FMC Marketing Ltd

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Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 17 April 2017, at the following location: Grand Union Studios 1.21, 332 Ladbroke Grove, London, W10 5AD. At this inspection we found that the provider was providing responsive services. However, they were not providing safe, effective, caring and well-led services.

In August 2017 the provider removed this location from their registration and added the following location to their registration: 69 Old Street, London, EC1V 9HX. We carried out an announced comprehensive inspection on 5 December 2017 to ask the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were: Are services safe?

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

Are services effective?

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

Are services caring?

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

Are services responsive?

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

Are services well-led?

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

Our key findings were:

- The provider identified, assessed and mitigated most risks to patients. However, there were risks associated with identification checking and security of data if the provider ceased to continue trading and a lack of ability to share information with a patient's GP.
- There were systems to learn from incidents and events. Safeguarding processes were in place and staff had relevant training.
- Assessments of patients' needs and documentation related to treatment were thorough and comprehensive. The provider offered treatment in line with national guidance.
- Consent procedures were in place and these were in line with legal requirements. There was an appropriate system for recording and updating patient care and treatment information.
- Patients' individual needs were included in their assessments. There was timely access to treatment once requested.

Summary of findings

- There was a complaints process and we saw complaints were investigated and responded to.
- According to patient feedback obtained by the provider, services were delivered in a compassionate and caring manner and their privacy and dignity was respected.
- Although qualifications were checked, there was not a system to ensure staff maintained skills and experience on an ongoing basis.
- The process for monitoring safety alerts needed to evidence that alerts were reviewed upon receipt.
- The system for checking the identity of patients and gaining consent to share information with a patients GP needed reviewing to ensure all risks were mitigated.
- There was a clear ethos of patient centred care. Governance arrangements were mostly in place and enabled the day to day running of the service and identified where improvements may be required to the quality of the service. Patient feedback was encouraged and considered in the running of the service.

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.

You can see full details of the regulations not being met at the end of this report.

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 always providing safe care in accordance with the relevant regulations.

Are services effective?
We found that this service was providing effective care in accordance with the relevant regulations.

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

Are services responsive to people's needs?
We found that this service was providing responsive care in accordance with the relevant regulations.

Are services well-led?
We found that in some areas this service was not providing a well-led service in accordance with the relevant regulations.

FMC Marketing Ltd

Detailed findings

Background to this inspection

Background

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.

FMC Marketing Ltd was established in 2003 to provide an online clinic, consultation, treatment and prescribing service for a limited number of medical conditions to patients in the United Kingdom, Germany, Scandinavia and Portugal. They registered at Grand Union Studios 1.21, 332 Ladbroke Grove, London, W10 5AD until August 2017 when they de-registered and registered a new location at 69 Old Street, London, EC1V 9HX. When they changed location they were registered as a new provider although the legal entity remains the same.

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.

The number of conditions treated had recently been reduced to; weight loss, hair loss, contraception, anti-malaria, period delay, smoking cessation, allergy management, acne and erectile dysfunction. FMC Marketing Ltd consists of four members of staff which includes the registered manager, patient services manager and two GPs. The provider had recently recruited these two GPs to provide clinical services and were no longer using previous clinicians. The GPs were employed to undertake remote patient consultations by reviewing patient requests and completed medical questionnaires when patients apply for medicines on-line. The service's call centre is open between 10am and 3pm Monday to Friday. However, patients are able to submit a request for treatment 24 hours a day, seven days a week on the providers website. Requests for treatment received up to 3pm on a weekday were generally dealt with within a three hour timescale. Other requests were dealt with the following working day. This is not an emergency service. Subscribers to the service pay for their medicines when their on-line application has been assessed and approved. Once approved by the prescriber, prescriptions are issued to one of the pharmacies used by the provider who are contracted to supply the prescribed course of treatment. FMC Marketing Ltd is operated via four separate websites (www.firstmed.co.uk, www.prima-med.com, www.pharmadoctor.co.uk and www.myonlinedoctor.co.uk).

How we inspected this service

Our inspection team was led by a CQC Lead Inspector accompanied by a GP Specialist Adviser.

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

During our visit we:

- Spoke with the registered manager, the patient services manager and the two GPs employed by the service.
- Reviewed organisational documents.
- Reviewed patient consultation records.

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

questions:

- Is it safe?

Detailed findings

- 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

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

Safety systems and processes

The service had mostly clearly defined and embedded systems, processes and practices in place to keep people safe and safeguarded from abuse, which included:

- Arrangements were in place to safeguard children and vulnerable adults from abuse that reflected relevant legislation and local requirements and policies were accessible to all staff. The policies clearly outlined who to contact for further guidance if staff had concerns about a patient's welfare. There was a lead member of staff for safeguarding. All staff had completed safeguarding vulnerable adults and children training to suitable levels.
- There was a log of recruitment checks held by the provider. This indicated that all recruitment checks had been undertaken prior to employment. The provider's recruitment policy clearly stated that checks required included: proof of identification, two references, proof of qualifications, registration with the appropriate professional body and the appropriate checks through the Disclosure and Barring Service (DBS). To verify the logs' accuracy we looked at two full sets of records for members of staff and saw that all the checks stated as checked in the log had been reviewed.
- Qualifications and registrations with the General Medical Council for GPs were checked and recorded.
- The provider did not have a system in place to monitor the ongoing training needs and GP registration checks.

Risks to patients

Most risks to patients were assessed and managed.

- The provider checked the professional indemnity of their clinical professionals.
- There was a continuity plan for emergencies which may occur and affect the running of the service. This plan was available to staff.
- The IT and encryption systems in place, together with a number of comprehensive policies protected the storage and use of all patient information. The service was able to provide a clear audit trail of who had access to records and from where and when. The provider was registered with the Information Commissioner's Office and had a procedure in place to govern information governance and data protection.
- The provider had separate business continuity and incident response plans in place to minimise the risk of losing patient data.
- The provider was unable to explain and provide assurance that patient data would be stored appropriately should the service cease trading.
- Patient identity was checked upon registering using an external global identification verification company, the company checked identity using a range of sources including credit agencies, voting registers and telephone databases. A system was in place to identify and highlight patients with multiple registrations or using more than one of the company's websites by their name, post code and email address details to prevent over prescribing. The doctor had access to the patients previous records held by the service.
- Although patient identity verification checks were in place, with a further photo identity check for those that failed the initial check, there was no process in place to identify patients who may be under the age of 18 and accessing services covertly or by masquerading as someone else.

Information to deliver safe care and treatment

Patient records were stored securely using an electronic record system. Correspondence was shared with external professionals in a way that ensured data was protected. Information required passwords and other control measures in order to access any data shared with external providers. The provider expected that the GP would conduct consultations in private and maintain the patients confidentiality and this was supported by a confidentiality policy.

Risks related to patients' diagnoses and other health and wellbeing risks were recorded in patients' records. There were alerts on the system where staff needed to be made aware of any risks for their consideration.

GP contact details were requested by the provider. However, there was no prerequisite to provide these details which may pose a risk to patients if the provider had concerning information. If consent to share information with a GP was given we saw evidence that the appropriate level of information was shared.

Are services safe?

Safe and appropriate use of medicines

The provider told us that they had issued around 7,000 prescriptions in the previous nine months and at the time of our inspection had 7,500 active patients registered with them.

Since our last inspection the new clinical team had started the process of reviewing all the clinical questionnaires to ensure they were evidence based. The provider had a prescribing policy and a system in place to monitor the quality or prescribing. The provider told us that they were in the process of employing a further GP to carry out a periodical independent clinical audit of patient consultations and prescribing. We saw evidence that this recruitment had taken place.

If medicine was deemed appropriate or necessary following a consultation, the prescribing doctor was able to issue a private prescription to patients. The doctor could only prescribe from a set list of medicines for the conditions which they treated. There were no controlled drugs on this list (drugs with the potential to cause addiction or medicines used in the treatment of long term conditions requiring monitoring).

The service's websites advertised what medicines were available for the conditions they treated. Once the doctor selected the medicine and dosage, relevant instructions were given to the patient regarding when and how to take the medicine, the purpose of the medicine, details of any likely side effects and what they should do if they became unwell. The IT system used by the provider prevented patients from accessing multiple prescriptions as far as possible by checking for duplicate names, postcodes and email addresses.

Track record on safety

There were systems to identify, assess and mitigate risks. For example:

Standard operating procedures were in place governing the management of significant and adverse events. The provider had recorded 41 significant events during the previous 12 months and we saw evidence of these being investigated thoroughly, responded to appropriately and learning identified.

Learning from incidents was discussed with staff as and when they happened and more formally at quarterly review meetings. We saw evidence from events 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. All staff had undertaken duty of candour training and we saw evidence of the duty of candour being discussed as an agenda item at review meetings.

There was a system for receiving and acting on safety alerts. The practice learned from external safety events as well as patient and medicine safety alerts.

Are services effective?

(for example, treatment is effective)

Our findings

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

Effective needs assessment, care and treatment

The service assessed 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.

- We reviewed a number of medical records and were assured that the GPs employed by the provider were assessing patients' needs and delivering care in line with relevant and current evidence based guidance and standards, including National Institute for Health and Care Excellence (NICE) evidence based practice. For example, we saw evidence of the doctor declining a request to prescribe a weight loss medicine to a patient, who had been prescribed the medicine for a number of years and had reported no weight loss for a period exceeding 12 weeks.
- We found further questions needed to be added to some of the questionnaires to ensure compliance with evidence based practice guidelines. The clinical staff were already aware of this and were in the process of improving it.
- The provider and the GPs told us that a system was in place to enable the prescribing GP to seek further information from a patient if required before approving an order.

Monitoring care and treatment

- There was limited evidence of clinical audit or clinical quality improvement activity which demonstrated improvements to patient clinical care or outcomes. At the time of our inspection there was no process in place to audit, monitor or review the clinicians prescribing or consultations. The provider was aware of the need to improve in this area and at the time of our inspection was in the process of employing an additional clinician to aid quality improvement processes.
- The provider had a policy in place to monitor patient care which included collation and review of data from adverse events, significant events, patient consultations, complaints and negative patient survey results. They carried out a continual customer service call handling satisfaction audit.
- The significant event process was a means of monitoring care outcomes. Any incidents or concerns identified through referral, assessment or treatment were assessed and lessons recorded. The provider carried out patient and post consultation surveys and were able to demonstrate that the results of these together with complaints and significant/adverse events were reviewed, discussed and lessons learned identified at quarterly review meetings.

Effective staffing

All staff had proof of their qualifications checked prior to working for the centre. All staff completed induction training on the first day of their employment.

The provider had guidance within policies which it required all staff to read and refer to as a condition of their contract of employment. The provider kept a log of when the clinicians appraisal was due with a view to completing annually. All the GPs had been employed within the last six months so were not yet due an appraisal with FMC Marketing Limited.

Coordinating patient care and information sharing

We reviewed the system for sending and receiving patient correspondence. We found that letters were sent to GPs where necessary explaining what medicines had been prescribed, including the quantity and dosage. Correspondence received by the provider was reviewed and recorded on patient notes.

Consent to care and treatment

Patients were consulted regarding consent to treatment and sharing of information. There was supporting guidance regarding the Mental Capacity Act 2005 in the provider's policies. The service displayed full, clear and detailed information about the cost of assessments on their website.

Are services caring?

Our findings

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

Kindness, respect and compassion

The provider carried out patient surveys. At the end of every consultation, patients were sent an email asking for their feedback. Results were discussed and analysed at regular review meetings and a procedure was in place governing monitoring and responding to patient feedback including complaints, significant events, feedback following patients consultation and surveys.

Involvement in decisions about care and treatment

Patient information guides about how to use the service and technical issues were available on the websites operated by the provider. A customer support team was available during normal office hours to respond to any enquiries. There was patient information literature which contained information for patients and relatives including treatment information. This included the strengths and limitations of the different types of treatment. Details of the GPs including GMC number were available to patients.

Privacy and Dignity

The provider had a policy in place to ensure that clinicians working remotely kept patient information secure. Electronic records were kept which protected patient data. Staff were required to read the confidentiality policy and statement regarding patient information was included in their contracts.

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 people's needs

Whilst the provider's website was available 24 hours a day and seven days a week their call centre was open between 10am and 3pm Monday to Friday. Requests for treatment received up to 3pm on a weekday were generally dealt with within a three hour timescale. Other requests were dealt with the following working day. It was clear from the provider's websites what services were on offer. This service was not an emergency service. Patients who had a medical emergency were advised to seek immediate medical assistance via their own GP, 999 or NHS 111 service.

The provider's websites allowed people to contact the service from abroad. The medical

practitioners were required to be based within the United Kingdom. Patients signed up to receiving this service from a computer, mobile phone or other portable device with internet access.

The provider offered consultations to anyone over the age of 18 who requested and paid the appropriate fee, and did not discriminate against any client group. If a patient could not submit their request through the website due to a disability the provider told us they made arrangements for a member of staff to discuss this over the telephone and input the information for them.

Patients were able to access a brief description of the doctor before requesting treatment. The provider employed one female and one male doctor to facilitate patient choice.

Listening and learning from concerns and complaints

The provider had a complaints policy which set out the process for dealing with complaints. This included:

- Investigation of any complaint would take place.
- That a response would be made within 28 days.
- Where a patient could take their complaint if they were not satisfied with the response.

A copy of the provider's complaints procedure, which included timescales for dealing with complaints, was available on all the websites operated by the provider. The provider had recorded 37 complaints during the previous 12 months and we found that these had been investigated and responded to appropriately. There was evidence of patient feedback including complaints being reviewed regularly and discussed and minuted at review meetings.

There was clear information on the service's website detailing how the service worked and a set of frequently asked questions for further supporting information. The website had a set of terms and conditions and details of how the patient could contact them with any enquiries. Information about the cost of the consultation and treatment was made apparent when the patient had created an account.

The provider understood the need to seek patients consent to care and treatment in line with legislation and guidance and had recently reviewed and improved changed the way in which they sought consent to care and treatment on their websites through the introduction of tick box form. Staff understood their responsibilities in relation to seeking consent and had undertaken training in relation to the Mental Capacity Act 2005.

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 in some areas this service was not providing a well-led service in accordance with the relevant regulations.

Leadership capacity and capability;

The provider had the experience, capacity and capability to run the service and ensure patients accessing centre received high quality assessment and care. It was evident through discussions with sub-contracted staff the service prioritised compassionate care. A GP we spoke with told us

the provider communicated well with staff and ensured they were supported to undertake their roles.

Vision and strategy

FMC Marketing Limited list their aims and objectives as being 'to provide a high quality, internet healthcare service which includes confidential on-line health assessments with a medical practitioner and the private prescription of medicines'. There was a clear organisational structure and staff were aware of their own roles and responsibilities. There was a range of service specific policies which were available to all staff and had recently been reviewed and updated.

There were a variety of checks in place to monitor the customer service side of the operation which included monitoring and audits of telephone calls with customer service staff. The provider told us that there was no current process in place to monitor the quality of the doctors' consultations or prescribing. The provider was in the process of employing a further GP to carry out a periodical independent clinical audit of patient consultations and prescribing and had developed a protocol to govern this activity. We saw evidence that this recruitment was in progress.

There were arrangements for identifying, recording managing and learning from risks, significant events, complaints and patient feedback. These were reviewed regularly and discussed further at review meetings.

Culture

The two directors of the company were responsible for the day to day running of the service. One of the directors acted as registered manager and was responsible for regulatory compliance and clinical matters. The other was responsible for financial matters and patient/commercial services. The directors told us and we saw evidence that following recruitment of two new GPs the directors involved them in the day to day operation and development of the service including improving medical questionnaires and developing clinical policies and protocols.

We were told that the directors covered for each other during absences and that as it was a very small staff group, leave was arranged in advance and arrangements were in place to ensure only one member of staff was off at a time whenever possible.

The reporting of concerns and investigation into complaints showed openness and honesty. This indicated that the provider paid due diligence to the duty of candour in the way they operated their services. 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.

Governance arrangements

The service had a governance framework which mostly supported the delivery of the strategy and good quality care. Service specific policies and procedures were in place and accessible to staff. These included guidance about confidentiality, record keeping, incident reporting and data protection. There was a process in place to ensure that all policies and procedures were kept up to

date.

There were policies and IT systems in place to protect the storage and use of all patient information. The service could provide a clear audit trail of who had access to records and from where and when and was registered with the Information Commissioner's Officer. Requests from patients to access their records were dealt with in line with the Data Protection Act 1998. A business continuity plan was in place to minimise the risk of losing patient data but did not detail what would happen to patient data should the company cease trading, in line with the requirements for the retention of medical records from the Department of Health and Social Care.

Managing risks, issues and performance

Are services well-led?

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

The service mostly identified, assessed and managed clinical and environmental risks related to the service provided. We saw risk assessments and the control measures in place to manage some of those risks. However, some risks identified at the previous inspection in April 2017 had not been fully rectified. For example:

- Although patient identity verification checks were in place, with a further photo identity check for those that failed the initial check, there was no process in place to identify patients who may be under the age of 18 and accessing services covertly or by masquerading as someone else.
- GP contact details were requested by the provider. However, there was no prerequisite to provide these details which may pose a risk to patients if the provider had concerning information. If the provider had concerns regarding the welfare of a patient they would not have the GP details to enable them to share information if required.
- Governance systems and processes did not provide oversight and monitoring of the ongoing training needs and registration checks of staff that provide services to patients, in order to ensure they have the skills and knowledge required to provide care safely and effectively.

Engagement with patients, the public, staff and external partners

The service encouraged and valued feedback from patients and their families. They acted to improve services on the basis of this feedback.

- Comments and feedback were encouraged. These were reviewed and considered by the provider including negative comments.
- The service reviewed the feedback from patients who had cause to complain. A system was in place to assess and analyse complaints and then learn from them if relevant, acting on feedback when appropriate.
- Patient feedback was sought post consultation and patients were able to rate the service they had received. Patient feedback and identified learning was reviewed and discussed at regular meetings
- The directors told us that staff were able to provide feedback about the quality of the operating system and any change requests were logged, discussed and decisions made for the improvements to be implemented.
- The provider had a whistleblowing policy (a whistle blower is someone who can raise concerns about practice or staff within the organisation).

This section is primarily information for the provider

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
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **How the regulation was not being met:** • We were not assured that patient confidentiality was being comprehensively protected as there was no policy in place to protect patient data should the company cease trading. • There was limited evidence of clinical audit or clinical quality improvement activity which demonstrated improvements to patient clinical care or outcomes. there was no process in place to audit, monitor or review the clinicians prescribing or consultations. • Although patient identity verification checks were in place, with a further photo identity check for those that failed the initial check, there was no process in place to identify patients who may be under the age of 18 and accessing services covertly or by masquerading as someone else. • GP contact details were requested by the provider. However, there was no prerequisite to provide these details which may pose a risk to patients if the provider had concerning information. • Governance systems and processes did not provide oversite and monitoring of the ongoing training needs and registration checks of staff that provide services to patients, in order to ensure they have the skills and knowledge required to provide care safely and effectively.