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; Fax: +44 (0)1932 336618; Website: www.gov.uk

Manufacturer's/Importer's Authorisation

SECTION 1A

1. Authorisation Number

ManA 15981

2. Name and address of Authorisation Holder

Safapac Limited

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:
S0124	Safapac Limited	4 Stapledon Road, Orton Southgate, Peterborough, PE2 6TB, United Kingdom

4. Legally registered address of Authorisation Holder

4 STAPLEDON ROAD, ORTON SOUTHGATE, PETERBOROUGH, PE2 6TB, UNITED KINGDOM

5. Scope of authorisation and dosage

See ANNEX 1

6. Legal basis of authorisation

See Section 1B of licence.

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS
VETERINARY MEDICINES DIRECTORATE

SECTION 1A (continued)

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

Penny Brown

8. Date

9 January 2015

9. Annexes attached

Annex 1

Annex 2

Optional Annexes

Annex 1 (Site Information)

Annex 2 (Name of Qualified Person)

Annex 3 (Contract Laboratories)

Annex 4 (Storage Sites)

Annex 5 (Contract Manufacturing Sites)

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: 01932 336911; Fax: 01932 336618; Website: www.gov.uk

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.

DEPARTMENT FOR ENVIRONMENT FOOD AND RURAL AFFAIRS
VETERINARY MEDICINES DIRECTORATE

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.

Veterinary Medicines Directorate

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 2

VARIATION HISTORY

This page will be amended if the licence is varied.

DATE	VARIATION DETAIL
09/01/2015	Update to new VMD format including removing authorisation for 1.2.1.6, and adding authorisation for 1.2.1.5, 1.2.2, and 1.5.1.5..
09/01/2015	Variation to remove Mr R Smith as QP and add Mr J C Blaydes, remove Mr S Steele as PM and add Mr T Morris, remove Mr S Steele and T Morris as QC and add Mr J C Blaydes as QC. Remove CEMAS Limited and Broughton Laboratories Limited as contract laboratories.

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS
VETERINARY MEDICINES DIRECTORATE

Veterinary Medicines Directorate

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

NAME AND ADDRESS OF SITE:	
SITE NAME:	Safapac Limited
ADDRESS:	4 Stapledon Road, Orton Southgate, Peterborough, PE2 6TB, United Kingdom
VMD SITE NUMBER:	S0124

TYPE OF PRODUCTS HANDLED
Veterinary Medicinal Products

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

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS
VETERINARY MEDICINES DIRECTORATE

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

1.1.2	***Terminally Sterilised (processing operations for the following dosage forms)***	**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	***Batch certification***	Not Authorised

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	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	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**	Authorised

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

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**	Not Authorised

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	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**	Authorised
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	Authorised
	1.6.4 Biological	Not Authorised

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

None

ANNEX 2 – QUALIFIED PERSON

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
VMDQP0149	Mr J C Blaydes	Yes	No	No	Yes
1401603	Mr T W Morris	No	No	Yes	No

Key to Roles:

QP – Qualified Person
TQP – Transitional Qualified Person
PM – Production Manager/Supervisor
QC – Person responsible for Quality Control