

# Gordons Partnership

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## Pharmacy Law - Autumn Update 2024

Autumn has brought the hard hitting Darzi report and more prosaically, the latest set of amendments to the regulations covering NHS pharmacies.

### Regulatory changes

#### NHS services

The first of the amendments to The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 has been generally publicised but the second may be less well known...

##### 1. Original Pack Dispensing

From 1 January 2025, different quantities to those ordered on a prescription form may be supplied, to allow a drug to be provided in its manufacturer's original outer packaging. These amendments will not apply to controlled drugs under Schedules 2 to 4 of the Misuse of Drugs Regulations 2001 or to special medicinal products under the Human Medicines Regulations 2012.



The quantity of the drug dispensed must be within 10% of the quantity on the prescription, and the pharmacist supplying the drug must be professionally satisfied that the patient will be able to follow the medication instructions as set by the prescriber, as well as determine whether it is reasonable and appropriate to supply a different quantity.

##### 2. Requirement for Market Entry references dropped

From 1 October 2024, there will be no requirement for references to be provided in market entry fitness to practise applications. This should speed up the processing of applications and enable them to be processed within the time frame envisioned by the regulations.



#### Puberty Blocking Medication Ban

A number of changes have been implemented by both the Government and the GPhC in relation to the prescribing of puberty-blocking medications, as a result of the Cass report, which was an independent review of NHS gender identity services for children and young people. This report was published in April 2024 and led to subsequent guidance reforms from NHS England and the GPhC. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Amendment) Regulations 2024 came into force on 26 June 2024 and prevents GPs from prescribing NHS medicinal products containing gonadotrophin-releasing hormone analogues.

The Government also passed the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (England, Wales and Scotland) Order 2024, effective from 3 June 2024. This restricted all prescribing and supply of puberty-suppressing

hormones to children and young people under 18 in England, Wales and Scotland, where prescriptions were issued by prescribers registered in the EEA or Switzerland.

This ban was judicially reviewed in *The King (on the application of (1) Transsexual CIC and (2) YY v Secretary of State for Health and Social Care and another*, [2024] EWHC 1936 (Admin). The two Claimants, (C1 - an organisation supporting transgender people in the UK and C2 - a 15-year-old transgender female) claimed that as there had been no formal consultation - normally required under the procedure to pass this order - it was unlawful. In the alternative, they argued that the consultation carried out by the Secretary of State was only partial, unfair and unlawful as it failed to consult the first Claimant, and that this breached Article 8 of the ECHR.

The application was dismissed by Mrs Justice Laing J, who held that the Secretary of State was entitled to conclude that the Cass Review provided the best and most up-to-date scientific evidence available and did not need to conduct further research (through a consultation). Regarding a voluntary consultation being conducted by the Secretary of State and the subsequent procedure for this, the court found, among other things, that there was an exemption from the consultation requirements when the emergency procedure was followed. The Article 8 argument was dismissed as healthcare policy matters had repeatedly been found to be within a State's margin of appreciation and the European Court of Human Rights had never previously found a State breaching Article 8 by refusing to authorise certain types of medical treatments.

This order was extended by the Government through the Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition) (Extension) Order 2024 and is now due to expire on 26 November 2024. The Secretary of State has indicated her wish to make this a permanent ban but will need to conduct a formal consultation to do so, under the procedure in the Medicines Act 1968.

## Guidance on NHS market entry applications

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, Regulation 31 was created to prevent two NHS pharmacy contracts existing at the same location. This is a complex regulation and NHS Resolution have published detailed guidance.

<https://resolution.nhs.uk/wp-content/uploads/2024/08/NHS-Resolution-Regulation-31-Guidance-Note-August-2024.pdf>

## Advertisements and Menopause

The Advertising Standards Authority (ASA) continues its vigilance regarding medicinal claims and have ruled that a paid advertisement from KeyForHer, a manufacturer of food supplements, has breached the UK Code of Non-Broadcast Advertising and Direct and Promotional Marketing and cannot appear again in its current form.

The advertisement made claims that would likely lead consumers to believe that their food supplements could resolve symptoms of perimenopause and menopause. Claims that food supplements can prevent, treat or cure human diseases are prohibited, as they are considered to be medicinal claims and can only be made in relation to licensed medicinal products.

Although menopause is not recognised by the ASA as a medical condition, this decision indicates that claims that products can treat symptoms of menopause will be considered to be medicinal in nature.



## Proposals before Parliament

### Controlled Drugs

Parliament will consider an Order to class certain drugs, among them Xylazine, a high-strength veterinary sedative, as controlled drugs under The Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2024. The order was laid before parliament on 2 September 2024. Concern over the increasing combination of heroin and Xylazine, and cannabis and Xylazine have led to a proposal for this drug, commonly known as 'tranq', to be specified as a Class C drug.

### GPhC Consultations

Earlier this year the BBC carried out an undercover investigation into buying three prescription-only medicines (an anti-anxiety drug, a painkiller and a sleeping medication) from online pharmacies. The investigation was triggered by comments from a coroner criticising the safety controls of on-line pharmacies.

On 22 February 2024 the GPhC responded to the investigation by setting out its current record on enforcement. (They set out that since April 2019, 680 inspections of online pharmacies have been conducted. Only 72% met all the standards and enforcement action has been taken against 54 distinct online pharmacies. There are currently 263 open online Fitness to Practise cases.)

The GPhC said they would keep the guidance under review and have now published the next proposed iteration. The consultation about the proposed changes to the guidance on providing pharmacy services at a distance, including on the internet can be found here: <https://www.pharmacyregulation.org/about-us/getting-involved/consultations/proposed-changes-guidance-providing-pharmacy-services-distance-including-internet>

It was a short running consultation that started in mid September and ended on 9 October 2024, but the draft guidance is still available and worth a read. The key proposed changes to the guidance are:



- Emphasising the responsibilities of the Superintendent Pharmacist
- Adding safeguards when supplying high risk medicines
- Adding weight loss medication and others to examples of medicines that should not be supplied on a questionnaire alone.
- Guidance if there is no consent to share information with a GP.
- There is one relaxation to the current guidance- at the moment a person cannot choose a prescription-only medicine before there has been an appropriate consultation with a prescriber. The new guidance allows a person to indicate their preferred choice of medicine but there must be a consultation before supply.

## Frequently Asked Questions

On the back of the Boots closures and applications to meet the gap left, our frequently asked question relates to market entry:

**Q:** I am making an application for inclusion in the pharmaceutical list. I have not already given Fitness to Practise information. As well as the full Fitness form, do I also need to send the form confirming that my pharmacy is lawfully trading (the Annex 2 form)?

**A:** No. From the current Pharmacy Manual -

"It should be noted that where the applicant is not already included in the relevant pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application, it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form."



### About the Author

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## Property Corner - Commercial Leases: What are a Tenant's Repairing Obligations

A tenant of a commercial lease will be subject to various obligations and covenants, foremost amongst which are obligations to repair the property. Failure to comply with repairing obligations would amount to a breach of the lease, which could lead to forfeiture or a claim in dilapidations. Understanding the tenant's repairing obligation is fundamental to protecting the tenant's legal position.

Commonly, when the lease lets a whole building, the tenant repairs the whole property, both inside and out. However, where the lease is of part only, the landlord is likely to retain responsibility for repair of structure, with the tenant responsible for internal repairs.

Where a tenant covenants to repair the whole of the property the likelihood is that the tenant will have to repair all the structural elements of the property – roof, foundations, structural walls, etc.

Where a tenant covenants only for internal repairs it is important to read and understand the lease in order to be aware of those parts of the building it must repair, and which fall to the landlord to repair. The property that the tenant repairs may (or may not) include window frames, internal non-structural walls, false ceilings and floors (or floorboards), etc.

Apart from advising our tenant clients to understand the extent of their repairing obligations, we always recommend that they carry out a survey, so that they are fully aware of the likely extent of those obligations.

Further, we advise our clients of the risk of a claim for dilapidations arising from a failure to properly repair. Whilst dilapidations claims deserve a note of their own, tenants should aware that, at the end of the term, their landlord may make a claim arising from the tenant's failure to repair. Such claims can be quite expensive and time-consuming, so understanding the importance of repairing the property in line with the terms of the lease at the outset should save time and money later on.

It is important to seek legal advice when entering a commercial lease. Failure to understand or comply with Tenant's obligations (particularly repairing obligations) may prove costly.

Our experienced commercial property team led by **Adrian Jones**,  
can assist with all of your commercial real estate needs.

If you require assistance, please contact us on 01483 451 900 or email [sols@gordonsols.co.uk](mailto:sols@gordonsols.co.uk)

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

**Articles:** [Hub and Spoke - If the election is tomorrow there is not enough time: Susan Hunneyball Chemist & Druggist](#)

**We will be at the Pharmacy Show at the NEC on 13 and 14 October 2024. Come and find us at stand H09.**

# Gordons Partnership

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