Medicines & Healthcare products Regulatory Agency

MHRA

MIA NUMBER: MIA 4286 Version: 21

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's/Importer's Licence

SECTION 1A

1. Licence Number

MIA Number: MIA 4286

2. Name of Licence Holder

BRAY GROUP LIMITED

3. Trading Style

4. Address(es) of manufacturing/importing site(s)
(All authorised sites should be listed if not covered by separate licences)

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
1167	BRAY GROUP LIMITED	1 REGAL WAY, FARINGDON, SN7 7BX, UNITED KINGDOM

5. Legally registered address of Licence Holder

REGAL WAY, FARINGDON, SN7 7BX, UNITED KINGDOM

6. Scope of licence and dosage form

See ANNEX 1

7. Legal basis of licence

See Section 1B of licence.

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

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SECTION 1A (continued)

9. Date 22/07/2019

10. Annexes attached

Annex 1

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)

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SECTION 1B

1. This licence is granted in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.

2. It authorises the processes of manufacture and/or assembly and/or importation of 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 licence holder named. All manufacturing and/or assembly and/or importation operations in respect of those products for which a product licence 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 licence 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 Licensing Authority for such tests to be carried out on his behalf by that person and
   c) make arrangements for a qualified person to be available at all times for the purpose of checking that each batch of medicinal products has been manufactured and assembled in accordance with the appropriate provisions and to certify accordingly in a register.

3. The operations referred to in Section 3 shall be undertaken by the personnel named therein or by such other person as may be approved by the Licensing Authority.

Attention is drawn to the structure of this licence (as detailed on page 4 of Section 1) and to its completeness in accordance with that structure. This is of particular relevance where the holder of the licence is using it as evidence to a third party in support of claims to carry out those operations and activities to which this licence applies on premises and using personnel covered by this licence.

SECTION 1B (continued)

4. The licence holder's arrangement for:

   a) identification and storage of materials and ingredients before and during manufacture and for the storage of medicinal products after manufacture and assembly;
   b) ensuring a satisfactory turnover of stock of medicinal products;
   c) maintaining records of production, of analytical and other testing procedures and a register certified by a qualified person for each batch of proprietary medicines manufactured;
   d) keeping reference samples of materials used in the manufacture of any medicinal products shall be in accordance with the particulars contained in or furnished in connection with the application of this licence, or shall be in accordance with such other arrangements as may from time to time be approved by the Licensing Authority

5. The licence holder must inform the Licensing Authority in advance of any change to the details submitted or included in this licence. All changes must be approved by the Licensing Authority 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 licence prior to commencing operations. The manufacture and/or assembly and/or importation of any proprietary medicinal product pursuant to this licence shall not commence until the approval of the Licensing Authority has been given on the appropriate product licence to the site(s) named on this licence being used for the manufacture of that product.

6. A licence may be suspended if any fees are not paid in full as they fall due.

7. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).

8. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.

9. Licence Structure

   This Licence is divided into three sections.

(a) Section 1 (this section) identifies the licence holder and holds the authorising name for the issue of the licence. This section would not usually be replaced during routine variations of the licence unless the licence holder details are varied.

(b) Section 2 lists variations to the licence. A replacement section 2 will be issued each time the licence is varied.

(c) Section 3 contains the details relating to each site named on the licence. 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.

(d) The licence holder is required to attach to his licence any replacement pages issued by the Licensing Authority and to mark or destroy superseded pages as to render them invalid.

Medicines & Healthcare products Regulatory Agency

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MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's/Importer's Licence

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
14/09/1994	Initial Application
19/12/1994	Company wish to add site in Farringdon, Oxon for Storage and Distribution
02/12/1996	Variation to 1) add new site at 1 Regal Way, Faringdon to replace Park Road site (2) delete HF Gough as QP and add Dr SJ Pearce as QP: Dr Pearce was granted QP eligibility on 16/03/95 by the RSC (Cert. No. 487) so does not appear in the Pink Book (1993).
04/03/1999	Renewal Site 9391 - Activities - add Pf, Pp and Pt
18/03/2003	Variation to add activity codes Pf, Pl, Pc & Pi at site 8434; add dosage codes Ne, Nl& No at site 9391 and replace Mr H A Fecher with Dr S J Pearce as SC at both sites.
03/03/2004	Renewal.
29/06/2005	Variation to replace Stuart Pearce as QP; delete Tony Fecher as PM and add Ray Fecher as PM.
18/12/2006	Variation to add new QP and QC- Mr G Biadglgne and delete QC Mr G Osoborne
03/11/2008	Update licence to EUDRA GMP format.
02/07/2009	Variation to delete site 31304, change LHC to Mr N Jones, edit site functions at site 1167 and delete Mr Garrad and Dr Pearce from the licence.
02/07/2009	Internal variation to add Mr Jones as site contact.
08/03/2010	Variation: 1. Add Mr Peter Skellon as an additional QP. 2. Remove Mr G Biadglgne as QP & QC and replace with Ms M Ball as a QC.
10/03/2010	Internal variation to reinstate Mr G Biadglgne as QP
31/08/2011	Internal Variation: Remove Mr Brigdalane from licence as a QP.
08/11/2011	Variation to add QP
28/03/2012	Variation to add additional Qualified Person Mr R Haslam.
23/04/2014	Variation to delete QPs Mr Peter Philip Skellon, Ms Wanda Maria Jay and QC Mr Herbert Anthony Fecher

04/05/2018	Variation to add Mr Yogesh Krishan Dave as QP
26/11/2018	Variation: - Add Dr. Atula Patel as QP. - Remove Mr Robert Paul Haslam as QP
22/07/2019	Variation to add Dr Andrew Burbage (125549) as QP on site 1167

Medicines & Healthcare products Regulatory Agency

MHRA

MIA NUMBER: MIA 4286 MHRA Site No: 1167 VERSION: 21

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's/Importer's Licence

SECTION 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:

SITE NAME:	BRAY GROUP LIMITED
ADDRESS:	1 REGAL WAY, FARINGDON, SN7 7BX, UNITED KINGDOM
MHRA SITE NUMBER:	1167

TYPE OF PRODUCTS HANDLED

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to Part 1)	Authorised
Importation of Medicinal Products (according to Part 2)	Not 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	**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	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	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 Other non-sterile medicinal products	Not Authorised
1.2.2	**Batch certification**	Not Authorised

1.3	Biological medicinal products	Manufacture
1.3.1	***Biological medicinal products***	
	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***	
	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), medicinal gases, 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 products:**	
	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	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 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:

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
1375270	Mr N Jones	No	No	No	No
122773	Mr R M Fecher	No	No	Yes	No
1762827	Mr Yogesh Krishan Dave	Yes	No	No	No
2405152	Mrs Mandy Ball	No	No	No	Yes
7526278	Dr Atula Patel	Yes	No	No	No
125549	Dr Andrew Samuel Burbage	Yes	No	No	No

Key to Roles:

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

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
1167	BRAY GROUP LIMITED	1 REGAL WAY, FARINGDON, SN7 7BX, UNITED KINGDOM