using the proposed manufacturing facility, or longer if less than 3 time points are available (including the zero time point), as well as commitment to notify NPCB of any failures in the ongoing long term				

NO.	REVISION	UPDATES						REFERENCE	
		SECTION/ APPENDIX	DETAILS						
					stability studies. 10. Certificates of analysis for drug products manufactured at the new manufacturing site 11. Rationale for considering the proposed formulation/filling suite as equivalent 12. Information on the proposed production facility involved in the manufacture of the drug product, including the complete set of floor plans and flow charts (drawings, room classification, water systems,				

NO.	REVISION	UPDATES					REFERENCE	
		SECTION/ APPENDIX	DETAILS					
					HVAC systems), as well as the cleaning and shipping validation, as appropriate [if applicable] 13. Information describing the change-over procedures for shared product-contact equipment or the segregation procedures, as applicable. If no revisions, a signed attestation that no changes were made to the change-over procedures [if applicable] 14. Results of the environmental monitoring studies in			

<table>
<tr><th>NO.</th><th>REVISION</th><th colspan="2">UPDATES</th><th>REFERENCE</th></tr>
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<tr><td></td><td></td><td></td><td colspan="2"><table>
<tr><td></td><td>classified areas [if applicable]</td><td></td></tr>
<tr><td>Fees</td><td colspan="2">RM1000 (processing fee)

+ RM3000
(analysis fee – single active ingredient)
OR
+ RM4000 (analysis fee – two or more active ingredients)</td></tr>
<tr><td>Processing timeline</td><td>120 working days</td><td>245 working days</td></tr>
<tr><td colspan="3">NOTE: There can be only <u>one</u> Final Release Site for each MAL no.</td></tr>
</table></td><td></td></tr>
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NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
6.	July 2016	**SECTION 5 : TYPES OF APPLICATION**	**Addition of section 5.1.3 REGISTRATION OF STARTER PACK/ PATIENT INITIATION PACK** a) Starter pack /patient initiation pack may consist of: i) Combination of products with different strengths which are packed together in one packaging such as blister or calendar pack. ii) Combination of more than one pre-filled pen containing different strengths of preparation in one packaging. iii) Must be registered under the same product owner and PRH. b) Justified and proven specific dosing regimen demonstrated through clinical studies. c) Each product must be differentiated in terms of its physical description, e.g. colour, shape/size etc. to avoid confusion during drug administration. d) For products in calendar pack packaging type, additional beneficial criteria such as different strength of tablets arranged in order of the day available per week can be implemented to assist the patients. e) Labelling requirement specifically for starter pack /patient initiation is shown in **Table V**:	Policy Meeting No. 01/2016

<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></td><td></td><td></td><td>
<table>
<tr><th>No.</th><th>Outer Label</th><th>Immediate Label</th></tr>
<tr><td>1.</td><td>Statement of starter pack/patient initiation pack
Individual name for each products</td><td>Individual name for each products</td></tr>
<tr><td>2.</td><td>Individual registration number for each products</td><td>Individual registration number for each products</td></tr>
<tr><td>3.</td><td>Name and address of manufacturer and product registration holder</td><td>Name and address of manufacturer and product registration holder</td></tr>
<tr><td>4.</td><td>Individual batch number for each products</td><td>Individual batch number for each products</td></tr>
<tr><td>5.</td><td>Manufacturing date
(according to the earliest manufacturing date from the individual products)</td><td>Manufacturing date
(according to the earliest manufacturing date from the individual products)</td></tr>
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<tr><td></td><td></td><td></td><td>
<table>
<tr><td>6.</td><td>Expiry date
(according to the shortest expiry date from the individual products)</td><td>Expiry date
(according to the shortest expiry date from the individual products)</td></tr>
<tr><td colspan="3"><u>Note:</u>
These labeling requirements for a starter pack/patient initiation pack shall as well be subjected to other labelling requirements as stated in Appendix 9.1: Label (mock-up) for Immediate Container, Outer Carton and Proposed Package Insert)</td></tr>
</table>
</td><td></td></tr>
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<tr><td>7.</td><td>July 2016</td><td>SECTION 16.5 : APPLICATION FOR A CONVENIENT PACK</td><td>a) Additional information on differentiation from Combination Pack (Combo Pack) and Starter Pack/Patient Initiation Pack:

<u>Table XX:</u>
<table>
<tr><th>No.</th><th>Particulars</th><th>Convenient Pack</th><th>Combination Pack

(Combo Pack)</th><th>Starter Pack/ Patient Initiation Pack</th></tr>
<tr><td>1.</td><td>New registration number (MAL No.) to be assigned upon approval</td><td>No</td><td>Yes</td><td>No</td></tr>
<tr><td>2.</td><td>Mode of application</td><td>Variation Type II</td><td>Application for registration as a new product</td><td>Application for registration as a new product and variation</td></tr>
</table></td><td>Policy Meeting No. 01/2016</td></tr>
</table>

NO.	REVISION	UPDATES						REFERENCE
		SECTION/ APPENDIX	DETAILS					
			3.	Purpose of product	For convenience of the consumer	For therapeutic regimen	For dosing regimen	
			4.	New indication	No	Yes	No	
			5.	Sale of product	Can be sold individually or as a pack	Only to be sold as a pack	Only to be sold as a pack	
			6.	Example	Confinement Set or *Set Jamu Bersalin*	Klacid HP7 (for treatment of peptic ulcer diseases associated with H. pylori infection)	Products that require dose tapering either to reduce systemic side effect or for dose adjustment to achieve the desired maintenance dose	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
8.	July 2016	**SECTION 12 : INSPECTION**	**Addition of section 12.2 : MANAGING CHANGES OF MANUFACTURERS, IMPORTERS & WHOLESALERS FACILITY** **12.2 MANAGING CHANGES OF MANUFACTURERS, IMPORTERS & WHOLESALERS FACILITY** This section only focuses on manufacturing and storage / warehouse facility changes. Changes on products particulars should be addressed under the Section E of Post Registration Process whereby it discusses on Amendments to Particular of a Registered Products. Changes at manufacturers, importers and wholesalers facility can potentially have a quality and safety impact. It is the responsibility of the site to assess information on the changes occurs through formal change control system and risk management, where applicable. Manufacturers, Importers and Wholesalers are recommended to have a system for categorizing types of changes. All changes to the facility are required to notify Centre for Compliance & Licensing (CCL) prior to implementation of changes. Notification of changes will be review to assess the significance and it may be verified during scheduled GMP/GDP inspection. The CCL will communicate further and arrange for an investigative/for-	Policy Meeting No. 01/2016 & Premises Inspection Evaluation Committee Meeting No. 06/2016

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			cause inspection focusing on these changes, if necessary. Types of notification are as follow: 12.2.1 Immediate notification This notification is applicable to manufacturer, importer and wholesalers that plan/undergo a major/significant/substantial change that could have an impact on the product quality and safety. The Immediate Notification shall be made in writing to Centre for Compliance & Licensing (CCL) for the purpose of approval and at least 6 months before the implementation of changes. The following information is needed: a) Description of changes to the facility b) Plan of changes (For example: Gantt Chart, Validation Master Plan, etc) c) Details of the products affected, where applicable d) Information on variation category, where applicable (e.g.: Major/Minor Variation) e) Registration of Company Certificate (ROC), where applicable Normally, proposed changes of local manufacturing facility may require a layout plan approval from CCL by completing 'Borang	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			Permohonan Penilaian Pelan Susun Atur Premis Pengilang, BPFK-503. Example of changes that require immediate notification (these are non-exhaustive examples): a) Change of manufacturing site of drug product / drug substance b) Change of warehouse facility / alternative warehouse facility/ addition of warehouse facility (e.g. Cold room) c) Major change of manufacturing process d) Major renovation or introduction of new / addition to the facility (e.g: new processing line / new production block / addition of utility system) e) Addition of repacking facility f) Introduction of highly potent, sensitizing active substances or biological active substances to the site 12.2.2 Periodical Notification This notification is applicable to manufacturer, importer and wholesalers that plan/undergo a minor change that would not give any impact to the product quality and safety. The notification shall also be made in writing to Centre for Compliance & Licensing with the information of changes. The notification details will be verified during GMP/GDP inspection or by documentation review, where necessary. Where applicable,	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			proposed changes of local manufacturing facility may require a layout plan approval from CCL by completing 'Borang Permohonan Penilaian Pelan Susun Atur Premis Pengilang, BPFK-503. Example of changes that require periodical notification (Below are non-exhaustive examples): a) Change of manufacturing rooms (rename / relocate manufacturing rooms) b) Addition of facility that does not give any impact to the existing site (e.g.: Addition of sampling room / QC / Office) c) Change of key personnel (e.g.: QA/QC Manager, Production Pharmacist) d) Minor change of manufacturing process e) Addition of manufacturing equipments (e.g.: new capsulation / tableting machine) f) Change of company name or address (e.g.: street name, postal code)	

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<tr><th>SECTION/ APPENDIX</th><th>DETAILS</th></tr>
<tr><td>9.</td><td>July 2016</td><td>SECTION 12 : INSPECTION</td><td>
Additional of new statements under column Product Type/ Category in Table XIII

Additional of a hyperlink under column Guidelines on Good Distribution Practice (GDP); 2nd Edition 2013

The related GMP and GDP guidelines referred are as below in Table XIII:

<table>
<tr><th>Guidelines</th><th>Product Type/ Category</th></tr>
<tr><td>PIC/S Guide to Good Manufacturing Practice for Medicinal Products *</td><td>• Pharmaceuticals (Poison and Non-Poison)
• Veterinary Medicinal Products
• Investigational Medicinal Products
• Active Pharmaceutical Ingredients</td></tr>
<tr><td>GMP Guideline for Traditional Medicines and Health Supplements, 1st Edition, 2008</td><td>• Traditional Products
• Health Supplements</td></tr>
<tr><td>Guidelines on Good Manufacturing Practice (GMP) for Cosmetic (Annex 1, Part 9)</td><td>• Cosmetics</td></tr>
</table>
</td><td>Policy Meeting No. 01/2016
&
Premises Inspection Evaluation Committee Meeting No. 06/2016</td></tr>
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<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes, 1st Edition, January 2015</td><td>• Veterinary Premixes</td></tr>
<tr><td>Guidelines on Good Distribution Practice (GDP); 2nd Edition 2013

Supplementary Notes For Management Of Cold Chain Products/ Materials Chapter 15 Guidelines On Good Distribution Practice (GDP)</td><td>• For activities related to the storage and distribution by manufacturers, importers and wholesalers (where applicable)</td></tr>
</table>
* Refer to Pharmaceutical Inspection Co-operation Scheme (PIC/S) website at www.picscheme.org
</td><td></td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
10.	July 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 *Bisphosphonate* (alendronate, clodronate, ibandronic acid, pamidronate, risedronate, zoledronic acid): **WARNINGS AND PRECAUTIONS FOR USE (sisip bungkusan):** *Osteonecrosis of the external auditory canal has been reported with bisphosphonates, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections.* **ADVERSE DRUG REACTIONS (sisip bungkusan):** *Very rare: Osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction).* **POSSIBLE SIDE EFFECTS (RiMUP):** *Very rare* • *Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear*	**Circular** : BPFK/PPP/07/25 (38); Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 7 Tahun 2016 : Direktif Bagi Semua Produk Yang Mengandungi Bisphosphonate (Alendronate, Clodronate, Ibandronic Acid, Pamidronate, Risedronate, Zoledronic Acid) Dengan Risiko Kesan Advers Berkaitan *Osteonecrosis Of The External Auditory Canal*

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
11.	July 2016	**APPENDIX 9.2 : SPECIFIC LABELLING REQUIREMENTS**	**Addition of the following under Appendix 9.2 SPECIFIC LABELLING REQUIREMENTS** The following statement shall be included in the package insert of product that contains mycophenolate (mycophenolate mofetil dan mycophenolic acid): ***CONTRAINDICATIONS*** • *[Product name] is contraindicated during pregnancy due to its mutagenic and teratogenic potential (see Use in Special Populations: Pregnancy).* • *[Product name] is contraindicated in women of childbearing potential not using highly effective contraceptive methods (see Use in Special Populations: Pregnancy).* • *[Product name] is contraindicated in women who are breastfeeding (see Use in Special Populations: Breastfeeding).* ***USE IN SPECIAL POPULATIONS*** ***Pregnancy*** *[Product name] is contraindicated during pregnancy and in women of childbearing potential not using highly effective contraceptive methods. (see Contraindications).* *Before the start of treatment, female and male patients of reproductive potential must be made aware of the increased risk of pregnancy loss and congenital malformations and must be*	**Circular** : BPFK/PPP/07/25 (37) Arahan Pengarah Kanan Perkhidmatan Farmasi Bilangan 6 Tahun 2016 : Direktif Untuk Semua Produk Yang Mengandungi Mycophenolate (Mycophenolate Mofetil Dan Mycophenolic Acid): Pengemaskinian Sisip Bungkusan Dengan Maklumat Keselamatan Berkaitan Risiko Kesan Teratogenik

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			counseled regarding pregnancy prevention, and planning. *Prior to starting therapy with [product name], female patients of childbearing potential must have **two negative serum or urine pregnancy tests** with a sensitivity of at least 25 mIU/mL; The second test should be performed 8-10 days after the first one and immediately before starting [product name]. Repeat pregnancy tests should be performed during routine follow-up visits. Results of all pregnancy tests should be discussed with the patient. Patients should be instructed to consult their physician immediately should they become pregnant.* *Due to the mutagenic and teratogenic potential of mycophenolate, **women of child bearing potential** should use **two reliable forms of contraception** simultaneously, including at least one highly effective method, before beginning mycophenolate therapy, during therapy, and for six weeks following discontinuation of therapy, unless abstinence is the chosen method of contraception.* ***Sexually active men** are recommended to use condoms during treatment and for at least 90 days after cessation of treatment. Condom use applies for both reproductively competent and vasectomised men, because the risks associated with the transfer of seminal fluid also apply to men who have had a vasectomy. In addition, **female partners of male patients** are recommended to use highly effective contraception during treatment and for total of 90 days after the last dose of [product name].*	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			Congenital malformations, including multiple malformations have been reported post-marketing in children of patients exposed to mycophenolate in combination with other immunosuppressants during pregnancy. The following malformations were most frequently reported: • *Facial malformations such as cleft lip, cleft palate, micrognathia and hypertelorism of the orbits;* • *Abnormalities of the ear (e.g. abnormally formed or absent external/middle ear) and eye (e.g. coloboma, microphthalmos);* • *Malformations of the fingers (e.g. polydactyly, syndactyly, brachydactyly);* • *Cardiac abnormalities such as atrial and ventricular septal defects;* • *Oesophageal malformations (e.g. oesophageal atresia);* • *Nervous system malformations (such as spina bifida).* *In the medical literature, malformations in children from mycophenolate-exposed pregnancies have been reported in 23% to 27% of live births. For comparison, the risk of malformations is estimated at approximately 2% of live births in the overall population and at approximately 4% to 5 % in solid organ transplant patients treated with immunosuppressants other than mycophenolate.* *Cases of spontaneous abortions have also been reported in patients exposed to mycophenolate, mainly in the first trimester. In*	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			the medical literature, the risk has been reported at 45% to 49% following mycophenolate exposure, compared to a reported rate between 12 and 33% in solid organ transplant patients treated with other immunosuppressants. *Studies in animals have shown reproductive toxicity.* ***Breastfeeding*** *[Product name] is contraindicated during breastfeeding due to the potential for serious adverse reactions in nursing infants (see Contraindications).* *Studies in rats have shown mycophenolate to be excreted in milk. It is not known whether this medicine is excreted in human milk.* ***ADVERSE DRUG REACTIONS*** ***Post-marketing experience:*** ***Congenital Disorders*** *Congenital malformations have been reported post-marketing in children of patients exposed to mycophenolate in combination with other immunosuppressants during pregnancy (see Use in Pregnancy).* ***Pregnancy, Puerperium and Perinatal Conditions*** *Cases of spontaneous abortions mainly in the first trimester in*	

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			patients exposed to mycophenolate have been reported (see Use in Pregnancy).	