Medicines & Healthcare products Regulatory Agency

MHRA

File Ref: Insp GDP 6699/14748554-0003
Inspection Date: 9th and 10th February 2021
Company: TESTERWORLD LIMITED

OFFICIAL – COMMERCIAL

[redacted]
TESTERWORLD LIMITED
7 REGENTS DRIVE,
LOW PRUDHOW INDUSTRIAL ESTATE,
PRUDHOW.
NE42 6PX.

12/02/2021

[redacted]

Case No: Insp GDP 6699/14748554-0003

Dear [redacted]

THE HUMAN MEDICINES REGULATIONS 2012
Good Distribution Practice WDA(H) 6699

I refer to the inspection carried out at your company's premises at Units 3&4 Trade Link, Weston Avenue, Grays on 9th and 10th February by [redacted] and [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 and to require the issue of a Statement of non-compliance with GDP.

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.

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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

It would be appreciated if your response was in the following format:

1. Restate the deficiency number and the deficiency as written below.
2. State the proposed corrective action and the target date for completion of these action(s)
3. Include any comment that the company considers appropriate.
4. Please provide the response as a word document.

Yours sincerely,

[redacted]

Lead Senior GDP Inspector
Tel: [redacted]
Mobile: [redacted]
email: [redacted]

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

1 CRITICAL

1.1 The Licence holder had failed to maintain a quality system setting out responsibilities, processes and risk management. This was evidenced by:

1.1.1 Deviation 20 dated 5/8/2020 did not consider the impact of potential supply of narcotic and psychotropic medicines to persons where monitoring and controls were not in place. Only sales taking place during June and July 2020 were considered within the deviation report. The Deviation Report failed to properly qualify the extent and cause of the issue, including identifying appropriate CAPA, applying quality risk management and assessing the potential regulatory and public health issues;

1.1.2 The limited impact assessment associated with Deviation 20 was carried out 'manually' and did not include an investigation of the sales via the [redacted] system. It could not be demonstrated that the [redacted] system, reportedly 20 years old, had been effective in blocking unauthorised sales; evidenced by the procurement of narcotic and psychotropic substances by [redacted] who were not in possession of the requisite Home Office Licences to purchase or hold such products. A full investigation into the ineffectiveness of the 'No To MDA's' classification had not been conducted.

1.1.3 Deviation 20 identifies the root cause to be a flaw in the [redacted] system but fails to capture any actions taken to correct or quantify the 'Flaw' or it's wider impact.

1.1.4 SOP WT 01 – Responsible Person Operating procedure for West Thurrock dated 1/11/2016 was not in line with activities defined in other processes. E.g. section 2 referred to the depot manager checking product categories, a function being performed from the Gosforth site by [redacted] Section 3 stated the [redacted] and [redacted] are responsible for the supplier validations.

1.1.5 The QMS as implemented and maintained did not appear fit for purpose and there was evidence that procedures were not being regularly reviewed and updated, alongside there being evidence that written procedures were not being followed.

1.1.6 there was evidence that the management review process was not effective, for example procedure PRH01 v3 dated 12/11/2019 – Customer Validation had not been updated to reflect the end of the Transition Period and referred to checks on EUDRA GMDP and to decommissioning products for Article 23 customers.

1.1.7 there was evidence that the procedures in place relating to CAPA and Deviations were not being followed, including key decisions relating to the DE group processes and procedures made during quality meetings neither recorded nor appropriately actioned.

1.1.8 There was no record, change control or other documentation to indicate that the reclassification of Gabapentin and Pregabalin in April 2019 had been introduced in a timely manner and inappropriate sales prevented.

Regulations 43(1) & 43 (12) of The Human Medicines Regulations 2012 and GDP Chapter 1

1.2 The Licence Holder had failed to provide adequate resources and personnel to the role of Responsible Person to ensure the proper distribution of medical products, evidenced by:

1.2.1 The Responsible Persons [redacted] and [redacted] had failed to fulfil their duties under WDA(H) 6699.

1.2.2 There was no evidence of effective RP oversight relating to initial and ongoing customer qualification. In several instances during the inspection it was ascertained that customers holding WDA's had been incorrectly set up as pharmacies, allowing them access to medicines listed under the Misuse of Drugs Act 1971 when not appropriately authorised.

1.2.3 A customer account was live for [redacted] the weekly verification checks conducted by the RP's had not identified that [redacted] had their WDA(H) suspended on the 10th December 2020.

1.2.4 Individual roles and responsibilities of the three Responsible Persons across the DE company group were not defined, including identifying where duties were delegated.

1.2.5 There was no evidence of a system in place to ensure that the Responsible Persons had ensured the accuracy of records within the [redacted] system, used to reportedly ensure that medicinal products were only supplied to appropriately authorised persons.

Regulations 45 (1) & (2) of The Human Medicines Regulations 2012 and GDP Chapter 2, sub-section 2.2

1.3 The Licence holder Testerworld Limited t/a DE Pharmaceuticals could not demonstrate that medicines had been supplied only to those entitled to receive them. Specifically:

1.3.1 The company had supplied psychotropic & narcotic medications to [redacted] who were not entitled to hold products listed under schedules 2-5 of the Misuse of Drugs Act 1971, including but not limited to Clonazepam, Lorazepam, Nitrazepam, Tramadol, Zopiclone,

Pregabalin, Gabapentin and Co-Codamol. The supply took place over a prolonged time period from March 2018 to August 2020 and amounted to in excess of 38,000 packs over the period in question.

1.3.2 The company had misclassified the [redacted] account as a Pharmacy on initial set up of the account from the Basingstoke Office and failed to reverify that the details were correct when transferring the account to the Thurrock Office.

1.3.3 The company having discovered the mis-supply of the product failed to notify the incident to the Home Office.

1.3.4 The company had failed to trend unusual sales patterns and had no process in place to detect the increase in frequency and volume of the orders.

1.3.5 The company had failed to implement adequate controls on the [redacted] system to prevent supply of medicinal products to persons not authorised to receive them. Schedule 3 products such a Tramadol were misclassified on the system and not covered by the 'No To MDA' category set up by the IT department.

1.3.6 As a result of the failure to correctly classify products including but not limited to Tramadol and Phenobarbitone within in the computer system the Licence Holder had failed to prevent the unauthorised supply of medicines to persons of unknown entitlement to handle them in undefined quantities. The scope of this issue had not been properly qualified by the company despite the issue first being identified more than six months prior to the inspection.

1.3.7 There is no description of the various categories of customers assigned within the [redacted] system.

1.3.8 The initial account for [redacted] was opened without evidence of a WDA(H) being in place or verification that the premises was a pharmacy. There is no record of any RP oversight in the on boarding of this customer.

1.3.9 Order Capping SOP WT35 dated 28th March 2018 was presented indicating caps on 4 products, Diazepam, Nitrazepam Zolpidem and Zopiclone. [redacted] stated that 'most caps' were now in place apart from 'some' schedule 5 items and indicated that the caps were set at 3 times national prescription averages. This was found not to be the case as Diazepam 10mg was routinely being supplied at 30 times the national prescription averages with sales data not being trended.

Regulation 44(5) of the Human Medicines Regulation & GDP Chapter 5, sub-section 5.3

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2 MAJOR

2.1 Premises and Equipment were deficient in that;

2.1.1 The computer system was not described within the quality system, including processes for the secure back-up, retention & restoration of records and there had been no assessment of the need to validate or qualify the system

2.1.2 'NO TO MDA' is identified on deviation 20 as being insufficient to block some schedule 3 products from inappropriate sale and ineffective at blocking schedule 4 and 5 products from inappropriate sale

2.1.3 Alterations to data within the [redacted] system are not auditable and it is not possible to ascertain which changes have been made, by whom, and when.

GDP Chapter 3, sub-sections 3.3.1, 3.3.2

3 OTHER

None observed

4 COMMENT

4.1 As set out in paragraph 8.7 of MHRA guidance note 6, the Licensing Authority considers that the Responsible Person role is most effectively carried out as a function separate to that of the commercial management of the business.