



Veterinary Medicines Directorate

VETERINARY MEDICINES DIRECTORATE
On behalf of the Secretary of State for the
Department for Environment, Food and Rural Affairs (Defra)

ISSUED BY:
VETERINARY MEDICINES DIRECTORATE
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Tel: +44 (0)1932 336911; Website: www.gov.uk

Manufacturer's/Importer's Authorisation

SECTION 1A

1. Authorisation Number

ManA 1296

2. Name and address of Authorisation Holder

NORTHAMPTON GENERAL HOSPITAL
Radiotherapy Department, Luke Radiotherapy Building, Northampton General Hospital, Cliftonville,
Northampton, NN1 5BD

3. Address(es) of manufacturing/importing site(s)

(All authorised sites should be listed if not covered by separate licences)

| VMD SITE NUMBER: | SITE NAME: | ADDRESS: |
|------------------|------------------------------|--|
| S0536 | Northampton General Hospital | Radiotherapy Department, Luke Radiotherapy Building, Northampton General Hospital, Cliftonville, Northampton NN1 5BD |

4. Legally registered address of Authorisation Holder

Radiotherapy Department, Luke Radiotherapy Building, Northampton General Hospital,
Cliftonville, Northampton NN1 5BD

5. Scope of authorisation and dosage

See ANNEX 1

6. Legal basis of authorisation

See Section 1B of licence.





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SECTION 1A (continued)

7. **Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation**

CONFIDENTIAL

8. **Date**

09 January 2020





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Manufacturer's/Importer's Authorisation

SECTION 1B

1. This authorisation covers the processes of manufacture and/or assembly and/or importation of veterinary medicinal products of the description or general classification at the premises specified and in accordance with the particulars set out in Section 3 by the authorisation holder named. All manufacturing and/or assembly and/or importation operations in respect of those products for which a marketing authorisation is required shall be conducted so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured and/or assembled and/or imported or the specification under which the products are sold or supplied.

In relation to such products the authorisation holder shall either:

- a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification, or
 - b) make arrangements with a person approved by the Secretary of State for such tests to be carried out on his behalf by that person, and
 - c) make arrangements for a Manufacturing Qualified Person (MQP) to be available at all times for the purpose of checking that each batch of veterinary medicinal products has been manufactured and assembled in accordance with the appropriate provisions and to certify accordingly in a register.
2. The authorisation holder must inform the VMD, acting on behalf of the Secretary of State, in advance of any change to the details submitted or included in this authorisation. All changes must be approved by the Secretary of State prior to becoming effective. This includes any changes to named premises, persons, operations processes or structural alterations. If the business should change hands the new company or person must obtain a new authorisation prior to commencing operations. The manufacture and/or assembly and/or importation of any veterinary medicinal product pursuant to this authorisation shall not commence until a marketing authorisation has been granted naming the site named on this authorisation as being used for the manufacture of that product.





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SECTION 1B (continued)

3. The names and addresses of holders of manufacturing authorisations for veterinary medicinal products together with addresses of authorised sites will be published on the EudraGMP database at www.eudragmp.ema.europa.eu.
4. Further information and specified guidelines may be obtained from the VMD website www.gov.uk.
5. Authorisation Structure

This authorisation is divided into three sections.

- (a) Section 1 (this section) identifies the authorisation holder and holds the authorising name. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.
- (b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.
- (c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.





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Manufacturer's/Importer's Authorisation

SECTION 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

| NAME AND ADDRESS OF SITE: | |
|----------------------------------|--|
| SITE NAME: | Northampton General Hospital |
| ADDRESS: | Radiotherapy Department, Luke Radiotherapy Building, Northampton General Hospital, Cliftonville, Northampton NN1 5BD |
| VMD SITE NUMBER: | S0536 |

| TYPE OF PRODUCTS HANDLED |
|--------------------------------------|
| <i>Veterinary Medicinal Products</i> |

| AUTHORISED OPERATIONS | |
|---|----------------|
| Manufacturing Operations (according to Part 1) | Authorised |
| Importation of Medicinal Products (according to Part 2) | Not Authorised |





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ANNEX 1 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

| 1.1 | Sterile Products | Manufacture |
|-------|--|----------------|
| 1.1.1 | Aseptically Prepared (processing operations for the following dosage forms) | |
| | 1.1.1.1 Large volume liquids | Not Authorised |
| | 1.1.1.2 Lyophilisates | Not Authorised |
| | 1.1.1.3 Semi-solids | Not Authorised |
| | 1.1.1.4 Small volume liquids | Not Authorised |
| | 1.1.1.5 Solids and implants | Not Authorised |
| | 1.1.1.6 Other aseptically prepared products | Not Authorised |





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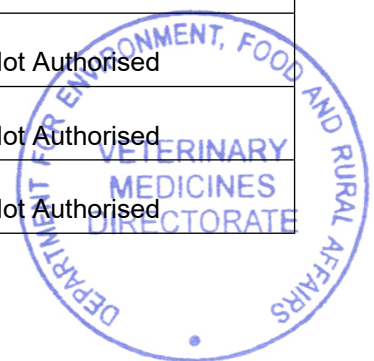
| 1.1.2 | <i>Terminally Sterilised (processing operations for the following dosage forms)</i> | Manufacture |
|--------------|--|--------------------|
| | 1.1.2.1 Large volume liquids | Not Authorised |
| | 1.1.2.2 Semi-solids | Not Authorised |
| | 1.1.2.3 Small volume liquids | Not Authorised |
| | 1.1.2.4 Solids and implants | Not Authorised |
| | 1.1.2.5 Other terminally sterilised prepared products | Not Authorised |
| 1.1.3 | <i>Batch certification</i> | Not Authorised |





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| 1.2 | Non-sterile products | <i>Manufacture</i> |
|-------|--|--------------------|
| 1.2.1 | Non-sterile products (processing operations for the following dosage forms) | |
| | 1.2.1.1 Capsules, hard shell | Not Authorised |
| | 1.2.1.2 Capsules, soft shell | Not Authorised |
| | 1.2.1.3 Chewing gums | Not Authorised |
| | 1.2.1.4 Impregnated matrices | Not Authorised |
| | 1.2.1.5 Liquids for external use | Not Authorised |
| | 1.2.1.6 Liquids for internal use | Not Authorised |
| | 1.2.1.7 Medicinal gases | Not Authorised |
| | 1.2.1.8 Other solid dosage forms | Not Authorised |
| | 1.2.1.9 Pressurised preparations | Not Authorised |
| | 1.2.1.10 Radionuclide generators | Not Authorised |
| | 1.2.1.11 Semi-solids | Not Authorised |
| | 1.2.1.12 Suppositories | Not Authorised |
| | 1.2.1.13 Tablets | Not Authorised |
| | 1.2.1.14 Transdermal patches | Not Authorised |
| | 1.2.1.15 Intraruminal devices | Not Authorised |
| | 1.2.1.16 Veterinary premixes | Not Authorised |
| | 1.2.1.17 Other non-sterile medicinal product | Not Authorised |
| 1.2.2 | Batch certification | Not Authorised |





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| 1.3 | Biological medicinal products | Manufacture |
|--------------|---|----------------|
| 1.3.1 | <i>Biological medicinal products (list of product types)</i> | |
| | 1.3.1.1 Blood products | Not Authorised |
| | 1.3.1.2 Immunological products | Not Authorised |
| | 1.3.1.3 Cell therapy products | Not Authorised |
| | 1.3.1.4 Gene therapy products | Not Authorised |
| | 1.3.1.5 Biotechnology products | Not Authorised |
| | 1.3.1.6 Human or animal extracted products | Not Authorised |
| | 1.3.1.7 Tissue engineered products | Not Authorised |
| | 1.3.1.8 Other biological medicinal products | Not Authorised |
| 1.3.2 | <i>Batch certification (list of product types)</i> | |
| | 1.3.2.1 Blood products | Not Authorised |
| | 1.3.2.2 Immunological products | Not Authorised |
| | 1.3.2.3 Cell therapy products | Not Authorised |
| | 1.3.2.4 Gene therapy products | Not Authorised |
| | 1.3.2.5 Biotechnology products | Not Authorised |
| | 1.3.2.6 Human or animal extracted products | Not Authorised |
| | 1.3.2.7 Tissue engineered products | Not Authorised |
| | 1.3.2.8 Other biological medicinal products | Not Authorised |





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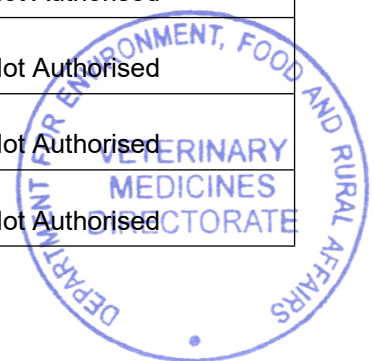
| | | |
|--------------|---|--------------------|
| 1.4 | Other products or manufacturing activity (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc). | Manufacture |
| 1.4.1 | Manufacture of: | |
| | 1.4.1.1 Herbal products | Not Authorised |
| | 1.4.1.2 Homoeopathic products | Not Authorised |
| | 1.4.1.3 Other | Not Authorised |
| 1.4.2 | Sterilisation of active substances/excipients/finished product: | |
| | 1.4.2.1 Filtration | Not Authorised |
| | 1.4.2.2 Dry heat | Not Authorised |
| | 1.4.2.3 Moist heat | Not Authorised |
| | 1.4.2.4 Chemical | Not Authorised |
| | 1.4.2.5 Gamma irradiation | Not Authorised |
| | 1.4.2.6 Electron beam | Not Authorised |
| 1.4.3 | Others: Manufacture of active substance (biological) Restricted to Photon beam irradiation of lungworm larvae for inclusion in Bovilis Huskvac Vm01708/4328 | Authorised |





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| | | |
|--------------|---|----------------|
| 1.5 | Packaging | Manufacture |
| 1.5.1 | Primary packing | |
| | 1.5.1.1 Capsules, hard shell | Not Authorised |
| | 1.5.1.2 Capsules, soft shell | Not Authorised |
| | 1.5.1.3 Chewing gums | Not Authorised |
| | 1.5.1.4 Impregnated matrices | Not Authorised |
| | 1.5.1.5 Liquids for external use | Not Authorised |
| | 1.5.1.6 Liquids for internal use | Not Authorised |
| | 1.5.1.7 Medicinal gases | Not Authorised |
| | 1.5.1.8 Other solid dosage forms | Not Authorised |
| | 1.5.1.9 Pressurised preparations | Not Authorised |
| | 1.5.1.10 Radionuclide generators | Not Authorised |
| | 1.5.1.11 Semi-solids | Not Authorised |
| | 1.5.1.12 Suppositories | Not Authorised |
| | 1.5.1.13 Tablets | Not Authorised |
| | 1.5.1.14 Transdermal patches | Not Authorised |
| | 1.5.1.15 Intraruminal devices | Not Authorised |
| | 1.5.1.16 Veterinary premixes | Not Authorised |
| | 1.5.1.17 Other non-sterile medicinal products | Not Authorised |
| 1.5.2 | Secondary packing | Not Authorised |





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| | | |
|------------|--------------------------------------|----------------|
| 1.6 | Quality control testing | Manufacture |
| | 1.6.1 Microbiological: sterility | Not Authorised |
| | 1.6.2 Microbiological: non-sterility | Not Authorised |
| | 1.6.3 Chemical/Physical | Not Authorised |
| | 1.6.4 Biological | Not Authorised |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

None

