Medicines & Healthcare products
Regulatory Agency

OFFICIAL – COMMERCIAL

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[redacted]
AHP MEDICAL SUPPLIES LIMITED
64 BOROUGH HIGH STREET
LONDON
SE1 1XF
UNITED KINGDOM

21/05/2024

Case No: Insp GDP 19142/18450370-0005

Dear [redacted]

THE HUMAN MEDICINES REGULATIONS 2012 (SI 2012/1916)
WHOLESALE DEALER'S AUTHORISATION: WDA(H) 19142

I refer to the inspection carried out at your premises at AHP MEDICAL SUPPLIES LIMITED on 14/05/2024 by [redacted]

The inspection findings indicate that there are serious deficiencies in your operations which could provide grounds under Regulation 26 of the Human Medicines Regulations 2012 for the Licensing Authority to take formal action against your licence.

The failures to comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use are listed in the Appendix to this letter. A reference to these guidelines is given for those deficiencies classified as critical and major.

The inspection report has been referred to the Licensing Authority for consideration and possible action. Correspondence relating to this inspection, including any proposals you have for dealing with the deficiencies identified, should be addressed to the Chair of the Inspection Action Group, 10 South Colonnade, Canary Wharf, London, E14 4PU within 7 days. Electronic correspondence may be sent to IAGSecretariat@mhra.gov.uk . A copy of the response should also be sent to the Inspectors [redacted]

Your response should be in the following format:

1. Please provide the response as a Word format document.
2. Restate the deficiency number and the deficiency as written below.
3. State the proposed corrective action and the target date for completion of these action(s);

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4. Include relevant supporting evidence in relation to the corrective action(s) (for example, but not limited to, deviation or change control documentation); supporting evidence should be provided in an appropriate format (for example PDF, Excel spreadsheet).
5. Provide any comment that the company considers appropriate.
6. Please supply any documentation specifically requested within the deficiencies.

In cases where it appears to the Licensing Authority that in the interests of safety it is necessary to suspend a licence with immediate effect under Regulation 28 of the Regulations, this may take place before the 7-day response period (referred to above) has elapsed.

Yours sincerely,

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

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Inspection Date: 14/05/2024
Company: AHP MEDICAL SUPPLIES LIMITED

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

1 CRITICAL

1.1 The Licence Holder, [redacted] had failed to comply with the guidelines on good distribution practice. This was demosntrated by:

1.1.1 [redacted] had failed to review the licence variation to ensure that it was reflective of the intended wholesale operations. Specifically:

- Authorisations for *1.2 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*, *1.3 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*, and *4.5 Traditional Herbal Medicinal products* had been included in the variation even though there was no intention to wholesale products in either of those categories.
- The named authorisation holder contact had not been updated to reflect personnel changes. Specifically, [redacted] remained as a licence holder contact despite [redacted] no longer fulfilling this role in the organisation.

1.1.2 [redacted] had failed to provide such arrangements for storage and distribution of medicinal products that would ensure medicinal product was to be held at premises located in the UK and specified in the licence. This was evidenced by:

- The transport arrangements as outlined in the quality technical agreement with [redacted] were inclusive of storage of cold-chain goods at premises other than those listed on WDA(H) 19142 for up to 36 hours.
- The above arrangements were also reflected in [redacted] dated 14/01/2024 referring to temporary storage, which was not appropriate in regard to there being no 3rd party site named on the licence that would facilitate the storage of cold-chain stock for any amount of time.
- There was lack of reassurance that medicinal products would be transported in under labelled conditions. Specifically, a duty for maintaining temperature conditions was placed on the contract

acceptor despite the use of non-temperature controlled vehicles as described in the quality technical agreement.

- Transport arrangements were not fully demonstrated to be suitable for the distribution of medicinal products. For example, there was no evidence of audit completed on the transport company.
- The transport validation report did not capture whether stock would be kept on the vehicles or unloaded during overnight storage. There were no details pertaining to how the shipment was packed for the validation study.
- Ambient mapping did not indicate if temperature adjustment equipment had been in use during the mapping exercise.
- The use of the temperature control equipment was not documented with a written procedure.
- The conditioning and preparation of ice packs for cold-chain orders had not been described with a written procedure. [redacted] only referred to taking out the ice-packs out of the fridge 30 minutes before packing an order.

1.1.3 [redacted] had failed to ensure that a Responsible Person who, in the opinion of the Licensing Authority, demonstrated adequate knowledge & experience of the activities to be carried out and of the procedures to be performed under the licence, so as to fulfill their responsibilities in ensuring the ongoing compliance of the company with Good Distribution Practice and ensure that the quality of medicinal products was maintained through the supply chain. This is a repeat finding.

1.1.4 [redacted] had failed to ensure that there were suitable arrangements for the storage and archiving of obsolete documentation. This is a repeat finding.

1.1.5 [redacted] had failed to demonstrate the effectiveness of the customer qualification mechanism for the full scope of proposed customers. For example:

- The effectiveness of the supplier and customer qualification activities was not fully demonstrated. The example customer qualification check of [redacted] did not provide adequate reassurance that there was a robust mechanism that would ensure medicinal products were only to be supplied to persons who were suitably authorised to receive them.
- Customer Account Opening Form and GDP Questionnaire, [redacted] referred to customer operations including Import and Manufacture even though the company had submitted a variation to remove export.

The form had not been tailored for the proposed customer base. Specifically, it referred to QP/QA personnel and chapters of GDP, which would not be applicable to registrants from GMC, GDC, NMC, HCPC, RSVP, or GPhC as listed on the form.

1.1.6 He had allowed for supplies of cold-chain stock, [redacted], on 28 separate occasions in 2021-2023 without authorisation for cold-chain on WDA(H) 19142. These incidents had not been identified or investigated during the review of supplies conducted by the nominated RP.

Reference: The Human Medicines Regulations 2012 (as amended), Regs 18(3), 43(1), 43(3), 45(1), and Good Distribution Practice, Chapter 3, Chapter 4 & Chapter 5, sub-section 5.3)

1.2 The Responsible Person was deficient in that:

1.2.1 [redacted] had failed to demonstrate adequate knowledge pertaining to good documentation practice principles. This is a repeat finding. This was evidenced by:

- [redacted] failure to implement suitable document management mechanisms as demonstrated in 1.1.3. Specifically, there being no documented arrangements in place for the archiving of obsolete and superseded documents other than Standard Operating Procedures.
- The deviation log failed to contemporaneously capture the close out of deviation records raised in 2023.
- [redacted] had failed to maintain logs quality documents as per the company's own procedures.
- Uncontrolled documents were in use instead of the controlled documents as referenced in the relevant SOPs. For example, the change control log presented was not a controlled document and was not the form [redacted] as defined in [redacted] or [redacted] for logging risk assessment.
- Training records for staff were not compliant with good documentation practice principles in that SOP versions were not recorded and therefore it could not be ascertained as to which version an employee had been trained on.

1.2.2 [redacted] had failed to ensure that a quality system compliant with the requirements of Good Distribution Practice and relevant UK legislation had been implemented and maintained. This is a repeat finding. Evidence included, but was not limited to:

- Deviation management as described in SOP [redacted] was self-contradictory in that it required planned deviation to be raised as change controls (Section [redacted]), but also referred to planned and unplanned deviations in Section [redacted]
- [redacted] contained an obsolete MHRA address.
- The quality technical agreement with [redacted] made references to products covered by a marketing authorisation granted by an EU/Member State, section [redacted] which was outside the scope of activities on the licence. The QTA also referred to RPi released stock, the validity of which statement could not be confirmed on the basis of the licence scope.
- [redacted] referred to Export.
- There was no mechanism for the qualification of veterinary customers even though there was an intention to supply such customers with human medicines.
- The mechanism for Corrective and Preventative actions had not been demonstrated to be effective. For example, the refresher training on the correct process to record fridge temperatures as identified with [redacted] and [redacted] had not been recorded.
- [redacted] incorrectly put the onus for reporting product quality complaints on the MA-holder as opposed to the wholesaler receiving the complaint, which was not acceptable.

1.2.3 [redacted] had failed to implement an acceptable procedure pertaining to Falsified medicines awareness. Specifically, [redacted] was considered unacceptable in that it specifically required notification of the supplier in case of identification of a falsified medicines. The procedure only required segregation of stock after it being confirmed as falsified and therefore increasing the risk of supplying falsified medicines to patients.

1.2.4 [redacted] had failed to implement a customer qualification mechanism that was reflective of the proposed scope of customers. Specifically, [redacted] referred to GMP, GLP, and GCP facilities being supplied. There were no detailed checks implemented for registrants from GDC, NMC, HCPC, General Chiropractic Council, independent prescribers. There was no mechanism implemented for the delivery address qualification of non-WDA customers. Periodic re-checks solely covered licence holders.

1.2.7 [redacted] had failed to identify that medicinal products for which the company did not hold the relevant authorisation had been wholesaled as identified in 1.1.6.

1.2.8 [redacted] had failed to demonstrate the approval of outsourced activities, in particular in relation to transportation of medicinal products using [redacted] there was no mechanism to ensure that the contract provider had been suitably qualified.

References: The Human Medicines Regulations 2012 (as amended), Regs 45(2) and Good Distribution Practice Chapter 1, Chapter 2, sub-section 2.2

2 MAJOR

None

3 OTHER

None

4 COMMENT

None