

National Authority of Medicines and Health Products, I.P.

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION
(MEDICINAL PRODUCTS FOR HUMAN USE)**

- | | |
|--|---|
| 1. Authorisation Number | : A009/21/H/001/2021 |
| 2. Name of Authorisation Holder | : Xpharma, Lda. |
| 3. Legally registered address of Authorisation Holder | : Avenida das Robínias, n.º 10, Sintra, 2635-545
Rio de Mouro, Portugal |
| 4. Address(es) of Site(s) | : Estrada da Quinta, n.º 148 e n.º 148 A,
Manique de Baixo, Cascais, 2645-436
Alcabideche, Portugal |
| 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 |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | : Maria Fernanda Ralha Henriques Matos, +351
21 7987278 |
| 8. Signature | : |
| 9. Date | : 2021-04-29 |
| 10. 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 (Optional) Additional provisions based
on national requirements |

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Xpharma, Lda., Estrada da Quinta, n.º 148 e n.º 148 A, Manique de Baixo, Cascais, 2645-436 Alcabideche, Portugal

1. MEDICINAL PRODUCTS

- 1.1 with a Marketing Authorisation in EEA country(s)
- 1.2 without a Marketing Authorisation in the EEA and intended for EEA market*

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

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

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.3 Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): National legal basis of authorisation: Art. 94.º of Decree-law 176/2006, of 30th August.

WDA scope activity - Wholesale Distributor.

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

**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)

Dr (a). António Manuel Silva Chaves Carvalho