

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

| NO. | REVISION         | UPDATES  |   | REFERENCE  |   |
|-----|------------------|--|---|--|---|
|     |                  | SECTION/<br>APPENDIX   | DETAILS   |  |   |
| 1.  | February<br>2015 | Section E,<br>Inspection,<br>Licensing<br>and<br>Relevant<br>Documents | <b><u>Amendment at Section E: Inspection, Licensing and Relevant Documents</u></b><br><b><u>Subsection 13.1: Inspection</u></b> |  | Memo from PKP. Ref:<br>(37)dIm.BPFK/30/06/1<br>Bhgn 7 |
|     |                  |  | <b>Guidelines</b>   | <b>Product Type/<br/>Category</b>  |   |
|     |                  |  | PIC/S Guide to Good<br>Manufacturing<br>Practice for<br>Medicinal Products *  | Pharmaceuticals<br>(Poison and Non-Poison)<br>Veterinary Products  |   |
|     |                  |  | Guideline on Good<br>Manufacturing<br>Practice (GMP) for<br>Veterinary Premixes;<br>1 <sup>st</sup> Edition, January<br>2015    | Veterinary Premixes  |   |
|     |                  |  | Guidelines on Good<br>Distribution Practice<br>(GDP); 2 <sup>nd</sup> Edition<br>2013   | For activities related to<br>the storage and<br>distribution by<br>manufacturers, importers<br>and wholesalers (where<br>applicable) |   |

| NO. | REVISION   | UPDATES  |  | REFERENCE |
|-----|------------|--|--|-----------|
|     |            | SECTION/<br>APPENDIX   | DETAILS  |           |
| 2.  | April 2015 | Section A:<br>General<br>Overview  | <b><u>Deletion of Section A: General Overview, Subsection 2.2: (vi)</u></b>              |           |
| 3.  | April 2015 | Section A:<br>General<br>Overview  | <b><u>Amendment of Section A: General Overview, Subsection 2.2: (vii) and (viii)</u></b> |           |
| 4.  | April 2015 | Appendix<br>10:<br>Regulation<br>of<br>Veterinary<br>Products in<br>Malaysia | <b><u>Amendment of Appendix 10: Regulation of Veterinary Products in Malaysia</u></b>    |           |

| NO. | REVISION | UPDATES              |   | REFERENCE |
|-----|----------|----------------------|---|-----------|
|     |          | SECTION/<br>APPENDIX | DETAILS   |           |
|     |          |                      | <p style="text-align: center;"><b>REGULATION OF<br/>VETERINARY PRODUCTS</b></p> <pre> graph TD     Root[REGULATION OF VETERINARY PRODUCTS] --&gt; Category1[Products containing:<br/>1) Scheduled Poison (as in First Schedule of Poison Act 1952)<br/>2) Non Scheduled Poison / OTC<br/>3) Pesticides for Internal Use<br/>4) Pesticides for External Use (Control of endoparasite)]     Root --&gt; Category2[Products containing:<br/>1) Animal feed<br/>2) Feed additives]     Root --&gt; Category3[Products containing:<br/>1) Pesticides as listed under First Schedule of Pesticide Act 1974 for External Use only]     Category1 --&gt; BPFK[BPFK]     Category2 --&gt; DVS[Department of Veterinary Services (DVS)]     Category3 --&gt; PesticideBoard[Pesticide Board] </pre> <p>•Products containing feed additives in combination with scheduled poisons will be regulated by the DCA.<br/>•Products containing pesticide ingredients in combination with scheduled poisons will be regulated by the DCA.</p> |           |

| NO. | REVISION  | UPDATES                           |   | REFERENCE |
|-----|-----------|-----------------------------------|---|-----------|
|     |           | SECTION/<br>APPENDIX              | DETAILS   |           |
| 5.  | July 2015 | Section A:<br>General<br>Overview | <b><u>Addition of Section A: General Overview, Subsection 2.4</u></b>               |           |
| 6.  | July 2015 | Section A:<br>General<br>Overview | <b><u>Amendment of Section A: General Overview, Subsection 2.6</u></b>              |           |
| 7.  | July 2015 | Section A:<br>General<br>Overview | <b><u>Addition of Section A: General Overview, Subsection 2.2: (x) and (xi)</u></b> |           |

| NO. | REVISION        | UPDATES  |   | REFERENCE                                       |
|-----|-----------------|--|---|---|
|     |                 | SECTION/<br>APPENDIX   | DETAILS   |   |
| 8.  | October<br>2015 | Section A:<br>General<br>Overview<br><br>Appendix 1:<br>Fees   | <u><b>Amendment of Section A: General Overview, Subsection 2.5</b></u><br><br><u><b>Amendment of Appendix 1: Fees, Subsection 1.2</b></u>   |   |
| 9.  | August<br>2016  | Appendix 1:<br>Fees<br><br>Appendix<br>1.1 – 11<br><br>Step 2:<br>New<br>Registration<br>Application<br>Form | <u><b>Amendment of Appendix 1: Fees, Subsection 1.4</b></u><br><br><u><b>Amendment of Numbering of Appendices</b></u><br><br><u><b>Addition of Section D: Label (Mockup) For Immediate Container, Outer<br/>Carton And Proposed Package Insert, Specific Labelling Requirements</b></u><br><br><u><b>Amendment of Section 2: Guide On How To Fill The Online Application<br/>Form For A Product Registration: Check List Of Product Registration Form<br/>Entry</b></u> | Notice Ref:<br>(40)dIm.BPFK/PPP/01<br>/03/Jld 3 |