Medicines & Healthcare products Regulatory Agency

MHRA

OFFICIAL – COMMERCIAL

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[redacted]
Cantourage UK Limited
Unit 6
13 Ramsgate Street
London
E8 2FD
United Kingdom

17/10/2024

Case No: Insp GDP 54893/27645170-0001

Dear [redacted]

SUBJECT: AUTHORISATION / REGISTRATION NO. WDA (H) 54893 THE HUMAN MEDICINES REGULATIONS 2012 (as amended) (SI 2012/1916)

May I thank you and your colleagues for the courtesy and co-operation shown to me during the inspection of your premises at Cantourage UK Limited on 30/09/2024.

During the inspection a number of failures to comply with the principles and guidelines of Good Distribution Practice of Medicinal Products for Human Use were observed and these are listed in the Appendix to this letter.

Please reply within 28 days, giving your proposals for dealing with these matters, together with a timetable for their implementation. Please send your response electronically by e-mail to me at the email address below.

Your response should be in the following format:

1. Restate the deficiency number and the deficiency as written below;
2. State the proposed corrective action and the target date for completion of these action(s);
3. Include any comment that the company considers appropriate and relevant supporting evidence in relation to the corrective action(s) (for example, but not limited to, deviation or change control documentation);
4. Please provide the response as a word document. Supporting evidence should be provided in an appropriate format (for example PDF, Excel spreadsheet).

Yours sincerely

[redacted]

[redacted]
Senior GDP Inspector
E-mail: [redacted]

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

FAILURES TO COMPLY WITH THE GUIDELINES ON GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS FOR HUMAN USE

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] here 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 [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 [redacted] **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

4 COMMENT

None