|  |
| --- |
| **Regulation 62 notice—Changes to key personnel and GMP contact in relation to a manufacturing licence** |

**Company Details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Company Name** |  | **Licence No** |  |
| **Site Address** |  |

**Section A—Change to key personnel**

Please provide information below. Please note that these people will be listed in the APVMA’s record as having responsibilities which relate to the APVMA Licence to Manufacture Veterinary Chemical Products and that there are specific responsibilities associated with these roles which are described within the *Agricultural and Veterinary Chemicals Manufacturing Determination 2014* and the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*. A person should be nominated for both roles even if you hold a single step licence for both analysis and testing or release for supply.

Persons nominated as having responsibility for production and quality are considered to be persons who make or participate in making decisions that affect the whole or a substantial part of the applicant’s affairs. Accordingly, the declaration below must be signed. If the APVMA identifies that any persons to whom this declaration relates do not meet this criteria, the APVMA may suspend or cancel your licence to manufacture veterinary chemical products under Section 127 of the Agvet Codes.

Person responsible for production of chemical products by or on behalf of the licence holder:

|  |  |  |  |
| --- | --- | --- | --- |
| **Last name** |  | **Title***(Mr, Ms, Dr etc)* |  |
| **First name** |  |
| **Position in company** |  |
| **Degree/diploma/experience \*** |  |
| **Field of study** |  |
| **Years of experience** |  |

\* where space is insufficient, attach list.

Person responsible for quality control measures that are, or are to be employed in the manufacture of chemical products:

|  |  |  |  |
| --- | --- | --- | --- |
| **Last name** |  | **Title***(Mr, Ms, Dr etc)* |  |
| **First name** |  |
| **Position in company** |  |
| **Degree/diploma/experience \*** |  |
| **Field of study** |  |
| **Years of experience** |  |

\* where space is insufficient, attach list.

**Section B—Change to manufacturers GMP contact**

|  |  |  |
| --- | --- | --- |
| **Former GMP contact person**  | **Title**(Mr, Ms, Dr etc) |  |
| **Last name:** |  |
| **First name:** |  |
| **New GMP contact person** | **Title**(Mr, Ms, Dr etc) |  |
| **Last name:** |  |
| **First name:** |  |
| **Company position** |  |
| **Phone number** |  | **Mobile number** |  |
| **Fax number** |  | **Email address** |  |
| **Postal address** |  |

**Declaration:**

|  |
| --- |
| I, ...................................................................................................................................................**Declaration Part 1:*** **declare that in accordance with paragraph 123(1)(e) AND 123(1b) of the Agvet Code, neither:**
* I, as the applicant for the Licence to manufacture veterinary chemical products (the Applicant); or
* any person who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Applicant’s affairs; or
* I, as a person who is a major interest holder of the body corporate which holds the Licence

have, within the 10 years immediately before this application:* been convicted of an offence against an agvet law; or
* been convicted of an offence against a law of this or another jurisdiction relating to chemical products; or
* been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
* been charged before a court of an offence included above and the court has been satisfied that the charge or charges have been proved, but the court has made an order dismissing the charge or charges or discharging me without proceeding to a a conviction; or
* been ordered to pay a pecuniary penalty for the contravention of an agvet penalty provision; or
* been ordered to pay a pecuniary penalty for the contravention of another law of this or another jurisdiction relating to chemical products; or
* been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
* contravened a condition of a manufacturing licence issued under an agvet law; or
* held a manufacturing licence or permit that was cancelled under an agvet law, other than paragraph 127(1)(d) or (e) of this Code or a corresponding provision of the Agvet Code of another jurisdiction; or
* been a manager, or major interest holder, of a body corporate in respect of which any of the matters, noted above, applied in that 10 year period, if the conduct resulting in that matter occurred when the person was a manager or major interest holder of the body corporate.

**Declaration Part 2:** * declare that in accordance with paragraph 123(1)(f) of the Agvet Code, neither the:
* I, as the applicant for the Licence to manufacture veterinary chemical products (the Applicant); or
* any person who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Applicant’s affairs; or
* I as, a person who is a major interest holder of the body corporate which holds the licence

Has, within the 5 years immediately before this application failed to comply with a manufacturing principle in connection with the manufacture of chemical products.**Declaration Part 3:** * declare that I cannot make the declarations set out in Declaration Parts 1 and/or 2 above, because:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* request that the APVMA consider the following special circumstances in this case:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Please attach further details if required.Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_             Date:       *Giving false or misleading information is a serious offence and may lead to prosecution for an offence against the Agricultural and Veterinary Chemicals Code.* |

|  |
| --- |
| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* declare I am aware it is an offence to manufacture chemical products which are prohibited from manufacture under the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* unless such manufacture is permitted in accordance with conditions or restrictions prescribed in the legislation.
* declare that I will not be conducting any step in the manufacture of a chemical product which are prohibited from manufacture under the *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* unless such manufacture is permitted in accordance with conditions or restrictions prescribed in the legislation.
* declare that the information provided with this application is complete and correct.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_             Date:     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_     *Giving false or misleading information is a serious offence and may lead to prosecution for an offence against the Agricultural and Veterinary Chemicals Code.* |

**Section C—Privacy statement**

Your personal information is collected by the Australian Pesticides and Veterinary Medicines Authority (APVMA) for the purpose of assisting the APVMA to perform its functions under the *Agricultural and Veterinary Medicines (Administration) Act 1992* and related legislation, including for the purpose of processing applications.

Your personal information will be managed in accordance with the *Privacy Act 1988*.

More information about the way in which the APVMA will manage your personal information, including its Privacy Statement, is available at [www.apvma.gov.au/node/3207](http://www.apvma.gov.au/node/3207)

**Section D: Further Information**

1. APVMA Legislation

The APVMA’s legislation can be accessed via the APVMA’s website: [www.apvma.gov.au](http://www.apvma.gov.au)

(b) Manufacturing Principles and Code of GMP

The *Agricultural and Veterinary Chemicals Manufacturing Determination 2014* (MPs) and the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products, 2007* are available on the APVMA’s website: [www.apvma.gov.au](http://www.apvma.gov.au)