Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GDP INSPECTION REPORT

WDA(H) 15956/18074392

HEALTHCARE AT HOME LIMITED

ISSUED BY:

[redacted]

GDP Inspector

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File Ref: **Insp GDP 15956/18074392-0001**
Inspection Date: **25/01/2018**
Company: **HEALTHCARE AT HOME LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 15956/18074392-0001
2. Inspected site(s) and contact details:	
HEALTHCARE AT HOME LIMITED UNIT 20 DARKLAKE PARK DARKLAKE VIEW ESTOVER PLYMOUTH PL6 7TL UNITED KINGDOM	
3. Authorised operations:	
☐ Procurement ☒ Holding ☒ Supply ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	25/01/2018
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

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7. Introduction:

Business Background

This is a branch depot of Healthcare at Home which was previously at Unit 7, 53 Sisna Park Road but has relocated to this site the company started operating from this site at the end of November 2017. The move was performed and site active prior to the approval of the site by the MHRA. The site operates according to customer request as much as possible and site is a transit shed with the products being trunked from Burton Upon Trent overnight to be delivered into Plymouth which are then delivered using the 5 vehicles that operate from the site.

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: First inspection for this site.

8. Scope of Inspection:

Initial 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, Supply.

10. Activities not inspected:

Procedures and technical agreements have been reviewed recently in other inspections and this inspection focussed predominantly on areas relevant to this location.

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11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

  The quality system is centralised at Burton and can be accessed through the companies DMS system but hard copies of relevant procedures were also being maintained on site. Any quality related activity is reported back to the LST (Logistics Support Team) based in Burton who then maintain any records of action taken. See findings in PIL.

- **Personnel**

  There are[redacted] full time drivers and[redacted] ead drivers based on site. Individuals are trained based upon a basic matrix which contains a mix of web based packages and procedures. Re-training moving forward will be similarly based and controlled through the QMS. There is a dedicated training provider ([redacted] for any classroom based training who is based out of the Burton site. Training matrix was not reflective of the current approved procedures.

- **Premises and Equipment**

  Modern warehouse unit 332 sq. m. with large loading doors with a large purpose built cold store and ambient area for any stock that will be held prior to shipping or for return to Burton.

[redacted]

Inside the cold store there are two chiller units and 4 electronic temperature sensors located at mid height level Internal space inside the ambient area, both the ambient and fridge areas had specific areas for quarantine.

Temperature monitoring systems is electronic ([redacted]) and is set with an audible alarm in the unit and the set-points of the alarms were demonstrated on the system. Temperature mapping had been performed of the area.

- **Documentation**

  Controlled procedures are held on site. All supply activity is controlled electronically and records retained centrally. Example of procedures that had been superseded were still available for the staff, all documentation relating to the delivery is sent back to Buxton to be reviewed and archived.

- **Operations**

  Local operations are confined to distribution activity. Deliveries are trunked to site, arriving in the early morning. Each van run is pre-sorted prior to arrival and is held in the cold room or controlled ambient are as required. The drivers load their deliveries after a second QA check and deliver them throughout the day.

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

  These activities are managed centrally at Burton. All returns flow back down the supply chain to Burton.

- **Outsourced Activities**

  The arrangement for the outsourcing of drivers was reviewed in detail in July 2017 at the Burton office. Staffing is outsourced but all activity takes place under the umbrella of the Healthcare at Home QMS.

- **Self-Inspection**

  Self-inspection had been performed of the previous site in February 2017 but QA did not have any oversight of this. The plan for self-inspection was still in draft and to be approved.

- **Transportation**

  [redacted] Vehicles are leased for this site. They are monitored by probes which are fed back into the system via [redacted] The [redacted] system tracks each vehicle and it is possible to see position and speed of any vehicle along with the eta at the next scheduled drop.

  Journey tickets are taken from each vehicle at the end of each daily run that are stored in the transport department in Burton. This paperwork was not available during the inspection.

13.	**Other specific issues identified:**
14.	**Miscellaneous:**
15.	**Annexes attached:**

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

1 CRITICAL

None

2 MAJOR

2.1 Incorporation of and assessment of the site move was not documented to an appropriate level with a lack of RP oversight to ensure the accuracy and quality of the records.

1. Change control was not fully documented.

- Change control had not been raised in a timely manner with no recorded impact assessments and CAPA actions documented.
- There was a lack of appropriate identification of tasks to ensure that actions for the new site move were appropriately identified, tracked and resourced.
- Appropriate risk assessments of the site had not been completed.
- Identified action for calibration of the fridge sensor was found to have been completed in January 2018 after the move and after operations had started in November 2017.

2. Companies CAPA tracking system was found to not have been maintained with no comments for actions taken and outstanding actions noted from as far back as October 2016.
3. Non-Conformance Reports for temperature deviations were found be lacking detail with no assessments on the impact on product quality with some forms with missing entries.
4. Superseded document was found to still be available with all the valid and approved procedures in the company's SOP folder.

EU GDP 2013/C 343/01 Sub-section 1.2, 1.5, 2.2 and 4.2

2.2 Medicinal products were being held in premises other than those named on WDA(H) 15956. It is understood that Healthcare at Home have been occupying and operating from these premises since November 2017. This is in breach of provisions laid out in UK legislation.

The Human Medicines Regulations 2012 [SI 2012/1916] Regulation 18

3 OTHER

3.1 Training was deficient in that the records for training had not been maintained. Training records were reviewed and it was found that some drivers had not been trained in the current valid and approved procedure.

EU GDP 2013/C 343/01 Sub-section 2.4

3.2 Self-inspections were deficient in that:

1. The recent self-inspection report for the site had not been reviewed by the RP to ensure necessary corrective actions are put into place.
2. There was no prearranged programme in place for the self-inspection activities.

EU GDP 2013/C 343/01 Sub-section 8.2

4 COMMENT

The RP was not in attendance for the inspection but was available on the phone.

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17. Inspectors' Comments:

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 04/01/2021

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:** 26/01/2018 Distribution of Report: [redacted]