

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

- | | |
|--|---|
| 1. Authorisation Number | UK WDA(H) 36296 |
| 2. Name of Authorisation Holder | BIONICAL LIMITED |
| 3. Legally registered address of Authorisation Holder | BIONICAL LIMITED, UNIT 2, STRETTON BUSINESS PARK 2, BRUNEL DRIVE, STRETTON, BURTON-ON-TRENT, DE13 0BY, UNITED KINGDOM |
| 4. Address(es) of Site(s) | BIONICAL LIMITED, UNIT 2, STRETTON BUSINESS PARK 2, BRUNEL DRIVE, STRETTON, BURTON-ON-TRENT, DE13 0BY, UNITED KINGDOM
BIONICAL LIMITED, THE PIAZZA, MERCIA MARINA, FINDERN LANE, WILLINGTON, DERBY, DE65 6DW, 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 | 21/06/2024 |
| 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:

BIONICAL LIMITED, UNIT 2, STRETTON BUSINESS PARK 2, BRUNEL DRIVE, STRETTON, BURTON-ON-TRENT, DE13 0BY, 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

2.1 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

2.6b Products not certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.2 Medicinal products derived from blood

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:

BIONICAL LIMITED, THE PIAZZA, MERCIA MARINA, FINDERN LANE, WILLINGTON, DERBY, DE65 6DW, 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

2.1 Procurement

2.3 Supply

2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.2 Medicinal products derived from blood

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