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GDP INSPECTION REPORT
WDA(H) 42792/9152832
LONDON CLAREMONT CLINIC LIMITED

ISSUED BY:


GDP Inspector

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File Ref: Insp GDP 42792/9152832-0004
Inspection Date: 10/11/2015
Company: LONDON CLAREMONT CLINIC LIMITED

GDP Inspection Report

1. Report Reference no.:	Insp GDP 42792/9152832-0004
2. Inspected site(s) and contact details:	LONDON CLAREMONT CLINIC LIMITED 50-52 NEW CAVENDISH STREET LONDON W1G 8TL UNITED KINGDOM [REDACTED]
3. Authorised operations:	<input checked="" type="checkbox"/> Procurement <input checked="" type="checkbox"/> Holding <input checked="" type="checkbox"/> Supply <input type="checkbox"/> Export <input type="checkbox"/> Brokering <input type="checkbox"/> Other activities: (please specify)
4. Inspection date(s):	10/11/2015
5. Inspector(s):	Name(s) of the Inspector(s). [REDACTED] [REDACTED] MHRA
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 42792

7. Introduction:

Business Background

London Claremont Clinic, formerly known as London Cavendish Clinic, operates as a private medical consultation clinic, specialising in ophthalmology, oncology and epidemiology. Within the clinic, a pharmacy operation engages in limited wholesale activities. The wholesale dealer's authorisation is to enable supply of medicines to the clinics within the building, private clinics within the area and to one wholesale client [REDACTED]

Categories:

MEDICINAL PRODUCTS

- ☒ with a Marketing Authorisation in EEA country(s)
☐ without a Marketing Authorisation in the EEA and intended for EEA market* **Needs to be added to WDA(H)**
☐ 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 **Needs to be added to WDA(H)**
 - ☐ Immunological medicinal products **Needs to be added to WDA(H)**
 - ☐ 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: 23/04/2014

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

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

Previous inspection findings relating to the quality system, training and complaints had been closed out. There was an ongoing deficiency relating to temperature recording.

Major changes since the previous inspection:

No major changes were identified since the previous inspection.

8. Scope of Inspection:

Routine 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:

Procurement, Holding, Supply

10. Activities not inspected:

None
11. Personnel met during the inspection:
12. Inspectors findings and observations relevant to the inspection and deficiencies:

- **Quality Management**

The quality system was suitable for the operation, however some areas were not specific to the operations carried out for example returns and temperature monitoring. Written procedures were in place for quality risk management and change control; however these activities had not been implemented. The company were wholesaling biological and unlicensed medicines, which were currently not listed as functions on the WDA(H)

- **Personnel**

The organisation structure consisted of the RP reporting directly into the directorate board. Some locum pharmacists were also trained to a level of GDP, allowing for responsibility cover when appropriate. Other than this, the RP assumed all duties at the site.

The RP job description was available for inspection, detailing responsibilities and duties. A training record for the RP and locum staff was reviewed. It was noted that due to a lack of version control in the procedures, the training logs of each staff were not able to accurately reflect training provided or required after SOP updates. Further to the last inspection, guidelines implemented in November 2013 were also encompassed in the training documentation.

The RP seemed aware of responsibilities and training appeared to have been conducted where duties have been delegated.

The RP displayed adequate GDP and Falsified Medicine training awareness.

- **Premises and Equipment**

The primary wholesale room is located in the basement of the building, in a well-lit, temperature controlled room. There were two pharmacy fridges designated for goods in and goods out, with a calibrated thermometer in each. It was noted that the procedure in place required 2-3 probes for each fridge, which was not observed during the inspection. There were a further two calibrated thermometers for the ambient temperature recording and areas had been segregated for goods in, returns and quarantine. Additionally, some ambient and cold chain stock was found to be kept within the pharmacy area shelving and fridge respectively. This stock was for supply to the clinic rooms and whilst it was segregated was not being routinely temperature monitored with calibrated thermometers.

A pest control contract was in place; however recommended actions had not been completed.

- **Documentation**

Written procedures had been approved by the RP; however they did not encompass version update, change control or a description of any changes. A number of links within the SOPs were out of date.

An spreadsheet system was in place, used to document purchases and sales, along with copies of invoices. This system was used to cross reference generated invoices and stock receipt. Electronic data is backed up by an external company onto an internet "Cloud" based system. Invoice records were generated via paper after despatch and a hard copy kept. Records of previous stock transactions appeared adequate and demonstrable against sales invoices.

- **Operations**

A validation system for customers (both and the medical clinics) was in place. This encompassed all requirements of licence, GDP certification checks, CQC and GMC checks. A similar system was in place for the suppliers. There was a monthly check of the suspended list and a further 6 monthly re-verification. Goods were temperature checked, before being checked off when received against the supplier invoices and a purchase order, cross referenced via spreadsheet. Spot-checks demonstrated the robustness of the system. Medicines stored in the wholesale room were all intended for one customer and purchased to meet the customer need. Stock purchased for wholesale to the clinic rooms was stored within segregated areas of the pharmacy. All medicines are despatched on a FEFO basis.

Delivery notes were despatched electronically and not physically with stock

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

The RP displayed a good understanding of falsified medicine and counterfeit medicine awareness, as well as reporting responsibilities. The inspectors recommended the updating of procedures to reflect the MHRA DMRC and Yellow Card reporting schemes.

It was stated that no ambient returns were accepted, and would only be in the event of the clinic making an error. Cold chain returns were not accepted in any circumstances. If ambient stock was returned, the RP described the process of quarantine and disposition assessment in line with procedures. The SOP was specific to [REDACTED] and did not encompass the supply to medical clinics.

Complaints logs were examined, divided into "Service" and "Quality" complaints adequately. It was noted that the contact details for the Defective Medicines Recall Centre (DMRC) and Case Referral Centre (CRC) in the event of falsified medicine notification were not listed on the SOP.

The recall process was displayed as being robust and tested yearly. A record of previous MHRA records was on hand at the time of inspection, as well as evidence of mock recall activities.

- **Outsourced Activities**

Outsourced activities were identified as pest control and a transport agreement with [REDACTED] for the collection of medicines.

The pest control technical agreement was found to be deficient, in that the organisation appeared in breach of service agreements by not swiftly completing recommended actions from 02/15 regarding metal shutter repair & proofing to prevent rodent activity.

- **Self-Inspection**

The self-inspection programme was reviewed and found to be adequate and completed on schedule, on a quarterly basis, although the procedure allowed for every 6 months.

- **Transportation**

[REDACTED] collect all goods and a technical agreement was in place. Clinics supplied presently are all in the same building and collected by the appropriate doctors. Fridge and ambient medicines were packed and labelled appropriately.

- **Specific Provisions for Brokers**

Not applicable to the business model

13. Other specific issues identified:
None
14. Miscellaneous:
Not applicable
15. Annexes attached:
None
16. List of Deficiencies classified into critical, major and others:

1. CRITICAL

None observed at this inspection

2. MAJOR

None observed at this inspection

3. OTHER

The company had handled medicinal products not authorised on their WDA(H). This included biological and unlicensed medicines. Please confirm that a variation will be submitted.

Human Medicines Regulation 2012 43(5)

The Quality Management System was deficient in that:

There was no evidence of a change control log to document or assess any changes relating to wholesale taking place on site.

EU GDP Chapter 1.4

Training records were deficient in that:

There was no system for recording which version of procedures personnel had been trained on.

EU GDP 2.4.

The returns procedure was deficient in that:

It did not encompass the supply of medicines to the clinic rooms and customers not holding a WDA(H). Please see attached guidance issued by the MHRA and provide the updated SOP

EU GDP Chapter 6.3

Premises and equipment were deficient in that:

There was no daily temperature recording for the ambient and refrigerated medicines stored for wholesale to the clinic rooms.

The thermometer in use for the refrigerated medicines was not calibrated.

EU GDP 3.2.1, 3.3

Pest control arrangements were deficient in that:

There was no evidence that the recommendations made by the pest control company in February 2015 had been completed.

London Cavensdish Clinic was in breach of their written agreement with the pest control company by not implementing the advised changes.

EU GDP 3.2, 7.3

Written procedures were deficient in that:

Quality procedures regarding disposition of stock was not updated with DMRC contact details or the Yellow Card reporting scheme.

The written procedure describing temperature monitoring was not in line with activities undertaken.

EU GDP 4.2

The supply of medicinal products was deficient in that:

There was no delivery note enclosed with the medicinal products that detailed the date, name and pharmaceutical form of the medicinal product, quantity supplied, name and address of the supplier, name and address of the consignee.

EU GDP 5.8

17. Inspectors' Comments:

Satisfactory response to the post inspection letter, continued support of the licence will be recommended to the Licensing Authority.

18. Recommendations:

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Continued support of your wholesale dealer's authorisation (42792) 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 10/11/2018

19. Summary and conclusions:

Within the scope of the inspection, the company operates in accordance 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.

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

Name:

[Redacted]

Signature:

[Redacted]

Organisation:

MHRA

Date: 11/12/2015

Distribution of Report:

[Redacted]