

Yakub Chemist Limited

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Inspection report

1 Highview Close Hamilton Office Park Leicester Le4 9LJ Tel: 0116 251 5199

Website: www.medicines2u.com

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Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at Yakub Chemist Limited on 10 April 2017. Yakub Chemist Ltd is an online service that allows patients to request treatment for a specific condition through the website www.medicines2u.com; this request is reviewed by a GP who then prescribes a medicine to treat the condition. This medicine is dispensed by a third party pharmacy and delivered by an external courier service. Medicines were dispatched through an affiliated pharmacy.

We found this service did not provide safe, effective and well led services in accordance with the relevant regulations but did provide caring and responsive services.

Our key findings were:

- Patients accessed the service through a website and were able to select treatment for a variety of conditions that included asthma, diabetes, erectile dysfunction and sexual health.
- We found systems were in place to protect personal information about patients but information being sent to the GP working for the service was not secure. Both the company and individual GPs were registered with the Information Commissioner's Office.

- There was a policy in place to check the patient's identification but this was only done under certain circumstances. For example, if the patient gave contradictory answers when completing the medicine request questionnaire.
- The service shared information about treatment with the patient's own GP in line with General Medical Council Guidance.
- Prescribing was not monitored to prevent any misuse of the service by patients or to ensure the GP was prescribing appropriately but the service was planning on employing a clinician to monitor prescribing.
- There were systems in place to mitigate safety risks including analysing and learning from significant events and safeguarding.
- The provider was aware of and complied with the requirements of the Duty of Candour.
- There were appropriate recruitment checks in place for all staff.
- Patients were treated in line with best practice guidance and appropriate medical records were maintained.
- Information about services and how to complain was available.
- There was a clear business strategy and plans in place.
- Staff we spoke with were aware of the organisational ethos and philosophy and told us they felt well supported and that they could raise any concerns.

Summary of findings

- There was a lack of clinical governance systems and processes in place to ensure the quality of service provision.
- The service did not have arrangements in place to provide cover for when the GP was unavailable.
- The service did not have a system in place to ensure patient safety and medicine alerts were disseminated to staff.
- The service encouraged and acted on feedback from both patients and staff.

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

- Provide care and treatment in a safe way for service users.
- Assess the risks to the health and safety of service users of receiving the care or treatment and do all that is reasonably practicable to mitigate any such risks.

- Assess, monitor and improve the quality and safety of the service.
- Maintain secure, encrypted records in respect of each service user.
- Employ sufficient numbers of suitably qualified staff and ensure they receive appropriate training.

The areas where the provider should make improvements are:

• Consider the need to minute all team meetings

We are now taking further action against the provider Yakub Chemist in line with our enforcement policy.

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.

- 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 but since the inspection we were informed that this had now been put in place.
- Both the service and the GPs were registered with the Information Commissioner's Office. The service had a business contingency plan.
- 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.
- There were systems in place for identifying, investigating and learning from incidents relating to the safety of patients and staff members.
- The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.
- All staff had received 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. All staff had access to local authority information if safeguarding referrals were necessary.

Are services effective?

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

- The patient's identification was not always checked upon registering with the service or ordering a medicine.
- Consent to care and treatment was sought in line with the provider policy. The GP had received training about the Mental Capacity Act.
- 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, for example, National Institute for Health and Care Excellence (NICE) best practice guidelines were not always being followed in relation to asthma care and informing the patients' NHS GP.
- We reviewed a sample of anonymised consultation records that demonstrated appropriate record keeping and patient treatment.
- If the provider could not deal with the patient's request, this was adequately explained to the patient and a record kept of the decision.
- There were induction and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment.

Summary of findings

• The service did not keep a formalised record of training for staff and we found that some staff members had not completed training such as adult safeguarding.

Are services caring?

We found that this service was providing caring services in accordance with the relevant regulations.

- We were told that the GP undertook consultations in a private room.
- We did not speak to patients directly on the days of the inspection but we reviewed online feedback which showed that patients were happy with the service provided. The service was rated 9.5 stars out of 10.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

- There was information available to patients to demonstrate how the service operated.
- Patients registered on the provider's website could access a variety of medicines by completing a questionnaire
 designed to assist the GP in making a decision if a prescription should be issued. The website was accessible 24
 hours a day. The GP could contact the customer directly by telephone where necessary to gather additional
 information
- Information about the service's GP was available on their website. The service employed only one GP, and there were no formal arrangements in place for when the GP was unavailable.
- Information about how to make a complaint was available on the service's website and a complaint form was available on request. Contact details were provided for customers to escalate their complaint; however, the organisations listed were unable to consider specific complaints about healthcare.

Are services well-led?

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

- There were business plans in place. 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.
- There was a management structure in place and the staff we spoke with understood their responsibilities. Staff were aware of the organisational ethos and philosophy and they told us they felt well supported and could raise any concerns with the provider or the manager.
- The service encouraged patient feedback. There was evidence that staff could also feedback about the quality of the operating system and any change requests were discussed.
- The service was committed to continuous improvement; for example, they were in the process of recruiting a second GP whose role would be to review clinical decisions made by the prescribing GP, in order to ensure that these are appropriate.



Yakub Chemist Limited

Detailed findings

Background to this inspection

Background

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 analysed by a GP and a prescription is issued. The service started operating within the last 12 months and has issued approximately 400 prescriptions.

The website can be accessed 24 hours a day but the service processes orders from 9am to 5pm Monday to Friday.

The provider employs a GP with a licence to practice 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 accompanied by a second CQC inspector, a GP specialist

advisor and a member of the CQC medicines team. We conducted our inspection on 10 April 2017 when we visited Yakub Chemist's registered location at 1 Highview Close, Hamilton Office Park, Leicester, LE4 9LJ.

Before visiting, we reviewed a range of information we hold about the service and asked other organisations to share what they knew.

During our visits we:

- Spoke with a range of staff.
- · Reviewed organisational documents.
- Reviewed online patient feedback.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Why we inspected this service

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

Safety and Security of Patient Information

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

The provider made it clear to patients what the service offered but it did not inform patients that this service was not intended for use as an emergency service. The system was not designed to manage any emerging medical issues during a consultation but the system would highlight any clinical concerns to the GP reviewing the form. The service did not offer testing or referral services and the service was not intended for use for patients with either chronic conditions or as an emergency service.

There were policies and IT systems in place but we found the patient information was not always securely protected. Patient information was emailed to the home working clinician in the form of a hyperlink which was not encrypted and could be accessed without a password. The service informed us after the inspection that the hyperlink was now password protected. There were business contingency plans in place to minimise the risk of losing patient data.

On registering with the service patient identity was not verified. Patient identification would only be verified if the patient gave contradictory answers when completing the registration form and in this case a copy of photographic identification would be requested. The service relied on the payment process to prevent anyone other than the card holder ordering medicines. There was no system in place to ensure patients were the appropriate gender or age before prescribing certain medicines.

The GP did not have 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. The service did not treat children.

Prescribing safety

Medicines were prescribed to patients who had completed an online request form. The provider told us they planned to undertake monitoring to ensure prescribing was evidence based, but as a relatively new service this wasn't yet in place. If medicine was deemed necessary following a review of the request, the GP was able to issue a private

prescription to patients. Patients could request from a set list of medicines. There were no controlled drugs on this list. If the GP felt an alternative medicine was more suitable, they were able to prescribe it.

The website included information for patients on the purpose of the medicine and any likely side effects and what they should do if they became unwell, to help patients select the appropriate medicine and dosage of choice. Patients could contact the provider by telephone for additional support, along with additional information such as guidance on healthy eating and exercise for patients requesting medicines to help with weight loss.

The website advertised medicines for long term conditions such as asthma and high cholesterol. The provider did not have processes in place for monitoring patients with these conditions, but the requests they had received so far were seen as one-off requests from patients who could not get to their usual GP. They told us they would review the pattern of ordering to identify whether further support was needed for these patients.

Antibiotic prescribing was limited and in line with national guidance.

The system did not allow the GP, who was based remotely, to access the patient record, so when a patient requested a prescription staff checked to see if the same person had ordered that medicine before, and passed the information on to the GP so that they could take that into account when deciding to approve the prescription. This meant that the GP was relying on information collated by non-clinical staff in order to reach a decision.

Prescriptions were dispensed by the affiliated pharmacy. The service had a system in place to assure themselves of the quality of the dispensing process.

There were some systems in place to ensure that the correct person received the correct medicine. For each order received the service would perform a post code search on a search engine website to see if anyone in the geographical area had placed the same order previously. If the patient was not registered on the 192.com website a phone call would be made to verify identity.

Management and learning from safety incidents and alerts

There were systems in place for identifying, investigating and learning from incidents relating to the safety of

Are services safe?

patients and staff members and we reviewed examples of reporting forms. We were told that incidents were discussed verbally but these discussions were not recorded.

We saw evidence which demonstrated the provider was aware of and complied with the requirements of the Duty of Candour by explaining to the patient what went wrong, offering an apology and advising them of any action taken.

The provider was unable to demonstrate that medicine safety alerts issued by the MHRA or NICE guidance were distributed to clinical staff. There was no evidence or records kept to show that the provider had a process in place to identify relevant alerts, check patient records to identify whether any action was needed as a result of the alert and assess whether prescribing protocols needed to be changed in line with new guidance. We reviewed a folder that contained a single alert that was dated from 2015. After the inspection the provider informed us that they were now discussing alerts regularly in team meetings.

Safeguarding

Staff employed at the headquarters had received training in safeguarding and whistleblowing and knew the signs of abuse and to whom to report them. All GPs had received level three child safeguarding training but did not have up to date adult safeguarding training. The service provided us with evidence after the inspection that the GP had since completed the training. All staff had access to safeguarding policies and could access information about who to report a safeguarding concern to. We saw that the service had safeguarding scenario posters up within their premises.

The GP had received training about the Mental Capacity Act 2005. Staff understood and sought patients' consent to care and treatment in line with legislation and guidance. Where a patient's mental capacity to consent to care or treatment was unclear the GP assessed the patient's capacity and, recorded the outcome of the assessment.

Staffing and Recruitment

There were enough non-clinical staff to meet the demand of the service but the service only had one GP working for the service and did not have a contingency plan in place for their absence. There was a support team available to the GPs during consultations and a separate IT team.

The provider had a selection process in place for the recruitment of all staff. Required recruitment checks were carried out for all staff prior to commencing employment. Potential GP candidates had to be working in the NHS and continue to do so and be registered with the General Medical Council (GMC) and were on the GMC register list for GPs and had their appraisal. Those GP candidates that met the specifications of the service then had to provide documents including their medical indemnity insurance, proof of registration with the GMC and proof of their qualifications. We reviewed four recruitment files of clinical and non-clinical staff which showed the necessary documentation was available. GPs could not be registered to start any consultations until these checks and induction training had been completed.

Monitoring health & safety and responding to risks

The service had a procedure in place to assist in identifying patient identity using a credit card check but it did not detail an effective method to verify patient identity, as photographic ID would only be requested under certain circumstances such as a patient give contradictory answers. The service did not have any clinical or prescribing policies in place that would assist the GP working for the service. There were no systems in place to ensure prescribing was compliant with relevant guidelines.

Patients were not able to choose where their medicine was dispensed as prescriptions were issued directly to the affiliated dispensing pharmacy. The provider used a 'signed for' delivery service and maintained a log of despatch and receipt.

The provider headquarters was located within modern purpose built offices but the GP worked remotely by logging into the system. Patients were not treated on the premises and the GP carried out the online consultations remotely.

The provider expected that all GPs would conduct consultations in private and maintain the patient's confidentiality but no check for this was in place. The GP used their computer to access the patient medicine request forms but this was not done securely. IT support was available at all times in case the system went down.

Are services effective?

(for example, treatment is effective)

Our findings

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

Consent to care and treatment

There was clear information on the service's website with regards to how the service worked and what costs applied including a set of frequently asked questions for further supporting information. The website had a set of terms and conditions and details on how the patient could contact them with any enquiries. Information about the cost of the medicines was known in advance and paid for before the GP reviewed the questionnaire. If the request for medicine was not approved by the GP then the patient would be contacted and an explanation given as to why the request was declined. The payment would then be refunded.

Assessment and treatment

We were told that the GP assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) best practice guidelines but there was no system in place or auditing to ensure this was happening.

If the GP had not reached a satisfactory conclusion there was a system in place where the GP could contact the patient back via the customer service team.

Patients selected a treatment and completed an online form which included their past medical history. There was a set template to complete for the consultation that included questions that would assist the GP to decide if the medicine was appropriate. If the provider could not deal with the patient's request, this was adequately explained to the patient and a record kept of the decision.

The service monitored key performance indicators for consultations such as completed medicine orders and number of prescriptions issued but there was no clinical protocol in place to monitor that prescribing was in line with relevant guidelines.

Coordinating patient care and information sharing

When a patient contacted the service they were asked if the details of their consultation could be shared with their NHS GP but it was not mandatory for a patient to give their GP details. If patients agreed we were told that a copy of the consultation notes were shared with the GP and we saw evidence that this had happened. The provider informed us after the inspection that they had since changed their registration process so it was mandatory to provide details of the patient's NHS GP, but patients could still opt out for their GP to be contacted.

Supporting patients to live healthier lives

The service identified patients who may be in need of extra support or advice. For example, we were told that the service would ask patients that requested inhalers if they are having regular asthma reviews and we confirmed this from a review of medical records.

Staff training

All staff working on site had to complete induction training which included safeguarding and information governance but there was no formal training log to monitor completed training. Staff were aware of the GMC guidance on remote prescribing. We also noted that staff had completed other training such as health and safety and customer service. The service was unable to provide evidence that the GP had completed adult safeguarding training and information governance training at the time of the inspection. We were informed after the inspection that the GP had since completed these modules and we were provided with training certificated as evidence.

We looked at five staff files and found that adequate recruitment checks had been carried out. Staff files included information such as an application form, a signed contract and proof of identity. Administration staff received annual performance reviews and the GP had received their own appraisal.

Are services caring?

Our findings

We found that this service was providing a caring service in accordance with the relevant regulations.

Compassion, dignity and respect

We were told that the GP undertook consultations in a private room. The provider carried out random spot checks to ensure GPs were complying with the expected service standards and communicating appropriately with patients.

We reviewed patient feedback from an online feedback service (Trustpilot) and found that patients were satisfied with the service provided. Patients using the service described it as quick, efficient and easy to use. The service had been rated 9.5 out of 10 based on 163 returned feedback forms. Patients described the service as excellent and that they would happily use the service again. We noted that a response was provided to patients who were not satisfied with the service.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available. There was a dedicated team to respond to any enquiries.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing a responsive service in accordance with the relevant regulations.

Responding to and meeting patients' needs

Patients accessed the service via the provider's website. Customers selected from a list of conditions, and then selected one of the medicines available to treat that condition. Patients then completed a questionnaire designed to provide information to the service's GP in order to allow them to make a decision about whether to prescribe. In some cases the GP would ask the service's customer service officers to contact the patient to gather additional information. The GP could also contact the customer directly by telephone where necessary. The service had the facility for customers to submit photographs, for example, where medicine was sought for a skin condition; however, we were informed that this facility had never been used.

Patients who had a medical emergency were advised to ask for immediate medical help via 999 or if appropriate to contact their own GP or NHS 111.Staff told us they would contact the emergency services if necessary, using the person's computer IP address to locate them.

The digital application allowed people to contact the service from abroad but all GP practitioners were required to be based within the United Kingdom. The service

delivered medicines directly to patients. Medicines could be delivered to addresses outside of the UK (for example, to patients who were away on holiday). The service did not have translation services available to patients.

Tackling inequity and promoting equality

The provider offered consultations to anyone who requested and paid the appropriate fee, and did not discriminate against any client group.

Information about the service's GP was available on their website. The service employed only one GP, and there were no formal arrangements in place for when the GP was unavailable.

Managing complaints

Information about how to make a complaint was available on the service's web site; this included information about how a patient could escalate their complaint. The provider had developed a complaints policy and procedure. The policy contained appropriate timescales for dealing with the complaint. There was escalation guidance within the policy. A specific form for the recording of complaints had been developed, which was typically completed by the provider based on information provided by the customer by telephone or email; this form was also available to customers on request. The service had received one complaint since they began operating. We reviewed this complaint and found that it was handled correctly and the patient had received a satisfactory response.

Are services well-led?

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

Our findings

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

Business Strategy and Governance arrangements

The provider told us they had a clear vision to work together to provide a high quality responsive service that put caring and patient safety at its heart.

There was a clear staffing structure and staff were aware of their own roles and responsibilities. There were some service specific policies available; however, at the time of the inspection members of staff who worked remotely could only access these if they specifically requested them. Following the inspection the service informed us that they had created the facility for policies to be accessed remotely. There were some key areas where there was a lack of policies and procedures; for example, there was no prescribing policy. Some policies were not specific to the service, for example, the safeguarding policy was generic and lacked detail relating to services operating from a digital platform.

At the time of the inspection the provider was in the process of developing systems and processes in order to monitor the performance of the service, this included the introduction of a system for the review of prescribing decisions; however, these systems were not in place at the time. We saw evidence that team meetings were held regularly, where the performance of the service was discussed.

Care and treatment records were complete, legible and accurate; however, these were not routinely available to the GP and were not handled securely. If a patient had previously used the service, the GP would be alerted to this by administrative staff, and could then interrogate information in a spreadsheet in order to retrieve these details. Prescription requests, including patients' details were accessed by the GP via a website link which was emailed to them by administrative staff; this link was not password protected and there was no operating policy in place relating to data security when working remotely. Following the inspection the service informed us that they had changed their system to make all confidential information sent to the GP password protected.

Leadership, values and culture

The director who was also the registered manager had overall responsibility for the service and they attended the service daily. The service only had one GP, who was responsible for processing all prescription requests. There was no formal arrangement in place for this role to be covered in the GP's absence. The service had a dedicated IT specialist who led on both website development and general IT support.

Staff told us that the values of the service were focussed on supporting patients to access healthcare who would otherwise be reluctant or unable to visit a GP. They aimed to deliver a high-quality and efficient service to their customers.

The service had an open and transparent culture. We were told that if there were unexpected or unintended safety incidents, the service would give affected patients reasonable support, truthful information and a verbal and written apology. This was supported by an operational policy.

Seeking and acting on feedback from patients and staff

Patients could provide feedback on the service they had received via an online rating tool (Trust Pilot) and staff monitored feedback and provided a response. All feedback provided in this way was available to view on the service's website and was positive about the service received. Patients could also email or telephone the service directly to ask questions or raise a concern and the contact details were clearly displayed on the website. In addition, patients were emailed at the end of each transaction with a link to a survey they could complete.

The provider had a whistleblowing policy in place. A whistle blower is someone who can raise concerns about practice or staff within the organisation. The director was the named person for dealing with any issues raised under whistleblowing.

Continuous Improvement

The service consistently sought ways to improve. All staff were involved in discussions about how to run and develop the service, and were encouraged to identify opportunities to improve the service delivered.

Staff told us that team meetings were the place where they could raise concerns and discuss areas of improvement; the service aimed to hold these monthly, however, we saw

Are services well-led?

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

evidence that they were often held less frequently. Staff were able to give examples of suggestions they had made to improve the service which had been implemented. We also saw evidence that specific members of staff met as needed in order to discuss issues as they arose.

The service was also in the process of recruiting a second GP whose role would be to review clinical decisions made by the prescribing GP, in order to ensure that these were appropriate.

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
	Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:Safe care and treatment
	The provider had not ensured that the GP was able to access previous records without the need for the administration staff to perform a search.
	The provider was unable to demonstrate that medicine safety alerts issued by the MHRA or NICE guidance were distributed to clinical staff.
	The provider had not ensured there was an effective patient identification system in place.
	The provider did not keep a record of training for staff and the GP had not completed adult safeguarding training.
	The provider had not ensured that there was a system in place to monitor prescribing to confirm it was in line with relevant guidelines.
	Regulation 12 (1)

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance
	Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Good Governance

Enforcement actions

The provider had not ensured that relevant policies were in place and accessible to all staff

There was no system for quality improvement and audit.

Patient data was not found to be secure at all times

There was no contingency plan in place for when the GP was absent.

Regulation 17 (1)