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Pharmacy Law – The Spring / Summer 2023 Update

Supervision

On 1 August the Pharmacy Supervision Practice Group provided its recommendations. The report is an interesting read and feels like something the pharmacy profession has been anticipating for a long time.

The consensus was:

- the physical presence of a pharmacist was an important element of safe and effective community pharmacy and accessibility to patients and the public should be preserved and increased. Supervision did not mean directly observing every transaction though. The two-hour limit for absence should remain.
- In relation to delegation, the group agreed that legislation should be amended to enable aspects of the preparation, assembly, sale and supply of medicines to be delegated from the RP to appropriate members of the pharmacy team (including pharmacy technicians). To whom, from whom and lines of accountability must be clear.
- It was agreed that legislation should be amended to enable the preparation and assembly of medicines to take place outside the opening hours of the pharmacy without an RP being signed in, with accountability for dispensing accuracy resting with SP.

Once legislative and regulatory changes have been drafted, the proposals will be subject to a full consultation.

Regulatory change again - amendments to the 2013 regulations

There have been further amendments to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Regulations) which the government has said are seeking to address two problems. Firstly, the high numbers of unplanned temporary pharmacy closures. Secondly, the permanent closure of a number of 100 hours pharmacies meaning the loss of guaranteed extended hours for patients.

The changes, mainly in force from 25 May, that address these issues are:

a) To make it easier for contractors to close the pharmacy during the day to give staff a scheduled hour rest breaks. (However this does not change overall core hours a pharmacy is required to offer)

b) Allow 100 hours pharmacies to reduce their core opening hours to a minimum of 72 hours. (Pharmacies have to retain hours between 9-5pm Monday to Saturday, the total number of Sunday hours and the hours between 11am and 4pm on Sundays.
The reduced hours will also apply if the pharmacy seeks to relocate or change ownership. This has given rise to calls to the Gordon's offices and we are happy to help if needed.

c) Enable coordinated closures in the most affected areas via NHSE temporary local hours plan. Contractors can chose whether to sign up and there has to be consultation. It will be interesting to see how often this is actually implemented.

d) Require all contractors to have business continuity plans in place in the event of temporary closure for reasons outside of the contractors control. (Part of Terms of Service from 31 July 2023).

Other changes brought in at the same time include a welcome adjustment on fitness to practice information required where pharmacists are required to provide work history going back 7 years rather than the complete history as previously required. The previous arrangement caused difficulty for pharmacists with work gaps in early in their careers. Information already provided in the last 7 years will be valid as long as it is kept up to date.

There are also changes to Notices of Commencement and dates on which service provision must commence.

Official guidance on the changes is still awaited at the time of writing...

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Case updates

A number of cases have caught the attention of the regulatory world over this half year.

On-line pharmacy - *Hexpress R (Hexpress Healthcare Ltd) v Care Quality Commission [2023] EWCA Civ 238*

Hexpress is an online pharmacy with a website offering treatments including erectile dysfunction, weight loss and STIs. Patients fill in an online questionnaire which is referred to a medical practitioner who may prescribe. What is prescribed is then supplied by Hexpress. Hexpress was registered with CQC. Following inspections by CQC, a rating of Inadequate under the Safe domain in a draft report was given, while the overall rating was Requires Improvement. The grounds for appeal to the Court Appeal were:

- The CQC failed to independently review the Factual Accuracy Comments therefore being procedurally unfair,
- The CQC should have taken into consideration additional steps taken since inspection.

Both grounds were dismissed

- As an inspector independent of the inspection consider reviews, this element ensures any demonstrably wrong or misleading statements were corrected prior to publication,
- If CQC was under a duty to take into account improvements then there was a risk their report would never be finalised. CQC could choose to take into account improvements if it chose to.

An interesting case for pharmacies that are required to be registered by CQC and also for the general points that are likely to apply to pharmacy inspections.

Prescribing - Professional Standards Authority v General Medical Council and Professor Sundara Lingam [2023] EWHC 967 (Admin)

This case is about a UK doctor who wrote prescriptions for a UK pharmacy company for overseas patients without having even basic information. A High Court judge quashed a tribunal's decision to allow him to continue practicing with conditions.

Professor Lingam was provided with basic information by the pharmacy who appear to have used information from overseas consultants. He wrote prescriptions based on this information and called himself a "transcriber" rather than prescriber.

The charges against Professor Lingam alleged, among other things, that he had been provided with information by the Pharmacy that was insufficient to allow safe prescribing. Professor Lingam was also prescribing outside his expertise as a paediatrician.

The Medical Practitioners Tribunal imposed conditions of practice for a period of 24 months. The Professional Standards Authority (PSA) felt the decision was too lenient and appealed.

The judge agreed. The case has obvious relevance for all prescribers.

Professor Lingam was sent back to the Medical Practitioner Tribunal for sanction to be re-determined.

Pharmacist falsifying second check

An interesting Professional Standards Authority (PSA) appeal against a General Pharmaceutical Council decision that a pharmacist was not impaired was recently settled by consent.

This was an appeal against a decision to find that a pharmacist was not currently impaired when he had repeatedly falsified records of second checks of medication he dispensed, despite being warned not to. The appeal was upheld and the decision substituted with a finding of impairment and a warning.

A footnote from a dental case.

Not relevant for pharmacists now, but as clinical services grow it is interesting to see how other healthcare professionals are paid…

In *GDC v. Williams [2023] EWCA Civ 481* the Court of Appeal overturned the long held view that it is not permitted to mix NHS and private treatment by charging patients a private top-up fee in addition to the NHS charge for NHS treatment. Very briefly, the GDC said top-ups were not permitted by the dental regulations, but the Court of Appeal disagreed and said top- ups were permitted and are much closer to the spirit of NHS dentistry in that at least some of the treatment would be funded by the NHS. However NHS England has since indicated that it is considering its position and further actions may include changes to the regulations…

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“UK only” medicines pack labelling.

On 9 June 2023, the government published guidance relating to implementation of medicines labelling rules of the Windsor Framework. Medicinal products will be approved and licenced for the whole UK market (including NI) They will have to carry a clear “UK only” label, which may be placed anywhere on the pack.

The MHRA confirmed that “UK only” medicines packs will not need to comply with the EU Falsified Medicines Directive 2011/62/EU and bear two-dimensional barcodes and serialisation numbers. However, the MHRA “will expect anti-tamper devices to remain on all medicine packaging.”

The new measures will be effective from 1 January 2025. To provide a single deadline for new packaging requirements for the UK market, the MHRA will continue to allow manufacturers to supply medicines in legacy EU packaging until 31 December 2024 extending the previous deadline of 31 December 2023.

In addition, the MHRA clarifies that medicine packs already on the UK market and within the supply chain in existing packaging after 1 January 2025 may remain on the market until their expiry date.

Our frequently asked question for this edition is:

The GPhC have raised concerns about my Fitness to Practise. How long has the GPhC been taking to deal with initial concerns recently?

Significant delays have been reported… At the June 2023 GPhC council meeting papers reporting on Fitness to Practise revealed;

“…the open caseload continues to increase at investigation and get older. This is because there were more new cases coming in than cases closed or referred. As a result, at the end of Q4, 56% of all cases at investigation stage are over the age of 12 months old.”

For the quarter year the report covered zero cases were referred to the Investigating Committee (IC) stage within 52 weeks (12 months). The target was 80% to be dealt with within that time.

The delays could have a legal impact as well as, of course, the effect on career development and the general health and well-being of registrants. My article in Chemist and Druggist looks into the effect of the delays … https://www.gordonsols.co.uk/what-effect-are-delays-having-on-fitness-to-practise-proceedings/

If you have any specific queries about this issue, please do not hesitate to contact us.

Other topics that you may be interested in are available on the Gordons website:

Interim orders: Why should pharmacists be concerned?
Changes to Superintendent and RP roles.
Can pharmacists refuse to dispense medication on moral grounds?
Will regulatory reforms make fitness-to-practise processes swifter and fairer?

If you would advice on any of the issues raised, contact the author.

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This update should not be taken as advice for any particular circumstance and legal advice should be sought for a specific matter

The team will be at the Pharmacy Show again this year. Come and see us at Stand J03 (close to the restaurant area).