

**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) 27880 has been granted to –

<b>AUTHORISATION HOLDER:</b>	AH UK ANIMAL HEALTH (PVT) LIMITED
<b>TRADING AS:</b>	
<b>ADDRESS:</b>	COLLEGE MAINS ROAD, DUMFRIES, DG2 0NU, UNITED KINGDOM
<b>CONTACT NAME:</b>	Ms Marie McDonald

- (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 - 26/02/2019
- (e) Authorised by -

Name: Emanuela Krasteva

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

Date: 26/02/2019



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**VARIATION HISTORY**

<b>Date</b>	<b>Variation Detail</b>
29/09/2006	Initial Application
12/10/2006	Internal variation to add four sites.
18/10/2006	Internal variation to amend licence.
26/08/2008	Variation to add admin site in Belfast with site id 14718 with a RP Mr A Anderson.
29/08/2008	Variation to change site name for site 14718 to Henry Schein Minerva Dental.
22/05/2009	Variation to add Mr Mather as Responsible Person to sites 116552 and 406638, consolidate site information into a single site where company's are all interrelated and share procedures and stock.
04/08/2009	Internal variation: 1. Update site activities and product classes. 2. Site 120618 amend site name to Henry Schein UK Holdings Ltd.
01/10/2009	Variation to site 120618: add additional RP's, Mr RP Mather & Mr P Dodd.
12/01/2010	Variation to replace site 92800 with 18 Stanhope Place, London W2 2HH as procurement site
18/04/2010	Variation to add two additional sites; Site 91176 (College Mains Road, Dumfries) & 415939 (Units 1 & 2 Woodlands, Rougham)
24/06/2010	Internal variation to amend the site name for 120618
03/08/2010	Variation to remove site: 406638.
01/09/2010	Variation to site 464870: add to product class list. Site 14718: remove product classes. Site 120618: remove unlicensed medicinal products imported from within the EEA.
28/01/2011	Variation to add Biological Products to site 120618
02/12/2011	Variation to amend the site name and proposed trading style of site id 91176 to Henry Schein UK Holdings Ltd T/A Henry Schein Animal Health and the site name and proposed trading style of site id 415939 to Henry Schein UK Holdings Ltd T/A Henry Schein Animal Health
14/05/2012	Variation to amend site name, site 1353457, Site 14718 add Responsible Person Mr P Mather, delete Responsible Person Mr A Anderson.
27/07/2012	Variation to amend site functions for sites 14718, 89537, 91176, 116552,



	120618, 464870 and 1353457.
05/04/2013	Variation to remove medicinal gases from site 14718, 89537, 116552, 120618, 464870
22/05/2013	Variation to delete cold chain products from site 464870
14/08/2013	Variation:1. Add new site 2759. 2. Mr D Marsh to be added as an additional RP.
02/09/2013	Internal Variation to include GSL products site 2759.
13/10/2013	FMD update WLWDL converted to WDA(H)
11/12/2013	Internal variation to add import for export.
29/04/2014	Internal variation to amend licence holder address, site 91176 and 120618 remove 2.1 Procurement.
05/06/2014	Variation to remove site 89537.
28/08/2014	Variation to sites 14718, 116552, 1353457: remove cold chain. Also add site 10535096.
15/09/2014	Variation to add site 10535096, remove 4.7 Products Imported Outside of the EEA for Export to Countries Outside of the EEA from all sites.
13/11/2014	Variation to add third party sites 1057072 and 1767171 to the licence.
21/05/2015	Variation: 1. Change LH address to Ground Floor Westpoint Business Park, 4 Marchfield Drive, Paisley, PA3 2RB. 2.Update sites activities.Site 1353457 Delete 2.1 procurement 3.1.2. Medicinal products derived from blood Site 116552 The name should be updated to: Henry Schein Dental Delete 2.1 procurement Site 14718 The name should be updated to: Henry Schein Dental Site 464870 The name should be updated to: Henry Schein Dental Delete 2.1 procurement Site 91176 Delete 1.2 Without a Market Authorisation in the EEA and intended EEA market Remove trading as Blackwell Supplies
04/09/2015	Internal variation to amend licence information, revise communication address to EX39 5JL and company address to ME8 0SB. Site 120618 remove Minerva from the site name, Site 10535096 amend the spelling of the site name, Site 1353457 remove authorisation for procurement and 3.1.2 products derived from blood, Site 116552 remove authorisation for procurement and amend the site name to Henry Schein Dental Site 14718 amend the site name to Henry Schein Dental, Site 464870 Delete 2.1 procurement, amend the site name to Henry Schein Dental, Site 91176 Delete 1.2 Without a Market Authorisation in the EEA and intended EEA market and Remove trading as Blackwell Supplies.
04/09/2015	Internal variation to amend licence information.
17/09/2015	Internal variation: remove site 464870 and add new site 11980954.



26/11/2015	Internal variation to synchronise PCL Portal with Sentinel system.
30/11/2015	Variation: 1. Delete site 116552 and replace with 12857572. 2. Delete 3rd party sites 1057072 and 17671.
16/12/2015	Internal variation to amend out of sync licence documents and to accomodate inspectors request, site 12857572 remove other comments, add supply and remove export, site 14718 remove other, add supply, same for site 1353457. No Fee
16/02/2016	Variation to add trading styles. Delete site 116552, re-add site 120618. Update all the site names to Holder to Henry Schein UK Holdings Limited.
21/03/2016	Internal Variation to re- add to Peter Dodd to site ID 120618.
13/05/2016	Variation to site 91176 to replace Peter Dodd with Marie McDonald as Responsible Person and site contact.
19/12/2016	Variation to delete Blackwell Supplies from the trading style, remove Peter Dodd from the following sites: 415939, 10535096, 120618 and add Marie McDonald as RP to site no 415939
08/03/2017	Internal variation to amend the site name for site 10535096 to HENRY SCHEIN UK HOLDINGS LIMITED. (no fee)
11/07/2017	Remove the following site: HENRY SCHEIN UK HOLDINGS LTD (SITE ID: 415939) UNITS 1 & 2, WOODLANDS BUSINESS PARK, ROUGHAM INDUSTRIAL ESTATE, ROUGHAM, BURY ST EDMUNDS, IP30 9ND
29/10/2018	Add Vicki Snow as an additional Responsible Person to the following sites on WDA (H) 27880: Site 12857572 Site 10535096 Site 120618  Add Kirsty Pickles as an additional Responsible Person to the following sites on WDA (H) 27880: Site 14718 Site 1353457 Site 11980954
25/01/2019	Variation to change the company name to AH UK ANIMAL HEALTH (PVT) LTD, remove site 91176.
26/02/2019	WDA(H) Initial for AH UK ANIMAL HEALTH (PVT) LIMITED.





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

The premises –

<b>Site Name:</b>	AH UK ANIMAL HEALTH (PVT) LIMITED
<b>Address:</b>	COLLEGE MAINS ROAD, DUMFRIES, DG2 0NU, UNITED KINGDOM
<b>MHRA Site Number:</b>	91176

is named on Authorisation Holder number: WDA(H) 27880 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**

3.1.1 Narcotic or psychotropic products

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>	AH UK ANIMAL HEALTH (PVT) LIMITED
<b>Address:</b>	COLLEGE MAINS ROAD, DUMFRIES, DG2 0NU, UNITED KINGDOM
<b>MHRA Site Number:</b>	91176

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

Personnel

<u>Responsible Person</u>			
<u>Person Number</u>	<u>Name</u>	<u>Site</u>	<u>Role</u>
15397771	Ms Marie McDonald	91176	Responsible Person

