2013

HOME OFFICE DRUG DOMESTIC LICENSING ANNUAL RETURNS COMPLETION NOTES.

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

Published date: This version is version 1published18th December. It remain in force until revoked. You should always refer to the most up to date version of the completion guidance when submitting an annual return.

INTRODUCTION…… 3

DEFINITIONS…… 5

COMPLETING THE FORM…….. 6

RETURNING THE FORM…… 8

INTRODUCTION

1. **The Home Office Drug Licensing & Compliance Unit is the UK's Competent Authority for the purposes of licensing the licit use of Controlled Drugs and Precursor Chemicals and preventing their diversion to the illicit market.**

2. **We issue licenses for those who handle controlled drugs and precursor chemicals, including: companies and other organisations that intend to handle or use controlled drugs and precursor chemicals, doctors prescribing certain drugs for the treatment of addiction, individuals requiring personal import or export licenses to travel with prescribed medication containing controlled drugs. As a signatory to the UN Conventions, the HO is responsible for providing yearly statistical returns to the International Narcotics Control Board (INCB).**

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

3. **These annual statistical returns are separate, and distinct, from the annual compliance statements that are required from all licence holders.**

4. **The requirement to complete a full and accurate annual statistical return is a condition of any license and is clearly stated on the licence.** We expect to be in receipt of a fully completed return from **all** companies holding the following types of domestic controlled drug licences:
   - Production licences (subject to preparations exemption overleaf)
   - Cultivation of Cannabis and Opium (the DLCU will contact those how cultivate for a separate annual return, licensees who may fall into this category should contact DLCU for further guidance)
   - manufacture licences
   - supply licences e.g.
     - where a drug is supplied to the ‘retail’ market for consumption e.g. supply from a pharmaceutical wholesaler to retail pharmacies,
     - Supply from a manufacture to either research or educational establishment,
     - Supply from a pharmaceutical wholesaler to either NHS establishments or private healthcare organisations

Instances of serious (whether the first occasion or not), or persistent non-compliance, could lead to a revocation of the license.

End users do not need to complete a return.

5. This information has been published to assist licence holder to complete their annual returns for their controlled substances.

6. Only substances listed in the **annual statistical returns** must be reported upon. For substances who do not appear on the list in the form, then a return for that substance **is not** required.

7. A '**nil**' return must be provided if your company and/or licence was not in existence during the period covered by the form. Please state this in the cover email. Please refer to section 10 of the note.

8. If your licence existed 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.

9. If your company does not handle/trade/manufacture/produce/possess/supply any substances on the list of substances in the form, then you can simply email the Annual Drug Returns Inbox and state that you are providing a NIL return.

   Complete the subject line as follows "YYYY-MM-DD – CONTROLLED DRUGS ANNUAL RETURNS 2012 (COMPANY NAME)." There is no need to complete the sheet in this instance.

DEFINITIONS

The following definitions are provided to help identify who needs to complete an annual statistical return and what needs to be recorded.

10. **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.

11. **EXEMPTED PSYCHOTROPIC PREPARATIONS** under the 1971 Convention, Article 3, and if the Psychotropic preparation as listed under Schedule III of the Convention, and the signatory state has requested an exemption and it 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, then the Psychotropic 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 the DLCU. Those companies who do enter information in this area will be contacted to clarify the status of the substance. Licence holders should be aware to date the UK has not requested any exemption under this category.

12. **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 the period of 1st Jan to 31st Dec for the specific year and has been endorsed to reflect accurately the shipment date.

13. **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. Activities covered by UK domestic ‘manufacture’ and ‘produce’ licences would fall within this definition unless otherwise exempted.

14. **PREPARATION**: Preparation means a mixture, solid or liquid, containing a Controlled Drug.

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

16. **QUANTITIES USED FOR THE MANUFACTURE OF NON-PSYCHOTROPIC SUBSTANCES** (1971 Convention article 4): The use of such substances in industry for the manufacture of non-psychotropic 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.

17. **QUANTITES USED FOR THE MANFACTURE 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 MSR Schedule 5 Preparation) MUST PROVIDE AN RETURN.

    Schedule 5 Preparations may include:

    A preparation which is not designed for administration by injection and contains a compounded with one or more other ingredients and of those a Controlled drugs being one of the active substance of no more than 100 milligrams in each finished product (tablet, capsule) would be a Schedule 5 preparations.

    A prescription only medicine containing 30 mg Codeine phosphate per unit combined with 500mg paracetamol in tablet form.

    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.

    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 the Annual Returns purposes the quantities of Schedule 2drugs ‘consumed’ in the manufacture Schedule 5 preparations has been accounted for by the company who manufactured the Schedule 5 substance

18. 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

19. The form itself contains all the necessary headings. **IT MUST NOT BE ALTERED OR AMMENDED**. If you have any comments on a substance 'return' figure, please enter them in the notes field of the form. The previous version of the form had two cover sheets (one for narcotics and one for psychotropic's). This caused unnecessary confusion, and therefore the two cover sheets have been merged.

20. You should give substances in the Kilos, Grams, and Milligrams columns. **Kilos 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.**

21. Liquids should be provided in the base API equivalent, in solid measures e.g. Kilos, Grams and Milligrams only.

22. The form below includes all the headers from the returns form. It has been rotated for easier viewing. Notes are contained in the boxes in the example below.

23. You must use this return form, and not one you have designed. This is to allow us to effectively provide the INCB with the information they require.

24. You should complete one consolidated return to cover all your licensed sites; not a form per site. Please state in the covering email which sites your return covers, so we can be sure all the details have been provided

25. 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/from the list.

26. Save the form using the following format: "YYYY-MM-DD – CONTROLLED DRUGS Annual Returns 2012 - Controlled Substances - Company Name" You must save the form as an excel type file. PDF, word, text, gif, jpeg, pic or other file types will not be accepted.

27. For companies who produce controlled drugs as define in paragraph 16 above and transform this drug into another controlled or non-controlled substance such as Thebaine to Buprenorphine. The original substance should be recorded as in held in stock until the transformation to the final intend new drugs has been QA and confirmed. At that point the new drug substance can be counted as stock.

28. 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.

29. **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 complete the annual returns form.

RETURNING THE FORM

30. The form should be returned to the Annual Drug Returns Inbox.

31. Your email should include the following subject (with the appropriate date and company name in place of those given in the example below
YYYY-MM-DD – CONTROLLED DRUGS ANNUAL RETURNS 2012 (COMPANY NAME).

32. The amounts will be collated in an anonymised form and sent to the INCB in a collated return. They will not be able to identify individual amounts or companies. We will not disclose these amounts to other parties unless required to do so by appropriate legislation.

33. The amounts entered into the sheet for each drug substance reported have an indicator at the last column on the sheet which shows the balance. Companies should ensure the actual 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 low tolerance of 1%. Companies must ensure the data provided balances, if the difference is above the set tolerance the DLCU may make further enquires with companies.

    Companies must make note where there is difference in the balance of a drug substance and provide an explanation.

34. If you have not got sufficient information from your records to complete the form, you must contact us urgently.

35. 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 in readiness for these deadlines.

Author: Lee Smith Senior Operations Manager & Chris Fernandez-Packham Project Manager, Drugs Licensing and Compliance Unit.

Version: 2.1

Issued date: 18th December 2012