

SCHEDULE OF ADDITIONAL LICENCE CONDITIONS

The following additional conditions apply to and form part of Licence No. **6176** issued to the Licence Holder:

Chemika Pty Limited

ACN 093 373 534

- S1.1 This Licence authorises only those steps of manufacture, product type(s) and premises listed.
- S1.2 The Licence Holder must provide the original signed copy of the audit report together with details of all corrective actions they propose to make with respect to the identified non-conformances and the timeframe for their implementation. This documentation must be received by the APVMA within 25 working days of the audit in accordance with Regulation 61(8C)(a)(i).
- S2.1 The Licence Holder must perform all aspects of veterinary chemical manufacture, including analysis and testing, in accordance with Good Manufacturing Practice using the same:
- a) premises,
 - b) plant and equipment,
 - c) processes and procedures,
 - d) documentation, and
 - e) personnel (including those persons responsible for Production and Quality)
- that are used in the manufacture of human therapeutics, as inspected and licensed by the Therapeutic Goods Administration (TGA Licence No. **MI-2012-LI-00095-3**).
- S2.2 Prior to each TGA inspection, the Licence Holder must arrange for the TGA inspector to verify during the inspection that all aspects of veterinary chemical manufacture are carried out within the scope of that TGA licence.
- S2.3 The Licence Holder must maintain their TGA licence and advise the APVMA in writing within 10 working days, of any changes in the scope of that licence. The Licence Holder must also provide the APVMA with copies of all TGA inspection reports and correspondence related to the conduct and closure of such inspections, within 10 working days of receipt of those reports or correspondence.

Dated this 7th day of September 2016



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Rheannon McNeil
Assistant Director, Manufacturing Quality and
Licensing
Delegate of the Australian Pesticides and
Veterinary Medicines Authority

This licence remains the property of the APVMA and must be returned on request