

# Registered pharmacy inspection report

**Pharmacy Name:** Galexa Pharmacy, 61 Annesley Road, Hucknall, Nottingham, Nottinghamshire, NG15 7DR

**Pharmacy reference:** 9010911

**Type of pharmacy:** Internet / distance selling

**Date of inspection:** 15/09/2021

## Pharmacy context

This is a distance selling pharmacy which offers services to people through its website, [galexapharmacy.co.uk](http://galexapharmacy.co.uk). The pharmacy specialises in the supply of medicines to people residing in care homes. Members of the public can also nominate the pharmacy to receive and dispense their prescriptions. The pharmacy supplies some medicines in multi-compartment compliance packs, designed to help people to take their medicines. The pharmacy premises are not generally accessible to members of the public due to its distance selling model. This means the pharmacy supplies medicines through its delivery service. This inspection took place during the COVID-19 pandemic.

## 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
<b>1. Governance</b>	Standards not all met	1.1	Standard not met	The pharmacy does not identify key safety risks associated with providing its services. It has allowed its professional indemnity insurance arrangements to lapse. This puts people using the pharmacy's services at risk if something was to go wrong. And the pharmacy provides no assurance of the written procedures in place for its team members to follow.
		1.2	Standard not met	The pharmacy does not have robust processes to monitor adverse safety events. It doesn't encourage its team members to record details of mistakes made during the dispensing process. And pharmacy team members are not aware of the steps to take when managing a dispensing incident.
<b>2. Staff</b>	Standards met	N/A	N/A	N/A
<b>3. Premises</b>	Standards met	N/A	N/A	N/A
<b>4. Services, including medicines management</b>	Standards not all met	4.2	Standard not met	The pharmacy does not consider all of the risks associated with managing its services safely, including providing medicines in multi-compartment compliance packs. It does not consider the stability of medicines when supplying them in this way. And does not appropriately label the medicines with the date of supply.
		4.3	Standard not met	The pharmacy has inadequate management arrangements for storing some of its medicines. It does not store all stock medicines safely in their original packaging. And it does not always store higher risk patient returned medicines as it should.
<b>5. Equipment and facilities</b>	Standards met	N/A	N/A	N/A

## Principle 1 - Governance Standards not all met

### Summary findings

The pharmacy provides no assurances that it has written procedures in place to support the safe and effective provision of its services. This means team members may not be working in an established and consistent way. It does not use risk monitoring tools to help identify and manage the risks associated with its services. And there is evidence that key risks associated with record keeping and insurance arrangements have gone unidentified. Pharmacy team members consider feedback from people using the pharmacy's services. And they respond to this feedback well. Pharmacy team members are knowledgeable about safeguarding requirements. And they act appropriately to protect people's personal information.

### Inspector's evidence

The pharmacy had addressed some of the risks of managing its services during the COVID-19 pandemic. There was no evidence of formal risk assessments being undertaken for either the premises or the pharmacy team members. But the responsible pharmacist (RP), who was working alone during the inspection, wore a type IIR face mask and gloves when working. And team members had good access to supplies of personal protective equipment. The pharmacy had considered risks associated with infection control. There was plentiful space provided across the dispensary to allow team members to socially distance from each other whilst carrying out their roles.

The pharmacy's standard operating procedures (SOPs) were not available for inspection. The pharmacy's superintendent pharmacist (SI) was contacted during the inspection and informed the inspector that the SOPs were in a locked cabinet. Team members did not have access to this cabinet when the SI was not on duty as the SI kept the key. This meant that team members did not have ready access to procedures to support them in managing the safe and effective running of the pharmacy. There was no indication of the range of SOPs in place and there was no assurance provided that team members had read and understood the SOPs. This heightened the risk that something may go wrong when providing services as there was a potential for team members to be working in different ways. Evidence of other key documents such as a risk assessment of the pharmacy's services and business continuity arrangements were not seen.

The pharmacy had a formal near miss record. But no entries had been made in this record since 2019. The current process for managing a near miss was for the team to discuss the mistake and put in place actions to prevent similar mistakes occurring. The team did not document this learning or the actions it took to reduce risk. The RP explained these actions would include ensuring stock was rotated on the dispensary shelves to reduce the risk of a medicine expiring and separating different strengths of the same medicine when they were in similar packaging. The pharmacy had no evidence of incident reporting available and the RP was not familiar with how to manage or report an incident. But the RP confirmed that she would make the SI aware of any alleged incident, and would seek to clarify the details of the incident with the person reporting it.

The pharmacy had a complaints procedure. And this was advertised on its website and within its practice leaflet. The pharmacy had transferred ownership in January 2021 at which point the SI had also changed. Details of the SI provided within the complaints section of the website related to the previous ownership. This could be potentially confusing for people seeking to provide feedback. The RP

demonstrated how the team acted on feedback and requests. For example, the pharmacy had set up folders for each care home it provided services to. And each care home service was set up to the specific requirements of that home. Both pharmacists had completed training associated with protecting vulnerable adults and children. And team members had access to contact information for safeguarding agencies. The RP demonstrated an awareness of the need to apply vigilance when providing services to vulnerable people.

The pharmacy held personal identifiable information within the premises. And it adequately protected this information from unauthorised access. The RP was observed checking the identity of a caller before discussing any confidential information with them. The pharmacy had a cross-shredder for disposing of confidential waste. And there was no build-up of confidential waste waiting to be destroyed.

The certificate of professional indemnity insurance and public liability insurance displayed had expired on 28 February 2019 and belonged to the previous owner. The inspector received confirmation that the insurance arrangements had been renewed on 15 September 2021. The SI provided evidence of insurance arrangements running under the previous ownership up until 28 February 2021. But records held by the GPhC confirmed transfer of ownership was effective from 1 January 2021. This potentially meant claims between 1 January 2021 and 28 February 2021 may not have been covered by the insurance arrangements in place. Cover had lapsed completely from 01 March 2021 until 14 September 2021 when the issue was picked up during the inspection. This meant that the pharmacy did not have the necessary arrangements in place to cover any potential claims made during this period.

The pharmacy maintained running balances in the controlled drug (CD) register. Balances were routinely checked and signed upon receipt and supply of a CD. The RP also explained that a pharmacist undertook weekly balance checks of the register against physical stock. But this activity was not recorded. The register contained missing page headers and the address of the wholesaler was not always recorded in the register when the pharmacy received a CD. A physical balance check conducted during the inspection complied with the balance recorded in the register. Records associated with patient returned CDs were mostly in order. But some recently returned CDs had not been signed as destroyed in the register. The SI provided confirmation that she had personally undertaken this activity recently. And had then placed the destruction kits in the medicine waste bags ready for collection by a licensed waste carrier. Evidence of this was seen. RP records were in order. But the pharmacy was displaying two RP notices at the beginning of the inspection. A discussion took place about the need to display one clear notice related to the current RP. The pharmacy did not complete certificates of conformity related to unlicensed medicines in accordance with the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA). The pharmacy had only dispensed one unlicensed medicine to one person. And the RP confirmed the records would be brought up to date following a discussion about MHRA record keeping requirements.

## Principle 2 - Staffing ✓ Standards met

### Summary findings

The pharmacy employs a small and committed team to provide its services. Pharmacy team members have the confidence to provide feedback or raise concerns at work. And they receive some support for training associated with their roles. Members of the pharmacy team communicate with each other regularly through informal conversations. But they do not take the opportunity to record any learning from these conversations. This means they may miss opportunities to act to reduce risk or to learn from adverse events.

### Inspector's evidence

The pharmacy team consisted of the SI, another pharmacist (RP at time of inspection), a dispenser and a delivery driver. The RP was the only team member on duty during the inspection. But she explained that this was not a common arrangement and it was due to unplanned absence which was unavoidable. The team planned workload efficiently. This avoided the need for a pharmacist to self-check their own dispensing. The delivery driver had commenced their role recently and had not yet been enrolled on an accredited training course. A discussion took place about the changes to the GPhC's requirements for the education and training of pharmacy support staff which came into effect in October 2020. These changes required all team members to be enrolled on a GPhC accredited course relevant to their role within three months of commencing that role.

Pharmacy team members had access to reading materials to support their roles. And there was some arrangements for ongoing learning, particularly when new services were launched. For example, the RP had recently completed flu vaccination training. The pharmacy did not have a structured appraisal process to support the ongoing learning and development of team members. But the RP explained that the team regularly held meetings to share learning and feedback. And it was evident during the inspection that the RP felt comfortable in feeding back and referring any concerns to the SI. The pharmacy did not set specific targets for its team members to meet.

## Principle 3 - Premises ✓ Standards met

### Summary findings

The pharmacy premises offer a suitable space for providing healthcare services. They are clean, secure and include private space to provide consultation services. But the pharmacy doesn't keep its website up to date. This could potentially confuse and mislead members of the public wanting to use the pharmacy's services.

### Inspector's evidence

The pharmacy was adequately secure and clean. Lighting was sufficient throughout the pharmacy and air conditioning ensured the pharmacy stored medicines under 25 degrees Celsius. Team members had access to hand sanitiser whilst working. And hand washing facilities included antibacterial handwash and hot and cold running water.

The pharmacy didn't keep its website up to date. The name, address and contact information for the pharmacy was correct. But the details of the company that owned the pharmacy and the details of the SI published on the website belonged to the previous owner. The premises consisted of a foyer, a large consultation room/office and the dispensary. The dispensary was a good size for the level of activity carried out. There was separate space for completing administration tasks, labelling tasks, assembling medicines, accuracy checking and racking of compliance packs provided to the care homes. To the side of the dispensary was a room which provided storage for dispensary sundries and stationery. There was also access to a staff kitchen and toilet facilities off the dispensary. The consultation room was located at the front of the premises. It was not in regular use, but would sometimes be used to hold meetings with care homes. And the pharmacy was planning to run a flu vaccination service from the room. The pharmacy did store some yellow bags containing medicine waste in the room. This storage arrangement required review ahead of the room being used to provide any consultation service.

## Principle 4 - Services Standards not all met

### Summary findings

The pharmacy does not consider all of the risks associated with managing its services. This includes specific risks associated with removing medicines from their original packaging and supplying them in multi-compartment compliance packs. It does not always store medicines safely which further increases the risk of a mistake occurring during the dispensing process. The pharmacy's services are accessible to people. But it does not act to update its website as services and costs change. This could mislead people who try to access a service which the pharmacy no longer provides.

### Inspector's evidence

People accessed the pharmacy's services through either the website, by email or by telephone. Some information on the pharmacy's website was not up to date. For example, the website referred to some face-to-face consultation services including blood pressure checks and diabetes screening. The RP confirmed the pharmacy did not provide these services. Information relating to the price of prescriptions had not been updated since 2018. The website included an A-Z health information guide. And it advertised a new flu vaccination service which the team were in the process of introducing. The pharmacy's website also offered General Sales List (GSL) and Pharmacy (P) medicines for sale. This service was provided by a third-party pharmacy registered with the GPhC. The pharmacy did not advertise details of this third-party provider prominently on its website. But information was available upon check-out of baskets when people purchased medicines.

Members of the public either ordered their own prescriptions or contacted the pharmacy to order on their behalf. The pharmacy maintained an audit trail of the prescriptions it ordered. Care homes generally ordered their own prescriptions and these were transferred to the pharmacy through the Electronic Prescription Service (EPS). The pharmacy was provided with a copy of a re-ordering Medicine Administration Record (MAR) sheet. And this was checked against prescriptions received to help identify any missing items or queries. The pharmacy managed these queries through liaison with GP surgeries and care homes. It also ordered interim medicines on behalf of some homes and it had an audit trail to support it in doing this.

The pharmacy supplied medicines to care homes in multi-compartment compliance packs. The system used was a 28-day single medicine pack for each medicine the person was taking. The pharmacy placed these packs on coloured racking to help care home staff identify which time of the day the medicine was to be administered. The RP demonstrated how each home provided details of how it wanted packs to be racked. For example, by room number to help with efficiency when conducting the medicine rounds. The pharmacy supplied patient information leaflets to the homes for the medicines it supplied. But dispensing labels attached to the packs were post-dated. The RP explained these dates referred to the start date of the cycle. This meant the pharmacy was not accurately recording the date of dispensing. This process was not in keeping with labelling requirements. And it meant both pharmacy team members and care home staff had no information relating to how long the medicine had been assembled inside the pack. Team members took ownership of their work by signing the 'dispensed by' and 'checked by' boxes on the dispensing labels. And the pharmacy supplied MARs for each person's medicine.

The pharmacy supplied a small number of medicines to individual people in multi-compartment

compliance packs. There were no assembled packs on site on the day of inspection. The RP demonstrated how individual records for each person were used to support the dispensing process. These records included details of medication changes. The RP provided details relating to the team providing clear descriptions on the backing sheet for each medicine inside a compliance pack. And she explained how backing sheets were securely attached to these compliance packs. The RP also indicated that full dispensing audit trails would be provided on labels attached to the backing sheets.

Team members used baskets throughout the dispensing process. This kept medicines with the correct prescription form and helped to inform workload priority. The pharmacy managed workload associated with the care homes carefully to ensure the care homes received the medicines with enough time to check them prior to cycle start dates. The delivery driver did not keep an audit trail of the deliveries made to support the delivery process. But the pharmacy team clearly identified all prescriptions delivered each day in order to manage any queries that arose effectively. The pharmacy did not currently supply medicines through postal or courier services.

The pharmacy held some stock of higher risk medicines. The RP explained how the team completed some checks of these medicines. For example, asking care homes to provide details of recent INR tests for people taking warfarin. But no evidence of recording associated with these checks was seen. The RP had some awareness of the requirements of the valproate Pregnancy Prevention Programme (PPP). And confirmed that to her knowledge the pharmacy had not dispensed valproate to anybody within the high-risk group. A discussion took place about the pharmacy's specific responsibilities when dispensing valproate containing medicines to people within the high-risk group.

The pharmacy did not have adequate processes in place to help identify the suitability of medicines for supply in a multi-compartment compliance pack. And the RP was not aware of resources available to support with this assessment. Several medicines, including Epilim were supplied in 28-day compliance packs despite the manufacturer stating the medicine should not be removed from its original packaging until just prior to the dose being taken. The pharmacy had not completed a risk assessment or considered the manufacturer's recommendations when supplying medicines in this way. And the pharmacy's processes meant it could be supplying medicines that were not stable for the entire length of treatment it supplied each month. The pharmacy also used some white lidded tubs to store medicines in. It did this to help with efficiency when transferring these medicines to compliance packs. The tubs had been previously used to store other medicines and were washed and dried with the labels removed before being used again. The team identified the medicines in the tubs by attaching the details of the medicine from the original box, including batch number and expiry date. But there was no indication of any checks associated with a second person checking that the details on the tub matched the medicine inside. Or checks associated with the manufacturer's storage recommendations for the medicines, or assembly date on the tubs to identify how long the medicines had been removed from their original packaging.

The pharmacy sourced medicines from licensed wholesalers and specials manufacturers. Medicine storage in the dispensary required improvement. Not all medicines were held in their original packaging. And some medicines had been de-blistered from their foil packaging and were held loosely inside the original container. This did not adequately protect them from exposure to light or dust particles. The pharmacy held liquid medicines in their original packaging. And the team took care to identify the opening date of liquid medicines by applying labels with the date of opening to them.

The pharmacy had a secure cabinet to hold stock medicines subject to safe custody regulation. But some patient returned medicines which should have been stored in the cabinet were found in another cupboard which did not comply with these regulations. The RP acted immediately to store them within the legally compliant cabinet. The cabinet was a suitable size but the team had not made full use of



shelving provided with the cabinet to help keep medicines in a neat and orderly manner. The pharmacy stored medicines subject to cold chain requirements in a good size refrigerator. It kept a daily fridge temperature record (Monday-Friday). And this confirmed the medicines were stored between two and eight degrees Celsius as required. The team stored some food and drink items inside the fridge which was not ideal. But the pharmacy had considered risk when storing these items. For example, it stored medicines on the top few shelves of the fridge and food items at the bottom.

The pharmacy had a date checking matrix to support with regular date checks of stock medicines. The last date check was recorded in June 2021. A random check of dispensary stock found no out-of-date medicines. But a check of fridge stock found two expired insulin pens. The pharmacy had a good supply of yellow bags for holding medicine waste. And team members wore gloves and face masks when transferring out-of-date medicines and returns into these bags. It also had appropriate CD denaturing kits for the secure disposal of patient-returned CDs. The pharmacy received alerts relating to medicines from the MHRA. Team members checked these alerts, and the pharmacy maintained an electronic copy of the alert for reference purposes.

## Principle 5 - Equipment and facilities ✓ Standards met

### Summary findings

The pharmacy has the equipment and facilities it needs for providing its services. And pharmacy team members manage and use 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 to help resolve queries and to obtain up-to-date information. But team members didn't regularly access specific reference resources to support the services provided. For example, information about the stability of medicines when supplying them in compliance packs. The pharmacy's computer system was password protected. Each team member had their own NHS smart card. The pharmacy had a range of clean equipment available to support the delivery of pharmacy services. It stored counting apparatus for tablets and capsules, and British Standard measuring cylinders for measuring liquid medicines within the dispensary. Equipment associated with the supply of medicines in compliance packs was single use.

### 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.