

# FMC Marketing Limited - Grand Union Studios

## Quality Report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

## Ratings

Are services safe?

Are services effective?

Are services caring?

Are services responsive to people's needs?

Are services well-led?

# Summary of findings

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## Overall summary

### Letter from the Chief Inspector of General Practice

We carried out an announced comprehensive inspection at FMC Marketing Ltd on 19 April 2017.

FMC Marketing Ltd provides an online clinic, consultation, treatment and prescribing service for a limited number of medical conditions to patients from England, Italy, France and Germany.

We found this service was not providing safe, effective, caring or well-led care but were providing responsive services in accordance with the relevant regulations.

#### Our key findings were:

- The service had systems to keep service users safeguarded from abuse.
- Appropriate systems were in place to record and learn from significant and clinical events.
- There were some systems in place to protect patients personal information and the provider was registered with the Information Commissioners Office.
- The service encouraged and acted on feedback from patients.
- The service managed patients' applications for medicines in a timely way.
- Information about services and how to complain was available on the providers websites.
- The provider was aware of the requirements of the duty of candour.

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

- Add the name, GMC number and brief description of their doctor to their websites to enable potential patients to make an informed choice.
- Ensure medical questionnaires are updated to capture all potentially relevant information and reflect current best practice guidance.
- Ensure there is a formal process or policy in place governing the identification or classification of risk when assessing medical questionnaires.
- Introduce a programme of clinical audit and quality improvement activity.
- Ensure doctors employed by the service are appropriately appraised for their work with FMC Marketing Ltd.
- Ensure that there is an effective process in place for identifying and verifying patient identification.
- Ensure that doctors employed by the service have the skills, training, experience and medical indemnity required to enable them to carry out the role of online doctor.
- Continue with the introduction of a process to review and monitor prescribing and consultations.
- Ensure there is more clinical involvement and oversight in the day to day operation and running of the service.

### The areas where the provider should make improvements are:

# Summary of findings

- Update the medical emergency protocol to ensure a patients location as well as home address are known prior to consultation.
- Record a patients own GP details before consultation and treatment is approved.
- Take steps to ensure patient confidentiality is comprehensively protected when patient data is being accessed by the doctor and in the event that the company should cease trading.

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

## **Summary of any enforcement action**

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

**Professor Steve Field** CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

# Summary of findings

## The five questions we ask 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.

- All staff had received safeguarding training appropriate for their role and access to a relevant safeguarding policy detailing how to make a referral if necessary.
- Patient identity was verified by cross referencing credit/debit card details against a patients name and address. However, there were limited checks in place to ensure patients under the age of 18 were not accessing services covertly.
- There were enough non-clinical staff to meet the demand of the service and appropriate recruitment checks for all non-clinical staff were in place. There was no system in place to monitor the workload of the doctor.
- The provider had a protocol in place governing what action to take in the event of a medical emergency during a consultation which included ensuring a patients contact details were known. However, this did not include asking a patient for their current location and the system operated by the provider did not ensure a patients own GP details and contact number were known.
- Prescribing and consultations were not effectively monitored for risk. The provider did not have a prescribing policy or protocol.
- There were systems in place to meet health and safety legislation and to respond to patient risk.
- Systems were in operation to protect patient information and ensure records were stored securely but did not include what would happen to patient data should the company cease trading. The provider was registered with the Information Commissioner's Office. However, the provider also operated another online service from the same address which shared back office and IT functions with FMC Marketing Ltd. We were not assured that information sharing protocols between these two companies was compliant with data protection and Information Commissioners Office guidance.
- Information governance protocols did not dictate where and when it was appropriate for the doctor to access patient records. Staff had not undertaken information governance training.

# Summary of findings

- 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.

## **Are services effective?**

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

- We were told that the doctor assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards, for example, National Institute for Health and Care Excellence (NICE) evidence based practice. However, patient records we reviewed were not always consistent with this and did not demonstrate appropriate record keeping or patient treatment.
- There was a lack of formal clinical audit or quality improvement activity in which improvements to patient care and outcomes could be demonstrated.
- The provider had not taken steps to assure themselves that the doctor they employed had the skills, experience and training necessary to undertake the role of an online doctor or held appropriate medical indemnity insurance.
- An appraisal process was in place for non-clinical staff. The provider held a copy of the doctors NHS appraisal. However this did not make reference to the doctors work as an online doctor. The provider did not have a process in place to appraise or review the quality of the doctors consulting or prescribing.
- Medical questionnaires were not comprehensive and did not reflect best practice guidance.
- The provider had a consent policy and told us that consent to care and treatment was documented in line with the Mental Capacity Act (MCA) 2005. Staff had undertaken MCA training.

## **Are services caring?**

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

- There was no policy in place governing where and when it was appropriate for the doctor to carry out a consultation and we were not assured from a conversation we had with the doctor that consultations were always carried out in an appropriate location.
- We did not speak to patients directly during the inspection. However, we looked at patient satisfaction surveys carried out

# Summary of findings

by the provider. A survey of 119 patients had resulted in an average satisfaction score of 4.26 out of five. Another survey of 18 patients had resulted in an average satisfaction score of 4.56 out of five. A policy and system was in place to govern monitoring and responding to patients' feedback which included complaints, significant events, feedback following patient consultations and patient surveys.

## **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 on all three websites operated by the provider to explain how the service worked.
- Patients could sign up to receiving the service by either android or iOS application. The providers customer service centre was open between 9.30am and 5.30pm on a Monday to Thursday and from 9am to 5pm on a Friday. Patients could submit their request 24 hours a day and seven days per week on the providers website. Consultation requests submitted between 9am and 3pm on a Monday to Friday were generally dealt with within a three hours timeframe. Other requests were dealt with the following working day.
- Patients were not able to access a description of the GP and were not informed of the name of the consulting and prescribing GP until after their order had been approved. As the provider only employed one doctor patients were not able to choose either a male or female GP or one that spoke a specific language or had a specific qualification.
- There was a complaints policy which provided patients and staff with information about making and handling formal and informal complaints. Complaints and all other patients feedback was reviewed at bi-annual staff and work place review meetings.

## **Are services well-led?**

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

- We were not assured that there was an overarching governance framework to support clinical governance and risk management. There was little clinical input into the day to day running of the service.

# Summary of findings

- Additional focus on quality improvement was required. There was a lack of clinical audit activity and no arrangements in place at the time of the inspection to monitor or review prescribing and consultations.
- A brief business plan was in existence together with various policies and procedures relating to issues such as call recording, record keeping, medical emergencies, patients verification and obtaining patient feedback.
- A management structure was in place and staff understood their responsibilities in relation to their roles.
- The service encouraged patient feedback. There was evidence that this was discussed at staff meetings and that staff could also feedback about the quality of the operating system and procedures.
- Some systems were in place to ensure that all patient information was stored securely and kept confidential and the service was registered with the Information Commissioner's Office. However, the provider had not considered what would happen to patient data should they cease trading and did not have an information sharing protocol in place for the two separate companies they operated which shared back office functions and IT services. There was no process in place to ensure that the doctor was accessing patient information in a secure location.
- The provider had a number of policies and procedures to govern activity which were readily available to staff.

# Summary of findings

## Areas for improvement

### Action the service **MUST** take to improve

- Add the name, GMC number and brief description of their doctor to their websites to enable potential patients to make an informed choice.
- Ensure medical questionnaires are updated to capture all potentially relevant information and reflect current best practice guidance.
- Ensure there is a formal process or policy in place governing the identification or classification of risk when assessing medical questionnaires.
- Introduce a programme of clinical audit and quality improvement activity.
- Ensure doctors employed by the service are appropriately appraised for their work with FMC Marketing Ltd.
- Ensure that there is an effective process in place for identifying and verifying patient identification.

- Ensure that doctors employed by the service have the skills, training, experience and medical indemnity required to enable them to carry out the role of online doctor.
- Continue with the introduction of a process to review and monitor prescribing and consultations.
- Ensure there is more clinical involvement and oversight in the day to day operation and running of the service.

### Action the service **SHOULD** take to improve

- Update the medical emergency protocol to ensure a patients location as well as home address are known prior to consultation.
- Record a patients own GP details before consultation and treatment is approved.
- Take steps to ensure patient confidentiality is comprehensively protected when patient data is being accessed by the doctor and in the event that the company should cease trading.

# FMC Marketing Limited - Grand Union Studios

## Detailed findings

### Background to FMC Marketing Limited - Grand Union Studios

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 from England, Italy, France and Germany. The number of conditions treated had recently been reduced to three; weight loss, hair loss and erectile dysfunction.

FMC Marketing Ltd consists of five members of staff which includes the registered manager, commercial/patient services manager, technical services manager, patient services lead and a doctor. The doctor was not a GP but was registered with the General Medical Council (GMC) and contracted via an external provider 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 9.30am and 5.30pm on a Monday to Thursday and from 9am to 5pm on a 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 two pharmacies used by the provider who are contracted to dispense, pack and post (via registered mail) the prescribed course of treatment.

FMC Marketing Ltd is operated via three separate websites ([www.firstmed.co.uk](http://www.firstmed.co.uk), [www.prima-med.com](http://www.prima-med.com) and [www.myonlinedoctor.co.uk](http://www.myonlinedoctor.co.uk)).

FMC Marketing Ltd registered with the CQC at their current location in July 2016. 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 carried out an announced inspection of this location on 19 April 2017. We visited FMC Marketing Limited's operating site in Ladbroke Grove, London and spoke to their doctor and managers. We looked at the records, policies and other documentation the provider maintained in relation to the provision of services. We also spoke to pharmacists employed by the two pharmacies used by the provider to fill and deliver the prescriptions issued.

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?

## Detailed findings

Our inspection team was led by a CQC Lead Inspector. The team also included two GP specialist advisers, a second CQC inspector and a pharmacist specialist.

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

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

### **Safety and Security of Patient Information**

The provider made it clear to patients on their website what the limitations of the service were. There were processes in place to manage any emerging medical issues during the application and consultation process. The service was not intended for use by patients with either chronic conditions or as an emergency service. The provider had considered what action might be needed in the event of an emergency situation by ensuring a patient's contact details were known and had developed a medical emergency protocol. However, this did not include asking a patient for their current location or detail what steps should be taken for patients from the four other European countries outside the United Kingdom who were able to access services. In addition, although the protocol dictated that staff should signpost patients to their own GP or emergency medical services in the event of a medical emergency it made no provision for staff members to contact emergency medical services on a patient's behalf. The system operated by the provider did not ensure a patient's own GP details and contact number were known before treating the patient which could present problems should the FMC Marketing Ltd doctor need to contact them urgently.

The IT and encryption systems in place, together with a number of comprehensive policies protected the storage and use of all patient information. However, the directors of FMC Marketing Ltd were also the directors of another digital service provider operating from the same address and shared back office services, staff and IT systems. We were therefore not assured that information sharing between these two separate companies may not have been compliant with Data Protection Act and Information Commissioner's Office guidance. 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. However, staff had not received information

governance or Data Protection Act training and there were no policies or guidance to govern where and when the doctor was able to access patient records and requests that had been submitted.

The provider had separate business continuity and incident response plans in place to minimise the risk of losing patient data. We found no documented process for dealing with patient data should the provider cease trading. We also noted that there was no protocol in place for data security on GP's own devices when they were accessing the browser based service remotely.

Patient identity was not checked when they registered with the service. However it was checked the first time treatment was approved by the doctor using an external global identification verification company, which checked identity by comparing a patient's credit card details with their home address. We did not see any evidence of any additional security information being given to patients relating to the security of their individual accounts. For example protecting their username and password.

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 patient's previous records held by the service.

The provider had numerous information technology policies and procedures in place and it was evident during the inspection that staff were easily able to extrapolate data from the IT system for audit and review purposes. However, some of these policies required updating to improve patient confidentiality.

### **Keeping people safe and safeguarded from abuse**

Staff employed at the headquarters had received training in safeguarding and whistleblowing and knew the signs of abuse and to whom to report them. A safeguarding policy was in place which gave staff information on how to escalate concerns relating to safeguarding to the appropriate Local Authority safeguarding team. The registered manager had been designated as the safeguarding lead and was responsible for communicating with external agencies in the event of a safeguarding concern being raised. The doctor had undertaken child and adult safeguarding training and the provider retained copies of training certificates.

# Are services safe?

The service did not treat anyone under the age of 18. However, we did not see evidence of any safeguards to ensure this was the case.

## **Monitoring health & safety and responding to risks**

The provider carried out a monthly review of significant/adverse events, complaints and negative patient feedback to monitor risk. However there was no evidence of any clinical oversight or involvement in this process.

The doctor told us that they rated consultations for risk when reviewing medical questionnaires and before approving treatment and if there was any doubt or risks treatment would not be approved and a note detailing why would be recorded in the patient record. However, there was no formal process or policy in place governing the identification or classification of risk.

The provider headquarters were located within modern purpose built offices, which accommodated the IT system, management and administration staff. Patients were not treated on the premises and the doctor carried out the online consultations remotely. Administration staff had received training in health and safety including fire safety during their induction.

The provider expected that the doctor would conduct consultations in private and maintain the patients confidentiality. However, this was not documented in the doctors 'practising privileges agreement' or any data protection/information governance policy. The doctor told us that he had viewed patient data and undertaken online consultations whilst on holiday abroad.

There was a process in place to manage any emerging medical issues during a consultation which was governed by a medical emergency protocol. However, we did not feel that this was as comprehensive as it could have been as there was no provision in place to know a patients exact location or for staff to alert emergency medical services on a patients behalf. The service was not intended for use by patients with either chronic conditions or as an emergency service.

## **Staffing and Recruitment**

The provider told us that they felt there were enough staff to meet the current demand of the service. However, there were no formal arrangements in place to ensure that cover was readily available for the one doctor employed by the

provider should it be required during times of annual leave or sickness. The provider told us that they had not required cover for their current doctor for any period during the eight years they had been employed.

The provider had a selection process and policies and procedures in place pertaining to the recruitment of staff. Required recruitment checks had been carried out for all staff prior to commencing employment and staff had supplied declarations of their physical and mental fitness to perform their role. The doctor contracted to the service had provided documents including their medical indemnity insurance, proof of registration with the GMC and certificates for training in safeguarding. However we were not satisfied that the medical indemnity insurance in place was sufficient. We reviewed staff files of the five members of staff which showed necessary documentation was available. An induction process was in operation for newly recruited members of staff.

## **Prescribing safety**

The provider told us that they had issued 7,999 prescriptions in the previous 12 months and at the time of our inspection had 3,305 active patients registered with them.

We did not see any evidence to suggest that medicines prescribed to patients from an online form or during a consultation were monitored by the provider to ensure prescribing was evidence based. The provider did not have a prescribing policy or a system in place to monitor the quality or prescribing. This meant the provider could not be assured that the doctor was prescribing medicines safely and effectively in accordance with treatment protocols or recommended guidance. The provider told us that they were aware this was an area requiring improvement and for that reason had recently taken the decision to employ a further doctor to carry out a periodical independent clinical audit of patient consultations and prescribing. They had developed a protocol to govern this activity and it was anticipated that the doctor would commence employment mid May 2017.

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 three conditions which they treated. There were no controlled drugs on this list.

# Are services safe?

The service's websites advertised what medicines were available for each of the three conditions they treated. Once the doctor selected the medicine and correct 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.

A process was in place to check a patient's identity by comparing their credit or debit card details with their home address once treatment had been approved. However, there was no formal process in place to enable the provider to assure themselves that an under 18 year old was not using their parents credit card.

Patients were not able to nominate their own preferred pharmacy. The service had a contractual agreement with two affiliated pharmacies (which the Care Quality Commission do not regulate) to process and deliver the prescriptions they issued but did not have a system in place to monitor the quality of the dispensing process.

## **Information to deliver safe care and treatment**

Patient identity was not checked when a patient registered with the service. However it was checked the first time treatment was approved by the doctor. The doctor had access to the patient's previous records held by the service.

## **Management and learning from safety incidents and alerts**

Standard operating procedures were in place governing the management of significant and adverse events. The provider had recorded eight significant clinical 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 bi-annual staff and work place 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 bi-annual staff/work place review meetings.

Members of staff we spoke with during the inspection were able to describe what a patient or medicines safety alert was and what they would do if they received one. However, there was no formal procedure in place to govern this activity.

# 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 which included 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. The patient was not able to view the cost of treatment until they had commenced an online consultation.

Staff had undertaken training in relation to the Mental Capacity Act 2005 and the provider had a capacity and consent policy. The provider understood the need to seek patients' consent to care and treatment in line with legislation and guidance and had recently reviewed and updated their websites to reflect this.

### Assessment and treatment

We reviewed a number of medical records and were not assured that the GP employed by the provider was 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 continuing to prescribe a weight loss medicine to a patient, who had been prescribed the medicine for a number of years, despite the patient not reporting any weight loss for a period exceeding 12 weeks and there being no evidence of a discussion with the patient about the potential benefits/ limitations of using the medicine for a period exceeding 12 months.

The provider told us that a system was in place to enable the prescribing GP to seek further information from a patient if required and that this would normally be dealt with by non-clinical staff on the doctor's behalf. However there appeared to be no direct interaction between the patient and the GP. Patient notes were of poor quality and did not record relevant prescribing decisions. For example, we viewed a patient record where the doctor had doubled the dosage of a medicine used to treat erectile dysfunction yet no reason for this decision was noted in the patients record.

Patients completed online questionnaires relevant to the condition they were seeking treatment for which included their past medical history. However, medical questionnaires were not fully comprehensive and did not adhere to best practice guidance. For example, the weight loss questionnaire did not include a question to determine a patients actual blood pressure reading or to verify BMI; the erectile dysfunction questionnaire did not include a process to determine whether the patient had the symptoms of angina, cardiac failure or diabetes; the hair loss questionnaire did not explore the type of hair loss or explain the likely efficacy of the treatment. Neither was there a process in place to enable the patient to upload an image of their hair loss pattern to enable accurate diagnosis.

The service did not monitor consultations or carry out prescribing audits. They were aware of the need to improve in this area and were in the process of employing another doctor to periodically carry out an independent clinical audit of patient consultations.

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.

### Quality improvement

There was no evidence of clinical audit activity or of any formal quality improvement activity leading to improvements in patients care or outcomes. 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 bi-annual staff/ work place review meetings.

### Staff training

All staff completed induction training on the first day of their employment which included:

- Data Protection Act.
- Patient ID verification.
- Credit card handling.
- Complaints.
- Health and Safety related policies and procedures.
- Actions to be taken in the case of an emergency.

# Are services effective?

(for example, treatment is effective)

- Adverse events.
- Safeguarding.
- Reading and understanding the staff handbook.

Personnel files showed that non-clinical staff had undertaken a range of relevant training and a disclosure and barring service (DBS) check.

The provider had not taken any steps to assure themselves that the doctor had undertaken all training relevant to their role or that the doctor had the training and skills necessary to carry out the role of an online doctor given that their background was in emergency medicine. The provider told us that they had employed the doctor through a third party company who had been responsible for the recruitment process including the completion of pre employment checks.

Non clinical staff received an annual appraisal and performance review. There was no system in place to appraise the doctor and we were told that this was covered by their NHS appraisal. However, the doctor granted us permission to view their appraisal and we saw no evidence of discussion or review of their work as an online doctor. We would expect to see some form of independent appraisal specifically related to the work carried out for FMC Marketing Ltd.

## **Coordinating patient care and information sharing**

When a patient contacted the service they were asked if they wished to provide their own GP address and contact details and if details of their consultation could be shared with the GP. If patients agreed we were told that details of the medicines supplied were shared with the GP. However, patients could still access treatment without supplying their GP contact details which could present a problem if the doctor needed to make contact with the GP for any reason, for example to raise or discuss a safeguarding concern.

The range of conditions and treatment offered by the provider did not require them to request or analyse test results.

## **Supporting patients to live healthier lives**

We did not find any evidence of the service identifying or assisting patients who may be in need of extra support. Information available on the websites hosted by the provider did not contain links to additional health information or advice, for example weight loss.

# Are services caring?

## Our findings

We found that this service was not providing a caring service in accordance with the relevant regulations.

### **Compassion, dignity and respect**

We did not find evidence of any checks being in place to govern where and when the doctor accessed patient records or undertook consultations. No formal cover arrangements were in place for the doctor. The provider told us that cover had not been required for the doctor employed by the practice for a period of eight years and the doctor told us that he had carried out patient consultations whilst abroad on holiday.

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 bi-annual staff/work place 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.

Patients were not able to access a description of the doctor and were not given the doctors details until after the patients order had been approved. As the provider only employed one doctor patient choice was limited in terms of being able to select a doctor based on their gender or level of expertise. A member of the customer services team could speak German and an interpretation service was available for patients who spoke French and Italian.

An online survey of 18 patients who had used the service during the 12 months prior to our inspection showed that the provider had scored:

- 4.50 out of five for satisfaction with the thoroughness of the consultation questions
- 4.72 out of five for the quality of advice and instructions given on how to take medicines
- 4.44 out of five for further information being requested by the doctor.

A further customer services survey of 117 patients carried out between May 2015 and April 2017 revealed an average score of 4.44 out of five for satisfaction with customer services and 4.16 out of five in relation to the online system providing a patient with enough information to make an informed decision.

# 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**

Whilst the providers website was available 24 hours a day and seven days a week their call centre was open between 9.30am and 5.30pm on a Monday to Thursday and from 9am to 5pm on a 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 providers 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 providers websites allowed people to contact the service from abroad. The medical practitioner was required to be based within the United Kingdom but we were aware that the doctor was undertaking consultations whilst abroad. Any prescriptions issued were sent to one of two affiliated pharmacies contracted by the provider to dispense and dispatch the filled prescriptions.

Patients signed up to receiving this service from a computer, mobile phone or other portable device with internet access.

### **Tackling inequity and promoting equality**

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.

Patients were not able to access a brief description of the doctor and were not given the doctors details until after treatment had been approved. As the provider only employed one doctor patient choice in selecting a doctor was limited.

### **Managing complaints**

A copy of the providers complaints procedure, which included timescales for dealing with complaints, was available on all three websites operated by the provider. The provider had recorded two 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 at minuted bi annual staff/work place review meetings

### **Consent to care and treatment**

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 not made apparent until the patient had started a consultation.

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

### **Business Strategy and Governance arrangements**

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'. The provider had a brief business plan which had been developed in March 2017. However, this only gave an executive summary, personnel details and brief overview of their principal activities and risks. It did not give details of any future plans or development.

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 were regularly 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. However, the provider told us that there was no process in place to monitor the quality of the doctors consultations or prescribing. The provider was aware this was an area requiring improvement and was in the process of employing a further doctor to carry out a periodical independent clinical audit of patient consultations and prescribing and had developed a protocol to govern this activity.

There were arrangements for identifying, recording managing and learning from risks, significant events, complaints and patient feedback. These were reviewed on a monthly basis and discussed further at six month staff and work place review meetings.

Care and treatment records were stored securely and the provider had a number of policies in place governing patient confidentiality and security. We were not assured that patient records were complete and accurate as we saw records where decision making had not been recorded. For example, the decision to continue prescribing a weight loss medicine against recommended guidance and changes to medicine dosage.

### **Leadership, values and 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. None of the directors or non-clinical staff had any clinical expertise and there was very little evidence of the doctor being involved in the day to day operation or development of the service other than input into improving medical questionnaires.

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. There were no cover arrangements in place for the one doctor employed by the service. We were told that the doctor had not needed any time off and had not had any periods of sickness during the eight years they had been employed by the service. This raised concerns in relation to sustainability, workload and in respect of where and when the doctor was accessing patients records to carry out consultations.

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.

### **Safety and Security of Patient Information**

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. However, we were not assured that there was an information sharing agreement in place between the two separate companies operated by the provider which shared back office and IT systems. Neither were we assured that there was any policy in place governing where and when the doctor could view patient records or requests for consultation. 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.

Requests from patients to access their records were dealt with in line with the Data Protection Act 1998.

# Are services well-led?

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

## **Seeking and acting on feedback from patients and staff**

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 the doctor was 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. However, we saw very little evidence of clinical input into the running and development of the service.

The provider had a whistleblowing policy (a whistle blower is someone who can raise concerns about practice or staff within the organisation).

## **Continuous Improvement**

All non-clinical staff were involved in six monthly staff/work place review meetings which included discussions about how to run, develop and improve the service. We saw evidence of action points being identified and reviewed from the minutes of these meetings.

We were not assured that there was regular clinical oversight or involvement in the running of the service. Quality improvement and clinical audit activity was non-existent and there were no arrangements in place to monitor the quality of consultations or prescribing. The provider was aware of the need to improve in this area and at the time of our inspection they were in the process of employing another doctor to periodically review a sample (provisionally 5%) of consultations and prescribing. They had developed a protocol to govern this activity and it was hoped the additional doctor would be employed mid May 2017.

The provider had recently taken the decision to reduce the number of conditions they treated to three; hair loss, weight loss and erectile dysfunction. This decision had not only been based on the fact that over 99% of their patients only requested treatment for these conditions but had also taken into consideration clinical risk. However, we saw no evidence of clinical input into a formal process of risk assessment regarding this decision.

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
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p><b>How the regulation was not being met:</b></p> <p>The provider was not comprehensively assessing the risks to service users receiving care and treatment or doing all that is reasonably practicable to mitigate such risks:</p> <ul style="list-style-type: none"><li>• Medical questionnaires did not capture all potential relevant information.</li><li>• There was no system in place to ensure a patients location was known prior to consultation in the event of a medical emergency. GP contact details were not always captured.</li><li>• Staff had not undertaken training in relation to information governance.</li><li>• The doctor had not been appraised for their work as an online doctor.</li><li>• There were no arrangements in place to monitor prescribing or consultations. The provider did not have a prescribing policy.</li></ul> <p><b>This was in breach of regulations 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</b></p>

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p><b>How the regulation was not being met:</b></p> <p>The provider was not assessing, monitoring or improving the quality of the services provided in the carrying out of</p>

## Enforcement actions

regulated activity or assessing, monitoring and mitigating risks to the health, safety and welfare of service users who may be at risk arising from the carrying out of regulated activity.

- There was no evidence of clinical audit or clinical quality improvement activities.
- There was very little clinical oversight or involvement in the day to day running and operation of the service.
- The provider had not assured themselves that the doctor had the competence, skills, training or medical indemnity necessary to carry out the role of online doctor. The provider did not maintain training records for the doctor.
- Medical records were not contemporaneous.
- The process for identifying and verifying patient identity did not conform to General Medical Guidance.

**This was in breach of regulations 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.**