

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)

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.
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) 44739 has been granted to –

AUTHORISATION HOLDER:	PHARMASERVICESEU LLP
TRADING AS:	Pharmaservices
ADDRESS:	UNIT B3, 19 HERON ROAD, BELFAST, BT3 9LE, UNITED KINGDOM
CONTACT NAME:	Mr Mark Hedley

(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 - 19/12/2016

(e) Authorised by -

Name: Sean Kaiser

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

Date: 19/12/2016



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VARIATION HISTORY

Date	Variation Detail
01/12/2015	Initial Application for PHARMASERVICESEU LLP
27/10/2016	Variation to add third party site to perform contract packaging. PHARMARAM LIMITED site ID 357107
19/12/2016	Variation: 1. Add a new third party site, DIXONS PHARMACEUTICALS UK LIMITED. 2. Add Cold Chain activities to the licence.



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Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

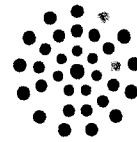
Site Name:	PHARMASERVICESEU LLP
Address:	UNIT B3, 19 HERON ROAD, BELFAST, BT3 9LE, UNITED KINGDOM
MHRA Site Number:	12469448

is named on Authorisation Holder number: WDA(H) 44739 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





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)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement

2.2 Holding

2.3 Supply

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

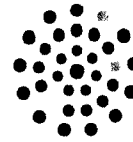
3.1 Products according to Art 83 of 2001/83/EC

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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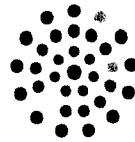
Annex 5 – Additional Provisions Based on National Requirements

Site Name:	PHARMASERVICESEU LLP
Address:	UNIT B3, 19 HERON ROAD, BELFAST, BT3 9LE, UNITED KINGDOM
MHRA Site Number:	12469448

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy





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

Site Name	Address	Authorisation Holder Number	MHRA Site Number
DIXONS PHARMACEUTICALS UK LIMITED	UNIT F4, IVANHOE BUSINESS PARK, TOM BILL WAY, ASHBY DE LA ZOUCH, LE65 2UY, UNITED KINGDOM	WDA(H) 33652	357107



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

Personnel

Responsible Person			
<u>Person Number</u>	<u>Name</u>	<u>Site</u>	<u>Role</u>
1269658	Mr Lal Chand Khindria	12469448	Responsible Person
117874	Mr Mark Hedley	12469448	Responsible Person

