Medicines & Healthcare products Regulatory Agency

MHRA

GDP INSPECTION REPORT

WDA(H) 16098/7561

PROCTER & GAMBLE UK

ISSUED BY:

[redacted]

Senior GDP Inspector

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Medicines & Healthcare products Regulatory Agency

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File Ref: **Insp GDP 16098/7561-0001**
Inspection Date: **21/10/2019**
Company: **PROCTER & GAMBLE UK**

GDP Inspection Report

1. Report Reference no.:	Insp GDP 16098/7561-0001
2. Inspected site(s) and contact details:	
PROCTER & GAMBLE UK THE HEIGHTS BROOKLANDS WEYBRIDGE KT13 0XP UNITED KINGDOM	
3. Authorised operations:	
☒ Procurement ☐ Holding ☒ Supply ☐ Export ☐ Brokering ☐ Other activities: (please specify)	
4. Inspection date(s):	22/10/2019
5. Inspector(s):	
Name(s) of the Inspector(s). Peter Brown Tanya Giles **MHRA**	
6. References:	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 16098

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7. Introduction:

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Business Background

The business operates as a virtual WDA(H) holder for an MIA, utilised to manage the planning, purchase and delivery of medicines. The company primarily procured from CMOs within the EEA & North America. The business primarily supplied Health & Beauty GSL & P lines. Product was held at the Skelmersdale site. The company held an MA for 6 products, over [redacted] lines. The business had recently merges PGT and Merck Consumer Health to created P&G Personal Health Care International.

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: N/A – First inspection of site.

Date of last inspection: N/A – First inspection of site.

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

N/A – First inspection of site.

Major changes since the previous inspection:
N/A – First inspection of site.

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.

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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, Supply
10. Activities not inspected:
None.
11. Personnel met during the inspection:
[redacted]
12. Inspectors findings and observations relevant to the inspection and deficiencies:

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- **Quality Management**

The company utilised a global QMS, with local processes adapted to meet the needs of the organisation. The principles of the QMS were based on Corporate Quality Policy, Procedures and Standards. A significant number of changes were being undertaken by the company following a re-structure, which included the implementation of SevenSeas QMS areas, which would include front line reporting mechanisms to the Competent Authority. This theme would be consistent through the inspection for EU GDP Compliance deficiencies.

The company utilised multiple [redacted] sources to control their operations pertaining to GDP. These included Trackwise pertaining to CMO sites, audits and complaints management, [redacted] detailing quality management, [redacted] detailing Digital Specification tools and artwork policies, My Training containing artwork and two GMP specific systems. The RP maintained oversight of these systems.

Deviation management was defined within [redacted] titled Quality System Failure Identification & Investigation Reporting. This defined 4 classification of deviation, including potential serious failures and serious failures. This was considered applicable if critical regulatory non-compliance were identified. Deviations were to be closed within 30 days, and QA could grant extensions where justified. QA retained ownership of CAPA assignment. No Deviations had been raised at the time of inspection.

CAPA management was defined within [redacted] This document detailed CAPA requirements. It was unclear exactly as to which CAPA process should be utilised to document EU GDP CAPA. It was noted existing systems lacked some medicine specific considerations within CAPA principles.

Change Control management was defined within various processes. Although generally acceptable, it was noted that no change control had been considered or raised to facilitate the addition of the Weybridge site to the licence, nor for the appointment of the proposed RP. The outputs of wider change control activities were examined.

Quality Risk management was defined within [redacted] This process defined a number of factors, such as KPIs and external sources, which could be considered pertinent to risk management. It was unclear as to what tools would be utilised to formally assess and define risk, or how risk and control measures would be formally assessed. It was accepted this process was undergoing change.

The management of outsourced activities were defined within processes, however, were not managed by the site. There was no proposal for the auditing of [redacted] or transport options. It was unclear as to how this would be managed locally. At the time, there was no proposed audit schedule. A process for Managing External Business Partners was in place, defined within a global process [redacted] Frequencies of audit had been defined depending on risk output.

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Management review was defined within [redacted]. This procedure detailed a requirement for quality management review; however, it was noted the process was not effective until 16/11/2019. No management review had been conducted to date, as a result. As a new site, this was considered acceptable.

- **Personnel**

A structure defining RP reporting lines within the organisation was in place. Responsibilities of the RP were included within [redacted] and document [redacted]

A document detailing the split of duties between the RP at this site and the GMP site was in place. The RP had undertaken GDP training via RSSL. The RP anticipated attending the Symposium to increase knowledge and evidence of MHRA Blog Review was available.

Training records were examined. It was noted the RP had recently undergone data integrity training, and the QA Lead had undertaken a 3-day GDP training course.

Training records were completed within an e-system, My Learning.

A training matrix was in place detailing responsibilities and requirements.

Training activities were defined within [redacted].

A sample request of sales team records was examined. It was described that this would be taken in house from April 2020. An example of GxP training these staff had undertaken was examined. The content of training appeared to be generally acceptable.

- **Premises and Equipment**

The premises consisted of dedicated office space, located in the Procter & Gamble building. This facility was utilised only to procure and supply medicines by way of flash transfer. There was no other activity conducted on site.

A number of [redacted] systems were utilised by the company. These processes were validated via the Corporate Digital Quality Group. The RP anticipated reviewing these changes by way of the Change Control approval and regulatory assessment. A written description of computerised systems was not in place at the time of inspection.

- **Documentation**

SOPs were electronically kept via [redacted] No paper-based records were in use.

Documentation appeared adequately version controlled and was appropriately authorised.

Electronic QMS documentation pertaining to change control outputs were in place, however, were not pertinent to the scope of the inspection.

Procurement and sales records were managed via a Merck SAP system. A change control to manage this via [redacted] was in place, undergoing Regulatory Assessment.

- **Operations**

Operations pertaining to Procurement & Supply were examined, defined within [redacted]

Qualification of customers and suppliers were considered. This included a review of QA documents from companies, as well as independent validation of credentials against MHRA & HPRA sources. These checks were defined as being due to review at a minimum of annually. The content of the processes appeared acceptable. Outputs of bona fide assessments had been reviewed by the inspector, which included annual and monthly checks which were being undertaken by the site.

Procedures or policy detailing the “sale”, or flash transfer, of stock had not been defined in process, however, was included within Quality Manual Documentation and appeared acceptable for the purpose of inspection.

Generally, processes pertaining to EU GDP activities were acceptable via SOPs and Quality Manuals.

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

  Complaints management was defined within policy and procedure [redacted] This process adequately detailed reporting mechanisms to the Competent Authority.

  Returns were not managed by the site primarily and were facilitated by [redacted] The RP on site could facilitate this, however it was unlikely this would occur. This was defined within a local SOP, however there was no consideration of RP approval within any documentation.

  Suspected Falsified Medicines awareness was detailed within a [redacted] document outside of the local supply chain. This lacked reporting mechanisms to the Competent Authority, although the RP provided assurances this would be in place by April 2020.

  Recall activities were designated as the responsibility of the site and RP, defined within [redacted]. This did not include classification of the class of recall, nor a requirement to test the recall system.

- **Outsourced Activities**

  A limited number of outsourced activities had been identified; however, this was likely to change by April 2020. It was anticipated that Transport and Storage via [redacted] would be included within outsourced activities.

  There were no written agreements with [redacted] or any alternate transport company at the time of inspection.

- **Self-Inspection**

  A self-inspection programme was in place. The programme was driven by way of using a global programme, which selected the type of site in use and populated questions which an auditor used to assess compliance.

- **Transportation**

  Transportation functions were provided by [redacted] This relationship had been established for some time, however, was due to end. No alternate provider had been sourced at the time of inspection. A rolling agreement with [redacted] was in effect on a month by month basis in the interim.

- **Specific Provisions for Brokers**

  Not applicable to business model.

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 observed.

2. MAJOR

None observed.

3. OTHER

3.1 Quality Management Systems were deficient, in that:

3.1.1 Some documentation, such as the Global CAPA Management process, lacked specific detail pertaining to medicines management.

3.1.2 There had been no change controls completed pertaining to the addition of the new site.

3.1.3 There had been no change controls raised pertaining to the proposed appointment of the RP.

EU GDP Chapter 1, sub-section 1.2

3.2 Quality risk management was deficient, in that there was no formal mechanism for quantifying and assessing risk levels, applicable to EU GDP.

EU GDP Chapter 1, sub-section 1.5

3.3 Complaints management was deficient, in that there was no formal mechanism to report quality complaints to the local Competent Authority.

EU GDP Chapter 6, sub-section 6.2

3.4 There were no technical agreements in place with transport providers.

EU GDP Chapter 7, sub-section 7.2, 7.3

3.5 There was no EU GDP Compliant written description of computerised systems.

EU GDP Chapter 3, sub-section 3.3.1

3.6 Recall activities were deficient, in that:

3.6.1 There was no local recall SOP defining recall classifications.

3.6.2 There had been no local mechanisms put in place to test the recall system.

EU GDP Chapter 6, sub-section 6.5

3.7 Returns activities were deficient, in that there were no mechanisms to formalise RP oversight of returns functions.

EU GDP Chapter 6, sub-section 6.4

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17. Inspectors' Comments:
The company must consider the implementation of [redacted] processes, which would include reporting mechanisms to the Competent Authority, as a priority. Satisfactory response to post inspection letter.
18. Recommendations:
[redacted]
19. Summary and conclusions:
[redacted]

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20. The inspection report should be signed and dated by the Lead Inspector:
Name: [redacted] **Signature:** [redacted] **Organisation:** MHRA **Date:** 21/10/2019 [redacted]

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