



Home Office

# **OXYCODONE IMPORT POLICY**

**A consultation paper**





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# Consultation Summary

## Scope of the consultation

<b>Topic of this consultation:</b>	This consultation focuses on the Government's policy on the import of oxycodone to the UK, with particular reference to import for re-export.
<b>Scope of this consultation:</b>	The Government is reviewing its existing policy on the import of oxycodone to the UK. The purpose of this consultation is to re-examine the policy from first principles and gather information and opinions from stakeholders. This consultation will focus on three key areas: the UK's obligations under the relevant UN conventions; the NHS's requirements for a secure supply of diamorphine; and competition issues in the UK pharmaceuticals market.
<b>Geographical scope:</b>	This policy applies to the whole of the United Kingdom.
<b>Impact assessment (IA):</b>	A consultation stage impact assessment has been prepared and can be found at annex A.

## Basic Information

<b>To:</b>	We are particularly keen to hear from businesses or organisations directly involved in the trade in, and/or manufacture of, oxycodone. We are also keen to hear from those involved in health care who use diamorphine, and those involved in issues around drug misuse.
<b>Duration:</b>	This consultation was published on 23 November 2009. It will close on 15 February 2010.
<b>Enquiries and responses:</b>	By post: Oxycodone Consultation Drugs Licensing and Compliance Unit 4th Floor Fry Building 2 Marsham Street London SW1P 4DF  By email: <a href="mailto:Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk">Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk</a>
<b>Additional ways to become involved:</b>	As this is a largely technical issue, of specialist interest, this will be a purely written exercise.
<b>After the consultation:</b>	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.

## Background

<b>Getting to this stage:</b>	<p>The policy proposals outlined in this consultation document are the product of deliberations between the Home Office, the Department of Health, and the Department of Business, Innovation and Skills.</p> <p>Details of the current regulatory regime can be found in the 'Background' section of this consultation document.</p>
<b>Previous engagement:</b>	<p>The Monopolies and Mergers Commission and the Office of Fair Trading have both conducted reviews of the trade in opium derivatives in the UK, but without a specific focus on oxycodone.</p> <p>"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.</p> <p>"Opium derivatives - a review of the undertakings given by MacFarlan Smith Ltd", Office of Fair Trading, March 2006</p> <p><a href="http://www.offt.gov.uk/shared_offt/reports/consumer_protection/oft834.pdf">http://www.offt.gov.uk/shared_offt/reports/consumer_protection/oft834.pdf</a></p> <p>"Opium derivatives - Government response to OFT's review of undertakings by MacFarlan Smith Ltd", September 2006</p> <p><a href="http://www.berr.gov.uk/files/file33800.pdf">http://www.berr.gov.uk/files/file33800.pdf</a></p>

Should you require a copy of this consultation paper in any other format, e.g. Braille, Large Font, or Audio, you should contact the Home Office Drugs Licensing and Compliance Unit at the address given above in the 'Enquiries and responses' section.

# 1. Introduction

The Government regulates the possession, supply, production and international trade in controlled drugs. It does so because of the very serious harm their misuse can cause to individuals and society.

Long-standing government policy has been to allow the import of controlled drugs from outside the EEA only if those drugs are not available from within the EEA. This policy applied to oxycodone in the same way that it applied to all other controlled drugs.

In 2008, following representations from within the UK pharmaceutical industry that this policy was too restrictive, the Government amended its policy to allow oxycodone imports from outside the EEA provided that all imports were re-exported. However, in 2009 the Government decided to revert to its previous policy on the grounds that import for re-export posed an unacceptable risk to the UK's access to diamorphine.

This consultation now seeks to gather responses to a set of policy proposals that balance the Government's three objectives in this area:

- to meet the UK's obligations under the relevant international Conventions on drug control
- to maintain a supply of diamorphine to the NHS
- to realise the benefits of competition in the UK pharmaceuticals industry for the UK economy

## **2. Background**

### **2.1. Oxycodone**

Oxycodone is an opioid analgesic. It is synthesised from thebaine which is itself derived from opium. Opioids are classified as ‘narcotic drugs’ under the relevant UN Conventions, and oxycodone is controlled as a Class A drug accordingly.

### **2.2. Legislation and international obligations**

Narcotic drugs are subject to Government 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 United Nations Single Convention on Narcotic Drugs 1961 (“the 1961 Convention”), of which the UK is a signatory, and the Misuse of Drugs Act 1971 which gives effect to the 1961 Convention in UK law.

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 narcotic 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 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 1961 Convention 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.<sup>1</sup>

The 1961 Convention also requires signatories to control under a licensing regime the domestic manufacture and trade, and import and export, of controlled drugs.<sup>2</sup>

The Misuse of Drugs Act 1971 puts that licensing requirement in place in the UK and gives the Secretary of State the power to determine the conditions upon which licences will be issued. The licensing system aims to prevent the misuse of drugs, and their diversion into the illicit trade, by monitoring and regulating their licit use throughout the supply chain.

### **2.3. Diamorphine supply for the UK healthcare sector**

The UK is a world leader in palliative care. It is one of the few countries in the world to use diamorphine, a powerful opioid analgesic which has proved to have certain advantages over other painkillers. It has a vital place in current clinical practice in the UK. The Government considers it essential that a suitable supply of diamorphine is maintained.

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<sup>1</sup> The 1961 Convention, Article 29, paragraph 3, and Article 30 paragraph 2.

<sup>2</sup> The 1961 Convention, Articles 29, 30, and 31.



Diamorphine is used in a number of situations:

- acute trauma pain
- acute cardiac pain and left ventricular failure
- management of cancer related pain in patients unable to take opioids orally
- postoperative pain
- some patients with chronic diseases (e.g. sickle cell anaemia)
- some people who are opiate dependent

Diamorphine has a more favourable side effect profile than morphine, in that it may cause less nausea and hypotension. Diamorphine is also more soluble than morphine which means that effective doses can be administered in smaller volumes. This is important in palliative care where patients may be emaciated.

Diamorphine supply is relevant to policy on oxycodone imports due to the current state of the UK opium derivatives market.

The Government is aware of only one commercial-scale manufacturer of diamorphine, Macfarlan Smith Limited (MSL). MSL also manufactures a variety of other opium derivatives, including oxycodone. Diamorphine is a relatively marginal product, because of the limited market for it compared with products such as codeine and oxycodone which are used more widely. MSL has informed the Government that if it cannot make sufficient profit from products such as codeine and oxycodone, it will not be able to continue manufacturing diamorphine. There is no known alternative manufacturer of diamorphine.

There is therefore a risk that policy on oxycodone imports could lead to the cessation of the supply of diamorphine to the NHS.

## **2.4. Government policy on oxycodone imports pre-1997**

It was long-standing government policy that imports of narcotic drugs would not be allowed if they were readily available from within the UK. The restriction would be relaxed in the event of any shortage of supplies within the UK.

This policy was based on two considerations:

1. The Government needed to meet its international obligations under UN drugs control Conventions by: (a) minimising, as far as was reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and (b) managing the manufacture and import of controlled drugs to keep within the estimate.
2. The Government needed to maintain a secure supply of diamorphine, a clinically vital opioid analgesic, for the NHS. As explained at section 2.3 above, due to the nature of the existing diamorphine market the NHS was dependent on one company for its diamorphine supply.

Since the UK was self-sufficient in oxycodone, this policy meant in practice that there were no permitted imports (bar very small quantities for research purposes and such like).

## **2.5. 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 prohibits restrictions on imports between member states of what is now the EU.

However, 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”.<sup>3</sup>

## **2.6. Changes to Government policy following the ECJ ruling**

Following this judgment, the Government changed its policy in 1997 to allow the import of controlled drugs from within the EU. The policy was subsequently expanded to encompass the European Economic Area (EEA).

The Government maintained its restrictions on imports from outside the EEA for the reasons given above: to keep international movements of controlled drugs to a minimum in order to reduce the risk of diversion, and 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.

## **2.7. Opium derivative import policies: international comparison**

The UK is not alone in restricting imports of opium derivatives. Other major European producers do not allow unrestricted imports. The United States of America, which also has a domestic supply of opium derivatives, and like the UK has a large and dynamic pharmaceutical industry, does not allow imports of opium derivatives except in exceptional circumstances, as determined at administrative hearings held by the Drug Enforcement Administration (DEA).

## **2.8. 2006 Office of Fair Trading review**

In March 2006 the Office of Fair Trading (OFT) published a review of the undertaking given by MSL in 1989 to publish and make generally available a list of maximum prices. These undertakings were given following a 1989 report by the Monopolies and Mergers Commission. Both the report and the review noted the monopolistic position held by MSL, the UK’s sole manufacturer of opium derivatives. The OFT review stated that there is a ‘competition problem’ in the sector, and that the main reason for it is the trading restrictions on opium derivatives that are maintained through 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’.

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<sup>3</sup> Judgement 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 Government welcomed the recommendation and committed itself to repeating the process of review every five years. The next review is due in 2011.<sup>4</sup>

## **2.9. Import for re-export**

In February 2008 the Home Office agreed to a request 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, however, 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.<sup>5</sup>

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

1. 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.
2. The Government was keen to maintain a secure supply of diamorphine. There was a risk that MSL, the sole known commercial-scale manufacturer of diamorphine, would cease to manufacture it if its financial viability was threatened by increased competition in the oxycodone market.
3. There was a risk that the estimate would be exceeded.

<sup>4</sup> "Opium derivatives - a review of the undertakings given by MacFarlan Smith Ltd", Office of Fair Trading, March 2006  
[http://www.offt.gov.uk/shared\\_offt/reports/consumer\\_protection/oft834.pdf](http://www.offt.gov.uk/shared_offt/reports/consumer_protection/oft834.pdf)

"Opium derivatives - Government response to OFT's review of undertakings by MacFarlan Smith Ltd", September 2006  
<http://www.berr.gov.uk/files/file33800.pdf>

<sup>5</sup> 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"

## 3. Issues

Government policy on the import of oxycodone should be based around three central considerations:

- To comply with the letter and the spirit of the UK's international obligations: (a) by minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion; and (b) by managing the manufacture and imports of controlled drugs to keep within the estimate system
- To maintain a secure supply of diamorphine, as required by the NHS
- The impact of licensing policy on competition in the UK pharmaceutical market

### 3.1. Compliance with international obligations

The Government considers that the 1961 Convention should be followed not only in the letter, but also in spirit. 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. Further, it is right that the Government manages the licensing system to ensure that the manufacture and import of controlled drugs stays within the estimate system.

The 'spirit' of the 1961 Convention is elucidated in the UN Secretary-General's Commentary on the Single Convention on Narcotic Drugs, 1961.<sup>6</sup> 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 estimates 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, 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)"<sup>7</sup>.

### 3.2. Security of supply for the NHS

Diamorphine is a powerful opioid analgesic which has proved to have certain advantages over other painkillers. It has a vital place in current clinical practice in the UK. The Government considers it essential that a reliable supply of diamorphine is maintained.

There is no policy principle that ties together the issues of diamorphine supply and oxycodone imports.

Due to current market conditions, as explained at section 2.3 above, this issue is linked at present to the policy on oxycodone imports. Were there to be manufacturers of diamorphine unaffected by oxycodone import policy, these issues would be de-coupled.

<sup>6</sup> Commentary on the Single Convention on Narcotic Drugs, 1961, United Nations Publications, New York, 1973.

<sup>7</sup> Commentary on the Single Convention on Narcotic Drugs, 1961, pages 39, 157, and 264.

### **3.3. Competition in the UK 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, encourages firms to deliver benefits to customers in terms of prices, quality and choice”. In general, competitive markets are in the public interest, bringing benefits to the UK economy and the taxpayer.

The Government accepted the OFT’s recommendation that it takes competition issues into consideration when devising licensing policy.<sup>8</sup> It is important that where regulation affects markets, it is operated in a transparent manner.

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<sup>8</sup> 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 Government is putting forward four policy options for the licensing of imports of oxycodone in the UK. Each one balances in different ways the need to:

- (a) reduce the risk of diversion,
- (b) maintain a secure supply of diamorphine for public health reasons, and
- (c) realise the benefits of competition for the UK economy and tax payer.

You are invited to comment on them, and suggest other options.

### **Option 1: Restrict imports from outside the EEA**

- Imports of oxycodone will only be allowed from within the EEA. Only if oxycodone is not available from within the EEA will imports from outside the EEA be allowed.
- If imports of oxycodone from outside the EEA do become necessary, the estimate for oxycodone will be broken down into quotas for imports and domestic supply to ensure that the NHS's supply of diamorphine is not threatened.

This option minimises the international movement of narcotic drugs as far as is possible given the current ECJ case law. It maintains a secure supply of diamorphine, but limits competition in order to achieve these goals. Market competition within the EEA will be permitted insofar as it does not threaten the viability of the NHS's supply of diamorphine.

### **Option 2: Allow limited imports from outside the EEA under a quota system**

- Imports will be allowed from outside the EEA and will not be limited to re-export
- The estimate for oxycodone will be broken down into quotas for imports and domestic supply to ensure that the NHS's supply of diamorphine is not threatened

This option allows for a greater level of international movement of narcotic drugs, with the risk of diversion that entails, in order to increase competition in the UK pharmaceutical market. That competition will be restricted only in so far as is necessary to maintain a secure supply of diamorphine for the NHS. The Government does not know at this stage to what extent limits on imports would be required. We invite respondents to submit information to allow the Government to estimate the likely level, if any, of limits on imports under this option.

At present, the Government is aware of only one company in the world, MSL, that manufactures diamorphine on a commercial scale. If current market conditions remain, options 1 and 2 will in practice mean using the quota system to ensure that MSL remains financially viable. However, the Government always has been, and remains, willing to licence other manufacturers of diamorphine and the quota system would be amended accordingly were other manufacturers to enter the market.

### **Option 3: Allow unrestricted imports from outside the EEA**

- Imports of oxycodone would be allowed from anywhere in the world
- The estimate would be the only limit on imports

This option maximises market competition, introducing a free market in oxycodone in the UK. It does nothing to minimise the international movements of narcotic drugs and therefore is liable to increase the risk of diversion. It does nothing to secure the supply of vitally needed diamorphine to the NHS.

### **Option 4: Allow imports for re-export**

- Imports would only be allowed provided the entire amount imported was for re-export and not for consumption within the UK
- Imports for re-export would be allowed from outside the EEA

This option allows market competition provided the oxycodone imported is re-exported. It maintains a restricted market for oxycodone that is not for re-export. As all imports will be exported, they will not directly affect the estimate (although if they displace domestically manufactured supply, the estimate may be affected if the domestic supply is not reduced). It does not minimise the international movement of narcotic drugs and therefore increases the risk of diversion. It does nothing to secure the supply of diamorphine for the NHS.

## **5. The Government's preferred option**

The Government's current preferred option is Option 1, to restrict imports from outside the EEA. This option is preferred because:

- it minimises international movements of controlled drugs, which have been identified as posing a high risk of diversion
- It minimises the potential for the mismanagement of the estimate and the accumulation of stocks of controlled drugs, which would be contrary to Article 29, paragraph 3 of the 1961 Convention
- It maintains the status quo in supply of diamorphine to the NHS
- It allows for market competition, albeit restricted to competition within the EEA.

A consultation stage impact assessment has been prepared and can be found at annex A of this document.



## 6. Consultation responses

We would welcome any comments on the policies proposed, and on the partial impact assessment at annex A. Any relevant information to support a more detailed impact assessment would also be welcomed.

Please send your responses to:

Oxycodone Consultation  
Drugs Licensing and Compliance Unit  
4th Floor Fry Building  
2 Marsham Street  
London  
SW1P 4DF

or by email to:

[Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk](mailto:Druglicensingconsultationsinbox@homeoffice.gsi.gov.uk)

Comments must be received by 15 February 2010.

### Responses: Confidentiality & Disclaimer

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

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

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

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

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

## Consultation criteria

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

### **Criterion 1**

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

### **Criterion 2**

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

### **Criterion 3**

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

### **Criterion 4**

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

### **Criterion 5**

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

### **Criterion 6**

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

### **Criterion 7**

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

The full Code of Practice on Consultation is available at:

<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html>

## Consultation Co-ordinator

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

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

**Nigel Lawrence, Consultation Co-ordinator**

Home Office  
Performance and Delivery Unit  
Better Regulation Team  
3rd Floor Seacole  
2 Marsham Street  
London  
SW1P 4DF

# Annex A: Consultation Stage Impact Assessment

Summary: Intervention & Options	
Department /Agency: Home Office	
Title: Impact Assessment of policy proposals for the regulation of imports of oxycodone	
Stage: Consultation	
Version: 1.0	Date: 12 November 2009
Related Publications: Oxycodone consultation document	
Available to view or download at: <a href="http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/">http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/</a>	
Contact for enquiries: Joe Barker	
Telephone: 020 7035 1868	

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

The trade in 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. Some UK pharmaceutical businesses claim that this policy is restricting competition in the market for oxycodone to a damaging extent.

Government 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.

## What are the policy objectives and the intended effects?

Government policy is driven by three objectives: (a) to minimise the international movements of controlled drugs; (b) to maintain a supply of diamorphine for the NHS; (c) to realise the benefits of competition in the UK pharmaceuticals market for the UK economy.

Intended effects: reduce the risk of harm caused by the misuse or diversion of controlled drugs whilst maintaining a secure supply of diamorphine for the NHS and a competitive UK pharmaceuticals industry.

## What policy options have been considered? Please justify any preferred option.

1. No change: Restrict imports from outside the EEA.
2. Allow limited imports from outside the EEA even if they are not for re-export.
3. Allow unrestricted imports from outside the EEA.
4. Allow imports from outside the EEA for re-export only.

Option 1 is the Government's preferred option because it represents the best balance of minimising the risk of diversion, maintaining a supply of diamorphine, and allowing market competition.

**When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?**

This policy will be reviewed in 2011, alongside the 5 yearly review of opium derivatives policy to which the government has already committed itself

**Ministerial Sign-off for consultation stage Impact Assessments:**

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

A handwritten signature in dark ink, reading "Alan Campbell". The signature is written in a cursive, flowing style.

Date: 12 November 2009

## Summary: Analysis & Evidence

### Policy Option: 1

#### Description: No change: Restrict imports from outside the EEA

<b>COSTS</b>	
Description and scale of <b>key monetised costs</b> by 'main affected groups'	
The scale of key monetised costs to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL COSTS</b>	
<b>One-off (Transition)</b>	Yrs
£ Unknown	
<b>Average Annual Cost (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other key non-monetised costs by 'main affected groups'	
-may lead to higher prices for UK oxycodone customers -may reduce growth in the UK pharmaceuticals industry due to artificially high oxycodone prices	
<b>BENEFITS</b>	
Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
The scale of key monetised benefits to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL BENEFITS</b>	
<b>One-off</b>	Yrs
£ Unknown	
<b>Average Annual Benefit (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised benefits</b> by 'main affected groups'	
Keeps international movements of oxycodone to a minimum, reducing the risk of diversion; prevents risk of UK oxycodone suppliers losing trade to international competitors; maintains secure supply of diamorphine for the NHS.	

## Key Assumptions/Sensitivities/Risks

-The UK pharmaceutical industry in areas using oxycodone may fail to reach its full potential if UK prices are higher than international competitors' prices.

Price Base	Time Period	Net Benefit Range (NPV)	NET BENEFIT (NPV Best estimate)
Year	Years	£ Unknown	£ Unknown

What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?				
Which organisation(s) will enforce the policy?	Home Office			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	N/A			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	Yes			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)				(Increase - Decrease)	
Increase of	£ Unknown	Decrease of	£ Unknown	Net Impact	£ Negligible

<b>Key:</b>	Annual costs and benefits: Constant Prices	(Net) Present Value
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## Summary: Analysis & Evidence

### Policy Option: 2

#### Description: Allow imports from outside the EEA under a quota system

<b>COSTS</b>	
Description and scale of <b>key monetised costs</b> by 'main affected groups'	
The scale of key monetised costs to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL COSTS</b>	
<b>One-off (Transition)</b>	Yrs
£ Unknown	
<b>Average Annual Cost (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised costs</b> by 'main affected groups'	
-UK oxycodone suppliers may lose business to foreign rivals undercutting their prices -increased risk of diversion in line with increased volume of international transit of oxycodone	
<b>BENEFITS</b>	
Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
The scale of key monetised benefits to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL BENEFITS</b>	
<b>One-off</b>	Yrs
£ Unknown	
<b>Average Annual Benefit (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised benefits</b> by 'main affected groups'	
UK pharmaceutical companies may become more competitive internationally and increase profits if able to source oxycodone more cheaply; benefit to the economy if UK pharmaceutical industry grows; secure supply of diamorphine can be maintained	



### Key Assumptions/Sensitivities/Risks

The Government does not manage the quota system effectively due to lack of market information, leading to either: oxycodone prices remaining artificially high in the UK due to lack of competition; or, the sole manufacturer of diamorphine going out of business due to the strong price competition.

Price Base	Time Period	Net Benefit Range (NPV)	NET BENEFIT (NPV Best estimate)
Year	Years	£ Unknown	£ Unknown

What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?				
Which organisation(s) will enforce the policy?	Home Office			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	N/A			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	Yes			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)					(Increase - Decrease)
<b>Increase of</b>	£ Unknown	<b>Decrease of</b>	£ Unknown	<b>Net Impact</b>	£ Negligible

<b>Key:</b>	Annual costs and benefits: Constant Prices	(Net) Present Value
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## Summary: Analysis & Evidence

### Policy Option: 3

#### Description: Allow unrestricted imports from outside the EEA

<b>COSTS</b>	
Description and scale of <b>key monetised costs</b> by 'main affected groups'	
The scale of key monetised costs to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL COSTS</b>	
<b>One-off (Transition)</b>	Yrs
£ Unknown	
<b>Average Annual Cost (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised costs</b> by 'main affected groups'	
Greater risk of diversion than option 2 in line with increased volume of international transit of oxycodone; UK oxycodone suppliers may lose business to foreign rivals; secure supply of diamorphine may be put at risk if UK's sole manufacturer goes out of business.	
<b>BENEFITS</b>	
Description and scale of <b>key monetised benefits</b> by 'main affected groups'	
The scale of key monetised benefits to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL BENEFITS</b>	
<b>One-off</b>	Yrs
£ Unknown	
<b>Average Annual Benefit (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised benefits</b> by 'main affected groups'	
Greatest potential for price reductions for UK oxycodone, in line with greatest possible level of competition; UK pharmaceutical companies may become more competitive internationally and increase profits, leading to benefits for the wider UK economy.	

### Key Assumptions/Sensitivities/Risks

The increased international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse; risk that sole UK manufacturer of diamorphine will go out of business, depriving NHS of a secure supply.

Price Base	Time Period	Net Benefit Range (NPV)	NET BENEFIT (NPV Best estimate)
Year	Years	£ Unknown	£ Unknown

What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?				
Which organisation(s) will enforce the policy?	Home Office			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	N/A			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	Yes			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)				(Increase - Decrease)	
Increase of	£ Unknown	Decrease of	£ Unknown	Net Impact	£ Negligible

<b>Key:</b>	Annual costs and benefits: Constant Prices	(Net) Present Value
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## Summary: Analysis & Evidence

### Policy Option: 4

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

<b>COSTS</b>	
Description and scale of <b>key monetised costs</b> by ‘main affected groups’	
The scale of key monetised costs to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL COSTS</b>	
<b>One-off (Transition)</b>	Yrs
£ Unknown	
<b>Average Annual Cost (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other <b>key non-monetised costs</b> by ‘main affected groups’	
Greater risk of diversion than option 1 in line with increased volume of international transit of oxycodone; UK oxycodone suppliers may lose business to foreign rivals; secure supply of diamorphine may be put at risk if UK’s sole manufacturer goes out of business.	
<b>BENEFITS</b>	
Description and scale of <b>key monetised benefits</b> by ‘main affected groups’	
The scale of key monetised benefits to the main affected groups is to be informed by consultation responses.	
<b>ANNUAL BENEFITS</b>	
<b>One-off</b>	Yrs
£ Unknown	
<b>Average Annual Benefit (excluding one-off)</b>	
£ Unknown	
<b>Total Cost (PV)</b>	
£ Unknown	
Other key non-monetised benefits by ‘main affected groups’	
Potential for price reductions for oxycodone consumers who re-export the product; UK pharmaceutical companies may become more competitive internationally and increase profits, leading to benefits for the wider UK economy.	

### Key Assumptions/Sensitivities/Risks

Increased international transit could lead to increased diversion and increased harm caused by drug misuse; risk that sole UK manufacturer of diamorphine will go out of business, depriving NHS of a secure supply; the estimate may still be exceeded if imports replace domestic supply.

Price Base	Time Period	Net Benefit Range (NPV)	NET BENEFIT (NPV Best estimate)
Year	Years	£ Unknown	£ Unknown

What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?				
Which organisation(s) will enforce the policy?	Home Office			
What is the total annual cost of enforcement for these organisations?	£			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	N/A			
What is the value of the proposed offsetting measure per year?	£			
What is the value of changes in greenhouse gas emissions?	£			
Will the proposal have a significant impact on competition?	Yes			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)				(Increase - Decrease)	
Increase of	£ Unknown	Decrease of	£ Unknown	Net Impact	£ Negligible

<b>Key:</b>	Annual costs and benefits: Constant Prices	(Net) Present Value
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# Evidence Base (for summary sheets)

## A. Strategic Overview

The UK regulates the possession, supply, production, import and export of narcotic drugs under the Misuse of Drugs Act 1971. Oxycodone falls within the remit of the 1971 Act. Narcotic drugs are controlled because of the very serious harm their misuse can cause to individuals and society.

Long-standing government policy has been to allow the importation of controlled drugs from outside the EEA only if they are not available from within the EEA. There has been feedback from within the UK pharmaceutical industry that this system is too restrictive, and that oxycodone imports should be allowed from outside the EEA.

This consultation seeks to gather responses to a set of policy proposals that balance the Government's three objectives in this area: to minimise the risk of diversion of controlled drugs; to maintain a supply of diamorphine to the NHS; to realise the benefits of competition in the UK pharmaceuticals industry for the UK economy.

### Administrative burdens

Options 2, 3 and 4 may result in an increase in applications for import and export licences. This would lead to an increase in the volume of work for licensees to submit applications, and the Home Office to process applications, than at present. The impact on administrative burdens would be negligible.

## B. Issue

### B.1 Groups Affected

Directly affected	Indirectly affected
The UK-based oxycodone manufacturer	The wider UK pharmaceuticals industry
UK-based oxycodone suppliers	Patients who rely on diamorphine for pain control
UK-based oxycodone customers	Customers for products made using oxycodone
International oxycodone suppliers	Those at risk of harm from the diversion of oxycodone or products made using oxycodone
	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

This 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 greatly in excess of the perceived cost to the individual. The market alone does not prevent narcotic drugs being diverted into the illicit trade. Therefore Government intervention, through its licensing system, is necessary.

## **C. Objectives**

### **C1. Objectives**

The Government has three objectives in formulating its policy on oxycodone imports:

- To minimise international movements of controlled drugs in order to reduce the risk of diversion
- To maintain a secure supply of diamorphine, as required by the NHS
- To realise the benefits of competition in the UK pharmaceutical market for the UK economy and the tax payer

### **C2. Background**

Oxycodone is an opioid analgesic. It is synthesised from thebaine which is itself derived from opium. Opioids are classified as ‘narcotic drugs’ under the relevant UN conventions.

Narcotic drugs are subject to Government 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.

Save 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 licit 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 1961 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 authorized to possess narcotic drugs.

It has 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 judgement in the European Court of Justice, this policy was amended to allow imports from within the European Economic Area.

### **The relationship between diamorphine and oxycodone**

The NHS uses diamorphine for pain control. The NHS has found it to have clinical benefits over other available pain killers. The Department of Health considers it essential that a supply of diamorphine is maintained.

Diamorphine is used in a number of situations:

- acute trauma pain
- acute cardiac pain and left ventricular failure
- management of cancer related pain in patients unable to take opioids orally
- postoperative pain
- some patients with chronic diseases (eg sickle cell anaemia)
- some people who are opiate dependent

Diamorphine has a more favourable side effect profile than morphine, in that it may cause less nausea and hypotension. Diamorphine is also more soluble than morphine which means that effective doses can be administered in smaller volumes. This is important in palliative care where patients may be emaciated.

To the Government's knowledge, diamorphine is only manufactured on a commercial scale by one company, Macfarlan Smith Limited (MSL) and the NHS is by far the largest end-user of diamorphine. MSL is also the UK's main supplier of oxycodone. If international competition in the oxycodone market leads to MSL's prices being undercut, there is a risk of it going out of business which would cause the NHS to lose its sole source of diamorphine.

### **Recent developments**

In February 2008 the Home Office agreed to a request 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, however, 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 (in the opinion of the Home Office) to Article 29 of the 1961 Convention.<sup>9</sup>

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

1. 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.

<sup>9</sup> 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"



2. The Government was keen to maintain a secure supply of diamorphine. There was a risk that MSL, the sole known commercial-scale manufacturer of diamorphine, would cease to manufacture it if its financial viability was threatened by increased competition in the oxycodone market.
3. There was a risk that the estimate would be exceeded.

## **D. Options**

### **Option 1: No change: Restrict imports from outside the EEA**

- Imports of oxycodone will only be allowed from within the EEA. If oxycodone is not available from within the EEA, imports from outside the EEA will be allowed
- If imports of oxycodone do become necessary, the estimate for oxycodone will be broken down into quotas for imports and domestic supply to ensure that the NHS's supply of diamorphine is not threatened

### **Option 2: Allow limited imports from outside the EEA under a quota system**

- Imports will be allowed from outside the EEA and will not be limited to re-export
- Where necessary, the estimate for specific narcotic drugs will be broken down into quotas for imports and domestic supply to ensure that the NHS's supply of diamorphine is not threatened

### **Option 3: Allow unrestricted imports from outside the EEA**

- Imports of oxycodone would be allowed from anywhere in the world
- The estimate would be the only limit on imports

### **Option 4: Allow imports from outside the EEA for re-export**

- Imports would only be allowed provided the entire amount imported was for re-export and not for consumption within the UK
- Imports of oxycodone for re-export would be allowed from anywhere in the world

## **E. Costs and Benefits**

The Government lacks detailed market data for oxycodone in both domestic and international markets. This means that this impact assessment will necessarily deal with impacts from market changes in general terms. The assumptions that inform this assessment are set out below. Consultation respondents are invited to submit detailed figures to inform Government policy and future iterations of this impact assessment.

### **General Assumptions and Data**

- In general, increases in the volume of international transit of controlled drugs increase the risk of diversion
- At present, misuse of oxycodone-based drugs in the UK appears to be rising, albeit from a low starting point (see table E.1).

**Table E.1: Number of deaths at which oxycodone was mentioned by the pathologist and/or coroner in the cause of death at inquest, 2001 – 2008**

Year	Number of deaths
2001	2
2002	0
2003	6
2004	3
2005	7
2006	5
2007	17
2008*	10

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.

\* Data for 2008 was incomplete at time of publication.

- In 2008 there were over 600,000 prescriptions for oxycodone-based drugs (both Oxycontin and Oxynorm) in England<sup>10</sup>
- The NHS spent approximately £10.4 million on injectable diamorphine in 2008 in England
- Clinical practice in the UK is such that diamorphine is regarded as the gold standard for pain relief, and it has clear advantages for patients, as described in the section entitled ‘The relationship between diamorphine and oxycodone’ above
- There is presently only one known manufacturer of diamorphine on a commercial scale
- In 2008 there were 9 companies in the UK who sold oxycodone, of which 6 only traded in very small amounts (less than 3kg)
- In general, increased market competition is good for consumers
- A more competitive UK pharmaceuticals industry is likely to benefit the economy

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.

<sup>10</sup> Prescription Cost Analysis, England 2008, page 130. Published by the NHS Information Centre.

<b>Table E.2: Oxycodone manufacture and consumption in the UK, 2003 – 2007</b>		
Year	Oxycodone manufactured (kg)	Oxycodone consumed (kg)
2007	9,206	217
2006	8,547	416
2005	10,888	501
2004	7,586	363
2003	4,692	251
Source: INCB Narcotic Drugs Statistics for 2007 (published by the United Nations, 2009)		

<b>Table E.3: Oxycodone imports and exports, 2003 – 2007</b>		
Year	Exports (kg)	Imports (kg)
2007	9,285	44
2006	7,370	379
2005	6,660	22
2004	5,092	17
2003	3,824	4
Source: INCB Narcotic Drugs Statistics for 2007 (published by the United Nations, 2009), INCB Narcotic Drugs Statistics for 2005 (published by the United Nations, 2007)		

## **Option 1 – No change: Restrict imports from outside the EEA**

### **Costs**

- may lead to higher prices for UK oxycodone customers
- may reduce growth in the UK pharmaceuticals industry due to artificially high oxycodone prices

### **Benefits**

- keeps international movements of oxycodone to a minimum and thus reduces risk of diversion
- prevents risk of UK oxycodone suppliers losing trade to international competitors
- maintains secure supply of diamorphine for the NHS

## **Option 2 – Allow limited imports from outside the EEA under a quota system beyond allowing imports for re-export only**

### **Costs**

- UK oxycodone suppliers may lose business to foreign rivals undercutting their prices
- increased risk of diversion in line with increased volume of international transit of oxycodone

### **Benefits**

- UK oxycodone customers may be able to obtain oxycodone more cheaply
- UK pharmaceutical companies may become more competitive internationally and increase profits
- benefit to the economy if UK pharmaceutical industry grows
- maintains secure supply of diamorphine for the NHS

## **Option 3 – Allow unrestricted imports from outside the EEA**

### **Costs**

- greater risk of diversion than option 2 in line with increased volume of international transit of oxycodone
- UK oxycodone suppliers may lose business to foreign rivals
- falling profits from oxycodone may drive the sole known diamorphine manufacturer out of business. If this were to occur, the NHS's supply of diamorphine would be threatened and the quality of patient care may suffer
- Environmental impact- if Option 3 were to lead to UK oxycodone customers purchasing all their supplies from beyond the UK there would be an increase in international freight movements. If all oxycodone currently manufactured in the UK was replaced by imports it would result in about 9,000 – 10,000 kg of extra freight (based on figures for UK manufacture of oxycodone, 2005 – 2007 at table E.3 above). Given the volume of international freight movements the impact of this increase would be negligible

### **Benefits**

- greatest potential for price reductions for UK oxycodone, in line with greatest possible level of competition
- UK pharmaceutical companies may become more competitive internationally and increase profits
- benefit to the wider economy if UK pharmaceutical industry grows

## Option 4 – Allow imports from outside the EEA for re-export

### Costs

- increased risk of diversion in line with increased volume of international transit of oxycodone
- UK oxycodone suppliers may lose business to foreign rivals
- falling profits from oxycodone sales may drive the sole known diamorphine manufacturer out of business. If this were to occur, the NHS's supply of diamorphine would be threatened and the quality of patient care may suffer

### Benefits

- UK oxycodone customers who export the finished product will have access to a wider market and may find cheaper sources of oxycodone than that currently available within the EEA
- UK pharmaceutical companies may become more competitive internationally and increase profits
- benefit to the wider economy if UK pharmaceutical industry grows

## **F. Risks**

### **Option 1 – No change: Restrict imports from outside the EEA**

- The UK pharmaceutical industry in areas using oxycodone may fail to reach its full potential if UK prices are higher than international competitors' prices
- Economic growth may fail to be maximised if the UK pharmaceutical industry does not reach its full economic potential
- Ongoing risk to continuity of supply for as long as the NHS is dependent on a single manufacturer of diamorphine

### **Option 2 – Allow limited imports from outside the EEA under a quota system**

- The Government does not manage the quota system effectively due to lack of market information, leading to either: oxycodone prices remaining artificially high in the UK due to lack of competition; or, the sole UK manufacturer of diamorphine going out of business due to the level of competition in the oxycodone market
- The increased international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse

### **Option 3 – Allow unrestricted imports from outside the EEA**

- The increased international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse
- The increased volume of imports could result in the UK breaking its INCB estimate
- If increased price competition leads to falling profitability of oxycodone supply in the UK, there is a risk that the sole manufacturer of diamorphine may go out of business
- If diamorphine is no longer available to the NHS, there is a risk that alternative drugs giving the same benefits to patients will either (a) not exist, therefore leading to a qualitative reduction in the quality of patient care; or (b) be available but at greater cost than diamorphine, imposing an extra cost on the exchequer

### **Option 4 – Allow imports from outside the EEA for re-export**

- The increased international transit of oxycodone could lead to increased diversion and increased harm caused by drug misuse
- 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
- If increased price competition leads to falling profitability of oxycodone supply in the UK, there is a risk that the sole manufacturer of diamorphine may go out of business

- If diamorphine is no longer available to the NHS, there is a risk that alternative drugs giving the same benefits to patients will either (a) not exist, therefore leading to a qualitative reduction in the quality of patient care; or (b) be available but at greater cost than diamorphine, imposing an extra cost on the exchequer

## **G. Enforcement**

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

## **H. Summary and Recommendations**

The table on the following page outlines the costs and benefits of the proposed changes. Option 1 is the Government's preferred option.

<b>Table H.1 Costs and Benefits</b>		
Option	Cost	Benefit
<b>1</b>	UK oxycodone customers would not have access to cheaper sources of oxycodone from outside the UK (not quantified)	Less risk of diversion of oxycodone (not quantified)
	Cost to the UK pharmaceuticals industry due to artificially high oxycodone prices (not quantified)	Secure supply of diamorphine for the NHS (not quantified)
		UK oxycodone suppliers would not face competition from beyond the EEA (not quantified)
<b>2</b>	UK oxycodone suppliers may lose business to rival suppliers from outside the EEA (not quantified)	UK oxycodone customers may be able to obtain oxycodone more cheaply (not quantified)
	Greater risk of diversion of oxycodone, leading to greater costs in tackling illegal drugs and treating drugs misusers (not quantified)	UK pharmaceuticals companies who use oxycodone to make products may become more competitive in international markets
		Benefit to the wider economy if the UK pharmaceutical industry grows
		Secure supply of diamorphine for the NHS and its patients (not quantified)
<b>3</b>	Greater risk of diversion of oxycodone, leading to greater costs in tackling illegal drugs and treating drugs misusers (not quantified)	UK oxycodone customers able to obtain oxycodone more cheaply (not quantified)
	UK oxycodone suppliers may lose business to rival suppliers outside the EEA (not quantified)	UK pharmaceuticals companies who use oxycodone to make products may become more competitive in international markets
	Risk that supply of diamorphine to NHS would cease and NHS would need to find alternative forms of pain relief and/or quality of patient care could suffer(not quantified)	Benefit to the wider economy if the UK pharmaceutical industry grows
<b>4</b>	Greater risk of diversion of oxycodone, leading to greater costs in tackling illegal drugs and treating drugs misusers (not quantified)	UK oxycodone customers able to obtain oxycodone more cheaply if they are importing for re-export (not quantified)
	UK oxycodone suppliers may lose business to rival suppliers outside the EEA (not quantified)	UK pharmaceuticals companies who import oxycodone for re-export may become more competitive in international markets
	Risk that supply of diamorphine to NHS would cease and NHS would need to find alternative forms of pain relief and/or quality of patient care could suffer(not quantified)	Benefit to the wider economy if the UK pharmaceutical industry grows



## 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). DLCU is already committed to a more general review of the UK opium derivatives market in 2011, and this policy will be reviewed at the same time.

## Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

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 UK market for oxycodone. This increased competition would be expected to drive down prices for oxycodone, which would result in two potential offsetting health effects.

First, reduction in oxycodone prices 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.

Second, reduction in oxycodone prices may adversely affect the business prospects of Macfarlan Smith Ltd (MSL), the only supplier to the UK market of diamorphine, another opiate analgesic. MSL have claimed to the Department of Health (DH) that their expected loss of revenue from oxycodone sales may render their business unviable, particularly if the market is opened up to other imports. DH are currently unable to verify or disprove this claim, or to determine if another supplier could be expected to replace MSL in the market. It is possible that the loss of economies of scale from production of oxycodone would result in greater costs in production of diamorphine. This increase in costs could be offset by an increase in the price of diamorphine - in which case the NHS would sustain a negative health impact, as funds otherwise used for treatments elsewhere in the NHS would be diverted to increased payments for diamorphine. It is also possible that the price increase required to maintain economic production would be so high that the NHS could no longer cost-effectively fund diamorphine treatments. In this case, there would be a health loss as NHS patients would no longer be able to access diamorphine. Clinical practice in the UK is such that diamorphine is regarded as the gold standard for pain relief, and it has clear advantages for patients. The Department of Health does not have sufficient information regarding the economics of diamorphine production to determine whether the price increase required to make production economically viable would render diamorphine too expensive for cost-effective use in the NHS.

### Competition Assessment

#### Option 1 – No change: Restrict imports from outside the EEA

Would the proposal:

- Directly limit the number or range of suppliers?

*This option directly limits the number or range of suppliers because imports from outside the EEA would not be allowed. There would be no limits on the number or range of suppliers from within the UK and EEA.*

- Indirectly limit the number or range of suppliers?

No.

- Limit the ability of suppliers to compete?

*This option does not limit the ability of suppliers within the EEA to compete. Suppliers from outside the EEA would not be able to enter the market.*

- Reduce suppliers' incentives to compete vigorously?

*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.*

## **Option 2 – Allow limited imports from outside the EEA under a quota system**

Would the proposal:

- Directly limit the number or range of suppliers?

*The number or range of suppliers would only be limited if the volume of imports from outside the EEA threatened the continuing supply of diamorphine to the NHS due to its impact on Macfarlan Smith Ltd. Were the diamorphine supply to be put in jeopardy imports from outside the EEA would be restricted (although not necessarily prevented altogether) and this would limit the amount of oxycodone that could be purchased from suppliers outside the EEA, although not the number or range of supplier.*

- Indirectly limit the number or range of suppliers?

No.

- Limit the ability of suppliers to compete?

*If the quota system was used to limit the volume of imports from outside the EEA the ability of suppliers from outside the EEA would be limited because the amount of oxycodone they could sell would be limited. The ability of suppliers from within the EEA would not be affected.*

- Reduce suppliers' incentives to compete vigorously?

*The use of a quota on imports from outside the EEA to protect the NHS's supplier of diamorphine would reduce that 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.*

## **Option 3 – Allow unrestricted imports from outside the EEA**

Would the proposal:

- Directly limit the number or range of suppliers?

No.

- Indirectly limit the number or range of suppliers?

No.

- Limit the ability of suppliers to compete?

No.

- Reduce suppliers' incentives to compete vigorously?

No.

#### **Option 4 – Allow imports from outside the EEA for re-export**

Would the proposal:

- Directly limit the number or range of suppliers?

*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.*

- Indirectly limit the number or range of suppliers?

No.

- Limit the ability of suppliers to compete?

No.

- Reduce suppliers' incentives to compete vigorously?

*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.*

#### **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 are small or medium enterprises (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 1 – No change: Restrict imports from outside the EEA**

This option would maintain the status quo.

#### **Option 2 – Allow limited imports from outside the EEA under a quota system**

This option would allow customers for 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 UK and/or 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.

#### **Option 3 – Allow unrestricted imports from outside the EEA**

This option would have the same impact on small firms as Option 2.

**Option 4 – Allow imports from outside the EEA for re-export**

This option would have the same impact on small firms as Options 2 and 3.

**Equality Impact Assessment**

All four 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 four options was found to be likely to have a disproportionate impact on any of the target areas, and it was decided that a full equality impact assessment was not required.

