Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number UK WDA(H) 14172

2. Name of Authorisation Holder MOVIANTO UK LIMITED

3. Legally registered address of MOVIANTO UK LIMITED, UNIT 1, BEDFORD LINK LOGISTICS PARK, BELL FARM WAY, Authorisation Holder KEMPSTON, BEDFORD, MK43 9SS, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 1, BEDFORD LINK LOGISTICS PARK, BELL FARM WAY, KEMPSTON, BEDFORD, MK43 9SS, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT F2, GRAFTON WAY, BASINGSTOKE, RG22 6HY, UNITED KINGDOM

MOVIANTO UK LIMITED, MPS 4, MAGNA PARK SOUTH, LUTTERWORTH, LE17 4XP, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 1, VICTORIA INDUSTRIAL PARK, VICTORIA ROAD, DARTFORD, DA1 5AJ, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 2, EASTER PARK, BAKER ROAD, NELSON PARK WEST, CRAMLINGTON, NE23 1WQ, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 2, FINEPOINT, FINEPOINT WAY, KIDDERMINSTER, DY11 7FB. UNITED KINGDOM

4. Address(es) of Site(s)

MOVIANTO UK LIMITED, UNIT 1, YORK ROAD, CHAPELHALL, AIRDRIE, ML6 8HW, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 4, THE RIDGE, HAVERHILL BUSINESS PARK, HAVERHILL, CB9 7AE, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 10, ACCESS 18, KINGS WESTON LANE, BRISTOL, BS11 8AZ, UNITED KINGDOM

MOVIANTO UK LIMITED, ACE 135, 5 KINSALL GREEN, WILNECOTE, TAMWORTH, B77 5PB, UNITED KINGDOM

MOVIANTO UK LIMITED, GIMBALD CRAG CLOSE, ST JAMES BUSINESS PARK, KNARESBOROUGH, HG5 8PJ, UNITED KINGDOM

MOVIANTO UK LIMITED, BUILDING 1, HAYDOCK GREEN, PENNY LANE, H<mark>AY</mark>DOC<mark>K</mark>, ST. HELENS, WA11 9SE, UNITED KINGDOM

MOVIANTO UK LIMITED, 204 BEDFORD AVENUE, SLOUGH, SL1 4RY, UNITED KINGDOM

MOVIANTO UK LIMITED, UNIT 9 XPRESSWAY BUSINESS PARK, CHUDLEIGH, NEWTON

ABBOT, TQ13 0FJ, UNITED KINGDOM

 ${\tt MOVIANTO~UK~LIMITED,~UNIT~4,~BROOKLANDS~BUSINESS~PARK,~DINNINGTON,}\\$

ROTHERHAM, S25 2RJ, 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

Confidential

authorisation

8. Date

08/10/2024

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:

MOVIANTO UK LIMITED, UNIT 1, BEDFORD LINK LOGISTICS PARK, BELL FARM WAY, KEMPSTON, BEDFORD, MK43 9SS, 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
- 2.5 Other Activities

Labelling of a medicinal product (COVID-19 Vaccine Janssen) to take account of a change to the shelf life of the product because of the thawing when used for vaccination or immunisation against coronavirus, under Regulation 3A(3) of Human Medicines

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1 Narcotic or psychotropic products

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT F2, GRAFTON WAY, BASINGSTOKE, RG22 6HY, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, MPS 4, MAGNA PARK SOUTH, LUTTERWORTH, LE17 4XP, 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
- 2.5 Other Activities

Labelling of a medicinal product (COVID-19 Vaccine Janssen and COVID-19 Vaccine Pfizer) to take account of a change to the shelf life of the product because of the thawing when used for vaccination or immunisation against corona

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 1, VICTORIA INDUSTRIAL PARK, VICTORIA ROAD, DARTFORD, DA1 5AJ, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 2, EASTER PARK, BAKER ROAD, NELSON PARK WEST, CRAMLINGTON, NE23 1WQ, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 2, FINEPOINT, FINEPOINT WAY, KIDDERMINSTER, DY11 7FB, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 1, YORK ROAD, CHAPELHALL, AIRDRIE, ML6 8HW, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 4, THE RIDGE, HAVERHILL BUSINESS PARK, HAVERHILL, CB9 7AE, 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

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products

- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, UNIT 10, ACCESS 18, KINGS WESTON LANE, BRISTOL, BS11 8AZ, 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)
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2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.2 Holding
- 2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

MOVIANTO UK LIMITED, ACE 135, 5 KINSALL GREEN, WILNECOTE, TAMWORTH, B77 5PB, 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)
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2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.2 Holding
- 2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.1.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
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Name and address of the site:

MOVIANTO UK LIMITED, BUILDING 1, HAYDOCK GREEN, PENNY LANE, HAYDOCK, ST. HELENS, WA11 9SE, 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)
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2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.2 Holding
- 2.3 Supply
- 2.5 Other Activities

Labelling of medicinal product (COVID-19 Vaccine Moderna) to take account of a change to the shelf life of the product because of the thawing when used for vaccination or immunisation against coronavirus, under Regulation 3A(3) of Human Medicines

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
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MOVIANTO UK LIMITED, 204 BEDFORD AVENUE, SLOUGH, SL1 4RY, UNITED KINGDOM

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Name and address of the site:

MOVIANTO UK LIMITED, UNIT 9 XPRESSWAY BUSINESS PARK, CHUDLEIGH, NEWTON ABBOT, TQ13 0FJ, UNITED KINGDOM

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Any restrictions or clarifying remarks (for all users)

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Name and address of the site:

MOVIANTO UK LIMITED, UNIT 4, BROOKLANDS BUSINESS PARK, DINNINGTON, ROTHERHAM, S25 2RJ, UNITED KINGDOM

1. MEDICINAL PRODUCTS

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