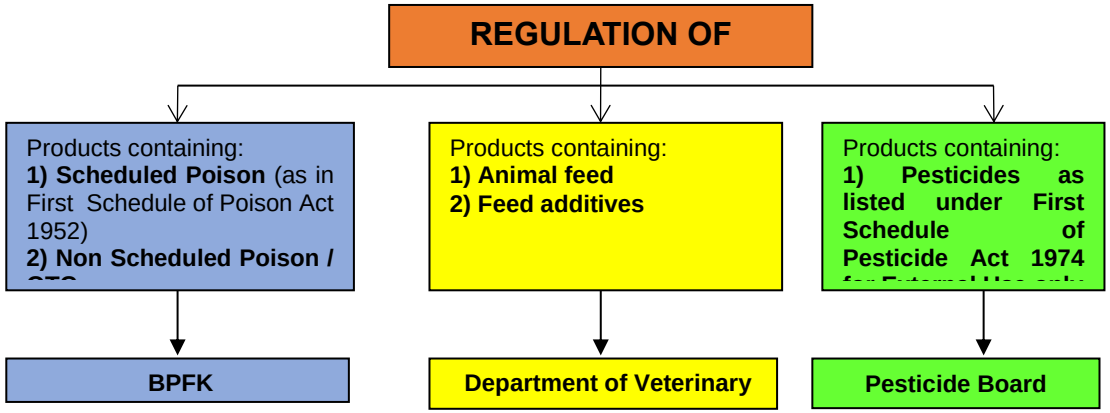
**LIST OF UPDATES ON REGOVP, VERSION 3, JULY 2014**

<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><br><br><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>

<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>3.</td><td>April 2015</td><td>Section A: General Overview</td><td><u>Amendment of Section A: General Overview, Subsection 2.2: (vii) and (viii)</u></td><td></td></tr>
<tr><td>4.</td><td>April 2015</td><td>Appendix 10: Regulation of Veterinary Products in Malaysia</td><td><u>Amendment of Appendix 10: Regulation of Veterinary Products in Malaysia</u><br> 

<br>• Products containing feed additives 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>
<tr><td>6.</td><td>July 2015</td><td>Section A: General Overview</td><td><u>Amendment of Section A: General Overview, Subsection 2.6</u></td><td></td></tr>
</table>

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| 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 | **Amendment of Section A: General Overview, Subsection 2.5** | |
| | | Appendix 1: Fees | **Amendment of Appendix 1: Fees, Subsection 1.2** | |
| 9. | August 2016 | Appendix 1: Fees | **Amendment of Appendix 1: Fees, Subsection 1.4** | Notice Ref: (40)dlm.BPFK/PPP/01/03/Jld 3 |
| | | Appendix 1.1 – 11 | **Amendment of Numbering of Appendices** | |
| | | Step 2: New Registration Application Form | **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** | |

| 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 | **Amendment of Appendix 7: List of Ingredients (Active) Not Allowed to Be Registered by The Drug Control Authority** | |
| 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** | |

| NO. | REVISION | UPDATES | | REFERENCE |
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| | | SECTION/ APPENDIX | DETAILS | |
| 13. | February 2017 | Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis | **Addition of Appendix 1: List of Antimicrobials (Premix) Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis**<br><br>**Renumbering of all appendices** | |
| 14. | April 2017 | Glossary | **Addition of Glossary** | |
| | | Section D: Post-Registration Process | **Amendment of Section D: Post- Registration Process, Subsection 10.3 and 11.2.4** | |
| | | Appendix 1: List of Antimicrobials (Premix) | **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 | |
| | | Used in Food Producing Animals for Disease Treatment and Disease Prevention/ Metaphylaxis | | |
| | | Appendix 2: Fees | **Amendment of Appendix 2: Fees, Subsection 2.1, 2.4 and 2.5** | |
| | | Appendix 4: Guidelines On Application For Variation Of Registered Products | **Amendment of Appendix 4: Guidelines On Application For Variation Of Registered Products** | |
| | | Appendix 6: Change Of Product | **Amendment of Appendix 6: Change Of Product Registration Holder, Application, Processing Fee and Flowchart For The Change Of Product Registration Holder** | |

| NO. | REVISION | UPDATES | | REFERENCE |
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| | | SECTION/ APPENDIX | DETAILS | |
| | | Registration Holder | | |
| | | Appendix 11: Allowable Maximum Residual Limit (MRL) | **Amendment of Appendix 11: Allowable Maximum Residual Limit (MRL), B) Maximum Permitted Proportion Of Drug Residues In Aquaculture And Allowable Withdrawal Period** | |
| 15. | May 2017 | Appendix 9: Guideline for Stability Data | **Amendment of Appendix 9: Guidelines For Stability Data** | |
| | | Section 2: Guide On How To Fill The Online Application Form For A Product Registration | **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 | **Amendment of Section D: Label (Mock-Up) For Immediate Container, Outer Carton, Proposed Package Insert & Product Information Leaflet (PIL)** | |

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| | | SECTION/ APPENDIX | DETAILS | |
| | | Application Form | | |
| 17. | Oct 2018 | Section A: General Overview | **<u>Amendment of Section A: General Overview; Subsection 1.2</u>**<br><br>**<u>SECTION A: GENERAL OVERVIEW</u>**<br><br>**1. <u>INTRODUCTION</u>**<br><br>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).<br><br>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:- | JKPP 18/2018 Meeting Minutes |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | **(i) Dangerous Drugs Act 1952**;<br>**(ii) Poisons Act 1952**;<br>**(iii) Medicine (Advertisement & Sale) Act 1956**;<br>~~**(iv) Patent Act 1983**~~; and also<br>**(v)** Any **other relevant Acts.** | |
| | | | **<u>Addition in Section A: General Overview; Subsection 2.3</u>**<br><br>2.3 **Classification Criteria**<br>The following may be used as criteria to assist in the classification of products:<br><br>a) The primary intended purpose/indication of the product<br>b) The primary mode of action/ the principal mechanism of action<br>c) The substances and strength of the product<br>d) Classification of the products in reference countries | |
| | | Section 2: Guide On How To Fill The Online Application Form | **<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>**<br><br>**Product Validation** | |

<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>For A Product Registration</td><td>
<table>
<tr><th>No.</th><th>Step I: Product Validation</th></tr>
<tr><td>~~10.~~</td><td>~~**Patent Protection (Yes/No)**~~<br>~~If yes, please provide:~~<br>~~a) Patent Number~~<br>~~b) Filing Date~~<br>~~c) Grant Date~~<br>~~d) Patent Statement~~</td></tr>
</table>
<br>
**15.1 STEP 1: PRODUCT VALIDATION**<br><br>
• All fields are compulsory to be entered.<br>
• Option is given either to accept the validation result and submit; or override and manually select.<br>
• Once validation is verified and submitted, the related application form under Step 2 will be displayed.<br>
• Information entered in Step 1 will be captured in the database and need not be re-entered at Step 2.<br><br>
~~**[10] Patent Protection**~~<br><br>
~~Applicants who hold valid patents shall provide documentary evidence of the nature and extent of their patents.~~</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><u>Addition in Appendix 7: List of Permitted and Restricted Colouring Agents</u><br><br>7.2 List of Restricted Colouring Agents<br><br>The following colouring agents are ALLOWED in preparations as stated in the parentheses:<br><br><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>
<tr><td>18.</td><td>Jan 2020</td><td>Section A: General Overview</td><td><u>Amendment in Section A: General Overview; Subsection 2.3</u><br><br>2.3 Classification Criteria<br>The following may be used as criteria to assist in the classification of products:<br><br>a) The primary intended purpose/indication of the product<br>b) The primary mode of action/ the principal mechanism of action<br>c) The substances and strength of the product<br>d) Classification of the products in reference countries</td><td></td></tr>
</table>

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | 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.<br><br>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 Classification Decision | **Addition of Appendix 1: Summary of Feed–Drug Interphase Veterinary Product Classification Decision**<br><br>**Renumbering of all appendices** | |
| | | Appendix 2: Summary of Drug-Feed-Pesticide Interphase Veterinary Product | **Addition of Appendix 2: Summary of Drug – Feed – Pesticide Interphase Veterinary Product Classification Decision**<br><br>**Renumbering of all appendices** | |

<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>Classification Decision</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Section D: Post-Registration Process</td><td><u>Addition in Section D: Post- Registration Process; Subsection 11.4</u><br><br>11.4 New/ Additional Indication</td><td></td></tr>
<tr><td></td><td></td><td>Appendix 4: Fees</td><td><u>Addition in Appendix 4: Fees</u><br><br>2.4 Charges For Amendments To Particulars of A Registered Product<br><br>2.4.2 Variation & Additional Indication<br><br>
<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>
<tr><td></td><td></td><td>Appendix 3: List of Antimicrobials (Premix) Used In Food Producing Animals for</td><td><u>Amendment in Appendix 3: List of Antimicrobials (Premix) Used In Food Producing Animals For Disease Treatment And Disease Prevention/ Metaphylaxis</u><br><br>
<table>
<tr><td colspan="4"><s>POLYMYXINS</s></td></tr>
<tr><td><s>Colistin (Polymixin E)</s></td><td><s>Cattle, Swine, Chicken</s></td><td><s>Yes</s></td><td><s>Yes</s></td></tr>
</table></td><td></td></tr>
</table>

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | Disease Treatment and Disease Prevention/ Metaphylaxis | | |
| | | Appendix 8: List of Ingredients (Active) Not Allowed to Be Registered By The Drug Control Authority | **<u>Addition in Appendix 8: List of Ingredients (Active) Not Allowed to Be Registered By The Drug Control Authority</u>**<br><br>B. Ingredients not allowed for food-producing animals and aquacultures<br><br>16. Colistin | |
| | | Appendix 13: Allowable Maximum Residual Limit (MRL) | **<u>Amendment in Appendix 13: Allowable Maximum Residual Limit (MRL)</u>**<br><br>**A) MAXIMUM PERMITTED PROPORTION OF DRUG RESIDUES IN FOOD**<br><br>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>NO.</th><th>REVISION</th><th colspan="2">UPDATES</th><th>REFERENCE</th></tr>
<tr><th></th><th></th><th>SECTION/ APPENDIX</th><th>DETAILS</th><th></th></tr>
<tr><td></td><td></td><td></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="4">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~~</td><td>~~Colistin~~</td><td>~~150~~</td><td>~~30 days~~</td></tr>
</table>
</td><td></td></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>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15.2</u><br><br>
<u>Specific Labelling Requirements</u><br><br>
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<br><br><table><tr><th>No.</th><th>Substances</th></tr><tr><td>~~4.~~</td><td>~~Colistin~~<br><br>~~The following statement shall be included on the labels and in the package inserts of products containing colistin for food producing animals:~~<br><br>~~TO BE PRESCRIBED AND TREATED WITH BY REGISTERED VETERINARY SURGEONS ONLY~~</td></tr></table></td><td></td></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><br><br>8.1.2 Method of Evaluation<br><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></table></td><td>NPRA.600-1/9/12 (21)<br>21 Julai 2020</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>
<tr><td>4.</td><td>Generics<br>(Non-Scheduled Poison)<br>[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.
</td><td></td></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>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration, Subsection 15</u><br><br>15. <u>CHECK LIST OF PRODUCT REGISTRATION FORM ENTRY</u></td><td></td></tr>
<tr><td>20.</td><td>Aug 2020</td><td>Section D: Post-Registration Process</td><td><u>Amendment of Section D: Post-Registration Process, Subsection 10.3</u><br><br><s>Applicant shall submit the application to the Center for Product Registration, NPRA.</s></td><td></td></tr>
</table>

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | Any form of appeal **<u>shall not be considered</u>** 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.~~ | |
| | | | **<u>Amendment of Section D: Post-Registration Process, Subsection 11.3</u>**<br><br>From:<br><br>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.<br><br>To:<br><br>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<br><br>Bengkel Penyelarasan Pertukaran Pemegang Pendaftaran Produk-Change of Holder (COH) 16/7/2020<br><br>Mesyuarat Penyelarasan Proses Kerja Utama PPPK 29/7/2020 |
| | | | **<u>Amendment in Appendix 8: Change of Product Registration Holder</u>** | |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | Appendix 8: Change of Product Registration Holder | From:<br><br>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.<br><br>To:<br><br>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:<br><br>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.<br><br>To:<br><br>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. | |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | | |
| | | | From:<br><br>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.<br><br>To:<br><br>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.<br><br>h. The LOA must be submitted in the Product Owner's official letterhead. | |
| 21. | Jan 2024 | Glossary | **<u>Addition of 'Metaphylaxis'</u>**<br><br>Refers to the administration of the product at the same time to a group of clinically healthy (but presumably infected) in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease. The presence of the disease in the group/ flock must be established before the product is used. | |
| | | | **<u>Amendment of 'Repacker'</u>**<br><br>To: | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | Please refer to Drug Registration Guidance Document (DRGD). | Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | Table of Contents | **Amendment of Table of Contents**<br><br>Updates on formats and titles.<br><br>From:<br><br>12. POST MARKETING ACTIVITIES<br><br>12.1 Pharmacovigilance<br><br>12.2.1 Post-Market Surveillance<br><br>SECTION E: INSPECTION, LICENSING AND RELEVANT DOCUMENTS<br><br>13. INSPECTION, LICENSING AND RELEVANT DOCUMENTS<br><br>13.3 GMP Certificate<br><br>To: | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | 12. POST MARKETING ACTIVITIES<br><br>12.1 Product Quality Monitoring (PQM)<br><br>SECTION E: INSPECTION, LICENSING, CERTIFICATE AND RELEVANT DOCUMENTS<br><br>13. INSPECTION, LICENSING, CERTIFICATE AND RELEVANT DOCUMENTS<br><br>13.3 Certificate | |
| | | Section A: General Overview | **Amendment of Section A: General Overview; Subsection 1.4**<br><br>From:<br><br>Applicants are encouraged to be familiar with the contents of these guidelines and, the governing legislation before they submit applications for product registration.<br><br>To:<br><br>Applicants are encouraged to be familiar with the contents of these guidelines, the governing legislation and Drug Registration Guidance Document (DRGD) before they submit applications for product registration. | |

| NO. | REVISION | UPDATES | | REFERENCE |
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| | | SECTION/ APPENDIX | DETAILS | |
| | | | | |
| | | Section D: Post-Registration Process | **<u>Amendment of Section D: Post- Registration Process; Subsection 10.3</u>**<br><br>Addition of:<br><br>To maintain the registration of a product, the PRH shall comply with GMP requirements as stated in the directive issued by the Director of Pharmaceutical Services under Regulation 29, CDCR 1984. (Refer DRGD Section E: Post-Registration Process). | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | **<u>Amendment of Section D: Post- Registration Process; Subsection 11.4</u>**<br><br>Addition of:<br><br>The application may require comments from relevant specialists. | |
| | | | **<u>Amendment of Section D: Post- Registration Process; Subsection 12</u>**<br><br>Deletion of:<br><br>12.1 **Pharmacovigilance**<br><br>Amendment of: | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |

| NO. | REVISION | UPDATES | | REFERENCE |
|---|---|---|---|---|
| | | SECTION/ APPENDIX | DETAILS | |
| | | | From:<br><br>12.2 Post Market Surveillance<br><br>To:<br><br>12.1 Product Quality Monitoring (PQM)<br><br>12.1.1 Product Quality Monitoring (PQM) is conducted by NPRA to monitor the quality of registered products available in the market. The aims of PQM are to detect quality defect or non-compliant products and take necessary regulatory actions and/or measures in a timely manner to address any potential risks.<br><br>12.1.2 The same principle of PQM for registered products (human use) will be applied to veterinary products.<br><br>12.1.3 For further information, refer to Drug Registration Guidance Document (DRGD); Post Marketing Activities, Product Quality Monitoring (PQM). | |
| | | Section E, Inspection, Licensing and | **<u>Amendment of Section E: Inspection, Licensing and Relevant Documents</u>**<br><br>From: | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran |

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<tr><td></td><td></td><td>Relevant Documents</td><td>SECTION E; INSPECTION, LICENSING AND RELEVANT DOCUMENTS<br><br>To:<br><br>SECTION E: INSPECTION, LICENSING, CERTIFICATE AND RELEVANT DOCUMENTS</td><td>Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023</td></tr>
<tr><td></td><td></td><td></td><td><u>Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.1</u><br><br>From:<br><br>Inspection of GMP and GDP are conducted to ensure manufacturers', importers' and wholesalers' compliance towards the current GMP and GDP requirements besides ensuring the registered products that are put in the market are safe, efficacious and of quality.<br><br>The related GMP and GDP guidelines referred are as below:<br><br><table><tr><th>Guidelines</th><th>Product Type/ Category</th></tr></table></td><td>Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023</td></tr>
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<table>
<tr><td>PIC/S Guide to Good Manufacturing Practice for Medicinal Products *</td><td>Pharmaceuticals<br>(Poison and Non-Poison)<br>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>
* Refer to Pharmaceutical Inspection Co-operation Scheme (PIC/S) website at www.picscheme.org<br><br>Additional Information:<br>Please refer to (8)dlm.BPFK/PPP/07/25 Directive No. 2 Year 2014 and (26)dlm.BPFK/PPP/07/25 Directive No. 2 Year 2015 for the requirement on Head of Production for pharmaceutical, radiopharmaceutical and veterinary manufacturer.<br><br>To:<br><br>Inspection of GMP and GDP are conducted to ensure the compliance of manufacturers, importers and wholesalers with current GMP and GDP requirements besides ensuring that the registered products in the market are safe, efficacious and of quality.
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<tr><td></td><td></td><td></td><td>The related GMP and GDP guidelines referred are as below:<br><br><table><tr><th>Guidelines</th><th>Product Type/ Category</th></tr><tr><td>PIC/S Guide to Good Manufacturing Practice for Medicinal Products * and the related PIC/S Annexes*</td><td>Pharmaceuticals<br>(Poison and Non-Poison)<br>Veterinary Products</td></tr><tr><td>Guideline on Good Manufacturing Practice (GMP) for Veterinary Premixes; 1st Edition, January 2015</td><td>Veterinary Premixes for Medicinal Purpose</td></tr><tr><td>Guideline on Good Distribution Practice (GDP)</td><td>For activities related to the storage and distribution by manufacturers, importers and wholesalers (where applicable)</td></tr></table>* Refer to Pharmaceutical Inspection Co-operation Scheme (PIC/S) website at www.picscheme.org<br><br>Please refer to:<br>a) Direktif Bilangan 1 Tahun 2010 [BPFK/PPP/01/03(50)] Penguatkuasaan Keperluan Pelesenan Terhadap Premis Pengilang Tempatan yang Mengilang Produk Veterinar di Malaysia.</td><td></td></tr>
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| | | | b) Direktif Bilangan 2 Tahun 2014 [(8)dlm.BPFK/PPP/07/25] dan Bilangan 2 Tahun 2015 [(26)dlm.BPFK/PPP/07/25]: Keperluan Ahli Farmasi Berdaftar Sepenuh Masa Untuk Mengetuai Bahagian Pengeluaran Premis Pengilang Produk Farmaseutikal, Radiofarmaseutikal dan Veterinar yang Berdaftar dengan Pihak Berkuasa Kawalan Dadah (PBKD).<br>c) Directive No.10 Year 2022 (NPRA.600-1/9/13) for the requirement of GMP for sterile veterinary products. Direktif Bilangan 10 Tahun 2022 [NPRA.600-1/9/12(10)Jld.1] Pengemaskinian Keperluan Standard Pematuhan Amalan Perkilangan Baik (APB) Produk Steril Veterinar. | |
| | | | **<u>Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.1.1</u>**<br><br>From:<br><br>For details and forms please refer Guidance Document on Foreign GMP Inspection.<br><br>To:<br><br>For details and application for foreign GMP Inspection by NPRA, please refer Guidance Document Foreign GMP Inspection. | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | **<u>Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.3</u>** | Mesyuarat Jawatankuasa Kerja |

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| | | | From:<br><br>13.3 GMP Certificate<br><br>To:<br><br>13.3 Certificate | Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | Addition of:<br><br>13.3.1 Good manufacturing Practice (GMP) Certificate | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | **<u>Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.3.1</u>**<br><br>From:<br><br>1. The application of GMP Certificate shall be submitted online through QUEST3+. | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |

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| | | | To:<br><br>2. The application of GMP Certificate by local manufacturers shall be submitted via the online QUEST system, while applications from foreign manufacturers that have been inspected by NPRA shall be submitted manually via Borang NPRA/432/10 *Permohonan Sijil Amalan Perkilangan Baik (APB) Pengilang Luar Negara*. | |
| | | | **Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.4.2**<br><br>Renumbering of 13.4.2 to 13.3.2<br><br>From:<br><br>13.4.2 Imported products will also need to furnish either a:<br><br>To:<br><br>13.3.2 Certificate of Pharmaceutical Product (CPP) | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | **Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.3.2**<br><br>Addition of: | |

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| | | | (iii) Both CPPs and GMP certificates are mandatory for sterile preparations. | |
| | | | Deletion of:<br><br>CPPs are mandatory for sterile preparations. | |
| | | | From:<br><br>*[3Authority will usually recognize GMP Certification/ Manufacturing License issued by the relevant national or regional Veterinary Service or Department of Animal Health or Department of Agriculture.]*<br><br>To:<br><br>[*3For non- sterile veterinary products, authority will usually recognize GMP Certification/ Manufacturing License issued by the relevant national or regional Veterinary Service or Department of Animal Health or Department of Agriculture while for sterile veterinary products please refer to Directive No.10 Year 2022 (NPRA.600-1/9/13) for the requirement of GMP for sterile veterinary products*.] | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | | **Amendment of Section E: Inspection, Licensing and Relevant Documents; Subsection 13.4** | Mesyuarat Jawatankuasa Kerja Pasca Pendaftaran |

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| | | | Addition of:<br><br>13.4.2 GMP certificate (for details please refer to 13.3.1)<br><br>13.4.3 Certificate of Pharmaceutical Product (CPP) (for details please refer to 13.3.2) | Produk Veterinar (JKPPPVet) Bil 3/2023<br>3/11/2023 |
| | | Appendix 2: Summary of Drug-Feed-Pesticide Interphase Veterinary Product Classification Decision | **Amendment of Appendix 2: Summary of Drug – Feed – Pesticide Interphase Veterinary Product Classification Decision**<br><br>Addition of:<br><br>(4) Its analogues, homologues, compounds (other than compounds of phenol with a metal), intermediates, derivatives, esters, ethers, salts and other substances structurally derived | |
| | | Appendix 9: List of Permitted and Restricted Colouring Agents | **Amendment of Appendix 9: List of Permitted and Restricted Colouring Agents; Subsection 7.2**<br><br>From: | |

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<table>
<tr><th>NO.</th><th>COLOURING AGENTS</th><th>COLOUR INDEX NUMBER (CI)</th></tr>
<tr><td>28.</td><td>Uranine Sodium Salt/ D & C Yellow No. 8 (external use only)</td><td>45350</td></tr>
</table>
To:
<table>
<tr><th>NO.</th><th>COLOURING AGENTS</th><th>COLOUR INDEX NUMBER (CI)</th></tr>
<tr><td>28.</td><td>Uranine Sodium Salt/ D & C Yellow No. 8/ Fluorescein Sodium (external use only or for euthanasia only)</td><td>45350</td></tr>
</table>
</td><td></td></tr>
<tr><td></td><td></td><td>Appendix 14: Regulation of Veterinary Products in Malaysia</td><td><u>Amendment of Appendix 14: Regulation of Veterinary Products in Malaysia</u><br><br>Amendment of the chart diagram.</td><td></td></tr>
<tr><td></td><td></td><td>Section 2: Guide On How To Fill</td><td><u>Amendment of Section 2: Guide On How To Fill The Online Application Form For A Product Registration; Subsection 15.2</u></td><td></td></tr>
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| | | SECTION/ APPENDIX | DETAILS | |
| | | The Online Application Form For A Product Registration | <u>SECTION D: LABEL (MOCK-UP) FOR IMMEDIATE CONTAINER, OUTER CARTON, PROPOSED PACKAGE INSERT & PRODUCT INFORMATION LEAFLET (PIL)</u><br><br>Addition of:<br><br>iv) Use of QR code/barcode is permitted only for the purpose of monitoring inventory of the product, such as batch number, expiry date and manufacturing date, BUT NOT for linkage to any website. The addition of QR code/barcode for this purpose on registered product labels without variation approval from NPRA may be considered only if that is the only proposed change to the currently approved labels. | |
| | | | PART III and PART IV<br><br>Deletion of:<br><br>For innovator/ NCE products please submit the documents in hard copy (printed) to NPRA. | |