Wholesale Dealer's Licence

1. Authorisation number	**WL141 (1st variation)**
2. Name of authorisation holder	**Macure Healthcare Limited**
3. Legally registered address of authorisation holder	**7 Business House Suite Triq L-Arcisqof Pietru Pace Rabat VCT 2504 Malta**
4. Address(es) of site(s)	**62 Archlight Building Triq L-Gharbiel Is-Swieqi, SWQ 3251 Malta**
5. Scope of authorisation (complete for each site under 4)	**See Annex 1**
6. Legal basis of authorisation	**Medicines Act 2003 Part III Title III Art 54 Directive 2001/83/EC Title VII Art 77 S.L. 458.37 Reg.4**
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	**Prof. Charmaine Gauci Licensing Authority**
8. Signature	
9. Date of issue	**30th June 2022**
10) Validity: valid till	**3rd November 2024**

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11. 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

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Annex 1 SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site:

Macure Healthcare Limited
62 Archlight Building
Triq L-Gharbiel
Is-Swieqi, SWQ 3251
Malta

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in the EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement
2.3 Supply

3. Medicinal products with additional requirements

3.1 Products according to Art. 83 of 2001/83/EC[1]
3.1.1 Narcotic or psychotropic products
3.3 Cold chain products (requiring low temperature handling)

Any restrictions or clarifying remarks related to the scope of these wholesaling operations:
This site is not licensed for holding of human medicinal products.

1 Without prejudice to further authorisations as may be required according to national legislation
*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

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ANNEX 2 (Optional)

Address(es) of Contract Wholesale Distribution sites and their authorisation number:

Storage sites:

1.) **Magnum Medical Finland Oy**
Tuupakantie 32
Vantaa, FI-01740
Finland

Authorisation number: FIMEA/2019/000374

2.) **Allphar Services Limited**
Unit 645 & 646, Jordanstown Drive
Greenogue Industrial Estate, Rathcoole
Dublin
Ireland

Authorisation number: W0005/00005

3.) **Allphar Services Limited**
4045 Kingswood Road
Citywest Business Park
Dublin
Ireland

Authorisation number: W00005/00001

Parent company:
Macure Pharma ApS
Hejrevej 39, 2. sal
København NV, 2400
Denmark

Authorisation number: 3737

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ANNEX 3 (Optional)

Name(s) of responsible person(s)

Mr. Hilary Paul Agius

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ANNEX 4 (Optional)

Date of Inspection on which authorisation was granted	**03/11/2021** (new application, first GDP inspection)

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Conditions of Licence for Pharmaceutical Wholesale Dealers` Licences (including narcotic and psychotropic drugs)

The Licence Holder:

1. shall not, without the approval of the Licensing Authority, distribute any medicinal product which has not been specified in this licence either as such or as a class of medicinal product (e.g. narcotics and psychotropics) or dosage form which may be distributed by him.
2. shall provide and maintain such premises, equipment and staff as are necessary for the carrying out, in accordance with this licence and any relevant marketing authorization in force, of such stages of the distribution of the medicinal products as undertaken by him.
3. shall provide and maintain such premises, equipment, facilities and staff for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under this licence as are necessary to avoid deterioration of such products and he shall not use these premises for such purposes other than those specified in this licence.
4. shall notify the Licensing Authority in writing before making any material alteration in the premises or equipment used under this licence, or in the operations in which they are used and he shall notify the Licensing Authority in writing of any change that he proposes to make in any personnel named in this licence.
5.

(1) shall have at his disposal the services of a responsible person who has the qualifications and experience that satisfy the provisions of the Medicines Act (Chapter 458 of the Laws of Malta) and its subsidiary legislation, to carry out the functions specified in sub-paragraph (3) below

(2) shall at all times provide and maintain such staff, premises and facilities as will enable the responsible person to carry out the said functions

(3) the functions to be carried out by the responsible person to be as follows –

a) to ensure that these licence conditions are adhered to

b) to ensure that the conditions for storage of medicinal products is in accordance with the requirements of the marketing authorization and labeling

c) to monitor all areas used for storage and distribution

d) to maintain records as required by SL 458.37

e) to ensure that a quality system is maintained by the licensee in accordance with EU good distribution practice

f)to ensure and check that narcotics and psychotropics are sold, distributed or otherwise supplied only to authorized persons at all stages

g) to ensure that narcotics and psychotropics are stored on premises in a secure manner, under lock and key, to keep possession of the key at all times and to take the necessary steps to ensure security to prevent theft or other diversification of stock.

(4) the Licensing Authority may require the licence holder to temporarily suspend the person acting as such responsible person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfill his functions in accordance with sub-paragraph (3) above and the

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licence holder shall not permit that person to act as the responsible person pending the determination of such proceedings.

6. shall keep readily available for inspection by an officer responsible for the enforcement or execution of these conditions durable records of each purchase and sale in an appropriate register/s or other equivalent document/s appropriate for this purpose in a manner that ensures

traceability of the origin and destination of products and he shall permit such officer to take copies or make extracts from such records. Such records shall be retained for not less than 5 years.

7. shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which this licence relates. Such documents shall be available for inspection by an officer responsible for the enforcement of execution of these conditions.
8. shall, where he has been informed by the Licensing Authority that a medicinal product to which this licence relates has been found to give rise to unacceptable adverse reactions, if so directed by the Licensing Authority, immediately withhold that product from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies of such product already sold, supplied or exported.
9. shall not dispose of any medicinal product to which this licence relates except in accordance with the laws of the country.
10. shall supply such information as may be requested by the Licensing Authority for the purposes of these conditions about the medicinal products currently being distributed and about the operations being carried out in relation to such distribution.
11. shall for the purpose of enabling the Licensing Authority to ascertain whether there are any grounds for suspending, revoking or varying this licence granted under the Medicines Act - (Chapter 458 of the Laws of Malta), permit and provide all necessary facilities to enable any officer responsible for the enforcement or execution of the said Act to carry out such inspection, to take samples or to take copies of any documents in relation to any business carried on by the licence holder, for the purpose of verifying any statement contained in an application for this licence
12. shall where he has been informed by the Licensing Authority that any part of a batch to which this licence relates been found not to conform as regards quality with the specifications of the relevant product or found to be falsified as defined in the Medicines Act-(Chapter 458 of the Laws of Malta), if so directed by the Licensing Authority, immediately withhold the remainder of that batch from sale, supply or exportation and, insofar as may be practicable, immediately recall all supplies already sold, supplied or exported from that batch.
13. shall comply with the principles and guidelines of EU good distribution practice for medicinal products for human use laid down in Commission Directive 2001/83/EC as amended and in Eudralex Volume 4.

The Licence Holder and Responsible Person:

14. shall comply with the regulations as stipulated in the Medicines Act (Chapter 458 of the Laws of Malta) and its subsidiary legislation.

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