Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 23191/13746174

KNOX PHARMACEUTICALS LIMITED

ISSUED BY:

[redacted]

GDP Inspector

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Medicines & Healthcare products Regulatory Agency

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File Ref: **Insp GDP 23191/13746174-0005**
Inspection Date: **19/02/2021**
Company: **KNOX PHARMACEUTICALS LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 23191/13746174-0005
2. Inspected site(s) and contact details:	
KNOX PHARMACEUTICALS LIMITED UNIT 2 BARUGH WAY BARKER BUSINESS PARK MELMERBY RIPON HG4 5NG UNITED KINGDOM Site contact: [redacted]	
3. Authorised operations:	
☒ Procurement ☒ Holding ☒ Supply ☒ Export ☒ Products imported from countries on a list ☒ Products certified under Article 51 of Directive 2001/83/EC Variation to be submitted if required ☐ Products not certified under Article 51 of Directive 2001/83/EC ☐ Other activities: (please specify)	
4. Inspection date(s):	19/02/2021
5. Inspector(s):	
Names of the Inspectors. [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number: WDA(H) 23191

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7. Introduction:

Business Background

Knox Pharmaceuticals Limited was established in 1989 and operates as a global supplier of pharmaceuticals, offering a wide range of medicinal products which include Controlled Drugs, Cold-chain, POMs, Ps, GSL, Homeopathic products and THMP. The company also wholesale non-medicinal products and consumables.

Medicinal products are procured from mainline wholesalers and manufacturers, for onward supply to pharmacies and wholesalers located in the [redacted]

Export comprised of 100% of the company's wholesale activity. Introduced medicines were also being handled to meet customer demands.

Additionally, the company were regulated by the Department of Trade and registered as a consignor [redacted] is the Director of the company, and [redacted] is the named Responsible Person on the licence and had been working for the company since 2000.

This inspection was conducted remotely during the Covid-19 crisis, where movement restrictions were in place.

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

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Date of previous inspection:

Name of Inspector involved in previous inspection: [redacted]

Date of last inspection: 09/08/2017

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

Z Drug inspection

Major changes since the previous inspection:
No major changes reported.

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, 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**

  The quality management system (QMS) had been defined and covered generally all aspects of GDP activities. The handling of introduced medicines had not been adequately described. Both the Responsible Person and Licence Holder were competent in their understanding of the requirements of GDP, CAPA (Corrective and Preventative Action) and deviations; version control of the QMS was applied to the procedures.

  There was no defined process for quality risk managements. Risk assessments were unavailable for review covering the full scope of risks pertaining to GDP.

- **Personnel**

  The Responsible Person (RP) demonstrated a good knowledge of GDP and had been proactive in maintaining and developing his knowledge. Evidence of signed training records for all staff was seen for with an ongoing training programme in place to ensure knowledge is maintained. Which included training requirements for other regulatory authorities.

- **Premises and Equipment**

  The premises comprised of a large warehouse of standard steel frame, breeze block and steel cladding. Roller shutter doors on the side of the warehouse were used for goods in and goods out. The goods in area was designed to protect goods in case of poor weather. Calibrated temperature monitoring devices were in place with daily minimum and maximum recording evidenced. Mapping had been conducted; there was a password protected HVAC air-conditioning cooling and heating system in place, although the procedure for mapping had not been fully defined. A cold room was in place and had been temperature mapped, including an exercise to see the effects of leaving one of two doors open.

- **Documentation**

  Standard Operating Procedures were in place for all GDP activities, version control and training on SOP's was evidenced. The documentation process is well known; however, the process is not documented. Sales & purchase receipts, recalls, complaints will be dealt with at the site. Stock levels were documented for controlled drugs. An electronic portal was in place for customer orders, with the RP able to control the categories that the company can order.

- **Operations**

  The company's customers are all based overseas. Authority and licences to practice are checked with the local competent authority to confirm what drugs they are allowed to receive and what documentation is required. A competent authority database is kept with contact information, whilst also using the home office to help with the verification process.

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

  Complaints, returns, recalls and falsified medicines procedures had all been defined in the quality system and adequately understood by key staff.

- **Outsourced Activities**

  Transportation has been outsourced including transportation to the airport, and the flights. No SOP was in place to manage outsourced activities.

- **Self-Inspection**

  Process in place covering full scope of wholesale operations.

- **Transportation**

  Containers and packaging used for transport had not been documented to demonstrate products would maintain labelled conditions. Dedicated temperature-controlled vans (outsourced activity) in use had been temperature mapped.

  A formal risk assessment of the arrangements for the transportation of the full range of medicinal products supplied had been undertaken.

  CAA approved GPS trackers are used to monitor orders and are used from leaving their warehouse.

- **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 observed.

2. MAJOR

None observed.

3. OTHER

3.1 The quality management system was deficient in that:

3.1.1 There were no SOPs defining the company's approach to quality risk management.

3.1.2 There were no risk assessments available for review to demonstrate a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products.

3.1.3 There was no process for management review.

3.1.4 There was no process in place for the management and control of outsourced activities, ensuring that contracted operations are carried out in a defined, agreed and controlled manner to avoid any misunderstandings which could affect the integrity of the products.

3.1.5 The formal process defined in the quality system for handling product recalls was not reflective of activities conducted on site.

Reference: GDP 1.3, 1.4, 1.5, 6.5

3.2 Premises and equipment were deficient in that:

3.2.1 There was no formal description of the computerised systems involved in wholesale activities, including processes for the secure back-up, retention and restoration of electronic records.

3.2.2 There was no defined frequency for conducting temperature mapping exercises or subsequent risk assessment of the wholesale area.

Reference: GDP 3.2.1, 3.3.1

3.3 Operations were deficient in that:

3.3.1 Formal processes did not encompass all procedures, resources and activities to ensure confidence that medicinal products exported maintained its quality and integrity, and that supply was in accordance with the legislation in force in the relevant territory.

3.3.2 The qualification SOP was limited in scope and did not give reassurance that systems were in place to ensure the validity and ongoing compliance of suppliers and customers.

3.3.3 [redacted] incorrectly described the process for the handling of medicinal products pertaining to '1.3. Without an authorisation in the UK and not intended for the UK market', thus providing inadequate reassurance that such products would be procured, stored and supplied in accordance with the license authorisation.

Reference: GDP 5.9

3.4 Transportation was deficient in that:

3.4.1 Containers and packaging used (including its conditioning) to ensure medicinal products would maintain their integrity during transportation had not been documented in written procedures

Reference: GDP 9.3

17. Inspectors' Comments:	
4.1	Please ensure the Responsible Person has documented their delegated duties.
4.2	Please forward for review a copy of a competency assessment conducted on a key staff member.

18. Recommendations:

Continued support of your wholesale dealer's authorisation (WDA(H) 23191) 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 February 2024

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.

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20. The inspection report should be signed and dated by the Lead Inspector:
Name: [redacted]
Signature: [redacted]
Organisation: MHRA
Date: 26/02/2021
Distribution of Report: Knox Pharmaceuticals Limited