HOME OFFICE CONSULTATION ON THE INTRODUCTION OF CHARGES FOR CONTROLLED DRUG AND PRECURSOR CHEMICAL LICENCES

MARCH 2010

Scope of this consultation

Topic of this consultation:	This is a consultation on the introduction of charges for controlled drug and precursor chemical licences.
Scope of this consultation:	This consultation covers the charging regime for the following types of licence: • Controlled Drug domestic licences (i.e. licences to produce, supply and possess controlled drugs) • Controlled Drug import licences under the MDA 1971 • Controlled Drug export licences under the MDA 1971 • Cannabis cultivation licences • Precursor Chemical Category 1 licences and Category 2 registrations under Regulation EC 273/2004 • Precursor Chemical Category 1 Licences and Category 2 and 3 Registrations under Regulation EC 111/2005 • Precursor Chemical import authorisations • Precursor Chemical export authorisations
Geographical scope:	This consultation covers charging for all of the above controlled drug and precursor chemical licences, registrations and authorisations throughout the United Kingdom.
Impact assessment (IA):	A consultation stage Impact Assessment has been drawn up to accompany this document.

Basic Information

To:	This is a targeted consultation aimed at controlled drug and precursor chemical licensees and associated trade bodies. Since this is a largely technical issue, of little wider public interest, a full public consultation is not necessary.
Duration:	This consultation will commence on 29 March 2010 and end on 18 June 2010.
Responses and Enquiries:	Responses to this consultation should be addressed to: **Email**: DrugLicensingConsultationsInbox@homeoffice.gsi.gov.uk **Post**: Joe Barker Drugs Licensing and Compliance Unit 4th Floor Fry Building 2 Marsham Street London SW1P 4DF Any enquiries should be directed to the same address.
After the consultation:	We aim to publish the Government response on our website (www.drugs.homeoffice.gov.uk/drugs-laws/licensing) in Autumn 2010.

You should also contact the Drugs Licensing and Compliance Unit should you require a copy of this consultation paper in any other format, e.g. Braille, Large Font, or Audio

1. Executive Summary

The Government is proposing to introduce charges for controlled drug and precursor chemical licences. There were charges for many controlled drug licences until 2007. The Government believes that the current arrangements can be improved and in order to do this wishes to re-introduce charges to fund improvements to the Home Office's Drugs Licensing and Compliance Unit (DLCU) which will both improve services for licensees, and protect the public, through an increase in the number of Compliance Officers and the introduction a new IT system . Additionally, charges may discourage speculative applications, allowing DLCU to concentrate its resources on bona fide licensees.

2. Background

2.1. What are Controlled Drugs and Precursor Chemicals?

2.1.1. The Misuse of Drugs Act 1971 specifies certain drugs that are controlled due their potential to cause harm if misused. The Act introduced a licensing regime for the import, export, supply, possession, manufacture and production of controlled drugs. The purpose of drug control is to facilitate the licit uses of these substances, while preventing their misuse and their diversion into the illicit trade.

2.1.2. Precursor chemicals are substances that can be used in the illicit manufacture of narcotic drugs or psychotropic substances. The basis for precursor control is the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. This is implemented within the UK through European Union Council Regulations:

- Regulation (EC) No 273/2004 which controls intra-community trade
- Regulation (EC) No 111/2004 which controls trade between the Community and third countries
- Regulation (EC) No 1277/2005 provides further detailed information with regard to licensing

As with controlled drugs, the purpose of precursor chemical control is to facilitate their licit use whilst preventing their diversion into the illicit trade.

2.2. The pre-2007charging regime

2.2.1. Fees have been charged for controlled drug licences since at least the Dangerous Drugs Act 1951. A sliding scale of fees, related to the type of licence, was in use in various forms from the 1950s through to the cessation of fees in 2007.

2.2.2. Fees were charged per drug, per activity. Fees were calculated in line with the Treasury's Fees and Charges Guide on the basis of full-cost recovery. Both the licensing and the inspectorate functions were included in the calculation of 'full cost'.

2.2.3. The cost of a licence varied according to the activities it covered, with possession licences attracting the lowest fee, and manufacturing licences the highest. There was a separate fee for each drug licensed. For example, a

company licensed to possess three drugs would pay a fee three times as great as that of a company licensed to hold just one drug. Fees were discontinued in 2007.

3. Why re-introduce fees?

3.1 Rationale

3.1.1. Fees were discontinued in 2007 as part of a move towards greater self-regulation by licensees. Following an assessment the impact of this change DLCU has concluded that the system needs to be tougher in some respects in order to improve service to licensees and to reduce the risk of diversion. Over the coming year we aim to:

- **Introduce a new IT system.** This will allow applicants to apply for import and export licences online for the first time, using forms designed to ensure that the application process is quick and straightforward for users, reducing the number of invalid applications that have to be returned to licensees. It will also make the annual statistical return process more efficient and give DLCU joined-up data to make the scrutiny of applications more rigorous and effective.
- **Increase the number of Compliance Officers.** We will increase the number of Compliance Officers to ensure that our licensees receive the support and guidance they need in order to comply with their legal obligations.
- **Issue licences with time-limited validity.** The risk of diversion is increased if there are open-ended licences in circulation. A regular licence renewal process prompts licensees to evaluate their licensing requirements, and provides a regular check on compliance. The Government therefore intends to make controlled drug domestic licences, and precursor chemical licences and registrations, of one year's duration – options 2a and 2b give further details.

3.1.2. In order to fund these essential improvements to DLCU the Government wishes to introduce charging for licences. Licensees will receive an improved service and the wider public will benefit as the risk of the diversion of drugs and precursor chemicals into the illicit trade is reduced. An analysis of the results of compliance visits conducted in 2009 showed that risk-assessed compliance activity had a direct impact on decreasing the risk of diversion. The Government is determined to reduce the risk of dangerous drugs and their precursors being diverted into the illicit trade. An increase in the number of Compliance Officers will allow the Home Office to provide better guidance to licensees and increase both the level and the effectiveness of risk-assessed compliance activity, thereby reducing the risk of diversion. Fees may also discourage speculative applications, allowing DLCU to concentrate its resources on bona fide licensees.

3.2. The legal basis for charging

3.2.1. Section 30 of the Misuse of Drugs Act 1971 gives the Secretary of State the power to set fees for controlled drug licences. The power to charge fees for precursor chemical licences is found in Article 3 of Regulation (EC) No 273/2004 and Article 26 of Regulation (EC) No 111/2005.

3.2.2. Charging for controlled drugs would be conducted according to the principal of full cost recovery, in line with the HM Treasury guidance on fees and charges found in chapter 6 of *Managing Public Money* (available at: http://www.hm-treasury.gov.uk/d/mpm_whole.pdf). Charging for precursor chemical licences would also take account of the principles set down in the EU Regulations.

3.3. Is it proposed that any licences will remain free of charge?

3.3.1. The options set out at Section 3 below suggest two different approaches to the range of licences that should be charged for. The following licences will remain free of charge under all the options:

- Personal import and export licences – these are used by patients who need to take their medication abroad
- Doctors' licences – to allow doctors to prescribe controlled drugs in the treatment of addiction
- Group authorities – these are not issued to any individual, meaning there is no recipient to pay a fee

3.4. Charging principles that will apply to all charging options

3.4.1. Controlled drug domestic licences would be charged per activity. The four types of controlled drug domestic licence are:

- Possession
- Supply
- Production
- Manufacture

3.4.2. Precursor chemical licences and registrations would be charged per category. A 'category' is a group of chemicals as defined in Annex I of Regulation (EC) No. 273/2004.

3.4.3 Fees will apply to all applications. No refund will be made if an application is rejected because it has not been completed properly, nor if a licence is not granted because the application is refused.

3.5. How charges would be calculated

3.5.1. Charges would be calculated using a similar system to that used under the pre-2007 charging regime. Fee levels would be decided by a Home Office minister, not officials in DLCU, in line with HM Treasury guidance to ensure independent scrutiny of fee levels. Ultimately, Parliament will have the opportunity to scrutinise the fees set under the Misuse of Drugs Act 1971 as the fees will be prescribed in regulations.

3.5.2 The fee levels have not been set. The table below sets out some broad estimates of what fee levels can be expected:

Licence type	Lower range (£)	Upper range (£)
Annual controlled drug domestic	750	2,000
Annual cannabis cultivation	750	1,250

Annual precursor chemical category 1 licences	750	1,500
Annual precursor chemical category 2 and 3 registrations	50	200
Controlled drug import and export licences (per licence)	5	25
Precursor chemical import and export authorisations (per authorisation)	5	25

3.6 Northern Ireland

3.6.1. As these fees will be introduced under the Misuse of Drugs Act 1971, they will apply UK-wide, thus ensuring parity for all licensees. In Northern Ireland, administrative arrangements will continue as before with domestic controlled drug licences being issued through the Department of Health, Social Services and Public Safety. Licences for the import or export of controlled drugs and licences for precursor chemicals will continue to be issued by the Home Office Drugs Licensing and Compliance Unit.

4. Options

The Government proposes three options for charging in the 2010-11 financial year:

1. No change – no charges for any licences, registrations, or authorisations
2. Introduce charges for all controlled drug and precursor chemical licences, registrations, and authorisations
   (a) with domestic licences/registrations of one year's duration
   (b) with domestic licences/registrations of two years' duration
3. Introduce charges for controlled drug domestic licences only, with no charges for import and export licences or precursor chemical licences, registrations, or authorisations.

Option 1: No change – no charges for any licences, registrations, or authorisations

This option maintains the status quo, with no charges to be introduced for licences of any kind.

Arguments for this approach

- Does not introduce any additional administrative/regulatory burden on licensees

Arguments against this approach

- Fails to provide funding for improvements to service received by licensees

- Fails to provide funding for the strengthening of the licensing regime to protect the public through an increase in the number of Compliance Officers
- Fails to provide any deterrent to speculative applications. Service for bona fide licensees may suffer if DLCU resources are absorbed dealing with such applications.

Option 2a: Introduce charges for all controlled drug and precursor chemical licences with domestic licences of one year's validity

Charges to be introduced for the following licence types:

- Controlled drug domestic licences (i.e. licences to produce, supply and possess controlled drugs, charged per activity)
- Controlled drug import licences under the MDA 1971
- Controlled drug export licences under the MDA 1971
- Cannabis cultivation licences
- Precursor chemical Category 1 licences and Category 2 registrations under Regulation EC 273/2004
- Precursor chemical Category 1 licences and Category 2 and 3 registrations under Regulation EC 111/2005 (charged per category)
- Precursor chemical import authorisations
- Precursor chemical export authorisations
- Annual renewal of all the above licences and registrations, except import and export licences and authorisations.

Import and export licences would be charged per individual licence, regardless of the schedule or category of the substance being licensed. This reflects the fact that the scrutiny, and therefore the amount of work, that goes into an import or export application is the same regardless of the substance involved.

Domestic licences would have to be renewed on an annual basis. Renewal applications would generally be done on the documents, with site visits reserved for those assessed as being of particularly high risk.

Arguments for this approach

- It will fund improvements in service for licensees, in particular online application forms and increased support from Compliance Officers
- It will protect the public by funding measures to strengthen the licensing regime
- There is no cross-subsidisation between users of different licence types, as all will be charged at cost
- It will encourage the efficient use of licences and discourage wasteful or speculative applications
- The licence renewal process, since it is annual, will be relatively light-touch in the majority of cases without the requirement for a site visit.

Arguments against this approach

- It will increase costs for licensees
- The cost may discourage people who should have a licence from applying for one

Option 2b: Introduce charges for all controlled drug and precursor chemical licences with domestic licences of two years' validity

As option 2a above, but domestic licences would have to be renewed on a biennial basis. Given the length of time that will have elapsed since the last compliance check, site visits would be standard for renewal applications except where risk-assessment showed them to be unnecessary. Analysis of field visits conducted in 2009 showed that increased periods of time without contact between the Home Office and a licensee can be linked to increased levels of non-compliance. Therefore, risk-assessments on licensees on a biennial basis may well result in a higher numbers of site visits being required.

Arguments for this approach

- as option 2a above, but licensees would only need to go through the admin burden of a renewal application every two years

Arguments against this approach

- as option 2a above, but the admin burden would be greater for licensees, since the renewal process, though less frequent, would constitute a greater total admin burden due to the greater number of risk-assessed site visits on licensees than under option 2a.

Option 3: Charge only for those licences that were charged for in the past; i.e. controlled drug domestic licences

Charges to be introduced for the following licence types only:

- Controlled Drug domestic licences (charged per activity)
- Annual renewals of all such licences

Arguments for this approach

- The high volume of import and export licences required by some licensees could make charging for each licence impractical
- Controlled drug import and export licences, and all precursor chemical licences, were not charged for under the old, pre-2007 licensing regime

Arguments against this approach

- If the principle of charging is correct, it should be applied to all licences, registrations, and authorisations issued by the Home Office, unless special circumstances apply. No such special circumstances exist for controlled drug import and export licences and precursor chemical licences, registrations, and authorisations.
- This option would introduce cross-subsidisation, as controlled drug domestic licence holders would effectively be paying for import and export licences used by only some of their number, and all precursor chemical licences.
- Due to the high volume of applications, processing import and export applications forms a large proportion of DLCU's work. It is therefore right that they are charged for, even if the amount of work, per licence, is significantly less than that absorbed in processing a domestic licence or registration.

- Failing to charge for controlled drug import/export licences and all precursor licences would mean that there was no financial discouragement to speculative applications

The government's preferred option is option 2a. This option provides the fairest charging regime, with costs spread in a proportionate way across all licensees. An annual renewal process allows for a regular re-evaluation of licensing needs, with an appropriate, risk-assessed level of compliance activity.

5. Questions for respondents

About you

1) In which sectors do you operate? Please check all boxes that apply to you.

☐ Doctor's deputising service

☐ Drug detection dogs

☐ Education

☐ Exporter

☐ Forensic/Toxicology service

☐ Healthcare

☐ Importer

☐ Manufacture – pharmaceuticals

☐ Manufacture – other

☐ Private hospital/Treatment Centre/Clinic

☐ Product packaging/labelling

☐ Research and Development

☐ Trade body

☐ Waste disposal

☐ Wholesaler – pharmaceuticals

☐ Wholesaler – other

☐ Wholesaler – veterinary

☐ None of the above

If you selected 'None of the above' or any of the 'other' categories please give details below:

2) If you are a small or medium enterprise (SME – a business that employs 250 people or fewer) do you think the Government's preferred option would have a disproportionate impact on businesses like yours?

☐ Yes
☐ No

Please give reasons for your view and suggest alternative approaches that will better meet the needs of SMEs

Please continue on a separate sheet if necessary.

3) If you are responding on behalf of a university or other education institution, do you think the Government's preferred option would have a disproportionate impact on your sector?

☐ Yes
☐ No

Please give reasons for your view and suggest alternative approaches that will better meet the needs of the education sector

Please continue on a separate sheet if necessary.

4) Which licenses do you posses?
☐ Controlled drugs
☐ Precursor chemicals
☐ Cannabis cultivation

5) Do you use import and/or export licenses?
☐ Yes
☐ No

Response to proposals

6) Which option do you prefer? (Check one box)
☐ Option 1: No change
☐ Option 2a: Charges for all controlled drug, precursor chemical, and cannabis cultivation licences, with domestic licences valid for one year only

☐ Option 2b: as 2a above, but with domestic licences valid for two years
☐ Option 3: Charges for controlled drug domestic licences only

Please give reasons for your choice:

Please continue on a separate sheet if necessary.

7) Do you think the Government can achieve its aims through any alternative, non-regulatory solutions? Please suggest alternative approaches:

Please continue on a separate sheet if necessary.

8) What impact do you think re-introducing charges for licenses will have on government efforts to reduce the risk of harm caused by the illegal drug trade?
☐ Positive
☐ Neutral
☐ Negative

Please give reasons for your choice

Please continue on a separate sheet if necessary.

9) What impact do you believe re-introducing charges for licences will have on your business or organisation?
☐ Positive
☐ Neutral
☐ Negative

Please give reasons for your view

Please continue on a separate sheet if necessary.

10) Do you agree with the proposal to limit the duration of licences as described at paragraph 3.1.1?

☐ Yes
☐ No

Please give reasons for your view

Please continue on a separate sheet if necessary.

Processes

11) If charges are re-introduced, what payment method would you prefer?

☐ Online (debit/credit card)
☐ Telephone (debit/credit card)
☐ Cheque

12) Which approach to charging for import and export licences would you prefer?

☐ Payment at time of application
☐ On account with a monthly or quarterly payment of all charges accrued

Administrative burdens

It will allow us to produce a more robust Impact Assessment if we have accurate data to show how long it takes you to perform each activity required of you by the licensing regime.

13) Approximately how long does it take you to complete the following activities? Please give your answer in man-hours.

Activity	*Man-hours required to complete*
Controlled drug domestic licences	
Apply for a controlled drug domestic licence	
Apply for a CRB check	
Gather information in advance of a compliance visit from a Compliance Officer	
Make necessary arrangements to ensure that record keeping, standard operating procedures, and safe custody requirements are met	
Complete an annual statistical return	
Complete an annual statement of compliance	

Precursor chemical licences and registrations	
Apply for a precursor chemical category 1 licence	
Apply for a precursor chemical category 2 or 3 registration	
Apply for a CRB check	
Gather information in advance of a compliance visit from a Compliance Officer	
Make necessary arrangements to ensure that record keeping, standard operating procedures, and safe custody requirements are met	
Controlled drug import and export licences	
Apply for an import licence	
Apply for an export licence	
Precursor chemical import and export authorisations	
Apply for an import authorisation	
Apply for an export authorisation	

Equality Impact

14) Do you believe this proposal could have a negative or positive impact on any individual or representative group for reasons of:

- race/ethnicity
- disability
- gender
- gender identity
- religion/belief
- sexual orientation
- age

Comments: please give reasons for your view

Responses: Confidentiality & Disclaimer

The information you send us may be passed to colleagues within the Home Office, the Government or related agencies.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 [FOIA], the Data Protection Act 1998 [DPA] and the Environmental Information Regulations 2004).

If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Government Code of Practice on Consultation

The Consultation follows the Government's Code of Practice on Consultation – the criteria for which are set out below:

Criterion 1 – When to consult – Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 – Duration of consultation exercises – Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 – Clarity of scope and impact – Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 – Accessibility of consultation exercises – Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 – The burden of consultation – Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 – Responsiveness of consultation exercises – Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 – Capacity to consult – Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

The full Code of Practice on Consultation is available at:
http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

Home Office Consultation Co-ordinator

If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Nigel Lawrence. Please DO NOT send your response to this consultation to Nigel Lawrence. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

The Co-ordinator can be emailed at: Nigel.Lawrence@homeoffice.gsi.gov.uk or alternatively write to him at:

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