Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

GDP INSPECTION REPORT

WDA(H) 34868/13177435, 16653046

WE PHARMA LIMITED

ISSUED BY:

[redacted]

Head Office:
Inspection, Enforcement & Standards Division, MHRA
151 Buckingham Palace Road
London SW1W 9SZ

Telephone: 020 3080 6000
Email: info@mhra.gsi.gov.uk

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File Ref: **Insp GDP 34868/13177435, 16653046**
Inspection Date: **19/07/2017**
Company: **WE PHARMA LIMITED**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 34868/13177435, 16653046

2. Inspected site(s) and contact details:

WE PHARMA LIMITED

UNIT 7 (C/O THE LIGHTBOX) – site ID 13177435,

UNIT 30 (C/O THE LIGHTBOX) – site ID 16653046

111 POWER ROAD
LONDON
W4 5PY
UNITED KINGDOM

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[redacted]

3. Authorised operations:

Site 13177435 (office functions only)

- ☒ Procurement
- ☐ Holding
- ☒ Supply
- ☒ Export
- ☐ Brokering
- ☐ Other activities: N/A

Site 13177435 (storage and distribution only)

- ☐ Procurement
- ☒ Holding
- ☒ Supply
- ☒ Export
- ☐ Brokering
- ☐ Other activities: N/A

4. Inspection date(s):	19/07/2017

5. Inspector(s):

Name(s) of the Inspector(s)

[redacted]

MHRA

6. References:	WDA(H) 34868

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7. Introduction:

Site and RP variation.

WE Pharma T/A WEP Clinical.

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The company was formed in 2008 and currently has two directors among them the managing director who previously had various roles within the pharmaceutical industry. The company was set up with aim to support patient access to medicines where there are specific clinical needs and also to support various pharmaceutical research and development organisations by providing comparative samples.
The company operates a MS licence (no manufacture at site, import only) and a WDA(H) at the above-mentioned premises mainly to supply unlicenced medicinal products sourced from both within the EEA and non-EEA countries.
Unit [redacted] and Unit [redacted] were not physically connected and other business were operating in between them.
The company occasionally supplies licenced products to both UK and customers abroad mainly [redacted]
The company currently has approximately 50 suppliers and 100 customers worldwide including the [redacted].

The business model described was follows:

i) Supply of products licenced in the EEA to customers within the EEA and third countries mainly [redacted] for comparative studies. Products are sourced from UK suppliers.

i) Supply of products without a marketing authorisation in the EEA to customers within the EEA only. (Specials). Products are sourced from within the EEA. Customers are mainly healthcare professionals working in hospitals in [redacted] The requirement to comply with the importing regulatory requirements of the each Member State supplied was understood by both RPs, see PIL.
Products imported from third countries are only ever supplier on within the EEA to meet special clinical needs under the MS licence; the MS licenced activities were not covered as part of this inspection.

ii) Supply of products without a marketing authorisation in the EEA and intended for export. Such products are exported directly by WEP Clinical.

Both the nominated RPs stated they had read and understood the MHRA Guidance Note 14 including the notification scheme for each import of unlicenced medicines.

Couriers were used to deliver goods to the customers on behalf of the WEP Clinical – mainly [redacted]

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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 Home Office licences were in place.
- ☐ Medicinal products derived from blood
- ☒ Immunological medicinal products
- ☐ Radiopharmaceuticals (including radionuclide kits)

☐ Medicinal gases

☒ Cold chain products (requiring low temperature handling)

☐ Other products: N/A

Date of previous inspection:

Name(s) of Inspector(s) involved in previous inspection: [redacted]

Date of last inspection: 3/12/2015

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

Some GDP issues relating to SOPs, qualification checks on customers and training remain, see 16 below.

Major changes since the previous inspection:
New Site for Holding, Supply and Export Operations
New RPs appointed.
New IT systems
'Holding' removed from Unit 7

8. Scope of Inspection:
New RP and new site 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.
9. Inspected activities:
GDP Inspection of all GDP activities, operations, records and documentation under the licence pertaining to the two sites; Procurement, Holding, Supply, Export.
10. Activities not inspected:
[redacted] registration is detailed in the compliance assessment declaration however no link to WDA(H) was detailed at the inspection.

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11. Personnel met during the inspection:

[redacted]

12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

A combined QMS for WDA(H) and MS activities was in place. Clarity was requested on use of the WDA(H) and MS to ensure regulatory requirements in relation to unlicenced medicinal products were met for example, where unlicenced medicines were sourced from outside the EEA and sold within the EEA this would only be performed under the MS and QMS should reflect the relevant procedures and training to ensure compliance.

[redacted] will act as the Lead RP supported by [redacted] both had experience of working within the wholesale/GDP environment.

Accuracy and quality of records maintained by the Lead RP was raised at the inspection due to lack of clarity on whether records of operations had been made and how the records were maintained.

The change control procedure had been implemented for the site changes and a project plan was in place. It was discussed that changes in personnel such as RP changes should also be captured.

Actions points from management review meetings were documented and followed up.

Deviation reporting and CAPA processes were in place however clarity of the procedures and records maintained was requested.

Some amendments to the SOPs are required to ensure specific GDP requirements applicable to the WDA(H) functions were defined.

Clarity on the proposed operations for each site was requested, See 16 below.

- **Personnel**

An organisational chart was in place indicating staff reporting lines to the nominated RPs and the RPs reporting line to the Managing Director. [redacted] will deputise for [redacted] in his absence.

The process on how both RPS intend to maintain their knowledge and competence in GDP, continuous knowledge of the company's licenced activities, the relevant regulations and guidance was not defined.

Training records were presented as GDP certificates, SOP training logs which included falsified medicines awareness; the new RP was in the process of reviewing all records to identify any training needs.

Controlled drugs handling was covered within the SOPs.

- **Premises and Equipment**

The company operates from two units within an office block which hosts various other businesses. Both Units were accessible via a main entrance with controlled access.

Unit [redacted] was an office with a designated area within it marked for storage of medicinal products; Unit [redacted] was currently licenced for 'Holding'; all stock will be moved to Unit 30 once the variations are approved and Unit [redacted] will thereafter only be used for office functions. Risk-assessments in relation to the site changes had been incorporated in the project plan.

Unit [redacted] was located on the opposite side of Unit [redacted] from the main entrance and was purely a storage and distribution warehouse with shelving bays on all the 4 sides of the warehouse. A CD cabinet was located nearby the main entrance and a cool room was located at the rear nearby the Goods-in/out door.

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Both units had been mapped and temperature monitoring was taking place. Unit [redacted] had recently been mapped by a third party, [redacted] and a [redacted] temperature monitoring system was installed. An older temperature system was in use in Unit [redacted]; no issues were noted. Within Unit [redacted] there were 6 calibrated temperature monitoring probes set to alarm outside 15-25°C in the ambient storage areas including the CD cabinet, 2 probes were placed within the cold room set to alarm at 2-8°C and 1 in the freezer; access to temperature readings via the [redacted] system, back-up and review was described at the inspection.

Medicines will be stored on bays with location references. Quarantine areas were clearly marked. Process flows to ensure the stock remains within the legitimate supply chain and marked areas was discussed e.g. products obtained from outside the EEA for export only under the WDA(H).

Authorised access and specific key holders of the warehouse and CD cabinet was described as part of the security measures in place. An alarm system and external cameras were also in place.

Good receipt and dispatch will be done at the rear of Unit [redacted] via a wide lockable door with shutters on the

Cleaning and pest control procedures and logs were in place

A description of the new computer system employed for warehouse functions [redacted] was available and a description on its use was incorporated within the procedures.

- **Documentation**

The QMS was mainly paper based with some documents stored on Google cloud. All paper records were stored at the premises. Back-up of electronic records and document retention periods in line with GDP requirements were defined.

Review and update to reflect the personnel changes and audits by the Lead RP were in progress. The RP(s) involvement in approval of SOPs should be clearly indicated.

Some documentation was readily available however some records of bona fide checks, deviation reports and the resulting CAPAs were not readily available due to the way some records were maintained.

Samples of notifications to the MHRA for unlicenced medicines were made available.

- **Operations**

Qualification of suppliers and customers was defined as verifying licence authorisations and GDP certificates on EUDRA where applicable for suppliers however the records reviewed at the inspection indicate inadequate checks on licence authorisations. Where the company were unable to access an Authority website/published list, a statement from an organisation (supplier/customer) confirming they were authorised to supply/receive medicines was accepted as a method of verifying the licence authorisation (ref: [redacted]

The approved supplier and customer list contained 'inactive' entries and incomplete checks. There was no documentation available to provide assurance that personnel would not place or accept orders where checks on licence authorisations were incomplete (ref: [redacted]).

Most orders are placed with suppliers based on the customers' requirements as the company mainly deals with unlicenced medicines where evidence of clinical need is required. Customer orders are made via email with the appropriate documentation attached. Notarised translations are required where documents are not written in English. Telephone orders were mentioned however these were recorded and would only be acceptable for business model (i) above. The [redacted] system will maintain a full audit trail from procurement to supply; historic records will be stored in paper form or on Google cloud. Batch numbers and expiry date records are maintained.

Stock rotation and [redacted] systems were described. Review of records by the RPs was defined as part of the RP(s) responsibilities.

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

  The Lead RP was the designated person for managing both product and service related complaints. CAPA was incorporated as part of the complaint procedures and an example of a recent service related complaint was made available, see 16 below in relation to maintaining written records of any adverse reactions from unlicenced products supplied by the company.

  No returns would be put back to saleable stock.

  The recall procedure was tested annually and a record was in place; some considerations should be made to ensure all actions taken during the recall test were clearly documented.

  Reporting requirements to the MAH and MHRA including the Yellow Card online system in relation to suspected falsified medicines were defined however the SOP should be updated to clearly indicate the obligation to report rather than it just being advisable to do so as indicated.

- **Outsourced Activities**

  No other premises/organisations were detailed for procurement, holding, supply and export.

  Audits of the transport providers were taking place.

- **Self-Inspection**

  Self-inspections take place at least annually.

  Management was involved in review of the quality system and meeting outcomes were documented.

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- **Transportation**

  The company was using [redacted]

  Pre-validated packaging was used, however no validation had taken place to demonstrate suitability of the transport methods to the company's specific business model.

- **Specific Provisions for Brokers**

  N/A - The company is not involved in brokering medicines.

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

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

1 CRITICAL

None at this inspection.

2 MAJOR

None at this inspection.

3 OTHER

3.1 The business model under the WDA(H) was not clearly defined.

3.1.1 The company holds a MS licence (import only) at the same sites specified on the WDA(H). There was lack of clarity on the distribution activities undertaken under each licence.

Please provide a detailed written description of the proposed wholesale distribution activities including the process flow (product movement) under the WDA(H).

Please also kindly provide a copy of a recent supplier and a customer invoice for a product(s) supplied under the WDA(H).

3.1.2 In general, the QMS for the WDA(H) functions should be clearly defined.

EU Guidelines on GDP 1.2, 4.2

3.2 There was no defined process in place on how the two nominated Responsible Persons (RPs) intend to maintain knowledge and competence in GDP including keeping up to date with regulations, guidance and quality issues that impact the wholesale distribution activities.

EU Guideline son GDP 2.2, 2.4

3.3 The licence obligations in relation to wholesale distribution of unlicenced medicinal products "specials" were not clearly defined within the relevant procedures, specifically:

3.3.1 The requirement to notify the MHRA for each importation of an unlicenced medicinal product.

3.3.2 The requirement to maintain written records relating to details of any adverse reaction to the product sold or supplied of which the licence holder becomes aware of.

3.3.3 The requirement to comply with particular requirements of the Member State; where unlicenced medicines are supplied to another EEA Member State.

EU Guidelines on GDP 1.2

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3.4 Qualification of suppliers and customers was found to be deficient:

3.4.1 The process of initial qualification of suppliers and customers, maintenance of the records and the process for on-going verification was not clear.

3.4.2 There was insufficient documentation to demonstrate that medicinal products exported to third countries were only supplied to persons authorised to receive those medicines. For example, a customer in [redacted] had been verified by a statement provided by the same customer confirming that the customer was a research organisation.

EU Guidelines on GDP 5.2, 5.3, 5.9

3.5 Transportation arrangements were found to be deficient in that:

3.5.1 There was no evidence of a risk-assessment or validation of the transport arrangements for ambient, cold chain and controlled medicinal products in order to demonstrate that the methods used were safe, secure and that temperature conditions were maintained within acceptable limits during transport.

3.5.2 Retention of documents generated by the freight forwarders/transport companies on behalf of the company in relation to export under the WDA(H) was not captured within the written procedures.

EU Guidelines on GDP Chapter 9, 4.2

3.6 The premises were found to be deficient in the following respects:

3.6.1 There was no defined process/marked areas to maintain control of functions undertaken under the WDA(H), specifically, 1.3 medicinal products without a marketing authorisation in the EEA and not intended for the EEA market.

EU Guidelines on GDP 1.2, 3.2

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17. Inspectors' Comments:

[redacted]

18. Recommendations:

Your application for variation to a wholesale dealer's authorisation [WDA(H) 34868] granted 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.

Continued support of your wholesale dealer's authorisation (WDA(H) 34868) 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]

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

Name: [redacted]

Signature:

[redacted]

Organisation: MHRA

Date: 21/07/2017

[redacted]