

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 21678
2. Name of Authorisation Holder BETA PHARMACEUTICALS LIMITED
3. Legally registered address of Authorisation Holder BETA PHARMACEUTICALS LIMITED, EASTWAYS INDUSTRIAL ESTATE, 154 ENTERPRISE COURT, WITHAM, CM8 3YS, UNITED KINGDOM
- BETA PHARMACEUTICALS LIMITED, UNIT 2C, ALTBARN INDUSTRIAL ESTATE, ALTBARN ROAD, COLCHESTER, CO2 8LG, UNITED KINGDOM
- BETA PHARMACEUTICALS LIMITED, UNIT 3, SWANBRIDGE INDUSTRIAL PARK, BLACK CROFT ROAD, WITHAM, CM8 3YN, UNITED KINGDOM
4. Address(es) of Site(s) BETA PHARMACEUTICALS, 154 ENTERPRISE COURT, EASTWAYS INDUSTRIAL ESTATE, WITHAM, CM8 3YS, UNITED KINGDOM
- BETA PHARMACEUTICALS LIMITED, UNIT 5, BELLCROFT, EASTWAYS INDUSTRIAL ESTATE, WITHAM, CM8 3YU, UNITED KINGDOM
- BETA PHARMACEUTICALS LIMITED, UNITS 7 & 8, SWANBRIDGE INDUSTRIAL PARK, BLACK CROFT ROAD, WITHAM, CM8 3YN, 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 12/09/2023
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:

BETA PHARMACEUTICALS LIMITED, UNIT 2C, ALTBARN INDUSTRIAL ESTATE, ALTBARN ROAD, COLCHESTER, CO2 8LG, 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

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

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, 4.4 Pharmacy
Name and address of the site:

BETA PHARMACEUTICALS LIMITED, UNIT 3, SWANBRIDGE INDUSTRIAL PARK, BLACK CROFT ROAD, WITHAM, CM8 3YN,
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

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

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, 4.4 Pharmacy
Name and address of the site:

BETA PHARMACEUTICALS, 154 ENTERPRISE COURT, EASTWAYS INDUSTRIAL ESTATE, WITHAM, CM8 3YS, 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

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

3.3 Cold chain products (requiring low temperature handling)

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, 4.4 Pharmacy
Name and address of the site:

BETA PHARMACEUTICALS LIMITED, UNIT 5, BELLCROFT, EASTWAYS INDUSTRIAL ESTATE, WITHAM, CM8 3YU, 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)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

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, 4.4 Pharmacy
Name and address of the site:

BETA PHARMACEUTICALS LIMITED, UNITS 7 & 8, SWANBRIDGE INDUSTRIAL PARK, BLACK CROFT ROAD, WITHAM, CM8 3YN, 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

1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

3.1.3 Immunological medicinal products

3.3 Cold chain products (requiring low temperature handling)

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, 4.4 Pharmacy