

Home Office controlled drugs licences

If your service handles stocks of controlled drugs, you might need to have a Home Office controlled drugs licence. The Home Office Drugs and Firearms Licensing Unit (DFLU) issue these licences.

Holding stocks of controlled drugs

'Controlled drugs stock' refers to controlled drugs that a service holds that have not already been prescribed, administered, and/or supplied to individual people. Services hold these drugs as stock for future use.

The service can use the stock for administration, such as:

- during surgical procedures
- to supply to patients, for example, when a service discharges a patient.

'Stock' can be:

- a single box of one formulation of a medicine
- multiple packets of different medicines containing controlled drugs.

If you only handle patients' own controlled drugs, you do not require a Home Office licence.

Patients' own controlled drugs are those that have been personally prescribed and supplied to them. Record-keeping, witnessed destruction and 'safe custody' may still apply to patients' own controlled drugs, [depending on what schedule](#) they fall into.

If your service needs a controlled drugs licence, you must apply for it as soon as possible. If you do not have a licence and you need one, you may not have permission to hold stock of controlled drugs or receive them from wholesalers. This could affect the provision of certain treatments or services.

Examples of services that may need Home Office controlled drugs licences include:

- NHS and private hospitals and ambulance services
- private primary care clinics
- out-of-hours doctors' services
- care homes providing nursing care.

Guidance on the application process is on the [Home Office website](#).

Timescales for licence applications

It can take at least 6 months from the point of applying for a licence to receiving one, even if you have everything ready at the time of your application. This is because the process for obtaining one is intelligence-based and requires a physical site visit.

DFLU complete their own checks. This happens even if you have licences, registrations or authorisations with other agencies. Some services require a site visit by the DFLU as part of the application process. Once you submit an application that has been accepted as valid, DFLU will contact you within **16 weeks** to arrange the visit.

It is important to provide all information accurately and promptly to ensure your application is not delayed.

DFLU have advised:

- all first-time licensees, new sites and upgrades require a licensing visit
- renewal applications will have a visit every 1 to 5 years or more at the Home Office's discretion
- applications are only considered complete where all component parts of an application are correct and present
- if there is a delay because the Home Office has asked for more information regarding your application, it will take longer than 16 weeks to contact you to book a compliance visit.

New services

If you are a new provider and are registering with CQC and require a Home Office licence, you must apply for your licence as soon as possible.

You can apply for the licence while doing your CQC registration application. When applying for your controlled drugs licence, the DFLU will require evidence that you are in the process of obtaining your CQC registration.

You should:

- include as much information as you can on the application form
- have ready copies of correspondence with CQC, which you will need to supply on request.

Licence renewal for existing services

You must make an application for renewing a licence in good time. The covering letter issued with the controlled drugs licence indicates at the renewal stage whether a compliance visit will be necessary.

Where a visit is not required, you should submit an application at least 8-10 weeks before the expiry of your existing controlled drugs licence.

Where there is a visit required, you should submit an application at least 16 weeks before the expiry of your licence.

An automated 'reminder' email may be sent to your registered contact address up to 4 months before the expiry of your licence. If the person who is the registered contact for licences is no longer employed at your service, you may not receive a reminder email. Your service should have a process in place to identify when licences are due for renewal and to proactively update any personnel changes, obtaining new licences if needed.

If you are an existing licensee and you submit a replacement licence application before your previously issued licence expires, you can continue with your day-to-day business. You may continue operating under the conditions of your existing licence until consideration of your replacement licence application has been completed. This is on the condition that:

- your application has the same schedules and activities
- none of the details that are on your current licence have changed.

Please refer to your licence and any conditions within it for relevant details.

Changes to your licence

Changes that are a result of a sale or transfer of a service or organisation will likely invalidate your licence. You will need to apply to amend your licence. Examples of changes could include:

- a change of address
- a change of company registered address
- a change in service name or change in legal entity (where you are being given a new Companies House number).

Ensure you apply to amend your licence at the earliest opportunity. Do not wait for Companies House to complete the relevant changes. This could delay the new licence application process and your service's legal right to obtain and store controlled drugs.

If your company is a new legal entity, you will need to register for the Home Office drugs licensing system under the new legal entity company name before applying for a controlled drugs licence. If your application to register is accepted, you will be able to apply for a controlled drugs licence.

Evidence in support of your controlled drugs licence application

Provide the DFLU with evidence of your CQC registration.

If you are already registered with CQC

Upload a copy of your CQC registration certificate when applying for a controlled drugs licence.

If you are in the process of registering with CQC

Provide the DFLU with your CQC application confirmation reference and any supporting evidence relevant to the application. The CQC application confirmation reference will be a number or application validation reference. Once registration with CQC is complete, provide DFLU with your new registration certificate.

If you are making changes to your registration

When you apply for changes to your licence:

- provide the DFLU with your CQC enquiry reference
- provide the team with your new registration certificate when it arrives.

Changes include a change of name, address or the addition of another location.

Expedition of cases

Expedition of cases is reserved for only the most clinically imperative circumstances. The Home Office has provided a [form](#) you can use to request your application to be expedited.

DFLU have advised:

- Providers must not rely on this process, but instead plan ahead for any service changes.
- Provision of healthcare services is not an automatically accepted reason for expedition of an application.
- You must be able to explain:
 - which procedures are 'clinically imperative'
 - what alternative methods or locations of service delivery are available and the reasons you consider these cannot be utilised.