



Medicines & Healthcare products  
Regulatory Agency



**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

Ms Olive McCormick  
ALMAC CLINICAL SERVICES LIMITED  
9 CHARLESTOWN ROAD  
SEAGOE INDUSTRIAL ESTATE  
CRAIGAVON  
BT63 5PW  
UNITED KINGDOM



MIA(IMP) MIA(IMP) 20377  
NUMBER:

Version: 36

**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**

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**SECTION 1A**

**1. Authorisation Number**

MIA(IMP) Number: MIA(IMP) 20377

**2. Name of Authorisation Holder**

ALMAC CLINICAL SERVICES 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:
13423	ALMAC CLINICAL SERVICES LIMITED	SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM

**5. Legally registered address of Authorisation Holder**

SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM

**6. Scope of authorisation and dosage forms**

See Annex 2

**7. Legal basis of authorisation**

See Section 1B of authorisation.



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

Zdravka Ivanova

**SECTION 1A (continued)**

**9. Date** 15/11/2022

**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)



## 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 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use.
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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**Manufacturer's Authorisation - Investigational Medicinal Products**

**SECTION 2**

**VARIATION HISTORY**

This page will be amended if the licence is varied.

<b>Date</b>	<b>Variation Detail</b>
05/05/2004	
06/09/2006	Add Miss F Hannaway as Qualified Person. Change of QP's name from Dr KMS McNeill to Dr KMS Campbell. Remove Analytical site named "Pharmalytic". Include filling of primary containers with capsules. Change company name from Clinical Trial Services Limited to Almac Clinical Services Limited.
25/09/2006	Internal variation to create MIA(IMP) due to change in legislation effective 14-08-06
18/01/2007	Internal variation.
06/08/2007	Variation to add new storage-site.
26/11/2008	Update licence to EUDRA GMP format
12/12/2008	Internal variation to add other solid dosage forms 1.2.1.8 and text "placebo powders blistered for inhalers" to 1.2.1.15. Remove 1.5.1.11 primary packaging of other solid dosage forms in line with EUDRA requirements (site 13423). amend 1.3.1.1 to 1.2.2.6 to 1.3.2.1 to 1.3.2.6 Biologicals batch certification.
09/03/2009	Internal variation to amend section 2.2.3
06/11/2009	Variation to add Ms Cairtriona Lenagh as an additional QP to site 13423.
30/11/2009	Internal variation to add QC testing to site 13423.
25/01/2010	Variation to delete Dr K M S Campbell as a TQP from the licence and also to add site 383321 as a QC lab and change name of site 15328 to ALMAC PHARMA SERVICES LIMITED.
09/11/2011	Variation: Add Almac Sciences Elvington Science as a new C/L & Unit 21 Carn Industrial Estate as a S/H.
12/07/2013	Variation to remove P Diamond as a QP from site 13423



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05/03/2014	Variation to remove site 877913, site has been closed.
28/04/2014	Variation to remove Microbiological Sterility from site 13423.
21/07/2014	Internal variation to add Microbiological Sterility, site 13423 - 2.1.1. add Herbal and Homeopathic products under "Other", authorise site of physical importation, authorise intermediates 2.3.2.
20/04/2015	Variation: 1. Add Mr Jonathan Bradshaw as an additional QP. 2. Update site activities on site 13423.
27/07/2015	Internal Variation: Add 2.3.3 Herbal products and Homoeopathic products.
09/11/2015	Internal variation created in order to update and re-issue licence
27/01/2016	Variation: (Site 13423) Add Dr Jasbir Kumar Rattu as a QP Add Mr Shankhar Seetharaman as a QP
21/03/2016	Internal variation to add distribution to site 13423
12/01/2017	Variation: (Site 13423) Remove Dr Jasbir Kumar Rattu as a QP
19/05/2017	Variation: (Site 13423) Remove Mr Shankarnarayan Seetharaman as a QP Add Mrs Andrea Kingsland-Inwood as QP
19/07/2017	Variation: 1. Add new Contract Laboratory site id 16997281.
09/01/2018	Variation to add new contract laboratory Quality Context Limited and new QP
07/02/2018	Internal variation to correct the error against the Contract Lab; Quality Context Limited
21/09/2018	Variation to correct addresses for site 382319 and site 4243063; add Dr Ashley Massey as QP to site 13423
28/03/2019	Variation: - Remove site: 14292407 - Add activities to site:13423
16/04/2019	Internal variation
27/05/2020	Variation to add Non-Sterile Products Batch Certification, Sterile Products Batch Certification, Primary Packaging - Capsules, hard shell, Other solid dosage forms. Remove Mrs Andrea Yvonne Kingsland-Inwood as QP from site 13423. Update the address to sites 13423, 382319 and 4243063
03/06/2020	Internal variation (site 13423) to add Biological Active Substance and remove Mr Olayinka Lawal as QP.
23/02/2021	Variation to add Mr Aidan Gribbon and Mrs Andrea Yvonne Kingsland-Inwood as QPs
29/03/2021	Variation to add Products authorised under regulation 174 (supply in Response to spread of pathogenic agents etc) to site 13423
18/11/2021	Variation to -Remove site 382319. - Site 13423 - Add 2.3.4 Other importation activities. Add Dr Simon Coleman as QP.



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15/06/2022	Variation to add Mr Andrew Jameson as QP on site 13423
15/11/2022	Variation to: Remove Mrs Andrea Yvonne Kingsland-Inwood as QP and add Mr Andrew Norman Richards & Mr John Robert McCool as QPs on site 13423



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

### Manufacturer's Authorisation - Investigational Medicinal Products

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#### SECTION 3

#### ANNEX 2 - SITE INFORMATION

#### SCOPE OF AUTHORISATION

##### Name and address of site:

SITE NAME:	ALMAC CLINICAL SERVICES LIMITED
ADDRESS:	SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM
MHRA SITE NUMBER:	13423

##### 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	<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>	<b>Manufacture</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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<b>1.2</b>	<b>Non-sterile investigational medicinal products</b>	<b>Manufacture</b>
<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	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



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	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products Other solid dosage forms - Placebo Powders blistered for inhalers. Capsules, hard shell includes penicillins, hormones and cytotoxics/Capsules soft shell	Authorised
<b>1.2.2</b>	<b>Batch certification</b>	Authorised



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1.3	Biological investigational medicinal products	Manufacture
1.3.1	<b>Biological medicinal products (list of product types)</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
1.3.2	<b>Batch certification</b>	
	1.3.2.1 Blood products	Authorised
	1.3.2.2 Immunological products	Authorised
	1.3.2.3 Cell therapy products	Authorised
	1.3.2.4 Gene therapy products	Authorised



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	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



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<b>1.4</b>	<b><i>Other investigational medicinal products or manufacturing activity</i></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), medicinal gases, 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	Authorised
	1.4.1.2 Homoeopathic products	Authorised
	1.4.1.3 Other Importation of QP certified IMPs from a country on the <input type="checkbox"/> approved country for import list <input type="checkbox"/> / Herbal products, Homeopathic products, Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)  Special Requirements:  Other None	Authorised
<b>1.4.2</b>	<b>Sterilisation of active substances/excipients/finished products:</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	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised



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	1.4.2.6 Electron beam	Not Authorised
<b>1.4.3</b>	<b>Others</b>	Not Authorised



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<b>1.5</b>	<b>Packaging</b>	<b>Packaging</b>
<b>1.5.1</b>	<b>Primary packing</b>	
	1.5.1.1 Capsules, hard shell	Authorised
	1.5.1.2 Capsules, soft shell	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	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	Authorised
	1.5.1.13 Tablets	Authorised



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	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products  Placebo powders blistered for inhalers/Capsules, hard shell, Capsules, soft shell and tablets includes penicillins, hormones and cytotoxics	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>1.6.1 Microbiological: sterility</b>	Not Authorised
	<b>1.6.2 Microbiological: non-sterility</b>	Not Authorised
	<b>1.6.3 Chemical/Physical</b>	Authorised
	<b>1.6.4 Biological</b>	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

<b>2.1</b>	<b>Quality control testing</b>	<b>Import</b>
	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
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>	
<b>2.2.1</b>	<b>Sterile Products</b>	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
<b>2.2.2</b>	<b>Non-sterile products</b>	Authorised
<b>2.2.3</b>	<b>Biological medicinal products</b>	
	2.2.3.1 Blood products	Authorised
	2.2.3.2 Immunological products	Authorised
	2.2.3.3 Cell therapy products	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
<b>2.3</b>	<b>Other Importation Activities</b>	
	2.3.1 Site of Physical Importation	Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Authorised
	2.3.3 Biological Active Substances	Authorised
	2.3.4 Other Importation of QP certified IMPs from a country on the <input type="checkbox"/> approved country for import list <input type="checkbox"/> / Herbal products, Homeopathic products, Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)	Authorised

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



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**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>
19548626	Dr Ashley S M Massey	Yes	No	No	No
21125178	Mr Aidan Gribbon	Yes	No	No	No
628004	Miss F Hannaway	No	Yes	No	No
1477054	Mr Jonathan Bradshaw	Yes	No	No	No
120016	Mr P O'Connor	Yes	No	No	Yes
120020	Ms C Bradley	No	No	Yes	No
29872682	Mr Andrew Jameson	Yes	No	No	No
1759369	Mr Andrew Norman Richards	Yes	No	No	No
26099854	Dr Simon Coleman	Yes	No	No	No
1199793	Ms Caitriona Lenagh	Yes	No	No	No
628000	Ms Olive McCormick	No	Yes	No	No
627994	Mrs M J McWilliam	No	Yes	No	No
1722267	Mr John Robert McCool	Yes	No	No	No

**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**

<b>MHRA SITE NUMBER:</b>	<b>LABORATORY NAME:</b>	<b>ADDRESS:</b>
15328	ALMAC PHARMA SERVICES LIMITED	SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5UA, UNITED KINGDOM
383321	ALMAC SCIENCES LIMITED	ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM
16997281	ALMAC SCIENCES LIMITED	BLOCK A, BREAGH TRADE PARK, BREAGH DRIVE, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5XA, UNITED KINGDOM



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**ANNEX 9 – STORAGE SITES**

<b>MHRA SITE NUMBER:</b>	<b>SITE NAME:</b>	<b>ADDRESS:</b>
13423	ALMAC CLINICAL SERVICES LIMITED	SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM
4243063	ALMAC CLINICAL SERVICES LIMITED	UNIT 21A CARN ROAD, PORTADOWN, CRAIGAVON, NORTHERN IRELAND, BT63 5WG, UNITED KINGDOM