Australian Government
Australian Pesticides and Veterinary Medicines Authority

LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: **Syrinx Pharmaceuticals Pty Ltd** **Licence No:** **2227**
ACN 149 728 825

The APVMA hereby issues a licence under section 123 of the Agricultural and Veterinary Chemicals Code (Agvet Code) to the above named person (the Licence Holder) to carry out the following step(s) of manufacture:

Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging, labelling, blister and sachet packaging, tableting, tablet coating, capsule filling from bulk, freeze drying, storage and release for supply

This licence authorises the manufacture of the following type(s) of veterinary chemical products only:

Category 2 ***(Non-sterile veterinary chemical products other than ectoparasiticides, and premixes and supplements)*** **– tablets, capsules (hard shell), creams/lotions, pastes, liquids, powders and granules**

—at the following premises:

110 Merrindale Drive
CROYDON VIC 3136

This licence is subject to the conditions set out in subsection 126(4) of the Agvet Code, regulations 60, 61 and 62 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations) and the **additional conditions in the attached Schedule.**

This licence comes into force on the date of issue and replaces the previous licence issued on 8 December 2014. This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 9th day of April 2015

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Rheannon McNeil
Acting 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

SCHEDULE OF ADDITIONAL LICENCE CONDITIONS

The following additional conditions apply to and form part of Licence No. **2227** issued to the Licence Holder:

Syrinx Pharmaceuticals Pty Ltd

ACN 149 728 825

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-05038-3**).

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.

S2.4 This licence does not authorise the manufacture of preparations containing penicillins, cephalosporins, hormones, steroids or antineoplastic drugs.

Dated this 9th day of April 2015

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

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