

LIST OF UPDATES ON DRGD FIRST EDITION, REVISED JANUARY 2015

NO.	REVISION	UPDATES		REFERENCE		
		SECTION/ APPENDIX	DETAILS			
1.	JANUARY 2015	Section C : Quality Control	<u>Amendment at Section C : Quality Control, Subsection 11 : GUIDELINE FOR THE SUBMISSION OF PRODUCT SAMPLES FOR LABORATORY TESTING</u>	-		
2.	JANUARY 2015	Section C : Quality Control	<u>Deletion of Section C : Quality Control, Subsection 11.3 : APPEAL FOR RETESTING</u>	Circular Ref : (25) dIm.BPFK/PPP/01/03 Jld.3		
3.	JANUARY 2015	Section D : Inspection & Licensing	<u>Amendment at Section D : Inspection & Licensing, Subsection 12 : INSPECTION</u>	Memo from PKP. Ref : (37) dIm.BPFK/30/06/1 Bhgn 7		
			Table XII:			
			<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">Guidelines</th> <th style="text-align: center;">Product Type/ Category</th> </tr> </thead> <tbody> <tr> <td>PIC/S Guide to Good Manufacturing Practice for Medicinal Products *</td> <td> <ul style="list-style-type: none"> • Pharmaceuticals (Poison and Non-Poison) • Veterinary <u>Medicinal</u> Products </td> </tr> <tr> <td><u>GMP Guideline for Traditional Medicines and Health Supplements, 1st Edition, 2008</u></td> <td> <ul style="list-style-type: none"> • Traditional Products • Health Supplements </td> </tr> </tbody> </table>		Guidelines	Product Type/ Category
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4.	JANUARY 2015	Appendix 1 : FEES	<p><u>Amendment at Appendix 1 : FEES, Subappendix 1.3 : CHARGES FOR APPLICATION OF LICENSES</u></p> <p>After a product is registered, the applicant shall apply for a manufacturer/ import/ wholesale license. The processing fees are as specified below:</p> <table border="1"> <tr> <td>License</td> <td>Processing</td> <td>Timeline</td> <td>Validity</td> </tr> </table>	License	Processing	Timeline	Validity	-		
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5.	JANUARY 2015	APPENDIX 5: GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS	<u>Deletion of Subappendix 2.5.2 : APPEAL FOR SAMPLE RETESTING</u>	Circular Ref : (25) dIm.BPFBK/PPP/01/03 Jld.3
6.	JANUARY 2015	APPENDIX 14: GUIDELINES ON SAFETY DATA REQUIREMENTS FOR COMPLEMENTARY MEDICINE PRODUCTS	<u>Addition of Appendix 14 : GUIDELINES ON SAFETY DATA REQUIREMENTS FOR COMPLEMENTARY MEDICINE PRODUCTS</u>	Circular Ref : (25) dIm.BPFBK/PPP/06/17 Jld.51