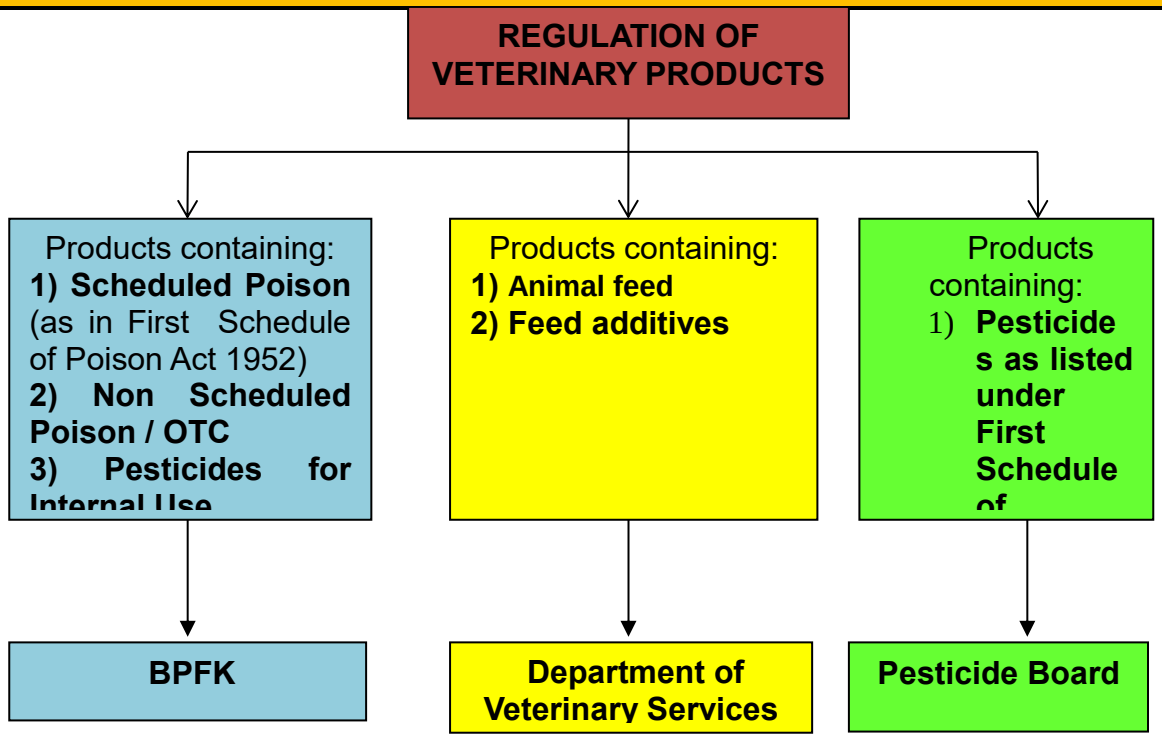
LIST OF UPDATES ON REGOVP, VERSION 3, JULY 2014

<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**	

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	



- 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
		SECTION/ APPENDIX	DETAILS	
5.	July 2015	Section A: General Overview	**Addition of Section A: General Overview, Subsection 2.4**	
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	**Amendment of Appendix 1: Fees, Subsection 1.4** **Amendment of Numbering of Appendices** **Addition of Section D: Label (Mockup) For Immediate Container, Outer Carton And Proposed Package Insert, Specific Labelling Requirements** **Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration: Check List Of Product Registration Form Entry**	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	**Amendment of Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority**	

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.** **<u>Addition in Section A: General Overview; Subsection 2.3</u>** 2.3 **Classification Criteria**	

<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>Section 2: Guide On How To Fill The Online Application Form For A Product Registration</td><td>
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.
• Option is given either to accept the validation result and submit; or override and manually select.
</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>

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>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
18.	Jan 2020	Section A: General Overview	**<u>Amendment 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 For classification of feed-drug interphase and feed-drug-pesticides interphase products as decided by the committee, please refer to **Appendix 1** and **Appendix 2** respectively. It shall be used as guidance for classification only. Applicant shall verify the interphase product classification with NPRA in order to determine whether the product shall be registered by the Authority or otherwise.	
		Appendix 1: Summary of Feed–Drug Interphase Veterinary Product	**<u>Addition of Appendix 1: Summary of Feed–Drug Interphase Veterinary Product Classification Decision</u>** **<u>Renumbering of all appendices</u>**	

<table>
<tr>
<td></td>
<td></td>
<td>Classification Decision

Appendix 2: Summary of Drug – Feed – Pesticide Interphase Veterinary Product Classification Decision

Section D: Post-Registration Process

Appendix 4: Fees</td>
<td><u>Addition of Appendix 2: Summary of Drug – Feed – Pesticide Interphase Veterinary Product Classification Decision</u>

<u>Renumbering of all appendices</u>

<u>Addition in Section D: Post- Registration Process; Subsection 11.4</u>

11.4 New/ Additional Indication

<u>Addition in Appendix 4: Fees</u>

2.4 Charges For Amendments To Particulars of A Registered Product

2.4.2 Variation & Additional Indication

<table>
<tr><th rowspan="2">Types of Amendment</th><th>Processing fee</th></tr>
<tr><th>Pharmaceutical</th></tr>
<tr><td>3. Additional Indication</td><td>RM 1000.00</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

		Appendix 3: List of Antimicrobials (Premix) Used In Food Producing Animals for Disease Treatment And Disease Prevention/ Metaphylaxis	**Amendment in Appendix 3: List of Antimicrobials (Premix) Used In Food Producing Animals For Disease Treatment And Disease Prevention/ Metaphylaxis**	
		Appendix 8: List of Ingredients (Active) Not Allowed to Be Registered By The Drug Control Authority	**Addition in Appendix 8: List of Ingredients (Active) Not Allowed to Be Registered By The Drug Control Authority**	
		Appendix 13: Allowable Maximum Residual Limit (MRL)	**Amendment in Appendix 13: Allowable Maximum Residual Limit (MRL)**	

~~**POLYMYXINS**~~			
~~Colistin (Polymixin E)~~	~~Cattle, Swine, Chicken~~	~~Yes~~	~~Yes~~

B. Ingredients not allowed for food-producing animals and aquacultures

16. Colistin

A) MAXIMUM PERMITTED PROPORTION OF DRUG RESIDUES IN FOOD

The food specified in column (2) of the Table below shall not contain the drug specified in column (1) thereof in proportions greater than the maximum permitted proportions specified opposite and in relation to that food in column (3) thereof.

<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>Section 2: Guide On How To Fill The Online Application Form For A Product Registration</td><td>
<table>
<tr><th>Substance</th><th>Drug Definition of residues in which MRL was set</th><th>Food</th><th>Maximum Residue Limits (MRLs) in food µg/kg</th></tr>
<tr><td rowspan="4">~~Colistin~~</td><td rowspan="4">~~Colistin~~</td><td>~~Milk (cattle)~~</td><td>~~50~~</td></tr>
<tr><td>~~Muscle, liver, fat (cattle, chicken, pig, rabbit and sheep)~~</td><td>~~150~~</td></tr>
<tr><td>~~Kidney (cattle, chicken, pig, rabbit and sheep)~~</td><td>~~200~~</td></tr>
<tr><td>~~Egg (chicken)~~</td><td>~~300~~</td></tr>
</table>
B) MAXIMUM PERMITTED PROPORTION OF DRUG RESIDUES IN AQUACULTURE AND ALLOWABLE WITHDRAWAL PERIOD
<table>
<tr><th>BIL</th><th colspan="3">PHARMACOLOGICALLY ACTIVE SUBSTANCES</th><th>MRLs µg/kg (ppb)</th><th>WITH DRAWAL PERIOD</th></tr>
<tr><td>~~26~~</td><td></td><td></td><td>~~Polymyxins~~ ~~Colistin~~</td><td>~~150~~</td><td>~~30 days~~</td></tr>
</table>
<u>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15.2</u>
<u>Specific Labelling Requirements</u>
Table 1: List of Substances Which Requires Specific Labelling Requirements:
<table>
<tr><th>No.</th><th>Substances</th></tr>
<tr><td>~~4.~~</td><td>~~Colistin~~</td></tr>
</table>
</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></td><td>
Table 2: Details of Specific Labelling Requirements
<table>
<tr><th>No.</th><th>Substances</th></tr>
<tr><td>~~4.~~</td><td>~~Colistin~~

~~The following statement shall be included on the labels and in the package inserts of products containing colistin for food producing animals:~~

~~TO BE PRESCRIBED AND TREATED WITH BY REGISTERED VETERINARY SURGEONS ONLY~~</td></tr>
</table>
</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>19.</td><td>Jul 2020</td><td>Section B: Product Registration Process</td><td><u>Addition in Section B: Product Registration Process; Subsection 8.1.2</u>

8.1.2 Method of Evaluation
<table><tr><th rowspan="2">No.</th><th rowspan="2">Product Category</th><th colspan="2">Method of Evaluation</th></tr><tr><th>Full Evaluation</th><th>Full Evaluation Abridged Registration Pathway*</th></tr><tr><td>1.</td><td>Innovator Products</td><td>√</td><td>√</td></tr><tr><td>2.</td><td>Generics (Scheduled Poison)</td><td>√</td><td>√</td></tr><tr><td>4.</td><td>Generics (Non-Scheduled Poison) [or known as OTC]</td><td>√</td><td>√</td></tr></table>* For details, please refer to Guidelines on Abridged Registration Pathway for Veterinary Products. The guideline provides information on the eligibility criteria, procedures and requirements for submitting application to register a product via abridged registration pathway. The implementation of the guideline was on 21 July 2020.

<u>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15</u></td><td>NPRA.600-1/9/12 (21) 21 Julai 2020</td></tr>
<tr><td></td><td></td><td>Section 2: Guide On How To Fill</td><td></td><td></td></tr>
</table>

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
		The Online Application Form For A Product Registration	15. **CHECK LIST OF PRODUCT REGISTRATION FORM ENTRY**	
20.	Aug 2020	Section D: Post-Registration Process	**Amendment of Section D: Post-Registration Process, Subsection 10.3** ~~Applicant shall submit the application to the Center for Product Registration, NPRA.~~ Any form of appeal **shall not be considered** if re-registration application is not submitted before the expiry date of a product registration ~~since reminder letter is issued 3 months prior to the expiry date.~~ **Amendment of Section D: Post-Registration Process, Subsection 11.3** From: Upon receipt of complete online application via QUEST system and hardcopy of original documents, the change of PRH application shall be processed within forty five (45) working days. To: Once NPRA deems the application is complete, the outcome of the change of PRH application shall be decided by the Drug Control Authority within forty five (45) working days.	Bengkel Penyelarasan Proses Kerja Utama PPPK 14/7/2020 Bengkel Penyelarasan Pertukaran Pemegang Pendaftaran

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
		Appendix 8: Change of Product Registration Holder	**<u>Amendment in Appendix 8: Change of Product Registration Holder</u>** From: Upon receipt of complete online application via QUEST system and hardcopy of original documents, the change of PRH application shall be processed within forty five (45) working days. To: Once NPRA deems the application is complete, the outcome of the change of PRH application shall be decided by the Drug Control Authority within forty five (45) working days. From: Application shall be rejected if the applicant fails to provide satisfactory required documents within 30 working days starting from the first date of correspondence by the evaluator. To: Application may be rejected if the applicant fails to provide satisfactory required documents within 30 working days starting from the first date of correspondence by the evaluator. From:	Produk-Change of Holder (COH) 16/7/2020 Mesyuarat Penyelarasan Proses Kerja Utama PPPK 29/7/2020

NO.	REVISION	UPDATES		REFERENCE
		SECTION/ APPENDIX	DETAILS	
			g. The Product Owner name and address in the letterhead of the LOA must be identical to the information of the Product Owner registered in QUEST for the product(s) concerned. To: g. The Product Owner name and address in the LOA must be identical to the information of the Product Owner registered in QUEST for the product(s) concerned. h. The LOA must be submitted in the Product Owner's official letterhead.	