Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 35184/7837

LAXMICO LIMITED
T/A B&S Distribution

ISSUED BY:

[redacted]

Lead Senior GDP Inspector

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Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: **Insp GDP 35184/7837-0024**
Inspection Date: **22/06/2022**
Company: **LAXMICO LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 35184/7837-0024
2. Inspected site(s) and contact details:	
LAXMICO LIMITED t/a B&S Distribution 23 WADSWORTH ROAD PERIVALE GREENFORD UB6 7JD 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):	22/06/2022
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number: WDA(H) 35184

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7. Introduction:

Business Background

The business serves some [redacted] customers which are predominantly within England and Wales. There is little coverage in Scotland. The customer base is predominantly pharmacies with some supply to other wholesalers and a handful of dispensing GP practices.

The company operate from a single site in Greenford and run their own fleet of [redacted] temperature controlled vehicles.

Since the previous inspection three cross docking hubs have been introduced [redacted]

The warehouse is 80% automated with an [redacted] system running on the ground floor level.

The company are members of HDA

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: 2/2/2021

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

Following a brief period of suspension, the licence was re-instated after the February 2021 inspection. There were still however 3 major points that required completion. These centred on Training and Personnel, Premises and Equipment and Operations. Sufficient progress was deemed to have been made to assure the inspectors that matters were in hand. The inspectors recommended to IAG following the February 2021 inspection that the licence be re-instated in full

The follow up inspection of 22nd June 2022 which is the subject of this report identified no deficiencies within the operation over the areas inspected.

Structure of companies within the group as follows:

[redacted]

Major changes since the previous inspection:

Site report major changes as follows:

Appointed permanent RP for the site in [redacted]

Strengthening of customer qualification and requalification procedure, including GPhC enforcement action checks and automated monthly checks against national databases

Product Sale Limits for every customer based on their prescription data

Daily and monthly limits imposed for all customers (rolling basis)

Introduction of training questionnaires – two way feedback system

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Improve temperature mapping procedure

Reduction on number of Controlled Documents – major revamp of QMS to make GDP centric

Increase of a new and validated temperature-controlled transport fleet. Including truckers to serve the new cross docking stations

Cross docking centres introduced

Weekly One to One with RP

Daily Escalation meetings with management teams.

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 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, Supply,
10. Activities not inspected:
11. Personnel met during the inspection:
[redacted]

12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

An electronic QMS was in operation. Self-inspections were being carried at 2 levels. Daily escalation processes and monthly QMR meetings were in place.

A change control log was in place and was reviewed for 2021-to inspection date. The log was maintained up to date. Change control records were raised contemporaneously and contained appropriate level of detail. Change control records reviewed:

- [redacted] - raised for the appointment of a new [redacted] opened 9-May-2022.
- [redacted] -raised for the implementation of the cross dock hub in [redacted]
- [redacted] both listed for [redacted] not adding substantial value
- [redacted] - raised for improving of the Recall process- 31-Mar-2022
- [redacted] - raised for the addition of [redacted] as an RP- 24 May 2021
- [redacted] - raised for the authorisation for increasing purchasing limits for lines with short expiry dates stock, opened 27-May-2021
- [redacted] - raised for the addition of purchasing limits- raised 16 November 2021
- [redacted] - raised for the addition of new features on [redacted] - raised 15 December 2021

There was an effective mechanism to manage deviations from implemented procedures. A deviation log in use. Deviation records included close out periods and criticality classification, which were considered suitable.

- **Personnel**

Organogram – B&S Distribution

[redacted]

[redacted] is taking a very active role in the company in terms of Leadership and Development.

[redacted] has been recruited as [redacted] was formerly with the [redacted]

[redacted] has joined as [redacted] and has formerly worked at [redacted]

[redacted] is the [redacted] and has taken the lead in the automation of the validation system for customers and suppliers and the limits and alerts for unusual sales patterns.

[redacted] has been recruited from [redacted] o [redacted]

[redacted] has taken up post and is supported by [redacted] and the QA team

Facilities continue to be under the remit of [redacted]

Some staff have been replaced as a result of the re-structure of the business supporting a tightened GDP focus within this, the distribution arm of the group.

Annual GDP refresher training for all staff had been implemented as well as an annual training on suspicious behaviour for key departments. There were training questionnaires in place to assess efficacy of training. External trainers had also been utilised.

- **Premises and Equipment**

  Storage:

  The warehouse was separated into 2 levels with Goods In processed at Level [redacted] and Goods Out at Level [redacted] There was purpose-built racking in place throughout the warehouse.

  There were dedicated segregation areas for the storage of schedules of controlled drugs, which had additional security measures. Schedule 2-3 controlled drugs were stored in a CD vault. Schedules 4-5 controlled drugs were also subject to segregation and additional security restrictions. FEFO principles were maintained using the bespoke warehouse management system.

  Security:

  The premises were secure with swipecard / fingerprint access in each area. Additional security measures were in place for high-risk areas, such as the controlled drugs storage. The controlled drugs vault was only accessible to authorised personnel; additional padlock and audible alarm upon access.

  Roller shutters were in place. Access for delivery vehicles was pre-booked; a sign off sheet was in place with Security allowing only deliveries that were expected to enter the premises.

  CCTV was in operation with motion sensors at points of access. 24-hour manned security was in operation at the site.

  The warehouse had dedicated storage for cold-chain and for CDs. There were A-frames in place and 2 cold-chain storage rooms (one for storage and one for dispatch). There are CD cages in each of the hubs.

  Temperature mapping was in place with temperature probes located per a temperature mapping exercise.

  Last temperature mapping was conducted in November 2021. The mapping was conducted in the scope of 7 days under normal operating conditions. Temperature monitors with alarms set at 10 and 23 degrees as warnings, and 8 and 25 degrees as actual alarms.

  A hot spot [redacted] was identified. A distinct change of temperature readings in at the hot spot mapping location had not been identified or investigated.

  Next summer mapping scheduled for 2022

Computerised systems

A bespoke IT system, [redacted] was built to automate the qualification and requalification processes for customers and suppliers. Data was mined directly from national databases and compared against a set of rules, which allowed automated identification of any discrepancies within the algorithm. As demonstrated during inspection, the algorithm was able to successfully capture suspensions and revocations of licences in a timely manner.

[redacted] was also used to mine prescribing data which allowed calculation of usage limits by separate customers. Any changes in the prescribing data required manual review and approval of suggestions made by the computer system. This was particularly enforced in relation to supply of controlled drugs to pharmacies to limit stockpiling and reduce the risk of diversion.

- **Documentation**

[redacted] was requested and reviewed this included data as to how failed deliveries would be recorded via the [redacted] handsets and detailed how they were to be handled and returned to depot on the trunkers as well as detailing the interim storage measures on a single vehicle.

The work instruction [redacted] supplemented the procedure and was also reviewed in depth, this being a new function.

There is no active temperature control within the hubs and they are not monitored on the [redacted] system, however all stock is transferred to the delivery vans on arrival of the trunker and any returns are stored within a vehicle with the ambient control running. This vichle whilst plugged in and running the controlled ambient parameters is transmitting to and is monitored by the [redacted] system. The cool boxes and the vehicles are continuously monitored via [redacted] for both temperature and for location.

An alert was notified on vehicle [redacted] on the [redacted] system at 1100hrs on 17/6/2022

This had been captured on deviation [redacted] an impact assessment had been raised for the elevated temperatures and CAPA 22 had been raised.

An engineer had been called but at the time of inspection had not yet visited to investigate. This demonstrates that documentation is being completed contemporaneously and that deviations are being investigated. The vehicle in question had 9 drops yet to make when the alert was triggered and the products were at the time of inspection awaiting a full assessment with regards to their final fate.

The validation data for the vehicle [redacted] – the trunker that services [redacted] was reviewed in depth including the data for one of the two mobile fridge units assigned to [redacted] Set points were 18 degrees for the vehicle and 5 for the fridge.

The test was carried out in April 2022 and included a record of how long the fridge took to reach operating temperature and how long it would hold temperature in an open door situation prior to sounding the alarm

- **Operations**

  The company had at the time of inspection [redacted] active suppliers, which were managed via the Supplier Approval System. The suppliers included WDA(H), MIA holders and non-WDA(H) holders (non-pharmaceutical stock). There were [redacted] active customers, which were primarily pharmacies, some WDA(H) holders and GP surgeries. Verification was carried out using [redacted] and QA verification. Active status was confirmed only after RP approval.

  Requalification checks were done on monthly basis via the automated IT system against national databases.

  New suppliers were being added through the change control process.

  [redacted] was a bespoke customer/supplier management data. Prescribing data was used to calculate prescription levels by different pharmacies/GP surgeries so that limits on orders can be identified.

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

  Recall off [redacted] from 11 April 2022 reviewed. The process was considered robust with the planned improvements to include checks for recalled products in returns being developed.

  Returns were processed by a trained member of staff with delegated RP duties in dedicated returns area. The Returns process was considered suitable for the size of the operation with delegated RP duties for authorisation of returned stock back into saleable inventory. Principles of quality risk management were implemented within the returns process.

  There were quarantine areas for the segregation of stock awaiting decision of final disposition.

  Recalled stock was segregated in a dedicated cage with additional access restrictions to authorised staff only.

- **Outsourced Activities**

  Currently one vehicle is provided by [redacted] his is the trunker used for the [redacted] cross docking facility. The unit owned by B&S Distribution currently under validation is due to take over this route in July/August 2022. The data for the outsourced vehicle was therefore not reviewed.

- **Self-Inspection**

  The lack of adverse inspection findings would indicate the self inspection process to be effective. The actual formal documented process was not reviewed in any degree of depth on this occasion.

- **Transportation**

  The transportation fleet included [redacted] temperature-controlled vans equipped with [redacted] temperature monitoring and GPS tracking systems . 2 temperature-controlled 18 tonne vehicles capable of transporting 16 pallets are currently in use with a further two under validation. The two validated vehicles serve [redacted] cross docking area. The trunker serving [redacted] is on hire from [redacted] and is due to be replaced by one of the two other owned vehicles currently completing validation.

  Each truncker has 2 associated refrigeration units which are globally tracked on the [redacted] monitoring system and are either in transit, at Wadsworth Road awaiting loading or at the Hub awaiting collection of the stock therein by the local delivery drivers.

  Manifests are issued to drivers in both paper and electronic format and are controlled via the handsets which transmits data back to Wadsworth Road

  Any failed deliveries are returned to the hub where they are stored in a single vehicle overnight with the power to the controlled temperature units switched on and monitored for return to Wadsworth Road via the Trunker the following day. The returns are then processed as normal.

The [redacted] emperature controlled vehicles are of two types, the [redacted] with the cool kit installation and the [redacted] modified vehicles. All are alarmed and covered by the [redacted] monitoring system.

There are [redacted] cross-docking facilities in [redacted] currently active with another site in or around [redacted] being finalised.

[redacted] has [redacted] vehicles this depot delivers from [redacted]

[redacted] Routes operate from [redacted] The deliveries go as far north as [redacted] with a once a week service to [redacted] customers

[redacted] routes operate from [redacted] – these cover customers in [redacted]

All cross docking sites have a [redacted] year lease and have been newly refurbished.

The [redacted] site will have [redacted] routes operating.

[redacted] vehicles are operating from Wadsworth Road. These cover sites within the [redacted] and go as far south as [redacted]

Hub Supervisors are trained at Wadsworth Road and training is cascaded to drivers at depot level. All hubs are manned by a supervisor and vehicles are stored within the hub overnight.

Customers are being phased back in with pharmacies in [redacted] not yet being serviced as the [redacted] and [redacted] routes are currently operating from Wadsworth Road.

Picking takes place at Wadsworth Road and trunkers leave at 0200hrs .

Trunker [redacted] that services [redacted] was inspected, the four probes were reading

[redacted]

[redacted]

[redacted]

[redacted]

The vehicle was in the yard parked up. [redacted] information for the probe [redacted] situated within this vehicle for June 1st to 22nd was requested and reviewed.

[redacted] Data for vehicle [redacted] seen returning from the delivery run was requested and reviewed.

Data was accessible as requested and showed no deviations. Data was consistent with activities of the two vehicles as described and with the dat on the [redacted] hand held scanners.

13. Other specific issues identified:

14. Miscellaneous:
15. Annexes attached:

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

1 CRITICAL

None

2 MAJOR

None

3 OTHER

None

17. Inspectors' Comments:
18. Recommendations:
"Continued support of your wholesale dealer's authorisation (WDA(H) 35184) 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 11/06/2025
19. Summary and conclusions:

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Within the scope of the inspection, the company operates 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: 28/06/2022

Distribution of Report: Site; Inspection case file.