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 123

2. Name and address of Authorisation Holder

Dales Pharmaceuticals Limited
Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom

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

VMD SITE NUMBER:	SITE NAME:	ADDRESS:
S0258	Dales Pharmaceuticals Limited	Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom

4. Legally registered address of Authorisation Holder

As Above

5. Scope of authorisation and dosage

See ANNEX 1

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SECTION 1A (continued)

6. Legal basis of authorisation

See Section 1B of licence.

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

CONFIDENTIAl

8. Signature

CONFIDENTIAL

9. Date

08 December 2022

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Manufacturer's/Importer's Authorisation

SECTION 1B

1. This authorisation covers the manufacture, assembly and/or importation of veterinary medicinal products at the premises specified. The dosage forms authorised to be manufactured and / or products to be imported, as well as details of specific manufacturing operations permitted at each site are specified in Section 3. For veterinary medicinal products requiring a marketing authorisation, all manufacturing, assembly and/or importation operations shall be conducted so as to ensure that product strength, quality and purity meet the requirements of the marketing authorisation, or in the case of outsourced manufacture, assembly and / or importation, the specification made by the contract giver.

   In relation to such products the authorisation holder shall either:

   a) provide and maintain such staff, premises and plant as are necessary to carry out any tests of the strength, quality or purity as required by the marketing authorisation / specification, or

   b) make arrangements with a person approved by the Secretary of State to carry out such tests on his behalf, and

   c) make arrangements for a Qualified Person (QP) 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.

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SECTION 1B (continued)

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.

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. A register of holders of manufacturing "specials" authorisations can be found at the VMD website www.vmd.gov.uk.

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 its details.

   (b) Section 2 lists variations to the authorisation.

   (c) Section 3 contains the details relating to each site named on the authorisation. Annex1 contain the details of the Authorisation holder's sites while Annex 2 lists the Qualified Person(s) and persons responsible for production and quality control. Annexes 3,4 and 5 list contracted sites (if applicable). Where the Authorisation holder has more than one manufacturing / importation site, separate versions of Annex 1 and Annex 2 along with versions of annexes 3, 4 and 5, as applicable, are included to fully capture the details for each.

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Manufacturer's/Importer's Authorisation

SECTION 3

ANNEX 1 – AUTHORISATION HOLDER'S SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:	
SITE NAME:	Dales Pharmaceuticals Limited
ADDRESS:	Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom
VMD SITE NUMBER:	S0258

TYPE OF PRODUCTS HANDLED
Veterinary Medicinal Products

AUTHORISED OPERATIONS	
Manufacturing Operations (according to Part 1)	Authorised
Importation of Medicinal Products (according to Part 2)	Authorised

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ANNEX 1 – AUTHORISATION HOLDER'S 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 i.e. B-lactam antibiotics, other highly sensitising antibiotics, live cells, pathogenic organisms (biosafety Level 3 or 4), radiopharmaceuticals, ectoparasiticides or other highly potent or highly toxic products this should be stated under the relevant product type and dosage

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

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1.2	Non-sterile products	Manufacture
1.2.1	***Non-sterile products (processing operations for the following dosage forms)***	
	1.2.1.1 Capsules, hard shell	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	Authorised
	1.2.1.6 Liquids for internal use	Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	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	Authorised
1.2.2	***Batch certification***	Authorised

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1.3	Biological medicinal products	Manufacture
1.3.1	***Biological medicinal products (list of product types)***	
	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	***Batch certification (list of product types)***	
	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	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***	Not Authorised

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1.5	Packaging	Manufacture
1.5.1	***Primary packing***	
	1.5.1.1 Capsules, hard shell	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	Authorised
	1.5.1.6 Liquids for internal use	Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	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***	Authorised

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

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

None

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ANNEX 1- AUTHORISATION HOLDER'S SITE INFORMATION (continued)

Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless otherwise stated

2.1	**Quality control testing of imported medicinal products**	**Import**
	2.1.1 Microbiological: sterility	Not Authorised
	2.1.2 Microbiological: non-sterility	Authorised
	2.1.3 Chemical/Physical	Authorised
	2.1.4 Biological	Not Authorised
2.2	**Batch certification of imported medicinal products**	
2.2.1	***Sterile Products***	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	***Non-sterile products***	Authorised

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2.2.3	***Biological medicinal products***	
	2.2.3.1 Blood products	Not Authorised
	2.2.3.2 Immunological products	Not Authorised
	2.2.3.3 Cell therapy products	Not Authorised
	2.2.3.4 Gene Therapy products	Not Authorised
	2.2.3.5 Biotechnology products	Not Authorised
	2.2.3.6 Human or animal extracted products	Not Authorised
	2.2.3.7 Tissue engineered products	Not Authorised
	2.2.3.8 Other biological medical products	Not Authorised
2.3	**Other importation activities** (any other relevant importation activity that is not covered above)	
	2.3.1 Site of physical importation	Authorised
	2.3.2 Importation of intermediate which undergoes further processing	Authorised
	2.3.3 Biological active substance	Not Authorised
	2.3.4 Other	Not Authorised

Any restrictions or clarifying remarks relating to the scope of these Importing operations:

None