Agence fédérale des médicaments et des produits de santé
Avenue Galilée 5/03
1210 BRUXELLES
www.afmps.be

JC PHARMA SRL : AUTORISATION GMDP n° 1552 H

En application des articles 12bis et 12ter de la Loi du 25 mars 1964 sur les médicaments :

la société : **JC Pharma SRL**

numéro d'entreprise	0460.070.010
siège social	Rue J. Bens 83 A, 1180 Bruxelles
siège administratif	Rue J. Bens 83 A, 1180 Bruxelles

dont les lieux d'opérations sont situés:

- Chaussée de Halle 156, 1640 Rhode-Saint-Genèse

est autorisée:

- à effectuer les activités reprises sur l'autorisation de distribution (WDA) (2 pages)

Pour le Ministre de la Santé Publique,
l'Administrateur-Général,
Xavier De Cuyper

Par ordre Philippe De Buck
DG Inspection – Chef de Division Autorisations

afmps fagg
Digitally signed by Philippe De Buck (Signature)
Date: 2022.06.20 08:49:19 +02'00'

Federal Agency for Medicines and Health Products (FAMHP)
Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS (BELGIUM)
www.fagg.be – www.afmps.be - www.famhp.be

Federal Agency for Medicines and Health Products

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number	:	1552 H
2. Name of Authorisation Holder	:	Jc Pharma
3. Legally registered address of Authorisation Holder	:	Joseph Bensstraat 83 A, Brussels, 1180, Belgium
4. Address(es) of Site(s)	:	Hallesesteenweg 156, Sint-Genesius-Rode, 1640, 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	:	
9. Date	:	2022-06-13
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: Jc Pharma, Hallesesteenweg 156, Sint-Genesius-Rode, 1640, Belgium

Human medicinal products

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

3.1.3 Immunological medicinal products
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