General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Isles Of Scilly Pharmacy, King Edward Lane, St. Mary's, ISLES OF SCILLY, TR21 0HE

Pharmacy reference: 1118528

Type of pharmacy: Community

Date of inspection: 13/11/2019

Pharmacy context

This is the only community pharmacy on the Isles of Scilly which are located off the coast of Cornwall. The pharmacy dispenses NHS and private prescriptions. It delivers medicines to residents on the other islands, sells over-the-counter (OTC) medicines and provides a range of other services such as Medicines Use Reviews (MURs), seasonal flu vaccinations and minor ailments. The pharmacy also supplies multi-compartment compliance aids to people in their own homes if they find it difficult to manage their medicines.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	1.7	Good practice	The pharmacy routinely manages information to protect the privacy, dignity and confidentiality of people who use the pharmacy's services. The team is suitably trained, the pharmacy has the appropriate procedures in place and additionally, has adjusted its internal processes in response to incidents. The pharmacy team proactively look for ways that they can suitably protect people's privacy
		1.8	Good practice	Members of the pharmacy team are trained through several methods and proactively ensure the welfare of vulnerable people
2. Staff	Good practice	2.2	Good practice	The pharmacy's team members have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or they are enrolled onto appropriate training. The team ensures that routine tasks are always completed so that the pharmacy operates in a safe and effective manner
		2.4	Good practice	The pharmacy has adopted a culture of openness, honesty and learning. The pharmacy has provided a range of resources to ensure the team's knowledge is kept up to date
		2.5	Good practice	Pharmacy staff are empowered and encouraged to provide feedback and raise concerns. They have the confidence to do this. The team has contributed to ways in which the pharmacy can become safer, team members have helped to improve the privacy of people and are currently ensuring the pharmacy's written instructions are fit for purpose
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Good practice	4.1	Good practice	The pharmacy has ensured its services are readily accessible despite its rural location. This includes the collection point set up to help provide access to medicines for residents on other islands

Principle	Principle finding	Exception standard reference	Notable practice	Why
		4.2	Good practice	The pharmacy ensures its services are effectively managed so that they are provided safely. The team makes appropriate clinical checks for people and there are audit trails to verify this
		4.3	Good practice	The pharmacy routinely ensures that its medicines and medical devices are obtained from reputable sources, that they are safe and fit for purpose, stored securely, supplied to people and disposed of safely and securely
		4.4	Good practice	The pharmacy is proactively raising concerns to the appropriate authorities when medicines or medical devices are suspected to be not fit for purpose
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

Overall, the pharmacy has safe working practices in place. It is particularly good at protecting people's private information. The team proactively monitors and seeks to protect the welfare of vulnerable people. Members of the pharmacy team monitor the safety of their services by recording the majority of their mistakes and learning from them. And, the pharmacy generally maintains its records in accordance with the law.

Inspector's evidence

This was a well-run and safe pharmacy. The pharmacy's workload was manageable during the inspection and it had an organised workflow. This included the layout of the dispensary. There were two distinct areas here. Staff processed and assembled prescriptions in batches from the back section. Once they were completed, they placed the assembled prescriptions on a ledge in front of them and from here, the pharmacists could then accuracy-check them at their own pace. The latter worked from a designated front unit.

On entering the building and the waiting area, there was signage on the pharmacy entrance stating that only one person at a time could enter the pharmacy. Staff monitored this and called people in when they were ready to deal with them. The pharmacists explained that this had been implemented in response to protecting people's confidentiality because they had become increasingly aware that everyone knew each other on the islands. By only allowing one person at a time into the pharmacy, they had reduced the footfall inside the premises and this had helped to protect and maintain people's privacy. Although the pharmacy's business considerably increased during the tourist seasons, this was described as still manageable, and this measure had helped the team to deliver thorough one-to-one consultations with people. The team had received feedback that when people who were partially deaf came into the pharmacy, conversations could be heard through the door by anyone in the waiting area. The team had subsequently placed a radio outside in the waiting area. This helped to minimise this and improved the privacy for people.

The pharmacy informed people about how their privacy was maintained. Confidential waste was segregated before being shredded and sensitive information on dispensed prescriptions awaiting collection could not be seen from the front counter or when people entered the pharmacy. Staff had been trained on the EU General Data Protection Regulation (GDPR) and had signed confidentiality statements. Summary Care Records were accessed for emergency supplies. The pharmacists explained that large numbers of tourists were seen during the seasonal months who often came without their medicines or required an emergency supply. Consent was obtained verbally from them, in writing and details confirmed so that they understood why the access was required. In addition, a documented action plan about information governance and how to routinely protect people's privacy had been completed in 2019. The pharmacy held meetings after incidents that had involved a breach of people's privacy and after the annual toolkit had been submitted. The pharmacists used feedback from staff and people and actively looked at ways in which they could make the pharmacy better at protecting people's confidentiality. Risk assessments and checklists had also been completed.

Staff were trained to identify signs of concern to safeguard vulnerable people. They described several incidents when they had become concerned about people and acted accordingly. This included

informing the surgery and vice versa about any local concerns such as if they noticed that people had lost weight or if people's behaviour had given them cause for concern. At their regular clinical meetings with the practice, they also gave or were given notice about anyone who was seen to be lonely so that they could be effectively monitored. Team members had read the relevant SOP, they took instructions from the pharmacists and had completed mandatory training with the medical practice. The latter was refreshed annually. Trained staff were also trained to level one through the Centre for Pharmacy Postgraduate Education (CPPE). New members of staff were still in the process of learning about this. Both pharmacists were trained to level two via CPPE, they had also completed the training with the medical practice and attended a face to face event about this. There was an SOP to support the process along with a policy on display, relevant contact details for the local safeguarding agencies were readily available and the pharmacy had a chaperone policy in place.

The pharmacy's stock holding was very organised, and this helped to reduce the likelihood of errors happening. The team had highlighted 'higher-risk' medicines such as look-alike and sound-alike (LASA) medicines. Posters about LASA's were also on display. Staff described sertraline and sildenafil being separated as well as amlodipine and amitriptyline. They stated that the pharmacists recorded their near misses. One pharmacist explained that because they had new members of staff, there had been more mistakes than usual being made, they were verbally discussed with the team at the time, staff were advised to take their time when dispensing and to slow down. However, details were not recorded during this period because the pharmacists wanted to help build the confidence of new members of the team. Overall, the team's near misses were recorded with reviews taking place every so often and annually to help identify any common themes or patterns. An annual patient safety report was seen completed. Routinely completing documented details about the review process was discussed at the time so that any remedial activity taken by the team could be better demonstrated.

Incidents were managed by pharmacists and their procedure was in line with the documented complaints policy. This included apologising, thanking people for bringing this to their attention, rectifying the situation, investigating and recording details. They were also reported to the National Reporting and Learning System (NRLS) and previous reports were seen to verify this. The superintendent explained that near misses were also reported to the NRLS. The pharmacy informed people about its complaints procedure. The second pharmacist explained that they discussed details with the team, raised the team's awareness when incidents happened, reflected on the situation and looked at external factors, root causes or ways to minimise this happening again in the future. This included looking at distractions and the internal temperature of the pharmacy.

The pharmacy held the required standard operating procedures (SOPs) to support its services. They were from Numark and were in the process of being updated and adjusted to match the team's processes. The SOPs were from 2019. Team members roles and responsibilities were defined within them and staff had signed to confirm that they had read the SOPs. In addition, the superintendent pharmacist asked staff to feedback about the contents of the SOPs, whether they were readable, relevant or the process required changing. Team members understood their roles and responsibilities and knew the activities that were permissible in the absence of the responsible pharmacist (RP). The correct RP notice was on display and this provided people with details of the pharmacist in charge of operational activities on the day.

The pharmacy's records relating to its services were in general, compliant with statutory requirements. This included a sample of registers seen for controlled drugs (CDs), records of emergency supplies, the RP record, most records of unlicensed medicines and private prescriptions. Balances for CDs were checked frequently and with every transaction. On randomly selecting CDs held in the cabinet, their quantities matched the balances that were recorded in the corresponding registers. The maximum and

minimum temperatures for the fridge were checked every day and records were maintained to verify that they remained within the required temperature range. Staff kept a complete record of CDs that had been returned by people and destroyed at the pharmacy. The pharmacy's professional indemnity insurance arrangements were through the Numark and this was due for renewal after 03 June 2020. There were the occasional crossed out entries within the RP record and occasional prescriber details missing from records of unlicensed medicines. Some incorrect prescriber details and the type of prescriber were seen in records of private prescriptions. This was discussed at the time.

Principle 2 - Staffing ✔ Good practice

Summary findings

The pharmacy has enough staff to manage its workload safely. Pharmacy team members are appropriately trained or undertaking training. The pharmacy provides them with a range of resources as part of their ongoing training. This helps keep the team's knowledge and skills up to date. In addition, the team is supported and encouraged to make suggestions to improve the safe running of the pharmacy.

Inspector's evidence

Staff present during the inspection included two pharmacists one of whom was the superintendent pharmacist (SI), a trained dispensing assistant who was due to leave and a trainee dispensing assistant who was enrolled onto accredited training with Buttercups There were also a few new starters. The team's certificates of qualifications obtained were seen and they wore name badges. The SI explained that the pharmacy's volume of dispensing and workload varied during the year due to the influx of tourists during the summer and migration of residents in the winter months.

Staff in training asked appropriate questions before selling medicines over the counter (OTC), their activities were supervised, and they referred to the RP when required. They were provided with set aside time at the pharmacy to complete their course material. To assist the team with ongoing training needs, staff could access a suite of resources and eLearning through the GP practice. They also described self-directed learning through completing OTC workbooks and quizzes, took instructions from the pharmacists and used relevant literature from companies. This helped to improve and keep their knowledge up to date. Staff progress was monitored annually with formal performance reviews taking place by the GP practice and SI. As they were a small team, details were discussed and provided verbally, staff read emails and team meetings were held when required.

The pharmacy held a whistleblowing policy and its business continuity as well as contingency plan were on display. Staff had the confidence to raise any concerns they may have had. They had done this in the past. Where concerns with other members of the team or pharmacists had been seen, they tried to resolve them internally first and had discussed details with the practice manager and partner(s) at the medical practice. The SI described recently changing the pharmacy team's staff working patterns and hours to reduce the risks associated with lone working. There were only two pharmacists on the islands (the two who were working at the pharmacy). As contingency, locum pharmacists were used. Team members were encouraged to provide feedback about the pharmacy's internal processes (as mentioned under the various principles).

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide a suitable environment to deliver its services. The pharmacy is clean. And, it has enough space to provide its services safely.

Inspector's evidence

The pharmacy premises were located inside the medical practice as a separate adjacent unit by the front entrance. There was a small waiting area just outside the pharmacy with seating available. As described under Principle 1, staff asked people to come into the pharmacy one by one. The pharmacy itself was of a medium size, it had a very small front counter area with a small range of Pharmacy (P) medicines stocked behind it. There was a barrier to restrict unauthorised entry into the dispensary and a small consultation room to one side. This was used to provide services or if additional privacy was required. The room was of a suitable size to conduct services and access to confidential information was restricted because of the way people were brought into the pharmacy and from how the room was used. There was enough work space in the dispensary for the pharmacy’s services to be carried out safely. The pharmacy was clean, suitably lit, well ventilated and professional in appearance. Staff could also share the facilities in the medical practice.

Principle 4 - Services ✔ Good practice

Summary findings

The pharmacy's services are easily accessible, and the team provides them in a safe and effective manner. The pharmacy obtains its medicines from reputable sources, it manages and stores them appropriately. And, the pharmacy is proactively identifying and reporting issues seen with medicines. And, it takes the appropriate action in response to safety alerts. This helps to ensure that people receive medicines and devices that are safe to use.

Inspector's evidence

The pharmacy's opening hours and details about the services that it provided were on display. There were four seats available for people waiting to enter the pharmacy as well as additional seating in the medical practice. This area also contained a vast amount of information for the local community as well as details about other services. This included an extensive range of leaflets, posters and a community noticeboard. Staff could signpost people to other organisations from documented information that was present and from their own knowledge. Entry into the medical practice was at street level from a wide, front door and there was clear, open space inside. This enabled people with wheelchairs to easily access the pharmacy's services. Staff described knowing regular users of the pharmacy's services who were partially deaf or visually impaired. They gave a one-to-one service and physically assisted people when necessary.

The pharmacy had set up a collection point with Royal Mail so that residents on the other islands could easily access and collect their medicines. Residents had given their consent for this and the service was necessary because of the pharmacy's rural location and potential difficulty for people on the other islands to routinely access the pharmacy's services. Staff at the pharmacy posted the medicines to the Royal Mail's depot which was on another island, the team explained that the Royal Mail's staff had been appropriately trained by the them and had signed confidentiality clauses. There was an SOP put into place by the pharmacy for them. Signatures were obtained from people when they come to collect their medicines. The pharmacy maintained audit trails confirming this and to verify when as well as to whom medicines were supplied in this way. CDs or fridge items were taken out by the doctor's working at the adjacent practice as they ran a clinic once a week on the other islands and the pharmacy would be notified if there were any uncollected medicines although this was described as quite a rare occurrence.

Due to its rural location, the pharmacy tried to offer as many services as possible. It held the required stock for the palliative care service and the SI explained that they routinely linked the alcohol brief intervention service in when MURs were conducted for people. This included providing lifestyle advice. People had been referred for alcohol detoxification in the past through this service. The SI also described the pharmacy's ability to provide emergency supplies helping to reduce the pressure on other healthcare services (from the medical practice). In the summer, one of the two modes of transport to the island (the Scillonian passenger ferry) had broken down and the pharmacy had provided emergency supplies to many tourists when they had run out of their medicines. This had helped keep appointments available at the medical practice for residents.

Documented details of interventions were seen. The pharmacy team routinely attended practice meetings where relevant concerns could be discussed or highlighted. If people were seen to be over-

ordering their medicines or if people were not taking their medicines as prescribed, this was addressed. The second pharmacist described seeing people with salbutamol inhalers on repeat who were overusing their inhalers. MURs were subsequently held with them, they were educated about their condition and use of medicines and referred to the practice for a review. This had helped reduce wastage. The second pharmacist also described a special interest in diabetes. People with this condition were identified, particularly if they were newly diagnosed so that they could discuss their medicines with them, reassure them about how to manage their condition or about any equipment provided. This helped to keep them informed and educated so that they could take their medicines as prescribed or monitor their condition effectively.

The pharmacy was healthy living accredited. There was a dedicated zone to provide people with information and relevant details about current health campaigns. Staff explained that they also posted information on the pharmacy's Facebook page. They had looked at the local health profile and identified the areas that most required intervention. This had helped raise people's awareness on certain topics. They were currently trying to raise awareness of the non-emergency telephone number 111. Previous campaigns involved providing information to manage respiratory tract infections, managing people's expectations about treatment, how long the condition could be expected to last for as well as educating them on warning signs. To increase people's knowledge about children's oral health, the pharmacy had liaised with the local dentist about which products they could stock, this included a gentle version of toothpastes for people undergoing chemotherapy. During the hay fever season, the SI explained that they had helped to reduce appointments with the GP by encouraging people to use OTC remedies.

The pharmacists administered influenza vaccinations as a private service. This was to supplement and held in conjunction with the service provided by the medical practice. The pharmacists had completed the appropriate training to provide the service, this included vaccination techniques and anaphylaxis. They obtained informed consent from people before vaccinating and details were sent to their GP. There was also suitable equipment to safely provide the service such as a sharps bin and adrenaline in the event of a severe reaction to the vaccine. In addition to the SOPs, the pharmacy held Service Level Agreements for the services that it provided, service specifications as guidance for the team and paperwork for the Patient Group Directions (PGDs). The latter had been signed by the authorised pharmacists.

During the dispensing process, the team used baskets to hold prescriptions and medicines to prevent any inadvertent transfer. They were colour co-ordinated to highlight priority. A dispensing audit trail through a facility on generated labels helped to identify staff involvement in processes. Dispensed prescriptions awaiting collection were stored with prescriptions attached. Details about fridge items and CDs (Schedules 2 to 4) were highlighted to help staff to identify them.

Staff explained that multi-compartment compliance aids were only supplied to people who found it difficult to take their medicines and they liaised with the person's GP to set this up initially. Weekly meetings were held with the GP practice to discuss suitability for this. Prescriptions were ordered by the pharmacy and cross-checked when received, against people's individual records. If any changes were identified, staff confirmed them with the prescriber and kept records to verify this. Descriptions of the medicines within the compliance aids were provided. All medicines were de-blistered into the compliance aids with none left within their outer packaging. Patient information leaflets (PILs) were supplied routinely and compliance aids were not left unsealed overnight. Mid-cycle changes involved people first being informed by the GP, if they were able to, the medicines were provided separately for people to take and new compliance aids were initiated from the start of the next cycle.

Team members were aware of the risks associated with valproates, they highlighted prescriptions to bring this to the attention of the pharmacist, there was a caution note placed in front of stock as an additional alert and the pharmacy held relevant educational literature to provide to people at risk, upon supply of this medicine. An audit had been conducted in the past to identify people who had been supplied this. Prescriptions for people prescribed high-risk medicines were routinely identified so that pharmacists could ask about relevant parameters and blood test results. The team used laminated cards for this purpose. There were details seen recorded to verify that appropriate checks had been made, this included information about the International Normalised Ratio (INR) level for people prescribed warfarin. People prescribed higher-risk medicines who received compliance aids were supplied with these medicines separately. Although the above process still took place, the team was not always recording relevant information here. This was discussed at the time and staff agreed to implement this into their practice.

The pharmacy stored its medicines in an organised manner and obtained them as well as medical devices from licensed wholesalers such as Phoenix, Alliance Healthcare and AAH. The Specials Laboratory was used to obtain unlicensed medicines. The team was trained on the processes involved with the European Falsified Medicines Directive (FMD). There was relevant equipment present and information about the process on display. The pharmacy was registered with SecurMed and staff were complying with the decommissioning process. They explained that on two separate occasions, the system had flagged suspicious medicines, and this had been reported. The pharmacy received drug alerts by email and through wholesalers, the team checked stock, and acted as necessary. An audit trail was available to verify this process. This was on the pharmacy's email system and the team also kept a documented log of the actioned drug alerts. In addition, the pharmacists had reported an incident in the previous year that involved citalopram where an unexpected reaction had been seen. This was via the Yellow Card Scheme to the Medicines and Healthcare products Regulatory Agency (MHRA), evidence of this was seen and relevant information was also provided to the people involved.

Medicines were rotated, and date-checked for expiry every month as well as upon receipt from the wholesalers. Staff identified short-dated medicines and kept records to verify this. There were no date-expired medicines or mixed batches present. Medicines were stored evenly and appropriately within the fridge. CDs were stored under safe custody. Keys to the cabinet were maintained during the day and overnight in a manner that prevented unauthorised access. The pharmacy used designated containers to hold medicines returned for disposal and there was a list for the team to identify hazardous and cytotoxic medicines. People returning sharps for disposal, were referred to the adjacent medical practice. Returned CDs were brought to the attention of the RP, details were noted, they were segregated and stored in the CD cabinet prior to destruction.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. The pharmacy keeps its equipment clean.

Inspector's evidence

The team had access to a range of equipment to provide the pharmacy's services safely. This included current versions of reference sources, clean equipment such as counting triangle, a separate one for cytotoxic medicines and standardised conical measures for liquid medicines. The dispensary sink used to reconstitute medicines was clean and there was hot and cold running water available as well as hand wash present. The CD cabinet was secured in line with statutory requirements. Medicines requiring cold storage were stored at appropriate temperatures within the medical fridge. Computer terminals in the dispensary were password protected and positioned in a manner that prevented unauthorised access. Cordless phones were available to maintain privacy if required. The pharmacy shared access to the shredder in the medical practice to dispose of confidential waste. Staff used their own NHS smart cards to access electronic prescriptions.

What do the summary findings for each principle mean?

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.