Yakub Chemist Limited

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Inspection report

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Ratings

Overall summary

We carried out an announced comprehensive inspection at Yakub Chemist Limited on 10 April 2017, during which we found that the service was not providing safe, effective or well-led services. However, we found that they were providing caring and responsive services in accordance with the relevant regulations.

Following our April 2017 inspection we issued two warning notices under Section 29 of the Health and Social Care Act 2008 which required the provider to become compliant by 28 August 2017. We issued one on 24 April 2017 in relation to breaches of Regulation 17 Good Governance and one on 28 July 2017 for breaches of Regulation 12 Safe Care and Treatment. The full comprehensive report on the 10 April 2017 inspection can be found by selecting the 'all reports' link for Yakub Chemist Limited on our website at www.cqc.org.uk.

This inspection was an announced focused inspection carried out on 6 and 11 September 2017. This was to check whether the provider had carried out their plan to meet the legal requirements in relation to the breaches in regulations that we identified in our previous inspection in April 2017. This report covers our findings in relation to those requirements and also additional improvements made since our last inspection.

Our key findings were:

- The provider was still not providing safe, effective or well-led services.
- The provider had not actioned the majority of concerns identified during the last inspection.
- Care was still not being delivered in line with current evidence based guidance. Policies did not reflect current guidance and medical questionnaires that patients completed did not reflect the policies.
- There was no evidence of effective clinical oversight.

Summary of findings

- Identification checks were not taking place routinely, nor were they completed when patient and cardholder details did not match. We saw evidence that identity checks had only been performed on nine patients since June 2017.
- Prescribing was still not monitored to ensure it was safe and in line with remote prescribing guidance.
- The provider was unable to demonstrate that medicine safety alerts issued by the MHRA or NICE guidance were acted upon or distributed to staff.
- The safeguarding policy was not specific to an online environment, did not reflect national current guidance and did not include sufficient information to protect patients.
- We were told that if a patient consented to their information being shared with their GP the provider would share the information appropriately; however, we reviewed evidence and found that information had not been shared with any GPs since April 2017. There were over 400 patient contacts that should have been shared with GPs. The administrator told us that this was a back log to be completed. The clinician was not aware of this and told us that the provider shared information with the patients GP immediately.
- The provider did not have an effective business continuity plan in place to provide a safe and effective service should the sole clinician or the information technology staff member be absent. This meant that if there was an alert or a patient safety incident when this staff member was unavailable, the provider would not be able to identify any patients at risk or take appropriate action.
- Following our previous inspection the provider had forwarded an action plan. This documented all the concerns from the warning notices previously issued and all but one of the actions required had been marked as complete. Evidence on the day of the inspection showed that this was not the case and that the provider did not have the understanding of the actions that they were required to take in relation to the breaches identified.

We identified regulations that were not being met and the provider must**:**

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.

We have taken urgent action in response to the concerns identified at Online Clinic (UK) Limited; we have suspended the provider's registration until 13 January 2018.

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 the service was not providing safe care in accordance with the relevant regulations.

- The clinician had access to the patient records held by the provider. However, the clinician did not look to see if the patient had any other previous records but assumed that the administrative staff would highlight this. The administrative staff said that they did check for any previous orders of medicines placed against the patient post code but did not routinely raise this with the clinician.
- Patient identification checks were not taking place routinely, nor were they completed when patient and cardholder details did not match. We saw evidence that identity checks had only been performed on nine patients since June 2017.
- Prescribing was still not monitored to ensure it was safe and in line with remote prescribing guidance.
- The provider was unable to demonstrate that medicine safety alerts issued by the MHRA or NICE guidance were acted upon or distributed to staff.
- The safeguarding policy that we were told by the provider was the current policy was not specific to an online environment, did not reflect the latest national guidance and did not include sufficient information to protect patients.

Are services effective?

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

- Evidence based guidelines such as NICE guidance were not always being followed. For example.
  - The asthma questionnaire did not include the Royal College of Physicians assessment questions, or any other validated tool to assess severity of the condition. In addition, it was not clear that the questionnaire would identify patients that were in the exclusion criteria in their asthma prescribing policy. In response to our findings, asthma medicines were removed from their website on the day of our inspection.
- Clinical policies that we reviewed did not reflect current evidence based guidelines.
- We saw that the policies in place were not always followed. The criteria and advice to patients stated in the policies were not mirrored in the patient questionnaires nor was the information available to patients when they accessed the service.
- We were told that if a patient consented to information being shared with their GP the provider would automatically share this information appropriately. We reviewed evidence and found that no information had been shared with any GPs since April 2017. There were over 400 patient contact details that should have been sent. The administrator told us that this was a back log to be completed. The clinician was not aware of this and told us that the provider shared information with the patients GP immediately.

Are services well-led?

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

- Following our previous inspection the provider had submitted an action plan. This documented all the concerns from the warning notices previously issued and all but one of the actions required had been marked as complete. Evidence on the day of the inspection showed that this was not the case and that the provider did not have the understanding of the action that they were required to take in relation to the breaches identified.

Summary of findings

- Policies did not support clinical governance and risk management. For example, prescribing policies were not in line with evidence based guidance and medical questionnaires did not support the provider's policies.
- On the first day of the inspection, the registered manager was unable to answer all questions relating to the service that they provided.
- There was not an effective business continuity plan in place to provide a safe and effective service should the sole clinician or the information technology staff member be absent. This meant that if there was an alert or a patient safety incident when this staff member was unavailable the provider would not be able to identify any patients at risk or take appropriate action.

Yakub Chemist Limited

Detailed findings

Background to this inspection

Yakub Chemist is an online service that allows patients to request prescriptions through a website which are then dispensed by the affiliated pharmacy. Patients register with the website www.medicines2u.com and select a condition they would like treatment for. The patient then completes a health questionnaire which is reviewed by a GP; if this request is approved a prescription is then issued and sent to the pharmacy also run by the same company for dispensing.

At the time of our most recent inspection we were told that the promoted products on line were for hormone replacement therapy (HRT), weight loss products and chlamydia medicines. Patients were also able to request medicines for asthma, male hair loss, period delay, acne, cold sores, emergency contraception and products to support smoking cessation. Following a concern we raised at the inspection on 6 September 2017 the provider withdrew the treatments for asthma.

The website can be accessed 24 hours a day but the service processes orders from 9am to 5pm Monday to Friday. The provider had employed a GP at our previous inspection. However, they now employ a clinician with a licence to practice that is not a GP, who works remotely in analysing patient information forms when patients apply online for prescriptions. A team of administration staff that support delivery of the service work at the registered location.

A Registered Manager is 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.

How we inspected this service

Our inspection team was led by a CQC Lead Inspector. On the first day the team included a GP specialist advisor and a member of the CQC medicines team and on the second day the team also included a CQC Inspection Manager.

Why we inspected this service

We undertook a review inspection of Yakub Chemist on 6 and 11 September 2017 to check compliance with the warning notices served following the inspection on 10 April 2017. The inspection focused on three of the five questions we ask about services; is the service safe, effective and well-led. This is because concerns were identified in these three areas during our previous inspection.

Are services safe?

Our findings

During our previous inspection on 10 April 2017 we found that the provider was not providing safe services in accordance with the relevant regulations. This was because:

- Patient information records were not always stored securely; patient information was accessed remotely by the GP via a hyperlink which was not password protected.
- The provider was unable to demonstrate that medicine safety alerts issued by the MHRA or NICE guidance were distributed to clinical staff.
- The GP did not have direct access to the patient's previous records held by the service and could only access the previous order history if informed by the customer service team that a previous order had taken place.
- Prescribing was not monitored to ensure it was safe and in line with remote prescribing guidance but patients were given appropriate information about their medications. The service told us that they intended to employ a clinician to monitor quality and prescribing.
- All staff had received adult and children safeguarding training appropriate to their role with the exception of the GP who had not completed adult safeguarding training. The service later provided us with evidence to show that the GP had since completed the training.

When we undertook this follow up inspection on 6 September 2017 we found that the provider had not addressed the majority of the concerns highlighted during our previous inspection. The provider was still not providing safe services.

Safety and Security of Patient Information

Patient information records were stored securely. Previously, patient details were sent via a hyperlink to an unencrypted email address. At this inspection we were told by the home working clinician that they were able to access the system directly. We were assured that the computer system was backed up to external servers and that they had adequate security controls in place.

The clinician therefore had access to the patient's previous records that were held by the service. We were told by the clinician that they did not look to see if the patient had any other previous records but assumed the administration staff would highlight this to them. The administration staff said that they checked on the post code for previous requests or orders but they did not routinely flag this to the clinician. There was no process in place for how to deal with this situation. This meant that the clinician was relying on potentially incomplete information collated by non-clinical staff in order to make a decision.

Prescribing safety

The provider told us in their action plan that was sent to us, that they used an external company to process identification checks. The clinician that we spoke with said that they understood appropriate identity checks were now completed by the administration staff on all patients. However, we found these were not completed routinely. We were told by the administrator that the identity checks were completed when there was a mismatch with the patient details. For example, if the patient name did not match the card holders name or a different address was used for billing and shipping. We reviewed three situations where the billing address did not match the card holder's address or the card holder's name did not match the patient name and there were no further identification checks completed. According to the action plan that was provided to us dated August 2017, the provider had the identification check arrangement in place since June 2017. We reviewed the system and saw that 10 checks had been completed and one of those was on the same person. The administrator told us that there was no policy in place to determine when the checks would take place and that it was at the administrator's discretion. However, we did find a policy for identification checks which stated patient identity should always be checked and confirmed. This policy had been reviewed by the Registered Manager in June 2017. We saw three examples where identity could not be proven, but a prescription was still issued.

Prescribing was not monitored to ensure it was safe and in line with remote prescribing guidance. Patients were able to access appropriate information about their medicines however the system that was used by the customers did not ensure medicine information was always provided or easily accessible.

We saw that patients were able to amend answers on the medical questionnaires; in some instances this enabled

Are services safe?

patients to give appropriate answers to have a prescription approved. These changes in response were not queried by administrative staff or the clinician to ensure the prescribing decision was safe.

Management and learning from safety incidents and alerts

There were no effective systems in place to deal with medicine safety alerts or NICE guidance. We were shown a file where medicines safety alerts were stored. The historical safety alerts within the file had all been printed on 31 August 2017. It was not clear how the clinician was made aware of these alerts, staff told us that the clinician had access to a Medicines2U (the name of the website patients used to access medicines) email account where these were automatically sent. However, the clinician told us that Medicines2U staff would forward any relevant alerts to them. Both the provider and the clinician were unable to recall any recent alerts. We reviewed the file and found that the most recent steroid medicine alert regarding chorioretinopathy, which is an eye disease that causes visual impairment, was not in the medicines safety alerts file. This meant that the provider was not aware of, or giving advice about potentially serious side effects associated with the medicines they were prescribing. There was no policy in place to determine lines of responsibility or the process to follow if an alert required changes to the medical questionnaires or prescribing policies. We were told by the registered manager that alerts would be discussed in their care meetings. The clinician did not attend these meetings. We saw that an alert regarding a risk of suicide with a medicine was documented in the care meeting minutes from 7 June 2017. However, the changes required for this alert were not evidenced in the patient questionnaire that we viewed.

Safeguarding

The safeguarding policy was not specific to an online environment. The policy did not reference any up to date guidance or how to identify abuse or doctor responsibilities regarding female genital mutilation or any consideration of modern slavery. We were also shown another version of the policy that we were told was updated; however this also was not relevant to the online environment.

Are services effective?

(for example, treatment is effective)

Our findings

During our inspection on 10 April 2017 we found that the provider was not providing effective services in accordance with the relevant regulations. This was because:

- The patient's identification was not always checked upon registering with the service or ordering a medicine.
- We were told that each GP assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards but we found this was not always happening.
- There was no evidence of safeguarding training for the GP that was working for the provider.

When we undertook this follow up inspection on 6 and 11 September 2017 we found that the provider had not addressed the concerns highlighted in our warning notice served following our April 2017 inspection.

Assessment and treatment

Evidence based guidelines such as NICE guidance were not always being followed. Clinical policies that we reviewed did not reflect current evidence based guidelines. For example,

- The asthma questionnaire did not include the Royal College of Physicians assessment questions, or any other validated tool to assess severity of the condition, to determine the severity of the condition. In addition, it was not clear that the questionnaire would identify patients that were in the exclusion criteria in their asthma prescribing policy. In response to our findings, asthma medicines were removed from their website on the day of our inspection.
- The questionnaire regarding female patients that wished to delay their period only offered the option of norethisterone and made no reference to risk of DVT (deep vein thrombosis) on the questionnaire. Current guidance recommends alternative management for this condition and neither the provider nor the clinician had identified that the policy did not reflected current guidance.
- The hair loss questionnaire for issuing finasteride did not contain the latest MHRA warning information about suicide risk. We were told by the administrator that the questionnaire had been amended but since then they thought that someone from the information technology team had removed this alteration. We saw no evidence of this and no evidence of a process of logging changes to the system.
- The policy for managing cold sores contained dosage frequencies of medicines that were not licensed or recommended for the condition.

We saw that the policies in place were not always followed and that the policy inclusion / exclusion criteria and advice to patient sections were not mirrored in the patient questionnaires or the advice given to patients who accessed the system. For example,

- The policy for smoking cessation therapy required a person to be smoking more than 20 per day or smoking within 30 minutes of waking to be eligible for the medicine offered by the service. We reviewed a record of a patient that had been prescribed the treatment when they had declared they were smoking five cigarettes a day. There was no section on the online questionnaire to state when they had their first cigarette of the day.
- The policy for using this medicine did not mention a history of psychiatric conditions being a reason for caution and requiring increased monitoring.

We were told that if a patient consented to information being shared with their GP the provider automatically shared this information appropriately. We reviewed evidence and found that information had not been shared with any GPs since April 2017. There were over 400 patient contacts that should have been shared with GPs; the administrator told us that this was a back log to be completed. However, they also said that this was not easy to do as the questionnaire asked for the GP name only and no further information such as address or other contact details.

Staff training

We saw evidence that the clinician had completed adult safeguarding and children safeguarding level three training in 2017.

Are services well-led?

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

Our findings

During our inspection on 10 April 2017 we found that the provider was not providing well-led services. This was because:

The service had some operating policies and procedures in place to support clinical governance and risk management; however, some key areas, such as prescribing, lacked a formal policy and some policies were generic and lacked specific detail to be relevant for a service operating from a digital platform.

When we undertook this follow up inspection on 6 and 11 September 2017 we found that the provider had not addressed the majority of the concerns highlighted during our previous inspection.

Business Strategy and Governance arrangements

The clinician we spoke with, who worked remotely, told us the prescribing policies had only been sent to them seven to 10 days prior to our inspection and that they had not yet had time to read them all. The clinician had not had any input to the prescribing policies.

Policies did not support clinical governance or risk management. For example, prescribing policies that were not in line with evidence based guidance and questionnaires that did not support the provider's policies. The safeguarding policy lacked detail relating to a digital service and did not reflect current guidance.

On the first day of the inspection the registered manager was unable to answer questions relating to the service that they provided. There was not an effective business continuity plan in place to provide a safe and effective service should the sole clinician or the information technology staff member be absent. This meant that if there was an alert or a patient safety incident when this staff member was unavailable the provider would not be able to identify any patients at risk or take appropriate action.

The Registered Manager did not have insight into or understanding of the requirements of the Health and Social Care Act regulated activities or how to achieve compliance. The Registered Manager did not know where to find the relevant information that they should use to ensure they met the regulations.

Continuous improvement

Following our previous inspection the provider had forwarded an action plan. This had all the concerns from the warning notices and all but one had been marked as complete by the provider. Evidence on the day of the inspection showed that this was not the case and that the provider did not have adequate understanding of the action they were required to take in relation to the breaches.