

Frequently Asked Questions

Pharmacy Registration and Renewal

1. Why must a pharmacy be registered?

A pharmacy must be registered because the supply of Pharmacy (P) medicines and Prescription Only Medicines (POMs) is restricted by law to being supplied from registered pharmacies only. There are however exemptions from this restriction which allows medicines to be supplied by:

- A doctor or dentist to their patient or to a person under whose care such a patient is.
- A hospital, or health centre, for the purposes of being administered in accordance with the directions of a doctor, a dentist, a supplementary prescriber or a non-medical independent prescriber. These supplies are defined as being made 'in the course of the business of the hospital'. Supplies that meet this definition include supplies made from the hospital pharmacy department to the hospital's wards or to the hospital's inpatients on its wards, or to the hospital's out-patients.

It is because of these exemptions that the GPhC does not register dispensing doctors' practices or hospital pharmacies that only make supplies that are defined as being made 'in the course of the business of the hospital' .

2. What are the criteria for pharmacy registration/renewal?

The GPhC can only register a pharmacy or renew the registration of a pharmacy where the owner's service model from that pharmacy includes one of the following:

1. The sale of Pharmacy (P) medicines
2. The supply of P medicines or Prescription Only Medicines (POMs) against prescriptions. The supply of medicines against prescriptions requires the product to be labelled for a specific patient as a dispensed medicinal product.
3. The supply of P medicines or Prescription Only Medicines (POMs) against prescriptions written by veterinary practitioners for the treatment of animals under the 'cascade'.

The 'cascade' is a provision set out in EU law that has been transposed into [UK legislation](#). It enables human medicines to be used in animals if a suitable authorised veterinary medicine is not available so increasing the range of medicines available to veterinary surgeons. Further information on the cascade, including requirements for prescriptions and labelling is available from the VMD website <http://www.vmd.defra.gov.uk/>

3. Why have you introduced registration criteria?

We have introduced registration criteria because it is important for us to be clear about the premises that are eligible to register and/or need to be registered with us and that therefore need to meet our new standards.

4. How will the GPhC use the registration criteria?

We will use the registration criteria to determine whether premises are eligible and required to be registered as a pharmacy with us.

5. How did you decide what the criteria should be?

The criteria for eligibility and requirement to register are set out in legislation. The criteria are currently in accordance with the [Human Medicines Regulations 2012](#) which came into force on 14 August 2012 and the remaining sections of the [Medicines Act 1968](#) and the [Pharmacy Order 2010](#).

The proposed registration criteria and standards were developed following extensive pre-consultation engagement work carried out in 2011, and a widely publicised consultation on *Modernising Pharmacy Regulation: A consultation on the draft standards for registered pharmacies*, that ran from 8 February to 7 May 2012.

A summary of the responses to the consultation can be found on our website:

<http://www.pharmacyregulation.org/get-involved/consultations/our-previous-consultations>

6. How often will the criteria be reviewed?

The criteria will be reviewed in the light of any relevant changes to medicines legislation.

7. Why don't all hospital pharmacies have to register?

Although the sale or supply of P medicines and POMs can only take place from a registered pharmacy, [legislation](#) gives an exemption from this requirement to hospitals, provided that the supply is made 'in the course of the business of that hospital' to its own in-patients or out-patients, (in accordance with the directions of a prescriber). Trusts/Health Boards may include several different hospitals on different sites but all the hospitals within a Trust/Health Board are viewed as being part of a single legal entity. The supply of medicines from one hospital to a patient in another hospital of the same Trust/Health Board is a supply within the same legal entity and would therefore be regarded as a supply in the course of the business of that hospital. As such the supplying hospital pharmacy would not be required to be registered with us.

8. In what circumstances would a hospital pharmacy need to apply for registration?

If the hospital pharmacy wished for example, to supply P medicines or POMs to patients in another hospital belonging to a separate Trust/Health Board, or to private patients of a separate legal entity based within the same hospital or to provide a community pharmacy service for members of staff and the public then the hospital pharmacy would need to be registered with the GPhC.

9. I intend to sell medicines over the internet. Do I need to register the premises from which I intend to supply medicines?

It depends on what medicines you intend to sell. If it is your intention to only sell medicines that are on the General Sale List (GSL medicines) over the internet, you do not meet our registration criteria and your premises are therefore not eligible to register. This is because GSL medicines can be sold from other retail outlets apart from registered pharmacies, such as supermarkets and petrol stations, when the appropriate legal conditions are met.

If however you intend to make sales or supplies of P medicines and/or POMs to patients and the public then the premises from which you make these supplies from must be registered as a pharmacy with us.

10. My service model consists solely of the supply of medicines for animal use. Am I eligible to register as a pharmacy?

Eligibility and requirements for registration were set out in *Modernising Pharmacy Regulation: A consultation on the draft standards for registered pharmacies*, a consultation which ran during Spring 2012. During that consultation, the GPhC discussed options for criteria relating to pharmacies that supply medicines for animal use.

If your service model consists solely of supplying medicines licensed for animal use only, then we cannot register your premises as a pharmacy.

However, if your service model includes the supply of P medicines or POMs against prescriptions written by veterinary practitioners for the treatment of animals under the 'cascade' then you are eligible and required to register your premises as a pharmacy. The law does not require that the actual supply of P medicines or POMs must be of a particular quantity annually, or amount to any particular proportion of the business.

This is a change from our previous interpretation which was that the medicines would have to be human medicines for use by human patients.

11. My service model consists solely of the manufacture of unlicensed medicines. Do I need to be registered as a pharmacy to do this?

You will only meet the registration criteria if the unlicensed medicine you manufacture is then supplied by you as a dispensed medicinal product, labelled for a specific patient against a prescription and supplied directly by you, or on your behalf, to the patient.

If this is not your service model then you will not be eligible for registration with the GPhC and would need to apply to the MHRA for a 'specials manufacturing licence'. This licence would permit you to manufacture an unlicensed medicinal product and to supply a stock of it by way of wholesale supply to a registered pharmacy (in this service model it is the registered pharmacy's role to label

the product for a specific patient as a dispensed medicinal product, and to make the supply to the patient).

12. What is meant by ‘Supply in circumstances corresponding to retail sale’?

‘Supply in circumstances corresponding to retail sale’ is defined in the Human Medicines Regulations 2012 as supply otherwise than by way of sale. Case law (Pfizer Corp v Ministry of Health 1965) has established that the supply of a P medicine or POM against an NHS prescription is not a retail sale. Such a supply is regarded as being made in ‘circumstances corresponding to retail sale’.

13. I am setting up a temporary pharmacy premises for a short period. Does this temporary premises need to be registered?

Yes the temporary pharmacy would need to be registered if your service model from that pharmacy includes the retail sale of Pharmacy (P) medicines, the retail sale of Prescription only Medicines (POMs) or the supply of Ps and POMs in circumstances corresponding to retail sale. You would need to make an application for registration and inform us of the expected duration of service provision from the temporary premises.

14. Would central hub pharmacies need to be registered?

A central ‘hub’ pharmacy is required to be registered if it is making supplies of P and POMs against prescriptions labelling the product for a specific patient as a dispensed medicinal product.