EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (LICENCE FEES) REGULATIONS 2010

2010 No. 2497

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations introduce a new fees structure for controlled drug licences. The fees structure is being revised in order to improve the service for licensees and to strengthen the regulatory regime to reduce the risk of controlled drugs being diverted into the illicit trade.

2.2 This instrument revokes the Misuse of Drugs (Fees) Regulations 1986 (as amended) which provide the current fee structure for controlled drug licences.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 These Regulations are being made in order to revise the fees structure for controlled drug licences. Certain substances are controlled under the Misuse of Drugs Act 1971 (the "1971 Act") because their misuse is capable of having harmful effects sufficient to constitute a social problem. A "controlled drug" means any substance or product for the time being specified in Part I, II, or III of Schedule 2 to the 1971 Act.

4.2 Broadly, section 3 of the 1971 Act prohibits the import and export of controlled drugs. Sections 4 and 5 of the 1971 Act make it unlawful to possess, supply, offer to supply, or produce a controlled drug. Section 6 makes it unlawful to cultivate any plant of the genus *Cannabis*. Section 7 of the Act sets out a number of exceptions to sections 3 – 6, including the provision for these activities to take place lawfully if done under and in accordance with the terms of a licence issued by the Secretary of State.

4.3 In parallel, under planned legislation, fees are to be introduced for precursor chemical licences, registrations, and authorisations. Precursor chemicals are those chemicals frequently used in or for the unlawful production of a controlled drug, but are separate from those substances which are the subject matter of these Regulations. EC regulations Nos. 273/2004 and 111/2005, which are directly effective in the United Kingdom, control these chemicals through a licensing system. Broadly, manufacture and supply within

the EU must be licensed or registered, and imports and exports with third countries require authorisation.

5. Territorial Extent and Application

5.1 This instrument applies to England, Wales and Scotland except for those regulations covering the import and export of controlled drugs (regulation 2(4), and regulation 2(5) to the extent that it applies to regulation 2(4)) which extend to the United Kingdom.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 These Regulations revise the fees structure for controlled drug licences. Fees were charged for controlled drug licences until 2007 at which point they were discontinued as part of wider changes to drugs licensing. The Misuse of Drugs (Licence Fees) Regulations 1986 (as amended) which provide for the current fee structure for controlled drug licences are being revoked, because a new charging structure is being introduced.

7.2 The Home Office's policy objective is to use fees revenue to improve the service received by licensees, and to strengthen the regulatory regime to reduce the risk of diversion of controlled drugs into the illicit market.

7.3 The Misuse of Drugs Act 1971 aims to prevent the misuse of dangerous drugs by restricting access to controlled substances, in part through a licensing regime. These regulations contribute towards the effective operation of the controlled drugs licensing regime by ensuring that it is properly funded to enable the delivery of a reliable, high-quality service for licensees.

7.4 Fees revenue will be used to shorten the turn-around times for licences; make advice and guidance on how to comply more readily available; and make applying for a licence more straightforward. The new regulatory regime will make all licences of time-limited validity, limiting the time that unused licences are in circulation. The increase in Compliance Officers and IT resources will allow the Home Office to introduce a more carefully targeted compliance regime, based on risk-assessment, in line with the Hampton Principles of good regulation. Sir Philip Hampton's 2005 review, 'Reducing administrative burdens: effective inspection and enforcement' considered how to reduce unnecessary administration for businesses. The Hampton Review set out some key principles that should be consistently applied throughout the regulatory system, the first of which was that regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate

resources on the areas that need them most (further details of the Hampton Principles can be seen here: http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system) .

7.5 Fees will be charged for licences to possess, supply, produce preparations, and produce base drugs. The policy position is that licences will need to be renewed on an annual basis. Low-risk licensees will be able to renew their licences using a light-touch paper-based process, with a correspondingly low fee. When, following a risk-assessment, the Secretary of State decides that a compliance visit is necessary as part of the licence renewal process, a higher fee will be charged to incorporate the cost of the compliance visit. A fee will be charged for each import or export licence. The issuing of replacements for lost or damaged licences will attract an administration fee.

7.6 Compliance visits are necessary for all first time applications, and for some renewals. A compliance visit involves a Home Office compliance officer visiting the site to be licensed in order to provide advice and guidance on how to meet the legal obligations of the licensing regime. This advice generally focuses on security arrangements, Standard Operating Procedures, stock audit and record keeping. Compliance officers also provide free advice to all licensees during the lifetime of the licence.

7.7 There are two separate types of licence to cultivate plants of the genus *Cannabis*, with the distinction between the two licences based on the tetrahydrocannabinol (THC) content of the plants. THC is the main psychoactive substance found in cannabis plants. Where the THC content is very low (in a similar way to article 1(4) of EC Regulation 1672/2000, regulation 2(2) refers to any such plant having a THC content not exceeding 0.2%) a less intrusive licensing regime is appropriate as the risk of diversion or misuse is low. Plants with a THC content not exceeding 0.2% are licensed when used for industrial purposes (e.g. the cultivation of hemp for fibre production). When the THC content of the plant exceeds 0.2% the risk posed by the plant is significantly greater and a more comprehensive licensing regime is required. Generally, licences for these plants are only granted for scientific research. The differing licence fees are proportionate to the differing levels of Home Office resources required to process the licence application.

7.8 There are approximately 2,600 controlled drug licensees. They cover a wide range of areas but are concentrated in the healthcare and pharmaceutical sectors. These changes are of direct relevance to all controlled drug licensees but, due to their technical nature, have raised little wider public interest. About 90 responses were received to the full public consultation proposing the re-introduction of fees published earlier this year, almost all of which came from licensees.

7.9 The market alone does not prevent the diversion of controlled drugs into the illicit trade, making government intervention necessary. The United Kingdom has international obligations, flowing from the United Nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971, to operate a licensing regime

that meets certain standards. Continuing to fund the licensing regime from general taxation through the Home Office budget would be likely to lead to degradation in service levels in coming years as the Home Office budget is reduced.

Comparison with fee levels under earlier fee regulations

7.10 Charging under the Misuse of Drugs (Licence Fees) Regulations 1986 (the "1986 Regulations") (as amended) ceased at the end of 2006. Licences have been issued free of charge since then.

7.11 The charging structure introduced by these Regulations is different from that which would apply under the 1986 Regulations (as amended) making a direct comparison impossible with fee levels set in 2003 (when the 1986 Regulations were last amended). Under the 1986 Regulations (as amended), the number of base drugs for which a licence was sought had a direct bearing on the fee, as the fee was charged per base drug, per activity. Under these Regulations, the number of base drugs is not taken account of (because this has no bearing on the amount of work absorbed in processing a licence application). Under the 1986 Regulations (as amended), there was no distinction in fee levels between first time applications and renewal applications, and there was no distinction in fee levels between renewals for compliant, low-risk licensees and those for less compliant or higher-risk licensees. These Regulations introduce fees for import and export licences for the first time.

7.12 As no direct comparison is possible, some illustrative examples are used instead to indicate the impact of changing the fee structure. The illustration is based on the assumption that the licensee holds 10 base drugs. The figures can easily be scaled up or down for those holding greater or fewer numbers of base drugs, as the fee under the 1986 Regulations was charged per base drug. The illustration is based on the assumption that the renewal under the new regime would be under the 'light touch' renewal regime for compliant, low-risk licensees. It is estimated that this would apply to about 90% of licensees. If renewals take place under the more rigorous renewals system for less compliant or higher risk licensees, the renewal fee would be £1,371. It is estimated that this would apply to about 10% of licensees.

Example 1: An applicant applying for a licence to possess 10 different base drugs for the first time would have paid £310 under the 1986 Regulations, as amended, (at £31 per base drug). They will pay £3,133 under these the Regulations (regardless of the number of drugs held). A licensee renewing a licence to possess and supply 10 different drugs would have paid £310 under the 1986 Regulations, as amended, (at £31 per base drug). They will pay £326 under these Regulations (regardless of the number of drugs held).

Example 2: An applicant applying for a licence to possess and supply 10 different base drugs for the first time would have paid £620 under the 1986 Regulations, as amended, (at £62 per base drug). They will pay £3,655 under these Regulations (regardless of the number of drugs held). A licensee

renewing a licence to possess and supply 10 different drugs would have paid £620 under the 1986 Regulations, as amended, (at £62 per base drug). They will pay £326 under these Regulations (regardless of the number of drugs held).

Example 3: An applicant applying for a licence to produce preparations containing controlled drugs, for 10 different base drugs, for the first time would have paid £1,240 under the 1986 Regulations, as amended, (at £124 per base drug). They will pay £4,178 under these Regulations (regardless of the number of base drugs held). A licensee renewing a licence to produce preparations containing controlled drugs, for 10 different base drugs, would have paid £1,240 under the 1986 Regulations (at £124 per base drug). They will pay £326 under these Regulations (regardless of the number of drugs held).

Example 4: An applicant applying for a licence to produce controlled drugs, for 10 different base drugs, for the first time, would have paid £1,860 under the 1986 Regulations (at £186 per base drug). They will pay £4,700 under these Regulations (regardless of the number of base drugs held). A licensee renewing a licence to produce base drugs, for 10 different base drugs, would have paid £1,860 under the 1986 Regulations (at £186 per base drug). They will pay £326 under these Regulations (regardless of the number of drugs held).

Example 5: A licensee issued with 50 import or export licences under the 1986 Regulations, as amended, would have paid nothing. Under these Regulations the fee will be £1,200 (£24 per licence).

7.13 Inflation, based on the Retail Prices Index (RPI) measure, has risen by about 24% since 2003, when the fee levels were last set (based on ONS figures available online here: http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=9412).

- ***Consolidation***

7.14 There are no issues relating to consolidation.

8. Consultation outcome

8.1 A full public consultation ran from March to June 2010 proposing the re-introduction of fees for controlled drug licences. About 90 responses were received. Almost all responses were from licensees. There were a small number from trade bodies representing groups of licensees in particular sectors.

8.2 Some licensees were supportive of fees in return for clearly defined improvements in service, for example, shortened turn-around times for licence applications. Others licensees mentioned the potential increase in the administrative burden on licensees; the effect on small businesses; and the

impact on non-commercial users of controlled drugs. There was also a concern that a "one size fits all" approach would lead to compliant licensees facing extra burdens because of the non-compliance of the few. The re-introduction of licences with a validity of one year was broadly welcomed by respondents.

8.3 The Home Office amended its policy in response to the concerns of licensees. The annual renewal process has been amended so that compliant, low-risk licensees will be able to use a light-touch renewal system with a correspondingly low fee. Higher-risk licensees will undertake a more rigorous licence renewal process, commensurate with the greater level of risk, that will carry a correspondingly higher-fee. The policy intention is to ensure that compliant licensees do not pay for the extra costs associated with higher-risk licensees; that the renewal process introduces the smallest administrative burden possible; and to introduce a further incentive to compliance.

9. Guidance

9.1 Guidance for licensees on the new fees will be made available on the Home Office drugs licensing website:
http://www.homeoffice.gov.uk/drugs/licensing/

10. Impact

10.1 An Impact Assessment has been prepared and is attached to this Explanatory Memorandum.

11. Regulating small business

11.1 The legislation applies to small business. A Small Firms Impact Test has been prepared and is annexed to the Impact Assessment.

12. Monitoring & review

12.1 The Home Office intends to achieve full cost recovery through fees. The fees will be monitored by the Home Office, and will be reviewed annually with HM Treasury.

13. Contact

Joe Barker at the Home Office Tel: 020 7035 1868 or email: joe.barker3@homeoffice.gsi.gov.uk can answer any queries regarding the instrument.

Title:	Impact Assessment (IA)
Impact assessment of re-introduction of charges for controlled drug and precursor chemical licences	**IA No:** HO0018
Lead department or agency: Home Office	**Date:** 01/10/2010
Other departments or agencies:	**Stage:** Final
	Source intervention: Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Joe Barker (020 7035 1868) joe.barker3@homeoffice.gsi.gov.uk

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

The Home Office's Drugs Licensing and Compliance Unit (DLCU) regulates controlled drugs under the Misuse of Drugs Act 1971, and precursor chemicals under EU Regulations. The Home Office operates a licensing system to prevent the misuse of controlled substances, and/or their diversion into the illicit trade. At present, licences are issued without a charge. The Home Office wishes to introduce charges for licences (including precursor registrations and authorisations), and limit the validity of domestic licences to one year, in order to fund improved services for licensees, and to strengthen the control system to protect the public from the harm of drug misuse. Government intervention is necessary because the market alone does not prevent the misuse and/or diversion of controlled substances.

What are the policy objectives and the intended effects?

The policy objective is to improve services for licensees, to strengthen the regulatory system to protect the public, and to properly apportion licensing costs to those benefiting from licenses rather than the taxpayer. The introduction of charges will allow the Home Office to fund a series of improvements to the regulatory regime. Alongside the introduction of fees, domestic licences will be given a time-limited validity in order to reduce the risk of licences falling into the wrong hands.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

(1) No change. Continue to issue licences for free; do not introduce changes to the licensing regime.
(2) Introduce charges for all controlled drug and precursor chemical licences with validity of one year for domestic licences.
(3) Introduce charges for all controlled drug and precursor chemical licences with validity of two years for domestic licences.
(4) Re-introduce charges for licences that have been charged for in the past only, i.e. controlled drug domestic licences only.
Option 2 is the Home Office's preferred option as it: (a) funds improvements to the regulatory regime, to the benefit of both licensees and the general public; (b) introduces a time-limit on the validity of licences, reducing the risk of them falling into the wrong hands, and (c) is the fairest approach to charging for licences. Option 2 has been amended to take account of consultation responses from licensees.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 10/2011
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:  Date:12 October 2010

Summary: Analysis and Evidence

Policy Option 1

Description:

Make no changes (do nothing)

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	**High:** 0	**Best Estimate: 0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

Other key non-monetised benefits by 'main affected groups'

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

The key risks of 'do nothing' are (a) that the current risk of diversion and consequent drug misuse will continue; (b) service standards for licensees may decline as the Home Office budget faces tight constraints over the next 4 years.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			November 2010		
Which organisation(s) will enforce the policy?			DLCU		
What is the annual change in enforcement cost (£m)?			£unknown		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro** £0	**< 20** £0	**Small** £0	**Medium** £0	**Large** £0
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	Yes	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainability Sustainable Development Impact Test guidance	No	

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

Introduce charges for all controlled drug and precursor chemical licences with validity of one year for domestic licences

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: **-11.0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low		2		
High				
Best Estimate	5.2		4.4	**34.5**

Description and scale of key monetised costs by 'main affected groups'

Licence fees are expected to cost licensees approximately £2.8m per annum. Additional DLCU costs and new IT costs come to £1.1m per annum. The re-introduction of an annual licence renewal process will result in an admin burden estimated at £90,000 per year.

Other key non-monetised costs by 'main affected groups'

This option sees the imposition of a 'charge' on companies which will result in an unquantifiable volume of 'deadweight loss'.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low		2		
High				
Best Estimate	3.2		3.1	**23.4**

Description and scale of key monetised benefits by 'main affected groups'

DLCU gains £2.8m per annum in revenue. Online applications give an annual admin saving for licensees of £225,000 and for DLCU of £35,000 from having to deal with fewer speculative applications.

Other key non-monetised benefits by 'main affected groups'

Licensees will see an improved service, in particular (a) improved turn-around times for licence applications; and (b) more readily available advice and guidance from Compliance Officers. The public will be better protected from the risk of the diversion and consequent misuse of controlled substances.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

It is assumed that improved licence application turn-around times will benefit business, but the scale of this benefit is unclear. It is assumed that a fee will reduce the number of speculative applications. It is assumed that the costs of drug misuse will be reduced and the scale of this benefit is potentially large. In estimating admin burden impacts, various standard assumptions relating to average wage and time required to complete tasks have been used. Site visits are assumed to be required for 10% of license holders.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options		
From what date will the policy be implemented?			November 2010		
Which organisation(s) will enforce the policy?			DLCU		
What is the total annual cost (£m) of enforcement for these organisations?			£unknown		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[2]? Equality and Human Rights Commission: General guidance	No	
Economic impacts		
Competition? Competition Impact Assessment	No	
Small firms? Small Firms Impact Test	Yes	
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 3

Description:

Introduce charges for all controlled drug and precursor chemical licences with validity of two years for domestic licences

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: **-10.8**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low		2		
High				
Best Estimate	5.2		4.4	**34.2**

Description and scale of key monetised costs by 'main affected groups'

Licence fees are expected to cost licensees approximately £2.8m per annum. Additional DLCU costs and new IT costs come to £1.1m per annum. The re-introduction of a biennial licence renewal process will result in an admin burden estimated at £60,000.

Other key non-monetised costs by 'main affected groups'

This option sees the imposition of a 'charge' on companies which will result in an unquantifiable volume of 'deadweight loss'.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low		2		
High				
Best Estimate	3.2		3.1	**23.4**

Description and scale of key monetised benefits by 'main affected groups'

DLCU gains £2.8m per annum in revenue. Online applications give an annual admin saving for licensees of £225,000 and for DLCU of £35,000 from having to deal with fewer speculative applications

Other key non-monetised benefits by 'main affected groups'

Licensees will see an improved service, in particular (a) improved turn-around times for licence applications; and (b) more readily available advice and guidacne from Compliance Officers. The public will be better protected from the risk of the diversion and consequent misuse of controlled substances.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

It is assumed that improved licence application turn-around times will benefit business, but the scale of this benefit is unclear. It is assumed that a fee will reduce the number of speculative applications. It is assumed that the costs of drug misuse will be reduced and the scale of this benefit is potentially large. In estimating admin burden impacts, various standard assumptions relating to average wage and time required to complete tasks have been used.

Site visits are assumed to be required for 20% of license holders.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options		
From what date will the policy be implemented?			November 2010		
Which organisation(s) will enforce the policy?			DLCU		
What is the total annual cost (£m) of enforcement for these organisations?			£unknown		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[3]? Equality and Human Rights Commission: General guidance	No	
Economic impacts		
Competition? Competition Impact Assessment	No	
Small firms? Small Firms Impact Test	Yes	
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[3] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 4

Description:

Re-introduce charges for licences that have been charged for in the past only, i.e. for controlled drug domestic licences only

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate: **-13.1**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low		2		
High				
Best Estimate	4.4		3.6	**28.4**

Description and scale of key monetised costs by 'main affected groups'

Cost to controlled drug domestic licensees estimated to be in the region of £2m per annum. Additional DLCU costs and new IT costs come to £1.5m per annum. The re-introduction of an annual licence renewal process will result in an admin burden estimated at £90,000 per annum.

Other key non-monetised costs by 'main affected groups'

This option sees the imposition of a 'charge' on companies which will result in an unquantifiable volume of 'deadweight loss'.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low		2		
High				
Best Estimate	2.0		2.0	**15.2**

Description and scale of key monetised benefits by 'main affected groups'

DLCU gains £2m per annum in revenue.

Other key non-monetised benefits by 'main affected groups'

Controlled drug domestic licensees will see an improved service, and the public will be better protected from the risk of the diversion and consequent misuse of controlled substances.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that failure to charge for precursor chemical licences, registrations, and import/export authorisations, as well as controlled drug import/export licences, will lead to lower levels of service for licensees in these areas. There is also a risk that there will be a lower level of compliance in these areas if they are not properly resourced due to lack of fees revenue, so there is a higher risk of diversion than under options 2 and 3. It is assumed that a fee will discourage speculative applications for controlled drug domestic licences. Admin burden assumptions as with options 2 and 3.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options		
From what date will the policy be implemented?			November 2010		
Which organisation(s) will enforce the policy?			DLCU		
What is the total annual cost (£m) of enforcement for these organisations?			£unknown		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[4]? Equality and Human Rights Commission: General guidance	No	
Economic impacts		
Competition? Competition Impact Assessment	No	
Small firms? Small Firms Impact Test	Yes	
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	
Wider environmental issues? Guidance has been created on the Defra site	No	
Social impacts		
Health and well-being? Health: Health Impact Assessment	No	
Human rights? Ministry of Justice: Human Rights	No	
Justice?	No	
Rural proofing? Commission for Rural Communities	No	
Sustainability? Defra: Think sustainable	No	

[4] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Implementation).

No.	Legislation or publication
1	The Misuse of Drugs Act 1971 (http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1971/cukpga_19710038_en_1)
2	Regulation (EC) No 273/2004 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:047:0001:0010:EN:PDF)
3	Regulation (EC) No 111/2005 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:022:0001:0010:en:PDF)
4	Regulation (EC) No 1277/2005 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:202:0007:0033:EN:PDF)
5	The consultation stage impact assessment http://www.homeoffice.gov.uk/publications/consultations/charges-drug-licensing/
6	Cost of Class A Drug Misuse (2003) http://rds.homeoffice.gov.uk/rds/pdfs06/rdsolr1606.pdf

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices – Option 2

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	1.0	1.9	0	0	0	0	0	0	0	0
Annual recurring cost	0.8	1.5	4.4	4.4	4.4	4.4	4.4	4.4	4.4	4.4
Total annual costs	1.7	3.5	4.4	4.4	4.4	4.4	4.4	4.4	4.4	4.4
Transition benefits	0.9	1.9	0	0	0	0	0	0	0	0
Annual recurring benefits	0.1	0.3	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1
Total annual benefits	1.1	2.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1

Totals may vary due to rounding.

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

A. Strategic Overview

A.1 Background

The Home Office's Drugs Licensing and Compliance Unit (DLCU) has responsibility for regulating controlled drugs and precursor chemicals (from hereon in controlled drugs and precursor chemicals together will be referred to as 'controlled substances'). Controlled substances are regulated because of the serious harm they can cause to both individuals and society as a whole if misused.

One of the central aspects of the regulatory system is the licensing regime. Those who wish to possess, supply, produce, manufacture, import or export controlled drugs must be licensed by the Home Office to do so. Broadly, those who wish to place precursor chemicals on the market or engage in importing and exporting beyond the EU, must also be licensed by the Home Office.

The aim of the licensing regime is to facilitate the licit use of controlled substances whilst preventing their diversion into the illicit trade. Diversion can take two main forms:

- the purchase of controlled substances from licit producers or distributors under false pretences
- the theft of controlled substances from licit producers or distributors.

The Government wishes to introduce charges for controlled drug and precursor chemical licences (including registrations and authorisations). Charges for licences will fund changes to the regulatory regime that will improve services for licences and protect the public. They will also ensure that the cost of risk assessing and authorising licences is born by those who benefit from them, not the taxpayer. Charges will be fixed on a sliding scale, based on the work entailed to process the licence application.

Alongside the re-introduction of charges the Home Office will also re-introduce time limits on the validity of licences.

Legislative background

Narcotic and psychotropic drugs are controlled under the Misuse of Drugs Act 1971. Section 30 of the Act gives the Secretary of State the power to set fees for licences. Precursor chemicals are controlled through EU regulations. Regulation (EC) No 273/2004 controls intra-community trade in precursor chemicals through a system of licensing and registration and provides the power for competent authorities to charge a fee for a licence or registration (Article 3). Regulation (EC) No 111/2005 controls trade in precursor chemicals between the Community and third countries and provides the power for competent authorities to charge a fee for a licence, registration or authorisation (Article 26).

The previous charging regime

Fees were charged for controlled drug licences from at least the time of 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 for controlled drug licences at the end of 2006.

Controlled drug licences were issued (and fees charged) per drug, per activity. Prior to 2003 fees only applied to certain schedules of drugs. From 2003 onwards, fees applied to drugs of all schedules.

Although the EC Regulations governing precursor control have always included the power to charge a fee, and other EU states charge fees, the UK has not previously done so.

Geographical scope

The geographical scope is the same for all four policy options:

- All precursor chemical policy applies to the whole of the United Kingdom
- Controlled drug import and export licensing policy applies to the whole of the United Kingdom
- Controlled drug domestic licensing policy applies to Great Britain only.

A.2 Groups Affected

The main groups affected by this proposal are:

(a) Current controlled drug and precursor chemical licensees

(b) Potential future controlled drug and precursor chemical licensees

Licensees are spread across a wide range of sectors. The major areas are:

- Pharmaceuticals – manufacture and wholesale
- Pharmaceuticals – import and export
- Healthcare
- Scientific research (including Research and Development for business)
- Higher Education
- Forensic/Toxicology services
- Veterinary products
- Chemicals – manufacture and wholesale
- Chemical import and export
- Manufacture of flavours and fragrances
- Drug detection dog training

We would expect future licensees to come from broadly the same sectors as those that are represented currently.

A.3 Consultation

Within Government
These proposals have been developed following consultation between officials at the Home Office, HM Treasury, the Department for Business, Innovation and Skills, the Department of Health, the Department for Energy and Climate Change, the Department of the Environment, Food, and Rural Affairs, and the Medicines and Healthcare products Regulatory Agency (MHRA).

Public Consultation
A full public consultation was conducted on this policy. The consultation was published on the Home Office website, and all existing licensees were contacted directly and invited to respond. Relevant trade bodies (for example, the Chemical Business Association) and other interested parties (for example, Higher Education funding councils) were also invited to respond.

91 responses were received. Of those who indicated a preference for one of the options presented in the consultation document, 26 respondents (29%) preferred one of the options that introduced a fee. 40 respondents (44%) preferred option 1 (no change) that would not result in a fee.

The common themes raised by respondents are outlined below:

- Some were willing to pay a fee in return for clearly defined benefits, shortened licence turn-around times in particular
- SMEs were concerned that the fees would fall disproportionately heavily on them
- Licensees conducting non-commercial enterprises (e.g. museums, educational establishments) requested an exemption
- Some respondents rejected the idea of fees in principle, arguing that the licensing system should be paid for the by general taxpayer
- There were concerns over the administrative burden of a licence renewal process
- It was suggested that low-risk licensees should pay lower fees and/or be granted licences of longer duration, than high-risk licensees, who should pay more and/or be granted licences of shorter duration

- It was claimed that the licensing regime does not reduce the risk of harm caused by dangerous drugs
- There were concerns that a “one size fits all” approach would be taken that did not take into account the different circumstances of licensees
- It was suggested that those holding small quantities of controlled substances should be exempted, or pay a lower fee than those holding large quantities of controlled substances

B. Rationale

The misuse of controlled drugs and precursor chemicals imposes a cost on society greatly in excess of the perceived cost to the individual. This cost comprises elements such as crime, anti-social behaviour, healthcare and employment. The market alone does not prevent the diversion of controlled drugs and precursor chemicals into the illicit trade, and individuals who misuse drugs may not fully take into account the wider social costs or the long term effects of their actions. Therefore Government intervention, through its licensing system, is necessary.

Issues with the previous licensing regime

In 2006/7, the Home Office altered the licensing regime to allow a greater level of self-regulation by licensees. This entailed the removal of fees for licences, the introduction of open-ended licenses, and a significant reduction in the number of Compliance Officers.

In 2008 the Home Office reviewed the impact of the self-regulation approach. It was found that self-regulation had increased the risk of diversion of controlled substances. In 2009 compliance visits were conducted on all new licensees who had gained a licence without having received a compliance visit under the 2006/7 self-regulation approach. Based on a sample of over 580 licensees visited in 2009, about 65% of precursor chemical licensees/registrants were found to have at least one incident of non-compliance, and about 50% of controlled drug licensees were found to have at least one incident of non-compliance.

These visits found that the risks identified in the earlier review were real, that there was an unacceptable level of non-compliance, and a risk of diversion of controlled substances, leading ultimately to substance misuse.

Licensees reported that, due to the reduced number of Compliance Officers, they lacked the guidance and advice they needed from the Home Office.

An improved service for licensees, combined with improved control measures, is required to reduce the real risk of diversion that was identified in 2009.

C. Objectives

The Government has three objectives in this area:

a. To use licence fee revenue to fund improvements to the service received by licensees

b. To use licence fee revenue to strengthen the regulatory regime to reduce the risk of diversion of controlled substances

c. To properly attribute licensing costs to those benefiting directly from licences rather than the general taxpayer.

a. Improvements to the service received by licensees

The Home Office objective is to:

- make advice and guidance from Compliance Officers more readily available for licensees
- improve licence turn-around times for controlled drug domestic licences and precursor chemical category 1 licences and category 2 and 3 registrations

- improve licence turn-around times for controlled drug import/export licences, and precursor chemical import/export authorisations
- ensure that the Drugs Licensing and Compliance Unit has the resilience to maintain improved service standards during a period of very significant cuts in government expenditure anticipated over the coming years.

b. Strengthening the regulatory regime

The Home Office objective is to reduce the risk of the diversion of controlled substances into the illicit trade. This will be achieved through the following actions:

- remove all open-ended licences (except when required in exceptional cases) to reduce the risk of licences falling into the wrong hands, and replace them with licences of time-limited validity
- improve levels of compliance through the increased provision of advice and guidance to licensees
- reduce the risk of diversion through IT-enabled checks on import/export applications
- provide an appropriate level of oversight of less compliant and higher risk licensees in line with our international obligations under United Nations drug control conventions.

c. Properly attributing licensing costs

The Home Office objective is to ensure that licensing costs are funded by those benefiting directly from licence services rather than the general taxpayer. This is particularly important in a time of increased pressure on the public purse.

D. Options

Option 1 is to make no changes (do nothing).
This option maintains the status quo.

Option 2 is to introduce fees for all controlled drug and precursor chemical licences, registrations, and authorisations, with a validity of one year (called option 2a in the consultation stage impact assessment)

The following licences would attract a fee, at approximately the levels set out in the table below:

Licensing Activity	Fee (£)
Controlled Drugs	
Possess: First time application	3,133
Supply: First time application	3,655
Produce (preparations): First time application	4,178
Produce (controlled drugs): First time application	4,700
Cannabis cultivation (Low THC): First time application	580
Cannabis cultivation: First time application	4,700
Controlled Drug renewal (all activities) - on the papers	326
Controlled Drug renewal (all activities) - including compliance visit	1,371
Import licence – controlled drugs	24
Export licence – controlled drugs	24
Replace a lost controlled drug domestic licence	45
Precursor Chemicals	
Category 1 licence first time application	3,655
Category 2 registration first time application	435
Category 3 registration first time application	435

Category 1 licence renewal application - papers only	326
Cat1 licence renewal application - including compliance visit	1,371
Category 2 or 3 registration renewal application - papers only	109
Category 2 or 3 registration renewal application - including compliance visit	1,153
Import authorisation – precursor chemicals	24
Export authorisation – precursor chemicals	24
Replace lost precursor chemical licence or registration	45

Charging would be on a full cost recovery basis, in line with HM Treasury guidance. Licence fees have been weighted to reflect the approximate level of work required to process the licence.

Controlled drug domestic licences would be charged per activity. The number of schedules would not be taken into account. Licences would have to be renewed on an annual basis.

First time applications would include the cost of a compliance visit, and reflect the extra work required for a new licence.

Renewals would be charged at a lesser rate than that for a new licence, and would be one of two types:

- A light-touch annual renewal conducted on the papers with no need for a compliance visit. This would be used for low-risk licensees.
- An annual renewal that included a compliance visit. This would be used either when DLCU considered the applicant to be higher risk, or if the applicant had not received a compliance visit for such an extended period of time that one had become necessary.

DLCU will decide, on a risk-assessed basis, which type of renewal application licensees must make.

Existing open-ended licences will be revoked and an annual licence must be obtained in its place. Existing licensees will pay a renewal fee to replace an open-ended licence with a like-for-like annual licence, not a first-time application fee.

Import and export licences will be charged per licence.

Replacements for lost or damaged domestic licence documents will also attract a fee.

Precursor chemical licences and registrations will be charged per category. The number of chemicals specified on the licence will not be taken into account. Licences and registrations would have to be renewed on an annual basis.

First time applications for category 1 licences would include the cost of a compliance visit. First time applications for category 1 licences and category 2 and 3 registrations will reflect the cost of the extra work required for a new licence or registration.

Renewals will be charged at a lesser rate than that for a first time application, and would be one of two types:

- A light-touch annual renewal conducted on the papers with no need for a compliance visit. This would be used for low-risk licensees.
- An annual renewal that included a compliance visit. This would be used either when DLCU considered the applicant to be higher risk, or if the applicant had not received a compliance visit for such an extended period of time that one had become necessary.

DLCU will decide, on a risk-assessed basis, which type of renewal application licensees must make.

Import and export authorisations will be charged for per licence.

Replacements for lost licence and registration documents will also attract a fee.

Option 3 is to introduce fees for all controlled drug and precursor chemical licences, registrations, and authorisations, with a validity of two years (called option 2b in the consultation stage impact assessment)

As option 2 above, but controlled drug domestic licences and precursor chemical licences and registrations would have to be renewed on a biennial basis.

Option 4 is to introduce fees for those licences that were charged for under the old charging regime only, i.e. for controlled drug domestic licences only (called option 3 in the consultation stage impact assessment)

The following licences only would be charged for:

- Controlled drug domestic licences (i.e. licences to possess, supply, produce preparations and produce controlled drugs)

Charging would be on a full cost recovery basis, in line with HM Treasury guidance. Precursor chemical licences, registrations and authorisations, and controlled drug import and export licences would continue to be issued for free.

E. Appraisal (Costs and Benefits)

General Assumptions and Data

Background information illustrating the scale of the problems caused by the misuse of drugs:

- The most recent estimate (for 2003/4) put the cost of class A drug misuse in the UK alone at £15.4 bn per year. Crime costs accounted for about 90% of this figure, with health costs and drug-related deaths accounting for about 9%. Though these estimates are out of date, costs are still considered to be substantial.
- There are an estimated 332,000 problem drug users in the UK
- Between a third and a half of acquisitive crime is estimated to be drug related (*Drugs: Protecting Families and Communities: The 2008 Drug Strategy* p.8)
- Over 1,000 drug related deaths occur each year as illustrated by Table E1

E1: Numbers of deaths where selected substances were mentioned on the death certificate, total mentions, 2005 – 09, England and Wales

	2005	2006	2007	2008	2009
Heroin and morphine	842	713	829	897	880
Methadone	220	241	325	378	408
Cocaine	176	190	196	235	202
All amphetamines	103	92	97	99	76
MDMA/ecstasy	58	48	47	44	27
Cannabis	19	17	12	19	22
Gamma-hydroxybutyrate (GHB)/Gamma-butyrolactone (GBL)	4	7	9	20	16
All benzodiazepines	190	177	207	230	261
Temazepam	45	42	45	37	38
Diazepam	101	89	123	133	160
Nitrazepam	11	8	10	-	5
Zopiclone/zolpidem	48	39	51	36	79
Barbiturates	14	17	6	13	13

Source: Office for National Statistics *Deaths related to drug poisoning in England and Wales, 2009*
Figures for deaths registered in 2008 are provisional.

It is assumed that more effective regulation of controlled substances reduces the risk of their diversion into the illicit trade. The Home Office review of licensing in 2008 found that those licensees who had

never received a compliance visit, and the associated advice and guidance on how to comply with legal obligations, represented a particularly high risk of diversion.

The illicit trade in controlled drugs and precursor chemicals is international. It is assumed that more effective controls in the UK will contribute towards international efforts to tackle transnational drug markets, which will in turn reduce drugs harms in the UK.

Unfortunately these assumptions cannot be quantified due to the lack of data on the supply of drugs for illegal use. Since illegal dug use is a 'hidden market' there is no effective means of collecting data on it

It is assumed that a reduction in turn-around times for licence applications will be of benefit to business. Consultation respondents specifically mentioned this as a service improvement that they considered important. Delays in processing licences make it hard for business to plan effectively, and make UK businesses less internationally competitive. The Home Office does not possess sufficient data to quantify this benefit.

Administrative Burden calculations:

The ***domestic license*** 'baseline' admin burden was calculated in two steps. Firstly, the volume of new licenses (340 controlled drug and 680 precursor chemical in 2009) was multiplied by the time required to complete the various application tasks (see table E2) and by an average wage of £16.50 (a standard admin burdens assumption). Secondly, the stock of licenses (2,100 in 2009) was multiplied by the time required to complete compliance tasks (see table) and the same average wage. The stock is assumed to remain constant, implying that the 340 new licenses are offset by 340 withdrawals (although in the current regime, companies have no obligation or incentive to formally withdraw a license).

To check sensitivity, a stock growing by 340 licenses per year was also modelled but did not result in a significant increase in the present value costs.

The domestic license admin burden under each option was modelled in the same way, except that the additional tasks (highlighted in **red** in the table) were added to the calculation. Note that the reapplication estimates incorporate the probability of a site visit required, thought to be twice as likely under the biennial system. The additional tasks translate into an annual increase in the admin burden of £90,000 under Option 2 and 4, and £60,000 under Option 3.

The ***import and export license*** calculation was performed in the same way. To calculate the baseline admin burden, the volumes of controlled drug export licenses (8,000 in 2008), controlled drug import licenses (3,500), and precursor chemical import and export licenses (360) were multiplied by the time required to apply for these licenses annually (see table) and by the average wage of £16.50. Volumes are again assumed to remain constant over time.

Under the options, the application tasks are the same for each license type, so the total volume (11,860) was multiplied by the time required to apply under the new IT system (highlighted **red** in the table) rather than the old tasks which are no longer required (highlighted **green** in the table) and the same average wage. Since the new process is less time consuming, this translates into an admin burden saving of £225,000 per year.

For the biennial option (3), the calculations were the same but based on the relevant tasks in the table below and on the assumption that *half* the stock of licenses would be reapplied for each year. This represents a simple method for modelling biennial rather than annual applications. To test sensitivity, a more complex method was modelled in which the entire existing stock would have to reapply in 2010 and every two years thereafter. Modelling the admin burdens in this way made no significant difference to the final result.

Table E2. Admin Burden Assumptions – *estimates derived from consultation responses supplemented with DLCU operational knowledge where necessary*

Task	Time (hrs) – Current	Time (hrs) - Options
To apply for a new domestic licence		
Complete online application form	3.4	3.4
Submit application fee payment	-	0.25
Apply for CRB check	3.1	3.1
Site visit	7.9	7.9

Any further actions	18.9	18.9
Email to confirm follow up actions completed	1	1
Possible second site visit	4	4
To comply with licence conditions during the life of a licence		
Complete annual statistic return	32	32
Complete Annual Statement of Compliance	2.5	2.5
Report thefts and losses	0.25	0.25
Report any changes of personnel, company name, etc	0.5	0.5
After 1 year, re-apply.	-	2.8*
Submit application fee payment	-	0.25
Biennial re-application, including site visit	-	3.6†
To apply for CD export licences		
Complete application form in hard copy alongside original import permit document.	1.6	-
Apply online using form and submit application fee payment	-	0.45
To apply for CD import licences		
Email completed MS Word application form.	1.6	-
Apply online using form and submit application fee payment	-	0.45
To apply for Precursor import and export licences		
Submit completed hard copy application form.	1.5	-
Apply online using form and submit application fee payment	-	0.45

*Option 2 and 4 (annual reapplications) only.

†Option 3 (biennial reapplications) only.

Timing:

It has been assumed that the policy will be in place for 6 months of the financial year 2010/11. Therefore costs and benefits which accrue regularly throughout the year have been halved for the 2010/11 estimates. In addition, it has been assumed that it will take approximately 18 months until the whole stock of domestic license holders has completed application for a license under the new conditions. Therefore the full costs (administrative burden) and benefits (receipt of fee) will not reach their maximum until 2012/13.

How will the new measures improve services for licensees and protect the public from harm?

Fees will fund two new measures that will both improve services for licensees and protect the public from harm by reducing the risk of diversion:

- an increase in the number of Compliance Officers
- a new IT system

Compliance Officers

Compliance Officers provide advice and guidance to licensees to help them meet their legal obligations, in particular providing advice as to how to meet minimum requirements for:

- Safe custody and site security
- Standard Operating Procedures
- Record keeping and audit

This advice is provided both on-site, at the time of a compliance visit, and on an ad hoc basis in response to telephone and email enquiries.

An increase in the number of Compliance Officers will:

2. Improve the turnaround time for new controlled drug domestic licence and precursor chemical licence and registration applications. At present, due to the low number of Compliance Officers, controlled drug domestic licence applications are taking approximately 16 weeks to process. Because there are more applications than the current complement of Compliance Officers can manage, applications must wait for a Compliance Officer to become available to conduct a compliance visit. Once more Compliance Officers are in place, the turn-around time for domestic licence applications, for which all relevant information has been received, will be significantly reduced. This is likely to improve productivity and profitability in the controlled drug and and precursor chemical markets.

3. Improve the availability of expert advice and guidance to all licensees. The current complement of Compliance Officers cannot provide the level of service desired by some licensees, and, because of the volume of queries they receive from licensees, are unable to deal effectively with all of them. Improved availability will reduce inefficiencies in the process and reduce the risk of diversion occurring through negligence or lack of knowledge of best practice.

4. Provide an appropriate level of oversight of less compliant and higher-risk licensees to ensure that they meet their legal obligations. This will reduce the risk of diversion that was uncovered following the review of the self-regulation approach in 2008/9.

The new IT system

DLCU is procuring the National Drug Control System (NDS) from the United Nations Office of Drugs and Crime. NDS is already used by over 40 countries around the world to manage their drugs licensing operations. NDS will allow:

- Licensees to make applications for import and export licences online for the first time, and remove the need for them to calculate the drug base weight of the preparations they are shipping. This, currently, is the most time consuming aspect of the application. Therefore the administrative burden will be reduced.

- DLCU to process import/export licence applications more efficiently, keeping the turn-around time to a minimum. Under the current licensing system there is a very low level of resilience. Even comparatively small increases in the volume of applications, changes in staff availability, or changes to process requirements, can cause very significant increases in the turn-around time of import/export licences. This can have serious ramifications for licensees, many of whose businesses depend upon being able to ship goods to overseas customers on time. Therefore productivity and profitability is likely to be increased.

- DLCU to risk-assess import/export licence applications more robustly, with IT-enabled built-in checks on applications. This will reduce the risk of diversion.

Option 1: No change – no fees introduced for any licence

Costs & Benefits

- No additional costs or benefits from Option 1.
- This option is a continuation of the status quo; hence the current risk of diversion and consequent drug misuse will remain.

Option 2 – Introduce charges for all controlled drug and precursor chemical licences with validity of one year for domestic licences and registrations

Policy Costs

- Licensees will have to pay for licences that they have previously received for free, amounting to around **£2.8million** per annum.
- A charge, like a tax, alters the natural market equilibrium and brings about a net loss to society known as 'deadweight' – a reduction in the overall benefit to consumers and producers derived from the market. The scale of this loss is dependent on the structure of demand and supply in the markets affected by fee introduction. Sufficient data to estimate this structure is unavailable so it has not been possible to quantify the cost of deadweight.
- No behavioural response, i.e. changes in the stock or composition of license holders resulting from increased costs, has been modelled as it is assumed that costs would be offset by the improved service received.
- Additional DLCU running costs resulting from this option will total around **£1.1m** per annum, primarily on staffing costs (extra Compliance Officers and licence processing staff).
- Introduction of the new IT system will cost an additional **£0.4m** per annum

Administrative Burdens

- Controlled drug domestic licences, and precursor chemical licences and registrations, will have to be renewed annually. Compliance visits would only be required on a risk-assessed basis, with the great majority of renewals being processed through a light-touch document-based application process. This will result in an increased administrative burden on companies estimated to total **£90,000** per annum based on the assumption that each licence or registration renewal will entail 2 hours of work for the licensee plus 10 minutes to pay the fee and 4 hours preparing for a site visit for the 10% of licensees estimated to need one.
- No firm knowledge of the change in the total stock of license holders over time is available; therefore the stock was assumed to *remain constant* at its 2009 level. A more complex approach whereby the stock grows each year by the number of new licenses in 2009 was also tested but was not ultimately adopted since it made little difference to the final figures.
- Standard assumptions relating to average wage and time required to complete administrative tasks were followed for the admin burden estimate but *no economies of scale* (for example, time saved as a result of performing multiple tasks at the same time) were assumed for multiple license holders, so the estimate is *conservative* in that regard.

TOTAL COSTS

- Total quantifiable costs come to **£4.4m** per annum, or **£34.5m** over 10 years discounted according to standard Green Book practice.

Policy Benefits

- DLCU gains **£2.8m** per annum in revenue from the charge
- Increased numbers of Compliance Officers will be able to provide greater levels of support and guidance to licensees, to help them comply with their legal obligations. This benefit is not quantifiable.
- Shortened turn-around times for licence applications will benefit business in terms of productivity and profitability. This benefit is not quantifiable.
- A fee may discourage speculative applications, freeing up Home Office resources to concentrate on bona fide licence applicants. Assuming that 50% of DLCU time is spent processing licenses, it is estimated that a monetary benefit of up to **£35,000** per annum may accrue. This benefit is small in comparison to other components of the measure so sensitivity to this assumption is low.
- There is an increase in 'fairness' resulting from the charge since licensing costs will be apportioned to those who derive benefit from possessing a licence rather than the taxpayer. This is not quantifiable.

- This option is expected to reduce the risk of diversion and subsequent misuse of substances due to the introduction of annual licence renewals, and greater number of compliance officers. The total cost of Class A drug misuse alone was estimated in 2003/4 to be £15.4bn of which £1.4bn was related to health costs and deaths and £14bn to crime costs. As an illustration, in order to offset the negative value of the quantifiable outcomes listed above, the policy would only have to reduce *health*-related harms by 0.1% per annum, or *crime*-related harms by 0.01% per annum[5].

Administrative Savings

- The new IT system is expected to result in an administrative burden saving of **£225,000** per year. This is based on the assumptions that import/export applications will now take around 5 minutes less than under the old system.

TOTAL BENEFITS

- Total quantifiable benefits come to **£3.1m** per annum, or **£23.4m** over 10 years discounted according to standard Green Book practice.

Option 3 – Introduce charges for all controlled drug and precursor chemical licences with validity of two years for domestic licences

Policy Costs

- As for option 2 above.

Administrative Burdens

- As option 2 above, but licences would be renewed biennially. The admin burden would be less than under option 2 although twice as many site visits are predicted to be required (in 20% of cases under biennial renewals, 10% of cases for annual renewals). Compliance visits would be needed in a larger number of cases because of the length of time that had elapsed since the last compliance check. This will result in an increased administrative burden on companies estimated to total **£60,000** per year.

TOTAL COSTS

Total quantifiable costs come to **£4.4m** per annum, or **£34.2m** over 10 years discounted according to standard Green Book practice.

Policy Benefits

- As for option 2 above.

Administrative Savings

- As for option 2 above.

TOTAL BENEFITS

Total quantifiable benefits come to **£3.1m** per annum, or **£23.4m** over 10 years discounted according to standard Green Book practice The risk of diversion of controlled substances is greater under this option than under option 2 due to the less frequent contact higher risk licensees would have with DLCU.

Option 4 – Re-introduce charges only for those licences that were charged for in the past, i.e. controlled drug domestic licences only

Policy Costs

These are equivalent to options 2 and 3 above except that:

- The amount of fees revenue raised would be approximately **£2million**, as fees would only be raised to cover the cost of the work required to cover controlled drug domestic licensing.
- Any deadweight loss resulting from the charge would only apply to controlled drug domestic licensees, and would be smaller in total than under options 2 and 3.

[5] Although the cost of Class A drug misuse in 2010/11 might be different from the 2003/04 estimate, it is unlikely that these 'break even' percentages would be significantly different.

Administrative Burdens

- As options 2 and 3 above, but the administrative burden of making a payment would only fall on controlled drug domestic licensees, not on precursor chemical licensees and registrants.

TOTAL COSTS

Total quantifiable costs come to **£3.6m** per annum, or **£28.4m** over 10 years discounted according to standard Green Book practice

Policy Benefits

These are equivalent to options 2 and 3 except that:

- Fees revenue would only be able to fund an increased number of compliance officers to work on controlled drug domestic licences. Precursor chemical licensees and registrants would not benefit as to use the new compliance officers on precursor chemical work would result in cross-subsidisation, whereby controlled drug domestic licensees would be funding the work on precursor chemical licensees. Such cross-subsidisation is not allowed under HM Treasury fees policy.
- Resources would only be available to fund improvements in the service for controlled drug domestic licensees. Licence turn-around times for all other work (controlled drug import and export licences, precursor chemical licences, registrations, and import/export authorisations) would not improve.
- The benefit from a reduction in speculative applications would only apply to controlled drug domestic licence applications and this is estimated to be of minimal monetary value.
- The increase in "fairness" would only apply to controlled drug domestic licences. All other licensing work would continue to be funded by the general taxpayer.
- The reduction in the risk of diversion would only apply to controlled drug domestic licences. The risk of diversion in the import and export of controlled drugs, and all activities relating to precursor chemicals, would not be addressed.

Administrative Savings

- None.

TOTAL BENEFITS

Total quantifiable benefits come to **£2m** per annum, or **£15.2m** over 10 years discounted according to standard Green Book practice

Comparison of likely licence fee costs on companies

Table E2 below shows the likely annual licence fee payments required under the four options by four 'typical' companies.

- Company A: a multi-site pharmaceutical manufacturer. Company A holds licences to produce schedule 2, 3 and 4 part 1 preparations at three different sites. It uses 500 export licences per annum.
- Company B: a small pharmaceutical Research and Development company. They hold a licence for a single site to possess controlled drugs in schedules 2 and 3.
- Company C: a large chemical trader, holding a precursor chemical category 1 licence for one site, and a category 2 registration for another. It uses 300 export licences per annum.
- Company D: a small fragrances manufacturer. It holds a single category 2 registration.

	Option 2	Option 3	Option 4
Company A **Multi-site pharmaceutical manufacturer and**	3 x controlled drug "possess" renewals @£326 each= £978 500 x export licences	3 x controlled drug "possess" biennial renewals @£326 each= £978, annualised=£489.	3 x controlled drug "possess" renewals @£326 each=£978 No fee for export

exporter	@£24 each= £12,000 **Total: £12,978**	500 x export licences @£24 each= £12,000 **Total: £12,489**	licences. **Total: £978**
Company B **Pharmaceutical R&D**	1 x controlled drug "possess" renewal @£326 **Total: £326** If Company B was risk assessed as requiring a compliance visit with the renewal, the fee would be **£1,371**	1 x controlled drug "possess" biennial renewal @£326, annualised=£163 **Total: £163** If Company B was risk assessed as requiring a compliance visit with the renewal, the fee would be £1,371, annualised= **£686**	1 x controlled drug "possess" renewal @£326 **Total: £326** If Company B was risk assessed as requiring a compliance visit with the renewal, the fee would be **£1,371**
Company C **Large chemical trader**	1 x category 1 licence renewal @£326; 1 x category 2 registration renewal @£109. 300 x export authorisations @£24 each= £7,200 **Total: £7,635**	1 x category 1 biennial licence renewal @£326, annualised= £163; 1 x category 2 registration renewal @£109, annualised=£55 300 x export authorisations @£24 each= £7,200 **Total: £7,418**	No fee for precursor chemical licences or registrations. **Total: £0**
Company D **Small fragrance manufacturer**	1 x category 2 registration renewal @£109 **Total: £109** If Company D was risk assessed as requiring a compliance visit with the renewal, the fee would be **£1,153**	1 x category 2 registration renewal @£109, annualised=£55 **Total: £55** If Company D was risk assessed as requiring a compliance visit with the renewal, the fee would be £1,153, annualised= **£577**	No fee for precursor chemical licences or registrations. **Total: £0**

F. Risks

Option 1 – Make no changes (do nothing)

- The Home Office is unable to introduce necessary changes to the licensing regime due to lack of funding. This risk is greater now than in the consultation stage impact assessment given the financial climate that all government departments are now operating in. There is now a significant risk that the Home Office will be unable to maintain current levels of customer service and regulatory control due to budget constraints.
- The Home Office will continue to deal with speculative applications, taking resources away from bona fide licensees

- Providing licences for free may lead to a perception that licences are of little value, and this may in turn lead to lower levels of compliance. There was evidence of this attitude amongst a minority of licensees during the 2008/9 review.

Option 2 – Introduce charges for all controlled drug and precursor chemical licences with validity of one year for domestic licences and registrations

- There is a risk, estimated to be relatively low since there have been fees in the past for controlled drug licences, that the licence fee may deter applicants who should have a licence from applying for one.
- There is a risk that the fee, and the increased admin burden, may result in companies with marginal profits leaving the industry with possible ramifications for those sectors in which their licensed substances are employed. This risk is difficult to estimate with certainty as licensees may respond differently to the additional cost in different ways, but given the low cost of licence renewal, it is estimated to be a low risk.
- The administrative burden of paying a fee and making annual licence renewal applications may not be sufficiently compensated for by an improved service to licensees through the provision of online application forms, an increase in the number of Compliance Officers, and improved turn-around times for applications. The level of this risk will vary between licensees, as the impact of improvements may vary depending upon the activities undertaken by licensees (e.g. an improvement in turn-around times for import/export licences will only be of benefit to those licensees who import or export, whereas an improvement in turn-around times for domestic licences will benefit all licences).
- The impact of the new system on reducing the risk of diversion and consequent substance misuse may be minimal.

Option 3 – Introduce charges for all controlled drug and precursor chemical licences with validity of two years for domestic licences

- As for option 2, but, due to the slightly lower admin burden at the licence renewal stage, the risk of companies with marginal profits leaving the industry is also lower.
- Due to the lower level of oversight provided by a biennial renewal regime, there is a greater risk that the impact of the new system on reducing the risk of diversion may be minimal than under option 2.

Option 4 – Re-introduce charges only for those licences that were charged for in the past, i.e. controlled drug domestic licences only

As for Option 2 plus:

- A system whereby precursor chemical licences are free when controlled drug licences are charged for may lead to the perception that precursor chemical licences are not taken seriously by the Home Office and are not of value. This may lead to either an increase in speculative applications and/or a lessening in compliance levels by precursor chemical licensees. There was evidence of this attitude amongst a minority of licensees during the 2008/9 review.
- A system whereby import/export licences are free when all other licences are charged for may lead to the perception that import/export licences are not of value. This may lead to an increase in speculative applications, and/or a lessening in compliance. This is estimated to be a relatively low risk as most users of import/export licences are well established licensees.

G. Enforcement

This policy will be enforced by the Home Office's Drugs Licensing and Compliance Unit.

Fees for controlled drug domestic licences and precursor chemical licences and registrations will be charged at point of application. Licences will not be issued if the fee is not paid.

Fees for controlled drug import and export licences, and precursor chemical import and export authorisations will be charged in arrears, on a quarterly basis. Due to the high volume of imports

and exports it would be impractical for both licensees and the Home Office for the fee to be paid at point of application.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	Charge to licensees: £2.8m/year Additional DLCU costs: £1.1m/year IT system: £0.4m/year Admin burden increase: £0.1m 'Deadweight': (not quantified)	Charge taken by DLCU: £2.8m/year Admin burden decrease: £0.2m Reduction in speculative applications: neg Improved service provided: (not quantified) Reduced risk of diversion: (not quantified)
	Total: £4.4m/year	**Total: £3.1m/year**
3	Charge to licensees: £2.8m/year Additional DLCU costs: £1.1m/year IT system: £0.4m/year Admin burden increase: £0.1m 'Deadweight': (not quantified)	Charge taken by DLCU: £2.8m/year Admin burden decrease: £0.2m Reduction in speculative applications: neg Improved service provided: (not quantified) Reduced risk of diversion: (not quantified)
	Total: £4.4m/year	**Total: £3.1m/year**
4	Charge to licensees: £2.0m/year Additional DLCU costs: £1.1m/year IT system: £0.4m/year Admin burden increase: £0.1m 'Deadweight': (not quantified)	Charge taken by DLCU: £2.0m/year Improved service provided: (not quantified) Reduced risk of diversion: (not quantified)
	Total: £3.6m/year	**Total: £2.0m/year**
Source:		

The Government's preferred option is option 2. It is the preferred option because:

- It generates fee revenue sufficient to improve services for both controlled drug and precursor chemical licensees.
- It generates fee revenue sufficient to strengthen the regulatory regime and thereby reduce the risk of diversion of controlled substances into the illicit trade, contributing to the reduction of drugs harms both within the UK and internationally.
- It introduces an appropriate level of control on compliance through the annual renewal process. The frequency of renewals will be subject to review after 2 years to ensure that the benefits of greater oversight justify the slightly greater admin burden caused by annual renewals, as opposed to biennial renewals.
- The administrative burden imposed is relatively small, particularly for compliant, low risk licensees who will see their licence renewals dealt with under a light-touch application process.
- Although the monetised costs and benefits for this option are negative, the benefits of faster licence turn-around and reduced risks of diversion have not been monetised. When these are taken into account, it is considered that the true impact of this policy will be positive, with the benefits outweighing the costs.

I. Implementation

The Government plans to implement these changes in November 2010.

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by DLCU and will be subject to an annual review shared with HM Treasury. The frequency of renewal applications (and thus the duration of licences) will be subject to review 2 years after the policy has been implemented.

K. Feedback

DLCU will seek the feedback of licensees when it conducts its Post Implementation Review of this policy (see Annex 1) below.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added to provide further information about non-monetary costs and benefits from Specific Impact Tests, if relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their actual costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review]; To review fees policy
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] To check that the fees regulations are operating as expected; to ensure that full cost recovery is achieved; to assess the benefits licensees have received through improvements in service; to assess the level of risk of diversion; to assess whether the frequency of licence renewals is set at the right time period.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] The approach for the review will be defined once the policy is launched and a first appreciation of its impacts can be made.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] Performance from October 2008 to October 2010 will form the baseline for the purposes of comparison.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] 1. Increased number of compliance officers. 2. Improved licence-turn around times. 3. Reduced risk of diversion of controlled substances. 4. Full cost recovery.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] Information will be monitored by DLCU.
Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

Annex 2. Specific Impact Tests

Statutory Equality Duties

Equality Impact Assessment

This policy was screened for its Equality Impact on the six Home Office equality target areas of race, disability, gender, gender identity, religion and belief, sexual orientation and age. The public consultation document included a question on equality impacts and no responses were received suggesting that there would be any impact on equality for any of the target areas. This policy is not considered to have a disproportionate impact on any target area and therefore no full equality impact assessment has been completed.

Economic Impacts

Small Firms Impact Test

These proposals will affect small businesses. This Small Firms Impact Test sets out how the Government has considered the impact on small- and medium-sized enterprises (SMEs), what SMEs said in response to the consultation document published in March 2010, and the additional options the Government has investigated following the consultation.

A. Industry structure

The Home Office's controlled drug and precursor chemical licensing regimes cover a wide variety of sectors. At an early stage of policy development the Home Office sent a data gathering questionnaire to existing licensees (both for controlled drug and precursor chemicals). About 70 responses were received. Of the respondents:

- 16% were micro businesses (less than 10 employees)
- 19% were small businesses (10 - 49 employees)
- 24% were medium-sized businesses (50 – 249 employees)
- One respondent was a social enterprise.

The public consultation document had a question specifically aimed at SMEs which was answered by 36% of respondents.

Whilst we do not have precise figures, it is clear that a significant proportion of licensees are SMEs.

Measures of the number of employees alone do not show the diversity of SME licensees. The data gathering questionnaire also asked for information on turnover and the annual revenue licensees generate from their use of controlled drugs and/or precursor chemicals.

- 21 SME respondents gave annual turnover figures. They ranged from £63,000 p/a to £26million p/a, with a median of £4.85million.
- 15 SME respondents gave figures for annual revenue generated from work using controlled drugs or precursor chemicals. This ranged from £500 to £11.75million, with a median of £43,000.

It is clear that, whilst a significant number of respondents fall within the industry definition of an SME by employee headcount, a number of these businesses have a significant financial turnover and would not qualify for SME status by this measure.

B. Consultation to date

A full public consultation was launched in March 2010. The Home Office contacted all licensees to invite them to reply, and also invited responses from other interested parties such as trade associations. The consultation asked SMEs if they considered the proposals to fall disproportionately heavily on them, and asked for suggestions for alternative solutions. Of about 90 responses received, 33 respondents (36%) answered the question. The Home Office also received responses from trade associations representing large numbers of SMEs in the chemicals sector. One trade association gave figures for its SME representation. 92% of its membership were SMEs, of which:

- 8% were micro businesses (less than 10 employees)
- 38% were small businesses (10 - 49 employees)
- 46% were medium-sized businesses (50 – 249 employees)

The key theme from the responses from SMEs are discussed below. Full details of the consultation responses can be seen in the Consultation Response Document, available on the Home Office website. The Home Office has worked closely with the Better Regulation Executive in the Department for Business, Innovation and Skills and HM Treasury to develop its proposals.

C. Options

Option 1 – No change (do nothing)

This option would not have any disproportionate impact on SME licensees.

Since the consultation document was published it has become clear that the Home Office budget will be under tight constraints for at least the duration of this parliament. If fees revenue is not available there is a real risk that drugs licensing would see a significant decline in service standards caused by lack of resources. This decline in service would have a negative impact on SME licensees as delays in licence issuance would adversely affect their ability to carry out business and have a negative effect on turnover.

Option 2 – Introduce fees, limit the validity of licences to 1 year

This option would re-introduce fees for controlled drug domestic licences; and introduce them for the first time for controlled drug import and export licences, and precursor chemical licences, registrations, and authorisations. All licences will have a time limited validity of 1 year. Open-ended licences will be revoked and replaced with annual licences.

SME respondents to the consultation suggested that this option would have a disproportionate impact on their businesses as the cost of the fee would be proportionately higher for them than it would be for a larger business.

Option 3 – Introduce fees, limit the validity of licences to 2 years

This option would re-introduce fees for controlled drug domestic licences; and introduce them for the first time for controlled drug import and export licences, and precursor chemical licences, registrations, and authorisations. All licences will have a time limited validity of 2 years. Open-ended licences will be revoked and replaced with biennial licences.

SME respondents to the consultation suggested that this option would have a disproportionate impact on their businesses as the cost of the fee would be proportionately higher for them than it would be for a larger business.

Option 4 – Introduce fees for controlled drug domestic licences only

This option would re-introduce fees for controlled drug domestic licences only. This would result in improved service for these licenses only. All other licence types (controlled drug import/export licences, and precursor chemical licences, registrations and authorisations) would be likely to see a diminution of service as they would be funded from the Home Office budget, which is likely to face tight constraints for at least the term of the current parliament.

SME controlled drug domestic licensees would face a fee whereas SME precursor chemical licensees would not.

D. Additional options considered for SMEs

SME respondents to the public consultation suggested that SMEs should be either exempted from fees entirely or helped in some way so that the impact upon them was not disproportionate. Five options were considered: (a) public subsidy for SME licensing, so the taxpayer pays for the service rather than the SME; (b) cross-subsidy within the fee structure, so that larger businesses would pay for the licensing of SMEs; (c) de-regulation SMEs so that the regulatory and administrative burden is lighter, and the fee is made smaller; (d) tapering fees so that SMEs paid less; (e) relaxing payment requirements for SMEs to ease cashflow problems.

(a) Public subsidy for SME licensees

Under this option, the cost for licensing SMEs would be paid by the general taxpayer through a public subsidy, rather than the SME that actually receives the licence.

Fees are set according to the principles set out in HM Treasury guidance (*Managing Public Money*). Fees must be set to recover the full cost of providing the service. If the work done to provide licences for SME licensees is not funded by the SMEs themselves, it would have to be funded through a public subsidy from the budget of a government department – ultimately funded by the general taxpayer.

Table D1. Pros and Cons of public subsidy	
Pros	***Cons***
SMEs would be exempt from fees, lessening the regulatory burden they face in the form of fee costs	The general taxpayer would be fund a service that should be paid for by the recipient who receives the direct benefit of the service.
SMEs would also make a small administrative burden saving through not having to make a payment	The Home Office budget will be tightly restricted for at least the duration of the current parliament. There is no spare capacity to fund the license fees of SMEs.
	No other government department offered to fund SME licences from within its budget
	There would be an additional administrative burden, for both Government and licensees, in determining which licensees are SMEs and who would therefore qualify for the public subsidy
	SMEs may get an unfair competitive advantage over non-SMEs

(b) Cross-subsidy from larger businesses

A related option also considered would be to fund SME licensing through a cross-subsidy within the fees structure, whereby larger companies pay for SME licensing through their licence fees.

The Home Office budget is being reduced and does not have the capacity to pay for the licensing of SMEs. No other government department offered to fund licences for SMEs,
meaning that this public subsidy option could not be pursued further.

Table D2. Pros and Cons of cross- subsidy	
Pros	***Cons***
SMEs would be exempt from fees, lessening the regulatory burden they face in the form of fee costs	HM Treasury guidance advises strongly against cross-subsidies (whereby one group of fee payers subsidies another group) in fees regimes as they may foster wasteful or inefficient patterns of consumption.
SMEs would also make a small administrative burden saving through not having to make a payment	There was no apparent justification for making large licensees pay the costs of SMEs.

(c) De-regulation of SME licensees

The Government explored options for de-regulating the licensing of SMEs. The licensing regimes for controlled drugs and precursor chemicals are both the result of international obligations under UN conventions (the UN Single Convention on Narcotic Drugs 1961 and the UN Convention on Psychotropic Substances for controlled drugs, the UN Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988 for precursor chemicals). Obligations under these conventions are put into effect through domestic law for controlled drugs, in the form of the Misuse of Drugs Act 1971 and the

Misuse of Drugs Regulations 2001. They are put in place through EC regulations for precursor chemicals (regulations [EC] No 273/2004, [EC] No 111/2005, and [EC] No 1277/2005).

Table D3. Pros and Cons of de-regulation	
Pros	***Cons***
SMEs would be exempt from fees, lessening the regulatory burden they face in the form of fee costs	The current licensing regime does not go beyond the United Kingdom's core international obligations. SMEs, therefore, could not be de-regulated without contravening those international obligations.
SMEs would face a lower administrative burden in general, as the level of regulation dropped	SMEs have <u>not</u> been found to be lower risk than larger businesses, so there is no justification for de-regulating on the basis of risk-assessment.
	De-regulating SMEs alone would give SMEs a competitive advantage over other licensees
	Determining the cut-off point between SMEs who qualify for de-regulation, and other licensees who do not, would in itself constitute an administrative burden for both Government and licensees.

<u>(d) Fee levels related to turnover or number of employees</u>

Consultation respondents suggested that the fee level should be related to the size of the licensee's business. Under this option the fee level would be directly related to the size of the business paying the fee, with micro businesses paying the smallest fee, and small and medium-sized businesses paying proportionately more.

Table D4. Pros and Cons of fees related to size of business	
Pros	***Cons***
SMEs would pay a lower fee, lessening the regulatory burden they face in the form of fee costs	Following HM Treasury guidance, fees are calculated on the basis of the amount of Home Office resource that is absorbed in processing each type of licence, registration, or authorisation. The size of the business does not determine the amount of resource absorbed in processing a licence. This approach would not be consistent with HM Treasury policy which binds the setting of fees levels.
The impact of fees on SMEs would be directly proportionate to their size	The fees revenue raised from SMEs would not cover the cost of providing the licensing service for these licensees. This would mean that a public subsidy or a cross-subsidy

	would be required to make up the difference (see options [a] and [b] above)
The Government would gain some fees revenue to help fund improvements in service for all licensees (albeit at a lower rate than if the fees were not tapered in this way)	

(e) Flexible payment schedule for small businesses

The Government considered an option to make it easier for SME licensees to pay their fees. As cash flow can be a particularly difficult problem for small businesses their licence fee payments could perhaps be deferred, or paid by instalments. This would help small businesses adapt to the new fees regime. For example, if fees could be paid in 12 monthly instalments, an SME renewing a category 1 precursor licence would pay just £27 a month. An SME moving into the controlled drug field for the fist time would be able to pay £261 a month over the course of the year for a licence to possess controlled drugs, rather than having to find £3,133 up front.

Table D5. Pros and Cons of a flexible payment schedule

Pros	***Cons***
Small businesses get help to adjust to the introduction of fees	Spreading payments across 12 months is a greater administrative burden for the Home Office than single payments
Cash-flow problems are mitigated as the payment schedule is flexible to suit the needs of the licensee.	Deferred payments may increase the risk of bad debts.
	There may be difficulties aligning payment in instalments with government accounting rules.

Government proposal

Having considered the pros and cons of each of the options the Government proposes to further explore option (e), a flexible payment schedule for small businesses. The Home Office would welcome further feedback from small businesses on which sorts of payment flexibilities would help. This approach has been taken because:

- it would help small businesses adjust to the new fees regime
- it would help small businesses with cash flow difficulties
- it would maintain the principle that the direct recipient of the service should pay for it, without cross-subsidy or public subsidy
- it would ensure that the Home Office continues to regulate SME licensees in line with the United Kingdom's international obligations