

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, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS,
UNITED KINGDOM
- GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS,
HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM
4. Address(es) of Site(s)
GLAXO OPERATIONS UK LTD (WARE) TA GLAXO WELLCOME OPERATIONS, PRIORY
STREET, WARE, SG12 0DJ, UNITED KINGDOM
- GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS,
HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, 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 16/04/2024
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 LTD TRADING AS GLAXO WELLCOME OPERATIONS, 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) in GB or EEA 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) in the UK 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

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 LTD (WARE) T/A GLAXO WELLCOME OPERATIONS, 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) in GB or EEA 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) in the UK 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

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 LTD TRADING AS GLAXO WELLCOME OPERATIONS, 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) in the UK 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