Finnish Medicines Agency

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	:	006126/06.08.00.04/2018
2. Name of Authorisation Holder	:	SAM Nordic Oy
3. Legally registered address of Authorisation Holder	:	Sinimäentie 8 B, Espoo, FI-02630, Finland
4. Address(es) of Site(s)	:	Sinimäentie 8 B, Espoo, FI-02630, Finland
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	:	2018-12-31
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: SAM Nordic Oy, Sinimäentie 8 B, Espoo, FI-02630, Finland

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)
1.2 without a Marketing Authorisation in the EEA and intended for EEA market*

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art. 83 of 2001/83/EC **
3.1.2 Medicinal products derived from blood
3.1.4 Radiopharmaceuticals (including radionuclide kits)
3.3 Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): Products without a Marketing Authorisation and intended for EEA market are released to consumption by a hospital pharmacy or a pharmacy. Batch specific control of medicinal products derived from blood has to be handled according to Fimea's administrative regulation prior to releasing marketing authorised or special-licence medicinal product to consumption.

*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