



GDP INSPECTION REPORT

WDA(H) 54893/27645170

CANTOURAGE UK LIMITED

ISSUED BY:



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



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

GDP Inspection Report

1. Report Reference no.:	Insp GDP 54893/27645170-0001
2. Inspected site(s) and contact details:	
Cantourage UK Limited Unit 6 13 Ramsgate Street London E8 2FD United Kingdom	
3. Authorised operations:	
<input checked="" type="checkbox"/> Procurement <input type="checkbox"/> Holding <input checked="" type="checkbox"/> Supply <input checked="" type="checkbox"/> Export <input checked="" type="checkbox"/> Products imported from countries on a list <input type="checkbox"/> Products certified under Article 51 of Directive 2001/83/EC <input checked="" type="checkbox"/> Products not certified under Article 51 of Directive 2001/83/EC <input type="checkbox"/> Other activities: (please specify)	
4. Inspection date(s):	30/09/2024
5. Inspector(s):	
Name(s) of the Inspector(s). [REDACTED] MHRA	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 54893



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

7. Introduction:

Business Background

The company were a holder of a wholesale dealers licence following their initial application in 2021. The company specialise in the supply of unlicensed [REDACTED]. Approximately [REDACTED] of the company's products were procured from [REDACTED] manufacturers based within countries on the list with the remaining being from [REDACTED] main UK suppliers. The company had submitted a variation to move to a new site due to [REDACTED] [REDACTED] Storage and logistics [REDACTED] [REDACTED]. The company's product range was [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: [REDACTED]

Date of last inspection: 28/09/2021

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

6 others around the QMS, personnel, equipment, documentation, operations [REDACTED]

Major changes since the previous inspection:

Variation to add 1.3 and export, alongside a new site. New site since initial inspection.



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

8. Scope of Inspection:
Variation 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, Supply and Export.
10. Activities not inspected:
Self-inspection.
11. Personnel met during the inspection:
<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 250px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 200px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 250px; height: 15px;"></div>
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 model with procedures in place for deviations, CAPAs and change controls.

Change control [REDACTED] raised [REDACTED] to cover the addition of [REDACTED] o the company's licence. The change control failed to cover a MHRA inspection and the reason for the change.

SOP [REDACTED] covered [REDACTED] which had been added in the current variation. The procedure failed to capture the validity period of [REDACTED] and the customer qualification procedure had not been updated [REDACTED]

Change control [REDACTED] raised 15/03/2024, to over the companies move to a new site. Evidence of the company's Home Office application was seen; however, the description of the change was missing.

Deviation [REDACTED] raised 27/09/2023, related to the relationship between the supplementary prescriber and initiator not being known despite both parties being known. The order was processed before the error was found. The relationship was retrospectively established. The deviation was reported to the RP 02/10/2023. Change control [REDACTED] raised 18/12/2023, was for the remedial actions. The deviation was signed 23/02/2024. There was no documented reason for the delay in creating the following documents.

Deviation [REDACTED] aised 10/12/2023, related to an oversupply of 2 packs, this was subsequently reconciled.

Deviation [REDACTED] raised 26/03/2024, related to a transportation exercise [REDACTED] [REDACTED] where 2 data loggers were sent over a few months period. However, only one was able to be attributed to consignment [REDACTED]

- Personnel**

There was a total of 11 people involved in GDP activity. There was an organogram in place. There was training records in place for staff members with appropriate training in place. The competency of staff to perform delegated responsibilities had not been documented. There was a delegation log in place.



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

- **Premises and Equipment**

The company were located within an office with appropriate security considerations.

- **Documentation**

Hard copy documents were some training records, with them being signed and scanned, alongside notarised documents. Everything else was stored electronically. The company utilised [REDACTED] for storage of the QMS. [REDACTED] was used to record transactional records.

For a batch of [REDACTED] the no objection letter for the importation was issued on 06/08/2024. The Certificate of Analysis was present for the batch (batch number [REDACTED] expiry 04/2025). The [REDACTED] authorities export certificate was issued 14/08/2024. The stock was received into [REDACTED] 19/09/2024. Full goods in checks were performed upon receipt. An amount of this batch was sold to [REDACTED]. The company were checked on the GPhC register on 19/01/2024. The prescription was from an independent prescriber, [REDACTED] who was qualified. The initiating prescriber was [REDACTED] who was qualified on the GMC specialist register most recently on [REDACTED]. The patient's prescription was written 18/09/2024. The initial prescription unmet clinical need was done 04/09/2022 and had not been reviewed since.

- **Operations**

Customers were predominantly GPhC registered pharmacies with supplies sent from [REDACTED] or directly from [REDACTED] where the products were sourced. There was some wholesaler-to-wholesaler supply.

[REDACTED] were initially qualified 26/04/2022 with MIA, MS and WDA licences with a GDP certificate. The companies GMP certificate was missing. The qualification was approved by the RP on the same day. There was evidence that the MS licence was checked on the day. The GDP certificate from [REDACTED] was on file and signed by the RP on 26/04/2022. For the 2024 checks the GDP certificate from [REDACTED] was created on 02/07/2024 with the WDA dated from [REDACTED].

[REDACTED] was originally qualified using their MIA and GMP certificate on 27/04/2021 which were issued [REDACTED] and [REDACTED] respectively. The most recent qualification was documented on 28/06/2024.

On the Home Office licence the RP is the person named as the authorised witness for destruction. SOP [REDACTED] stated that [REDACTED] were to be sent to [REDACTED] for destruction.

The company's customer [REDACTED] had their WDA and GDP last checked 24/05/2024. The principal prescriber was checked, but it had only been done initially and not annually.

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

A mock recall was performed 12/07/2024 for [REDACTED] units were identified as being purchased and sold with the report including evidence of purchase and sales orders.

- **[REDACTED] Activities**

An audit of [REDACTED] was performed on 26/07/2024 with an initial report created on the same day. The initial report was signed by the RP on 05/08/2024 and the final on 16/08/2024. The audit appeared to generally cover all areas required [REDACTED] for onward transport to the companies main [REDACTED] site. The latest QTA was signed 11/05/2022 was in date and seemed to generally cover all key areas.

[REDACTED] were audited 20/08/2024, with the previous one being 27/06/2022. There was a single major finding documented as a result of the audit. The audit report was circulated 28/08/2024, including to [REDACTED] however the report had not been signed off. The audit seemed to cover all key areas in sufficient detail but failed to demonstrate that transportation had been appropriately validated. The QTA was signed by the company 09/09/2022 with [REDACTED] signing 13/09/2022.



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

- **Self-Inspection**
Not inspected.
- **Transportation**
See chapter 7.
- **Specific Provisions for Brokers**
N/A

13. Other specific issues identified:
N/A
14. Miscellaneous:
N/A
15. Annexes attached:
N/A



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

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

1 CRITICAL

None

2 MAJOR

None

3 OTHER

3.1 The Quality Management System was deficient in that:

- 3.1.1 Change controls failed to be a fully reflective record of the changes being undertaken as evidenced by change control [REDACTED] and [REDACTED]
- 3.1.2 For deviation [REDACTED] there was non-attributable delays following the deviation until a change control was raised to perform preventative actions.
Reference – GDP Chapter 1.2

- 3.2 Training was deficient in that it was not documented the competency of staff members to perform delegated duties.
Reference – GDP Chapter 2.4

- 3.3 [REDACTED] was deficient in that:
- 3.3.1 SOP [REDACTED] failed to capture the validity period of the [REDACTED]
- 3.3.2 There was no provision to ensure supplies are only made to persons who are authorised or entitled to receive medicinal products.
Reference – GDP Chapter 5.9

- 3.4 Outsourced activities were deficient in that:
- 3.4.1 The audit of [REDACTED] failed to include all elements of [REDACTED] including but not limited to transportation validation.
- 3.4.2 The audit report of [REDACTED] produced 27/06/2024 could not be evidenced of being approved.
Reference – GDP Chapter 7.2

- 3.5 The supply to fulfil special patient needs was deficient in that it was not adequately documented that the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient.
Reference - The Human Medicines Regulations 2012, Regulation 167



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

4 COMMENT

None

17. Inspectors' Comments:
N/A
18. Recommendations:
<p><i>Your application for variation to a wholesale dealer's authorisation [WDA(H) 54893] granted pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will be recommended to the licensing authority.</i></p> <p><i>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".</i></p> <p>The provisional date for the next inspection of this site is 30/09/2028</p>
19. Summary and conclusions:
<p>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.</p> <p>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.</p>



File Ref: Insp GDP 54893/27645170-0001
Inspection Date: 30/09/2024
Company: CANTOURAGE UK LIMITED

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

Name:

[Redacted]

Signature:

[Redacted]

Organisation:

MHRA

Date: 17/10/2024

Distribution of Report: