Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

GDP INSPECTION REPORT

WDA(H) No: 15956 / 18500626

HEALTHCARE AT HOME LIMITED

ISSUED BY:

[redacted]
Senior GDP Inspector

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File Ref: **Insp GDP 15956/18500626-0002**
Inspection Date: **17 June 2019**
Company: **HEALTHCARE AT HOME LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 15956/18500626-0002

2. Inspected site(s) and contact details:

HEALTHCARE AT HOME LIMITED
107 STATION STREET
BURTON-ON-TRENT
DE14 1SZ

M[redacted]
Telephone: [redacted]
Email: [redacted]
Variation to remove [redacted]
Add [redacted] as a Responsible persons.
Remove 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market from all sites

3. Authorised operations:

- ☒ Procurement
- ☐ Holding
- ☐ Supply
- ☐ Export
- ☐ Brokering
- ☐ Other activities: (please specify)

4. Inspection date(s):	17 June 2019

5. Inspector(s):

Name(s) of the Inspector(s).

[redacted]

MHRA

6. References:	Wholesale Distribution Authorisation Number WDA(H) 15956

7. Introduction:

Business Background

Healthcare at Home were primarily a home delivery service delivering medicines and medical equipment throughout the UK to 1.4m patients in their homes.

The company employed approximately 1500 staff including 800 nurses and pharmacists.

The national Distribution centre is based close to this new site, at Fifth Avenue, Centrum 100 Business Park in Burton Upon Trent, which handled some [redacted] orders daily.

Wholesale activity was limited to a small number of high value products sourced directly from the manufacturers. Wholesale represented approximately [redacted] of the turnover.

WDA(H) categories:

MEDICINAL PRODUCTS

☒ with a Marketing Authorisation in EEA country(s)

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

☐ 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: 06 November 2018

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

Previous inspection findings relating to the quality system and the qualification of suppliers and customers had not been adequately addressed.
The business model had been simplified by the relocation of [redacted] activity.
The effectiveness of recall arrangements had been tested.

Major changes since the previous inspection:

CAR received
Changes to key staff
Wholesale activity for [redacted] transferred to HaH BV 25 March 2019
Deviations 1117, CAPA 147, Change Controls 63.

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:
Procurement, 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**

  At the time of inspection, the Quality System was still under remediation. A number of SOPs were held in draft status and the corresponding work instruction had not been updated.

  SOPs retained references to business models and customer types which were no longer part of the service offering e.g. [redacted] Import / Export activities and the handling of [redacted] consignment stock.

  Procedures relating to wholesale activities required urgent management review as up to 12% were in breach of the company's KPI targets for completion.

  Wholesale procedures had not been amended to reflect the reclassification of [redacted]

  The application for a variation had been made for GSL only

  The role of the Responsible Person(s) in authorising all GDP related activities was not made explicit within the quality system.

  The centralised ISO 9001 system incorporated change control, deviation capture, CAPA reporting and management review.

  This site covered complaints handling, invoicing logistics support, procurement, supplier and customer qualification and recalls.

  KPI s were reportedly reviewed every month and supported by monthly and weekly governance meetings.

- **Personnel**

  Following significant changes to key personnel, all staff had not completed GDP awareness training.
  There was no assessment of the effectiveness of training / staff competency in relevant SOPs.
  It was not possible to trace which version of SOP staff had been trained to.

- **Premises and Equipment**

  The premises consisted of a large shared office site which acted as a central Head Office procurement and administration site for Healthcare at Home pharmacy and wholesale operations.

- **Documentation**

  SOPs were subject to formal document control, version control and authorisation by the RP.
  Documentation was accessible to staff on sharepoint.
  Arrangements to prevent inadvertent use of obsolete procedures, documents, forms etc were in place.
  Records were seen to be made contemporaneously.
  Stock history, transactions and invoices were readily available.
  Retention periods were stated to be 5 years.

- **Operations**

  Key operations were generally described in the Quality System which included appropriate supporting documentation.
  The qualification of suppliers and customers was not being conducted in accordance with GDP requirements e.g. the frequency of checks required against suspended and revoked licences.
  There was no formal procedure in place for the Responsible Person(s) to approve all wholesale suppliers and customers.
  The Responsible Person(s) was not involved in the approval of new product introductions for wholesale.
  There were no procedures in place to monitor and report unusual stock transactions for products which may be subject to falsification, diversion or abuse.
  Full audit trails were in place.

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

  The RP had responsibility for monitoring and recording complaints, reviewing CAPA records and determining the final disposition of returns.
  Complaints procedures distinguished between complaints of a service/ distribution nature and those relating to Product Quality issues.
  The was no time specific returns policy for ambient and cold chain products.
  The returns procedure did not describe the role of the Responsible Person in authorising the final stock disposition for customer returns.
  The test recall had not been reviewed in accordance with the SOP.
  Records of all recall alerts were maintained, including those with a negative outcome.
  A test of the effectiveness of the recall procures had been conducted
  There was an awareness of Falsified medicines, segregation and reporting requirements.
  The reporting procedures incorporated links to the MHRA 'Yellow Card' on line reporting system.

- **Outsourced Activities**

  The technical agreement in place with [redacted] had not been reviewed or updated since it came into effect in May 2015.

- **Self-Inspection**

  Self-inspection arrangements were in place. Self-inspections were conducted on an annual basis and recorded.
  Self-inspections covered most aspects of GDP and incorporated reviews of deviation reports CAPA input, change control and follow up.
  The company were also subject to MHRA PV and GPhC inspections.

- **Transportation**

  Transport arrangements included the use of temperature controlled dual chamber vehicles which were leased and maintained by Healthcare at Home.

  The drivers were contracted from [redacted] who provided training – arrangements were under review.

  The logistics team monitor temperatures during transport.

- **Specific Provisions for Brokers**

  N/A

13. Other specific issues identified:
Security arrangements were discussed during the inspection INC [redacted]-Theft of 1,450 various types of medicines from a cold chain fridge within the depot in [redacted] Theft reported to CRC on 06/01/2019. INC [redacted]-Theft of 12x [redacted], 4x [redacted] 4x [redacted] 4x [redacted] 4x [redacted] 4x [redacted], 12x [redacted] 56x [redacted] 1x [redacted]). Theft reported to CRC on 01/03/2019.
14. Miscellaneous:
N/A
15. Annexes attached:
N/A

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

1 CRITICAL

None observed

2 MAJOR

2.1 The Quality System was deficient in that:

2.1.1 At the time of inspection, the Quality System was still under remediation. A number of SOPs were held in draft status and the corresponding work instruction had not been updated.
2.1.2 SOPs retained references to business models and customer types which were no longer part of the service offering e.g. [redacted] Import / Export activities and the handling of [redacted] consignment stock.
2.1.3 Procedures relating to wholesale activities required urgent management review as up to 12% were in breach of the company's KPI targets for completion.
2.1.4 Wholesale procedures had not been amended to reflect the reclassification of [redacted]
2.1.5 The application for a variation had been made for GSL only
2.1.6 The role of the Responsible Person(s) in authorising all GDP related activities was not made explicit within the quality system.

3 OTHER

3.1 Personnel – staff training was deficient in that:

3.1.1 Following significant changes to key personnel, all staff had not completed GDP awareness training.
3.1.2 There was no assessment of the effectiveness of training / staff competency in relevant SOPs..
3.1.3 It was not possible to trace which version of SOP staff had been trained to.

(EU GDP References: 2.3, 2.4)

3.2 Operations – Qualification of suppliers and customers was deficient in that:

3.2.1 The qualification of suppliers and customers was not being conducted in accordance with GDP requirements e.g. the frequency of checks required against suspended and revoked licences.
3.2.2 There was no formal procedure in place for the Responsible Person(s) to approve all wholesale suppliers and customers.
3.2.3 The Responsible Person(s) was not involved in the approval of new product introductions for wholesale.

(EU GDP References: 5.2, 5.3)

3.3 The arrangements for returns and recalls were deficient in that:

3.3.1 The was no time specific returns policy for ambient and cold chain products.
3.3.2 The returns procedure did not describe the role of the Responsible Person in authorising the final stock disposition for customer returns.
3.3.3 The test recall had not been reviewed in accordance with the SOP.

(EU GDP References: 6.3, 6.5)

3.4 The control of outsourced activities was deficient in that:

3.4.1 The technical agreement in place with [redacted] had not been reviewed or updated since it came into effect in May 2015.

17. Inspectors' Comments:

[redacted] are approved as Responsible Persons.

18. Recommendations:

Your application for variation to a wholesale dealer's authorisation [15956] granted 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.

Continued support of your wholesale dealer's authorisation (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 *June 2022*.

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.

20. The inspection report should be signed and dated by the Lead Inspector:

Name:

[redacted]

Signature:

[redacted]

Organisation:

MHRA

Date: 29 November 2019

Distribution of Report: