

Health Products Regulatory Authority

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

1. Authorisation Number : W00118/00001
2. Name of Authorisation Holder : Prodent Limited T/A Promed
3. Legally registered address of Authorisation Holder : M50 Business Park, Ballymount Road Upper, Ballymount, Dublin 12, -, -, Ireland
4. Address(es) of Site(s) : Laharn, Tulligmore, Killorglin, Kerry, -, -, Ireland
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 : 2018-04-06
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: Prodent Limited T/A Promed, Laharn, Tulligmore, Killorglin, Kerry, -, -, Ireland

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

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.4 Other products: Please see restrictions or clarifying remarks (for all users).

Any restrictions or clarifying remarks (for all users): 3.4.1 Prescription only medicinal products
3.4.2 Medicinal products for general sale
3.4.3 Over the counter medicinal products for sale through pharmacies only
3.4.4 Unauthorised medicinal products
3.4.11 Exempt medicinal products

*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