White Pharmacy Ltd

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Inspection report

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Date of inspection visit: 14 July 2017
Date of publication: 12/09/2017

Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced focused inspection at White Pharmacy Ltd on 14 July 2017.

We carried out our initial inspection on 12 and 16 January 2017. Following this inspection conditions were placed on the provider's registration. Further inspections were undertaken on 28 March 2017 and 22 May 2017. At these inspections we found further improvements were still required.

This report covers the findings from the 14 July 2017 focused inspection. This inspection was carried out to review the provider's compliance with the conditions imposed on their registration following our inspection in May 2017. During the inspection we found further improvements were still required. The reports from our comprehensive inspections in January 2017, March 2017 and May 2017 can be found by selecting the 'all reports' link for White Pharmacy Ltd on our website at www.cqc.org.uk.

We found this service did not provide safe and well led services in accordance with the relevant regulations.

Our key findings were:

- We identified continued significant risks to the safety of patients' health and welfare, which related to insufficient or ineffective systems in place in relation to remote prescribing of medicines having regard to the General Medical Council (GMC) 'Good practice in prescribing and managing medicines and devices' guidance.
- We found cases of long term opioid analgesic and neuropathic pain relief prescribing with no access to the patients' full medical history. We saw individual risks had not been identified in the prescribing of these specific medicines and no contact had been made with the patients' GP. Furthermore, there was no documented consideration of the risks of long term opioid analgesics use and management plans for individual patients.
- Patients were at risk of harm because effective governance systems and processes were not in place to keep them safe
- The care and treatment records of patients did not always contain sufficient documentation of clinical rationale for decisions to prescribe medicines where consent was not given to contact a registered GP.
- The prescribing policy (implemented on 12 June 2017) did not outline the corporate responsibilities in relation to the issuing of prescriptions, or the governance processes in place to ensure patient safety is assured.

We identified regulations that were not being met. The areas where the provider must make improvements are:

Summary of findings

- Ensure care and treatment is provided in a safe way for all patients. Including the safe and effective prescribing of medicines.
- Implement effective governance systems and processes to enable the provider to assess, monitor and improve risks relating to the health, safety and well being of patients and staff.

Summary of any enforcement action

We are now taking further action in relation to this provider and will report on this when it is completed.

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

- We identified continued significant risks to the safety of patients' health and welfare, which related to insufficient or ineffective systems in place in relation to the remote prescribing of medicines and not having regard to the General Medical Council (GMC) 'Good practice in prescribing and managing medicines and devices' guidance. Medicines prescribed to patients during a consultation were not always monitored by the provider to ensure prescribing was evidence based.
- Patients were at risk of harm because systems and processes were not in place to keep them safe. For example, where a patient had either told the provider that they did not have a registered GP or that they did not consent for their GP being informed about the medicines they were being prescribed (especially medicines containing opioids), there was insufficient clinical rationale for the decision to prescribe recorded in the patient's records.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations.

- There were insufficient systems or policies in place to ensure safe prescribing guidelines.
- There was a lack of arrangements for identifying, recording, managing risks to ensure the implementation of mitigating actions. Therefore effective action was not always undertaken to mitigate these risks. The lack of governance arrangements for monitoring prescribing resulted in patients being at risk of harm.
- The care and treatment records of patients did not always contain sufficient documentation of clinical rationale for decisions to prescribe medicines where consent was not given to contact a registered GP.
- The prescribing policy (implemented on 12 June 2017) did not outline the corporate responsibilities in relation to the issuing of prescriptions, or the governance processes in place to ensure patient safety is assured.

White Pharmacy Ltd

Detailed findings

Background to this inspection

White Pharmacy Ltd is based in an industrial unit in Farnham, Surrey. White Pharmacy Ltd employs information technology (IT), pharmacy, dispensing and office staff at this site. They also have contracted clinicians who work remotely to authorise the prescriptions requested by patients.

The service is accessed through a website www.whitepharmacy.co.uk. Orders can be placed seven days a week and the service is available to patients in the UK and the European Union. Orders are processed onsite by staff working during normal working hours; Monday to Friday 9am to 5pm. Patients are able to register with the website, select a condition they would like treatment for and complete a consultation form which is then reviewed by a clinician and a prescription is issued if appropriate. When certain medicines are ordered for new patients for the first time, such as opioid analgesics and neuropathic pain relief medicines, a pharmacist speaks with the patient to discuss their treatment. The prescription is sent to the affiliated pharmacy before being supplied to the patient. (The affiliated pharmacy is regulated by General Pharmaceutical Council). Patients to the service pay for their medicines when their on-line application has been assessed and approved.

White Pharmacy Ltd was registered with the CQC on 12 June 2015 and they have a registered manager in place. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

We carried out our initial inspection on 12 and 16 January 2017. Following this inspection conditions were placed on the provider's registration requiring changes to be made to how the provider operated. Further inspections were undertaken on 28 March 2017 and 22 May 2017. At those inspections we found further improvements were still required and additional conditions were added following the May 2017 inspection.

This report covers the findings from the 14 July 2017 inspection. This inspection was carried out to review the provider's compliance with the conditions. During the inspection we found there had not been sufficient improvements to meet the conditions imposed.

During our inspection, we spoke with the registered manager, the acting medical director, and a superintendent pharmacist. We looked at policies, other documentation and patient records.

Our inspection team was led by a CQC Lead Inspector who was accompanied by two GP specialist advisers and a member of the CQC medicine team.

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Are services safe?

Our findings

At our three previous inspections in January 2017, March 2017 and May 2017, we found the provider was not providing safe services in accordance with the relevant regulations. Patients were at risk of harm because systems for prescribing high risk medicines were not in place to keep them safe.

At this follow up inspection on 14 July 2017 we specifically looked at the conditions imposed and whether the provider had implemented changes to meet these conditions.

We found that this service was not providing safe care in accordance with the relevant regulations.

Prescribing safety

We identified continued significant risks to the safety of patients' health and welfare, which related to insufficient or ineffective systems in place in relation to remote prescribing of medicines taking into account the General Medical Council (GMC) 'Good practice in prescribing and managing medicines and devices' guidance.

During the inspection we reviewed 48 patient records and found cases of opioid analgesics and neuropathic pain relief medicines being prescribed for periods of time in excessive of up to two years with no contact made with the patient's GP and no access to the patient's full medical history. Following a further CQC review of 29 of these records, we identified 29 patient records where patients had been prescribed medicines unsafely.

We saw an example of a patient being prescribed an opioid medicine despite the patient telling White Pharmacy Ltd that their GP would not prescribe it. White Pharmacy Ltd did not confirm with the GP the reason for this to ensure there was no clinical reason not to prescribe.

We saw an example of a patient being prescribed medicines containing paracetamol and codeine for migraines, despite the prescribing GP documenting that the medicine was not recommended for the condition it was being prescribed for. There is a risk that the medicine prescribed could be the cause of further rebound headaches and therefore increasing the risk of more medicine being taken. There was a lack of detailed history by the prescribing doctor to assure themselves that this diagnosis was correct.

In the records we reviewed there was insufficient clinical rationale of why the medicines prescribed, including the quantities, were appropriate despite being unable to share information with a General Practitioner or how patient safety would be assured in the absence of information sharing.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

At our three previous inspections in January 2017, March 2017 and May 2017, we found the provider was not providing safe services in accordance with the relevant regulations. Patients were at risk of harm because systems for prescribing high risk medicines were not in place to keep them safe.

At this follow up inspection on 14 July 2017 we specifically looked at the conditions imposed and whether the provider had implemented changes to meet these conditions.

We found that this service was not providing well led services in accordance with the relevant regulations.

Business strategy and governance arrangements

There was insufficient systems or policies in place to ensure safe prescribing guidelines such as having regard to the General Medical Council (GMC) 'Good practice in prescribing and managing medicines and devices' guidance. Although the provider had increased their contact with patient's GP from around 8% to around 22% there were still concerns with the prescribing of opioid analgesics and neuropathic pain relief medicines. The provider had implemented a prescribing policy to ensure the effective management of medicines and support clinicians with their prescribing decisions. This policy was implemented on 12 June 2017 following the imposition of an urgent condition of registration requiring the provider to ensure that an effective written prescribing policy was implemented to support safe prescribing. However, the prescribing policy did not outline the corporate responsibilities in relation to the issuing of prescriptions, or the governance processes in place to ensure patient safety was assured. There was a lack of detail within the policy in relation to clinical rationale; it stated that if no consent is obtained, a clinical rationale must be documented.

The was a lack of governance arrangements for monitoring prescribing resulted in patients being at risk of harm. We saw an example of a patient that had a documented action plan in place, to register with a GP and provide evidence of this, before any further medicines would be provided. Despite this action plan, we saw that further prescriptions had been issued, despite no evidence that registration with a GP had taken place as required by the plan.

Leadership, values and culture

The significant levels of risk found at this inspection was a direct result of the provider not ensuring appropriate systems had been implemented to effectively identify, manage and mitigate risk, particularly when prescribing opioid analgesics and neuropathic pain medicines.

On the 14 July 2017 we collected evidence which demonstrated that patients will or may be exposed to a significant risk of harm. This issue had been highlighted to the provider previously and they had failed to sufficiently mitigate this risk.

During the inspection we found changes to clinical processes and governance systems were made with a lack of provider and clinical awareness and acknowledgement of the risks of opioid analgesics and neuropathic pain medicine prescribing.

There was an interim medical director in place and the provider was advertising for a permanent post. The provider told us that they had recently taken on a clinical advisor to offer advice with implementing governance systems.