Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 40398/18835731

PRIME PHARMACARE LIMITED

ISSUED BY:

[redacted]

GDP Inspector

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Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: **Insp GDP 40398/18835731-0003**
Inspection Date: **30/05/2024**
Company: **PRIME PHARMACARE LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 40398/18835731-0003
2. Inspected site(s) and contact details:	
PRIME PHARMACARE LIMITED UNIT 25-32 DEVONSHIRE HOUSE 582 HONEYPOT LANE STANMORE HA7 1JS UNITED KINGDOM UNIT 14 THE HAWTHORN CENTRE ELMGROVE ROAD HARROW HA1 2RF	
3. Authorised operations:	
☒ Procurement- only site 18835731 ☒ Holding ☒ Supply ☒ Export ☒ Products imported from countries on a list- only site 18835731 ☒ Products certified under Article 51 of Directive 2001/83/EC- only site 18835731 ☐ Products not certified under Article 51 of Directive 2001/83/EC ☐ Other activities: (please specify)	
4. Inspection date(s):	30/05/2024
5. Inspector(s):	
Name(s) of the Inspector(s). [redacted] **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 40398

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7. Introduction:

Business Background

The business model remained largely unchanged with the exception that the authorisation to trade in controlled drugs was being removed from the scope of authorised activities. The company was a short-line wholesaler covering a range of UK and international customers. They procured
stock from EEA and UK for onwards supply mostly for export. Their customers were located in [redacted]
(mostly medical devices, part of a supply to [redacted]. Mainly fulfilling shortages in those countries.
The main suppliers were [redacted]
There was an intention to export on behalf of manufacturers directly to end users. Manufacturers were located primarily in the [redacted] some were located in [redacted]
Customers included wholesalers in [redacted]. Stock was UK licensed stock.
Veterinary licensed products available through [redacted]

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:

Date of last inspection:

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

4 major findings pertaining to RP competence, outsourced activities, importation activities, and quality management. 1 other finding pertaining to self-inspection. All closed satisfactorily following the previous inspection.

Major changes since the previous inspection:
Variation to add site 36189272. Remove 3.1.1 Narcotic or psychotropic products from site 18835731

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:
11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

  There were 2 adapted sets of procedures for the activities listed for each site. Separate SOP indices were in operation. Both QMSs were available in paper copies.

  Change management was in use. Example reviewed: [redacted] dated 10 Nov 2022- limited considerations on staff, but JDs prepared and evidence of training seen.

  Risk assessments were being conducted for specific areas of the business. RA pertaining to selling diazepam to [redacted] was reviewed in more detail.

  Deviations: D0170 raised 08/02/2024 and D0171 raised 16/02/2024 both pertaining to incorrect commodity codes on export documents.

  Deviations were being raised for temperature excursions.

  As part of the inspection, the following standard operating procedures were reviewed:

  - [redacted] issue date 07 May 2024 Supplier Management Procedure- limited in scope in that it lacked detail on how the company would conduct independent bona fide checks on suppliers.
  - [redacted] Issue Date 07 May 2024 Customer Verification Procedure was unacceptable in that it allowed for the export of Specials outside the EU.
  - [redacted] Roles and Responsibilities of Responsible Person for Import version 09 issue date 7 May 2024- limited detail but broadly acceptable

- **Personnel**

  A company organogram was in place including roles and responsibilities for all staff.
- **Premises and Equipment**

  Both sites were visited as part of this inspection. The premise were considered suitable for the safe storage of medicinal products. There were temperature loggers in place for temperature monitoring.
  A temperature mapping had been conducted for the [redacted]
- **Documentation**

  Documentation was readily available for review. Principles of good documentation practice were not applied in full to all key documents (see Operations).
- **Operations**

  There were lists available of approved customers and suppliers, both of which were uncontrolled documents.
  Supplier qualification records sampled as follows:
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

  Transactions audit trails reviewed satisfactorily.
- **Complaints, Returns, Suspected Falsified Medicinal Products and Recalls**

  Recall activities were broadly compliant. Last live recall was a [redacted]

  Returns management and customer complaints management not reviewed in detail.
- **Outsourced Activities**

  Please see Transport
- **Self-Inspection**

  Failed to implement a robust self-inspection process. For example, the self-inspection report dated 25/04/2024 failed to capture that change control records were not raised proactively, for example for the implementation of the Windsor Framework. The report pertaining to the review of the quality system and GDP processes dated 25-04-2024 was limited in scope and failed to capture findings as identified above. There were no references pertaining to CAPAs raised in relation to self-inspection findings.

- **Transportation**
- Transport validation:
  - UK- not reviewed in detail
  - Export transport validation had been conducted for a number of routes across different territories. Sample of a [redacted] for ambient stock to [redacted] was reviewed and mostly considered acceptable, the stock included [redacted] (on export ban list, which as of 4 December 2023 was added in all forms to export ban list, but previously only in oral and injectable forms whereas the exported product was eyedrops).
    A cold-chain transport validation study sample for a shipment in Februayr 2024 to [redacted] was reviewed.
  - Quality technical agreements with transport providers- there were some contracts, primarily of commercial nature, with some of the transport providers. Specifically, there was no QTA with [redacted] despite the scope of outsourced transportation and customs agent activities outsourced to them.
    The QTA with [redacted] dated 01/03/2024 was reviewed in detail. Mostly ok, but lacked detail pertaining to how quickly deviations would be notified to [redacted] or who would

be responsible for reporting potential theft of medicinal products, including CDs. There was no evidence that the updated guidance for transport of controlled medicines issued by the [redacted] had been taken into consideration.

- Audits on transport providers- not conducted
- Packaging qualification for cold-chain stock- see lane study of cold chain delivery to
- Evidence of [redacted] yes, reviewed

- **Specific Provisions for Brokers**

  Not applicable

13.	**Other specific issues identified:**
14.	**Miscellaneous:**
15.	**Annexes attached:**

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

1 CRITICAL

None

2 MAJOR

2.1 The Responsible Persons failed to demonstrate that they maintained their knowledge up to date and ownership of the QMS: The RPs failed to review and update the QMS so that it fully reflected all GDP activities authorised within the scope of the licence. This is a repeat finding. They had not implemented documented procedure or procedures pertaining to how export activities would be controlled. For example, there was no mechanism pertaining to checks on the export ban list or strategic goods list (even though such checks were being allegedly conducted). The RPs failed to demonstrate adequate knowledge pertaining to how to check if products would be authorised in the destination. The RPs failed to demonstrate adequate understanding pertaining to wholesaling specials. Specifically, they failed to demonstrate knowledge pertaining to the restrictions of exporting specials to third countries. This is a repeat finding. The RPs had failed to implement principles of good documentation practice across all quality documents. For example, not all quality documents were controlled. Failed to demonstrate the effectiveness of change management in that upcoming regulatory changes such as Windsor Framework had not been proactively managed through change control. There was lack of reassurance that the RPs had implemented such processes and mechanisms in place as to ensure that customers would only be supplied with such products as authorised in their respective licences and territories. There was no mechanism in place pertaining to how the licensing status and ability to supply specific medicinal products in certain territories would be established. For example, a number of products in UK-specific livery had been supplied to [redacted] without any evidence that the customer was authorised to receive such products. There was no mechanism to ensure that customs declarations were accurately and completely filled out by [redacted] There was no mechanism to engage with the freight forwarder and customs agents. For example, the customs declaration for export of [redacted] (black triangle warning) was not completed in full and did not fully demonstrate where the product was delivered to. They had failed to review the QTA for transport to ensure that it captured all necessary detail. There was evidence that incorrect commodity codes had been in use and there was lack of reassurance that the RPs had adequate knowledge to identify where commodity codes were incorrect. Risk

	assessment dated 24/05/2024 pertaining to risks of misuse of diazepam was considered inadequate in that the document stated no risk even though there were risk identified. RPs had failed to implement principles of quality risk management to any areas of GDP other than transportation and storage temperatures. Failed to implement a robust self-inspection process. For example, the self-inspection report dated 25/04/2024 failed to capture that change control records were not raised proactively, for example for the implementation of the Windsor Framework. The report pertaining to the review of the quality system and GDP processes dated 25-04-2024 was limited in scope and failed to capture findings as identified above. There were no references pertaining to CAPAs raised in relation to self-inspection findings. No dedicated export procedure. [redacted] issue date 07 May 2024 Supplier Management Procedure- limited in scope in that it lacked detail on how the company would conduct independent bona fide checks on suppliers. [redacted] Issue Date 07 May 2024 Customer Verification Procedure was unacceptable in that it allowed for the export of Specials outside the EU. There was no mechanism for ensuring that medicinal products were authorised to be supplied in the destination territory.
EU GDP	1.2, 1.5, 2.2, 4.2, 5.2, 5.3, 5.8, 5.9, 7.2, 8.2

3 OTHER

None

4 COMMENT

None

17. Inspectors' Comments:
18. Recommendations:

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**Your application for variation to a wholesale dealer's authorisation [WDA(H) 40398] granted pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will be recommended to the licensing authority.*

**Continued support of your wholesale dealer's authorisation (WDA(H) 40398) 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 30/05/2027

19. Summary and conclusions:

Within the scope of the inspection, the company operatesin 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:
Organisation: MHRA
Date: 05/08/2024
Distribution of Report: