

MD Direct Ltd

MD Direct Ltd

Inspection report

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Essex
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Website: www.assetchemist.co.uk

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Overall summary

Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at MD Direct on 13 December 2016. MD Direct is an online service that allows patients to obtain a prescription and purchase medicines.

Our key findings across all the areas we inspected were as follows:

- There were no effective systems in place for recording, reporting and learning from significant events or safety alerts.
- Risks to patients were not appropriately assessed or managed. For example, we found patients being prescribed large quantities of inhalers but there was a lack of monitoring or follow up for these patients whose condition could put them at serious risk of harm.
- Some non-clinical staff with no formal training assessed patients' needs. Staff training was ineffective and training of clinical staff had not been assessed or monitored by the provider.
- Information about services was available on the provider's website. Information on how to complain was located within the terms and conditions section of the website. The provider told us that they did not document complaints.
- There was little understanding of continuous improvement.

- The clinician was working outside of her scope of practice, and told us they were not competent to carry out the role. The service had some policies which staff were not aware of and were ineffective.
- During the inspection the provider of the service failed to demonstrate they had the experience, capacity and capability to run the service and ensure high quality care.
- The service did not proactively seek feedback from staff or patients.
- The service did not have vision or values that were shared with staff.
- The provider was aware of the requirements of the duty of candour.

After the inspection we wrote to the provider outlining the seriousness of our concerns and our intention to take enforcement action. The provider responded saying they would voluntarily cancel their registration and stop providing services to patients immediately.

Had the provider remained registered we would have required them to take the following actions:

- Ensure there is a system to ensure recording, assessing and managing significant events.
- Ensure prescribing decisions are made appropriately and in line with clinical best practice and that appropriate safety advice is provided with each prescription.
- Ensure systems are in place to deal with emergency situations.

Summary of findings

- Ensure systems are in place to assess capacity and obtain consent.
- Ensure systems are in place to action patient safety and MHRA alerts.
- Ensure systems are in place to confirm a patient's identity.
- Ensure feedback from patients and staff is gathered to improve services.
- Ensure there is effective governance in place and that staff have received the training needed to perform their role and that they have access to policies and procedures.
- Ensure there is a policy in place for data security, safeguarding, and that the practice has an effective business continuity plan.

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

- Patients were at risk of harm because systems and processes were not in place to keep them safe. For example, there was no system in place to confirm patients' medical history and previous prescribing decisions for prescribing medicines, and no system for managing medical safety alerts.
- The sole clinician employed by the service was registered with the General Medical Council (GMC) but not a qualified GP or on the specialists register, and had not received any training in order to safely perform their role.
- The provider received the prescription requests from another service. The provider accepted the decision of non-clinical staff working for the other service were working outside the scope of their competence. For example, non-clinical staff working at the other service could decline a prescription request if they felt it was inappropriate.
- The provider did not keep recruitment files for staff.
- The service did not have a contingency plan in place to deal with the clinician being unavailable.

Are services effective?

We found this service was not operating in accordance with the relevant regulations.

- The provider did not ensure that their sole clinician was working within relevant guidelines and their clinician was unaware of guidance pertaining to the clinical scenarios they were prescribing for.
- Patient outcomes were hard to identify there was no quality improvement activity or audits. There was evidence that the assessment of a patient was not comprehensive.
- Basic care and treatment requirements were not met. Patients did not receive appropriate "safety net" advice to support the medicines they were prescribed.
- Consent to care and treatment was not sought in line with the Mental Capacity Act 2005, there was no provider policy relating to capacity and consent.

Are services caring?

- The provider informed us that a survey had been carried out on the overall satisfaction of the service patients were able to leave feedback on the 'Trustpilot' website.
- Information on the provider's website informed patients about each medicine that was on offer and what might be the suitable dose for the condition it was intended for.

Are services responsive to people's needs?

We found this service was not operating in accordance with the relevant regulations.

- Systems and processes for gathering and acting on patient feedback were limited.
- Complaints were not documented by the provider.
- There was no information of the provider's website to advise anyone with an emergency to contact the appropriate service.

Summary of findings

Are services well-led?

We found this service was not operating in accordance with the relevant regulations.

- We were shown no evidence that the service had a clear vision to deliver high quality care and promote good outcomes for patients.
 - The service had a number of policies and procedures to govern activity; these were not readily available to staff.
 - The service did not hold regular governance meetings and issues were discussed at ad- hoc meetings which were not documented.
 - The service had not proactively sought feedback from staff or patients.
 - Staff had not received performance reviews and did not have clear training/personal development objectives.
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MD Direct Ltd

Detailed findings

Background to this inspection

MD Direct Ltd. is an online service that allows patient to purchase medicines through a website. Patients are able to register with the website www.assetchemist.co.uk and complete a health questionnaire which is then reviewed by a doctor and a prescription is issued. Patients are also able to access medicines if they already have a prescription which may have been issued outside of the UK and want to purchase medicine through www.assetchemist.co.uk. Asset Chemist has a contract in place with MD Direct to provide the prescribing service. Patients using the service pay for their medicines when their on-line application has been assessed and approved by a clinician. Once approved by the prescriber working for MD Direct, medicines are dispensed by Asset Chemist, packed and posted; they are delivered by a third party courier service. MD Direct has issued over 3200 prescriptions in the last 12 months.

MD Direct employs a doctor on the GMC register to work remotely in undertaking patient consultations when they apply for prescriptions on-line. The service is accessed 24 hours a day seven days a week through a website and orders would be processed seven days a week and is available to patients worldwide. This is not an emergency service.

MD Direct was registered with the CQC on 19 May 2015. A registered manager is in place. (A registered manager is a person who is registered with the CQC 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 conducted our inspection on 13 December 2016 when we visited MD Direct Limited's operating site in Essex. We spoke with the registered manager and the sole clinician working there. We also visited the Asset Chemist location, with the permission of the Superintendent Pharmacist as Asset Chemist is not regulated by CQC. We looked at policies, other documentation and anonymised patient records.

To get to the heart of people's experiences of care, we always ask the following five questions of every service and provider:

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

Our inspection team was led by a CQC Lead Inspector. The team included a GP specialist adviser, a second CQC inspector, a member of the CQC medicines team, and a further specialist advisor.

We inspected this service as part of our comprehensive inspection programme. We carried out a comprehensive inspection of this service under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. The inspection was planned to check whether the provider is meeting the legal requirements and regulations associated with the Health and Social Care Act 2008, to look at the overall quality of the service.

Are services safe?

Our findings

Safe track record

- The service had a generic policy in place for reporting and recording significant events and staff told us they would inform the registered manager of any incidents. Since the time of registration in May 2015 only one significant event was recorded. This was raised when a prescription was issued incorrectly. The service was only made aware of the incident after a patient complained which led to an investigation and some improvements were made to prevent a reoccurrence.
- As there had only been one significant event raised, the provider was unable to carry out an analysis of significant events to identify trends and patterns. We saw no evidence that the provider ensured that learning from significant events was disseminated to staff and embedded in policy and processes. There was also no evidence available that significant events or case reviews were discussed in team meetings

Overview of safety systems and processes

The service did not have clearly defined and embedded systems, processes and services in place to keep patients safe and safeguarded from abuse:

- A safeguarding policy was available on the registered manager's computer and in printed form so not available to staff who worked remotely. Clinical staff had no awareness that a policy was in place for the service. The doctor had received training on safeguarding children and vulnerable adults relevant to their role. The registered manager was the safeguarding lead for the service but had not completed the correct level of safeguarding training relevant to perform this role safely and effectively. The service's policy stated that the safeguarding lead must be a GMC registered clinician, which the registered manager was not. When given a safeguarding scenario by the inspecting team, the registered manager was unable to provide us with a suitable course of action to protect the patient. Clinical staff told us it would be difficult to identify any potential safeguarding issues with the current clinical consultation system and had no idea how they would deal with any safeguarding concerns if they arose.
- We asked about how patient safety alerts were dealt with and we were told that alerts were not received by

the doctor. There was no system in place for recording and monitoring safety alerts, such as those provided by the Medicines and Healthcare products Regulatory Agency (MHRA). The registered manager told us that copies of alerts were kept at a separate location but were not disseminated to, or discussed with clinical staff at MD Direct. This meant that the provider had no oversight as to whether any patients were or had been prescribed medicines which were the subject of safety alerts.

- We were told by the provider that a patient's identity would be verified by comparing details on a submitted prescription to what the patient had entered during the online registration. However, no identity checks were performed for patients that had not submitted any previous prescription. We were told that the service would rely on patients entering accurate and truthful information during the registration process. This meant that there was a risk that prescriptions could be issued to people under 18 years of age.
- The provider did not keep any employment personnel files for staff members so it was not possible to ascertain if recruitment checks had been undertaken prior to employment. The clinician told us that a Disclosure and Barring Service (DBS) check was in place at the time of starting employment but a copy was never provided to the service. The provider was also unable to provide us with proof that the doctor had medical indemnity insurance.
- The sole clinician employed by the service was registered with the General Medical Council (GMC) but not a qualified GP or on the specialists register. They acknowledged that they were not adequately trained to carry out this role effectively.

Medicines Management

- We asked the provider what systems were in place to identify and analyse any incidents, near misses and clinical errors. We were told that any issues that arose between the prescriber and the pharmacy or the prescriber and the patients requesting prescriptions were dealt with as they arose. There was no system in place for recording these types of incidents, and therefore no opportunity to review or audit them.
- We asked how the list of medicines for which prescriptions could be requested via the affiliated

Are services safe?

pharmacy website had been developed. There was no documented strategy for considering the range of medicines to make available, and there had been no risk assessment undertaken when developing the list.

- We noted that the provider prescribed unlicensed medicines, for example a medicine which is licensed for use in prostate enlargement but which was being used for hair loss. Because the medicine was being used outside of the licensed indications, the leaflet supplied by the manufacturer did not include information which was relevant to the patients. We did not see evidence of consent by the patient to acknowledge and accept that they were receiving a medicine for use outside of its licence, and no records were kept of the rationale for prescribing. This posed a risk to the patients and was not in accordance with General Medical Council guidance.
- Since patients could be based anywhere in the world the provider was unable to adhere to local prescribing guidelines for antibiotics and therefore could not ensure the appropriate use of antimicrobials.
- In addition to offering prescriptions for the medicines listed on the website, the provider issued prescriptions for other medicines including repeat prescriptions for long term conditions, based on information supplied by the patient to show that they had previously been prescribed the medicine such as a previous prescription. However, we found that patients were not always providing proof of a previous prescription. We saw that prescriptions, including some from overseas, would be transcribed and signed by the doctor. These prescriptions included medicines for diabetes, Parkinson's disease, heart disease and Lithium for bipolar disorder, all conditions which require regular monitoring. There was no provision within the service for the doctor to undertake this monitoring, and no evidence that they ascertained that it was being carried out elsewhere.
- We saw that a prescription was issued for a medicine used to prevent organ transplant rejection, which is intended to be prescribed by qualified transplant specialists. The provider told us that they would transcribe prescriptions for fertility treatment, originally prescribed by overseas fertility clinics. The doctor issuing the prescriptions did not have any training in

these specialist fields and relied on the original prescriptions. This was not in line with general medical council guidance on prescribing which requires the doctor signing the prescription to take clinical responsibility.

- Some of the original prescriptions were not in English, and although a manager told us they would always contact the original prescriber and ask them to re-issue an English version, another person told us they sometimes used Google translate. This meant that the doctor signing the prescription may not have understood the directions intended by the original prescriber.

Monitoring risks to patients

Risks to patients were inadequately assessed and managed.

- There were few procedures in place for monitoring and managing risks to patient and staff safety. There was no health and safety policy available. Only the provider's staff used the premises but no consideration as to the workplace risks had been given or to staff working remotely.

Arrangements to deal with emergencies and major incidents

The service did not have adequate arrangements in place to respond to emergencies and major incidents.

- There were no systems or protocols in place to deal with medical emergencies should one take place during an on line consultation. The service also had no way to identify the location of a patient.
- The service had a business continuity plan in place for major incident such as power failure or building damage. The plan was incomplete and did not contain any staff details other than the registered manager. There was also no consideration given to how the provider would deal with all the personal data held on their computer systems should the company cease trading. The registered manager told us the IT system was contracted out to a third party but was unsure if the data was secure and encrypted at all times and we were unable to confirm this. MD Direct was not registered with the Information Commissioner's Office (ICO).

Are services effective?

(for example, treatment is effective)

Our findings

Effective needs assessment

- The service had no overall strategy for assessing the needs of patients who were requesting prescriptions. Staff employed by another organisation at a different location were working on the customer service desk and were responsible for processing on-line application forms, which included a questionnaire specific to the medicine applied for. We were told non-clinical staff working for the other provider decided if a customer was making an inappropriate request, for example, a repeat request for codeine based products; however there was no policy in place to provide guidance to staff, but we were told that staff had received training for this role. Once the application was processed, this would be sent to the doctor at MD Direct for review. If there was a need for the clinician to converse with the applicant, this could be facilitated through e-mails but we saw limited evidence that this was regularly happening. The doctor we spoke with told us they were not aware of relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) best practice guidelines.
- We were provided with a spreadsheet which detailed all orders processed. We randomly selected 20 orders and requested the full record. We saw several examples of prescribing which was unsafe and put patients at risk. For example a patient was prescribed five salbutamol inhalers for asthma without consideration of the risk that the patient's condition could be severe. Another patient was prescribed one box of co-codomol and 10 boxes of ibuprofen (840 tablets) for 'casual headaches'.
- There was no system in place to ensure patients were being monitored by a GP or physician. There were examples of patients with long term conditions being prescribed large quantities of medicines which would also require having regular blood tests and there was no evidence to support that this was happening. The service did not share information with a patient's GP or regular physician, and did not prompt the patient permission to share information on registration.
- We found that some of the questionnaires completed by patients did not request adequate information to make an informed clinical judgement.

Management, monitoring and improving outcomes for people

There was no evidence of quality improvement including effective clinical audit.

- We asked to see examples of clinical audits and quality improvement activity but the service had not carried out any clinical audits or quality improvement.
- There was no evidence that the service participated in any benchmarking or peer review.
- We were provided with no examples of where audit or assessment of the service had led to any improvements for patients.
- There was no evidence of improved health outcomes for patients or that the service was encouraging people to lead healthier lives.

Effective staffing

We were shown no evidence that the staff had the skills, knowledge and competence to deliver effective care and treatment.

- The service did not have an induction programme for newly appointed staff.
- The doctor did not have an awareness of how to access the service policies and did not have any clinical supervision or peer support. The doctor also told us that they had not received any training for this role and that they were not competent to do the job.
- The service could not demonstrate how they ensured role-specific training and updating for relevant staff. For example, training for on-line consultations. The service did not have any training records for any employees at MD Direct.
- The provider had no oversight of continuous professional development of the doctor.

Coordinating patient care and information sharing

The information needed to deliver care and treatment was not available to relevant staff in a timely and accessible manner as staff did not have access to a patient's medical notes and were reliant on the patient's summary of their medical history. Clinicians were unable to be certain what other medicines patients were taking before deciding on whether to approve a prescription application.

- This was not an NHS provider, so did not have access to 'special notes'/summary care record which detailed information provided by the person's GP.

Are services effective?

(for example, treatment is effective)

- The provider told us that they did not share information with the person's usual doctor or GP with whom they were registered, and we saw that there was no option on the registration or order forms for patients to consent to the information being shared.
- We saw no evidence of the provider working collaboratively with other services, other than the supplying pharmacy.
- Staff did not understand the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. staff were unable to describe the action they would take in response to assessing patients capacity to make their own decisions Management and clinicians we spoke with believed that the fact a patient was able to complete an on-line form was sufficient to evidence their capacity to make decisions about their care.
- The provider told us they only treated adults (over 18 years). However, there was no evidence that they carried out checks on whether applicants were over 18 years.

Consent

Staff did not have an understanding of how to seek patients' consent to care and treatment in line with legislation and guidance.

Are services caring?

Our findings

Kindness, dignity, respect and compassion

The provider informed us that a survey had been carried out on the overall satisfaction of the service and had achieved a score of 70%. However we were not provided with how many patients had responded or what questions were asked. We were also told that the time for processing prescriptions had been reduced from two days to 24 hours but there was no data available to confirm this.

Care planning and involvement in decisions about care and treatment

The service provided limited facilities to help patients be involved in decisions about their care:

- Staff told us that translation services were not available for patients who did not have English as a first language. The provider's website only had information and application forms in English.
- Information on the provider's website informed patients about each medicine that was on offer and what might be the suitable dose for the condition it was intended for.
- The price of prescriptions was clearly displayed on the Asset Chemist website accessed by patients using the service.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Responding to and meeting people's needs

- All patients using the service referred themselves for medicine prescriptions. None were referred from NHS services.
- The website was available 24 hours a day, seven days a week. Patients logged onto the provider's website and gave their personal details and credit card information for payment purposes. Once they had completed an online questionnaire for their preferred medicine, the application was sent via the system to the customer service desk. An assessment was made by non-clinical staff at this stage as to the validity of the application. Once it passed or failed this stage it was sent via the system onto one of the prescribing clinicians, who made a further assessment and either declined or approved the application. The reasons for applications being declined were passed by the clinician to the customer service team who would respond to the applicant and feedback the reason for the decision. The reason for the decision to decline and the feedback to the customer were not always recorded, so were unavailable for scrutiny by the inspection team. Approved applications led to a prescription being issued and the medicines being dispensed by the supplying pharmacy, then packed and posted out by the pharmacy staff. A third party courier company were responsible for delivery to the patient's address which would require a signature for receipt.

Tackling inequity and promoting equality

- The provider treated all adults aged 18 years and over (although there were no systems in place to ensure those using the service were over 18 years). The provider did not discriminate against any client group.
- No translation services were provided either on the website or in any correspondence with the patient. The provider had made no assessment of the need for patients with sensory impairment and how they might potentially access their website. For example, the use of screen readers.

Access to the service

- Patients accessed the service via the website from their computer or other portable device with internet access.
- This was not an emergency service. There was no information of the provider's website to advise anyone with an emergency to contact the appropriate service (999, their own GP or NHS 111).

Listening and learning from concerns and complaints

- The service did not have a complaints policy in place, but in the service's terms and conditions information was given on how to complain using an email address.
- The website had a 'contact us' form for patients to get in touch if they had any issues or questions. The provider told us that patients have complained previously if their orders were rejected or delayed but complaints were not documented.
- We were told that the website company provided feedback on usage of the website but we were not provided with any further information.
- The service did not have a contingency plan in place to ensure there was adequate cover if the sole doctor at the service was unavailable.

Are services well-led?

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

Our findings

Vision and strategy

We were shown no evidence that the service had a clear vision to deliver high quality care and promote good outcomes for patients.

- The service had a statement of purpose, however staff could not tell us about its contents and objectives. The statement of purpose stated that patients would be seen by a GP prior to commencing a course of treatment, which was not happening at the time of this inspection.
- There was no strategy or supporting business plans that reflected the vision and values and the service did not have vision for the future.
- There was no clear organisational structure.
- We were told that no structured business or quality meetings took place and that when informal discussions did take place, these were not documented.

Governance arrangements

The service had no overarching governance framework to support the delivery of the strategy and good quality care:

- Policies were written but not all staff knew of their location. The policies we looked at were generic

downloaded policies and some were incomplete and lacking detail. For example the business continuity policy did not contain enough information for the service to be able to deal with an incident.

- There was no system of quality improvement including clinical and internal audit to monitor quality and to make improvements.
- Arrangements for identifying, recording and managing risks, issues and implementing mitigating actions were sparse. There was no risk register and little awareness of clinical risk.
- The provider was not carrying out the service in line with their own statement of purpose. Their statement of purpose on file stated that a GP would see a patient prior to commencing a course of treatment.

Leadership, and culture

During the inspection the provider of the service failed to demonstrate they had the experience, capacity and capability to run the service and ensure high quality care.

Seeking and acting on feedback from patients, the public and staff

Patient feedback was limited and the provider did not document patient complaints or comments and was unable to demonstrate that any improvements had been made in response to patient feedback.