

Is Your Team GPhC Inspection Ready?

* There will now be three types of inspections: intelligence-led, routine and themed
* As a general rule, inspections are to be **unannounced**- each pharmacy is expected to be visited every 3-5-year cycle and more frequent if there is local intelligence
* Each principle will have four possible results: ‘standards not all met’, ‘standards met’, ‘good practice’, and ‘excellent practice’
* Inspection outcomes will be either ‘standards met’ or ‘standards not met’
* Inspection reports will be published from Quarter 1 2019/20
* Examples of notable practice will be shared in a ‘knowledge hub’ on the new website

The standards you must meet are all detailed on the GPhC page

<https://www.pharmacyregulation.org/sites/default/files/Inspection%20Decision%20Making%20Framework%20Nov%202013.pdf>

https://www.pharmacyregulation.org/sites/default/files/document/standards\_for\_registered\_pharmacies\_june\_2018\_0.pdf

Please Note the GPhC inspection visits will now be **unannounced** so it’s even more important that the whole pharmacy team are aware of the standards and can provide evidence to support they are meeting them on the day!!

To assist pharmacy owners/superintendent pharmacists in ensuring that the required procedures are in place for the safe management of CDs, the GPhC did produce a Controlled Drug self-assessment form for England and Scotland. Although the GPhC don’t use this anymore it will help to ensure you audit your processes around CDs. The audit is available here under CD self-assessment

<https://psnc.org.uk/sefton-lpc/other-services/cd-reporting/>

We recommend this is completed prior to the inspection and be available for the GPhC inspector

All pharmacy premises and staff should be suitably prepared to host a General Pharmaceutical Council (GPhC) inspection **at all times**.

The GPhC will be holding pharmacy owners and superintendent pharmacists accountable for the outcomes of the inspection, so owners and superintendent pharmacists should ensure all their pharmacy teams are suitably prepared.

The GPhC inspection guidance is available here <https://www.pharmacyregulation.org/inspecting-registered-pharmacies>

<https://www.pharmacyregulation.org/standards>

For DSPs and those providing services at a distance - https://www.pharmacyregulation.org/sites/default/files/document/guidance\_for\_registered\_pharmacies\_providing\_pharmacy\_services\_at\_a\_distance\_including\_on\_the\_internet\_april\_2019.pdf

The new GPhC inspection model places an emphasis on patient safety. After initially reviewing the standards and collecting evidence for inspection, pharmacy staff should continually renew evidence, and receive training

Suitable procedures should be in place to meet standards when locum pharmacists are present, during staff absences or during times of pharmacy maintenance. This may mean reviewing procedures on a day-to-day basis, as necessary, to ensure the pharmacy is complying with GPhC standards.

**How to prepare staff for a General Pharmaceutical Council inspection**

GPhC inspectors will be observing interactions with patients and questioning and posing scenarios to staff. All pharmacy staff should be appropriately trained, and it may be beneficial to talk them through the inspection process and prepare them for questioning by the inspector, so they do not feel put ‘on the spot’ during an inspection.

Staff should participate in ongoing training, not just their initial training, in order for a pharmacy to achieve a higher rating in the inspection.

The locum packs can be used to help ensure locums have all relevant pharmacy information to keep them well informed for an inspection.

**How to prepare staff for an inspection —**

* Use the PSNC /NPA resources
* Review SOPs regularly
* Role play with staff questioning them as the inspector might
* Internal information on inspections relating to the pharmacy chain/ individual pharmacy
* Meeting with all staff in advance to discuss the inspection process
* Carry out your own internal inspection/ self-audit

**How to host an inspector**

Staff should be prepared to talk to the inspector on the day. Services should be thought about in advance in order to accommodate the needs of the inspector, for example, time needed for the inspector to speak to pharmacists.

The GPhC inspector will give an outline of what the inspection is and how it will be conducted, before going onto the services provided and the staff present or not present. This would be good knowledge for the staff to have

Staff should be polite and courteous to the inspector and should be open when answering questions. When the inspector first arrives in the pharmacy, the responsible pharmacist (RP) should try and ascertain the plan of the inspector for the inspection.

**Hints and tips for the day**

* Sell what you do — promote yourself and your team
* Be open and give as much information as possible
* Make sure you show them everything — the inspector may not ask
* Promote yourself and your team — effectively communicate to the inspector what the pharmacy does
* Ensure all staff know where all information is, including things such as

patient group direction documents/SLAs , safety incident reports and near miss logs, guidance on child protection and vulnerable adults, Complaints logs, Training files, locum packs, cleaning matrix, Health and safety audits, Fire assessment audits, equipment service docs, IG toolkit certificate, CAS alert process, whistleblowing policy

They have grouped the standards under five principles. The principles are the backbone of the regulatory approach and are all equally important.

The principles:

**Principle 1: The governance arrangements safeguard the health, safety and wellbeing of patients and the public.**

Standard operating procedures (SOPs)

Staff have clear roles

Complaints procedure is in place- Staff can explain complaints procedure

Appropriate records are kept- CD register, Private prescriptions, emergency supplies, Extemp preps, specials, RP logs, CAS alert actioning

Patient confidentiality is protected- consent forms

Safeguarding Children and vulnerable adults- staff trained and now where local contact details are held, Flow charts

Incident Reporting and near miss reporting – review and analysis evidence

Patient safety reports

Indemnity Insurance details to hand

IG Toolkit completed and certificates to hand, confidentiality agreements – staff understand GDPR

**Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.**

Sufficient staff with appropriate skill mix

Training is appropriately supervised- Training records

Incentives and/or targets should not affect Professional judgement- staff understand not to accept inducements often called bribery and anti-corruption policies

Culture of openness, honesty and learning- staff learning around incidents

Staff performance appraisals

Whistleblowing – evidence of staff training

Further info for meeting principal 2 can be found here - <https://www.pharmacyregulation.org/sites/default/files/document/guidance_to_ensure_a_safe_and_effective_pharmacy_team_june_2018.pdf>

**Principle 3: The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.**

Well‐maintained, clean and safe pharmacy premises- cleaning matrix

Well‐designed and compliant with the Health Act and protects patient’s privacy

Clean and hygienic- infection control materials

Secure ‐ ensuring protection of both stock and patient information

Health and safety audits, Fire assessment audits, equipment service docs

**Principle 4: The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.**

Clearly displayed pharmacy services- Posters, practice leaflets to hand

Services benefit the local community- adjustments available when needed e.g. hearing loops, staff can describe all enhanced and advanced services

Promotion of healthy lifestyles- leaflets and staff aware of signposting information and recording, evidence of public health campaign participation

Stock is sourced, stored, supplied and disposed of appropriately- date checking matrix

Recalls and alerts are actioned- CAS alert process

Targeting of high-risk meds and promotion of healthy lifestyles in diabetes/CVD etc. and recording of interventions

Evidence of compliance with FMD

Disposal of medicines – hazardous waste bins, protocols for accepting waste, equipment e.g. gloves, aprons, spillage kits

**Principle 5: The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public**.

Clean, well‐maintained equipment is available- evidence of maintenance /calibration and PAT testing

Equipment is fit for purpose and to the appropriate safety Standard – up to date reference sources

IT equipment protects confidentiality- passwords

**Inspection reports**

The evidence collected by the inspectors will be used to assess whether a pharmacy has met all of the standards.

The  [**Inspection Decision-Making Framework**](https://www.pharmacyregulation.org/sites/default/files/document/gphc-inspections-decision-making-framework-1.3-april-2019.pdf) is used when assessing if a pharmacy has met all of the standards. **The Decision-Making Framework is a guide to help support inspectors to make consistent decisions**.

At the end of the inspection the inspector will go through their findings with the Responsible Pharmacist, who will be asked to confirm they have received feedback from the inspection. The Responsible Pharmacist has an opportunity to make any additional comments. This is important to show that the evidence recorded on the report is an accurate reflection of what the inspector saw and was shown on the day.

Pharmacies which have not met one or more of the standards will also be asked to [**complete an improvement action plan**](https://www.pharmacyregulation.org/inspections/improvement-action-plans) setting out what action they are planning to take to improve against those standards.

**Outcomes from inspections**

The outcome a pharmacy will receive from an inspection has changed as part of our updated approach. There are now two potential outcomes; standards met or standards not all met.

All of the standards will need to be met for a pharmacy to receive a ‘standards met’ outcome, and any pharmacy not meeting all the standards will need to complete an improvement action plan, as before. The improvement action plan will be published alongside the report on the new inspection’s website.

The pharmacy will also receive one of four possible findings for each of the five principles within the standards for registered pharmacies. The four possible findings are:

‘excellent practice’

‘good practice’

‘standards met’

‘standards not all met’

**Improvement action plans**

All pharmacies which have not met one or more of the standards during an inspection will be required to complete and implement an improvement action plan.

The pharmacy would be **expected to tell the GPhC within 5 days**of the action they intend to take to meet the standards and improve practice in the pharmacy. They will consider some flexibility in this timescale if there are exceptional reasons why this deadline cannot be met.

They require improvement **action plans to be filled in by the owner and superintendent pharmacist and returned to them**. The inspector will already have identified whether the improvement action in relation to each standard, must be completed within 10, 20 or 60 working days. The pharmacy owner and superintendent will identify when the actions will be completed within these timescales and who will be responsible for this. Pharmacy owners and superintendent pharmacists will be expected to action their improvements as soon as possible, especially where a risk to patient safety has been identified.

Improvement action plans will be published on the new inspections’ publication website alongside the inspection report.

**Next steps**

When the actions set out in the improvement action plan have been completed, the owner or superintendent pharmacist must notify the GPhC (set an alarm!) . Once the inspector is satisfied that evidence has been provided that indicates completion of the improvement action plan, a new inspection will be scheduled six months from the date when the inspection report was sent to the owner. However, the Inspector is quite flexible when they return to the pharmacy and it may be sooner than 6 months if there is a serious concern about patient safety. The visit at 6 months will be a full inspection visit with a new report.

At the 6-month inspection, the inspector will visit the pharmacy again to assess whether the pharmacy is meeting the standards and that the improvements are being sustained. If that is the case, then they will issue an updated report with the new overall outcome showing that the pharmacy has met all of the standards. This report will be published on the inspection publication website, once it has been through the usual pre-publication process.

**Publication of inspection reports**

GPhC will publish reports from **pharmacy inspections that take place from April 2019 onwards**. Reports will be published on a new pharmacy inspection publication website which will launch in Summer 2019.

**Before an inspection report is published, it goes through a quality assurance process**. The pharmacy owner or superintendent pharmacist will be given an opportunity to review the report and check its factual accuracy before the report is finalised.

Inspection reports will then usually be published on the new pharmacy inspection publication website within six weeks of the inspection taking place.

**Review of overall outcome of the inspection process**

Pharmacy owners and superintendent pharmacists can ask for a formal review of the overall outcome of an inspection where they consider that the evidence does not support the outcome.

The owner or superintendent must [**complete this form requesting a review**](https://www.pharmacyregulation.org/sites/default/files/document/request-for-review-of-overall-inspection-outcome.docx) -  (on click the form will attempt to download automatically) and send by email to [**inspectionreviews@pharmacyregulation.org**](mailto:inspectionreviews@pharmacyregulation.org) **within 5 working days of receipt** of the final report.

GPhC has produced a guide to the review process: -

<https://www.pharmacyregulation.org/sites/default/files/document/guide-to-process-for-review-of-overall-outcome-of-an-inspection-april-2019_0.pdf>

**Enforcement action**

The GPhC’s overall approach is to support and encourage pharmacy owners to meet the standards for registered pharmacies.

They have a number of different enforcement options available to us to secure compliance with our standards. These r**ange from improvement action plans to statutory enforcement powers including improvement notices and conditions on registered pharmacy premises**.

They will use their statutory enforcement powers in situations when a pharmacy owner does not complete an improvement action plan and carry out the necessary changes to make sure the standards are met, or in situations when there is a serious risk to patient safety.

**[To support consistent decision-making, they have published a new enforcement policy](https://www.pharmacyregulation.org/sites/default/files/document/registered_pharmacies_enforcement_policy.pdf" \t "_blank)** for registered pharmacies which sets out our approach and principles we will follow when using our enforcement options, to support consistent decision-making. <https://www.pharmacyregulation.org/sites/default/files/document/registered_pharmacies_enforcement_policy.pdf>

**Hints and tips for responding**

* On holiday — let the GPhC know; NPA Members have been able to delay their response (as have GPhC inspectors who have been on holiday)
* Ensure areas of patient safety are dealt with promptly through action plans – Set Reminders!! Make someone accountable
* Set deadlines to ensure action plans are met

**Further resources**

<https://www.pharmacyregulation.org/helpful-resources>

The GPhC Inspector for Sefton is **Craig Whitelock -Wainwright** and is happy to answer any questions you may have

General Pharmaceutical Council

25 Canada Square | Canary Wharf | London |E14 5LQ

Direct: 0203 713 7922

Email: Craig.Whitelock-Wainwright@pharmacyregulation.org

www.pharmacyregulation.org