Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 15956/16934323

HEALTHCARE AT HOME LTD

ISSUED BY:

[redacted]

GDP Inspector

Head Office:
Inspection, Enforcement & Standards Division, MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Telephone: 020 3080 6000
Email: info@mhra.gsi.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: **Insp GDP 15956/16934323-0002**
Inspection Date: **22/01/2020**
Company: **HEALTHCARE AT HOME LTD**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 15956/16934323-0002
2. Inspected site(s) and contact details:	
HEALTHCARE AT HOME LTD UNIT 34 CROWTHER ROAD WASHINGTON NE38 0AQ UNITED KINGDOM Site contact & Responsible Person: [redacted]	
3. Authorised operations:	
☐ Procurement ☒ Holding ☒ Supply ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	22/01/2020
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 15956

File Ref: **Insp GDP 15956/16934323-0002**
Inspection Date: **22/01/2020**
Company: **HEALTHCARE AT HOME LTD**

7. Introduction:

Business Background

Healthcare At Home Limited's main area of business is a Home Care delivery company dispensing and delivering a prescriptions service to patients at home. They also supply other wholesalers, hospitals and clinics
The organisation carries out wholesale deliveries to customer in the UK. There are two main distribution sites, one in Featherstone and one in Burton on Trent with cross docking sites located throughout England, Scotland and N. Ireland.
The main site head office site is located at Burton on Trent where they procure stock, process orders, conduct customer and supplier verification checks, action returns and recalls.

Review of WDA(H)

MEDICINAL PRODUCTS

☒ with a Marketing Authorisation in EEA country(s)

☐ without a Marketing Authorisation in the EEA and intended for EEA market*

☐ without a Marketing Authorisation in the EEA and intended for exportation

Medicinal products with additional requirements

☐ Products according to Art. 83 of 2001/83/EC

- ☒ Narcotic or psychotropic products
- ☒ Medicinal products derived from blood
- ☒ Immunological medicinal products
- ☐ Radiopharmaceuticals (including radionuclide kits)

☐ Medicinal gases

☒ Cold chain products (requiring low temperature handling)

☐ Other products: (please specify here or make a reference to Annex 5)

Date of previous inspection:

Name(s) of Inspector(s) involved in previous inspection: [redacted]

Date of last inspection: 17/01/2017

Overview of inspection findings from last inspection and the corrective action taken:

One Major deficiency related to scope of licence and two other deficiencies related to the quality management system and premises and equipment. Deficiencies had been actioned and inspection case folder closed out.

Major changes since the previous inspection:
Change of key staff: Responsible Person, Depot Operations Team Leader, Head of Warehouse and Distribution and Head of Central Clinical Logistics.
New van fleet introduced company wise.
[redacted] emperature monitoring equipment installed.

File Ref: **Insp GDP 15956/16934323-0002**
Inspection Date: **22/01/2020**
Company: **HEALTHCARE AT HOME LTD**

8. Scope of Inspection:
Routine inspection assessing compliance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the Human Medicines Regulations 2012 as amended.
9. Inspected activities:
GDP Inspection of all GDP activities, operations, records and documentation under the licence pertaining to this site; Holding and Supply.
10. Activities not inspected:
N/A
11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

  The quality system captured and reflected wholesale activities authorised on the granted licence.

  Processes were in place in relation to change control, deviation management and quality risk management, incorporating Corrective/Preventative Actions.

  A process of regular management review was in place.

  A comprehensive risk assessment of wholesale operations had been carried out.

- **Personnel**

  [redacted] had been appointed as Responsible Person (RP) had been appointed, with clear authority and responsibilities.

  Training records in place for the Responsible Person, demonstrating their ongoing awareness of and competence in Good Distribution Practice.

  There was evidence that the RP fulfilled their responsibilities personally and was continuously available.

  There were an adequate number of trained and competent personnel available to carry out wholesale activities.

  The organisational structure of the wholesale distributor was set out in an organisation chart.

  A structured training programme was in place.

  A process was in place for the regular assessment of the effectiveness of training.

A process of regular refresher training was in place, including general GDP and falsified medicines awareness.

- **Premises and Equipment**

  Premises were considered suitable and adequate for the scale and nature of wholesale operations.

  Medicinal products were stored in clearly marked, segregated areas.

  Access to the storage areas was subject to appropriate controls.

  Processes were in place for quarantining products.

  Receiving and dispatch bays provided adequate protection from prevailing weather conditions.

  A preventative pest control programme was in place, records were maintained.

  A formal assessment of the relatively small storage areas had been carried out.

  Equipment used to control or monitor the storage areas was calibrated to a traceable National standard.

  Processes were in place for the back-up, retention and restoration of electronic records.

- **Documentation**

  Reliance for demonstrating compliance was primarily placed on electronic records.

  Documentation was considered to be of adequate scope, written in clear language.

  A process was in place for document control.

  Documentation relevant to wholesale activities would be retained for a minimum of five years.

  Records included all details relevant to the procurement and supply of products.

  Evidence was that records would be made at the time activities took place.

- **Operations**

  A process was in place for the qualification and regular re-qualification of customers.

  Processes were in place for the receipt of goods.

  Medicinal products were adequately segregated from other goods.

- **Complaints, Returns, Suspected Falsified Medicinal Products and Recalls**

  Processes were in place for the handling of customer complaints, returns and product recalls.

- **Outsourced Activities**

  N/A

- **Self-Inspection**

  A process of regular self-inspection was in place.

  The outcome of self-inspection activities was communicated to relevant staff.

- **Transportation**

  The wholesale distributor operated its own fleet of delivery vehicles and drivers.

  Processes were in place for ensuring that the required storage conditions for products were maintained throughout transport.

  Processes were in place for the assessment of deviations during transit.

  Processes were in place for ensuring that vehicles and equipment used to transport products to the customer were suitable for use and appropriately maintained.

  A formal risk assessment of the arrangements for the transportation of the full range of medicinal products supplied had been undertaken.

  Processes were in place for the use of both active and passive packaging systems.

- **Specific Provisions for Brokers**

  N/A.

13. Other specific issues identified:
N/A
14. Miscellaneous:
N/A
15. Annexes attached:
N/A

File Ref: Insp GDP 15956/16934323-0002
Inspection Date: 22/01/2020
Company: HEALTHCARE AT HOME LTD

16. List of Deficiencies classified into critical, major and others:

1. CRITICAL

None observed.

2. MAJOR

None observed.

3. OTHER

3.1 Transportation was deficient in that:

3.1.1 Validation studies and risk assessments of the company's use of temperature-controlled vehicles were unavailable for review, thus providing inadequate reassurance that medicinal products would maintain the required storage condition during transportation as described by the manufacturers or on the outer packaging. Please supply a written protocol and subsequent results of the assessment.

Reference: EU GDP 9.2

3.2 Premises and equipment were deficient in that:

3.2.1 The calibration certificate for the thermometer used for the ambient storage area had not been adequately reviewed and validated to ensure the three-point calibration would not compromise the accuracy of the temperature readings.

Reference: EU GDP 3.3

17. Inspectors' Comments:

4.1 The company are to review the licensed activities authorised at the site of inspection. 'Narcotic or Psychotropic products' has been authorised on the licence; however, storage and wholesale of such products do not take place. Please confirm for the internal variation to be applied to remove this activity.

4.2 The company are to update their processes on environment control to reflect the change from [redacted] to [redacted]

Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: **Insp GDP 15956/16934323-0002**
Inspection Date: **22/01/2020**
Company: **HEALTHCARE AT HOME LTD**

18. Recommendations:
Continued support of your wholesale dealer's authorisation (WDA(H) 15956) pursuant to Regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916] (a "wholesale dealer's licence") will be recommended to the licensing authority. *Site and authorisation pursuant to Regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916] (a "wholesale dealer's licence") will next be inspected as part of the MHRA's risk-based inspection programme, the frequency of inspection being determined by the nature of the activities the licence holder undertakes and previous compliance history. The risk profile of a company may change over time and consequently provisional re-inspection dates given in this report may change".* The provisional date for the next inspection of this site is [redacted]
19. Summary and conclusions:
Within the scope of the inspection, the company operates in accordance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the Human Medicines Regulations 2012. The GDP certificate reflects the status of the inspected site at the time of the inspection noted above. Inspections of other sites that are named on the licence may cause this certificate to be withdrawn if Regulatory action against the licence is taken by the Licensing Authority.

20. The inspection report should be signed and dated by the Lead Inspector:
Name: [redacted] **Signature:** [redacted] **Organisation:** MHRA **Date:** 28/10/2020 Distribution of Report: [redacted]