Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GDP INSPECTION REPORT

WDA(H) 18716/9273505

ETHIGEN LIMITED

ISSUED BY:
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Medicines & Healthcare products Regulatory Agency

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File Ref: **Insp GDP 18716/9273505-0007**
Inspection Date: **20/06/2017**
Company: **ETHIGEN LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 18716/9273505-0007

2. Inspected site(s) and contact details:

ETHIGEN LIMITED

ETHIGEN HOUSE
UNITS 10-16 COLVILLES PLACE
KELVIN INDUSTRIAL ESTATE
EAST KILBRIDE
GLASGOW
G75 0SN
UNITED KINGDOM
[redacted]

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3. Authorised operations:

- ☒ Procurement
- ☒ Holding
- ☒ Supply
- ☒ Export
- ☐ Brokering
- ☐ Other activities: (please specify)

4. Inspection date(s):	20/06/2017

5. Inspector(s):

Name(s) of the Inspector(s).

Madeleine Ault

Peter Brown

MHRA

6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 18716

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7. Introduction:

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Business Background

Ethigen are a wholesaler, primarily servicing the North of England, Scotland and some parts of Northern Ireland. Ethigen had recently been inspected under Insp[redacted], where the majority of business functions were inspected. Products are procured from wholesalers (including those that are also pharmacies) and manufacturers within the EEA. Products are sold to wholesalers and pharmacies within the EEA. The site also holds a GMP MIA Licence to conduct PLPI operations under [redacted] which was outside of the scope of this inspection.

Review of WDA(H)

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 intended for exportation

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: (please specify here or make a reference to Annex 5)

Date of previous inspection:

Name(s) of Inspector(s) involved in previous inspection: Peter Brown & Madeline Ault

Date of last inspection: 14/03/2017

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

Significant GDP observations were made during the previous recent inspection. Due to the short timeline since the previous inspection, findings and corrective actions were not reviewed.

Major changes since the previous inspection:
None.

8. Scope of Inspection:

For cause inspection assessing compliance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and the Human Medicines Regulations 2012 as amended.

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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:
Personnel, QMS, Premises and self-inspection activities were not inspected.
11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

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- **Quality Management**

  Not within the scope of inspection.

- **Personnel**

  A training record for the depot manager at a cross docking site was available for inspection, as well as driver records, and found to be reasonable.

  Both records and interview detailed adequate GDP awareness and medicines management training.

- **Premises and Equipment**

  Not within the scope of inspection.

- **Documentation**

  Sales and purchase records of [redacted] sales through 2016 to date were examined. Some sites of note were identified by inspectors, to which further enquiries may be made.

  [redacted] records were examined and found to correlate appropriately, allowing reconciliation. Data of purchases vs sales for 2016 against the entire range of [redacted] were inspected and found to reconcile. Copies of documentation were provided to inspectors and taken off site for further consideration. Some sites of note were identified by the inspectors, however these were supplied prior to Ethigen review processes being put in place.

  It was noted that the R.P committed to supply full [redacted] data records to the MHRA. This was completed.

  Transit records were kept by the [redacted] system, which detailed route journeys, van locations and route timing from all depots at head office on a live basis.

- **Operations**

  The Inspectors reviewed evidence of ongoing Controlled Drugs order review processes and methods. Ongoing data was in place ongoing review of unusual sales patterns vs a 6-month average and assessment of movements. The R.P displayed awareness of appropriate questioning of orders, where controlled drug

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sales were assessed vs percentages of overall spend and ongoing knowledge of customer bases. This was evaluated by a pharmacist on site.

[redacted] was inspected to assess the due diligence considerations around [redacted]. The inspectors provided some advice surrounding practise detail and staff training, as well as MHRA contact details. Staff scope should also be considered.

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

Not within the scope of inspection.

- **Outsourced Activities**

Not within the scope of inspection.

- **Self-Inspection**

Not within the scope of inspection.

- **Transportation**

Cross docking operations were reviewed as part of the inspection. Those managed by [redacted] at Bolton were examined. In [redacted] absence, the site is managed by [redacted] and/or [redacted] The depot manager based at East Kilbride has inspected all sites. There are further depots at Belfast, Birmingham and Newcastle

The process was described as having a large trunker vehicle depart from Glasgow to Bolton at around 01:00 to 02:00, arriving in Bolton at approximately 05:00 to 06:00 After unloading, the vehicle travels onwards to Birmingham, arriving around 0730 – 0800. Each vehicle takes approximately 8 – 10 pallets per trip. No cold chain is despatched via cross docking sites. Around 2 – 5% of stock represents controlled drugs. Further trunkers are dispatched from East Kilbride to Newcastle and Belfast

Goods despatched from the Bolton site cover approximately a 50-mile radius over 12 routes using 12 drivers (including [redacted] , returning in approximately 6 hours with one route run undertaken by [redacted] Drivers leave the depot between 06:20 and 08:15 to commence their runs. The depot alarm is then set. Returns are collected on an ad-hoc basis. The intention is that all drop off will be by 1pm and all vehicles returned to the depot. The maximum route is around 7 hours with around 28 drops. All vehicles are expected to have returned to the depot before 3 to 4pm where returns are collated. The trunker then returns to East Kilbride carrying returns

Storage facilities consist of a small depot, where stock is not routinely held on site. Most vehicles are utilised and stored by drivers. The unit has sufficient space for [redacted] There was instruction to ensure returned goods are sent back to the depot. Failed deliveries are also returned to the depot. Further advice regarding validation of transport route given where stock is held but not able to be immediately returned. Around 12 staff are employed at the site.

All products, including returns, are tracked throughout. Route journey times were recorded electronically in real time via a PDA issued to the driver. This data is collated electronically. These were inspected via the [redacted] system, a system in place for 8 months. Several records reviewed to see how this takes place and can be audited. Map view showed location of vans and records showed complete history. Where stock is required to be returned this is requested by East Kilbride and if not received at East Kilbride as expected is followed up. Records of return requests and failed deliveries inspected.

All routes are currently monitored using loggers and validation processes in place. The routine monitoring requires a logger probe located in the vehicle as a consignment package. There is currently no formal randomisation of probe location or plans to do so.

No risk assessment had been conducted to assess stock being left out of controlled conditions during static points at the depot. An audit has been carried out by the depot manager and further considerations are given under the transport validation process. Vehicles had not been temperature mapped although this is planned. The plan is to also include a validation with an additional temperature probe fixed to the external surface of the packing.

- **Specific Provisions for Brokers**

  Not applicable.

13. Other specific issues identified:
None.
14. Miscellaneous:
None.
15. Annexes attached:
N/A

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

1. **CRITICAL**

   None reported.

2. **MAJOR**

   None reported.

3. **OTHER**

   None reported.

17. Inspectors' Comments:

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Due to a recent inspection, only activities pertaining to GDP Chapters 5 and 9 of MHRA interest were reviewed by Inspectors.

It should be noted that although no observations were made during this targeted inspection, this is not prejudiced and shall not take precedent over observations made pertaining to the full scope of GDP Operations conducted during March 2017. Refer to Insp[redacted]

18. Recommendations:

Continued support of your wholesale dealer's authorisation (WDA(H) 18716) pursuant to Regulation 18 of the Human Medicines Regulations 2012 [SI 2012/1916] (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 [SI 2012/1916] (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[redacted]

19. Summary and conclusions:

[redacted]

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20. The inspection report should be signed and dated by the Lead Inspector:
Name: Madeleine Ault **Signature:**   **Organisation:** MHRA **Date:** 26/07/2017 [redacted]

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