Registered pharmacy inspection report

Pharmacy Name:Boots, D80, Bay 71 D80 Warehouse, Harrimans Lane, NOTTINGHAM, Nottinghamshire, NG7 2SD

Pharmacy reference: 1096181

Type of pharmacy: Internet / distance selling

Date of inspection: 25/11/2022

Pharmacy context

The pharmacy is open seven days a week and is located at the company's head office site in Nottingham. Its main activity is dispensing private prescriptions for the Boots Online Doctor service, which is provided by a Care Quality Commission (CQC) registered online healthcare provider. People access the prescribing service via the website onlinedoctor.boots.com. The pharmacy acts as a second site, when necessary, to supply Pharmacy (P) medicines to people ordering from its website www.boots.com. And it provides a hepatitis B and flu vaccination service to people working at its head office site. The pharmacy also operates a medicine redistribution service to a network of Boots pharmacies to help reduce medicine wastage. The pharmacy operates through a distance-selling model. This means people do not visit the pharmacy premises and instead receive their medicines through a postal delivery service.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	People receiving contraception pill services and erectile dysfunction services from the pharmacy, can choose their preferred medicine on the website prior to starting an appropriate consultation with a prescriber. This is not in line with GPhC Guidance.
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards met

Summary findings

The pharmacy identifies and manages most risks associated with its services. It responds to feedback from people, and it manages people's private information securely. Pharmacy team members have the knowledge to recognise and raise safeguarding concerns. And they show a good commitment to patient safety and care by continually discussing and learning from mistakes they make when dispensing and supplying medicines. Its management team works closely with the prescribing service team to monitor risks. But this joint working doesn't include good sharing of information with the team at the pharmacy to help with the quality of clinical checks on prescriptions.

Inspector's evidence

The pharmacy's main activity was dispensing private prescriptions for the online doctor service. It was associated with a CQC registered prescribing service. The service was advertised as 'Boots Online Doctor'. The prescribing service employed a chief medical officer, a number of GPs as well as pharmacist and nurse independent prescribers. A dedicated clinical team at the pharmacy's superintendent pharmacist's (SI's) office worked directly with the prescribing service in monitoring and developing the service. This work included fortnightly clinical review group meetings. The responsible pharmacist (RP) was not fully aware of the policies, guidance, and processes for which the online prescribing service worked within and did not attend the meetings. Meetings were held at a management level and details from these meetings were not routinely fed back to the team working within the pharmacy. The RP had proactively contacted the team at the prescribing service to understand some policies, including the maximum prescribing quantities for some medicines.

The pharmacy had a risk register that covered a wide range of potential risks and actions to reduce and mitigate the these. This included risks about resource issues and ability to dispense all prescriptions received from the prescribing service, within the agreed timelines. And there was evidence of these being reviewed periodically with version control in place. The pharmacy had recently introduced a second risk register due to an upcoming change in the business model which would include the supply of cold-chain medicines from the pharmacy. It had begun to map some of the operational risks and controls associated with providing this service. But the risk register did not include details of clinical considerations for providing this service.

The pharmacy's standard operating procedures (SOPs) were up-to-date and related to the pharmacy's service model, including specific SOPs for the online doctor service and stock redistribution service. The pharmacy acted as a contingency site for the supply of P medicines to people. This operation was currently dormant, but an appropriate SOP was in place to support the service. Information within the SOP included the maximum supply allowed for some medicines such as pseudoephedrine and painkillers. Team members received regular time at work to complete learning associated with SOPs. And they were mostly observed following the SOPs when carrying out activities. But a SOP relating to the clinical check of prescriptions for the online doctor service referred pharmacists to consider accessing a person's NHS Summary Care Record to support them in completing the clinical check in the absence of a full medication record. The RP explained that this function was not available and as such this part of the process could not be followed. The pharmacy completed a weekly clinical governance audit. This focused on ensuring the team was up to date with key tasks associated with record keeping,

recording adverse events and stock management tasks. There was also evidence of weekly clinical governance meetings taking place between the RP and pharmacy manager. The pharmacy team did not complete their own clinical audits such as audits relating to the frequency of supplies or interventions made. And it was not aware of any clinical audits or prescribing reviews that had taken place of the online prescribing service. Following the inspection, the SI's office advised that the prescribing service provided assurance of monthly audits in compliance with prescribing policies. But information from these audits was not shared directly with the pharmacy team.

Pharmacists had access to a service summary sheet for the online doctor service. This was used as part of the clinical screening and checking process. The sheet consisted of the name of the medicine, description of the condition and the age range of the person that it would be suitable for, but didn't have any information on doses, maximum quantities or the frequency prescriptions could be repeated. When asked, the RP was unaware of any document or policy setting out maximum quantity restrictions for individual treatment areas to support them in their clinical checking process. The SI's team had sought assurances that the prescribing service had a risk assessment for each medicine it prescribed. And it had satisfied itself that clinicians working for the prescribing service had been provided with this information to support them in prescribing safely. But this risk assessment was not shared with the pharmacy to help inform the pharmacist's clinical check and any follow-up intervention activity. This meant pharmacists had to rely on other methods for obtaining further information when required. For example, there was evidence of the prescribing service sharing specific treatment plans for two medicines following the RP requesting these. Pharmacists also communicated with clinicians via a webbased messaging channel.

The pharmacy had tools to support its team members in recording mistakes found and corrected during the dispensing process, known as near misses. Near misses in the stock redistribution area, and previously the P medicine supplies area, were reported to the RP, who recorded these on a paper near miss log. There was fewer than one mistake recorded per month from the sample seen. The RP discussed these mistakes with the team members involved to help their learning. There was an emphasis on team members working in the stock redistribution area carrying out rigorous checks when completing tasks, for example for quantities and expiry dates, to help reduce the risk of errors. Team members knew the importance of these checks and how picking accuracy improved when they scanned barcodes using handheld scanners. Team members in the online doctor service dispensary demonstrated the importance of using safety tools provided within the patient medication record (PMR) system. This included scanning barcodes of medicines when dispensing and double-checking dosing information when labelling. Pharmacy team members understood how to respond to, and report mistakes identified following a person receiving their medicine, known as dispensing incidents. And the pharmacy kept dispensing incident reports with details of the outcome of the investigation and the actions taken to reduce the risk of a similar incident occurring. The pharmacy used both near miss reports and dispensing incident reports to inform monthly patient safety briefings. It produced and displayed action plans following these meetings, and these were reviewed the following month to help monitor improvement. Team members were knowledgeable about recent actions taken to reduce risk. For example, double checking the spelling of people's names and addresses when creating new PMR entries. And reviewing the placement of stock within the dispensary to reduce the risk of picking errors relating to medicines with similar names.

The online doctor website provided clear information about how people could provide feedback or raise a concern about the service. A frequently asked questions section of the website provided a telephone number for people to speak to a pharmacist from the company's online prescription service team if needed. But the main route of feedback was through the prescribing service's customer service team. This team facilitated most communication between the pharmacy and people using the online

doctor service. The RP provided examples of how they had responded to recent queries raised by a people via the customer service team. And they could directly contact people using the service if consent for pharmacy contact was provided, this consent was recorded on prescriptions.

The pharmacy had up-to-date professional indemnity insurance. The RP notice was clearly displayed with the correct details of the RP on duty and the RP record conformed to requirements. The pharmacy held its private prescription register electronically. A sample of entries within the register were seen to be completed in accordance with legal requirements. The pharmacy received prescriptions from the prescribing service through secure email which encrypted the PDF prescription files. The SI's office provided assurance that the electronic signatures on the prescription met legal requirements. It confirmed that the signatures were applied by the prescriber following review of the consultation. And that electronic signatures were linked uniquely to the signatory, capable of identifying the signatory and created using means over which the signatory could maintain sole control.

The pharmacy had specific procedures relating to information governance and data security. It held people's confidential information securely. And there were assurances that information held electronically was regularly backed up. The online doctor website contained details of its privacy policy for people to read. The pharmacy held confidential waste securely and this was collected periodically for secure destruction. The SI's team had worked with the prescribing service to define identification requirements for people using the online doctor service. Identification check requirements varied for individual services and the RP had good knowledge of the checks in place for the range of services provided. The pharmacy had assured itself that prescribing services approach to patient identification checks was proportionate to the level of risk for each service and in line with national guidance such as joint the 'Standards for Online and Remote Providers of Sexual and Reproductive Health Services' published by the Faculty of Sexual Health & Reproductive Healthcare of the Royal College of Obstetricians & Gynaecologists (FSRH) and the British Association for Sexual Health and HIV (BASHH).

The pharmacy's SOPs included specific SOPs relating to safeguarding vulnerable people. And contact information for safeguarding teams was accessible. The prescribing service did not issue prescriptions to people under the age of 16, and the pharmacy checked the age on prescriptions. The pharmacy was assured that treatments for mental health and wellbeing were only prescribed by the prescribing service following a video or telephone consultation. This provided an additional safeguard to potentially vulnerable people. And the webpage for depression and anxiety signposted people experiencing a mental health crisis, or at risk of self-harm or suicide to relevant healthcare and support services. The pharmacist was aware of how to report a safeguarding concern, this included liaising with the prescribing service to share details of the concern.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy employs a suitable team of people to manage its workload. It reviews its staffing levels and the skill mix of its team to ensure they remain appropriate. And it has suitable contingency arrangements in place in case of staff absence. It responds positively to feedback provided by its team members. And they demonstrate enthusiasm for their roles. They are keen to engage in shared learning opportunities designed to improve safety.

Inspector's evidence

A pharmacy manager supported the team in an operational role, they didn't hold any pharmacy qualifications and as such didn't complete any tasks relating to registrable activity. The manager worked with pharmacists and the SI's team to manage the risks associated with the pharmacy's services. The RP on duty was a regular pharmacist. The pharmacy employed six qualified dispensers and two trainee dispensers, one of which was the assistant manager. A number of regular pharmacists worked across the seven-day working week with two on duty each weekday and one working at weekends. The pharmacy continually reviewed its staffing levels and skill mix. The latest review had resulted in the recruitment of a pharmacy technician, to work in an accuracy checking role. This new team member was due to commence work at the pharmacy shortly. The pharmacy had suitable business contingency arrangements in place to support it in managing its services. These included the option to switch off the delivery option on the online doctor website, this meant people using the service would only see an option to pick up their medicine at a Boots pharmacy local to them. Pharmacists working within head office roles also supported the service when required. For example, on the day of inspection the second pharmacist on duty was a senior manager within the company and was covering a regular pharmacists leave.

The pharmacy employed another four team members. These team members were working in the stock redistribution area. They did not have formal qualifications and as such they were not involved in the dispensing process. They had received on-the-job training during their induction period, and they described how they had read written procedures as part of their training. There were plans for them to be enrolled on the pharmacy advisor course to expand their roles to support the online doctor service. A trainee team member reported feeling supported in their learning. But they explained that their accredited learning programme was currently on pause. This was reported to be because of planned changes being applied to the training website which meant it was inaccessible for a period of around six weeks. Another team member who had recently transferred to the pharmacy described a supportive induction programme. All team members completed regular learning activities and they were supported through a structured appraisal process. The SI's office provided information about how it had assured itself of the training arrangements for prescribers working for the online doctor service. This included tailored assessments and continual learning. The pharmacy had key performance indicators to help ensure it dispensed prescriptions in a timely manner. A screen in the dispensary displayed current workload and supported the team in managing this target. There was evidence of the RP and other pharmacists being empowered to exercise their professional judgement and challenge decisions made by prescribers. An example of this involved a prescription for a steroid inhaler with uncommon dosage instructions. The actions taken by the pharmacist to query the dose with the prescriber and clarify with the person using the inhaler was documented on the PMR.

All team members engaged in regular briefings related to workload and upcoming changes. Some meetings for specific services were only attended by team members working in the online doctor dispensary. All members of the pharmacy team openly discussed learning following mistakes. And the latest patient safety briefing was displayed in the online doctor dispensary to support team members in referring to the actions they had agreed on to reduce repetitive mistakes. The pharmacy had a whistle blowing policy and it displayed details of how its team members could provide feedback at work. Pharmacy team members explained how they could share ideas or raise a concern at work. Several team members confirmed how their feedback being taken onboard. For example, a member of the stock redistribution team described how their feedback had informed changes to the way the team recorded stock on a spreadsheet to improve efficiency.

Principle 3 - Premises Standards not all met

Summary findings

People using the online doctor service website can in some circumstances choose their preferred medicine prior to starting a consultation with a prescriber. This is not in line with GPhC guidance and is inconsistent with how the website is laid out for other conditions. The pharmacy premises are clean and secure. And they provide a suitable environment for the delivery of pharmacy services.

Inspector's evidence

The pharmacy premises were secure from unauthorised access. They were clean and were maintained to an appropriate standard. The pharmacy monitored room temperatures to ensure it kept medicines in an ambient environment and it had suitable heating and ventilation systems to support it in doing this. Lighting throughout the premises was sufficient. The premises consisted of a reception area, a consultation room, staff facilities, office spaces, and a large dispensary used for the online doctor service dispensing. There was also a designated area used for picking and packing tasks associated with the supply of P medicines. And separate areas used to manage the stock redistribution service, and for holding medicine waste and fridges containing medicines and vaccinations requiring cold storage. The consultation room was a good size and equipped suitably to provide the vaccination services. Colleagues working across the head office site reported to the pharmacy's reception when attending for a vaccination and they were escorted to and from the consultation room.

People accessed the online doctor service through a dedicated website. A frequently asked questions section of the website provided information to people about the pharmacy if they chose to receive their medicine via the 'deliver to me' method. This information included the pharmacy's registration number and details of how to check the registration of the pharmacy. But details of the SI were not kept up to date. The website overall was professionally laid out with relevant information about the different health conditions and the treatments offered through the service. In most cases people began a consultation from the conditions page. This meant they did not choose a medicine prior to starting a consultation. But webpages associated with contraception pill services and erectile dysfunction services were set out differently to other conditions. There was the option to start the consultation process from the conditions page. But there was also an option for people to start the consultation process from their preferred medicine. Proceeding with the consultation in this way meant people were selecting a medicine prior to the consultation process and this was not in line with GPhC guidance.

Principle 4 - Services Standards met

Summary findings

The pharmacy makes sure its services are accessible to people. It obtains its medicines from reputable suppliers. And it stores its medicines safely and securely. The team completes regular checks of medicines to make sure they are in good condition and are suitable to supply. Pharmacists make meaningful interventions about the suitability of prescribed medicines. But they do not always have important information and tools available to support them in doing this.

Inspector's evidence

People accessed the private online doctor service through a website, for a limited range of conditions. And the pharmacy supplied the medicines for people who selected home delivery. The website contained supportive information about each condition and further information about the medicines prescribed for these conditions, so people had healthcare information helping them make an informed choice on accessing the private services. The frequently asked questions section of the website provided further information about the service and timescales associated with the service. The website promoted collection from a Boots Pharmacy as the fastest option to people. Some medicines were only available for store collection. These currently included medicines used as part of the weight loss service and those where people were required to take them immediately. The pharmacy was not involved in any processes where the medicine was supplied by a local Boots pharmacy. The RP explained that counselling and safety netting was provided by the prescribing service via treatment plans which were generated for each medicine and sent to the person. But the treatment plans were not provided to the pharmacy team to support the delivery of the service unless specifically requested. The RP demonstrated two treatment plans that had been provided after a specific request had been made.

The pharmacy received prescriptions electronically in the form of encrypted PDF documents. It could view these on a separate portal to its PMR system. Team members printed a copy of the prescription to begin the dispensing process. They generated a pharmacist information form (PIF) and attached it to prescriptions and included information about the person's allergy status, their previous dispensed medication history, and general contraindications. The dispenser also recorded the age of the person on the prescription for the pharmacist to check against the service summary sheet to help make sure the treatment was appropriate for the person. And they recorded previous dispensing history to help inform the pharmacist's clinical check. Pharmacy team members took ownership of their work by completing audit grids on prescriptions to identify who had labelled and assembled the medicine, who had clinically checked the prescription, who had accuracy checked the medicine, and who had packaged the medicine ready for delivery. A dispenser demonstrated the checks made of the postal address label against the prescription form. Pharmacy team members also signed the 'dispensed by' and 'checked by' boxes on medicine labels as part of the dispensing process. They used deep trays to keep different people's prescriptions and medicines separate. They processed one prescription at a time at their workstation and workflow was efficient. Medicines were delivered to people in robust boxes via tracked post. On the date of inspection, the website was clearly advertising delays in the expected delivery dates of medicines due to strike action by the postal workers. There was a clear audit trail in place to confirm that handover to the mail carrier had been completed.

The prescribing service identified certain medicines that were not suitable for prescribing more than once if a person did not give consent for the private service to contact their NHS GP. But the pharmacy team couldn't see if a person had consented and if so any details of this correspondence. This made the effectiveness of the clinical check more difficult. Pharmacists did not have access to records of people's consultations, or notes relating to a person's treatment plan or any follow-up notes to assist in their clinical check. This meant the opportunity for the pharmacy to complete an independent second check of prescriptions in line with the prescribing policy and additional patient information was missed. Pharmacists had access to the PMR, and the web-based communication channel to contact prescribers if required. The conversations on the channel were logged so any member of the team was able to follow up on a query. Recent examples recorded included, a prescription for a duplicate order of a medicine for the treatment of bacterial vaginosis being questioned. This was appropriately cancelled. The RP stated that this communication method was efficient and that response time from the online prescribing service was usually within 30 minutes. If these could not be resolved within 72 hours, the prescription was cancelled by the pharmacy with the prescribing service informed of the reason.

The RP was not aware of how the online prescribing service monitored any issues relating to over or repeat ordering. Following the inspection, the SI's office advised that the prescribing service employed pharmacy technicians who performed an additional check on the frequency and interval between patient requests to check whether the prescription was due. There was evidence of queries relating to quantities being recorded on the pharmacy-prescriber web-based communication channel. And this was checked by pharmacists regularly. The RP was able to give examples of interventions involving repeat supplies or quantities of medicine prescribed. For example, the RP discussed queries related to medicines for erectile dysfunction. They had noted that a person had been prescribed eight tablets and then a prescription for a further eight was provided the same month. The RP had learnt that the prescribing service had a policy that set out a maximum supply of 16 tablets per month. Another example included a one-year supply of finasteride for the treatment of hair loss in men being questioned. The pharmacy had been advised it was within the prescribing service's maximum quantity. The RP also shared an interventions log which had been started in the month of the inspection. The log showed that a prescribed to a male.

Pharmacists administering flu and hepatitis B vaccinations had completed appropriate vaccination training. They accessed up-to-date and legally valid patient group directions (PGDs) to support them in providing the service. The service was managed through a booking system to help pharmacists plan their workload. The pharmacy redistributed stock between some of the company's branches. The service aimed to reduce medicine waste. Other Boots branch teams completed relevant paperwork when they identified stock that was no longer used. They then sent the stock to the pharmacy. If suitable, stock was then sent out to branches that had been identified as using the stock. Most medicines redistributed were in original packs. The team explained the restrictions to the service, which included no redistribution of controlled drugs (CDs) and medicines requiring cold storage. There had been occasions when branches had not followed these restrictions, and the pharmacy had a controlled drug cupboard and a CD destruction register to appropriately record and store CDs before destruction. These errors were reported to the RP and to the supplying branch. On receipt, team members checked the stock for suitability for onward supply. This included checking expiry dates and medicine packaging for any signed of damage. For full packs, the team checked the seal was intact or the quantity was correct. Short-dated stickers were attached as required. The company had expanded this service and the pharmacy received incomplete packs, known as split packs, from its NHS prescription hub pharmacy. There were additional checks and safeguards in place to make sure this stock was appropriate for onward supply. This included checking the quantity, batch number and expiry on the internal blisters of the packs on receipt. This stock was stored separately, with the quantity clearly

indicated on the outside of the pack. Different quantities, for example 28, 56 and 84 packs were stored separately in the same tote, in an organised manner. Team members received picking notes, which indicated the stock and quantity to be selected for redistribution. They checked the quantity displayed on the pack, against the quantity in the pack and against the picking note. And they re-checked the expiry date during the picking process to reduce the risk of errors. The stock was re-distributed to branches in sealed, suitably robust cardboard boxes. The pharmacy tracked the delivery of these boxes from the pharmacy, through the wholesaler warehouse to the delivery point, to ensure stock was not mislaid.

The pharmacy obtained its medicines from licensed wholesalers. It stored medicines in an orderly manner throughout the pharmacy. Medicines requiring cold storage were held in medical fridges. These fridges had data trackers and the pharmacy kept a temperature record to show that it kept medicines subject to cold storage between two and eight degrees Celsius as required. The pharmacy followed robust date checking processes for each service it provided. A random check of medicines in different service areas found no out-of-date medicines and short-dated medicines were identified. The pharmacy had large medicinal waste bins for disposing of out-of-date and damaged medicines. These were collected through a private waste contractor. The pharmacy received emails of drug alerts electronically. There was an audit trail in place to confirm the team checked and actioned the alerts.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. It maintains its equipment to ensure it remains in safe working order. And its team members use the equipment in a way which protects people's confidentiality.

Inspector's evidence

Pharmacy team members had access to up-to-date electronic reference resources. For example, the British National Formulary (BNF). And they could access the internet and company intranet to help resolve queries and to obtain up-to-date information. Electrical equipment was in good working order and there was evidence of monitoring checks to ensure it was safe to use. Pharmacists providing vaccination services had access to appropriate equipment to support these services, including medicines used to treat an anaphylactic reaction. The pharmacy's computer systems were password protected and information was regularly backed up. Access to the premises was restricted and as such people's personal information was protected from unauthorised access. The pharmacy kept archived records, such as copies of prescriptions, incident reports and PGD consultation forms in locked cabinets. It stored packages of assembled medicines waiting for dispatch securely with a full audit trail in place to support safe handover to the mail courier.

Finding	Meaning	
Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.	
✓ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.	
✓ Standards met	The pharmacy meets all the standards.	
Standards not all met	The pharmacy has not met one or more standards.	

What do the summary findings for each principle mean?