Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 56454/36097517
&
WDA(H) 56454/36097552
&
WDA(H) 56454/27764294

TARGET HEALTHCARE (WHOLESALE) LIMITED

ISSUED BY:
[redacted]
Senior 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.gov.uk

Medicines & Healthcare products Regulatory Agency

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File Ref: **Insp GDP 56454/36097517-0001**
Inspection Date: **20/05/2024**
Company: **TARGET HEALTHCARE (WHOLESALE) LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 56454/36097517-0001
2. Inspected site(s) and contact details:	
Target Healthcare (Wholesale) Limited 19 Glenburn Road East Kilbride Glasgow G74 5BA United Kingdom	
3. Authorised operations:	
☐ Procurement ☒ Holding ☒ Supply ☐ Export ☐ Products imported from countries on a list ☐ Products certified under Article 51 of Directive 2001/83/EC ☐ Products not certified under Article 51 of Directive 2001/83/EC ☐ Other activities: (please specify)	
4. Inspection date(s):	20/05/2024
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 56454

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7. Introduction:

Business Background

The company were a wholesale dealer who purchased branded and generic products from predominantly manufacturers (>90%) for supplies to pharmacies (>90%) and other wholesalers. The customer base was predominantly pharmacies within the [redacted] with occasional supply further afield in [redacted]. At the time of the inspection~30% of supplies was delivered to [redacted] however due to Target Healthcare[redacted] gaining a wholesale licence this was decreasing.

Review of WDA(H)

MEDICINAL PRODUCTS

☒ With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

☐ Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

☐ Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

☐ With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

Medicinal products with additional requirements

☐ Narcotic or psychotropic products

☐ Medicinal products derived from blood

☐ Immunological medicinal products

☐ Radiopharmaceuticals (including radionuclide kits)

☐ Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

☐ Medicinal gases

☐ Cold chain products (requiring low temperature handling)

☐ Other products

Date of previous inspection:

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

Date of last inspection: 08/12/2022

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

Majors against QMS and personnel

Major changes since the previous inspection:
New warehouse and admin office

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8. Scope of Inspection:
Variation inspection assessing compliance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use and the Human Medicines Regulations 2012.
9. Inspected activities:
GDP Inspection of all GDP activities, operations, records and documentation under the licence pertaining to this site; Procurement, 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**

  There was a quality management system in place that was generally reflective of the ongoing business model with processes in place for deviations, CAPAs and change controls.

  Change control [redacted] was documented during the inspection a demonstrated good control over the majority of factor identified for the addition of the [redacted] sites. However not all procedures had been updated to reflect this change, as [redacted] Warehouse temperature Mapping and Monitoring, was found to only refer to the original site, as did [redacted] Falsified Medicines.

  Monthly management review meetings were taking place which included monitoring a series of KPIs. These KPIs were raw numbers and included no consideration for levels at which action would be required.

  Risk assessment [redacted] was raised for the use of pallet covers at the new site at [redacted] The original risk identified was the lack of protection from prevailing weather conditions. This scored 32 on a 3 fold (1-5 scale) FMEA model. The use of pallet covers reduced the risk to a new score of 12. [redacted] Goods In, was altered to reflect the new use of the covers. The SOP only reflected the use at the original site and not the new one.

  Deviation [redacted] was raised regarding an old customer account form still being in use. This led to [redacted] The [redacted] had copies of new customer account forms that they would use to sign customers up with for the company, however these were forms that had been superseded. There was limited overall knowledge regarding the extent to which QMS elements were external to the company. Document control within the company was generally compliant with no locally saved documents.

  Risk assessment [redacted] was raised 26/01/2024 and close 29/01/2024 covering the use externally of a controlled document, however at the tie of the inspection there had been no CAPA raised or further action taken.

  Deviations [redacted] leading to [redacted] was raised following the failure of [redacted], created 09/22/2023, to create a more robust system for printing labels to reduce to possibility of operators selecting an incorrect delivery address. The company had tried to create an address book to upload to [redacted] website, which failed

with the new system being based upon a barcode which would pull from an internal system to populate the [redacted] website.

Deviation [redacted], raised 19/12/2023, was raised due to the delivery of medicinal products to a [redacted] to the intended pharmacy. A complaint was also received for the misdelivery, [redacted] 07/11/2023. The [redacted] delivered the stock to the pharmacy following the misdelivery.

Change control [redacted] was raised to document the need to create an SOP to define the obligations of the licence holder, with [redacted] documenting the obligations of the licence holder and [redacted] computerised systems fully describing the current IT systems.

- **Personnel**

  There was approximately 50 people within the company, comprising mainly of warehouse staff, with 6 people within the QA teams and a further 6 focusing on procurement and supply. The Glenburn Road site would usually be operated with a maximum of 2 members of staff. Staff members involved within quality had received training had been on external courses and symposium, with GDP consultants also coming to perform training at the companies premises.

  Individuals within the company had their own training account with individual modules attributed to them in a matrix style. A training list on SOPs was maintained. Any certificates from external courses was kept separately within the system. During the inspection it could not be fully evidenced that there was full evidence of ongoing professional development.

  There was a quality technical agreement in place for the provision of [redacted] as a contract RP within the business that appeared to cover all necessary areas and was signed on 27/09/2022.

- **Premises and Equipment**

  19 Glenburn Road (Site ID 36097517) The site was an industrial unt which had been equipped for the storage of medicinal product. The site had a HVAC system installed and fans for additional distribution of the air. There had been racking installed for the storage of palletised medicinal products with ~400 pallet space for storage, 45 for goods in and 31 for goods out. There were 15 permanent temperature loggers in place which were connected to a [redacted] The site was secured with a CCTV system, gated site access, site access control and monitored alarm systems. There was a gated rear yard for deliveries and collections. There were 2 other storage warehouses within the larger unit but these were not for the storage of medicinal products. The site operated 9am-5pm 5 days a week. Outside the building there was no protection from the elements provided for deliveries or collections by a canopy or similar structure.

  Orbital House, 3 Redwood Crescent (Site ID 36097552) this site was a modern serviced office unit with access to the office restricted by fob access.

  8 Redwood Crescent (Site ID) The site comprised of ~6,000ft2 of warehouse space and included office and meeting space. The warehouse was equipped with 10 air conditioning units and fans for air mixing. There was 15 temperature monitoring locations within the warehouse. The site was secured with a CCTV system, alarms and access control. The site operated approximately 20 hours a day Monday to Friday with it being open on Saturday morning for collection of orders for delivery. On the external side of the building where delivery vehicles were loaded a canopy had been created between 2 shipping containers. The warehouse was generally clean and tidy.

  A [redacted] temperature monitoring system was in place across both warehouses. A temperature fallout for a single logger was seen within the system on 28/02/2024 for the Glenburn Road site, however when the connection was re-established then the data was uploaded to the system.

  8 Redwood Crescent was temperature mapped by [redacted] over the period 11/01/2024 to 18/01/2024. Generally across the warehouse the temperatures were complaint. There were 2 temperature drops observed within the data with the cause not being attributed to in the report. Over the final 2 days of the data the goods in area saw drops as low as 5.6°C. This was verbally attributed to the external cold temperatures during the mapping exercise and multiple deliveries being received. The outside temperature monitor failed to record during the mapping exercise and as a result there was no outside temperature reference to demonstrate that

it had been performed under representative conditions. There was no comment within the mapping report of the locations of permanent loggers prior to the exercise or if any movement had occurred as a result of the mapping.

[redacted] performed a temperature mapping exercise on the Glenburn Road site over the period 11/01/2024 to 18/01/2024. The temperatures generally showed compliance with steady readings. Two short periods where temperatures dropped to 9°C had not been commented upon in the report. The location of the permanent loggers had not been captured either within the temperature mapping report or the change control [redacted] for the addition of the new site to the licence.

Risk assessment [redacted] had been produced for the remapping of the warehouses on an 18 month cycle.

- **Documentation**

  SciLife was the cloud based [redacted] a cloud based temperature monitoring system ad Microsoft Business Central was a cloud ERP system for customer and supplier control and inventory control.

- **Operations**

  At the time of the inspection the company had qualified 121 suppliers and 1903 customers, not all of these were live. [redacted] had their qualifications checked and were found to be complaint.

  The company planned to operate with full pallets at the Glenburn Road site with stock fed into 8 Redwood Crescent.

  Medicines disposal was documented in a medical disposal log. [redacted] was looked at and covered the period 26/03/2024 to 23/04/2024. It contained an Excel download from Business Central with all items contained within listed.

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

  The company experienced a returns rate of 0.07% of lines against the number of lines supplied, with the majority of the reasons been that the items being returned were ordered in error. Returns [redacted] were present in the warehouse during the inspection and appeared to be proceeding compliantly.

  A mock recall was performed on 10/01/2023 for [redacted] with the accompanying report stating the 25 had been purchased, 12 sold and 13 remaining. The purchase and sales data had been pulled from Business Central, however this evidence was not presented in it's primary form at any point. The customers who had purchased the products were informed that they would receive an automated email from the company's Business Central system as part of the recall and that it was to be ignored. The recall was signed off on 01/02/2024.

- **Outsourced Activities**

  See chapters 2 and 9.

- **Self-Inspection**

  There was a self-inspection process in place with 16 specific areas identified. S127, complaints, recalls, returns, quarantine and disposal, and S125, quality risks management were both inspected having been performed in the last 12 months and seemed to cover most areas within their scope.

- **Transportation**

  Transport was outsourced to the wider Target Healthcare group for deliveries to pharmacies within the central belt region of [redacted] was used for deliveries to pharmacies outside of this region and [redacted] for pallet deliveries. Deliveries to [redacted] were done via ferry, but with the [redacted] business now established this will be reducing as an area of activity.

There was a quality technical agreement in place with Target Healthcare Group for the provision of transportation services. This agreement was signed 24/08/2023. An audit was performed 21/02/2024. Deviation [redacted] was raised as 6 issues were identified.

[redacted] was raised for issues raised with the use of [redacted] This was predominantly where 8 boxes of a 9-box order were delivered on a Saturday with the last box delivered on the following Monday. This box was reported as missing on the Monday morning prior to it being delivered later that day. There was no confirmation that the customer [redacted] was contated regarding the issue.

A deviation was raised for the use on [redacted] where the company had failed to validate them prior to their use, but there was no points raised to rectify this.

- **Specific Provisions for Brokers**

  N/A

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

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

1 CRITICAL

None

2 MAJOR

None

3 OTHER

3.1 **The Quality Management System was deficient in that:**

3.1.1 The procedures were not reflective of the business model as they only referred to a single site, and not all named on the licence.

3.1.2 [redacted] failed to cover to full scope of required operational changes, including but not limited to the sites impacted.

3.1.3 The company had failed to implement any mitigation or corrective actions following the creation of [redacted], the failure to pre-qualify [redacted] prior to its use.

3.1.4 [redacted] failed to confirm the fate of stock items following its mis-delivery.

3.1.5 There was a lack of oversight and control evidenced on controlled documents by external companies.

Reference – GDP Chapter 1.2, 1.5 & 4.2

3.2 **Training was deficient in that it could not be evidenced that all key personnel were maintaining their continuing development through regular training.**

Reference – GDP Chapter 2.4

3.3 **Premises and equipment was deficient in that:**

3.3.1 It was not fully evidenced that it had been performed under representative conditions, including but not limited to referencing the external temperature.

3.3.2 Temperature mapping reports failed to have a clear conclusion regarding the permanent locations of monitoring locations.

Reference – GDP Chapter 3.2.1

3.4 **Recalls were deficient in that it could not be fully evidenced that a full reconciliation could be performed.**

Reference – GDP Chapter 6.5

4 COMMENT

None

17. Inspectors' Comments:
N/A
18. Recommendations:
Your application for variation to a wholesale dealer's authorisation [WDA(H) 56454] granted pursuant to Regulation 18 of the Human Medicines Regulations 2012 (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 (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 20/05/2027
19. Summary and conclusions:
Within the scope of the inspection, the company operates/does not operate in accordance with the principles of good distribution practice referred to in regulation C17 of 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: 10/06/2024
Distribution of Report: