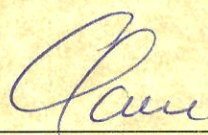




Manufacturing/Importation Licence

1. Authorisation number **ML013**
2. Name of authorisation holder **Pharmadox Healthcare Ltd**
3. Address(es) of manufacturing site(s) **KW20A Kordin Industrial Park
Paola PLA3000
Malta**
**Warehouse No.1 and No.2
Hal Farrug Road
Luqa LQA9040
Malta**
4. Legally registered address of authorisation holder **KW20A Kordin Industrial Park
Paola PLA 3000
Malta**
5. Scope of authorisation and dosage forms **ANNEX 1 and/or ANNEX 2**
6. Legal basis of authorisation **Directive 2001/83/EC Title IV Art 40
Directive 2001/20/EC Art 13
Medicines Act 2003 Part III Title II Art 37
Legal Notice 490 of 2004 Regulation 13 & 14
Legal Notice 119 of 2006 Regulation 7
Legal Notice 381 of 2005 under Medicines Act 2003
regulation 3(3)**
7. Name of Responsible officer of the Competent authority of the member State granting the manufacturer's licence **Dr. Charmaine Gauci
Licensing Authority**
8. Signature 
9. Date **24th September 2018**
10. Validity:

This licence is valid for three years from date of last renewal inspection, the latest of which was conducted on **17th - 18th July 2018**.



11. Annexes attached: Annex 1 and/or Annex 2
- Optional annexes as required:
- Annex 4 - Addresses of Contract Laboratories
 - Annex 5 - Name of Qualified Person/s
 - Annex 6 - Name of responsible persons
 - Annex 7 - Date of inspection on which authorisation granted,
scope of last inspection
 - Annex 8 – (Manufactured/imported products authorised)



Scope of Authorisation

ANNEX 1

Name and address of the site:

Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola PLA 3000, Malta

Human Medicinal Products

Authorised Operations

1. Manufacturing Operations (according to part 1)
2. Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.3 *Batch certification*

1.2 Non-sterile products

1.2.2 *Batch certification*

1.5 Packaging

1.5.2 *Secondary packing*

1.6 Quality control testing

1.6.1 *Microbiological: sterility*

1.6.2 *Microbiological: non-sterility*

1.6.3 *Chemical/Physical*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Re 1.1: Products falling under this category may only be released by Mr John W. Holloway.

Re 1.5: This licence is being granted for the secondary packaging of medicinal products and will also include the assembly operation and over-labelling on the primary packaging of medicinal products.

Luqa site is licensed for warehousing purposes only.



Part 2 – IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

- 2.1.1 Microbiological: sterility*
- 2.1.2 Microbiological: non-sterility*
- 2.1.3 Chemical/Physical*

2.2 Batch certification of imported medicinal products

- 2.2.1 Sterile products*
 - 2.2.1.1 Aseptically prepared*
 - 2.2.1.2 Terminally sterilised*

- 2.2.2 Non-sterile products*

2.3 Other importation activities (any other importation activity that is not covered above)

- 2.3.1 Site of physical importation*

Any restrictions or clarifying remarks related to the scope of these Importing operations

Re 2.2.1: Products falling under this category may only be released by Mr John W. Holloway. Luqa site is licensed for warehousing purposes only.



ANNEX 2

Name and address of the site:

Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola PLA 3000, Malta

Human Investigational Medicinal Products

Authorised Operations

1. Manufacturing Operations of Investigational Medicinal Products (according to part 1)
2. Importation of Investigational Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1 Sterile investigational medicinal products

1.1.3 *Batch certification*

1.2 Non-sterile investigational medicinal products

1.2.2 *Batch certification*

1.5 Packaging

1.5.2 *Secondary packing*

1.6 Quality control testing

1.6.1 *Microbiological: sterility*

1.6.2 *Microbiological: non-sterility*

1.6.3 *Chemical/Physical*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations
Re 1.1: Products falling under this category may only be released by Mr John W. Holloway.
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Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

2.1 Quality control testing of imported investigational medicinal products

2.1.1 Microbiological: sterility

2.1.2 Microbiological: non-sterility

2.1.3 Chemical/Physical

2.2 Batch certification of imported investigational medicinal products

2.2.1 Sterile products

2.2.1.1 Aseptically prepared

2.2.1.2 Terminally sterilised

2.2.2 Non-sterile products

2.3 Other importation activities

2.3.1 Site of physical importation

Any restrictions or clarifying remarks related to the scope of these importing operations

Re 2.2.1: Products falling under this category may only be released by Mr John W. Holloway.

Luqa site is licensed for warehousing purposes only.



ANNEX 4 (optional)

Addresses of Contract Laboratories

**APL Swift Services (Malta) Ltd.
HF26, Hal Far Industrial Estate
Hal Far, Birzebbugia BBG 3000
Malta**

**Astron Research Limited
2nd & 3rd floor, Sage House
319, Pinner Road, Harrow
HA1 4HF, United Kingdom**

**Zentiva, k.s.
U kabelovny 130
Dolní Měcholupy
Praha 10, 102 37
Czech Republic**



ANNEX 5 (optional)

Names of Qualified Persons

Mr John W. Holloway (sterile and non-sterile medicinal products)

Ms Sandra Saliba Sammut (for non-sterile solid dosage form medicinal products and/or secondary packaging process only)

Mr Mark Ellul (for non-sterile solid dosage form medicinal products only)

Mr Andrea Cini (for non-sterile solid dosage form medicinal products and/or secondary packaging process only)



ANNEX 6 (optional)

Name of person responsible for quality control

Mr Keith Frendo

Name of person responsible for production

Mr Peter Seychell



ANNEX 7 (Optional)

Date of Inspection on which authorisation was granted: **17th - 18th July 2018**

Scope of last inspection: **Renewal of manufacturer's licence**