

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 52217

2. Name of Authorisation Holder XIEL LTD

3. Legally registered address of Authorisation Holder XIEL LTD, 2 YELLING MILL, YELLING MILL LANE, DOWNSIDE, SHEPTON MALLET, BA4 4JT, UNITED KINGDOM

4. Address(es) of Site(s) XIEL LTD, 2 YELLING MILL, YELLING MILL LANE, DOWNSIDE, SHEPTON MALLET, BA4 4JT, 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 17/06/2022

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:

XIEL LTD, 2 YELLING MILL, YELLING MILL LANE, DOWNSIDE, SHEPTON MALLET, BA4 4JT, 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

2.6 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

3.1.4 Radiopharmaceutical (including radionuclide kits)

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

Name and address of the site:

XIEL LTD, GROUND FLOOR, MILLBROOK DEPOT, YELLING MILL LANE, DOWNSIDE, SHEPTON MALLET, BA4 4JT, 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

2.3 Supply

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

3.1.4 Radiopharmaceutical (including radionuclide kits)

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