

Registered pharmacy inspection report

Pharmacy Name: Norchem House Pharmacy, Chilton Way, Chilton Industrial Estate, Chilton, Ferryhill, County Durham, DL17 0PD

Pharmacy reference: 9010694

Type of pharmacy: Dispensing hub

Date of inspection: 28/05/2019

Pharmacy context

The pharmacy is a self-contained unit within the warehouse facilities of Norchem. The activities undertaken are prepacking and assembly of medicines to supply to registered pharmacies within the same legal ownership. The multi-compartmental compliance packs are filled using a robotic system, with some manual input. The pharmacy supplies a limited amount of pharmacy only (P) medicines to members of staff who work in the warehouse and store.

Overall inspection outcome

✓ **Standards met**

Required Action: None

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 met	N/A	N/A	N/A
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 has a set of written procedures. The company reviews these as required and acts to change processes to improve the safety and service for people. The team members have a clear understanding of the roles and tasks. And they work in a safe way to provide services to people. The team members record and discuss mistakes that happen. They use this information to learn and make changes to help prevent similar mistakes happening again. The pharmacy asks its users for their views and uses feedback for learning to improve the services.

Inspector's evidence

The pharmacy had up to date standard operating procedures (SOPs) which the head office had recently updated following a concern raised. And subsequent changes to procedures reviewed and adopted immediately to improve its service.

The pharmacy had standalone SOPs for the hub service and for the spoke hub. And traditional SOPs which included general dispensing and procedures. The company had reviewed the SOPs for the hub and spoke in May 2019 with changes to the communication process between the hub and spoke. The company had instigated changes following a concern where there had been a failure in communication which had resulted in a compliance pack not being suitably checked. This now provided an electronic recording system through a management programme and would ensure the team members logged any messages. And the process was robust, providing an audit to ensure the team members completed any tasks following communication. The team members were in the process of reading the SOPs but were aware of the changes made. The pharmacist manager had discussed the changes with the team. The pharmacy team had adopted the changes. She was going through the SOPs and highlighting the relevant parts. The pharmacy team members were reading and signing once read.

The pharmacy also had supplementary SOPs for the Falsified Medicines Directive (FMD). The hub pharmacy team had previously read the SOPs, issue 1 which ensured they understood both the hub and spoke tasks. Some of the team members worked across both hub and spoke premises. This helped them have a good understanding of the systems and how the processes worked.

The pharmacy had two robots in place. The system used was the Synmed dispensing support unit (DSU) supported by Positive Solutions computer system. There was no original pack dispensing undertaken. The level of work had increased over the last year. And the company had decided to put an additional robot in place. The pharmacy had decided to add an additional robot, rather than put in a bigger unit. This allowed resilience if one unit failed to work.

Each robot had a picking head and could undertake packs for two patients at a time, eight trays.

The clinical checks were undertaken at the spokes. The hub could not resolve issues with quantities or backing sheets not showing all the prescription details. If the hub had any issues they sent these back to the spoke; such as if there was an odd drug missing, quantity issue or start date.

The master computer received the files and the pharmacist had a chart and the pharmacist allocated work to one or the other robot. The pharmacist could override the system and if required she could

switch work to the other robot. The computer was password protected and there was finger print recognition for the software access.

The computer produced bar codes stickers and it scanned these. The computer linked the bar code stickers to the patient and medicine administration sheets (MAR). The unit informed the dispenser if they needed to fill any items by hand and on the MAR sheet this was further indicated with an asterix. The team used this as an indicator in the final accuracy check and recording any near misses.

The screen showed the four trays and where to put the medication. The team member placed the tray into the robot unit after they had completed the manual fill. They scanned the bar code and the robot would only run if all the details matched up.

The team member took the trays out on racks once the robot had filled the trays. The team member then undertook a cell count. The team member counted all the individual items in a cell. They advised that if any cells contained more than seven items or if the medication could not be clearly seen, they would not seal the trays. This allowed the accuracy checker to count and check items using tweezers. And seal once checked. The team had developed a system and discussed situations where larger tablets could obscure smaller tablets, so they left these trays unsealed.

The team normally completed the trays about one week before they were due to go to patients. This allowed time for the spoke to resolve any issues. The completed checked trays were then prepared in batches and placed in tote boxes, sealed with cable ties. The team labelled the tote boxes and the system generated lists. These were then placed for delivery to the spokes. Audits trials were in place throughout the whole process from the beginning to end. And the further improvement of a more robust audit for the message facility.

The pharmacy recorded near misses using two specific templates. One for the robot errors and one for the pharmacy near misses. The pharmacy used these to differentiate between the needs for the processes. The robot headings included jumpers, missing, duplicates and breakages. The form had a space for comments. If there was a count issue with the robot then the team would look at changing the lid size to see if that would rectify the error. Or if tablets chipped then they would change this for a team member to fill the tray manually or change the de-blistering process. And manually de-blister. The team used pots of paracetamol as they were not suitable for de-blistering in the machine and the team had to pop these by hand. So, the always tried to source pots.

The team had recorded errors during the dispensing process such as picking errors with Madopar capsules given instead of co-beneldopa.

The pharmacist had told the new members about the near miss logging process and the benefits from learning from it. They tended to ask questions when selecting items and tried to learn as they went along. The pharmacist reminded them of the importance of the cell count. The team had training on the selection of the head size for the lids to ensure that they selected correctly, and this prevented any double drops.

The pharmacy prepared reports monthly and the team discussed these, and they shared learning. And any other issues raised with SynMed.

The team had a process place where the spokes could raise any issues to them. And they addressed these and used these for learning.

The pharmacy had current indemnity insurance in place.

The pharmacy had the correct Responsible pharmacist (RP) notice displayed and the pharmacists completed the records as required.

The pharmacy had no controlled drugs which required them to make entries in the CD register. The spokes dealt with ant CD requiring entries.

The pharmacy did not receive patient returned medicines from people with people returning these to their spoke pharmacy.

The team had read General Data Protection Regulation (GDPR) information. The team members had confidentiality agreements.

The IT system was password protected and required logins and fingerprint recognition.

The pharmacy put confidential waste in bags for offsite shredding.

The pharmacy had a safeguarding policy. They were all aware of this. But had no direct access to patients.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has systems in place to make sure it has enough staff with the right skills to provide its services. The team members understand their roles and responsibilities in providing services. The pharmacy supports the pharmacy team to learn and develop. And it provides access to ongoing training. The pharmacy team members support each other in their day-to-day work. The pharmacy team members openly discuss their ideas to improve ways of working. And they feel comfortable raising any concerns they have.

Inspector's evidence

There was one pharmacist, three accuracy checking technicians (ACTs), and six dispensers who worked at the pharmacy. The ACTs worked at spoke pharmacies, and generally there was one ACT present at any time. Four dispensers worked full time. One dispenser had recently completed the technicians' course and waiting to become registered with the GPhC. Three of the dispensers were relatively new to the dispensing hub and the company was enrolling them on the dispensing course.

There were other pharmacists who worked in the building and they assisted when required. The pharmacist manager explained that she planned work ahead and at busier times, the pharmacy could get more assistance, with either pharmacists or additional ACT support. The two dispensers who worked part time provided additional support when required and overtime was in place for this to be undertaken.

Several of the team worked across the spoke pharmacies and hub, so continued to learn and kept up to date in matters by doing this. They received the learning materials and updates from the head office to ensure they kept up to date. They kept up to date with over-the-counter products and advice for these products.

The pharmacy team members rotated tasks within the hub which ensured they were all skilled for all roles. The tasks included stock management, owings and de-blistering.

The team members received informal one to ones within the pharmacy and they were able to discuss development needs. The pharmacist had supported the dispensers doing her technicians course.

On-going training was being done with the newer starters. The team members assisted them during this time. And they all felt able to ask for help due to the different nature of the work. The pharmacist advised that the trainee dispensers would attend other branches for certain elements of their training.

The team carried out tasks and managed their workload in a competent manner discussing any issues which arose and dealing with any telephone queries. The team members had been able to discuss openly the recent concern raised. And discussed how to work to avoid repetition.

The team said they could raise concerns about any issues within the pharmacy by speaking to the pharmacist, area manager or the superintendent (SI). Both the area manager and SI attended and worked at the hub, so were readily contactable.

There was a whistleblowing policy and telephone numbers were available, so the team members could easily and confidentially raise any concerns outside the pharmacy if needed.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is secure, safe and clean, and suitable for the pharmacy services it provides. It had facilities available for private conversation if required.

Inspector's evidence

The pharmacy was clean, tidy and organised. And fitted out to a suitable standard with space for dispensing, storing stock, de-blistering and multi-compartmental compliance packs waiting delivery to the spokes. The sinks, benches, shelves and flooring were all clean and the team members completed a cleaning rota once they had completed tasks. The room temperature was comfortable and well lit.

The pharmacy daily tasks sheet checklist which covered good housekeeping including cleaning the counter spaces during the day. It also had a weekly and monthly tasks checklist which included cleaning the robots and the glass units.

The pharmacy followed the standards for Good Distribution Practice which was the same as the warehouse. The team members were not allowed to have any hot drinks in the pharmacy. And encouraged to have their breaks when required, using the staff facilities.

There were rooms available for private consultations should any person wish a private discussion with the pharmacist or member of the pharmacy team.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy has systems in place to ensure that the stock is suitable for the process used. And makes changes when this is not the case. This ensures people receive medicines fit for use. The pharmacy gets its medicines from reputable suppliers. It generally adheres to storage requirements during the dispensing process. It takes the right action if it receives any alerts that a medicine is no longer safe to use. And takes the correct action to return it to the supplier. The pharmacy supplies medicines in multi-compartmental compliance packs to the spoke pharmacies to provide to people. This helps people to take their medicines at the right time. The pharmacy provides descriptions with the packs to show what each medicine looks like. But on occasions the descriptions may not be the same. This may cause confusion to people when identifying their medicines.

Inspector's evidence

The pharmacy supplied limited amounts of Pharmacy Only (P) medicines to members of staff who worked in the warehouse and offices. The pharmacist undertook all P sales and dealt with any related questions or healthcare advice. The pharmacy included photographs of medicines on the backing sheets, with the front and back of the medication shown. The spoke inputted the information of the medication used. And it was the brand of stock with the spoke had. This was usually the same as the hub. The company were aware that on occasions the brand used at the hub was different. And descriptions may not always reflect the medication brand. The company was addressing this issue.

The hub did not supply any Patient information leaflets (PILs) to the spokes. The hub removed all the PILs from the packets during the de-blistering process. There was work in progress with Positive Solutions and SynMed to look at providing the PILs during the production process. At the moment, the hub discarded all the PILs for recycling during the de-blistering process. And the spokes printed off PILs and supplies these with the packs to people.

The pharmacy team were aware of the Pregnancy Prevention Programme for valproate. But they had no direct access to any patients.

The pharmacy kept delivery sheets as an audit trail for the delivery of medicines from the hub to spokes. Drivers should have signed for the tote boxes taken although out of about 12 sheets looked at, the drivers had not signed about half of these. The pharmacist explained that the drivers should sign the sheets for audits. But they could identify the driver by the route.

The pharmacy stored medicines in an organised way, within the original manufacturers packaging and at an appropriate temperature. The team followed the processes for de-blistering the packs and placing the tablets in to containers, suitably labelled, including the bar codes. The team recorded the date of the de-blistering for each batch.

The pharmacy kept stock for the more commonly used items in the middle of the filling unit. The team members checked daily to ensure that the containers had enough for the workload and usage. Each

robot had 400 canisters. Records were kept of all replenishments.

The pharmacy team checked expiry dates on products. The team did not put anything in to the robot unless it had over three months left before the expiry date. The did not accept anything short dated from the wholesaler. They used their own wholesaler. And AAH and Alliance. They had no fridge lines or any specials.

The pharmacy team continually review the medicines used in the robots to ensure that they are suitable for the process used. And tablets do not become chipped or broken during the process. Learning had also been undertaken on the fragility of some tablets and these were added manually during the process to ensure that people did not receive any damage items.

The team had an idea of the Falsified Medicines Directive (FMD) process and they were scanning products currently in the process.

The team used appropriate medicinal waste bins for any waste medication from obsolete or damaged stock.

The pharmacy had a process to receive drug safety alerts and recalls. The team actioned these and kept records of the action taken. The pharmacy received emails from the head office and they confirmed that they had taken the appropriate action or if they had not required to take any action.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The equipment the pharmacy uses in the delivery of its services is clean and well maintained to ensure it is fit for purpose. The pharmacy team members protect confidential information.

Inspector's evidence

The pharmacy had access to a range of up to date reference sources, including the British National Formulary (BNF). And it used the internet as an additional resource for information. The pharmacist had apps for resources which she referred to when required.

The team members cleaned the robots routinely and followed maintenance schedules. The engineers came every 50 days as part of the routine maintenance. The team used a separately marked box for cytotoxic drugs. The team added these items to trays by hand. The team had access to disposable gloves and alcohol hand washing gel. The team members cleaned the box which they used for popping tablets for de-blistering, after each change of medication, to avoid contamination.

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.