

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

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

1. Authorisation Number : A006/13/H/002/2017
2. Name of Authorisation Holder : Laboratórios Basi - Indústria Farmacêutica, S.A.
3. Legally registered address of Authorisation Holder : Parque Industrial Manuel Lourenço Ferreira, Lote 15, Mortágua, 3450-232 Mortágua, Portugal
4. Address(es) of Site(s) : Parque Industrial Manuel Lourenço Ferreira, Lotes 2, 10 e 11, Mortágua, 3450-232 Mortágua, 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 : 2017-07-26
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: Laboratórios Basi - Indústria Farmacêutica, S.A., Parque Industrial Manuel Lourenço Ferreira, Lotes 2, 10 e 11, Mortágua, 3450-232 Mortágua, Portugal

1. MEDICINAL PRODUCTS

- 1.1 with a Marketing Authorisation in EEA country(s)
- 1.3 without a Marketing Authorisation 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 Products according to Art. 83 of 2001/83/EC **
 - 3.1.1 Narcotic or psychotropic products
- 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.

Updating of the Annex 3 regarding a change of the Responsible Person.

The Authorisation number A006/13/H/002/2017 replaces the previous one with the Authorisation number A006/H/001/2016, of 2013-02-08.

*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

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1. MEDICINAL PRODUCTS

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- 2.2 Holding
- 2.3 Supply
- 2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.3 Cold chain products (requiring low temperature handling)
- 3.4 Other products: Investigational Medicinal Products.

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

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