Home Office

Oxycodone Import Policy
Second Consultation

September 2014

Contents

Consultation Summary

Scope of the consultation

Topic of this consultation:

Second consultation on the Government's policy on the import of oxycodone to the UK.

Scope of this consultation:

On behalf of the Government, the Home Office is reviewing the existing policy on the import of oxycodone to the UK. A first consultation was held between November 2009 and February 2010. The purpose of this second consultation is to present two additional policy options for the licensing of imports of oxycodone in the UK alongside the options first proposed in 2009.

Geographical scope:

This import policy applies to Great Britain. However, licensing for imports into and exports from Northern Ireland would be carried out by the Home Office on behalf of the devolved administration.

Impact assessment (IA):

A consultation stage impact assessment has been prepared and is at annex A.

Basic Information

To: we are particularly keen to hear from businesses or organisations directly involved in the trade in, and/or manufacture of, oxycodone and those involved in issues around drug misuse.

Duration: This consultation was published on 25 September 2014. It will close on 20 November 2014.

The consultation is taking place online at the following link:

http://www.homeofficesurveys.homeoffice.gov.uk/s/OxycodoneImportPolicyConsultation

Additional ways to become involved: This consultation concerns a largely technical issue of specialist interest. For this reason the consultation will be a purely written exercise through an online portal.

After the consultation: A summary of responses will be published before or alongside any further action. Implementation of the proposed policy will take place as early as possible, subject to comments received in response to this consultation and the views of ministers across Government.

Enquiries
If you have any queries regarding the consultation or your proposed response, please contact the Drugs and Firearms Licensing Unit on the following email address:

Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk

Getting to this stage:

The policy proposals outlined in this consultation document have been developed to reflect responses to the first consultation.

Details of the current regulatory regime can be found in the Background section of this consultation document.

Previous engagement:

The Home Office conducted a first consultation on the policy on the import of oxycodone into the UK between November 2009 and February 2010.

The Monopolies and Mergers Commission and the Office of Fair Trading conducted reviews of the trade in opium derivatives in the UK in 1989 and 2006 but without a specific focus on oxycodone:

"*Opium Derivatives: A report on the matter of the existence or possible existence of a monopoly situation in relation to the supply in the United Kingdom of opium derivatives",* Monopolies and Mergers Commission, April 1989.

"*Opium derivatives - a review of the undertakings given by Macfarlan Smith Ltd",* Office of Fair Trading, March 2006

https://web.archive.org/web/20061023195805/http://www.oft.gov.uk/News/Publications/Leaflet+Ordering.htm

"*Opium derivatives - Government response to OFT's review of undertakings by Macfarlan Smith Ltd*", September 2006

http://www.berr.gov.uk/files/file33800.pdf

Should you require a copy of this consultation paper in any other format, e.g. Braille, large font, or audio, you should contact the Drugs Licensing and Compliance Unit in the Home Office at the address given above in the Basic Information section.

Please note: the Home Office is not responsible for the content of external sites.

1. Introduction

The Home Office regulates the possession, supply, production and import and export of drugs subject to statutory control under the Misuse of Drugs Act 1971 (the 1971 Act). It does so because of the very serious harm misuse of these controlled drugs can cause to individuals and society.

The Home Office's policy on imports of oxycodone was originally to restrict imports from outside the EEA. In 2008 and following representations from the UK pharmaceutical industry, the Home Office amended that policy to allow oxycodone imports from outside the EEA provided that all imports were re-exported. In 2009 the Home Office took a decision to revert to the previous policy. This was because it was then considered that import for re-export posed an unacceptable risk to the UK's access to diamorphine.

The need to formalise or change this situation informed the Home Office's first consultation, between November 2009 and February 2010, on four policy options for the licensing of imports of oxycodone in the UK. Building on the responses to the first consultation, the Home Office has identified two additional proposals (Options 6 and 7 in the current consultation). The Home Office has also included an option which would maintain the current situation.

After careful consideration the Home Office has decided to launch this second consultation in which:

- two additional options are presented alongside the original four and a further option which would maintain the current situation – all options are high level at this stage; and

- views are invited on whether there is a place for exemptions for specific uses of oxycodone.

The Government's policy on the import of oxycodone is based on two central considerations:

- compliance with the UK's international obligations by: **(a)** minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and **(b)** managing the manufacture and imports of controlled drugs to keep within the UN estimate (see section 2: Background); and

- realising the economic benefits of competition in the UK pharmaceuticals market;

whilst ensuring a supply of pain-relieving drugs is available to meet patient care demand.

2. Background

2.1. Oxycodone

Oxycodone is an opioid analgesic. It is synthesised from thebaine which is derived from opium or 'poppy straw'. Opioids are classified as 'narcotic drugs' under certain UN Conventions (see section 2.2) and oxycodone is controlled in the UK as a 'Class A' drug (it is listed in Part 1 of Schedule 2 to the 1971 Act).

2.2. Legislation and international obligations

Narcotic drugs are subject to statutory control because of the serious harm they can cause to individuals and society as a whole if misused.

The manufacture, supply, import and export of narcotic drugs are governed by the provisions of the United Nations Single Convention on Narcotic Drugs 1961 ("the 1961 Convention"), of which the UK is a signatory state, and the 1971 Act.

The 1961 Convention states that narcotic drugs constitute 'a serious evil for the individual' and a 'social and economic danger to mankind'. At the same time it recognises that these drugs are 'indispensable for the relief of pain'. The aim of the Convention is to limit the use of narcotic drugs exclusively to medical and scientific purposes.

One of the ways in which it seeks to do so is through an estimate system whereby each signatory state provides an annual estimate ("the estimate") of the amount of each narcotic drug that their country will require over a calendar year. The estimate takes account of the amounts acquired through import and/or manufacture in that year. Estimates are submitted to, and approved by, the International Narcotics Control Board (INCB), the independent, quasi-judicial body that monitors UN drugs control conventions. Countries must not exceed their estimate without good reason and prior approval by the INCB. Estimates can be varied in-year following a consultation and scrutiny process with the INCB.

The 1961 Convention requires signatory states to prevent the accumulation of excess controlled drugs in the possession of manufacturers, traders, distributors and others authorised to possess such substances.[1] The 1961 Convention also requires signatories to control these drugs domestically under a licensing regime governing their manufacture and trade, and import and export.[2]

In the UK, the 1971 Act and secondary legislation made under it govern the control of drugs generally. The statutory framework includes a licensing system. Under that system the Secretary of State has discretion to issue licences and to determine any conditions placed upon those licences. The licensing system aims to strike a balance between enabling supply and preventing the misuse of drugs and their diversion into the illicit market by monitoring and regulating their legal, approved and licensed use throughout the supply chain.

[1] The 1961 Convention, Article 29, paragraph 3, and Article 30 paragraph 2.

[2] The 1961 Convention, Articles 29, 30, and 31.

2.3. Diamorphine supply for the UK healthcare sector

Diamorphine, an opiate derivative, is an analgesic used in UK healthcare. Macfarlan Smith Limited (MSL) is understood to be the sole supplier of the raw diamorphine used in making the precise dose ampoules used in the NHS and is thought to be the only viable UK based supplier currently. The Home Office will need to consider the impact of any new import policy on the security of supply to the NHS of diamorphine.

2.4. Restrictions on intra-EU trade

In 1990 a UK pharmaceutical company applied for a licence to import diamorphine from the Netherlands where it was manufactured at the time. This led to a series of legal challenges culminating in the case R v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd in the European Court of Justice (ECJ).

The March 1995 judgment in this case determined that restricting imports from within the European Community would put the UK in contravention of Article 28 of the EC Treaty. Article 28 EC (as it then was – now Art 34 TFEU) prohibited restrictions on imports between member states of what is now the EU.

The court also held that a country could derogate from Article 28 EC under the conditions in Article 30 EC, which allows restrictions on intra-EU trade "*which are justified on grounds of public morality, public order, public safety, the protection of human or animal life or health*".

Therefore, restrictions on imports would be permitted "*if protection of the health and life of humans requires a reliable supply of drugs for essential medical purposes to be safeguarded, and that objective cannot be achieved as effectively by measures less restrictive of intra-Community trade*".[3]

2.5. Changes to import policy following the ECJ ruling

Following this judgment, the Home Office changed its policy in 1997 to allow some import of controlled drugs, including narcotic active pharmaceutical ingredients (APIs), from within the EU. The policy was subsequently expanded to encompass the European Economic Area (EEA).

The Home Office maintained some restrictions on imports, specifically APIs, from outside the EEA to keep international movements of controlled drugs to a minimum in order to reduce the risk of diversion. The measure was also taken to secure the supply of diamorphine. The relaxation of the restrictions on intra-EEA trade was in recognition of the fact that a reliable supply of diamorphine could be maintained alongside free movement of goods within the EEA.

2.6. Office of Fair Trading review (2006)

Following a 1989 report by the Monopolies and Mergers Commission, the Office of Fair Trading (OFT) published a review (March 2006) of the undertaking given by MSL in 1989 to publish and make generally available a list of maximum prices. The report and the review noted the dominant position held by MSL, the UK's sole manufacturer of opium derivatives.

[3] Judgment of the Court 28 March 1995, Case C-324/93 R v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd., Operative Part, paragraph 3.

The OFT review stated that there was a 'competition problem' in the sector. It concluded that the main reason for this was the trading restrictions on opium derivatives stemming from the Government's licensing policy. The OFT report recommended that the Government '*takes into consideration competition issues for the purposes of devising future licensing policy*'. [4]

The Home Office welcomed the recommendation and committed to reviewing the import policy every five years. Review cannot sensibly take place until there is an established policy. The review cycle will start once any new oxycodone import policy is adopted and has become established.

2.7. Import for re-export

In February 2008 the UK pharmaceutical industry requested permission to import oxycodone. The Home Office agreed on the condition that the complete quantity was re-exported. The decision was based on the fact that imports that are re-exported do not have any impact on the estimate as they are not retained in the country.

The Home Office subsequently identified a risk that the estimate may be exceeded if imports for re-export were to replace the domestically manufactured supply that would normally have been exported, and domestic manufacture were to continue at existing levels. Stockpiling of unsold domestically-manufactured oxycodone would lead to a significant rise in levels of oxycodone held in the UK, which would be inconsistent with Article 29 of the 1961 Convention.[5]

The current import policy is as published in response to an FOI request on 15 March 2012:[6]

The four main principles of the policy are (full published policy at chapter 6):

1. Imports for re-export purposes only within the EEA.[7]

2. 'Parallel Imports' whereby EEA sourced Active Pharmaceutical Ingredients (APIs) are packaged or tableted in another EEA country and subsequently imported into the UK. This provision only applies to a handful of companies for whom this practice has been long operational.

3. Small quantities (a small number of grams) of oxycodone that are intended for research purposes only may be imported from anywhere in the world and applications are considered on a case by case basis.

4. 'Personal' imports/exports of oxycodone - containing controlled drugs in line with the pre-existing personal import policy (less than three months supply and/or travel of three months duration.

As with any general policy, this policy is susceptible to exceptions which may be made on reasonable grounds.

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[4] "Opium derivatives - a review of the undertakings given by Macfarlan Smith Ltd", Office of Fair Trading, March 2006 http://www.oft.gov.uk/shared_oft/reports/consumer_protection/oft834.pdf

[5] The 1961 Convention, Article 29 Manufacture states: "…3. The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions

[6] https://www.gov.uk/government/publications/importation-policy-for-controlled-drugs-into-the-uk-with-specific-reference-to-oxycodone

[7] This refers to the import of oxycodone originating in the EEA and being imported from and re-exported to EEA states only.

3. Issues

The Government's policy on the import of oxycodone is based on two central considerations:

- compliance with the UK's international obligations by: **(a)** minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and **(b)** managing the manufacture and imports of controlled drugs to keep within the estimate system; and

- realising the economic benefits of competition in the UK pharmaceuticals market;

whilst ensuring a supply of pain-relieving drugs is available to meet patient care demand.

3.1. Compliance with international obligations

The Home Office considers that the letter and 'spirit' of the 1961 Convention should be followed. This was elucidated in the UN Secretary-General's Commentary on the Single Convention on Narcotic Drugs 1961.[8] It makes clear that minimising international transactions of narcotic drugs is central to the 1961 Convention. The Commentary states that *"[t]he provisions governing imports, exports and the transit of international shipments through third countries were not adopted for economic reasons, but because such international transactions have been considered to constitute particularly dangerous situations in which drugs can be diverted into illicit channels*". It goes on to describe the purpose of the estimate system as being "*to limit to the greatest extent possible the danger that persons engaged in the legal drug trade may divert surplus quantities into illicit channels*".

Finally, the Commentary states that "*in order effectively to carry out such a system of quotas and governmental records, it may be advisable or even essential to keep to a minimum the number of licences of manufacturers and international traders (importers as well as exporters)*".[9]

Therefore, within the context of limiting the use of narcotic drugs exclusively for medical and scientific purposes, it is desirable to minimise international movements of controlled drugs in order to reduce the risk of diversion. As part of that it is right that the Home Office manages the licensing system to ensure that the manufacture and import of controlled drugs stays within the estimate agreed.

[8] Commentary on the Single Convention on Narcotic Drugs, 1961, United Nations Publications, New York, 1973.

[9] Commentary on the Single Convention on Narcotic Drugs, 1961, pages 39, 157, and 264.

3.2. Competition in the EEA pharmaceutical market

The Office of Fair Trading describes competition as "*a process of rivalry between firms seeking to win customers' business. This process of rivalry, where it is effective, has numerous benefits; competition can drive down prices, increase innovation and productivity, and hence increase the quality of products and, more generally, increases the diversity of choice available to customers*".[10] In general, competitive markets are in the public interest, bringing benefits to the UK economy by contributing towards national competitiveness and, in this context, meeting the needs of patient care. Competition is a fundamental objective of the EEA.

The Home Office accepted the OFT's recommendation that it should take competition issues into consideration when devising licensing policy.[11] It is important that, where regulation affects markets, it is operated in a transparent manner. The options in this consultation document would have different levels of impact on competition and have been assessed in this context.

As has already been noted, MSL has over time acquired what may be described as a dominant position in the market for supply of oxycodone in the UK. The existence of a dominant position is not in itself a breach of competition law, but the existence of such a position and how it affects the market may need to be scrutinised to ensure that there is no unlawful impact on competition.

The other aspect of competition that needs to be considered is the possible impact on UK suppliers of oxycodone if changes were made to introduce more competition into the UK market. There would need to be specific consideration of the impact of these changes not being reciprocal with arrangements in other countries with a significant supplier industry.

[10] http://www.competition-commission.org.uk/assets/competitioncommission/docs/pdf/non-inquiry/rep_pub/rules_and_guide/pdf/cc2

[11] The OFT's recommendation was made in Opium Derivatives: A review of the undertakings given by Macfarlan Smith Limited (OFT834), March 2006, paragraph 5.17.

4. Options

The Home Office conducted a first consultation in 2009. It did not find the responses to the four options (Options 2 to 5, now amended, as set out in the table on page 12) in the first consultation sufficiently compelling to adopt any of them at that time.

As part of its response in 2009 one respondent suggested a further option. That suggestion forms the basis of Option 6, one of two additional options developed for this second consultation exercise. Option 7 was developed by the Home Office to take account of as wide a range of interests as possible. The Home Office has also included an option (Option 1) to remain with the current interim system – effectively no change.

The Home Office is inviting views on all seven options. Given the passage of time and changing market conditions since publication of the first consultation, respondents to that consultation may wish to submit further and additional comments on the original options, 2 to 5, or indicate whether their original response still stands.

At this stage, and subject to this consultation, option 7 appears to represent the best balance between the benefits of increased competition and the risks from diversion of oxycodone.

It is important to note that when the options refer to 'within the EEA' this means:

(a) the import comes from an EEA state;

(b) the oxycodone (API) originates in an EEA state whether it is for domestic use or re-export; and

(c) if for re-export, the destination of the re-export is an EEA State.

Option	Description	Effect/s
1	No change – maintain interim policy	- Imports of oxycodone will only be allowed in accordance with the current interim policy.
2	Restrict imports from outside the EEA	- Imports of oxycodone will be allowed from within the EEA for any purpose (subject to INCB estimates). - Only if oxycodone is not available from within the EEA will imports from outside the EEA be allowed for re-export or any other purposes (subject to INCB estimates).
3	Allow limited imports from outside the EEA under a UK defined quota system (to be determined)	- Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). - Imports will be allowed from outside the EEA in addition (subject to a UK defined quota) and will not be limited to re-export.
4	Allow unrestricted imports from outside the EEA	- Imports of oxycodone will be allowed from anywhere in the world for any purpose; and - The INCB approved estimate will be the only limit on imports.
5	Allow imports from outside the EEA for re-export	- Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). - Imports from outside the EEA will be allowed from outside the EEA for re-export purposes only. There will be no restriction on quantities.
6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	- Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). - Imports from outside the EEA will be allowed for any purpose, including for re-export, but only if there is inadequacy of supply or supplier in the EEA.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	- Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). - Imports will only be allowed from outside the EEA for any purpose other than for re-export, if there was inadequacy of supply or competition within the EEA. - Imports from outside the EEA for the sole purpose of re-export outside of the EEA will be allowed irrespective of whether there are adequate supply or suppliers within the EEA. Imports for consumption within the UK, whether all or part of a shipment, would not be permitted.

5. Exemptions and questions

5.1 Exemptions

Where oxycodone imports are restricted, the Home Office considers it may be appropriate to include in its new import policy a small number of exemptions for the import, from anywhere in the world, of oxycodone for specific, thematic use. Such use might include, for example:

- clinical trials; and
- research.

The Home Office is therefore keen to hear respondents' views on:

- whether exemptions for certain uses would be appropriate;
- whether uses other than use for clinical trials and research should be considered; and
- what quantity limits might be appropriate for each such use.

5.2 Questions

The Home Office has a number of more general questions that it would welcome respondents' views on:

- what the retail/wholesale price difference between oxycodone from UK/EEA/outside EEA is;
- if the market was opened up to EEA/outside EEA, what proportion of the UK market would be imported and what proportion domestically sourced;[12]
- whether oxycodone manufacture would remain profitable for UK firms if the market was opened up to EEA/outside EEA (please provide justification for your response);
- whether there is room for innovation in the UK oxycodone market and, if so, whether opening the market to foreign imports could help to achieve this;
- whether oxycodone manufacture, export and import can be considered in isolation or, whether, given the limited sales volume in the UK, that parallel manufacture of other pharmaceuticals or intermediate products is necessary for economic viability; and
- whether widening the import and export markets could encourage more UK companies to enter the oxycodone market.

(See section 7 for information on confidentiality)

[12] 100% is domestically sourced currently

6. Interim import policy
(published on 15 March 2012 as an FOI response)

The UK will allow the import of oxycodone from within the EEA for re-export only. Small amounts may be imported from worldwide locations for research purposes.

Background

In February 2008 the Home Office agreed to a request from the pharmaceutical industry to import oxycodone from outside the EEA on the condition that the complete quantity was re-exported. This decision was based on the fact that imports that are re-exported do not have any impact on the estimate. This is because any increase in stocks through imports is balanced out by the re-exports.

Subsequently the Home Office identified a risk that the estimate may be exceeded if imports were to replace domestically manufactured supply, and domestic manufacture were to continue at existing levels. This would lead to a significant rise in levels of oxycodone in the UK as unsold domestically-manufactured oxycodone was stockpiled. Further, the accumulation of excess narcotic drugs would run counter to Article 29 of the 1961 Convention.

Current position

We currently permit the following:

1. Imports for re-export purposes only within the EEA.

2. ‘Parallel Imports’ whereby EEA sourced Active Pharmaceutical Ingredients (API’s), are packaged or tableted in another EEA country for subsequent import to the UK. This provision only applies to a handful of companies for whom this practice has been long operational; we do not propose to increase the numbers of companies whilst the consultation remains unconcluded.

3. Small quantities (a small number of grams) of oxycodone that are intended for research purposes only, may be imported from anywhere in the world and applications are considered on a case by case basis.

4. ’Personal’ imports/ exports of oxycodone - containing CDs in line with the pre-existing personal import policy (less than three months supply and/or travel of three months duration). Our response to the oxycodone consultation will be available shortly. Until such time, however, this interim policy remains in force and we will not consider granting any imports/ exports outside of this policy.

There is no policy for the commercial importation of controlled drugs beyond oxycodone, with the exception of the policy on codeine. The policy on codeine is already in the public domain and can be found in the Office of Fair Trading Opium Derivatives Report March 2006, the most recent report into opium derivatives.

Any consideration, if any, of controlled drug import policies beyond oxycodone will not be undertaken until after the formal oxycodone policy is determined.

The annual estimate for oxycodone is set by the International Narcotics Control Board (INCB), and is in the public domain. The Home Office does not set a requirement or quota for importation amounts of oxycodone or other controlled substance unless stated, for individual licence holders.

7. Consultation responses

The Home Office would welcome any comments on the policies proposed and on the initial impact assessment at annex A. Any relevant information to support a more detailed impact assessment would also be welcomed.

The consultation is taking place online at the following link:

http://www.homeofficesurveys.homeoffice.gov.uk/s/OxycodoneImportPolicyConsultation

If you have any queries regarding the consultation or your proposed response, please contact the Drugs and Firearms Licensing Unit on the following email address:

Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk

Comments must be received by 20 November 2014.

Responses: Confidentiality & Disclaimer

The information you send us may be passed to colleagues within the Home Office, other Government departments and related agencies for use in connection with this consultation.

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

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

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

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

ANNEX A

Title: Impact Assessment of policy proposals for the regulation of imports of oxycodone	Impact Assessment (IA)
IA No: **tbc**	**Date:** 25 September 2014
Lead department or agency: HOME OFFICE	**Stage: Draft**
Other departments or agencies:	**Source of intervention: Domestic**
	Type of measure: Primary legislation
	Contact for enquiries: **Claire Gipson 02070350571**

Summary: Intervention and Options

RPC Opinion: N/A (not regulatory)

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
NK	NK	NK	No	NA

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

The import and export of oxycodone, an opioid controlled drug, is regulated by the Government. Current policy prevents the grant of licences for the import of controlled drugs from outside the European Economic Area (EEA) if they are already available within the EEA. Government regulation of and intervention in the trade in controlled drugs is necessary because of the very serious harm they can cause if misused or diverted into the illicit trade. The Government consulted on this issue in 2009 but without final resolution.

What are the policy objectives and the intended effects?

The Government's policy on the import of oxycodone is based on two central considerations:

- compliance with the UK's international obligations by: **(a)** minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and **(b)** managing the manufacture and imports of controlled drugs to keep within the estimate system; and
- realising the economic benefits of competition in the UK pharmaceuticals market, whilst ensuring a supply of pain-relieving drugs is available to meet patient care demand.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (see table below for option differentiation)

1. Do nothing: maintain interim policy.
2. Restrict imports from outside the EEA.
3. Allow limited imports from outside the EEA even if they are not for re-export.
4. Allow unrestricted imports from outside the EEA under a quota system.
5. Allow imports from outside the EEA for re-export only.
6. Allow imports from outside the EEA only if there is inadequacy of supply or supplier within the EEA.
7. As per option 6, but imports will also be allowed from outside the EEA where those imports are for re-export purposes only.

At this stage, and subject to this consultation, option 7 appears to represent the best balance between the benefits of increased competition and the risks from diversion of oxycodone.

Will the policy be reviewed? Yes, when the policy is established and when evidence is available					
Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded: 0**	**Non-traded: 0**	

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) that the benefits justify the costs

Signed by the responsible Minister:

Option	Description	Effect/s
1	No change – maintain interim policy	• Imports of oxycodone will only be allowed in accordance with the current interim policy.
2	Restrict imports from outside the EEA	• Imports of oxycodone will be allowed from within the EEA[1] for any purpose (subject to INCB estimates). • Only if oxycodone is not available from within the EEA will imports from outside the EEA be allowed for re-export or any other purposes (on a temporary basis to address the shortfall and subject to INCB estimates).
3	Allow limited imports from outside the EEA under a UK defined quota system (to be determined)	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will be allowed from outside the EEA in addition (subject to a UK defined quota) and will not be limited to re-export.
4	Allow unrestricted imports from outside the EEA	• Imports of oxycodone will be allowed from anywhere in the world for any purpose; and • The INCB approved estimate will be the only limit on imports.
5	Allow imports from outside the EEA for re-export	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports from outside the EEA will be allowed from outside the EEA for re-export purposes only. There will be no restriction on quantities.
6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports from outside the EEA will be allowed for any purpose, including for re-export, but only if there is inadequacy of supply or supplier in the EEA.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will only be allowed from outside the EEA for any purpose other than for re-export, if there was inadequacy of supply or competition within the EEA. • Imports from outside the EEA for the sole purpose of re-export outside of the EEA will be allowed irrespective of whether there are adequate supply or suppliers within the EEA. Imports for consumption within the UK, whether all or part of a shipment, would not be permitted.

[1] It is important to note that when the options refer to 'within the EEA' this means: (a) the import comes from an EEA state; (b) the oxycodone (API) originates in an EEA state; and (c) if for re-export, the destination of the re-export is an EEA State.

Summary: Analysis & Evidence Policy Option 2

Description: Restrict imports from outside the EEA

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate:

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

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

NK

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

- Restricting imports from outside the EEA could potentially lead to higher prices and less choice in oxycodone products for UK oxycodone customers. This could lead to less oxycodone being sold than under a more competitive option, and a potential impact on consumer welfare.

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

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

NK

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

- With imports restricted from outside the EEA, there is a lower risk of diversion into the illicit trade due to the reduced volume of international transit of oxycodone. This would reduce the risk of harm from misuse.
- Domestic manufacturers of oxycodone would be protected from competition from rivals outside the EEA and could earn greater profits. We expect this benefit to be smaller than the loss in consumer welfare.

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

- The UK pharmaceutical industry could be adversely affected if domestic oxycodone prices are higher than those of international competitors.
- If the UK already has a comparative advantage in oxycodone production, there may not be additional costs from restricting competition.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	Benefits:	Net:	No	NA

Summary: Analysis & Evidence Policy Option 3

Description: Allow limited imports from outside the EEA under a UK defined quota system

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:**

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

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

NK

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

- As a result of international competition, domestic oxycodone suppliers may lose business to foreign rivals or be forced to lower their prices. This would result in a diminution of profits.
- There is an increased risk of diversion in line with increased volume of international transit of oxycodone.

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

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

NK

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

- Increased international competition in the UK oxycodone market could enable domestic buyers to source oxycodone more cheaply from a variety of sellers. As a result these domestic firms could benefit from increased profits.
- International competition for the UK market may increase growth and innovation in the UK pharmaceuticals industry. This may in turn increase the international competitiveness of the UK pharmaceuticals industry.
- There could be wider benefits to the UK economy if the EEA pharmaceutical industry grows.

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

- The Government might not manage the quota system effectively due to lack of market information. This could lead to an excess of oxycodone being stockpiled in the UK and the risks of diversion associated with this, or alternatively insufficient oxycodone to meet UK needs.
- Exposing the UK market to competition could prevent the UK market from becoming more competitive in the long-run.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Summary: Analysis & Evidence Policy Option 4

Description: Allow unrestricted imports from outside the EEA

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:**

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

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

NK

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

- As a result of international competition, domestic oxycodone suppliers may lose business to foreign rivals or be forced to lower their prices. This would result in a loss of profits.
- There is a significantly increased risk of diversion in line with increased volume of international transit of oxycodone.

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

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

NK

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

- Free trade in oxycodone sales offers the greatest potential for competition between sellers of oxycodone. Greater international competition for the UK market could lead to price reductions and greater product choice; enabling domestic buyers to source oxycodone more cheaply from a variety of sellers. This would lead to an increase in consumer welfare.
- The greater level of international competition for the UK market may increase innovation and competitiveness in the UK pharmaceuticals industry which would benefit consumers.
- There could be wider benefits to the economy of the UK if the EEA pharmaceutical industry grows as more trade opportunities and employment will potentially be generated.

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

- The increased international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse.
- Exposing the UK market to unrestricted competition could prevent the UK market from becoming more competitive in the long-run.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Summary: Analysis & Evidence Policy Option 5

Description: Allow imports from outside the EEA for re-export

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:**

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

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

NK

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

- There is a greater risk of diversion than in allowing imports only from within the EEA (option 1) in line with increased volume of international transit of oxycodone.
- As a result of international competition, domestic oxycodone manufacturers may lose business to foreign rivals or be forced to lower their prices. This would result in a loss of profits.

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

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

NK

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

- UK pharmaceutical companies who export the finished product could have access to a wider range of manufacturers and may find cheaper sources of oxycodone than are currently available within the EEA.
- The greater level of international competition for the UK market may increase growth and innovation in the UK pharmaceuticals industry. This may increase the international competitiveness of the UK pharmaceuticals industry.
- There could be wider benefits to the economies of the UK if the EEA pharmaceutical industry grows as more trade opportunities and employment will potentially be generated.

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

- Increased international transit could lead to increased diversion and increased harm caused by drug misuse.
- Exposing the UK market to only partially restricted competition could prevent the UK market from becoming more competitive in the long-run.

BUSINESS ASSESSMENT (Option 5)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Summary: Analysis & Evidence Policy Option 6

Description: Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:**

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

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

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

- If imports are allowed from outside the EEA because supply or number of suppliers is deemed to be inadequate then there is a greater risk of diversion with increased volume of international transit.
- If there is considered to be an inadequate number of suppliers/monopolistic position leading to inadequate competition in the UK and EEA, then allowing international imports will increase competition in the UK market for oxycodone. Increased international competition may lead to domestic oxycodone suppliers losing business to foreign rivals if the latter are able to offer lower prices and greater choice in oxycodone products.

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

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

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

- The provision for adequacy of supply ensures that the UK has a sufficient oxycodone to meet its healthcare needs (amount may vary year on year), as per the Government's objectives for the licensing of imports of oxycodone.
- The provision for adequacy of number of suppliers (i.e. more than a monopolistic position) ensures that UK oxycodone customers benefit from competitive prices and greater choice. As a result, domestic firms which source oxycodone for their manufacturing processes could benefit from increased profits.
- The greater level of international competition for the UK market may increase growth and innovation in the UK pharmaceuticals industry. This may increase the international competitiveness of the UK pharmaceuticals industry. There could be wider benefits to the economies of the UK if the EEA pharmaceutical industry grows.

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

- The increased international transit could lead to increased diversion and increased harm.
- There is a risk that '*inadequacy of supply'* could be defined inappropriately, leading to either a build up in supply (with increased risks of diversion) or a deficient supply (relative to UK needs) of oxycodone in the UK. Similarly, how *inadequacy of suppliers* is defined will determine how UK businesses are affected and to what extent the above benefits of competition are realised.
- However, given the size of the EEA market there is no reason to think that an adequate supply will not be met from within the EEA. Increased competition would still enable consumers to source better quality/cheaper products.

BUSINESS ASSESSMENT (Option 6)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Summary: Analysis & Evidence Policy Option 7

Description: As option 6, but imports will also be allowed from outside the EEA where those imports are for re-export purposes only.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013/14	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:**

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

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

NK

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

- As option 6, however there is an increased risk of diversion in line with an increased volume of international transit of oxycodone.

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

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

NK

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

- As option 6, however the benefits associated with free trade and increased competition are greater proportionate to the greater openness of the UK oxycodone market.
- The freer international movement of oxycodone would bring benefits in terms of making international research trials easier.
- UK pharmaceutical companies may become more competitive internationally and increase profits leading to benefits for the wider UK economy as more trade opportunities and employment will potentially be generated.

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

- Increased international transit could lead to increased diversion and increased harm.
- Given the size of the EEA market there is no reason to think that an adequate supply will not be met from within the EEA. Increased competition would still enable consumers to source better quality/cheaper products.

BUSINESS ASSESSMENT (Option 7)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Evidence Base

A. Strategic Overview

A.1 Government priorities

The Government's policy on the import of oxycodone is based on two central considerations:

- compliance with the UK's international obligations by: **(a)** minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and **(b)** managing the manufacture and imports of controlled drugs to keep within the estimate system; and

- realising the economic benefits of competition in the UK pharmaceuticals market;

whilst ensuring a supply of pain-relieving drugs is available to meet patient care demand.

A.2 Background

Oxycodone is an opioid analgesic which is widely used by medical professionals to treat pain. It is synthesised from thebaine which is derived from opium. Opioids are classified as 'narcotic drugs' under the relevant UN conventions.

Narcotic drugs are subject to legal control due to the serious harm they can cause to both individuals and society as a whole if misused.

The manufacture, supply, import and export of narcotic drugs is governed by the provisions of the Misuse of Drugs Act 1971 ("the Act") and the United Nations Single Convention on Narcotic Drugs 1961 ("the 1961 Convention") of which the UK is a signatory.

Except where regulations provide for the lawful import, export, supply, possession, administration, manufacture or production of a drug controlled under the Act, such activities require a licence granted by the Secretary of State. The licensing system aims to prevent the misuse of drugs, and/or their diversion into the illicit trade by monitoring and regulating their licit use throughout the supply chain. Data given at tables E.2 and E.3 below show volumes of oxycodone used in the UK in the legal trade.

The 1961 Convention aims to limit the use of narcotic drugs exclusively to medical and scientific purposes. It seeks to do so through a quota system whereby each signatory provides an annual estimate ("the estimate") of the amount of each narcotic drug that their country will acquire through import and/or manufacture over the coming year. Estimates are submitted to, and approved by, the International Narcotics Control Board (INCB, the independent, quasi-judicial body that monitors UN drugs control conventions). Countries must not exceed their estimate without good reason and prior approval by the INCB. The Convention also requires signatories to prevent the accumulation of drugs in excess of those required for the normal conduct of business in the possession of manufacturers, traders, distributors and others authorised to possess narcotic drugs.

In common with some other countries such as France and Spain, it had been long-standing Government policy to allow imports of oxycodone (along with all other narcotic drugs) only if it is not available from within the UK. Following a judgment of the European Court of Justice, this policy was amended to allow some imports from within the EEA even if oxycodone were available within the UK.

A.3 More recent developments

In February 2008 the Home Office agreed to a request from the pharmaceutical industry to import oxycodone from outside the EEA on condition that the complete quantity was re-exported. Imports that are re-exported do not have any impact on the estimate because the overall quantity remains balanced.

Subsequently, the Home Office identified a risk that the estimate may be exceeded if imports for re-export were to replace the domestically manufactured supply that would normally have been exported, and domestic manufacture were to continue at existing levels. Stockpiling of unsold domestically-manufactured oxycodone would lead to a significant rise in levels of oxycodone held in the UK, which would be inconsistent with Article 29 of the 1961 Convention.[2]

The decision to allow imports for re-export was rescinded in February 2009 based on three factors:

- it was still considered desirable to minimise, as far as was reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion;

- there was a risk that Macfarlan Smith Limited (MSL), which was then (and still) thought to be the sole known commercial-scale manufacturer of raw diamorphine in the UK, would cease to manufacture it if its financial viability was threatened by increased competition in the oxycodone market. This was linked to a high priority the Government placed on maintaining a secure supply of diamorphine; and

- there was a risk that the estimate would be exceeded.

However, since that time the Home Office has continued to receive feedback from the UK pharmaceutical industry that the policy of only allowing imports from within the EEA is too restrictive and does not foster sufficient competition in the market. The Home Office notes that MSL has acquired what may be called a dominant position in the market and this may be damaging to competition. The view has been expressed that, notwithstanding the potential market risks, oxycodone imports should be allowed from outside the EEA in some form.

[2] The 1961 Convention, Article 29 Manufacture states: "…3. The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions

B. Issue

B.1 Groups Affected

Directly affected	Indirectly affected
UK-based oxycodone manufacturer/UK-based suppliers	The wider UK/ EEA pharmaceuticals industry
UK and EEA-based oxycodone suppliers and manufacturers	Patients who rely on oxycodone for pain control
UK-based oxycodone customers	Customers for products made using oxycodone
	Individuals who might misuse oxycodone products
	Law enforcement agencies and providers of health services for drug users
	The exchequer

B.2 Consultation

Within Government
The Home Office has developed these proposals in consultation with the Department of Health and the Department of Business, Innovation and Skills.

Public Consultation
A consultation-stage impact assessment accompanies the public consultation on this matter.

B.3 Rationale for Government intervention

The misuse of drugs imposes a cost on society which exceeds the perceived cost to the individual. This is largely through the perpetration of crime and the accompanying burden on public services such as health and criminal justice. The market alone does not prevent narcotic drugs being diverted into the illicit trade. Therefore Government intervention, through its licensing system, is necessary to minimise these harms.

With the proviso that any general policy is susceptible to exceptions on reasonable grounds, the Home Office currently operates the interim policy at chapter 6. The Home Office has received feedback that this policy is too restrictive and that a more competitive market can be encouraged without unduly increasing the risk of diversion.

The Monopolies and Mergers Commission and the OFT have conducted reviews of the trade in opium derivatives in the UK, although without a specific focus on oxycodone. In the UK there is currently only one manufacturer of opium derivatives, MSL. Its position may be in effect monopolistic or at least dominant. The 2006 OFT review stated that there was a 'competition problem' in the pharmaceutical sector and that the main reason for the dominant position of MSL was the trading restrictions on opium derivatives maintained through the Government's licensing policy. The Government accepted the OFT's recommendation that it should take competition issues into consideration when devising future licensing policy.[3] The Government recognises that, whilst the existence of a dominant position in the market is not necessarily contrary to competition law, such a position and its effects on the market may need to be scrutinised in order to avoid unlawful impact on competition.

[3] The OFT's recommendation was made in Opium Derivatives: A review of the undertakings given by Macfarlan Smith Limited (OFT834), March 2006, paragraph 5.17; Government response was in: "Opium derivatives - Government response to OFT's review of undertakings by Macfarlan Smith Ltd", September 2006, http://www.berr.gov.uk/files/file33800.pdf

C. Objectives

C1. Objectives

The Government's policy on the import of oxycodone is based on two central considerations:

- compliance with the UK's international obligations by: **(a)** minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and **(b)** managing the manufacture and imports of controlled drugs to keep within the estimate system; and

- realising the economic benefits of competition in the UK pharmaceuticals market;

whilst ensuring a supply of pain-relieving drugs is available to meet patient care demand.

D. Options

The Home Office is considering six options to meet the policy objectives. They all have the potential to increase competition by allowing imports from outside the EEA subject to certain conditions. A seventh option reflects the principle of the current situation which is to allow imports for re-export only within the EEA.

Option	Description	Effect/s
1	No change -maintain interim policy	• Imports of oxycodone will only be allowed in accordance with the current interim policy.
2	Restrict imports from outside the EEA	• Imports of oxycodone will be allowed from within the EEA for any purpose (subject to INCB estimates). • Only if oxycodone is not available from within the EEA will imports from outside the EEA be allowed for re-export or any other purposes (on a temporary basis to address the shortfall and subject to INCB estimates).
3	Allow limited imports from outside the EEA under a UK defined quota system (to be determined)	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will be allowed from outside the EEA in addition (subject to a UK defined quota) and will not be limited to re-export.
4	Allow unrestricted imports from outside the EEA	• Imports of oxycodone will be allowed from anywhere in the world for any purpose; and • The INCB approved estimate will be the only limit on imports.
5	Allow imports from outside the EEA for re-export	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports from outside the EEA will be allowed from outside the EEA for re-export purposes only. There will be no restriction on quantities.
6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports from outside the EEA will be allowed for any purpose, including for re-export, but only f there is inadequacy of supply or supplier in the EEA.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will only be allowed from outside the EEA for any purpose other than for re-export, if there was inadequacy of supply or competition within the EEA. • Imports from outside the EEA for the sole purpose of re-export outside of the EEA will be allowed irrespective of whether there are adequate supply or suppliers within the EEA. Imports for consumption within the UK, whether all or part of a shipment, would not be permitted.

E. Appraisal

The Home Office has attempted to source market data for oxycodone in both domestic and international markets to help quantify the potential scale of policy impact. There is a marked absence of available data. This means that the initial assessment considers the impacts of the proposed policy options in non-monetised terms.

Consultation respondents are invited to submit detailed figures to inform Government policy and future iterations of this impact assessment (in accordance with the confidentiality information in section 7).

E.1 General Assumptions and Data

Misuse of oxycodone

- In general, increases in the volume of international transit of controlled drugs lead to an increase in the risk of diversion.
- Deaths from oxycodone-based drugs in the UK appear to be rising, particularly since 2007[4] albeit from a low starting point and with a relatively low overall volume. The latest figures showing a small decline (see table E.1).

Table E.1: Number of deaths in which oxycodone was mentioned in the cause of death at inquest by the pathologist and/or coroner, 2001 – 2012.[5]

Year	Number of deaths
2012	30
2011	32
2010	25
2009	19
2008	18
2007	16
2006	5
2005	7
2004	3
2003	6
2002	0
2001	2

[4] http://www.sgul.ac.uk/research/projects/icdp/our-work-programmes/pdfs/np-SAD_13th_annual_report_2012.pdf

[5] Source: National Programme on Substance Abuse Deaths (np-SAD). These data do not cover the whole UK: they cover most post-mortems in England and Wales, all in Northern Ireland, and most over-dose deaths in Scotland. These figures therefore represent minimum numbers.

The oxycodone industry

- In 2013 there were 1.1 million prescriptions for oxycodone-based drugs (both oxycontin and oxynorm) in England.[6] This is compared to over 600,000 in 2008.[7] The total sales volume of these prescriptions was £52 million (Net Ingredient Cost).
- In 2008 there were nine companies in the UK who sold oxycodone of which six traded only in very small amounts (less than 3kg).
- The scale of the oxycodone trade in the UK can be seen in the tables below which show the most recent information available for both imports and exports and domestic manufacture and consumption.
- The United Kingdom was the main exporting country in 2012 (53 per cent of world exports) followed by the United States (13.5 per cent) and the Netherlands (12 per cent).[8]

Table E.2: Oxycodone manufacture and consumption in the UK, 2003 – 2012[9]

Year	Oxycodone manufactured (kg)	Oxycodone consumed (kg)
2012	11,857	1,464
2011	12,965	830
2010	9,792	993
2009	11,484	2,442
2008	12,339	1,823
2007	9,206	217
2006	8,547	416
2005	10,888	501
2004	7,586	363
2003	4,692	251

[6] Prescription Cost Analysis, England 2013, page 130. Published by the NHS Information Centre.

[7] Prescription Cost Analysis, England 2008, page 130. Published by the NHS Information Centre.

[8] http://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2013/Annex_4_

[9] Source: INCB Narcotic Drugs Statistics for 2012 (published by the United Nations, 2014)

Table E.3: Oxycodone imports and exports, 2003 – 2012[10]

Year	Oxycodone Exports (kg)	Oxycodone Imports (kg)
2012	15,176	3,979
2011	14,541	3,959
2010	12,327	4,197
2009	11,442	2,863
2008	11,336	2,296
2007	9,285	44
2006	7,370	379
2005	6,660	22
2004	5,092	17
2003	3,824	4

Competition

- The OFT describes competition as '*a process of rivalry between firms seeking to win customers' business*'. This process of rivalry, where it is effective, has numerous benefits. Competition can drive down prices, increase innovation and productivity, and hence increase the quality of products and, more generally, increase the range of choice available to customers.[11] In general, competitive markets are in the public interest and can bring benefits to a country's economy. In the UK, competition may also better meet the needs of patient care. Competition is a fundamental objective of the EEA. Where there is a monopolistic or dominant position, there is no or little competition.

- Even if not a monopoly, market dominance by one supplier may act as a brake on competition.

- A supplier with market dominance may act in a way which is not consistent with the public interest such as by charging higher prices and/or engaging in price discrimination at the expense of customers.[12] Moreover there is a risk that a monopoly or dominant firm may price discriminate between buyers in a way which does not reflect costs. For instance, volume based discounts may significantly favour large volume customers at the expense of small volume customers. This may mean that small volume customers are priced out of the market. Allowing a company to exploit a monopoly position is usually not in the public interest and allowing a firm to exploit a dominant position may or may not be in the public interest.

[10] Source: INCB Narcotic Drugs Statistics for 2012 (published by the United Nations, 2014)

[11] http://www.competition-commission.org.uk/assets/competitioncommission/docs/pdf/non-inquiry/rep_pub/rules_and_guide/pdf/cc2

[12] http://www.oft.gov.uk/shared_oft/reports/consumer_protection/oft834.pdf

- The Monopolies and Mergers Commission and the OFT have conducted reviews of the trade in opium derivatives in the UK although without a specific focus on oxycodone. In the UK there is still believed to be currently a sole manufacturer of opium derivatives, MSL. The 2006 OFT review stated that there was a 'competition problem' in the pharmaceutical sector and that the main reason for this being maintained was through the Government's licensing policy.

- The Home Office accepted the OFT's recommendation that it should take competition issues into consideration when devising future licensing policy.[13] All but one of the policy options under consideration would increase competition either in the EEA (through the cessation of the interim policy) or internationally or both, thereby leading to potential benefits for oxycodone customers and the UK economy more broadly as well as meeting the needs of patient care.

Diamorphine supply for the UK healthcare sector

- Diamorphine, an opiate derivative, is an important painkiller used by the NHS. The Department of Health is keen to maintain a secure supply of diamorphine to it. MSL, which is currently the sole known commercial-scale manufacturer of diamorphine in the UK, has suggested that increased competition in the oxycodone market might threaten its financial viability meaning that it would have no incentive to continue to manufacture diamorphine.

- The Home Office recognises that it needs to consider the impact of any new import policy in the wider context of the security of supply to the NHS of diamorphine. The Home Office wishes to test through consultation whether or not the introduction of any new policy might threaten supplies of opiate derivatives, specifically diamorphine, to the NHS.

- Greater competition in the UK pharmaceutical market could in time give rise to longer term benefits in the supply of diamorphine in terms of lower prices and a wider range of providers. This would provide greater security to users in the UK healthcare sector.

UK Business Impact

- MSL could potentially lose business to international competitors under some of the proposed policy options. The company is concerned that if the UK opens up its pharmaceutical market but other countries are interpreting their obligations under the Convention in a way that precludes MSL from competing with their domestic suppliers, MSL will be disadvantaged.

- However, it has been suggested that to allow MSL to maintain its market position without opening the issue for consultation might possibly run contrary to EU free market principles albeit the European Court of Justice has stated that derogation from these is permitted in certain circumstances.

- There is also a wider international dimension. If consultation led to the introduction of a more open import policy beyond the EEA, it would provide greater trade opportunities in the UK for businesses from other countries, such as the USA, which as allowed under the Convention operate a more restrictive policy. Again, this could lead to an established UK company being disadvantaged.

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[13] The OFT's recommendation was made in Opium Derivatives: A review of the undertakings given by Macfarlan Smith Limited (OFT834), March 2006, paragraph 5.17; Government response was in: "Opium derivatives - Government response to OFT's review of undertakings by Macfarlan Smith Ltd", September 2006, http://www.berr.gov.uk/files/file33800.pdf

- Any loss to an individual company might be outweighed by the gains to UK importers of oxycodone more generally. Furthermore, it is possible that any losses to UK business from international competition could be offset by future gains to UK business. This could possibly occur if increased competition encourages innovation in the UK pharmaceuticals industry.

- The little commercial data available suggests that MSL's total sales in 2011 were £83 million.[14] Further company data suggest that MSL's profit may be in the region of £19 million.[15] Some proportion of this is derived from MSL's oxycodone manufacture. We therefore estimate that £19 million is the maximum potential loss to UK business from greater exposure to international competition. However, as explained above, we would expect any loss to be outweighed by gains for oxycodone importers. The Home Office is unable to monetise the precise impact that each option would have on MSL or other UK businesses because of the absence of relevant data in the public domain. However, it is possible to estimate the relative size of the impact of each option.

- In the light of the information gaps identified above the Home Office invites UK business and other consultees to submit data which supports their consultation response or would be useful in illustrating any impact of the proposed policy options on UK business. These data will be treated in accordance with the confidentiality information outlined in section 7.

[14] http://www.matthey.com/AR11/report_of_the_directors/fine_chemicals_division_02.html#API_Manufacturing_Businesses

[15] The fine chemicals division of MSL's parents company, of which MSL is a component, had a 2011 return on sales of 22.9%. If MSL's return on sales were equivalent to the division's average, this would imply a profit of £19 million. (http://www.matthey.com/AR11/report_of_the_directors/fine_chemicals_division_01.html#Performance)

E.2 Costs and Benefits

Option	Description	Cost	Benefit
1	No change- maintain interim policy	• No change	• No change
2	Restrict imports from outside the EEA	• International competition may result in domestic oxycodone suppliers losing business to foreign rivals, if they are able to offer lower prices and greater choice in oxycodone products.	• There would be a slight (temporary) increase in competition as imports from outside the EEA would be allowed (within INCB limits) if the UK's oxycodone requirements could not be met from the EEA market. Likely to create increased competition within the EEA.
3	Allow limited imports from outside the EEA under a UK defined quota system	• International competition may result in domestic oxycodone suppliers losing business to foreign rivals, if they are able to offer lower prices and greater choice in oxycodone products. • Management of quota would create an administrative burden and potentially increases bureaucracy and process burden on industry. • Requirement for stringent monitoring and safeguards to prevent system manipulation introduces a new burden. • There is an increased risk of diversion in line with increased volume of international transit of oxycodone	• Increased international and EEA competition in the UK oxycodone market could enable domestic buyers to source oxycodone more cheaply from a variety of sellers. Domestic firms could benefit from increased profits. • International and a greater level of EEA competition for the UK market may increase growth and innovation in the UK pharmaceuticals industry; may increase the international competitiveness of the UK pharmaceutical industry. • There could be wider benefits to the economies of the UK if the EEA pharmaceutical industry grows.

4	Allow unrestricted imports from outside the EEA	• International competition may cause domestic oxycodone suppliers to lose business to foreign rivals, if they offer lower prices and greater choice in oxycodone products. • With unrestricted imports from outside the EEA there is a significantly greater risk of diversion in line with increased volume of international transit of oxycodone.	• An open market for oxycodone sales in the EEA and internationally offers the greatest potential for competition between sellers of oxycodone. Greater international competition for the UK market could lead to price reductions; enabling domestic buyers to source oxycodone more cheaply from a variety of sellers; domestic firms could benefit from increased profits. • International and a greater level of EEA competition for the UK market may increase growth and innovation in the UK pharmaceutical industry; may increase the international competitiveness of the industry. • There could be wider benefits to the economies of the UK if the EEA pharmaceutical industry grows.
5	Allow imports from outside the EEA for re-export	• Increased volume of international transit of oxycodone increases the risk of diversion. • Greater competition. Domestically produced oxycodone which is exported and subsequently imported for re-export may have to compete against oxycodone manufactured abroad and imported into the UK for re-export. Domestic oxycodone manufacturers may lose business to foreign competitors if those manufacturers can offer lower prices and greater choice in oxycodone products.	• UK oxycodone customers who export the finished product will have access to a wider market and may find cheaper sources of oxycodone than currently available within the EEA – although there will also be greater EEA based competition. • International and a greater level of EEA competition for the UK market may increase growth and innovation. This may increase the international competitiveness of the UK pharmaceuticals industry. • There could be wider benefits to the economies of the UK if the EEA pharmaceutical industry grows.

6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• Imports from outside the EEA increase the volume of international transit of oxycodone and therefore the risk of diversions. • If there is considered to be an inadequate number of suppliers in the UK and EEA, then allowing international imports will increase competition in the UK market for oxycodone. Increased international competition may lead to domestic oxycodone suppliers losing business to foreign rivals, if the latter are able to offer lower prices and greater choice in oxycodone products.	• The provision for adequacy of supply ensures that the UK has a sufficient supply of oxycodone. • The provision for adequacy of number of suppliers ensures that UK oxycodone customers benefit from competitive prices and greater choice. Domestic firms which source oxycodone for their manufacturing processes could benefit from increased profits. • International and a greater level of EEA competition for the UK market may increase growth and innovation. This may increase the international competitiveness of the UK pharmaceuticals industry. • There could be wider benefits to the UK economy if the EEA pharmaceutical industry grows.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	• As option 6, however there is an increased risk of diversion in line with increased volume of international transit of oxycodone.	• As option 6, however the benefits associated with free trade and international and a greater level of EEA competition are in line with the greater market openness. • Freer international movement of oxycodone would make international research trials easier. • Emerging markets could be regulated through normal import/export controls. • Any company could enter the import/export market. • UK pharmaceutical companies may become more competitive internationally and increase profits, leading to benefits for the wider EEA economy.

F. Risks

Option	Description	Risks
1	No change – maintain interim policy	• No change
2	Restrict imports from outside the EEA	• A lack of international competition in the UK market may inhibit growth and innovation in the UK pharmaceuticals industry. This may adversely affect the international competitiveness of the UK pharmaceutical industry.
3	Allow limited imports from outside the EEA under a UK defined quota system	• The Government might not manage the quota system effectively due to lack of market information. This could lead to an excess of oxycodone being stockpiled in the UK and the risks of diversion associated with this. Alternatively, if the quota under estimate the need for oxycodone imports then there could be insufficient oxycodone to meet UK needs. • Management of the quota would create an administrative burden and potentially increases bureaucracy and process burden on industry. • Requirement for stringent monitoring and safeguards to prevent system manipulation. • The increased volume of EEA and international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse.
4	Allow unrestricted imports from outside the EEA	• The increased volume of EEA and international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse. • There is a risk that domestic supply of diamorphine might be disturbed, either temporarily or more fundamentally, by the greater openness of the UK oxycodone market and greater EEA and international competition among manufacturers and suppliers. • The increased volume of EEA and international imports could result in the UK breaking its INCB estimate.

5	Allow imports from outside the EEA for re-export	• The increased EEA and international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse. • There is a risk that domestic supply of diamorphine might be disturbed, either temporarily or more fundamentally, by the greater openness of the UK oxycodone market and greater competition among manufacturers and suppliers. • If imports replace domestic supply, and domestic supply is not reduced in line with the increase in imports, the UK could still break its INCB estimate regardless of the fact that all imports are for re-export.
6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• The increased EEA and international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse. • Given the size of the EEA market there is no reason to think that an adequate supply will not be met from within the EEA. • There is a risk that '*inadequacy of supply'* could be defined inappropriately, leading to either an excess or deficient supply of oxycodone in the UK. This could lead to stockpiling in the first case and the risks of diversion associated with this, and insufficient supply to meet UK needs in the second case. • Similarly, how *inadequacy of number of suppliers* is defined will determine how UK businesses are affected and to what extent the above benefits of competition are realised. • There is a risk that domestic supply of diamorphine might be disturbed, either temporarily or more fundamentally, by the greater openness of the UK oxycodone market and greater competition among manufacturers and suppliers.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	• As option 6, however the risk of diversion is increased in line with the scale of international transit of oxycodone. • There is a risk that domestic supply of diamorphine might be disturbed, either temporarily or more fundamentally, by the greater openness of the UK oxycodone market and greater competition among manufacturers and suppliers. • There is a further risk of diversion to particularly to high risk countries (where there is a higher risk of diversion to the illicit market).

As can be seen from Table F.1, there is a clear trade off between two policy objectives of increasing competition and reducing the risk of diversion from oxycodone trade. The greater openness to global trade of options 4, 5 and 6 brings benefits associated with a greater level of competition. However the increased global transit of oxycodone under these options involves a higher risk of diversion compared to the other options. At this stage, option 7 appears to represent the best balance between the benefits from increasing competition and the risks from diversion of oxycodone.

Table F.1 Ranking options by the impact on competition and on the risk of diversion (note Option 1 – no change – is not included in this table).

Rank	Competition Impact (most competitive=1)	Risk of diversion (highest risk=1)
1	Option 4 – Allow unrestricted imports from outside the EEA	Option 4 – Allow unrestricted imports from outside the EEA
2	Option 7 - As per option 6, but imports will also be allowed from worldwide where those imports are for re-export purposes only.	Option 7 - As per option 6, but imports will also be allowed from worldwide where those imports are for re-export purposes only.
3	Option 6 - Allow imports from outside the EEA only if there is inadequacy of supply or supplier within the EEA	Option 6 - Allow imports from outside the EEA only if there is inadequacy of supply or supplier within the EEA
4	Option 5 – Allow imports from outside the EEA for re-export	Option 5 – Allow imports from outside the EEA for re-export
5	Option 3 – Allow limited imports of both domestically and foreign manufactured oxycodone from outside the EEA under a quota system	Option 3 – Allow limited imports from outside the EEA under a quota system
6	Option 2 – Restrict imports from outside the EEA	Option 2 – Restrict imports from outside the EEA

G. Enforcement

The Home Office's Drugs Licensing and Compliance Unit and enforcement authorities, such as the police, will enforce whichever policy option is chosen.

H. Summary and Recommendations

The table below summarises the costs and benefits of the proposed changes. At this stage, option 7 appears to represent the best balance between the benefits from increasing competition and the risks from diversion of oxycodone.

Table H.1 Costs and Benefits (not quantified)

Option	Cost	Benefit
1	• No change	• No change
2	• Domestic suppliers may lose business to foreign rivals offering lower prices and greater product choice.	• Slight temporary increase in competition as imports from outside the EEA would be allowed (within INCB limits) if UK requirements could not be met from the EEA market. Likely to create increased competition from within the EEA.
3	• Domestic suppliers may lose business to foreign rivals offering lower prices and greater product choice. • Management of quota = administrative and security burden on government and process burden on industry. • Increased risk of diversion commensurate with increased volume of international transit.	• International and increased EEA competition could enable domestic buyers to source oxycodone more cheaply and therefore benefit from increased profits. • International and increased EEA competition may increase growth and innovation in the UK pharmaceuticals industry.
4	• Domestic suppliers may lose business to foreign rivals offering lower prices and greater product choice. • Increased risk of diversion commensurate with increased volume of international transit.	• An open market (EEA and internationally) offers the greatest potential for competition between sellers, possible price reductions, greater choice and greater profits for UK companies. • International and greater EEA competition may increase growth and innovation in the UK pharmaceuticals industry.

5	• Increased volume of international transit of oxycodone increases the risk of diversion. • Domestically produced oxycodone which is exported and subsequently imported for re-export may have to compete against oxycodone manufactured abroad and imported into the UK for re-export.	• Access to a wider market and may find cheaper sources than currently available within the EEA only. • International and greater EEA competition may increase growth and innovation in the UK pharmaceuticals industry.
6	• Increased risk of diversion commensurate with increased volume of international transit. • Domestic suppliers may lose business to foreign rivals offering lower prices and greater product choice.	• The provision for adequacy of supply ensures that the UK has a sufficient supply of oxycodone. • The provision for adequacy of number of suppliers ensures that UK oxycodone customers benefit from competitive prices and greater choice. • International and increased EEA competition may increase growth and innovation in the UK pharmaceuticals industry.
7	As option 6, and increased risk of diversion commensurate with increased volume of international transit.	• As option 6, however the benefits associated with free trade and increased (EEA and international) competition are greater in line with the greater openness of the UK oxycodone market. • Emerging markets could be regulated through normal import/export controls. • Any company could enter the import/export market.

I. Implementation

Implementation of the proposed policy will take place as early as possible, subject to comments received in response to this consultation and the views of ministers.

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by the Home Office Drugs Licensing and Compliance Unit (DLCU).

Specific Impact Tests: Checklist

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	Yes
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annex 1: Specific Impact Tests

Health Impact Assessment

The proposed measures to open up the market could lead to greater competition in the EEA market for oxycodone. This increased competition would be expected to drive down prices for oxycodone, which could lead to cost savings in the NHS, which in turn would free resources to fund additional treatments, resulting in health benefits for NHS patients.

Competition Assessment

Option	Description	Directly limit the number or range of suppliers?	Indirectly limit the number or range of suppliers?	Limit the ability of suppliers to compete?	Reduce suppliers' incentives to compete vigorously?
1	No change- maintain interim policy	No change	No change	No change	No change
2	Restrict imports from outside the EEA	This option potentially increases the number of EEA suppliers on the cessation of the interim policy.	No	This option does not limit the ability of suppliers within the EEA to compete. Suppliers from outside the EEA however are not able to enter the market unless supplies in the EEA market are insufficient to meet demand and the market entry would only be for the duration of the shortfall.	This option does not reduce EEA suppliers' incentives to compete vigorously against each other. Suppliers from outside the EEA would not be able to enter the market. This in itself may, if the intra-EEA market is not competitive, reduce EEA suppliers' incentives to compete vigorously compared with an open market.

3	Allow limited imports from outside the EEA under a UK defined quota system	No	No	If the quota system was used to limit the volume of imports from outside the EEA the competition ability of suppliers from outside the EEA would be limited because the amount of oxycodone they could sell would be limited. The competition ability of suppliers from within the EEA would not be affected and would potentially be increased on cessation of the interim policy.	The use of a quota on imports from outside the EEA would reduce supplier's incentives to compete vigorously in the oxycodone market. However, competition from within the EEA would not be restricted in any way, so a strong incentive to compete would exist.
4	Allow unrestricted imports from outside the EEA	No	No	No	No
5	Allow imports from outside the EEA for re-export	Customers importing oxycodone in order to re-export it would have no limit placed on the number or range of suppliers with whom they could do business. Customers importing oxycodone for any purpose other than re-export would be limited to using suppliers within the EEA.	No	No	Restrictions on the market for oxycodone purchased for domestic consumption (ie not for re-export) may reduce suppliers' incentives to compete vigorously. However, competition from within the EEA would not be restricted in any way, so a strong incentive to compete would exist.

6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	No, if there is adequate supply and number of suppliers in the EEA on the cessation of the interim policy.	No	No, EEA producers may be encouraged to compete.	This option may increase EEA suppliers' incentives to compete vigorously against each other. Suppliers from outside the EEA would only be able to enter the market if supply or number of suppliers in the EEA were inadequate.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	Customers importing oxycodone in order to re-export it would have no limit placed on the number or range of suppliers with whom they could do business. Customers importing oxycodone for any purpose other than re-export would be limited to using suppliers within the EEA if competition and supply are adequate.	No	No	This option may increase EEA suppliers' incentives to compete vigorously against each other where the market is for oxycodone purchased for domestic consumption (ie not for re-export). However, competition from within the EEA would not be restricted in any way, so a strong incentive to compete would exist.

Small Firms Impact Test

None of the companies known by the Government to supply significant amounts of oxycodone (taken to mean more than 10 kg per annum, as reported in the 2008 Annual Statistical Return to the Home Office) in the UK is a small or medium enterprise (collectively, SMEs).

Businesses and organisations of all sizes would have to comply with regulations on imports so the impact of any changes would not be judged to be disproportionate.

Option	Description	Impact on small firms
1	No change – maintain interim policy	No change
2	Restrict imports from outside the EEA	This option would increase the potential for EEA based small firms to enter the market on the cessation of the interim policy.
3	Allow limited imports from outside the EEA under a UK defined quota system	• This option would allow customers of oxycodone to access a wider range of suppliers. If those suppliers from beyond the EEA were to provide oxycodone more cheaply than EEA suppliers all customers would benefit, and all current and new EEA oxycodone suppliers would suffer if their prices were undercut. • Whilst we have information showing that current UK oxycodone suppliers are generally not SMEs, we do not know the make-up of UK oxycodone customers. Since all customers would benefit from reduced prices in the market, we would not judge the impact to be disproportionate.
4	Allow unrestricted imports from outside the EEA	This option would have the same impact on small firms as Option 3.
5	Allow imports from outside the EEA for re-export	This option would have the same impact on small firms as Option 3.

6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• This option would allow customers for oxycodone to access a wider range of suppliers. If supply or competition were judged to be inadequate in the EEA, and those suppliers from beyond the EEA were to provide oxycodone more cheaply than EEA suppliers, all customers would benefit, and all current EEA oxycodone suppliers would suffer if their prices were undercut. This should promote competition amongst EEA suppliers. • Whilst we have information showing that current UK oxycodone suppliers are generally not SMEs, we do not know the make-up of UK oxycodone customers. Since all customers would benefit from reduced prices in the market we would not judge the impact to be disproportionate. Our assessment remains the same whether the market is driven by increased intra-EEA competition, or imports from outside the EEA as a result of inadequate supply or suppliers.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	This option would have the same impact on small firms as Option 6.

Equality Impact Assessment

The options were screened for their impact on the following equality target areas:

Race
Disability
Gender
Gender Identity
Religion and Belief
Sexual Orientation
Age

None of the options was found to be likely to have a disproportionate impact on any of the target areas. It was consequently decided that a full equality impact assessment was not required.

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