



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

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1A

1. Authorisation Number

MIA(IMP) Number: MIA(IMP) 15140

2. Name of Authorisation Holder

HAMMERSMITH MEDICINES RESEARCH 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:
671693	HAMMERSMITH MEDICINES RESEARCH LIMITED	CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED KINGDOM

5. Legally registered address of Authorisation Holder

CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED KINGDOM

6. Scope of authorisation and dosage forms

See Annex 2

7. Legal basis of authorisation

See Section 1B of authorisation.

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** 16/04/2018

10. **Annexes attached**

Annex 2

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 authorisation is granted in accordance with the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] which implement Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001.
2. It permits the authorisation holder named on page 1 of Section 1 of the authorisation to manufacture, assemble and/or import investigational medicinal products for human use in accordance with Regulation 41 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] (as detailed in section 3 of this authorisation) and is subject to the provisions identified on page 2 of Section 1 of this authorisation.
3. In this document a Manufacturers Authorisation for Investigational Medicinal Products may be referred to as MIA(IMP) and the Medicines and Healthcare products Regulatory Agency (acting on behalf of the Licensing Authority as defined in Regulation 6 of The Human Medicines Regulations 2012 (SI 2012/1916) may be referred to as MHRA.
4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the manufacture, assembly or importation of investigational medicinal products.

Attention is drawn to the structure of this authorisation (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 authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.





SECTION 1B (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

- (a) Section 1 (this section) identifies the authorisation holder and the responsible officer for the issue of the authorisation. 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.
 - (d) The authorisation holder is required to attach to his authorisation any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.
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6. Provisions

- a) The provisions of Schedule 7 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] shall apply to the authorisation. For manufacture and/or assembly Parts 1 and 2 of Schedule 7 apply and for importation Parts 1 and 3 of Schedule 7 apply in accordance with Regulation 40(4) of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] subject to Regulation 38(2).





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SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
18/03/2004	Initial Application
30/07/2006	Variation to add Ms K Heukelbach as Production Manager.
17/12/2006	Variation to remove Mrs.S.Robertson-Doran as Production Manager.
02/03/2007	Variation to add 2 contract sites Butterworth Laboratories Limited and McEwen Laboratories Limited.
17/09/2007	Variation to update site numbers - have replaced 8904 with 37191.
20/06/2008	Internal variation to amend licence to authorise importation of, Immunological products, biotechnology products, radiopharmaceutical products, sterile aseptic products (2.2.1.1), terminally sterilised (2.2.1.2) and non-sterile products (2.2.2)
18/10/2008	Update licence to EUDRA GMP format
28/01/2009	Variation change communication address & site address to Cumberland Avenue Park Royal London NW10 7EW.
10/02/2009	Internal variation to amend legally registered address.
06/08/2009	Variation to authorise the following on site 671693 : Section 1.1.16 (Other aseptically prepared products), 1.4.1.4 (Other), 1.4.2.1 (Filtration), 1.5.1.10 (Radionuclide Generators), 1.6.3 & 2.1.3 (Chemical/physical testing)
28/01/2010	Internal Variation to amend the status of Dr M Boyce and Dr S Warrington to the correct status of Transitional Qualified Person.
21/02/2011	Variation to add Penn Pharmaceutical Services Limited (Site 15302) as a storage and handling site
01/11/2011	Variation to QP/QC to licence (Ms Linda Clark)
30/03/2012	Variation to remove a site, McEwans Laboratory (Site 10512), add site functions to site 671693 and add NCIMB Limited
01/11/2012	Variation: ADD NEW CONTRACT LABORATORY SITE ID 321374.
21/03/2013	Variation to add David Pooley as a QP to site 671693
10/04/2013	Variation to add Amanda Peter as TQP and remove Dr J B Kay, site 671693
19/08/2013	Variation to add Daniele Bassanese as QP for Site ID 671693





12/12/2013	Variation to add additional storage and handling site; Biostore UK Limited
19/02/2014	Variation to remove Mr David Pooley as Qualified Person from site 671693
16/05/2014	Variation to site 671693: remove QC and QP Linda Clark, add Steve Warrington as QC, add Amanda Peter as QC and add Malcolm Boyce as QC
29/05/2014	Internal variation to reverse changes version 21 to version 20 - applied incorrectly to the MIA(IMP).
09/07/2014	Variation to remove Site Personnel- Danielle Bassanes Site ID 671693. Addition of Almac Group Ltd as a storage site.13423
02/02/2016	Variation: Remove Ms Linda Clark as QC/QP
25/07/2016	variation to add David Laskow-Pooley as QP to site 671693
28/09/2016	Variation: Remove site id 321374.
12/07/2017	Variation To: -Removal of NCIMP (Contract laboratory) -Addition of a storage site for retention samples (Yourway Transport Limited)
22/08/2017	Variation: 1. Update site activities. 2. Add new S/H site 8641729.
26/10/2017	Internal Variation: subsection 1.3.2.2; 1.3.2.5 and 1.3.2.6 to state authorised.
08/01/2018	Internal Variation: to authorize 1.3.2.2, 1.3.2.5 and 1.3.2.6
16/04/2018	Variation: change production manager from Kristen Heukelbach to Luke Benjamin





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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	HAMMERSMITH MEDICINES RESEARCH LIMITED
ADDRESS:	CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED KINGDOM
MHRA SITE NUMBER:	671693

Type of products handled

Human Investigational Medicinal Products for phase I, II, III clinical trials (optional)
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Authorised operations

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





ANNEX 2 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- 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 Investigational Medicinal Products	Manufacture
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
	1.1.1.1 Large volume liquids	Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Authorised
	1.1.1.4 Small volume liquids	Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products Radiopharmaceuticals; Site of physical importation; Importation of intermediate for further processing	Authorised





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>	Authorised





1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	<i>Non-Sterile Products (processing operations for the following dosage forms)</i>	
	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	Not 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	Not Authorised





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	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised
1.2.2	<i>Batch certification</i>	Authorised





1.3	Biological investigational 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	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	Authorised
	1.3.1.6 Human or animal extracted products	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</i>	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	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	Authorised





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	1.3.2.6 Human or animal extracted products	Authorised
	1.3.2.7 Tissue Engineered Products	Not Authorised
	1.3.2.8 Other biological medicinal products	Not Authorised





1.4	<i>Other investigational medicinal products or manufacturing activity</i> (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	Authorised
	1.4.1.2 Homeopathic products	Authorised
	1.4.1.3 Other Radiopharmaceuticals; Site of physical imporation of intermediate for further processing	Authorised
1.4.2	Sterilisation of active substances/excipients/finished products:	
	1.4.2.1 Filtration	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	Packaging
1.5.1	Primary packing	
	1.5.1.1 Capsules, hard shell	Authorised
	1.5.1.2 Capsules, soft shell	Authorised
	1.5.1.3 Chewing gums	Authorised
	1.5.1.4 Impregnated matrices	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	Authorised
	1.5.1.11 Semi-solids	Authorised
	1.5.1.12 Suppositories	Authorised
	1.5.1.13 Tablets	Authorised
	1.5.1.14 Transdermal patches	Authorised





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	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	Secondary packing	Authorised





1.6	Quality control testing	
	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 2 – SITE INFORMATION (continued)
Part 2 – IMPORTATION OF INVESTIGATIONAL 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	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	Sterile Products	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	Non-sterile products	Authorised
2.2.3	Biological medicinal products	
	2.2.3.1 Blood products	Authorised
	2.2.3.2 Immunological products	Authorised
	2.2.3.3 Cell therapy products	Not Authorised





	2.2.3.4 Gene therapy products	Authorised
	2.2.3.5 Biotechnology products	Authorised
	2.2.3.6 Human or animal extracted products	Authorised
	2.2.3.7 Tissue Engineered Products	Not Authorised
	2.2.3.8 Other biological medicinal products	Not Authorised
2.3	Other Importation Activities	
	2.3.1 Site of Physical Importation	Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Authorised
	2.3.3 Other	Not Authorised

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





ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>			
		<u>QP</u>	<u>TQP</u>	<u>PM</u>	<u>QC</u>
8814929	Mr David Laskow Pooley	Yes	No	No	No
19322620	Mr Luke Benjamin	No	No	Yes	No
41171	Dr S Warrington	No	Yes	No	No
42217	Ms A Peter	No	Yes	No	No
138841	Dr M Boyce	No	Yes	No	Yes

Key to Roles:

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





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ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
5712	BUTTERWORTH LABORATORIES LIMITED	54-56 WALDEGRAVE ROAD, TEDDINGTON, TW11 8NY, UNITED KINGDOM





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ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
671693	HAMMERSMITH MEDICINES RESEARCH LIMITED	CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED KINGDOM
13423	ALMAC CLINICAL SERVICES LIMITED	SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, BT63 5PW, UNITED KINGDOM
15302	PENN PHARMACEUTICAL SERVICES LIMITED	UNITS 23-24, TAFARNAUBACH INDUSTRIAL ESTATE, TAFARNAUBACH, TREDEGAR, NP22 3AA, UNITED KINGDOM
6696800	BIOSTORE UK LIMITED	1 BREWSTER SQUARE, BRUCEFIELD INDUSTRIAL ESTATE, LIVINGSTON, EH54 9BJ, UNITED KINGDOM
8641729	YOURWAY TRANSPORT LIMITED	2 PULBOROUGH WAY, HOUNSLOW, TW4 6DE, UNITED KINGDOM

