LIST OF UPDATES ON REGOVP, VERSION 3, JULY 2014

<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>February 2015</td><td>Section E, Inspection, Licensing and Relevant Documents</td><td><u>Amendment at Section E: Inspection, Licensing and Relevant Documents Subsection 13.1: Inspection</u>

<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 Products</td></tr><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</td><td>For activities related to the storage and distribution by manufacturers, importers and wholesalers (where applicable)</td></tr></table></td><td>Memo from PKP. Ref: (37)dlm.BPFK/ 30/06/1 Bhgn 7</td></tr>
<tr><td>2.</td><td>April 2015</td><td>Section A: General Overview</td><td><u>Deletion of Section A: General Overview, Subsection 2.2: (vi)</u></td><td></td></tr>
</table>

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

<table>
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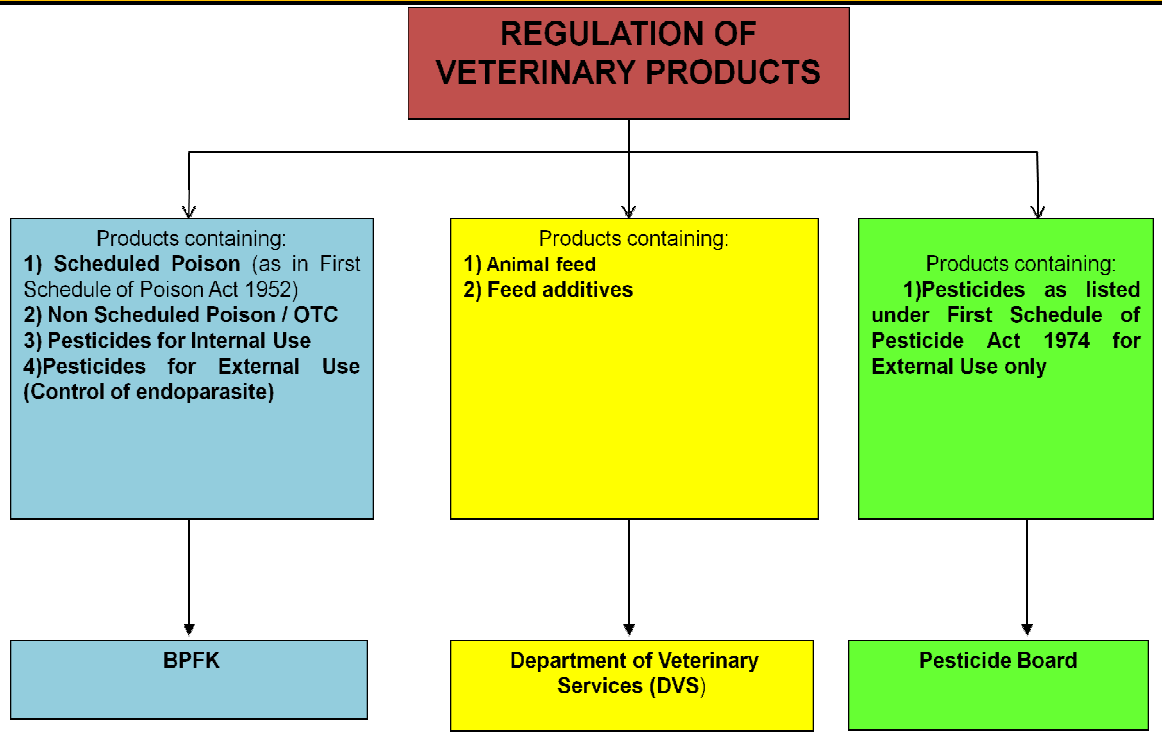
<tr><td></td><td></td><td></td><td> 

•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.</td><td></td></tr>
<tr><td>5.</td><td>July 2015</td><td>Section A: General Overview</td><td><u>Addition of Section A: General Overview, Subsection 2.4</u></td><td></td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
6.	July 2015	Section A: General Overview	**Amendment of Section A: General Overview, Subsection 2.6**	
7.	July 2015	Section A: General Overview	**Addition of Section A: General Overview, Subsection 2.2: (x) and (xi)**	
8.	October 2015	Section A: General Overview Appendix 1: Fees	**Amendment of Section A: General Overview, Subsection 2.5** **Amendment of Appendix 1: Fees, Subsection 1.2**	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
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)dlm.BPFK/ PPP/01 /03/Jld 3
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>**	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
11.	December 2016	Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority	**Amendment of Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority**	
12.	January 2017	Section A: General Overview	**Addition of Section A: General Overview, Subsection 2.5**	
13.	February 2017	Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment	**Addition of Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis** **Renumbering of all appendices**	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
		and Disease Prevention/ Metaphylaxis		
14.	April 2017	Glossary Section D: Post-Registration Process Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis	**Addition of Glossary** **Amendment of Section D: Post- Registration Process, Subsection 10.3 and 11.2.4** **Amendment of Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis**	

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

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
15.	May 2017	Appendix 9: Guideline For Stability Data Section 2: Guide On How To Fill The Online Application Form For A Product Registration	**Amendment of Appendix 9: Guidelines For Stability Data** **Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15, 15.1 and 15.2**	
16.	June 2017	Step 2: New Registration Application Form	**Amendment of Section D: Label (Mock-Up) For Immediate Container, Outer Carton, Proposed Package Insert & Product Information Leaflet (PIL)**	
17.	Oct 2018	Section A: General Overview	**Amendment of Section A: General Overview; Subsection 1.2** **SECTION A: GENERAL OVERVIEW** **1. INTRODUCTION**	JKPP 18/2018 Meeting Minutes

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			1.1 The Control of Drugs and Cosmetics Regulations 1984 was gazetted in June 1984, with the establishment of the Drug Control Authority (DCA) as the licensing authority. The daily operations of drug and cosmetic registration, together with the attendant monitoring and surveillance activities have been delegated to the National Pharmaceutical Regulatory Agency (NPRA). 1.2 The guidelines outlined in this document are primarily drawn up in accordance to the legal requirements of the **Sale of Drugs Act 1952** and the **Control of Drugs and Cosmetics Regulations 1984.** While every effort has been made to include the legal requirements of other related legislation, wherever possible, applicants are reminded that it is still their responsibility to ensure that their products duly comply with the requirements of these legislation, namely:- **(i)** **Dangerous Drugs Act 1952**; **(ii)** **Poisons Act 1952**; **(iii)** **Medicine (Advertisement & Sale) Act 1956**; ~~**(iv)** **Patent Act 1983**~~; and also **(v)** Any **other relevant Acts.**	

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<tr><th>SECTION/ APPENDIX</th><th>DETAILS</th></tr>
<tr><td></td><td></td><td>Section 2: Guide On How To Fill The Online Application Form For A Product Registration</td><td>
<u>Addition in Section A: General Overview; Subsection 2.3</u>

2.3 Classification Criteria

The following may be used as criteria to assist in the classification of products:

a) The primary intended purpose/indication of the product
b) The primary mode of action/ the principal mechanism of action
c) The substances and strength of the product
d) Classification of the products in reference countries

<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 and Subsection 15.1</u>

Product Validation
<table>
<tr><th>No.</th><th>Step I: Product Validation</th></tr>
<tr><td>~~10.~~</td><td>~~Patent Protection (Yes/No)~~
~~If yes, please provide:~~
~~a) Patent Number~~
~~b) Filing Date~~
~~c) Grant Date~~
~~d) Patent Statement~~</td></tr>
</table>

15.1 STEP 1: PRODUCT VALIDATION

• All fields are compulsory to be entered.
</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></td><td></td><td>Appendix 7: List of Permitted and Restricted Colouring Agents</td><td>

Option is given either to accept the validation result and submit; or override and manually select.
Once validation is verified and submitted, the related application form under Step 2 will be displayed.
Information entered in Step 1 will be captured in the database and need not be re-entered at Step 2.

<u>~~[10] Patent Protection~~</u>
~~Applicants who hold valid patents shall provide documentary evidence of the nature and extent of their patents.~~
<u>Addition in Appendix 7: List of Permitted and Restricted Colouring Agents</u>
7.2 List of Restricted Colouring Agents
The following colouring agents are ALLOWED in preparations as stated in the parentheses:
<table>
<tr><th>NO.</th><th>COLOURING AGENTS</th><th>COLOUR INDEX NUMBER (CI)</th></tr>
<tr><td>29.</td><td>Malachite Green</td><td>42000</td></tr>
</table>
</td><td></td></tr>
</table>