

***Federal Agency for Medicines and Health Products***

**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION**

1. Authorisation Number : 2055 H
2. Name of Authorisation Holder : The Simple Pharma Company Limited SRL de droit irlandais
3. Legally registered address of Authorisation Holder : Place Marcel Broodthaer, 8, Bruxelles, 1060, Belgium
4. Address(es) of Site(s) : Place Marcel Broodthaer, 8, Bruxelles, 1060, Belgium
5. Scope of authorisation (complete for each site under 4) : ANNEX 1
6. Legal basis of authorisation :
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation : Confidential, Confidential
8. Signature :
9. Date : 2022-01-11
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:** The Simple Pharma Company Limited SRL de droit irlandais  
, Place Marcel Broodthaer, 8, Bruxelles, 1060, Belgium

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

1.1 with a Marketing Authorisation in EEA country(s)

#### **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):** 3.3 Authorized temperature for the cold chain : 2-8 °C

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