

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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|-----|----------|----------------------|---------|-----------|
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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 |
|-----|-----------|-----------------------------------|---|-----------|
| | | SECTION/ APPENDIX | DETAILS | |
| 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> | |

| NO. | REVISION | UPDATES | | REFERENCE |
|-----|---------------|--|---|-----------|
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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> | |