

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
On behalf of the Licensing Authority under The Human Medicines Regulations  
2012 (SI 2012/1916)

## **Wholesale Distribution Authorisation (Human)**

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1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.
2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.
3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.
4. The authorisation is not transferable to another legal entity.
5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:
  - there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product
  - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
  - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012 (SI 2012/1916).
6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance with, The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]
7. If the intention is to import licensed medicinal products from outside the EEA an application for a manufacturer's licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.



8. If the intention is to import a special medicinal product from outside the EEA into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.
9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.
10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.
11. The Medicines and Healthcare Products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).
12. Further information and specified guidelines may be obtained from the UK government website [www.gov.uk/mhra](http://www.gov.uk/mhra).
13. Authorisation Structure

This Wholesale Distribution Authorisation is divided into five annexes.

- (a) Annex 1: Scope of wholesale distribution authorisation
- (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
- (c) Annex 3: Name(s) of responsible person(s.)
- (d) Annex 4: (Optional) Date of Inspection on which authorisation was granted
- (e) Annex 5: Additional provisions based on national requirements

**Attention is drawn to the structure of this authorisation and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.**



14. Authorisation Holder

(a) Authorisation Holder Number: WDA(H) 40443 has been granted to –

<b>AUTHORISATION HOLDER:</b>	INCEPTUA LIMITED
<b>TRADING AS:</b>	
<b>ADDRESS:</b>	FLOOR 2, VISTA, WILLIAM STREET, WINDSOR, SL4 1BA, UNITED KINGDOM
<b>CONTACT NAME:</b>	Ms Christina Neuschl

- (b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.
- (c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.
- (d) Date granted - 26/03/2018
- (e) Authorised by -

Name: Yaseen Edoe

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 26/03/2018



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### VARIATION HISTORY

Date	Variation Detail
20/03/2012	Initial Application for Multipharma Clinical Supplies Limited
21/03/2012	Internal variation
08/02/2013	Variation to remove Mr Richard William King and replace with Mrs Jacqueline Anne Peck as Responsible Person, site 4645286
20/02/2013	Internal variation to change the communications address to; 39 Southern Way, Farnborough, Hampshire, GU14 0RE
14/10/2013	FMD update WL/WDL converted to WDA(H)
17/12/2013	Internal variation to authorise import for export, add 1.3, 2.4 and 4.7.
29/05/2014	Internal variation to generate correct licence document due to system error.
23/08/2016	Variation to change the company contact, communications contact, invoicing contact and change of the site contact to Ms Christina Neuschl
14/02/2017	Variation to remove Medicinal Gases from license Addition of supply to license
28/03/2017	Variation to change company name/same legal entity from Multipharma Clinical Supplies Limited to Inceptua Limited
18/01/2018	Variation: 1. Add new site. 17765024. 2. Change LHC to Mrs Jacqueline Peck.
26/03/2018	Adding a third party site: McGregor Cory Limited Removal of Cavendish Square Site Amendment to contact telephone number for Christina Neuschl Amendment to company address, contact address & invoice address Amendment to invoice contact



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**Annex 1 – Scope of Wholesale Distribution Authorisation**

The premises –

<b>Site Name:</b>	INCEPTUA LIMITED
<b>Address:</b>	FLOOR 2, VISTA, WILLIAM STREET, WINDSOR, SL4 1BA, UNITED KINGDOM
<b>MHRA Site Number:</b>	17765024

is named on Authorisation Holder number: WDA(H) 40443 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

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

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**Annex 1 - Scope of Wholesale Distribution Authorisation (continued)**

**USE OF PRODUCTS AT SITE**

**1. MEDICINAL PRODUCTS**

- 1.1 With a Marketing Authorisation in EEA member state(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market
- 1.3 Without a Marketing Authorisation in the EEA and not intended for EEA market

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

**3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

**3.1 Products according to Art 83 of 2001/83/EC**

- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products

- 3.3 Cold chain products (requiring low temperature handling)



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**Annex 5 – Additional Provisions Based on National Requirements**

<b>Site Name:</b>	INCEPTUA LIMITED
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<b>MHRA Site Number:</b>	17765024

**4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE**

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy
- 4.5 Traditional Herbal Medicinal products



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**Annex 2 – Address(es) of Contract Wholesale Distribution Sites and their Authorisation Number**

<b>Site Name</b>	<b>Address</b>	<b>Authorisation Holder Number</b>	<b>MHRA Site Number</b>
MOVIANTO UK LIMITED	1A PROGRESS PARK, ELSTOW, BEDFORD, MK42 9XE, UNITED KINGDOM	WDA(H) 14172	5680
MCGREGOR CORY LIMITED	CHERWELL 1 & 2, MIDDLETON CLOSE, BANBURY, OX16 4RS, UNITED KINGDOM	WDA(H) 14238	4858





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**Annex 3 – Name(s) of designated Responsible Person(s)**

**Personnel**

<b><u>Responsible Person</u></b>			
<b><u>Person Number</u></b>	<b><u>Name</u></b>	<b><u>Site</u></b>	<b><u>Role</u></b>
4524453	Mrs Jacqueline Anne Peck	17765024	Responsible Person

