



Home Office

Controlled Substance Domestic Application & Case Processing Guidance

This guidance has been issued to guide customers through the controlled substance application and case process.



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Home Office Controlled Drug and Precursor Licence and Registrations - An Overview of the Application and Case Process

Applications must be made online using the designated application portal [here](#). We do not accept hard-copy applications or submission of documents by email in lieu in lieu of an application by the designated portal.

How do I register for your drug licensing system?

You must first register as a user of the system, choosing your own username. Each registration is considered carefully on its merits taking account of the ability of the applicant to comply with regulatory standards in order to be issued with a licence under the terms of the Misuse of Drugs Regulations 2001. Therefore, it is important that you provide information that will support your proposals at this stage as it is where an initial view is reached as to whether your proposals have a prospect of success.

Should your registration application be successful, your password will be emailed separately to you. Home Office staff do not have access to these; if you lose or forget your password, you must request another. Please do not register more than once. It will slow the application process down.

Contact us via email: DFLU.dom@homeoffice.gov.uk if- having checked your spam- you have not received a response to your registration request within 5 working days, having all emails and registration numbers to hand.

What happens if my registration application is unsuccessful?

Should your registration application be unsuccessful, you can apply to register again. This new registration would be considered according to its merit. However, you would need to address the points outlined in your unsuccessful registration application. If future registration applications are made on the same basis of an unsuccessful registration application, they will not receive a response.

If your registration is rejected, you will be informed by email and given a reason for this.

What happens if my company changes its name?

If you are changing your company name, contact us to discuss how to make your application. Please do not re-register as a system user unless you are a new legal entity.

How do I apply for a licence?

Log into the application portal and select the correct form; either:

- Controlled Drug licence application this includes all cannabis cultivation activities not covered by the hemp policy;
- Precursor Chemical Licence/ registration application; or
- Industrial Hemp (low THC Cannabis) cultivation licence.

There are typically nine 'stages' to the application form; you must fully complete these, and the application declaration, before submitting the form using the 'submit' button. If you do not receive an email acknowledgement for your application (please check your spam mailbox), or do not press 'submit', you have not made a valid application.

Application forms can be saved in draft for up to five days. Please note that you do not receive a warning when that time is nearly up, so please ensure you submit the form to avoid the need to rekey your details. We cannot view forms in 'draft', only once you have submitted them.

What is the 'amendment' form?

The amendment form is one you can use to make changes to an existing application you have lodged with us, but which has not been decided- for example, if you realise you have incorrectly named a drug.

Completing the amendment form is not an application in its own right. Nor can it be used to amend a licence which has already been issued or to apply for a further licence before the expiry of an existing one.

What information do I need to make the application?

You need to have to hand the following information:

- Person Details (names, business addresses, contact details, position)- of the people to be included on a licence- for example person in charge, authorised witness, person responsible for security, regulatory compliance etc.
- Company or Organisation Details- what you do, type of business, funding sources (profit/ charity etc), (company/ charity) registration details e.g. Companies House certificates, other relevant licence details- e.g. CQC, MHRA licences, GPhC registrations. Please note: if a registration is open-ended, you may still need to insert a future date in the box to proceed.
- Licences/registrations requested- what you are asking for, in terms of activities (possess/ supply/ produce), Schedules and drugs to be held,

Categories and chemicals to be held, and the reason you wish to hold licences/registrations- we need to understand why you are applying and be confident you are asking for appropriate licences/registrations.

- Schedule 1 Research on humans (if applicable) – you must submit a copy of the research protocol, MHRA (if applicable) and ethics approvals along with the details and names of those that have been delegated authorisation by the individual leading the trial.
- Cannabis cultivation (if applicable) – you must submit information on the seed type/cannabis strain, location and type of premises, the number of plants you wish to cultivate- including details on how many harvests you anticipate undertaking within a calendar year, and information about projected growth (if applicable). You will need to explain what you intend to do with the material cultivated and how the products can be lawfully be brought to market-either through your company or a licensed third-party- and provide details of the appropriate MHRA licences/registrations that are required to undertake these activities, research details and copies of protocols (if cultivating for research purposes) and your progress towards obtaining these;
- Precursor chemical applications only – We require a letter of good conduct about the Responsible officer.
- Disclosure and Barring Service (DBS)- formerly Criminal Records Bureau (CRB)- check details- We require an enhanced DBS check, obtained within this last three years through Security Watchdog:
<https://www.securitywatchdog.org.uk/dbs-application-guide>, *for drug licensing purposes*. When completing the online DBC check please enter **DLCU** in the Organisation reference box and **licence** in the organisation code box (. Details of the check- disclosure certificate, date, name the check is conducted in- must be provided for each person named on the application. If you have applied but not yet received the disclosure, input the application reference details. See details on the 'update' service below. Please note that if your DBS check is more than three years old the form will not accept the date.
- Premises details- be able to describe your premises, and physical security arrangements.
- Record Keeping and audit- what records, hard copy, electronic etc.
- Supplier/ customer details- where you are getting the drugs, and to whom you are intending to supply (where appropriate).
- Destructions- how you intend to deal with waste/ destructions.
- Documents- for example Standard Operating Procedures (SoPs), Technical Agreements, site layout- you can upload these to your application via the portal and should provide any relevant at the outset. There is a 10MB size limit.

- Fee Payment details- who we send the invoice to, their contact details including email address and any Purchase Order number you need us to quote.
- Where the licence is to be sent to – who we send the licence to their contact details including email address.

You must be aware that we hold all information securely and do not routinely share with third parties (except for the prevention of the diversion of drugs) in accordance with the data protection legislation including the General Data Protection Regulation but are bound by Freedom of Information principles. You can read details of how we handle your [personal information here](#).

What about the DBS ‘update’ service?

DBS checks are NOT portable, unless you have subscribed to the ‘update’ service.

Information about this service should be dispatched with your disclosure certificate. You have a limited window to ‘opt in’ and there is a fee for this service. If you are part of a large organisation and may not see the letter directly, ask your employer.

Please note Drug Licensing do not handle the physical checks or any documents associated with your DBS application. If you have subscribed to the update service please note this in your application- we will contact you for specific written (email) permission to verify/ check your details.

What happens after the form is submitted?

You should receive an email acknowledgement confirming submission within 48 hours. If not, check your spam and contact us with the ‘code’ shown on submission of your form.

If your application has been submitted, the following steps will occur:

> Validation-

We will firstly check your form and ensure it has been validly submitted. We can reject improperly completed forms- please complete the form fully and with accurate information.

> Triage-

We will carry out an initial appraisal of your application and decide which ‘track’ it will follow- i.e. whether we need to visit your premises or whether we can consider your application on paper. At this stage it will be assigned to a caseworker for either a paper-based consideration (no visit) or a compliance visit.

> Visits- as required

We will contact you to arrange a visit, if one is required. Please note we will not arrange a visit until all DBS checks have been completed and received by us.

All new licensee applications and new sites for existing licensees are visited as an integral part of the consideration process and before the issue of a licence.

‘Renewal’/ amendment/ further or additional licence applications may receive a visit, before the issue of new licences- we will make a risk-assessed decision whether to visit. On average, we aim to visit each site once every 3-5 years.

> Further information- as required

If you are asked to submit further information, or confirm details, we will ordinarily give you a set timescale for this to be done. This may be done at a compliance visit, and/or by email if we are not visiting you.

> Consideration and decision making-

We will make a full and balanced decision on your application for a licence; where cases are complex this can take time. All recommendations will be subject to approval by a senior officer.

> Fees payment-

Occasionally, you may be asked to pay in full when we receive your application, and this payment may be required before your application is considered further. If this applies to your application, you will be informed by email as soon as possible. If you want to withdraw your application at this stage, you will not be charged.

If we refuse your licence application, any fees already paid will be refunded.

Assuming your application is successful, you will be issued by email an invoice for immediate payment. We will not issue a licence until we receive full payment and you will not be able to lawfully operate without a licence being issued.

If at any stage, you wish to cancel your application a cancellation fee may be applied to your application. For further information please view the ‘after I apply’ section on our website [here](#)

What happens at a compliance visit?

A compliance officer will normally be with you for at least half a day, maybe longer. They will wish to discuss the application with those named on the application form, and physically visit the premises to be licensed, looking at systems, processes and the wider environment. You may feel some of the material discussed will have been

provided on your application form. This compliance visit will give you the opportunity to talk through and show how your company operates and complies with the Misuse of Drugs Act 1971 and associated regulations. Discussing this with you is an important part of the consideration and validation process and is standard procedure.

The Compliance Officer may feel that certain actions need to be undertaken, before we can consider issuing a licence. This could include documenting processes- e.g. key/ combination lock security procedures, updating SoPs, installing a key safe, or providing further information about your suppliers/ customers.

We will always work with you to agree those actions and timescales; please comply with them as failure to do so may delay your application or, in extreme examples, withdrawal of your application.

How do I prepare for a compliance visit?

Your assigned compliance officer will be in touch with you to arrange a date for their visit- please ensure all key personnel are available on the day of the visit, and advise us ASAP if there are any unavoidable changes to availability. Your compliance officer may request further documentation be sent to them before a site visit.

Please advise your compliance officer whether there are any specific site protocols (e.g. no food on site, clothing requirements), reporting or ID requirements. Your compliance officer will positively identify themselves to you, and expect to be asked to do the same, for example by showing your driving licence.

Expect to be asked a number of questions about your application, to physically 'walk through' the controlled drug process at your establishment, demonstrate your record keeping, illustrate key/ security arrangements and show us your drug stores.

Withdrawal of applications on account of failure to comply

Occasionally, we will withdraw an application where requested actions have not been undertaken in a reasonable or specified time. We will always contact you in writing (typically e-mail) setting out a timescale for an action to be taken, where we are intending to withdraw your application, so you have the chance to act.

It is your responsibility to progress DBS checks in a timely fashion- for example by taking identification documentation to the Post Office- failure to progress with your checks may mean your application is withdrawn by us. Failure to progress DBS checks is the most common reason for an application being withdrawn by us. Applications cannot be re-instated.

What happens if my application is refused?

Should your application fall to be refused you will have one calendar month from the date of the refusal letter to submit any further representations in respect of the decision, if you wish to. These will be considered accordingly.

You are free to re-apply but should only do so when you are in a position to provide additional information and directly addresses the reasons for refusal provided to you.

There is no option to appeal our decision to refuse an application or a decision to uphold that refusal following the submission of further representations. You have the option to take further action by following the Pre-Action Protocol for Judicial Review proceedings.

What does my licence/registration cover?

Controlled drug and precursor chemical licences/registration are:

- Time limited – valid for one year
- Premises and company specific (i.e. A B Drugs at 236a High Street)
- schedule and activity specific (controlled drugs only i.e. Schedule 2-possess & supply)
- Category, substance and activity specific (Precursor chemicals only i.e. Category 1 – Ephedrine - storage)
- Non-transferable (between premises or across drug schedules)
- Conditional - some conditions are standard to all licences, some may be dependent on schedules and activities and others are specific to the individual case situation. Conditions are reasonable, rational and proportionate and not for negotiation.

Do you have any top tips for licensees or prospective licensees?

- If you are a new/ prospective licensee, remember to complete both the registration and application processes outlined above. If you do not, we will not have an application to consider.
- Do not apply to register as a user of a system unless you can show your proposals are compliant with all applicable UK laws and policies. We will not approve registrations or applications when there is no lawful route to market for a proposed product.
- Read the guidance on our website, especially information about fees and licence application handling, SoPs, Security and Transit Guidance.
- Apply early. New/ first time licence applications will take around 12-16 weeks to complete, from the point at which we have received all DBS checks. If you do not have DBS disclosures in place, or have actions to complete before we

can issue you a licence, this process could be much longer. Where we need to visit an existing licensee at the point of renewal timescales will be similar.

- For existing licensees, read the covering letter sent with your licence last year. This may give an indication if we intend to visit you the following year, and the fee associated with this, so you can plan ahead.
- Apply for 'routine' renewals at least 4-6 weeks before the expiry of your licence. If you do not apply before your licence expires, you may not be able to continue to trade.
- Provide us with as much information as you can at the outset, and use the facility to upload documents through the licensing form.
- Tell us any target timescales, or applications made to other regulatory bodies- e.g. MHRA- in free text on the application form. We cannot guarantee to meet those timescales, and the existence of a timescale does not mean we will automatically expedite a case. We may well withhold issue of a licence until other Regulatory Bodies approve their related applications, but you should not delay application waiting for, say, CQC approval for a premises to be issued.
- Settle your invoices promptly- we will not issue a licence until we have received full payment of the licence fee.

What if I need more help?

If this document, or the other resources on our website do not fully answer your question, please ring 020 7035 8972 or email DFLU.dom@homeoffice.gov.uk. The Duty Compliance Officer is available weekdays on this number between 9am and 5pm.

If you know to whom your case has been assigned, please contact the Compliance Officer or Caseworker directly.