

Slimfactor Limited

Slimmingmedics High Wycombe

Inspection report

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Overall summary

We carried out a responsive, focussed inspection on 27 April 2016. CQC received information from a patient via another organisation, that raised some concerns and prompted us to carry out a focussed inspection. During the inspection we looked at specific areas to establish if the service was safe for people with regards to the management of medicines.

Our findings were:

Are services safe?

We found that the service was providing safe care with regards to the management of medicines in accordance with the relevant regulations.

Are services effective?

We found that this service was providing effective care with regards to the management of medicines in accordance with the relevant regulations.

Are services well-led?

We found that this service was providing well-led care with regard to medicines management in accordance with the relevant regulations.

Background

The Slimmingmedics High Wycombe clinic provides weight loss treatment and services, including medicines

and dietary advice to people accessing the service. The clinic is on the first floor of a shared building in a town centre location. The clinic is open for half a day on Wednesdays and Saturdays.

The clinic is run by doctors and a clinic manager who is also the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated regulations about how the service is run.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the provision of advice or treatment by, or under the supervision of, a medical practitioner, including the prescribing of medicines for the purposes of weight reduction. At the Slimmingmedics High Wycombe clinic the aesthetic cosmetic treatments that are also provided are exempt by law from CQC regulation. Therefore we were only able to inspect the treatment for weight reduction but not the aesthetic cosmetic services.

Summary of findings

Our key findings were:

- We did not find any evidence to support the concerns that prompted the focussed inspection.
- The provider did not always supply medicines in line with evidence based practice.
- There were appropriately qualified staff in the clinic to prescribe and supply medicines.

There were areas where the provider could make improvements and **should:**

- Review the process for ordering and transferring controlled drugs to bring it in line with good practice.
- Review the policies and procedures to make sure they are up-to-date, reflect current practice and legislation, and encourage continuous improvement.
- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available.
- Supply medicines in accordance with recognised clinical guidance and best practice.
- Review the information provided to patients so that it is clear, up to date and not misleading.
- Review the process for disposing of medicines so that it complies with the Misuse of Drugs Act 1971 and its associated regulations.

Slimmingmedics High Wycombe

Detailed findings

Background to this inspection

We carried out an unannounced, focussed, responsive inspection at the Slimmingmedics High Wycombe clinic on 27 April 2016. CQC received information from a patient via another organisation. The information raised some concerns about the management of medicines and prompted us to carry out a focussed inspection.

The inspection team was led by a CQC pharmacist specialist and a CQC pharmacist manager.

We carried out the 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.

Before visiting, we looked at a range of information that we hold about the clinic. We reviewed the last inspection reports from 2013 and 2014 and the notifications about the service. The methods that were used during our visit included interviewing staff, observations and reviewing documents.

Are services safe?

Our findings

Reliable safety systems and processes

Patients' medical information, clinical notes and record of medicines supplied were documented manually on record cards. The clinic stored the cards securely, and they could only be accessed by staff, which protected patient confidentiality. The doctors sometimes made prescribing decisions outside of the clinic's policies. For example, the doctors prescribed medication for people with a body mass index of 27 or less. While the doctor was able to explain the rationale for the clinical decision the justification was not clearly documented in the patient's notes.

Staffing

There was adequate staffing to meet the demands of the service. We looked at two personnel files, and found that recruitment checks had been undertaken prior to employment, including references and checks through the Disclosure and Barring Service (DBS). (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable). The doctors had appropriate professional registration with the General Medical Council.

Safe and effective use of medicines

The doctor told us and records showed that appetite suppressants were prescribed to people who used the service.

The medicines Diethylpropion Hydrochloride tablets 25mg and Phentermine modified release capsules 15mg and 30mg have product licences and the Medicine and Healthcare products Regulatory Agency (MHRA) have granted them marketing authorisations. The approved indications for these licensed products are "for use as an anorectic agent for short term use as an adjunct to the treatment of patients with moderate to severe obesity who have not responded to an appropriate weight-reducing regimen alone and for whom close support and supervision are also provided". For both products short-term efficacy only has been demonstrated with regard to weight reduction.

Medicines can also be made under a manufacturers specials licence. Medicines made in this way are referred to

as 'specials' and are unlicensed. MHRA guidance states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine.

At the Slimmingmedics High Wycombe clinic we found that patients were treated with unlicensed medicines. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy.

The British National Formulary states that Diethylpropion and Phentermine are centrally acting stimulants that are not recommended for the treatment of obesity. The use of these medicines are also not currently recommended by the National Institute for Health and Care Excellence (NICE) or the Royal College of Physicians. This means that there is not enough clinical evidence to advise using these treatments to aid weight reduction.

We checked how medicines were stored, packaged and supplied to people. We saw medicines stored securely and kept safely in the possession of the prescribing doctor when the clinic was open. Medicines were ordered by a branch clinic under the control of a doctor. Staff packaged the medicines in to labelled containers under the supervision of the doctor. The doctor transported the packed medicines from the branch clinic to the Slimmingmedics High Wycombe clinic. We saw transfer notes for the medicines received at the clinic. They did not state the name and address of the supplying or receiving clinic. The transfer documentation should allow for the movement of controlled drugs to be easily audited.

When the doctors prescribed medicines they were supplied to people in appropriate labelled containers which included the name of the medicine, instructions for use, the person's name and date of dispensing. The doctor made a record of the supply in the person's clinical notes.

There was not a clear procedure for the disposal of controlled drugs and we did not see evidence of a pharmaceutical waste disposal contract. The system for the disposal of medicines did not comply with the Misuse of Drugs Act 1971 and its associated regulations.

Are services effective?

(for example, treatment is effective)

Our findings

Assessment and treatment

During the initial consultation, the following information was collected from each person; weight, height, body fat percentage and answers to questions around their eating and exercise habits. Their body mass index (BMI) was calculated and target weights agreed and recorded. The doctor checked for contraindications to treatment such as uncontrolled diabetes and uncontrolled high blood pressure. We checked nine people's records and saw that they had health checks on their first visit and the doctor recorded any relevant concerns in the clinic notes.

The assessment protocol used by the clinic stated people with a Body Mass Index (BMI) above 30 would be considered for treatment with appetite suppressants and if they had comorbidities then treatment could start if the BMI was above 27. For people with a BMI below the level where appetite suppressants could be prescribed or the person could not take appetite suppressants for a clinical reason the clinic provided dietary advice and also had a herbal supplement for sale.

We saw evidence that the doctors referred people to their own GP for care when necessary. For example, if a person had high blood pressure or if the person was taking a medicine which meant they could not have new medicines prescribed from the clinic.

The doctor gave verbal information to people about the medicine and the clinic provided printed medicine information leaflets. However, some of the information leaflets were out of date. The doctor provided eating plans

and advice on healthy food, menu choices, food diaries and regular exercise. The doctor explained that a medicine may be supplied that does not have a manufacturer's product licence, but instead was made under a 'specials' licence and what that meant. However, the printed information given to people about unlicensed medicines was misleading because it stated that the unlicensed medicines could only be supplied by a specialist clinic such as Slimmingmedics High Wycombe. The manager said they will review and update the information leaflets.

We saw one person had attended the clinic for more than two years. The person received multiple prescriptions for phentermine capsules during that time. Information published by the MHRA and British National Formulary says that this medicine is only effective for 'short-term' use. We therefore cannot be sure that the doctors were providing clinically effective and safe treatments for the patients.

Consent to care and treatment

Consent was obtained from each person before treatment was commenced. The person's declaration included the information that the appetite suppressants phentermine and diethylpropion were produced under a 'specials' licence. People signed this declaration and consent before the doctor prescribed appetite suppressants.

Staff training and experience

The doctors were registered with the General Medical Council. One doctor completed revalidation in March 2015; their designated body was Weight Medics and we saw evidence of a named responsible officer.

Are services well-led?

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

Our findings

Governance arrangements

The clinic had a number of policies and procedures in place to govern activity and these were available to the staff. However, a different company, no longer connected

with Slimmingmedics, had produced the documents, and all the documents were dated 2011. The policies contained out of date information about the clinic and about medicines which were no longer kept at the clinic. The Registered Manager said that the documents would be reviewed and amended.