Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

OFFICIAL - COMMERCIAL

GDP Inspection Report

WDA(H) 8828

Company Name:
Fresenius Kabi Limited

Section 40

ISSUED BY:

[redacted]

Lead 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.gsi.gov.uk

Inspection Reference: Insp GDP 8828/18782463-0003 and Insp GDP 8828/261266-0040

Inspection Date: 26 July 2021

Company: Fresenius Kabi Limited

GDP Inspection Report

1. Report Reference no.:	Insp GDP 8828/18782463-0003 and Insp GDP 8828/261266-0040
2. Inspected site(s):	
Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park Runcorn. WA7 1NT Cestrian Court 2, Eastgate Way, Manor Park Runcorn. WA7 1NT	
3. Authorised operations:	
☐ Procurement ☐ Holding ☐ Supply ☐ Export ☐ Brokering Other activities:	
4. Inspection date:	26 July 2021
5. Inspector(s):	[redacted]
6. References:	WDA(H) 8828
7. Introduction:	

Fresenius Kabi Limited is a wholly owned subsidiary of the Fresenius SE & Co. KGaA health care group; a global healthcare company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. Calea UK are the Homecare division of Kabi.

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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 not intended for EEA market

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:

Date of previous inspection: 14/09/2020 (Cestrian Court) and 17/07/2019 (Cestrian Court 2)

Overview of the finding(s) from previous inspection and corrective action(s) taken:

"Other" deficiencies relating to personnel, falsified medicine awareness and self-inspection were identified at the July 2019 inspection.

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Major changes since the previous inspection:

Addition of a new Responsible Person [redacted]

8. Scope of Inspection:
Routine inspection assessing compliance with the Guidelines on Good Distribution Practice and the Human Medicines Regulations 2012 as amended.
9. I nspected activities:
☐ Procurement ☐ Holding ☐ Supply ☐ Export ☐ Brokering
10. Activities not inspected:
None.
11. Personnel met during the inspection:
[redacted]

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

- **Quality Management**

Processes were in place in relation to change control, deviation management and quality risk management, incorporating Corrective/Preventative Actions.

The quality system was subject to a regular review

A process of regular management review was in place

- **Personnel**

Responsible Person(s) had been appointed, with clear responsibilities

Training record(s) in place for the Responsible Person(s), demonstrating their ongoing awareness of and competence in Good Distribution Practice

There was evidence that the Responsible Person(s) fulfilled their responsibilities personally and was continuously available

There were an adequate number of trained personnel available to carry out wholesale activities

Roles and responsibilities of key staff were formally described, including where duties were delegated

A structured training programme was in place

- **Premises and Equipment**

Storage areas were equipped with adequate lighting

Medicinal products were stored in clearly marked, segregated areas

Access to the storage areas was subject to appropriate controls

Electronic segregation was used

Processes were in place for quarantining products

Processes were in place for prioritising products subject to specific storage conditions (for example cold-chain or Controlled Drugs)

Receiving and dispatch bays provided adequate protection from prevailing weather conditions

Processes were in place to segregate incoming, stored and outgoing products

Premises were clean and free from litter and dust

Processes were in place for the regular disposal of pharmaceutical waste

A preventative pest control programme was in place, records were maintained

Rest, wash and refreshment areas were separate to the storage areas; food, drink, smoking material or medicinal products for personal use were prohibited in the storage areas

A programme of planned maintainance was in place for key equipment

Equipment used to control or monitor the storage areas was calibrated to a traceable National standard

A description of the computerised systems involved in wholesale activities was available

- **Documentation**

Reliance for demonstrating compliance was placed on a mix of electronic and hard-copy records

Documentation was considered to be of adequate scope

The Responsible Person had approved signed and dated the quality system

A process was in place for document control

A process was in place for version control of documents

- **Operations**

Processes were in place for the qualification of suppliers

At the time of inspection the company's business model did not involve the use of brokers

A process was in place for carrying out due diligence on new suppliers

A process was in place for the qualification and requalification of customers

Processes were in place for the receipt of goods, including prioritisation of products requiring special storage or security measures

A process was in place for ensuring that products intended for destruction were identified and securely segregated

Processes were in place ensuring that the correct product was picked

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

A process was in place for the handling of customer complaints

A process was in place for the handling of customer returns

A process was in place for raising staff's awareness of potentially falsified medicinal products

A process was in place for handling product recalls

- **Outsourced Activities**

A process was in place for initiating and controlling outsourced activities as contract giver

- **Self-Inspection**

A process of regular self-inspection was in place

- **Transportation**

The processes relating to transportation were not reviewed in detail at this inspection

- **Specific Provisions for Brokers**

At the time of inspection reportedly brokering activities did not form part of the business model

13. Other specific issues identified:
None.
14. Miscellaneous:
Not applicable.
15. Annexes attached:
None.

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16. List of deficiencies classified into Critical, Major and Other:

1. CRIT ICAL

1.1 None observed.

2. M AJOR

2.1 Quality management was deficient in that:

2.1.1 there was inadequate assurance that the principles of quality risk management had been applied to the company's wholesale operations.

2.1.2 there was inadequate assurance that effective change control was being applied to significant changes to the company's operations, in accordance with the processes described in the quality system.

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2.1.3 the quality system implied that [redacted] was involved in licensable activities, without holding a relevant licence. In this respect it was considered that the quality system was not accurate in reflecting the company's wholesale activities.

2.1.4 there was inadequate assurance that Fresenius Kabi Limited had adequate oversight of outsourced activities, in particular where another company considered to be within the wider company group was providing services.

2.1.5 there was evidence that key documentation relating to outsourced activities had not been subject to effective review and contained material errors.

(Reference: Regulation 43(12) of the Human Medicines Regulations 2012 and Good Distribution Practice Chapter 1, sub-sections 1.2, 1.3 & 1.5)

2.2 Premises & equipment were deficient in that:

2.2.1 there was inadequate assurance that premises & equipment had been designed and maintained to ensure that medicinal products were stored within acceptable limits, in accordance with manufacturer's approved storage conditions.

2.2.2 there was no evidence of a formal risk assessment in relation to the re-mapping frequency of the medicinal product storage area.

2.2.3 there was no formal process for regularly testing the temperature monitoring system alarms.

(Reference: Regulation 43(3) of the Human Medicines Regulations 2012 and Good Distribution Practice Chapter 3, sub-sections 3.2, 3.2.1 & 3.3)

2.3 Documentation was deficient in that:

2.3.1 the quality system review period did not accord with the review period described in the company's annual self-inspection process.

2.3.2 there was evidence that records relating to deviation management were not being maintained contemporaneously.

2.3.3 customer qualification records were not always readily available.

(Reference: Good Distribution Practice Chapter 4, sub-section 4.2)

2.4 Operations were deficient in that:

2.4.1 there was no formal process in place in relation to the monitoring of suspicious transactions in narcotics & psychotropics and other dangerous products.

2.4.2 there was inadequate assurance that the proper legal basis of supply had been established for the full scope of the company's customer base.

2.4.3 the written procedure relating to customer qualification did not describe the process for qualifying the full range of the company's customers, consequently it could not be assured that supply was always made to appropriately authorized persons and sites.

(Reference: Regulations 44(5) & 250 of the Human Medicines Regulations 2012 and Good Distribution Practice Chapter 5, sub-section 5.3)

3. OT HER

3.1 Personnel was deficient in that:

3.1.1 there was inadequate assurance that the Responsible Persons had ready access to all information relating to the company's wholesale activities in order to be able to effectively fulfil their responsibilities.

3.1.2 there was no formal process for documenting the assessment of the effectiveness of training, indicating that personnel were considered competent to undertake the wholesale activities in which they had received training. This deficiency is noted particularly in relation to the "buddy" system used for the initial training of personnel.

(Reference: Good Distribution Practice Chapter 2, sub-sections 2.2 & 2.4)

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17. Inspectors' Comments:

[redacted]

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18. Recommendations:	
[redacted]	
19. Summary and conclusions:	
Within the scope of the inspection, the company operates in accordance with the Guidelines on Good Distribution Practice and the Human Medicines Regulations 2012.	
20. Signature of the lead inspector.	
	[redacted]
Name:	[redacted]
Date:	22 February 2022
Organisation(s):	MHRA
Distribution of Report:	[redacted]