

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
		SECTION/ APPENDIX	DETAILS	
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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**REGULATION OF
VETERINARY PRODUCTS**

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)

BPFK

Products containing:
1) Animal feed
2) Feed additives

**Department of Veterinary
Services (DVS)**

Products containing:
**1) Pesticides as listed
under First Schedule of
Pesticide Act 1974 for
External Use only**

Pesticide Board

- 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.

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>	

NO.	REVISION	UPDATES		REFERENCE
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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
		SECTION/ APPENDIX	DETAILS	
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>	
12.	January 2017	Section A: General Overview	<u>Addition of Section A: General Overview, Subsection 2.5</u>	

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13.	February 2017	Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis	<p><u>Addition of Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis</u></p> <p><u>Renumbering of all appendices</u></p>	
14.	April 2017	Glossary Section D: Post- Registration Process Appendix 1: List of Antimicrobials (Premix) Used in Food	<p><u>Addition of Glossary</u></p> <p><u>Amendment of Section D: Post- Registration Process, Subsection 10.3 and 11.2.4</u></p> <p><u>Amendment of Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis</u></p>	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
		Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis		
		Appendix 2: Fees	<u>Amendment of Appendix 2: Fees, Subsection 2.1, 2.4 and 2.5</u>	
		Appendix 4: Guidelines On Application For Variation Of Registered Products	<u>Amendment of Appendix 4: Guidelines On Application For Variation Of Registered Products</u>	
		Appendix 6: Change Of Product Registration Holder	<u>Amendment of Appendix 6: Change Of Product Registration Holder, Application, Processing Fee and Flowchart For The Change Of Product Registration Holder</u>	
		Appendix 11: Allowable	<u>Amendment of Appendix 11: Allowable Maximum Residual Limit (MRL), B) Maximum Permitted Proportion Of Drug Residues In Aquaculture And</u>	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
		Maximum Residual Limit (MRL)	<u>Allowable Withdrawal Period</u>	
15.	May 2017	Appendix 9: Guideline For Stability Data Section 2: Guide On How To Fill The Online Application Form For A Product Registration	<u>Amendment of Appendix 9: Guidelines For Stability Data</u> <u>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15, 15.1 and 15.2</u>	
16.	June 2017	Step 2: New Registration Application Form	<u>Amendment of Section D: Label (Mock-Up) For Immediate Container, Outer Carton, Proposed Package Insert & Product Information Leaflet (PIL)</u>	