

Medicines and Healthcare products Regulatory Agency

WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

| | |
|---|---|
| 1. Authorisation Number | UK WDA(H) 11545 |
| 2. Name of Authorisation Holder | AAH PHARMACEUTICALS LIMITED |
| 3. Legally registered address of Authorisation Holder | AAH PHARMACEUTICALS LIMITED, SAPPHIRE COURT, PARADISE WAY, WALSGRAVE TRIANGLE, COVENTRY, CV2 2TX, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, UNIT 2, ST PHILIPS CENTRAL, ALBERT ROAD, BRISTOL, BS2 0XJ, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, WEST AVENUE, TALKE, STOKE-ON-TRENT, ST7 1TL, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, UNIT 1, LEEDS 27 INDUSTRIAL ESTATE, BRUNTCLIFFE LANE, MORLEY, LEEDS, LS27 0YD, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, FARINGDON AVENUE, HAROLD HILL, ROMFORD, RM3 8SU, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, WOBURN ROAD, WINWICK QUAY, WARRINGTON, WA2 8UH, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, 6 BRETT DRIVE, BEXHILL-ON-SEA, TN40 2JP, UNITED KINGDOM |
| 4. Address(es) of Site(s) | AAH PHARMACEUTICALS LIMITED, BRITANNIA HOUSE, CENTURION PARK, WATLING STREET, WILNECOTE, TAMWORTH, B77 5PZ, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, UNITS 11/12 CALMORE INDUSTRIAL ESTATE, NUTWOOD WAY, TOTTON, SOUTHAMPTON, SO40 3SZ, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, HAMPDEN PARK INDUSTRIAL ESTATE, 204 POLMADIE ROAD, GLASGOW, G42 0PH, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, NEXUS POINT, ELLIOT WAY, PERRY BARR, BIRMINGHAM, B6 7UG, UNITED KINGDOM AAH PHARMACEUTICALS LTD T/A SANGERS AAH, 2 MARSHALLS ROAD, BELFAST, BT5 6SR, UNITED KINGDOM AAH PHARMACEUTICALS LIMITED, STONEFIELD WAY, RUISLIP, HA4 0JP, UNITED KINGDOM |

AAH PHARMACEUTICALS LTD- THE WOODS, PART GROUND FLOOR- THE WOODS,
HAYWOOD ROAD, WARWICK, CV34 5AH, UNITED KINGDOM

AAH PHARMACEUTICALS LIMITED, 120 LOBLEY HILL ROAD, GATESHEAD, NE8 4YR,
UNITED KINGDOM

AAH PHARMACEUTICALS LIMITED, SAPPHIRE COURT, WALSGRAVE BUSINESS PARK,
WALSGRAVE TRIANGLE, COVENTRY, CV2 2TX, UNITED KINGDOM

AAH PHARMACEUTICALS LIMITED, RIVERSIDE BUSINESS PARK, SWANSEA VALE,
SWANSEA, SA7 0AH, 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 24/06/2024
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:

AAH PHARMACEUTICALS LIMITED, UNIT 2, ST PHILIPS CENTRAL, ALBERT ROAD, BRISTOL, BS2 0XJ, 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

2.6 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
- 3.1.2 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)
- 3.2 Medicinal gases
- 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:

AAH PHARMACEUTICALS LIMITED, WEST AVENUE, TALKE, STOKE-ON-TRENT, ST7 1TL, 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)

1.4 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

3.1.2 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, 4.5 Traditional Herbal Medicinal products, 4.6 Homeopathics

Name and address of the site:

AAH PHARMACEUTICALS LIMITED, UNIT 1, LEEDS 27 INDUSTRIAL ESTATE, BRUNTCLIFFE LANE, MORLEY, LEEDS, LS27 0YD, 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

2.6 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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, FARINGDON AVENUE, HAROLD HILL, ROMFORD, RM3 8SU, 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

2.6 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
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products
- 3.2 Medicinal gases
- 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:

AAH PHARMACEUTICALS LIMITED, WOBURN ROAD, WINWICK QUAY, WARRINGTON, WA2 8UH, 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
- 2.6 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
- 3.1.2 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)
- 3.2 Medicinal gases
- 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:

AAH PHARMACEUTICALS LIMITED, 6 BRETT DRIVE, BEXHILL-ON-SEA, TN40 2JP, 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

2.6 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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, BRITANNIA HOUSE, CENTURION PARK, WATLING STREET, WILNECOTE, TAMWORTH, B77 5PZ, 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

2.6 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

3.1.2 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)

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, UNITS 11/12 CALMORE INDUSTRIAL ESTATE, NUTWOOD WAY, TOTTON, SOUTHAMPTON, SO40 3SZ, 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

2.6 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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

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

2.6 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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, NEXUS POINT, ELLIOT WAY, PERRY BARR, BIRMINGHAM, B6 7UG, 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

2.6 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

3.1.2 Medicinal products derived from blood

3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LTD T/A SANGERS AAH, 2 MARSHALLS ROAD, BELFAST, BT5 6SR, 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

2.1 Procurement

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

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

3.1.4 Radiopharmaceutical (including radionuclide kits)

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, STONEFIELD WAY, RUISLIP, HA4 0JP, 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

2.6 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

3.1.2 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)

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LTD- THE WOODS, PART GROUND FLOOR- THE WOODS, HAYWOOD ROAD, WARWICK, CV34 5AH, 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

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3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, 120 LOBLEY HILL ROAD, GATESHEAD, NE8 4YR, 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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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:

AAH PHARMACEUTICALS LIMITED, SAPPHIRE COURT, WALSGRAVE BUSINESS PARK, WALSGRAVE TRIANGLE, COVENTRY, CV2 2TX, 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

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3.1.3 Immunological medicinal products

3.2 Medicinal gases

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:

AAH PHARMACEUTICALS LIMITED, RIVERSIDE BUSINESS PARK, SWANSEA VALE, SWANSEA, SA7 0AH, 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

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2.2 Holding

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3.1.2 Medicinal products derived from blood

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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