

## Registration as a Broker of Medicinal Products (Human Use)

In case of a new registration as a broker, please proceed below.



If you are already registered as a broker, please indicate your registration number below (this number was sent to you following your initial registration) proceed by filling out only the changes to your registration.

Broker registration number:

### Section 1: Broker information

#### 1.1 Applicant information

*Registered Company Name or name of individual applying for registration:*

Avicenna Membership Services Limited

*Permanent address:*

SELSDON HOUSE 212-220 ADDINGTON ROAD SOUTH CROYDON CR2 8LD United Kingdom

*Contact details:*

*Contact Person:*

*Telephone/Mobile:*

*National Number:*

#### 1.2 Details of person with legal authority to apply on behalf of the proposed registration holder (if applicable)

*Name:*

*Address:*

SELSDON HOUSE, 212-220 ADDINGTON ROAD, 212-220 ADDINGTON ROAD 212-220 ADDINGTON ROAD SOUTH CROYDON CR2 8LD United Kingdom

*Contact details:*

*Telephone/Mobile:*

*E-mail:*

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**1.3 If different from 1.1, address for communications and/or invoicing**

Purchase Order Number:



**1.4 Submission Information**

Competent Authority: UK\_MHRA

**Section 2: Site information**

**2.1 Administrative data**

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Name:

Site Name: Avicenna Membership Services Limited

Permanent address:

SELSDON HOUSE, 212-220 ADDINGTON ROAD, 212-220 ADDINGTON ROAD 212-220 ADDINGTON ROAD SOUTH CROYDON CR2 8LD United Kingdom

Contact details:

Contact Person:



Telephone/Mobile:

National Number:

DUNS Number:

**2.2 Extra Information**

Tick this box if the emergency Plan is retained at a different address

Tick this box if the required documents or records required for compliance are retained at a different address

**2.3 Medicinal Products to be brokered**

Prescription only Medicines (POW)

Pharmacy (P)

General Sales List (GSL)

Indication of the range of medicinal products to be brokered:

### Section 3: Other information

Please include any other relevant information in relation with this brokering activity:

As advised by MHRA in recent GDP inspection (File Ref: Insp GDP 42916/19610-0007), we are registering company as Broker. Photo ID and residence proof of Responsible person of Avicenna Membership Services Limited are being submitted. [REDACTED] remains as contact person for brokering activity of company.

The submitted information shall be made publicly available and shall be consultable. For further information contact your NCA directly.

### Section 4: Information required for Inspectorate assessment

I confirm the medicinal products brokered are covered by a Marketing Authorisation granted pursuant to regulation (EC) No. 726/2004 or by the competent authority of an EU member State.

I confirm an emergency plan which ensures effective implementation of any recall of a medicinal product from the market ordered by the competent authorities or carried out in co-operation with the manufacturer or marketing authorisation holder is in place.

I confirm that a system to ensure that records either in the form of purchase/sales invoices, or on computer, or in any other form for any transaction in medicinal products brokered providing at least the following information, is in place:

- Date on which the sale or purchase of the product was brokered
- Name of medicinal product
- Quantity brokered
- Name of supplier or consignee, as appropriate
- Address of supplier or consignee as appropriate
- Batch number for products bearing the safety features

I confirm the records will be retained for a period of five years

I confirm compliance with the guidelines on good distribution practice (GDP) published by the European Commission in accordance with Article 84 of the 2001/83/EC Directive insofar as those guidelines apply to brokers.

I confirm a quality system setting out responsibilities, processes and risk management measures in relation to brokering activities are in place and will be maintained.

I am aware of the requirement to immediately inform the licensing authority and where applicable the marketing authorisation holder of medicinal products which I identify as, suspect to be, or have reasonable grounds for knowing or suspecting to be, falsified, and undertake to do so. I am aware that the mentioned premises may be subject to inspection by the Competent Authority.

To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete.

I will notify all changes to the above mentioned data without delay to the Competent Authority.

I agree with the Conditions set out in this declaration (name and signature)

Date:

29/01/2019

### Supporting Documentation

- Certificate of Incorporation (issued by Companies House or similar documents for Partnerships/Sole Traders).

- Photo ID - A copy of a document which may be used to identify the named person such as the information page from a passport or a photo card driver's licence.
- Proof of Residence - Photocopies of at least two recent (not older than three months) utility bills to confirm the residential address of the named person.
- A statement on how purchase/sales records are to be maintained.
- A statement on the quality system setting out responsibilities processes and risk management measures in relation to brokering activities.
- Standard Operating Procedures
  - (i) Procedure for complaints handling.
  - (ii) Procedure for informing competent authorities and marketing authorisation holders of suspected falsified medicinal products.
  - (iii) Procedure for supporting recalls.
  - (iv) Procedure for verifying that their supplying wholesale distributors hold a distribution authorisation, their supplying manufactures or importers hold a manufacturing authorisation and their customers are authorised to supply medicinal products in the member State concerned.

## Attached Documents

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Guid:	[REDACTED]
Name:	Certificate of Incorporation-Avicenna.pdf
Guid:	[REDACTED]
Name:	[REDACTED]-Driving Licence.pdf
Guid:	[REDACTED]
Name:	[REDACTED]-Council bill.pdf
Guid:	[REDACTED]
Name:	Standard Operating Procedures-Avicenna.pdf
Guid:	[REDACTED]
Name:	A statement on how purchase-sales from Avicenna.pdf
Guid:	[REDACTED]
Name:	A statement on the quality system from Avicenna.pdf