

***National Authority Of Medicines And Health Products***

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION**

**Human medicinal products**

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| 1. Authorisation Number  | : A009/21/H/003/2025   |
| 2. Name of Authorisation Holder  | : Xpharma Lda.<br>(ORG-100037452 / LOC-100059140)  |
| 3. Address(es) of Site(s)  | : Estrada Da Quinta 148 148a, Manique, Alcabideche,<br>2645-436, Portugal <b>ACTIVE</b>  |
| 4. Legally registered address of Authorisation Holder  | : Avenida Das Robineas 10, Rinchoa, Rio De Mouro,<br>2635-545  |
| 5. Scope of authorisation (complete for each site under 4)   | : ANNEX 1  |
| 6. Legal basis of authorisation  | : Art. 77(1) of Directive 2001/83/EC<br>National legal basis of authorisation: Art. 94.º of<br>Decree-law 176/2006, of 30th August.  |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | : Maria Fernanda Ralha Henriques Matos, +351 21<br>7987278   |
| 8. Signature   | :  |
| 9. Date  | : 2025-07-03   |
| 10. Annexes attached   | : Annex 1 Scope of wholesale distribution authorisation<br><br>Annex 2 (Optional) Address(es) of contract wholesale<br>distribution sites and their authorisation number<br><br>Annex 3 (Optional) Name(s) of responsible person(s)<br><br>Annex 4 (Optional) Date of Inspection on which<br>authorisation was granted<br><br>Annex 5 (Optional) Additional provisions based on<br>national requirements |

## **ANNEX 1**

### **SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION**

**Name and address of the site:** Xpharma Lda.

(ORG-100037452 / LOC-100062811)

, Estrada Da Quinta 148 148a, Manique, Alcabideche, 2645-436, Portugal **ACTIVE**

Human medicinal products

#### **1. MEDICINAL PRODUCTS**

- 1.1. with a Marketing Authorisation or registration in EEA country(s)
- 1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market\*
- 1.3. without a Marketing Authorisation or registration in the EEA and intended for exportation

#### **2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

- 2.1. Procurement
- 2.2. Holding
- 2.3. Supply
- 2.4. Export

#### **3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

- 3.1. Narcotic or psychotropic products\*\*
- 3.2. Products requiring low temperature handling
  - 3.2.1. Temperatures between 2 to 8 °C
- 3.3. Other products: (please specify here or make a reference to Annex 5) Cytotoxic medicinal products.

**Any restrictions or clarifying remarks (for all users):** WDA scope activity - Wholesale Distributor.

Updating of the Annex 1 regarding the inclusion of the 1.3. and the reference to Narcotic or Psychotropic products.

\*Art. 5 of Directive 2001/83/EC, Art. 83 of Regulation (EC) 726/2004 and Art. 110 of Regulation 2019/6.

\*\*Without prejudice to further authorisations as may be required according to national legislation.

## Anexo 3 / Annex 3

Nome(s) do(s) Director(es) Técnico(s) / Name(s) of Responsible Person(s)
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Dr (a). Cátia Souto Poças