

**Federal Agency for Medicines and Health Products**

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

1. Authorisation Number : 1441 H
2. Name of Authorisation Holder : Beldimed SA
3. Legally registered address of Authorisation Holder : Rue Zénobe Gramme 39, Andrimont, 4821, Belgium
4. Address(es) of Site(s) : Rue Zénobe Gramme 39, Andrimont, 4821, Belgium
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 : Confidential, Confidential
8. Signature :
9. Date : 2017-07-24
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:** Beldimed SA, Rue Zénobe Gramme 39, Andrimont, 4821, Belgium

<p><b>1. MEDICINAL PRODUCTS</b></p> <p>1.1 with a Marketing Authorisation in EEA country(s) 1.3 without a Marketing Authorisation in the EEA and intended for exportation</p>
<p><b>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</b></p> <p>2.1 Procurement 2.2 Holding 2.3 Supply 2.4 Export</p>
<p><b>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</b></p> <p>3.1 Products according to Art. 83 of 2001/83/EC ** 3.1.1 Narcotic or psychotropic products 3.1.3 Immunological medicinal products 3.3 Cold chain products(requiring low temperature handling)</p>

**Any restrictions or clarifying remarks (for all users):** 1.3

Warehouse under the authority of customs

2.1.

Also procurement of medicinal products from others country of European Community (or from the European Economic Space) than Belgium

2.2

The authorization is issued to the holding on behalf of other license-holding firms.

3.3.

Authorized temperature for the cold chain : (2-8)°C

1.3

Entrepôt placé sous l'autorité des douanes

2.1.

Egalement acquisition de médicaments via d'autres pays de la Communauté européenne (ou de l'Espace Economique Européen) que la Belgique

2.2

L'autorisation est émise dans le cadre du stockage pour d'autres firmes titulaire d'une autorisation.

3.3.

température autorisée pour la chaîne du froid : (2-8)°C

\*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