



# 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](http://www.gov.uk)

## Manufacturer's / Importer's Authorisation

### SECTION 1A

1. **Authorisation Number**  
ManA 2000
2. **Name and address of Authorisation Holder**  
Norbrook Laboratories Ltd, Station Works, Camlough Road, Newry, County Down,  
United Kingdom BT35 6JP
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:
S0334	Norbrook Laboratories Ltd	Station Works, Camlough Road, Newry, County Down, United Kingdom BT35 6JP
S0335	Norbrook Laboratories Ltd	105 Armagh Road, Newry, Country Down, United Kingdom BT35 6PU
S0336	Norbrook Laboratories Ltd	Factory No 4, Carnbane Industrial Estate, Newry, United Kingdom BT35 6QQ,

4. **Legally registered address of Authorisation Holder**  
Station Works, Camlough Road, Newry, County Down, United Kingdom BT35 6JP
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. 24 July 2024**



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**Manufacturer's/Importer's Authorisation**

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**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.



### 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](http://www.eudragmp.ema.europa.eu).
4. Further information and specified guidelines may be obtained from the VMD website [www.gov.uk](http://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**

<b>NAME AND ADDRESS OF SITE:</b>	
SITE NAME:	Norbrook Laboratories Ltd
ADDRESS:	Station Works, Camlough Road, Newry, BT35 6JP, United Kingdom
VMD SITE NUMBER:	S0334

<b>TYPE OF PRODUCTS HANDLED</b>
<i>Veterinary Medicinal Products</i>

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



## 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	<b><i>Aseptically Prepared (processing operations for the following dosage forms)</i></b>	
	1.1.1.1 Large volume liquids Special Requirements: B-lactam Antibiotics Other Cephalosporins	Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids Special Requirements: B-lactam Antibiotics Other Cephalosporins	Authorised
	1.1.1.4 Small volume liquids Special Requirements: B-lactam Antibiotics Other Cephalosporins	Authorised
	1.1.1.5 Solids and implants	Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised



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



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1.2	Non-sterile products	Manufacture
<b>1.2.1</b>	<b><i>Non-sterile products (processing operations for the following dosage forms)</i></b>	
	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	Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids Special Requirements: B-lactam Antibiotics	Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets Special Requirements: B-lactam Antibiotics Non-Steroidal Anti-Inflammatory Drug (NSAID)	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
<b>1.2.2</b>	<b>Batch certification</b>	Authorised





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1.3	Biological medicinal products	Manufacture
<b>1.3.1</b>	<b><i>Biological medicinal products (list of product types)</i></b>	
	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
	<b><i>1.3.2 Batch certification (list of product types)</i></b>	
	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



# Veterinary Medicines Directorate

<b>1.4</b>	<b>Other products or manufacturing activity</b> (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).	<b>Manufacture</b>
<b>1.4.1</b>	<b>Manufacture of:</b>	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
<b>1.4.2</b>	<b>Sterilisation of active substances/excipients/finished product:</b>	
	1.4.2.1 Filtration	Authorised
	1.4.2.2 Dry heat	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
<b>1.4.3</b>	<b>Others</b>	Not Authorised



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1.5	Packaging	Manufacture
<b>1.5.1</b>	<b>Primary packing</b>	
	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	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
<b>1.5.2</b>	<b>Secondary packing</b>	Authorised



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1.6	Quality control testing	Manufacture
	1.6.1 Microbiological: sterility	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



## ANNEX 1- SITE INFORMATION (continued)

### Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>	<b>Import</b>
	2.1.1 Microbiological: sterility	Authorised
	2.1.2 Microbiological: non-sterility	Authorised
	2.1.3 Chemical/Physical	Authorised
	2.1.4 Biological	Not Authorised
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>	<b>Import</b>
<b>2.2.1</b>	<b><i>Sterile Products</i></b>	
	2.2.1.1 Aseptically prepared	Not Authorised
	2.2.1.2 Terminally sterilised	Not Authorised
<b>2.2.2</b>	<b><i>Non-sterile products</i></b>	Authorised
<b>2.2.3</b>	<b><i>Biological medicinal products</i></b>	
	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



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	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
<b>2.3</b>	<b><i>Other importation activities</i></b> (any other relevant importation activity that is not covered above)	<b>Import</b>
	2.3.1 Site of physical importation	Not Authorised
	2.3.2 Importation of intermediate which undergoes further processing	Not 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



### IMPORTATION OF MEDICINAL PRODUCTS

Products authorised to be manufactured/imported (in accordance with Article 45 and 46 of Directive 2001/82/EC, as amended).

Number	Product Name	Country of Origin
Vm 02000/4324	Pestigon Spot-on for Cats	Republic of Ireland
Vm 02000/4325, Vm 02000/4326, Vm 02000/4327, Vm 02000/4328	Pestigon Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4354	FiprocLEAR Spot-on for Cats	Republic of Ireland
Vm 02000/4350, Vm 02000/4351, Vm 02000/4352, Vm 02000/4353	FiprocLEAR Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4398	Flick Spot-on for Cats	Republic of Ireland
Vm 02000/4320, Vm 02000/4321, Vm 02000/4322, Vm 02000/4323	Flick Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4329	Johnson's Fipronil Spot-on for Cats	Republic of Ireland
Vm 02000/4117	Pestigon Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4118, Vm 02000/4119, Vm 02000/4120, Vm 02000/4121	Pestigon Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4407	FiprocLEAR Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4408, Vm 02000/4409, Vm 02000/4410, Vm 02000/4411	FiprocLEAR Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4412	Fleanil Duo Spot-on for Cats and Ferrets	Republic of Ireland



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Vm 02000/4413, Vm 02000/4414, Vm 02000/4415, Vm 02000/4416	Fleanil Duo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4435, Vm 02000/4436	Moxi-Clear Spot-on for Cats (small, large)	Republic of Ireland
Vm 02000/4437, Vm 02000/4438, Vm 02000/4439 Vm 02000/4440	Moxi-Clear Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4427, Vm 02000/4428, Vm 02000/4429	Selapro Spot-on for Cats (very small, small, medium)	Republic of Ireland
Vm 02000/4430, Vm 02000/4431, Vm 02000/4432, Vm 02000/4433, Vm 02000/4434,	Selapro Spot-on for Dogs (very small, small, medium, large, very large)	Republic of Ireland
Vm 02000/4385	FiprocLEAR Spray	Republic of Ireland
Vm 02000/4381	Spotinor Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4382	Flydown Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4383	Norbrook Deltamethrin Spot-on Solution for Cattle and Sheep	Republic of Ireland





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**VETERINARY MEDICINES DIRECTORATE**  
On behalf of the Secretary of State for the  
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**Manufacturer's/Importer's Authorisation**

**SECTION 3**

**ANNEX 1 - SITE INFORMATION**

**SCOPE OF AUTHORISATION**

<b>NAME AND ADDRESS OF SITE:</b>	
SITE NAME:	Norbrook Laboratories Ltd
ADDRESS:	105 Armagh Road, Newry, BT35 6PU, United Kingdom
VMD SITE NUMBER:	S0335

<b>TYPE OF PRODUCTS HANDLED</b>
<i>Veterinary Medicinal Products</i>

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



## 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	<b><i>Aseptically Prepared (processing operations for the following dosage forms)</i></b>	
	1.1.1.1 Large volume liquids Special Requirements: Other Sulphonamides, substances with hormonal activity	Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids Special Requirements: Other Sulphonamides	Authorised
	1.1.1.4 Small volume liquids Special Requirements: Other Sulphonamides, substances with hormonal activity	Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised



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



# Veterinary Medicines Directorate

1.2	Non-sterile products	Manufacture
<b>1.2.1</b>	<b><i>Non-sterile products (processing operations for the following dosage forms)</i></b>	
	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	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	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
<b>1.2.2</b>	<b><i>Batch certification</i></b>	Authorised



# Veterinary Medicines Directorate

1.3	Biological medicinal products	Manufacture
<b>1.3.1</b>	<b><i>Biological medicinal products (list of product types)</i></b>	
	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
<b>1.3.2</b>	<b><i>Batch certification (list of product types)</i></b>	
	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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<b>1.4</b>	<b>Other products or manufacturing activity</b> (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).	<b>Manufacture</b>
<b>1.4.1</b>	<b><i>Manufacture of:</i></b>	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
<b>1.4.2</b>	<b><i>Sterilisation of active substances/excipients/finished product:</i></b>	
	1.4.2.1 Filtration	Authorised
	1.4.2.2 Dry heat	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
<b>1.4.3</b>	<b><i>Others</i></b>	Not Authorised



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1.5	Packaging	Manufacture
<b>1.5.1</b>	<b>Primary packing</b>	
	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	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	Not 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	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
<b>1.5.2</b>	<b>Secondary packing</b>	Authorised



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<b>1.6</b>	<b>Quality control testing</b>	Manufacture
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Not 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





## ANNEX 1- SITE INFORMATION (continued)

### Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

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



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<b>2.2.3</b>	<b><i>Biological medicinal products</i></b>	
	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
<b>2.3</b>	<b><i>Other importation activities</i></b> (any other relevant importation activity that is not covered above)	
	2.3.1 Site of physical importation	Not Authorised
	2.3.2 Importation of intermediate which undergoes further processing	Not 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



### IMPORTATION OF MEDICINAL PRODUCTS

Products authorised to be manufactured/imported (in accordance with Article 45 and 46 of Directive 2001/82/EC, as amended).

Number	Product Name	Country of Origin
Vm 02000/4324	Pestigon Spot-on for Cats	Republic of Ireland
Vm 02000/4325, Vm 02000/4326, Vm 02000/4327, Vm 02000/4328	Pestigon Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4354	FiprocLEAR Spot-on for Cats	Republic of Ireland
Vm 02000/4350, Vm 02000/4351, Vm 02000/4352, Vm 02000/4353	FiprocLEAR Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4398	Flick Spot-on for Cats	Republic of Ireland
Vm 02000/4320, Vm 02000/4321, Vm 02000/4322, Vm 02000/4323	Flick Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4329	Johnson's Fipronil Spot-on for Cats	Republic of Ireland
Vm 02000/4117	Pestigon Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4118, Vm 02000/4119, Vm 02000/4120, Vm 02000/4121	Pestigon Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4407	FiprocLEAR Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4408, Vm 02000/4409, Vm 02000/4410, Vm 02000/4411	FiprocLEAR Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4412	Fleanil Duo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4413, Vm 02000/4414, Vm 02000/4415, Vm 02000/4416	Fleanil Duo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland



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Vm 02000/4435, Vm 02000/4436	Moxi-Clear Spot-on for Cats (small, large)	Republic of Ireland
Vm 02000/4437, Vm 02000/4438, Vm 02000/4439 Vm 02000/4440	Moxi-Clear Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4427, Vm 02000/4428, Vm 02000/4429	Selapro Spot-on for Cats (very small, small, medium)	Republic of Ireland
Vm 02000/4430, Vm 02000/4431, Vm 02000/4432, Vm 02000/4433, Vm 02000/4434,	Selapro Spot-on for Dogs (very small, small, medium, large, very large)	Republic of Ireland
Vm 02000/4385	FiprocLEAR Spray	Republic of Ireland
Vm 02000/4381	Spotinor Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4382	Flydown Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4383	Norbrook Deltamethrin Spot-on Solution for Cattle and Sheep	Republic of Ireland



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

**Manufacturer's/Importer's Authorisation**

**SECTION 3**

**ANNEX 1 - SITE INFORMATION**

**SCOPE OF AUTHORISATION**

<b>NAME AND ADDRESS OF SITE:</b>	
SITE NAME:	Norbrook Laboratories Ltd
ADDRESS:	Factory No 4, Carnbane Industrial Estate, Newry, BT35 6QQ, United Kingdom
VMD SITE NUMBER:	S0334

<b>TYPE OF PRODUCTS HANDLED</b>
<i>Medicinal Products</i>

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



## 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	<b>Aseptically Prepared (processing operations for the following dosage forms)</b>	
	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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<b>1.1.2</b>	<b><i>Terminally Sterilised (processing operations for the following dosage forms)</i></b>	
	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
<b>1.1.3</b>	<b><i>Batch certification</i></b>	Authorised



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1.2	Non-sterile products	Manufacture
<b>1.2.1</b>	<b><i>Non-sterile products (processing operations for the following dosage forms)</i></b>	
	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	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	Authorised
	1.2.1.9 Pressurised preparations	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	Not Authorised
<b>1.2.2</b>	<b><i>Batch certification</i></b>	Authorised





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1.3	Biological medicinal products	Manufacture
<b>1.3.1</b>	<b><i>Biological medicinal products (list of product types)</i></b>	
	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
<b>1.3.2</b>	<b><i>Batch certification (list of product types)</i></b>	
	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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<b>1.4</b>	<b>Other products or manufacturing activity</b> (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).	<b>Manufacture</b>
<b>1.4.1</b>	<b><i>Manufacture of:</i></b>	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
<b>1.4.2</b>	<b><i>Sterilisation of active substances/excipients/finished product:</i></b>	
	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	Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
<b>1.4.3</b>	<b><i>Others</i></b>	Not Authorised



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1.5	Packaging	Manufacture
<b>1.5.1</b>	<b>Primary packing</b>	
	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	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	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	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
<b>1.5.2</b>	<b>Secondary packing</b>	Authorised



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<b>1.6</b>	<b>Quality control testing</b>	<b>Manufacture</b>
	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



## ANNEX 1- SITE INFORMATION (continued)

### Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

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



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<b>2.2.3</b>	<b><i>Biological medicinal products</i></b>	
	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
<b>2.3</b>	<b><i>Other importation activities</i></b> (any other relevant importation activity that is not covered above)	
	2.3.1 Site of physical importation	Not Authorised
	2.3.2 Importation of intermediate which undergoes further processing	Not 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



### IMPORTATION OF MEDICINAL PRODUCTS

Products authorised to be manufactured/imported (in accordance with Article 45 and 46 of Directive 2001/82/EC, as amended).

Number	Product Name	Country of Origin
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Vm 02000/4354	FiprocLEAR Spot-on for Cats	Republic of Ireland
Vm 02000/4350, Vm 02000/4351, Vm 02000/4352, Vm 02000/4353	FiprocLEAR Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
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Vm 02000/4320, Vm 02000/4321, Vm 02000/4322, Vm 02000/4323	Flick Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4329	Johnson's Fipronil Spot-on for Cats	Republic of Ireland
Vm 02000/4117	Pestigon Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4118, Vm 02000/4119, Vm 02000/4120, Vm 02000/4121	Pestigon Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4407	FiprocLEAR Combo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4408, Vm 02000/4409, Vm 02000/4410, Vm 02000/4411	FiprocLEAR Combo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4412	Fleanil Duo Spot-on for Cats and Ferrets	Republic of Ireland
Vm 02000/4413, Vm 02000/4414, Vm 02000/4415, Vm 02000/4416	Fleanil Duo Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland



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Vm 02000/4435, Vm 02000/4436	Moxi-Clear Spot-on for Cats (small, large)	Republic of Ireland
Vm 02000/4437, Vm 02000/4438, Vm 02000/4439 Vm 02000/4440	Moxi-Clear Spot-on for Dogs (small, medium, large, very large)	Republic of Ireland
Vm 02000/4427, Vm 02000/4428, Vm 02000/4429	Selapro Spot-on for Cats (very small, small, medium)	Republic of Ireland
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Vm 02000/4385	FiprocLEAR Spray	Republic of Ireland
Vm 02000/4381	Spotinor Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4382	Flydown Spot-on Solution for Cattle and Sheep	Republic of Ireland
Vm 02000/4383	Norbrook Deltamethrin Spot-on Solution for Cattle and Sheep	Republic of Ireland