Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 15956/18500626

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 15956/18500626-0001**
Inspection Date: **06/11/2018**
Company: **HEALTHCARE AT HOME LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 15956/18500626-0001
2. Inspected site(s) and contact details:	
HEALTHCARE AT HOME LIMITED 107 STATION STREET BURTON-ON-TRENT DE14 1SZ UNITED KINGDOM [redacted]	
3. Authorised operations:	
☒ Procurement ☐ Holding ☐ Supply **Required** ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	06 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 close to this new site, 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. This was a variation to add this this site to the licence as an admin only site. In effect, this is now the head office site, with warehousing still undertaken at Centrum 100 Business Park. Approximately [redacted] medicinal lines are wholesaled, mainly to clinics and hospitals. HaH are looking to become a third-party warehouse for [redacted] next year on a consignment model.

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: N/A

Date of last inspection: N/A

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

N/A

Major changes since the previous inspection:

New CEO and reorganisation of the quality team.

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8. Scope of Inspection:
Initial inspection of new admin site 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; Procurement 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**

  See section 16 below. There was a centralised CAPA Change Control and deviation system in place. This site covers; complaints, QMS, billing, logistics support, procurement, customer verification, recalls and HR. 2017 ISO 9001 accreditation. GDP non-conformances raised are reviewed by [redacted] team [redacted] quality staff members). KPI reviews every month and indirect verification assessments monthly; CAPA, complaints etc. Monthly and weekly governance meetings.

- **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**

  See section 16 below. This is an admin only site, all other sires are warehouse/pharmacy/storage. Shared building; 50% of ground floor and all of level 2.

- **Documentation**

  [redacted] is used for stock control and invoicing. All wholesale procurement is done from this site. SOP revision every two years; the author can reduce the review period. Live view in [redacted] Sales orders are raised into Sage by CPS team and an electronic purchase order is raised to the supplier. The procedures are available on SharePoint and unauthorised once printed.

- **Operations**

  See section 16 below. Administration for wholesale orders is managed at this site as part of logistics support. Schedule 4 medicines wholesaled but the Home Office licence does not cover this site. This may be required as a procurement site with the Home Office; HaH to check. Customers that haven't ordered in six months are put on hold, and rechecked when their next order is placed.

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

  See section 16 below. A recall exercise was submitted with the response to the post inspection letter. Recalls are centrally managed by the Chief Pharmacist, [redacted] Patient safety incidents to be logged onto CRM system and potential impact/risk to the patient goes through triage.

- **Outsourced Activities**

  Contracts with [redacted] and [redacted] in place. Issues with the temperature calibration of the probes used in the vans, undertaken by [redacted]

- **Self-Inspection**

  All aspects of GDP are looked at on an annual basis throughout the year on an audit schedule. There are six BSI trained auditors available. Company heavily audited by customers, Pv and GPhC.

- **Transportation**

  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:
Review of the licence across all sites required.
14. Miscellaneous:
N/A

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15. Annexes attached:
N/A

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

Site inspected alongside the Featherstone distribution site (362464), 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:
Temperature data recorded for items sent by [redacted] deliveries was reportedly available but not routinely collected. As these items tend to be cold chain and high value lines, it would be best practice to record this data. An example of a delivery of [redacted] was discussed at the time of the inspection.
18. Recommendations:
Your application for variation to a wholesale dealer's authorisation [WDA(H) 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. 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 2020, as this site is now essentially acting as the head office.
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]