Home Office

Home Office Controlled Drug Licensing Annual Returns

Guidance Notes

This guidance has been produced by the Drugs and Firearms Licensing Unit to assist license holders and applicants in understanding the annual returns process for controlled substances in the United Kingdom.

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Introduction

1. The Home Office Drugs and Firearms Licensing Unit (DFLU) is the UK's Competent Authority for the purposes of licensing the licit use of controlled drugs and precursor chemicals.

2. We issue licenses for those who handle controlled drugs and precursor chemicals, including, but not limited to: companies and other organisations that intend to handle or use controlled drugs and precursor chemicals. As a signatory to the UN Conventions, the Home Office is responsible for providing yearly statistical returns to the International Narcotics Control Board (INCB).

3. This information has been published to assist licence holders to complete their annual returns for their controlled substances. Only substances listed in the annual statistical returns must be reported upon. For substances that do not appear on the list in the form, then a return for that substance is not required.

4. Wholesalers, manufacturers, producers and suppliers of controlled drugs must supply the Home Office with annual statistical returns on the specified form by the 31st of January each year.

5. The requirement to complete a full and accurate annual statistical return is a condition of any licence. We expect to be in receipt of a fully completed return from all companies holding the following types of domestic controlled drug licences (end users please see section 6):

   - manufacture licences;
   - supply licences;
   - production licences (see section on 'preparation exemptions' below)
   - cultivation of cannabis and opium poppy - DLFU will contact those who cultivate and need to provide an annual return separately.

   If your domestic licence states produce, manufacture or supply then you will need to provide an annual return.

6. **End users** do not ordinarily need to complete a full return. If your company does not handle/trade/manufacture/produce/supply any substances on the list of substances in the form, please complete the **Nil Returns Statement Form** Controlled drugs: annual returns form - GOV.UK (www.gov.uk) and submit it to the Annual Drug Returns Inbox and state that you are providing a **NIL RETURN**.

   Do not complete the Annual Return sheet in this instance.

Some examples of **end users** are:

- pharmacies where medication is being dispensed to patients (e.g. hospital, community or prison pharmacies) or transferred to another pharmacy within the group or, for example to a local hospice
- hospitals where medication is being used in the treatment of patients, please note that hospital manufacturing units will need to supply an annual return
- dental practices or specialised surgical clinics, fertility clinics administering to patients
- ambulance groups
- sports clubs where medication is either being dispensed to a patient or destroyed via the appropriate channels due to expiry
- research facilities, analytical / standards testing facilities

7. **Supply to end users**.
   It is important to accurately record your supply to end users. If you are recording supply in this column please check with your customers that they are considering themselves an end user and are supplying a NIL return on this basis. This is to prevent double-counting of controlled drug stocks.

8. **Double Counting**
   In providing an annual drug return it is the responsibility of the licensee to ensure that stocks are not double counted.
   An example of double counting:

   Wholesaler A supplies 1000g of Methylphenidate to Pharmacy B and records the transaction as supply to end user. Pharmacy B dispenses 800g of this to patients and 200g onto Pharmacy C, another pharmacy in its group. Pharmacy B completes the annual return with 200g supplied to end user. This means that the 'consumption' of 200g Methylphenidate has been counted twice.

   A note on supply to hospitals and NHS trusts: If supplying to a large NHS trust it is important to account separately for controlled drugs being supplied to a trusts manufacturing unit (which should be recorded as supply to a UK intermediary) and controlled drugs being supplied for end use.

9. Licensees who fall into any category should contact DFLU at annualdrugreturns@homeoffice.gov.uk for further guidance if uncertain as to what information needs to be provided as soon as you receive the commission to provide an annual return.

10. If you held a licence for only part of the year, then a return will be needed for the substances listed for the period that the company and/or licence was in existence, including a nil return if applicable. For example if you became a new licensee during the year or closed your premises during the year (https://www.gov.uk/government/publications/controlled-drugs-licence-return-premises-closure-statement).

Definitions

11. The following definitions are provided to help identify who needs to complete an annual statistical return and what needs to be recorded. These may differ from those used more generally in a domestic licensing context and are based on INCB definitions.

12. Annex A provides extracts from the INCB guidance material to supplement the information given below.
    Annex_A-_INCB_definitions.pdf (publishing.service.gov.uk)

13. **Consumption:** A drug shall be regarded as "consumed" when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research.

14. **Exempted psychotropic preparations** (under the 1971 Convention, Article 3) *If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted.*

    If you handle such a preparation then you should provide the relevant information in this column. For further guidance you may wish to contact DLFU. Those companies who do enter information in this area will be contacted to clarify the status of the substance.
    Licence holders should be aware there are no UK preparations which are exempted under this category.

15. **Import & export**: The physical transfer of drugs (irrespective of whether a financial transaction is involved) from one State to another State, or from one territory to another territory of the same State.

    The transfer should only be counted if it has occurred between January 1 to December 31 for the specific year and has been endorsed or is due to be endorsed to reflect accurately the shipment date. Please also refer to section 30 on Third Party storage.

16. **Manufacture**: Manufacture means all processes, other than production, by which drugs may be obtained and includes the transformation of drugs into other drugs. It excludes the manufacture of preparations and the transformation of substances to salts e.g. Morphine to Morphine Sulphate. Activities covered by UK domestic manufacture and produce licences would fall within this definition unless otherwise exempted.

17. **Preparation:** Preparation means a mixture, solid or liquid, containing a controlled drug.

18. **Production:** Production means the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained. (1961 Convention article 1). Please note

that this is not directly equivalent to 'production' activities licensed under the Misuse of Drugs Regulations 2001. If you have a 'production' licence these activities should be treated as 'manufacture' for INCB reporting.

19. **Quantities used to manufacture narcotics:** Only enter data into this column if you are utilizing narcotic drugs for the manufacture of other narcotic drugs (for example, manufacturing codeine from morphine). The reported number should refer to the quantities of the drug utilized and not to the quantities of the drug to be obtained.

20. **Quantities used for the manufacture of psychotropic substances** (1971 Convention article 4) **and non-controlled substances**: The utilization of substances for the manufacture of other psychotropic substances or non-controlled substances, or products, subject to the application of the measures of control required by this Convention until the psychotropic substances come to be in such a condition that they will not in practice be abused or recovered; e.g. other substances/products which are not under international control. The reported number should refer to the quantities of the drug utilized and not to the quantities of the drug to be obtained.

21. **Quantities used for the manufacture of preparations listed in Schedule 5 to the Misuse of Drugs Regulations 2001**: Companies who manufacture preparations containing small quantities of Controlled Drugs in a finished form (i.e. a MDR Schedule 5 preparation), must provide an annual return to illustrate and account for the manufacturing.

    Schedule 5 Preparations may include:

    - a preparation which is not designed for administration by injection and contains a compound with one or more other ingredients and of those, a controlled drug being one of the active substance of no more than 100 milligrams in each finished product (tablet, capsule) would be a Schedule 5 preparation. For example, a prescription only medicine containing 30 mg of codeine phosphate per unit combined with 500 mg paracetamol in tablet form.

    For more guidance on the concentration of specific Controlled Drugs licensees can refer to the Misuse of Drugs Regulations 2001 Schedules 2 and 5.

    Companies who manufacture Schedule 5 preparations must:

    - Count the total amount of Controlled Drug contained within the finished Schedule 5 Preparation and add this to the opening stock,

    - Put the same amount in the Schedule 5 manufactured column, as this shows the deduction, utilised for manufacture of Schedule 5 preparation, from stock through the year.

    - Account for any production losses, assuming that the reality is that the quantity put into process is greater than the output of finished product.

- **Companies who purchase Schedule 5 preparations in finished form and resell to wholesalers and intermediaries must not report on these drug substances**. This is because for Annual Return purposes the quantities of Schedule 2 drugs "consumed" in the manufacture of these Schedule 5 preparations has been accounted for by the company who manufactured the Schedule 5 substance.

22. Companies who are engaged in the **supply to vessels and offshore installations** such as oil rigs, platforms etc., must provide a return to cover such supply as under '**supply to end user'.**

Completing the form

23. Please ensure you are using the latest version of the form which can be downloaded from *here* https://www.gov.uk/government/publications/controlled-drugs-annual-returns-form. These are updated annually and will include any relevant newly controlled substances. Any Annual Returns received on the previous year's form will be rejected.

    You must use the supplied return form. This is to allow us to effectively provide the INCB with the information they require. Please save and submit it in Excel format. Do not attempt to alter the form in any way.

24. You may complete one consolidated return to cover all your licensed sites; please note this on the cover sheet of the return form.

25. Kilograms and grams should be in whole numbers. Milligrams may go to 3 decimal places only rounding to the nearest whole number unless that would be 0, in which case round up.

26. Examples of how to calculate drug contents is shown below. Please also refer to the INCB Yellow and Green list for conversion factors.

    Equasym XL 10mg modified release, hard capsules x 30

    Each tablet contains 10mg of methylphenidate hydrochloride

    10mg x 0.865 (conversion factor) = 8.65mg Methylphenidate base

    8.65mg x 30 tablets = 259.5mg Methyphenidate

27. Liquids should be provided in the base API equivalent, in solid measures e.g. kilos, grams and milligrams only.

28. Some substances on the form might not be common. Others might not be on the list, despite being controlled under the Misuse of Drugs Act 1971. That is because this list is for the purposes of returns to the INCB. Do not add or remove substances to or from the list.

An example of this is Testosterone which is controlled in the UK but not internationally. In most cases these substances will not appear on the list.

29. For companies who produce controlled drugs as defined in paragraph 19 & 20 above and transform this drug into another controlled or non-controlled substance, the original substance should be recorded as held in stock until the transformation to the final intended new drug has been confirmed. At that point the new drug substance can be counted as stock, if applicable.

30. Companies whose drugs stocks may be in transit to a customer at the end of reporting year, these drugs must be included as part of their own drug stocks for annual returns purposes until the recipient takes full possession.

31. **Third party storage companies.** Companies who store on behalf of another licensed company for the purposes of storage and/or distribution of controlled drug are not required to complete an annual returns form. It is the responsibility of the company who owns the controlled drugs to ensure that an annual returns form is completed for their stock, but we accept local arrangements may be made such that a storage company may make this on their behalf. In these circumstances please make it clear on the return on whose behalf the return is being made. In this instance, it is your responsibility to ensure that there is no double-counting.

Returning the form

32. The form should be returned to the Annual Drug Returns Inbox at the following email address: annualdrugreturns@homeoffice.gov.uk. Please include the name of the company you are returning for in the title of the mail.

33. The amounts will be summarised and sent to the INCB in a collated return. Individual amounts or companies will not be identifiable. We will not disclose individual level data to other parties unless required to do so by the appropriate legislation.

34. The amounts entered into the sheet for each substance reported, have an indicator in the last column on the sheet which shows any variation. Companies should ensure the data submitted balances as closely as possible to 100%. Some drug substances have a variable tolerance of 5% and other high-risk drug substances have a lower tolerance of 1%. Companies must ensure the data provided balances within the set tolerances. The cell will be coloured red if the tolerances are exceeded. If the difference is above the set tolerance the DLFU may make further enquires with companies. Companies must provide an explanation where there is difference in the balance of a drug substance.

35. It is a condition of your licence that you provide a timely annual drug return. Please contact us if you do not have sufficient information from your records to complete the form. You should also contact us if more time is required, but please be aware that the submission dates are set by the INCB, so the Home Office has to ensure all forms are collated and processed according to these deadlines.

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