

LIST OF UPDATES ON REGOVP, VERSION 3, JULY 2014

NO.	REVISION	UPDATES		REFERENCE	
		SECTION/ APPENDIX	DETAILS		
1.	February 2015	Section E, Inspection, Licensing and Relevant Documents	<u>Amendment at Section E: Inspection, Licensing and Relevant Documents</u> <u>Subsection 13.1: Inspection</u>		Memo from PKP. Ref: (37)dIm.BPFK/30/06/1 Bhgn 7
			Guidelines	Product Type/ Category	
			PIC/S Guide to Good Manufacturing Practice for Medicinal Products *	Pharmaceuticals (Poison and Non-Poison) Veterinary Products	
			Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes; 1 st Edition, January 2015	Veterinary Premixes	
			Guidelines on Good Distribution Practice (GDP); 2 nd Edition 2013	For activities related to the storage and distribution by manufacturers, importers and wholesalers (where applicable)	
2.	April 2015	Section A: General Overview	<u>Deletion of Section A: General Overview, Subsection 2.2: (vi)</u>		

NO.	REVISION	UPDATES		REFERENCE
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3.	April 2015	Section A: General Overview	<u>Amendment of Section A: General Overview, Subsection 2.2: (vii) and (viii)</u>	
4.	April 2015	Appendix 10: Regulation of Veterinary Products in Malaysia	<u>Amendment of Appendix 10: Regulation of Veterinary Products in Malaysia</u>	

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			<p style="text-align: center;">REGULATION OF VETERINARY PRODUCTS</p> <pre> graph TD Root[REGULATION OF VETERINARY PRODUCTS] --> Box1[Products containing: 1) Scheduled Poison (as in First Schedule of Poison Act 1952) 2) Non Scheduled Poison / OTC 3) Pesticides for Internal Use 4) Pesticides for External Use (Control of endoparasite)] Root --> Box2[Products containing: 1) Animal feed 2) Feed additives] Root --> Box3[Products containing: 1) Pesticides as listed under First Schedule of Pesticide Act 1974 for External Use only] Box1 --> BPFK[BPFK] Box2 --> DVS[Department of Veterinary Services (DVS)] Box3 --> PB[Pesticide Board] </pre> <p>•Products containing feed additives in combination with scheduled poisons will be regulated by the DCA. •Products containing pesticide ingredients in combination with scheduled poisons will be regulated by the DCA.</p>	

NO.	REVISION	UPDATES		REFERENCE
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5.	July 2015	Section A: General Overview	<u>Addition of Section A: General Overview, Subsection 2.4</u>	
6.	July 2015	Section A: General Overview	<u>Amendment of Section A: General Overview, Subsection 2.6</u>	
7.	July 2015	Section A: General Overview	<u>Addition of Section A: General Overview, Subsection 2.2: (x) and (xi)</u>	

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8.	October 2015	Section A: General Overview Appendix 1: Fees	<u>Amendment of Section A: General Overview, Subsection 2.5</u> <u>Amendment of Appendix 1: Fees, Subsection 1.2</u>	
9.	August 2016	Appendix 1: Fees Appendix 1.1 – 11 Step 2: New Registration Application Form	<u>Amendment of Appendix 1: Fees, Subsection 1.4</u> <u>Amendment of Numbering of Appendices</u> <u>Addition of Section D: Label (Mockup) For Immediate Container, Outer Carton And Proposed Package Insert, Specific Labelling Requirements</u> <u>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration: Check List Of Product Registration Form Entry</u>	Notice Ref: (40)dIm.BPFK/PPP/01 /03/Jld 3

NO.	REVISION	UPDATES		REFERENCE
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10.	November 2016	Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority	<u>Amendment of Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority</u>	
11.	December 2016	Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority	<u>Amendment of Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority</u>	

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12.	January 2017	Section A: General Overview	<u>Addition of Section A: General Overview, Subsection 2.4</u>	