

**Federal Agency for Medicines and Health Products**

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

1. Authorisation Number : 1876 H
2. Name of Authorisation Holder : IKRIS Pharma International SPRL
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 : Xavier De Cuyper, +32 2 5284000
8. Signature :  Philippe DE BUCK,  
Head of Division Authorisations  
DG Inspection - FAMHP
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

13 SEP. 2017



**ANNEX 1**

**SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION**

**Name and address of the site:** Beldimed sa, Rue Zénobe Gramme, 39, Andrimont, 4821, Belgium

**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
- 2.3 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):** 1.3

Warehouse under the authority of the customs.

2.1

Also procurement of medicinal products coming from countries of the European Economic Area (EEA) other than Belgium.

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 l'Espace économique européen (EEE) que la Belgique.

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

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