Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 42430/19094302

LOGAN PHARMACEUTICALS 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 42430/19094302-0006**
Inspection Date: **13/05/2024**
Company: **LOGAN PHARMACEUTICALS LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 42430/19094302-0006
2. Inspected site(s) and contact details:	
Logan Pharmaceuticals Limited 77 Dunn Street Glasgow G40 3PA 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):	13/05/2024
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 42430

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7. Introduction:

Business Background

The licence holder was a company who procured medicines predominantly for export upon receipt of an order. Medicinal products were procured from a wide range of suppliers including marketing authorisation holders (e.g. [redacted], wholesalers [redacted] and pharmacies with wholesale licences. Current export customer was based in the [redacted] There was ~30 active suppliers and ~24-25 global customers. UK customers included wholesalers such as [redacted] There was irregular supply to pharmacies.

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: 11/02/2022

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

Other around the QMS

Major changes since the previous inspection:
Variation to add 2.6, 2.6a and an RPI, inspected in this inspection.

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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 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 and Export.
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 activities, with procedures in place for deviations, CAPAs and change controls.

  Change control [redacted], raised 27/03/24, was for the addition of RPi activities and the nomination of an RPi to the licence. The electronic folder associated with the change control included records for the training of the new procedure, the updated training matrix, job description for the RPi position, the submission confirmation screenshot, alongside the change control record. Other procedures had been updated to reflect the change.

  There was a global risk assessment in place that appeared to cover most of the major risks to GDP activities, which was updated to include risks associated with the new RPi process.

  [redacted] raised 28/07/2023, resulted from 3 findings in the companies self-inspection which was performed the previous 2 days. The record generally described the findings and the actions to take place following. The CAPA failed to include details of who performed particular actions.

  Deviation 8, raised 09/01/2023, occurred when the temperature monitors within the warehouse were still being used past their expiry. Fridge loggers went out of calibration in August 2022 until the discovery in January 2023, upon this discovery these loggers and he ambient ones (shortly to go out of calibration) were temporarily replaced with digital ones until replacement max/min thermometers were procured. The deviation led into [redacted] which was also raised on 09/01/2023, with the main action being to use calendar reminders. This CAPA was signed off after approximately 9 months as effective.

- **Personnel**

  There were 11 staff involved within GDP which included the outsourced RP and a single warehouse operative.

- **Premises and Equipment**

  The company operated from a modern warehouse which was secured within a gated site, CCTV, shutters, alarms and a police response. The warehouse was generally clean and tidy, with space allocated predominantly for palletised storage with some racking for individual boxes. Temperatures were recorded

daily using a max/min thermometer which were appropriate set up and calibrated. There was an air conditioning system in place for the ambient storage. The cold room was an addition to the side of the warehouse which was accessed internally from the warehouse.

The cold chain area was last mapped 22-27/12/23 with a clear methodology and conclusion which appeared to show temperature compliance for the storage of medicines. Within this report there was no clear comment regarding the positioning of temperature loggers, this was present in previous mapping exercises.

The last ambient temperature mapping activity took place 11-16/12/23 with the report having a clear report describing the exercise. The report demonstrated compliance with required temperatures for medicines storage. The last summer mapping, performed 16-23/06/23 was in temperatures upto 27.5°C.

Ambient and cold chain areas were re-mapped on a 6 monthly basis.

The company used [redacted] as a warehouse management system with batch and expiry recorded.

- **Documentation**

An order for [redacted] invoiced 21/02/2024, was investigated. The licence for the company was obtained, translated independently and confirmed with the appropriate authority in [redacted] The original supply came from [redacted] and the appropriate checks on their ability to procure and supply medicines had been documented. There was 2 temperature loggers within the delivery that showed compliance.

[redacted] had been appropriately qualified as a customer for a shipment on 05/06/2023. There was a single temperature logger placed within the shipment, there had been a single documented attempt by the company to retrieve the temperature data and there fore could not demonstrate that it had been transported to labelled conditions.

- **Operations**

[redacted] was written for the addition of RPi to the licence in the variation that was inspected during this inspection. The procedure was generally ok which included gaining documents from the manufacturer when purchased directly such as CoA or CoC. However there failed to be a provision to seek reassurance from a wholesaler that the products had been placed on the market when the company were unable to obtain documents for the QP release of the stock.

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

A live recall was performed following the receipt of [redacted] on 13/07/2023, with the recall initiated on the same day. The recall covered [redacted] formulations. The company was able to track all packs supplied and appropriately documented when they were unable to get them back from their customer.

- **Outsourced Activities**

The RP was outsourced with a minimum of 4 visits per year.

- **Self-Inspection**

The last self-inspection was performed 26-27/07/2023 with the company generally announcing good compliance. Findings led to a single [redacted] which is described in chapter 1.

- **Transportation**

Transportation was outsourced to [redacted] for export orders. [redacted] also performed export declarations on behalf of the company.

The quality technical agreement with [redacted] was signed by the company 13/12/2022 with [redacted] signing 09/01/23. The agreement seemed to cover all key areas.

The quality technical agreement with [redacted] was signed by both companies 23/03/2022 and appeared to cover all key areas. An audit was performed 12/05/2022 which covered all key areas.

See chapter 4 for more details about specific shipments.

- **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 **Transportation was deficient in that there was inadequate reassurance that it could be demonstrated that the required storage conditions for medicinal products could be maintained during transportation within the defined limited as described by the manufacturer.**

Reference – GDP Chapter 9.2

3.2 **The RPi process was deficient in that there was inadequate reassurance that the company could demonstrate that products to be imported had been placed on the market in the listed country.**

Reference- The Human Medicines Regulations 2012, Regulation 45AA (4)

4 COMMENT

None

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17. Inspectors' Comments:

N/A

18. Recommendations:

Continued support of your wholesale dealer's authorisation (WDA(H) 42430) 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 13/05/2028

19. Summary and conclusions:

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.

20. The inspection report should be signed and dated by the Lead Inspector:

Name: [redacted]

Signature: [redacted]

Organisation:

MHRA

Date: 16/05/2024

Distribution of Report: