

CIBG Ministerie van Volksgezondheid, Welzijn en Sport

WHOLESALE DISTRIBUTION AUTHORISATION, ORANGE PHARMA B.V., AT DEVENTER, GRANTED ON JULY  $1^{\rm ST}$  2008, MOST RECENTLY CHANGED ON JANUARY  $10^{\rm TH}$  2019

1. AUTHORISATION NUMBER

3967 G

2. NAME AND ADDRESS OF AUTHORISATION HOLDER

Orange Pharma B.V. at DEVENTER, 9165302

3. LEGALLY REGISTERED ADDRESS OF AUTHORISATION HOLDER

Danzigweg 16 7418 EN at DEVENTER

4. ADRESS OF SITE

DEVENTER

Danzigweg 16 7418 EN at DEVENTER

5. SCOPE OF AUTHORISATION

WHOLESALE ACTIVITIES

6. LEGAL BASIS OF AUTHORISATION

Article 18, Paragraph 1, of the Dutch Medicines Act (Geneesmiddelenwet)

7. SIGNATURE

On behalf of the minister for Medical Care,

Manager Farmatec

Mr. M.J. van de Velde

8. DATE

January 10th 2019

9. ANNEXES TO THE AUTHORISATION

Annex 1:

Wholesale Activities

Annex 3:

Responsible Person(s)



## ANNEX 1: SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION WITH REGISTRATIONNUMBER 3967 G

Name and address of the site: Danzigweg 16 7418 EN at DEVENTER

Wholesale Activities			
		Yes	No
1	MEDICINAL PRODUCTS		
	1.1 with a Marketing Authorisation in EEA country(s)		
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		
	3.1.2 Medicinal products derived from blood		
	3.1.3 Immunological medicinal products		
	3.3 Cold chain products (requiring low temperature handling)		

Any restrictions or clarifying remarks related to the scope of these wholesaling operations: n/a

ANNEX 3: RESPONSIBLE PERSON

Mr K.M. Barendregt