

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 15140

**2: Name of authorisation holder** HAMMERSMITH MEDICINES RESEARCH LIMITED

**3: Address(es) of manufacturing site(s)** HAMMERSMITH MEDICINES RESEARCH LIMITED,  
CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED  
KINGDOM

**4: Legally registered address of authorisation holder** HAMMERSMITH MEDICINES RESEARCH LIMITED,  
CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED  
KINGDOM

**5: Scope of authorisation and dosage forms** ANNEX 1 and/ or ANNEX 2

**6: Legal Basis of authorisation** Part 6 of The Medicines for Human Use (Clinical Trials)  
Regulations 2004 [SI 2004/1031]

**7: Name of responsible officer of the competent authority of the  
member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 06/12/2023

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.1 ] Large volume liquids [ 1.1.1.3 ] Semi-solids [ 1.1.1.4 ] Small volume liquids [ 1.1.1.6 ] Other aseptically prepared products Radiopharmaceuticals; Site of physical importation; Importation of intermediate for further processing

[ 1.1.3 ] Batch certification

**[ 1.2 ] Non-sterile investigational medicinal products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.6 ] Human or animal extracted products

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.6 ] Human or animal extracted products

**[ 1.4 ] Other investigational medicinal products or manufacturing activities**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.1 ] Herbal products

[ 1.4.1.2 ] Homoeopathic products

[ 1.4.1.3 ] Other

Importation of QP certified IMPs from a country on the approved country for import list/Radiopharmaceuticals; Site of physical importation of intermediate for further processing

[ 1.4.2 ] Sterilisation of active substances/excipients/finished products:

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.9 ] Pressurised preparations

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.1.14 ] Transdermal patches

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.1 ] Blood products

[ 2.2.3.2 ] Immunological products

[ 2.2.3.4 ] Gene therapy products

[ 2.2.3.5 ] Biotechnology products

[ 2.2.3.6 ] Human or animal extracted products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the approved country for import list/Radiopharmaceuticals; Site of physical importation of intermediate for further processing