

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 4
2. Name of Authorisation Holder GLAXO OPERATIONS UK LIMITED
3. Legally registered address of Authorisation Holder
GLAXO OPERATIONS UK LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG,
UNITED KINGDOM
GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT,
UNITED KINGDOM
4. Address(es) of Site(s)
GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT,
UNITED KINGDOM
GLAXO OPERATIONS UK LIMITED, PRIORY STREET, WARE, SG12 0DJ, UNITED
KINGDOM
5. Scope of authorisation (complete for each site under 4) ANNEX 1
6. Legal basis of authorisation Regulation 18 of the Human Medicines Regulations 2012
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation Confidential
8. Date 03/11/2025
9. Annexes attached Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 Additional provisions

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

1. MEDICINAL PRODUCTS

1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.3 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines

Name and address of the site:

GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

1. MEDICINAL PRODUCTS

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and intended for the UK market

1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

3.4 Other Products

Refer to the GMP and IMP products listed on Manufacturer/Importer licence MIA 4, and MIA(IMP) 4 licence. Not all of these require additional requirements for handling or control

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines, 4.2 General Sales List

Name and address of the site:

GLAXO OPERATIONS UK LIMITED, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

1. MEDICINAL PRODUCTS

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and intended for the UK market

1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) and not intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.4 Other Products

Refer to the GMP and IMP products listed on Manufacturer/Importer licence MIA 4, and MIA(IMP) 4 licence. These do not require additional requirements for handling or control

Any restrictions or clarifying remarks (for all users)

4 Categories of Products Handled at this Site: 4.1 Prescription Only Medicines