Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 15956/362464

HEALTHCARE AT HOME LIMITED

ISSUED BY:

[redacted]

GDP Inspector

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Medicines & Healthcare products Regulatory Agency

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File Ref: **Insp GDP 15956/362464-0004**
Inspection Date: **07/11/2018**
Company: **HEALTHCARE AT HOME LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 15956/362464-0004
2. Inspected site(s) and contact details:	
HEALTHCARE AT HOME LIMITED FEATHERSTONE DISTRIBUTION SITE JUNCTION CLOSE GREEN LANE INDUSTRIAL PARK FEATHERSTONE WF7 6ER UNITED KINGDOM Mrs [redacted]	
3. Authorised operations:	
☐ Procurement ☒ Holding ☒ Supply ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	07 November 2018
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number: WDA(H) 15956

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7. Introduction:

Business Background

Healthcare at Home (HaH) are primarily a home delivery service delivering medicines and medical equipment throughout the UK to 1.4m patients in their homes. They employ approximately 1500 staff including 800 nurses and pharmacists. The national Distribution centre is based at Fifth Avenue, Centrum 100 Business Park in Burton Upon Trent, which handles some [redacted] orders daily. Approx. [redacted] of the turnover can be attributed to wholesale deliveries. There is no difference in logistical throughput between the dispensed and wholesale orders (other than the home deliveries go via a pharmacy dispensing stage prior to packing). Both wholesale and home deliveries are managed in the same way on the same vehicles once they have left the Burton depot. There are 15 sites on the licence. Approximately [redacted] medicinal lines are wholesaled, mainly to clinics and hospitals. There are two main distribution sites, one in Featherstone and one in Burton on Trent, and one head office in Burton on Trent, with 12 cross docking sites.

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: 15 July 2015

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

Issue resolved.

Major changes since the previous inspection:

New CEO and reorganisation of the quality team.

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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**

  RP oversight visits are not recorded. Centralised CAPA, change control and deviation system in place, see section 16 below.

- **Personnel**

  A new CEO, Darryn Gibson joined the organisation on 01 June 2018 and [redacted] was appointed as Group Operations Director on 01 July 2018. There has been a reorganisation of clinical logistics to drive quality and [redacted] now reports directly into the Director and CEO. There is an annual GDP e-learning training package that is rolled out to all staff. Driver training undertaken by [redacted] is against a training package designed by HaH.

- **Premises and Equipment**

  Leased site approximately 3200 sq. used for storage, pick, pack and distribution throughout the UK. There was a pharmacy on site (registration number 1092334), licenced with the GPhC for the procurement and distribution of schedule 4 controlled drugs. The main warehouse contained a goods in area, storage area with metal and plastic racking. A large walk in cold room alarmed with a continuous monitoring system in place. There was a maintenance contract with [redacted] who also maintained the air conditioning unit. Temperature monitoring was conducted via a [redacted] with maximum and minimum recording evidenced on a daily basis, the system was fully calibrated. Temperature mapping had been conducted by [redacted] IT functions at 107 Station Street, Burton on Trent. Electronic quarantine and quarantine cage available. Fast action door issue logged through non-conformance. [redacted] in place. Audible

alarms on cold chain equipment; 2.5°C – 7.5°C, and ambient 15.5°C – 24.5°C. Pharmacy in the middle of the warehouse on the carpeted area.

- **Documentation**

  [redacted] is used for stock control and invoicing. SOP revision every two years; the author can reduce the review period. Live view in [redacted] Procedures are available on SharePoint and unauthorised once printed. Server back up of data.

- **Operations**

  Wholesale product trunking network to Featherstone distribution centre. Products come in pre-packed with their labels for onward distribution.

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

  Recalls and returns dealt with at the Burton on Trent site.

- **Outsourced Activities**

  Contract with [redacted] n place for the provision of fleet drivers, handled at head office.

- **Self-Inspection**

  Depots audited once a year, ad hoc site visits throughout the year are not recorded.

- **Transportation**

  A transit van was demonstrated; [redacted] with audible alarm for driver. Transport is in duel chamber vehicles that are leased and serviced by Healthcare at Home. Drivers are contracted out and provided and trained by [redacted] Vehicles are monitored, and drivers are required to ensure the vehicles have reached require temperatures prior to loading and are required to hand the data back to a lead driver at the return of the vehicle. These logs are sent back to head office where they are retained. The logistics team receive and act on the notification of any temperature excursions. There is a schedule of cleaning and maintenance. Calibration certificates provided by [redacted] of temperature monitoring equipment within the fleet vans did not guarantee calibration within the accuracy as required by GDP.

- **Specific Provisions for Brokers**

  N/A

13. Other specific issues identified:
A potential three-way T/A arrangement with [redacted] was discussed in relation to stock holding at [redacted] in the Netherlands. [redacted]
14. Miscellaneous:
N/A
15. Annexes attached:
None.

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

Site inspected alongside the new 107 Station Street site (18500626), one PIL sent for both sites.

1 CRITICAL

None observed.

2 MAJOR

None observed.

3 OTHER

3.1 Historical evidence of appropriate qualification and approval of suppliers, including that the supplier complies with the principles and guidelines of good distribution practices and that they hold an authorisation, had not been recorded or periodically rechecked according to a written procedure until very recently.

EU GDP Chapters 4 and 5, sub-sections 4.2 and 5.2

3.2 There was no schedule in place to capture 12-month rechecks of wholesale customers to ensure that they remain authorised and in possession of a wholesale distribution authorisation or entitled to supply medicinal products to the public, in line with the 12-month re-verification period stated by the company's procedures.

EU GDP Chapter 5, sub-section 5.3

3.3 Calibration certificates provided by [redacted] of temperature monitoring equipment within fleet vans did not guarantee calibration within the accuracy as required by GDP.

EU GDP Chapters 3 and 7, sub-sections 3.3 and 7.2

3.4 The quality system was deficient in that:

3.4.1 it did not include procedures to handle items 1.2 on the WDA(H) licence; 'without a marketing authorisation in the EEA and intended for EEA market';

3.4.2 ad hoc site visits to other branches by the Deputy RP were not routinely recorded or documented;

3.4.3 the rationale behind the attribution of low, medium and high risk to change control issues was not evident. It was not clear whether someone other than the initial requester assessed the low/medium/high risk for relevance and agreement, and what these categories meant;

3.4.4 there appeared to be a grey area with how non-conformance issues are triaged and followed up through the CAPA process to conclusion, for example, a recent self-inspection had identified that chilled products were being labelled in an ambient area at the Featherstone Distribution site. This non-conformance had been assigned to a category B non-conformance. There was no clarity with regards to what the categories A, B or C meant and it was not clear what, if anything, had been done since this observation was made, and whether any risk assessment to these products had been undertaken.

EU GDP Chapter 1, sub-sections 1.2, 1.4 and 1.5

3.5 The effectiveness of the arrangements for product recall did not appear to have been challenged in anger, and receipt of negative recalls were not recorded. *Please confirm that date of the last wholesale test recall in your response to this letter.*

EU GDP Chapter 6, sub-section 6.5

17. Inspectors' Comments:
N/A
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 2022.
19. Summary and conclusions:
Within the scope of the inspection, the company operates 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.

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20. The inspection report should be signed and dated by the Lead Inspector:
Name: [redacted]
Signature: [redacted]
Organisation: MHRA
Date: 28/11/2018
Distribution of Report: Case folder and site; [redacted]