Title: Oxycodone Import Policy Reform IA **IA No: HO0197** **Lead department or agency:** Home Office **Other departments or agencies:** Department of Health, Department for Business Investment and Skills	**Impact Assessment (IA)** **Date:**26/08/2015 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** DrugLicensingConsultationsInbox@homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

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, Two-Out?**	**Measure qualifies as**
£0	N/A	N/A	No	NA

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

Oxycodone is a powerful narcotic used by the medical profession; it is both produced and consumed in the UK. The possession, supply, production, import and export of oxycodone are regulated by the Home office as part of its statutory obligations under the Misuse of Drugs Act 1971 (MDA 1971). It does so because of the harm that misuse of these substances can cause to individuals and society. It is also legally required to manage the import and export of controlled narcotics under the MDA 1971 and the Misuse of Drugs Regulations (MDR 2001) as well as international treaties (the UN conventions on narcotics).

Currently, oxycodone can only be imported into the UK under certain conditions and only one company is currently producing the raw ingredient form of oxycodone (the active pharmaceutical ingredient, API) in the UK. These import controls limit competition, potentially increasing the price of drugs and reducing the competitiveness of the UK pharmaceutical industry. This impact assessment considers proposals to lift the import controls, allowing the free flow of oxycodone (subject to Home Office licensing and regulation).

What are the policy objectives and the intended effects?

The key objectives are to maintain an effective licensing regime for controlled drugs under the MDA 1971 and MDR 2001; ensure access for British consumers to the cheapest possible pharmaceuticals; and maintain and extend the competitiveness of the UK pharmaceutical industry.

The intended effects are an increase in competition in the market for oxycodone, in both its API and finished dosage format forms (FDF); and continuing effective control over the movement of controlled narcotics.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Seven policy options were considered at consultation stage (see paragraph 20 for a full list). Based on the response to the consultation as well as the available evidence these seven options have been reduced to three. Non-regulation options have not been considered as the Home Office is legally required to regulate controlled narcotics under the MDA (1971 and 2001) and international treaties.

Will the policy be reviewed?

The impact of the policy will be monitored by the Home Office, Department of Health and the Department of Business Investment and Skills and will be reconsidered if it results in significant problems.

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** **Yes**	**< 20** Yes	**Small** **Yes**	**Medium** **Yes**	**Large** **Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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: Mike Penning Date: 14 September 2015

Summary: Analysis & Evidence

Policy Option 2

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
2015/16	2015/16	10 yrs	Low: N/A	High: N/A	Best Estimate: £0m

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

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

Our best estimate is that the cost of this policy will be nil. This is based on the conclusion that MSL's oxycodone API prices are currently competitive, which is supported by the available evidence. This means that MSL is unlikely to lose business as a result of import controls being lifted to either the whole world or the EEA. As a result, there should be no further impacts on the wider UK economy or the supply of diamorphine.

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

There are three key non-monetised *potential* costs as a result of Option 2:

- A reduction in profits at UK companies. The available evidence suggests that UK oxycodone producers are price competitive and thus unlikely to suffer. It is however possible that the lowering of import controls could result in a loss of profits to MSL.
- The wider economic impact of the loss of oxycodone production. While MSL's competitive prices suggest that production will continue, if oxycodone production were halted or reduced this could have an impact on MSL's employees, suppliers and the UK economy as a whole. It is not possible to estimate the exact scale of this impact; as it depends on the extent to which resources currently employed by MSL can be re-deployed.
- An interruption in the supply of, or increase in the price of diamorphine. This would be caused by a decline in the cross-subsidisation of diamorphine, or a decline in economies of scope from reduced production of oxycodone. Without more information on MSL's profits, costs and business strategy, it is not possible to determine how likely it is that MSL might discontinue production of diamorphine.

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

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

The chief potential impact of the lifting of import controls is an increase in competition in the markets for oxycodone FDF and API. The available evidence suggests that the UK's API prices are currently competitive, at least on average, and the best estimate for the expected benefit from increased competition is therefore nil. If however MSL is not price competitive, then there is the potential for gains from competition.

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

There are three non-monetised potential benefits, primarily related to the well-recognised benefits of competition:

- First, increased competition in the API market could boost competition in the FDF market, potentially through eliminating practices such as price discrimination. Increased competition could reduce prices of both API and FDF, boost innovation and make the UK pharmaceutical industry more competitive.
- Second, by bringing the import policy for oxycodone in line with that of most other controlled substances, this option would lead to greater clarity and consistency in drug licensing and control regulations.
- Finally, this option should also increase security of supply.

Key assumptions/sensitivities/risks **Discount rate (per cent)** 3.5

There are two risks associated with Option 2:

- Option 2 carries a theoretical risk of increased diversion to the illicit market, although this risk is assessed to be minimal. There are tight controls surrounding the transit and sale of controlled drugs, and most diversion occurs post prescription.
- There is also a risk that MSL will exit the diamorphine market with no company stepping forward to provide diamorphine at a price reasonable to the NHS. This risk is not assessed to be significant due to the high value the NHS places on diamorphine and the relatively well known process for producing diamorphine. Additionally, if no new supplier comes forward the NHS can switch to the closest alternative, morphine. This would generate cost savings but potentially lead to a decline in patient welfare where morphine is not the most appropriate painkiller.

BUSINESS ASSESSMENT (Option 2)

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

Summary: Analysis & Evidence

Policy Option 3

Legislate to create a new criminal offence for the supply and importation of NPS. **FULL ECONOMIC ASSESSMENT**

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: £0m
2015/16	2015/16	10 yrs			

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

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

The costs for Option 3 are similar to those for Option 2, although on a smaller scale. The best estimate of costs is again assessed to be £0. In Option 3 the UK market for oxycodone will only be exposed to competition from within the EEA, as opposed to the wider world in Option 2. As a result, the potential costs of increased competition to UK companies and the subsequent impacts on the wider UK economy and supply of diamorphine are less likely to occur.

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

The potential non-monetised costs are the same as described for Option 2, although they are assessed to be even less likely to occur under Option 3.

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

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

The available evidence suggests that the UK's API prices are currently competitive, at least on average; the expected benefit from increased competition is therefore £0.

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

The potential non-monetised benefits are the same as described for Option 2, although they are assessed to be less likely to occur under Option 3.

Key assumptions/sensitivities/risks — **Discount rate (per cent)** 3.5

The risks for Option 2 also apply to Option 3, although on a reduced scale. In addition to these, a risk associated with Option 3 is that continuing to put in place any form of restriction on the importation of oxycodone will be vulnerable to a legal challenge. This is due to the policy being out of step with that for other controlled substances and generally not in keeping with the UK's commitment to free-trade.

BUSINESS ASSESSMENT (Option 3)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1. Oxycodone is an opioid analgesic. It is synthesised from thebaine which is derived from opium or 'poppy straw'. Opioids are classified as a 'narcotic drug' under certain UN Conventions and oxycodone is controlled in the UK as a 'Class A' drug under the Misuse of Drugs Act (MDA) 1971. Oxycodone is generally traded in both final dosage form (FDF) and as an active pharmaceutical ingredient (API). The former being the ready to consume formulation of the drug, as a tablet, solution or injectable ampoule; the latter is the basic ingredient of oxycodone on which all final products are based.

2. The possession, supply, production, import and export of both FDF and API forms of oxycodone are regulated by the Home office as part of its statutory obligations under the MDA 1971. It does so because of the harm that misuse of these substances can cause to individuals and society.

3. The original Home Office policy, pre 2008, was to restrict imports from outside the EEA, but allow them from countries within 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 policy was subsequently changed to its present form, which is as follows:
    - Imports for re-export purposes only within the EEA[1]. '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.
    - 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.
    - 'Personal' imports/exports of oxycodone – medications containing controlled drugs may be imported/exported by an individual in line with the pre-existing personal import policy (less than three months supply and/or travel of three months duration).

4. The need to formalise or to change this policy 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 identified two additional proposals and included an option which would maintain the current situation.

5. The Government's policy on the import of oxycodone is presently based on three central considerations. First, 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. Secondly, realising the economic benefits of competition in the UK pharmaceuticals market; and finally, ensuring a supply of pain-relieving drugs is available to meet patient care demand.

6. The Government did not find the responses to the four options presented in the first consultation sufficiently compelling to adopt any of them at that time. Given the passage of time and changing market conditions the Government undertook a second consultation to obtain a fresh appraisal of the options.

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

7. The manufacture and supply of oxycodone in the UK is dominated by two companies: Macfarlan Smith Limited (MSL) and NAPP pharmaceuticals group. MSL is the sole manufacturer of API within the UK; it supplies it to both UK manufacturers of FDF products as well as exporting it to foreign manufacturers. The vast majority of FDF produced in the UK is made by NAPP pharmaceuticals group, which again supplies both the UK and foreign markets. For a diagram providing an overview of the UK oxycodone market, see Annex A.

8. 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 supplier currently. Macfarlan Smith has signalled that it may have to reconsider its production of diamorphine, as well as other substances, if major changes are made to the oxycodone market. The Home Office will need to consider the impact of any new import policy on the security of supply to the NHS of diamorphine.

A.2 UK laws and conventions concerning controlled substances

9. Certain drugs are 'controlled' under UK law on account of the potential harm they pose to people consuming them. These 'Controlled Drugs' are listed in the Misuse of Drugs Act 1971 (MDA) and its' associated Misuse of Drugs Regulations 2001 (MDR). Both the MDA and the MDR represent the UK's treaty commitments under the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

10. Many of the drugs listed in the MDA and MDR have recognised therapeutic benefits and are available to the public, in the form of a 'medicinal product' and, generally speaking, on prescription only. Controlled drugs are sub-divided into 'Schedules', on account of the 'type' of drug and potential for misuse/ harm. The MDA sets out a number of 'restrictions' in respect of controlled drug use, and it provides for the operation of a licensing regime to enable the lawful use of drugs in certain limited circumstances where authority in not already granted under regulations. This licensing regime operates under the MDR and the Home Office are the Competent Authority for these purposes in Great Britain.

A.3 Groups Affected

11. A number of different groups are affected by this policy:
    - Macfarlan Smith Limited (MSL): MSL is currently the sole producer of oxycodone API in the UK, its revenue and profits are potentially affected by any change in import policy.
    - NAPP pharmaceuticals group: NAPP produces the majority of oxycodone FDF manufactured in the UK, some of which is subsequently supplied to the UK. Its profits and potentially its business strategy may be affected by the proposed changes.
    - Smaller FDF manufacturers: while NAPP produces the majority of oxycodone FDF, smaller amounts are produced by a number of smaller companies producing for both domestic and foreign consumption.
    - The NHS, private healthcare providers and patients: the NHS consumes the majority of both oxycodone and diamorphine produced in the UK; it will therefore benefit or suffer from any falls or increases in price, or from any issues in the supply of oxycodone or diamorphine. Similar to the NHS, private healthcare providers will also benefit or suffer as a result of these changes. Finally, patients will also be affected by price changes or any disruption in the supply of oxycodone or diamorphine. NHS patients will however be shielded from the impact of increased prices and will not benefit from any falls.
    - The wider UK economy: MSL's activities have a wider economic impact beyond the profit it generates from producing oxycodone. Producing oxycodone supports a wider supply chain, and it provides jobs to UK citizens who in turn spend within the UK economy.

A.4 Consultation

Within Government

12. Early engagement was sought and obtained from The Department of Health and the Department for Business, Innovation & Skills.

Public Consultation

13. The following companies responded:

    - Accord Healthcare; Actavis UK Ltd; Aesica Pharmaceuticals; Aspire Pharma Ltd; British Generic Manufacturers Association; Chanelle Medical UK Limited; C P Pharmaceuticals Limited; Cross Healthcare Ltd; Drugsrus Ltd; Forum Products Ltd; GSK; Idis Limited; Interpharm Limited; Janssen Cilag Ltd; LGC Standards; Macfarlan Smith Ltd; Napp Pharmaceutical Group; R W Unwin & Co Ltd; Sandoz (a Novartis Company); Siegfried Ltd; Teva UK Limited.

14. Although the respondents did not express a majority view in favour of any one option, two thirds of respondents identified a need for change from the current (interim) policy, with many (a) expressing a desire to place oxycodone on a similar footing to other substances (i.e., no specific "restrictive" import control) and (b) identifying a need to decouple the current link between oxycodone and diamorphine.

15. Generally speaking, respondents who supported a change from the status quo were FDF manufacturers, with the majority supporting increased liberalisation. Arguments put forward by respondents against Option 1 include:

    - The lack of rationale for oxycodone to be treated differently than other controlled substances and an objection to its relationship with diamorphine being a factor in any future decisions. As one respondent said: "it is not clear why oxycodone is treated differently from other controlled substances and it should not be bundled with diamorphine for this purpose."
    - Potential conflict between the current policy and European free trade rules. One respondent commented: "the Home Office should not impose any restrictions on the origin of the API as requiring the API to originate from the EEA is not consistent with free movement principles."
    - Potential savings to consumers and the NHS through increased competition and in turn lower prices. As one respondent commented: "by opening up the oxycodone market to competition, the NHS will benefit from lower costs."
    - The potential benefit to domestic FDF manufacturers through greater competition in the API market, both through lower prices and access to a broader range of products. One respondent argued that: "opening the UK market up to imports from the EEA/outside the EEA would enable access to alternative formulations and competition might support further development by domestic producers."

16. A small number of companies expressed in their response only an interest in maintaining the trade in reference standards[2] as this was their primary business. They did not further contribute to the wider questions posed.

17. Only two respondents indicated a preference for the current policy, an FDF manufacturer and an API producer. These respondents arguments can be summarised as:

    - The risk of diversion of oxycodone to the illicit market as a result of increased international flows of oxycodone.
    - The lack of any economic benefit to the proposed change. The respondents argued that the market was already sufficiently competitive and that lowering import controls threatened the sustainability of UK companies while providing no access to new markets for UK companies. One respondent argued that "any relaxation of the import restrictions relating to oxycodone, but particularly a relaxation to allow imports from outside the EEA, can be expected to result in [respondent] losing a considerable proportion of its sales of oxycodone API with an inevitable substantial impact on its profits."

[2] Small amounts of controlled substances are sold for the purposes of forensic testing, toxicology and medical research.

- The threat to the supply of pain relieving drugs to the NHS. Namely the potential cessation of the production of diamorphine.
- The respondents argued that increased international flows resulting from the proposed change would put the UK in violation of its international narcotic control treaty commitments.

B. Rationale

18. Controlled substances can impose large costs on both individuals and wider society through misuse. The Home Office intervenes in the market to prevent such misuse, regulating to ensure that substances are only used for legitimate purposes. As well as the necessity to limit harm, the Home Office is required by both UK law (under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001) and international treaties (the UN conventions on narcotics) to manage the system for the import and export of controlled narcotics. The current policy regarding the licensing of oxycodone has enabled a monopoly to form within the UK, with one company (MSL) enjoying market power in part due to restrictions brought about by the Home Office licensing regime. Intervention is therefore necessary to increase competition while maintaining an effective system of drug controls.

C. Objectives

19. The key objectives are to maintain an effective licensing regime for controlled drugs under the MDA 1971 and MDR 2001; ensure access for British consumers to the cheapest possible pharmaceuticals; and maintain and extend the competitiveness of the UK pharmaceutical industry.

D. Options

20. The initial consultation document listed seven options:
    - Option 1: No change, maintain interim policy.
    - Option 2: Imports will be allowed from within the EEA for any purpose (subject to INCB estimates). Imports from outside of the EEA will only be allowed if oxycodone is unavailable within the EEA.
    - Option 3: Imports will be allowed from within the EEA for any purpose (subject to INCB estimates). Imports from outside of the EEA will be allowed for any purpose subject to a quota system.
    - Option 4: Imports will be allowed for any purpose from anywhere in the world, INCB estimates will be the only limit on exports.
    - Option 5: Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). Imports from outside the EEA will be allowed for re-export purposes.
    - Option 6: Imports will be allowed from within the EEA for any purpose (subject to INCB estimates). Imports from outside of the EEA will only be allowed if oxycodone is unavailable within the EEA.
    - Option 7: Imports will be allowed from within the EEA for any purpose (subject to INCB estimates). Imports from outside of the EEA will be allowed for the purpose of re-export. Imports from outside of the EEA will also be allowed if there is inadequacy of supply.

    Of these Options, only 3 will be evaluated: Option's 1, 4 and 7, which are called Options 1, 2 and 3 in this impact assessment. These options were selected because initial analysis and evaluation suggested they were thought to be those most able to fulfil the objectives.

Option 1

21. Option 1 is to make no changes (do nothing). Imports of oxycodone will only be allowed in accordance with the current interim policy.

Option 2

22. Imports of oxycodone will be allowed from anywhere in the world for any purpose; with the International Narcotics Control Board (INCB) approved estimate as the only limit on

imports[3]. This is option 4 in the consultation document. This will apply to both FDF and API format oxycodone, although companies will be able to import FDF oxycodone after 3 months of the response being published while free trade (subject of course to usual drug control regulation) in API will follow 18 months later. This period of transition is to enable consumers and producers of oxycodone API and diamorphine to adapt to the new policy regime, identifying and arranging any new sources of these substances that may be needed as a result of the proposed changes.

Option 3

23. Imports from within the EEA will be allowed for any purpose (subject to the INCB estimates). Imports from outside the EEA will be allowed for re-export and in situations where there is an inadequacy of supply or competition within the EEA. This was option 7 in the consultation document.

E. Appraisal (Costs and Benefits)

General Assumptions and Data

Oxycodone

24. As part of the consultation process, the Home office received numerous responses from different interested parties. While a great deal of this information was extremely useful, not all of it can be published as it is commercially sensitive. As a result, the Home office cannot reveal all of the information used to inform its decision. This IA will at times make reference to assumptions reached based on information provided confidentially to the Home office. In particular, the information provided by MSL enabled the Home office to determine that MSL's prices are internationally competitive, a major issue within this IA. Other assumptions and relevant information are outlined below.

25. As discussed in the background section, MSL is the sole producer of oxycodone API in the UK. It supplies API to a number of different manufacturers of oxycodone FDF in the UK as well as exporting approximately 4,400kg of API per year. One of the UK manufacturers, NAPP pharmaceuticals, is also able to obtain API from a US sister company; Home office statistics suggest it imported 2,600kg of API in 2013. For a graphical overview of the market, please see Annex A.

26. Information seen by the Home office suggests that the majority of the oxycodone FDF manufactured in the UK is exported. Figures provided by MSL suggest that 1,800kg of API in the form of oxycodone FDF is consumed in the UK each year. MSL estimates that the revenue earned from oxycodone API consumed in the UK was £2.42m in 2013, this is 4% of what they estimate to be the value of the total oxycodone market: £62m. Given the 1,800kg MSL believes is consumed in the UK each year, this implies an average estimated cost per kilogram in the UK for API of £1,344[4].

Diamorphine Consumption

27. In total, the UK consumed approximately 73.5kg of diamorphine in 2013/14, costing approximately £8.3m. This is an estimate, based on consumption and pricing data gathered from the different constituent nations of the UK and their respective primary and secondary healthcare authorities. Not all of the data is available for the same years; so we assume that diamorphine consumption and prices are generally consistent from one year to the next. We explain the source of each of the figures in turn.

England:

28. The following information was directly provided by NHS England:

[3] The INCB estimates are annual figures produced for each country on their estimated need for those drugs controlled under the 1961 Single Convention on Narcotic Drugs.

[4] £1,344 = (£2,420,000 / 1,800kg)

- NHS England primary healthcare consumes approximately 34.6kg of diamorphine per year, costing £4.5m. This implies an average per capita consumption of 0.64mg[5] and a cost per milligram of £0.13[6].

- NHS England secondary healthcare consumes approximately 14.7kg of diamorphine per year, costing £1.3m. This implies an average per capita consumption of 0.27mg[7] and a cost per milligram of £0.09[8].

Northern Ireland:

- The following information was directly provided by Health and Social Care Northern Ireland:

    - NHS primary healthcare in Northern Ireland consumes 3.7kg of diamorphine per year. Implying a consumption per capita figure of 2.01mg[9].

    - NHS secondary healthcare in Northern Ireland consumes 4.5kg of diamorphine per year. Implying a consumption per capita figure of 2.44mg[10].

- We lack information on how much was paid for these amounts of diamorphine. If we assume similar costs per milligram as NHS England (£0.13 for primary healthcare, £0.09 for secondary healthcare), this implies a total spend of £0.5m[11] by primary healthcare in Northern Ireland, and £0.4m[12] by secondary healthcare in Northern Ireland.

Scotland:

29. The following information was directly provided by NHS Scotland:

    - NHS Scotland primary healthcare consumes approximately 1.7kg of diamorphine per year, implying a per capita consumption of 0.31mg[13].

30. We again lack information on spending. If we assume a similar cost per milligram as England (£0.13), this implies NHS Scotland primary healthcare are spending £0.2m[14] on diamorphine per year.

31. Based on an average of England and Northern Ireland's secondary healthcare consumption per capita (1.36mg), we can estimate secondary healthcare consumption in

[5] 0.64mg per capita = 34,600,000mg (34.6kg) of Diamorphine / 53.9m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[6] £0.13 per milligram = £4,500,000 / 34,600,000mg (34.6kg)
[7] 0.27mg per capita = 14,600,000mg (14.7kg) of Diamorphine / 53.9m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[8] £0.09 per milligram = £1,300,000 / 14,700,000mg (14.7kg)
[9] 2.01mg per capita = 3,700,000mg (3.7kg) of Diamorphine / 1.8m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[10] 2.44mg per capita = 4,500,000mg (4.5kg) of Diamorphine / 1.8m people (based on ONS population statistics for mid 2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[11] £500,000 = £0.13 * 3,700,000mg (3.7kg)
[12] £400,000 = £0.09 * 4,500,000mg (4.5kg)
[13] 0.31mg per capita = 1,700,000mg (1.7kg) of Diamorphine / 5.3m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[14] £200,000 = £0.13 * 1,700,000mg (1.7kg)

Scotland to be 7.2kg[15]. Using England's secondary healthcare cost per milligram (£0.09) implies a total spend of £0.6m[16].

Wales:

32. To develop a figure for Wales's primary healthcare consumption per capita, we use the average of England, Northern Ireland and Scotland's figures: 0.99mg. This implies a consumption figure of 3kg[17] and, using England's average spend per milligram (£0.13), a total spend of £0.4m[18].

33. We use the average of England and Northern Ireland's secondary healthcare consumption per capita (1.36mg) to estimate Wales's secondary healthcare consumption: 4.2kg[19]. Assuming Wales pays the same price per milligram as England (£0.09); this implies a cost of £0.4m[20].

Option 1 – Do nothing

Costs

34. Doing nothing will have no immediate impact on the production and pricing of Oxyocodone or diamorphine. However, there is a risk that the competition issues identified in this impact assessment will become more egregious over time, leading to higher prices and reduced downstream competition.

Option 2 - All barriers to the import of oxycodone FDF will be lifted within 3 months, restrictions on the import of the oxycodone API will be lifted after 18 months

Costs

35. There are three central *potential* costs of this policy: a potential reduction in profits for those UK companies producing oxycodone, the wider economic impact of a potential reduction in oxycodone production on the UK economy and a potential reduction in consumption or increased cost of diamorphine.

36. A decline in the production of oxycodone by UK manufacturers could affect those manufacturers producing either API or FDF. This would have two impacts, firstly on the profits of UK companies producing oxycodone and secondly on the wider British economy. There are two key factors that will determine the scale of these impacts.

- First, the scale of the decline in demand for UK manufacturer's oxycodone. At the upper end, production could cease entirely as companies choose to cease sourcing oxycodone from UK companies and switch to foreign competitors. At the other end of the scale, there could be no change in production.

- If there is a change in UK production levels, this could have an impact on the wider British economy. The size of this impact will depend on the extent to which those resources currently employed in the manufacture of oxycodone can be productively

[15] 7.2kg (7,200,000mg) = 1.36mg * 5.3m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[16] £600,000 = 7,200,000mg (7.2kg) * £0.09
[17] 3kg (3,000,000mg) = 0.99mg * 3.1m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[18] £400,000 = 3,000,000mg (3kg) * £0.13
[19] 4.2kg (4,200,000mg) = 1.36mg * 3.1m people (based on ONS population statistics for mid-2013, obtained from: http://ons.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=khmtODWSGpcGfUiY0IN61ssHCRBejzytx-XWryvNv1U,).
[20] £400,000 = £0.09 * 4,200,000mg (4.2kg)

redeployed to other parts of the economy. For example, if production of oxycodone ceases entirely and those previously employed in the manufacture of oxycodone are unable to find work, the negative impact on the British economy will be larger than if they are re-employed in similarly productive professions.

37. Diamorphine is a pain-killer used extensively in end of life care, relieving severe pain associated with surgery, and relieving breathlessness associated with pulmonary oedema. Changes in the market for oxycodone may affect the market for diamorphine, resulting in reduced availability or increased prices. This is based on MSL's assertion that 'a significant reduction in profits would force MSL to rationalise its production assets and reduce fixed costs'.

38. We examine the impact on business, the wider economy and the supply of diamorphine in turn.

Business

39. Lifting import controls on oxycodone could potentially impact the profits of manufacturers of both FDF products and the oxycodone API.

FDF Manufacturers:

40. In their consultation responses, most manufacturers of FDFs supported the lifting of import controls. There was little concern about any potential threat to their businesses as a result of this change. This suggests that their prices are internationally competitive already or that they are prepared to make changes to enable them to compete internationally. We lack the internationally comparable information on FDF prices to determine this; but, given that the majority of UK FDF oxycodone is exported, the former seems most likely. As UK FDF manufacturers would be unable to win business if their prices were not competitive.

41. One company, NAPP, supported allowing imports from anywhere in the world for re-export and from within the EEA for any purpose as opposed to the proposals in Option 2. They further stated that they were satisfied with the given level of competition. Assuming that NAPP is prepared to deal with competition from within the EEA, this suggests its concern is increased competition from international markets. It is not possible to identify how much profit NAPP might lose in due to increased international competition, as we lack information on the amount of oxycodone FDF NAPP provides to the UK market and its profit from this activity. Information provided confidentially to the Home office suggests that the impact on NAPP's profit is likely to be minimal.

API Producer:

42. There is currently only one company manufacturing API in the UK: Macfarlan Smith Limited (MSL). In general, we assume that no other UK company is likely to begin producing oxycodone, due to the dominant position of MSL. As a result, any impact on API manufacturing profits as a result of the lifting of import controls will fall entirely on this company. The extent to which this will occur depends on how competitive MSL's prices are, and on the business decisions taken by producers of FDF oxycodone.

43. In its consultation responses, MSL insists that its prices are competitive:

"The prices that MSL charges in the UK for oxycodone API are internationally competitive and similar to those charged in export markets where MSL continues to win business."

If true, this would mean that no manufacturer of oxycodone FDFs would have any reason to cease sourcing their API from MSL if the market was opened up to allow imports. As discussed above, information provided confidentially to the Home Office supports MSL's assertion. One possible explanation for competitive domestic prices of oxycodone is the

buying power of NAPP. The importance to MSL of sales to NAPP likely gives the company a degree of market power, enabling it to negotiate lower prices. This is an advantage that other domestic producers will not share. NAPP's buying power is further strengthened by two additional factors:

- NAPP is a multinational company with production sites across the world, enabling it to re-locate production to obtain the lowest possible prices for API. Attempts on the part of MSL to raise prices would therefore be futile, as NAPP would simply re-locate.

- NAPP is able to import API from its foreign subsidiaries, enabling it to bypass MSL to obtain the best prices. Currently, NAPP imports an estimated 2,600kg of oxycodone API from its foreign subsidiaries.

As NAPP continues to purchase API from MSL despite being able to obtain it from its foreign subsidiaries, this suggests that MSL's API is at least approximately price competitive with NAPP's internally sourced API. Although it is possible that factors such as convenience for NAPP's UK production sites also play a role.

44. Existing information suggests that MSL is able to provide API at internationally competitive prices, implying that NAPP has no incentive to obtain its API from another company. It is however possible, that other factors could influence NAPP's future decisions regarding its supply of oxycodone API. NAPP could choose to change the location of its production sites, or adopt different supply and production methods to enable it to source API from its own companies. In addition, many consultation respondents noted the larger role generics are set to play in the oxycodone market. As a result, the impact of lifting import controls on MSL's API manufacture business cannot be exactly estimated. The best estimate scenario, as discussed above, is that MSL's business is not negatively affected at all. The high cost scenario is the complete loss of UK sales, which could result in the complete closure of MSL's oxycodone business. This may occur despite MSL's export business remaining unaffected, due to the presence of economies of scale in the manufacture of oxycodone, meaning production is unsustainable without UK sales. We are unable to provide a calculated estimate of the costs such a closure may involve, as the information required is commercially sensitive and therefore confidential.

45. MSL may respond to this in two ways. First, it could become more efficient, modifying its production processes or introducing new technology in order to become price competitive with its foreign rivals. This would enable it to hold on to market share, limiting the damage to profits. Second, it could re-direct its economic resources (workers, plant machinery) towards producing something else, for example an alternative pain-killer. This would limit the damage to profit, although we assume that such an alternative would not be as profitable, otherwise MSL would already be performing these activities.

46. A fall in UK prices would initially only affect MSL's UK business, its exports remaining unaffected. It is however possible that production would not be sustainable without UK demand, due to economies of scale in the production of oxycodone API. It is also possible that MSL would halt production before profit is entirely wiped out, due to the rate of return falling below that expected by MSL's owners.

47. The evidence above suggests that NAPP pharmaceutical is, due to its market power, able to obtain competitively priced API despite MSL's nominally advantageous position. As a result NAPP should have little reason to end its arrangement with MSL. Smaller FDF manufacturers are unlikely to possess these advantages. Previous work by the Office for

Fair Trading[21], identified price discrimination[22] as a problem within the industry. It is not clear if this practice would persist under this option, but if smaller FDF manufacturers were still not receiving internationally competitive prices then they might abandon MSL and instead source API from its foreign competitors. It is not possible to exactly estimate the potential impact on MSL as we lack information on the value of the profits MSL currently earns through sales to smaller FDF manufacturers. It is also possible that MSL will respond to this reform by lowering the prices it offers these companies, in order to maintain market share.

48. Overall, based on the available evidence it does not seem likely that MSL will suffer significantly from the lifting of import controls. The evidence provided to the Home Office suggests that UK oxycodone API prices are competitive with the rest of the world. As a result, MSL is unlikely to face any reduction in profits and therefore to withdraw from the market. The best estimate of costs resulting from Option 2 is therefore nil. While based on the available evidence, this outcome is not assured and there remains a degree of uncertainty around the exact impact of option 2 on MSL. The size of this impact would depend on the difference between international prices and those offered by MSL and the fall in prices necessary to result in MSL deciding to leave the market. While a fall in prices is not assessed to be likely, it is however possible that MSL could lose profits as a result of strategic decisions by other firms in the face of the proposed changes. An alternative outcome is that MSL loses business from smaller purchasers of API, who are potentially suffering from price discrimination practices.

Wider British Economy

49. As well as earning profit for MSL, the manufacture and sale of oxycodone also generates wider economic value for the UK. People are employed at MSL's UK facilities and a wider value chain is supported by MSL's activities. If MSL were to abandon or reduce its manufacture of oxycodone, this could potentially have a negative impact on the wider UK economy. We are unable to identify the size of this impact as it requires commercially confidential information, although the impact itself may be ameliorated by two factors. Firstly, it is possible that MSL will re-deploy these economic resources to the production of an alternative product, limiting the impact on the wider economy, although probably not eliminating it entirely. Secondly, it is probable that instead of generating additional economic activity, MSL's oxycodone production may be displacing alternative economic activities. If MSL is displacing activity, rather than generating additional value; then resources currently employed by MSL will be redeployed elsewhere, outside of the firm, minimising the loss of economic benefit. Furthermore, if the current monopoly position is distorting production away from an economically efficient social optimum, then this would be pulling economic resources away from more productive activities. If this were the case then an increase in competition could actually increase GVA by bringing the market closer to the optimal position.

50. As discussed above, the available evidence suggests that MSL's prices are competitive and that there will therefore be no reduction in MSL's production of oxycodone as a result of option 2. The implied impact on the wider UK economy is therefore nil, which is the figure used as our best estimate. While the available evidence suggests this is the most likely outcome, it is possible that MSL are not price competitive with a corresponding effect on their profits, production and in turn the wider UK economy. We are unable to present these impacts, as estimating them relies on commercially sensitive information.

[21] http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/shared_oft/reports/consumer_protection/oft834.pdf

[22] Price discrimination in this context refers to the practice of providing favourable prices to certain purchasers. A key condition for price discrimination is market power, which would result from a lack of competition and which further reduces competition in downstream markets.

Diamorphine production

51. MSL is currently the only producer of the painkiller diamorphine that supplies it in the scale and format favoured by the NHS. MSL has signalled that the loss of its oxycodone business may force it to re-consider this production, as well as that of some other substances. Diamorphine is considered a vital drug by parts of the NHS and therefore any reduction in consumption could result in a reduction in patient welfare. Alternatively, current levels of supply could be maintained but with higher prices, imposing a fiscal cost on the NHS.

52. MSL may choose to withdraw from producing diamorphine if, for example, it is currently practising cross-subsidisation with regards to diamorphine and oxycodone. If there is cross-subsidisation, this would mean that MSL is currently subsidising diamorphine using profits from oxycodone and that therefore that the price of diamorphine is affected by the price of oxycodone. We assess this to be unlikely. Rather, MSL may be taking advantage of economies of scope[23] in the joint production of oxycodone and diamorphine; enabling MSL to offer lower prices only if it is producing both drugs.

53. Without more information on MSL's profits, costs and business strategy, it is not possible to determine how likely it is that MSL might discontinue production of diamorphine. It seems, however, unlikely that MSL would discontinue diamorphine if its profits from oxycodone are not drastically affected. In the event that MSL does withdraw from the diamorphine market, an alternative company could step forward to provide the product, although possibly at a higher price. To help ensure a smooth transition and a steady supply of diamorphine, the lifting of the oxycodone import controls will follow an 18 month 'grace period' to provide companies and healthcare provider's time to adapt. Despite the inevitable uncertainty surrounding the possible impact of this reform on diamorphine, there are a number of possible scenarios which can be considered:

    - There is no change to diamorphine production; MSL continues to deliver the product at current prices.
    - MSL continues to produce diamorphine but at increased prices, reflecting a reduction in cross-subsidisation or economies of scope.
    - MSL halts production of diamorphine. Another company enters the market to provide the NHS. If MSL leaves the market, this implies that the production of diamorphine is not profitable at current prices. Therefore a new market entrant will likely have to charge higher prices in order to make this production sustainable.
    - MSL halts production of diamorphine, not other company is able to provide diamorphine at a price satisfactory to the NHS.

54. Given the above scenarios, it is clear that a price increase is possible. Such a change could result in increased costs to the NHS, reduced diamorphine consumption or a combination of the two. The impact of this depends on the sensitivity of consumption to price increases, known as the price elasticity of demand. For example, a price elasticity of -1 means that a 1% increase in the price of diamorphine will lead to a 1% fall in demand. We are not able to determine the price elasticity of demand for diamorphine, as we lack sufficient information on hospital and primary healthcare procurement decision making. We can however present the outcomes of a range of possible interactions between price increases and price elasticities. Based on engagement with the Department of Health, we assume that diamorphine is replaced with its closest substitute: morphine at a ratio of 3:1

[23] An economy of scope is where a company obtains lower production costs as a result of producing two or more goods at the same time.

(3mg of Morphine for each milligram of diamorphine). In reality, other drugs may replace diamorphine depending on the needs of the patient. We also assume that the underlying demand for painkillers does not change. We base our estimate of costs on the current (weighted) average prices paid by the NHS for diamorphine (£112.96 per gram) and morphine (£4.05 per gram). As discussed above, the current consumption of diamorphine by the NHS is 73.5kg. The possible reduction in demand for diamorphine, increase in demand for morphine and fiscal impact, based on different price increases and price elasticities are presented below:

Estimated Reduction in Demand for Diamorphine (kilogram)

		Price Elasticity				
		0	-0.5	-1	-1.5	-2
Price Increase	10%	0.0	-3.7	-7.3	-11.0	-14.7
	20%	0.0	-7.3	-14.7	-22.0	-29.4
	30%	0.0	-11.0	-22.0	-33.1	-44.1
	40%	0.0	-14.7	-29.4	-44.1	-58.8
	50%	0.0	-18.4	-36.7	-55.1	-73.5
	60%	0.0	-22.0	-44.1	-66.1	-73.5
	70%	0.0	-25.7	-51.4	-73.5	-73.5
	80%	0.0	-29.4	-58.8	-73.5	-73.5
	90%	0.0	-33.1	-66.1	-73.5	-73.5
	100%	0.0	-36.7	-73.5	-73.5	-73.5

Estimated Increase in Demand for Morphine (kilogram)

		Price Elasticity				
		0	-0.5	-1	-1.5	-2
Price Increase	10%	0.0	11.0	22.0	33.1	44.1
	20%	0.0	22.0	44.1	66.1	88.2
	30%	0.0	33.1	66.1	99.2	132.3
	40%	0.0	44.1	88.2	132.3	176.4
	50%	0.0	55.1	110.2	165.3	220.5
	60%	0.0	66.1	132.3	198.4	220.5
	70%	0.0	77.2	154.3	220.5	220.5
	80%	0.0	88.2	176.4	220.5	220.5
	90%	0.0	99.2	198.4	220.5	220.5
	100%	0.0	110.2	220.5	220.5	220.5

Estimated Change in Cost to NHS (£m)

		Price Elasticity				
		0	-0.5	-1	-1.5	-2
Price Increase	10%	£0.8	£0.4	£0.0	-£0.4	-£0.8
	20%	£1.7	£0.8	-£0.2	-£1.1	-£2.0
	30%	£2.5	£1.0	-£0.5	-£2.0	-£3.4
	40%	£3.3	£1.2	-£1.0	-£3.1	-£5.3
	50%	£4.2	£1.3	-£1.6	-£4.5	-£7.4
	60%	£5.0	£1.3	-£2.5	-£6.2	-£7.4
	70%	£5.8	£1.2	-£3.4	-£7.4	-£7.4
	80%	£6.6	£1.0	-£4.6	-£7.4	-£7.4

Estimated Change in Cost to NHS (£m)						
		Price Elasticity				
		0	-0.5	-1	-1.5	-2
	90%	£7.5	£0.8	-£5.9	-£7.4	-£7.4
	100%	£8.3	£0.4	-£7.4	-£7.4	-£7.4

55. A 50% increase in the cost of diamorphine, with no change in diamorphine consumption (a price elasticity of 0) will cost the NHS £4.2m. Conversely, if the NHS replaced its entire supply of diamorphine with morphine, it would save approximately £7.4m. In some cases diamorphine may be a less appropriate form of medication, meaning this would potentially result in lower patient welfare.

56. The available evidence suggests that MSL should not lose any oxycodone business as a result of increased foreign competition; as a result our best estimate does not forecast any additional costs to the UK economy.

Costs summary

57. As discussed above there are three possible costs to the UK as a result of this option. Firstly, there may be an impact on the profits of UK businesses. We do not believe there will be a significant reduction in profits as a result of the lifting of import controls. Most of the evidence suggests that UK oxycodone API and FDF prices are competitive with the rest of the world, implying there will be no reduction in profits to UK companies. Our best estimate therefore forecasts no additional costs from lost profits as a result of this option. The possibility remains however, that producers of oxycodone FDF may choose to re-organise their production processes in response to the lifting of import controls, resulting in a loss of business to UK oxycodone API manufacturers.

58. A second possible cost is the impact of a decline in oxycodone production on the economy more widely. This impact is linked to both the competitiveness of UK oxycodone prices and the extent to which economic activity associated with oxycodone production could be replaced in its absence. Since there is little evidence that MSL will lose any business as a result of option 2, our best estimate includes no additional costs as a result of reduced economic activity. Finally, lifting oxycodone's import controls could result in MSL halting production of diamorphine, leading to an increase in prices and potentially a reduction in supply. The result of this will depend on how sensitive the NHS is to price increases, although it would result in some combination of increased fiscal costs and reduced patient welfare from reduced diamorphine consumption. For our best estimate, we assume that as MSL's business is likely to be unaffected, there will be no interruption in the supply of diamorphine or increase in prices.

Benefits

59. The chief potential impact of the lifting of import controls is an increase in competition in the markets for oxycodone FDF and API. This could produce two main benefits:

    - First, it could result in cheaper oxycodone FDF for consumers and the NHS.
    - Secondly, increased competition in the API market could boost competition in the FDF market, potentially through eliminating practices such as price discrimination. Increased competition could reduce prices, boost innovation and make the UK pharmaceutical industry more competitive.

60. There are also the general benefits of reduced complexity and bureaucracy in the controlled drugs system and greater security of supply.

Consumers and the NHS

61. Lowering the import controls for oxycodone would potentially lower prices for consumers in three ways; through enabling the importation of cheaper API; enabling the importation of cheaper FDFs; and through competition improvements in the market for FDFs.

62. As discussed above, the oxycodone API sold in the UK is believed to be price competitive, implying few additional benefits from reduced prices. This cannot however be established with absolute certainty, it is possible that a small number of FDF manufacturers are not receiving the best possible price due to price discrimination. It is also possible that MSL may not be price competitive overall, and that there are potential gains from reduced API prices. These possibilities are considered in turn.

63. A small number of FDF manufacturers may not be receiving the best possible price. It is these manufacturers, and their customers, who will potentially benefit from access to additional suppliers of API. It is not possible to estimate the size of the benefit as we lack information on the current prices charged to these companies by MSL, and the size of any potential reduction. We also cannot exactly determine who would benefit from any reduction. If the oxycodone produced by these companies is predominantly supplied to domestic consumers, then any benefit will be divided between manufacturers and consumers, depending on the degree of competition in the market. A high level of competition will ensure that manufacturers pass on the benefit of any reduction in the prices for inputs to consumers, while low levels of competition will enable the opposite. If manufacturers are supplying the international market then they are presumably doing so at competitive prices, as otherwise they would not be able to win business. As a result any benefit through cheaper inputs will be captured entirely by producers in the form of higher profit. This will be achieved either through higher market share, gained through lower prices; or a higher level of profit per unit of oxycodone. We would expect producers to adopt whichever strategy earns the higher level of profit.

64. As discussed above, the weight of available evidence currently suggests that MSL's prices are competitive, at least on average. If, however, MSL's prices are not internationally competitive then option 2 would result in savings for consumers and FDF manufacturers.

65. The lowering of import controls would also enable consumers and retail or bulk sellers of oxycodone to directly purchase oxycodone FDF from foreign suppliers, potentially causing a direct reduction in prices. There is currently no evidence that prices in the UK are higher than abroad, although lowering import controls would ensure that this remains the case. In general, we would expect prices in the UK and international markets to equalise (allowing for transport costs) after the lowering of import controls. We lack, however, information on international oxycodone FDF prices and so we cannot determine how large of a reduction, if at all, this might generate. We can however provide estimates of potential benefit for a range of potential price falls. We use the estimated value of the UK oxycodone FDF market: £62m, minus the £2.4m which is believed to be the value of the API included in these painkillers[24]. This leaves approximately £59.6m, the impact of price reductions on this total figure are shown below:

Price Reduction	Saving
5%	£3,000,000
10%	£6,000,000
15%	£8,900,000
20%	£11,900,000

[24] The £2.4m is subtracted to prevent double-counting.

25%	£14,900,000
30%	£17,900,000
35%	£20,900,000
40%	£23,800,000
45%	£26,800,000
50%	£29,800,000

66. Finally, by enabling foreign suppliers to enter the UK API market, the lowering of import controls should ensure high levels of competition. This will limit the market power of any current or future market actor, reducing the likelihood of practices such as price discrimination. This in turn may result in higher levels of competition in the market for FDFs, as new companies might find it easier to enter the market and smaller companies might find it easier to compete with larger rivals. This could lead to further reductions in prices.

67. Potential changes in the market for oxycodone provide a further impetus to ensure there is sufficient competition. Generics[25], generally produced by smaller manufacturing companies, are expected to play a much larger role in the market for oxycodone FDFs. This would likely reduce NAPP's market share and in turn its ability to secure lower API prices using its buying power. As a result, average API prices may begin to rise, with the increases likely passed on to consumers. Rigorous competition in the market for API would ensure the lowest possible API prices, preventing changes in the structure of the FDF market from affecting the price for API.

68. As we believe that the majority of oxycodone sold in the UK is price competitive, our best estimate of the additional benefits of option 2 is nil. It is however possible that MSL's prices may not be competitive; this would result in savings to consumers and UK pharmaceutical companies from lower prices.

Oxycodone Manufacturers

69. As well as consumers and the NHS, FDF manufacturers could potentially benefit from increased competition, both on an individual company basis through lower API prices and through overall gains in the competitiveness of the sector.

70. As discussed above, it is possible that smaller oxycodone FDF manufacturers are not receiving the best possible price. The benefit of cheaper inputs will fall to either consumers or manufacturers, depending on the level of competition in the FDF market. Alternatively, if manufacturers are supplying the foreign market, they will likely capture all of the benefits. This will be achieved either through higher market share, gained through lower prices; or a higher level of profit per unit of oxycodone. We would expect producers to adopt whichever strategy earns the higher level of profit. Increased production from an attempt to gain market share would potentially have a positive impact on the wider UK economy.

71. As well as the potential direct benefits of lower API prices, there should be benefits to the wider pharmaceuticals industry from ensuring that the market for FDFs is as competitive as possible. Previous work by the OFT identified price discrimination, associated with excessive market power being in the hands of one company, as a significant problem within the market for synthetic opoids[26]. By enabling some manufacturers of FDFs to

[25] A generic is a drug identical in chemical composition and effect to a patented drug, they are generally released after a patent has expired.

[26] http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/shared_oft/reports/consumer_protection/oft834.pdf

obtain cheaper API than others, price discrimination limits competition in the market for FDFs, preventing new companies from entering the market and entrenching the position of market incumbents. The extent to which the practice of price discrimination continues is unclear; however boosting competition will help ensure that it does not occur. This in turn could result in further reductions in prices, greater innovation and a more competitive UK FDF sector.

Reduced bureaucracy

72. A general benefit, accruing to all parties is that lowering import controls will significantly simplify the current system. Currently, oxycodone and codeine are the only controlled drugs with limits on its import and export. All other controlled drugs can be traded internationally freely, within the overall context of INCB restrictions and the UK's controlled drugs licensing regime. Lowering the barriers to importation and exportation would simplify the system, making it easier to manage and understand.

73. Additionally, all parties will benefit through greater security of supply. Currently, companies are able to request additional imports of oxycodone in the event of scarcity of supply. It remains a possibility however, that the Home Office will respond too slowly to requests, or reject such a request due to poor information. Liberalised international trade in oxycodone gives manufacturers and consumers more choices in where to source their oxycodone, ensuring security of supply.

Benefits Summary

74. There are four potential benefits as a result of Option 2.

75. Firstly, it is possible that enabling UK consumers and manufacturers to access foreign suppliers of oxycodone will enable them to purchase FDF and API at lower prices. The benefit of this is expected to be minimal as there is little evidence that UK FDF or API is over-priced, at least on average. It is possible however, that smaller manufacturers and their consumers are not receiving the best prices due to a lack of competition. Lowering import controls will boost competition, ensuring that all market actors receive the best possible prices and conferring a benefit to those manufacturers or consumers previously disadvantaged.

76. Secondly and closely related to the above, boosting competition in the market for oxycodone API should limit the practice of price discrimination which itself limits competition in the market for FDFs. The extent to which the practice of price discrimination continues is unclear; however boosting competition will ensure that it cannot occur. This in turn should enable further reductions in prices, greater innovation and a more competitive UK FDF sector.

77. The third and fourth benefits of Option 2 are greater clarity and consistency in drug licensing and control regulations, and increased security of supply.

Net effect

78. As discussed above the overall impact of the proposed changes depends on a number of factors and their interaction. These factors are:

- The price competitiveness of UK producers of oxycodone API and UK manufacturers of oxycodone FDF's.
- The strategic decisions of major FDF manufacturers.
- The displacement effect of MSL's API manufacture.
- The relationship between oxycodone and diamorphine.

- The price elasticity of demand for diamorphine.

79. The price competitiveness of UK manufacturers determines the overall impact of lowering import controls will have on UK businesses and consumers. If UK FDF and API prices are competitive with those of foreign competitors then there is no reason (pending any strategic decisions from major manufacturers) that UK businesses should lose revenue. Such competitiveness also limits the gains that consumers can expect to make. As a result our best estimate of the cost from depriving UK companies of profits as a result of option 2 is nil. Correspondingly, our best estimate of gains to UK consumers from lower prices is also nil.

80. Alternatively, if UK prices are not competitive, then there will be a cost to UK manufacturers from lost profits although at the same time there would be an equivalent benefit to UK consumers from lower prices.

81. If UK manufacturers lose market share to foreign companies either due to non-competitive prices or other companies' strategic decisions, then there will be a corresponding impact on the wider UK economy. The scale of this impact depends on the ability of MSL to re-deploy these resources to other productive activities and failing that, the ability of the wider economy to re-deploy these resources.

82. The relationship between oxycodone and diamorphine determines if a reduction in oxycodone production will lead to MSL abandoning diamorphine production. If MSL is currently cross-subsidising diamorphine using profits from oxycodone, then interrupting these profits could cause MSL to decrease its subsidisation of diamorphine. If MSL were to leave the market for diamorphine entirely, then another company would presumably enter the market, assuming that there was sufficient demand for diamoprhine at the new sustainable price. The overall impact would therefore be zero, as additional costs to the NHS would be compensated for by increased profits to MSL or a new entrant. Alternatively, if there are economies of scope in the production of diamorphine it is possible that no other company would be able to offer prices comparable with MSL. This would mean that a reduction in oxycodone manufacture could result in permanently higher diamorphine prices, without higher profits; an overall loss to the UK. The price elasticity of diamorphine consumption would determine how much of this loss to the UK is a result of higher fiscal costs to the NHS and how much is as a result of lower diamorphine consumption. Higher price elasticity will lead to substitution towards Morphine, a cheaper but not always well suited pain-killer. A lower price elasticity will result in increased costs to the NHS.

83. As the available evidence suggests that MSL's prices are competitive, we do not foresee any reduction in demand for MSL's API as a result of option 2. As a result there should be no decrease in either cross-subsidisation or economies of scope. Our best estimate of additional costs to the NHS is therefore nil.

84. Our best estimate of the overall net effect of option 2 is £0, with the 10 year NPV therefore also being £0. This is based on MSL's price being competitive, implying no cost to MSL from the lowering of import controls, no benefits to consumers from lower prices and no subsequent effects on the wider UK economy or the supply of diamorphine. This estimate fails to take into account the non-monetisable benefits of additional competition and greater simplicity.

Option 3 – Imports of oxycodone from within the EEA will be allowed for any purpose. Imports of oxycodone from without the EEA will be allowed in the event of inadequacy of supply or for the purpose of re-export.

Costs

85. The potential costs of Option 3 are similar to the potential costs of Option 2, only on a smaller scale. In Option 2 the UK market for oxycodone will only be exposed to competition from within the EEA, as opposed to the wider world in Option 2. While there will be a smaller increase in additional competition, the maximum potential costs and benefits remain the same. This is due to the uncertainty surrounding both international and European prices, and the extent to which the prices of UK companies are currently competitive. Limiting competition to the EEA may shield UK companies from their most threatening competitors, limiting the impact on profits. Alternatively it may make little difference, as EEA competitors undercut UK companies enough to force them out of the market for oxycodone.

86. In addition to lifting import controls to countries within the EEA, option 3 will enable manufacturers of FDF will to obtain oxycodone API if the subsequently manufactured FDF is exported. This is something which only NAPP is currently able to do, potentially putting greater competitive pressure on MSL.

87. The central potential costs of option 3 are:

- a reduction in profits for those UK companies producing oxycodone,
- the wider economic impact of a reduction in oxycodone production on the UK economy, and
- a reduction in the consumption of diamorphine or increased costs in purchasing diamorphine.

Businesses

88. Option 3 would allow UK companies and consumers to import oxycodone FDF and API from within the EEA into the UK, exposing UK manufacturers to greater competition and potentially affecting their profits.

FDF Manufacturers

89. As discussed above in paragraph 15, the majority of FDF manufacturers (including NAPP) raised no objection to the lifting of import controls within the EEA in its response to the consultation, which suggests that these manufacturers are prepared to face increased competition. The NAPP group would no longer be able to import API from its US sister company for any purpose, being limited instead to re-export. However, assuming NAPP continues to source the rest of its API from MSL, or from an alternative EEA supplier, this should not pose a problem. We therefore assess that it is unlikely that there will be any additional costs to the oxycodone FDF sector as a result of Option 3.

API Producers

90. As discussed above in paragraph 43, MSL is currently the only company manufacturing oxycodone API in the UK. Any costs resulting from additional competition will therefore be felt solely by this company. It is believed that MSL is currently providing the majority of its API at a competitive price as a result of the strong negotiating position of NAPP. Due to this, the best estimate of costs to MSL as a result of option 3 is nil. It is however possible that MSL's prices are not competitive within the EEA, this would likely result in MSL's oxycodone business closing, assuming MSL cannot make any efficiency improvements.

91. An alternative to either of the scenarios above is that MSL loses the business of smaller manufacturers, who, lacking the resources of NAPP may not be receiving the best

possible price. As a result of foreign competition, MSL may lose these companies business, or alternatively be forced to sell API at lower prices in order to maintain market share. In this case the scale of the loss of profit would depend on the increase in competition MSL faces. As a result, losses are likely to be smaller under this option than under Option 2. This is because Option 3 only involves lowering import controls to the EEA, as opposed to the whole world under Option 2. Depending on the international distribution of API prices, this could result in lower costs to MSL. For example if the lowest prices for API come from Asia or North America and European prices are broadly comparable to MSLs, then MSL will escape its most serious competition. As discussed above available evidence suggests that MSL's prices are competitive and that therefore there should be no loss of profit resulting from the lowering of import controls to the EEA.

Wider economy

92. As discussed above, oxycodone production in the UK generates wider economic benefits beyond profit for MSL. As a result, if changing market conditions forces MSL to halt production of oxycodone, this could have a negative impact on the wider economy.

    - MSL completely halts production of oxycodone in the UK, and doesn't re-deploy economic resources to the production new or existing products products.
    - That the wider economy is incapable of redeploying those resources to other activities.

93. Similarly to option 2, our best estimate of additional costs to the wider economy is £0, as the evidence currently suggests that MSL's prices are competitive.

Diamorphine

94. Similarly to Option 2, a reduction in profits or production of oxycodone could lead to MSL choosing to cease production of diamorphine, leading to an increase in prices (see paragraph 59 for an explanation). This in turn may lead to a reduction in consumption and in turn patient welfare, as well as increased fiscal costs to the NHS. As discussed in Option 2, we are unable to calculate the exact costs of this option without information on how health authorities will respond to price increases and the size of the increase in price. We would expect any reduction in cross-subsidisation or economies of scope and in turn increased prices for diamorphine, to be associated with an increase in competition in the oxycodone market. As we expect any increase in competition to be smaller under Option 3 than Option 2, we would therefore expect increases in the price of diamorphine to be smaller for Option 3 than that which may occur under Option 2.

95. Similarly, to option 2, our best estimate of additional costs is £0.

Costs Summary

96. As discussed above the costs associated with Option 3 are similar to those for Option 2. As the costs are primarily driven by competition, the costs for Option 3 are likely smaller than for Option 2, as we expect any increase in competition to be smaller for Option 3 than Option 2. This potential increase in competition will be particularly important for MSL, currently the evidence suggests that MSL sells its oxycodone API at prices that will be competitive within the EEA, this suggests that the impact on MSL will be minimal. Based on this, our best estimate of the potential costs is £0.

97. Secondly, if UK manufacturers do lose business to foreign competitors this will have an impact on the wider UK economy. Our best estimate assumes no wider impacts on the UK economy as a result of option 3.

98. Finally, in response to changes in the market for oxycodone, MSL may choose to halt production of diamorphine. This could, depending on the procurement decisions made by

hospitals and primary care commissioners, result in either lower consumption of diamorphine, with negative implications for patient welfare or higher fiscal costs to the NHS. For our best estimate, we assume that as MSL's business is likely to be unaffected, there will be no interruption in the supply of diamorphine or increase in prices.

Benefits

99. The potential costs of Option 3 are similar to the potential costs of Option 2. The main impact of lifting import controls to the rest of the EEA will be an increase in competition in the markets for oxycodone FDF and API. As import controls are only being lifted in relation to EEA countries, this will result in fewer potential sellers entering the UK market than if all import controls were lowered. As a result the increase in competition achieve by Option 3 would be smaller than that achieved by Option 2.

100. This could produce two main benefits:

- Firstly, it could potentially result in cheaper oxycodone for consumers, the NHS and oxycodone FDF manufacturers.
- Secondly, increased competition in the API market could itself boost competition in the FDF market, potentially through eliminating practices such as price discrimination. Increased competition would reduce prices, boost innovation and make the UK pharmaceutical industry more competitive.

Consumers and the NHS

101. As discussed above, lowering the import controls for the EEA will potentially lead to lower prices for consumers and the NHS. This will occur due to by enabling the importation of cheaper API and FDFs, and through competition improvements in the market for FDFs.

102. The benefits of cheaper API are likely to be minor, as the available evidence suggests that oxycodone prices are currently competitive. Our best estimate of the benefit from cheaper API prices is therefore £0. It is however possible that MSL's prices are not competitive, meaning that oxycodone FDF manufacturers or the NHS will benefit from cheaper oxycodone.

103. An alternative possibility is that only a small number of firms producing a small amount of oxycodone are receiving less than optimal prices. If this were the case these companies would benefit from lower prices for API. Who benefits from this cheaper API depends on the level of competition in the FDF market. It is not possible to estimate the exact gains from price reductions, as it is not clear what prices these smaller FDF manufacturers are paying, or how large a reduction in prices will occur, if at all (see paragraph 50 for a further discussion).

104. Cheaper FDF prices as a result of foreign manufacturers entering the UK market are a further potential benefit. The increase in competition will be smaller than for Option 1, but this could potentially result in a fall in prices.

Oxycodone Producers

105. As well as consumers and the NHS, FDF producers could potentially benefit from increased competition in the market for oxycodone API. As discussed above, some manufacturers may benefit from lower input prices, if this can be converted into increased profitability. The overall sector could also receive benefits through either limiting existing market power, or preventing any company from obtaining market power. As the increase

in competition would be smaller than that created by Option 2, the benefits are likely to be smaller. This will depend on the relative number of sellers in the EEA compared with the rest of the world.

Benefits Summary

106. There are two possible benefits that may result from Option 3. First, allowing foreign suppliers of FDFs and API to enter the UK market could increase competition and result in lower prices. A 10% fall in the price of API could save UK consumers and the NHS £240k per year; alternatively a 10% fall in the price of FDF could save UK consumers and the NHS £6m per year. As discussed above there is little evidence that the UK is on average receiving higher FDF and API prices than the rest of the world. The best estimate of benefit is therefore £0. It is however possible that the prices provided by MSL are not currently competitive; meaning that option 3 would result in gains to the NHS and oxycodone FDF manufacturers.

107. Secondly, increased competition in the API market could itself boost competition in the FDF market, potentially through eliminating practices such as price discrimination. Increased competition could reduce prices, boost innovation and make the UK pharmaceutical industry more competitive.

Net effect

108. The net impacts are similar to those examined in Option 2. Current evidence suggests that UK API and FDF prices are on average internationally competitive. This implies few overall changes to the market for oxycodone, and in turn diamorphine. The best estimate of net effect is therefore £0. In the event that oxycodone prices abroad are cheaper, then benefits to consumers or FDF manufacturers will generally be equivalent to profits lost by FDF or API manufacturers. Although this does assume that MSL's exports remain unaffected, as the profit these generate are a pure benefit to the UK. Additionally, it is possible that MSL may choose to halt production of oxycodone despite production still generating a profit, or strategic decisions by NAPP may lead to MSL's oxycodone business no longer being sustainable. In either of these eventualities, there will be a reduction in the production of oxycodone without any benefit to consumers. Determining the likelihood of such an eventuality is difficult without more information on the strategic priorities of MSL or NAPP.

109. It is possible that a decline in the production of oxycodone in the UK could result in higher prices for diamorphine. Depending on the price elasticity of consumption this could result in a combination of lower levels of consumption and a higher fiscal cost to the NHS. Diamorphine's substitute: morphine, is in general considerably cheaper. As a result a high price elasticity, meaning lower diamorphine consumption and higher morphine consumption, could generate fiscal savings, although these savings could be accompanied by a decline in patient welfare due to the use of an inappropriate painkiller in some cases.

110. Our best estimate of net effect is nil, although this fails to take into account the non-monetisable benefit of increased competition.

F. Risks

Option 1 – Do nothing

111. Option 1 is associated with three risks:

- The do nothing option retains an anomalous policy, out of step with that of other controlled drugs. This, together with its potential conflict with EU legislation and the broader free-trade approach of UK trade policy, creates the risk of a judicial review or other competition law based legal action. Indications provided by other companies within this market suggest that this risk is likely to occur in the absence of any action. It could result in the Home Office being forced to adjust its policy, generating reputational issues. Additionally, changes may not include an adjustment period, increasing the risk of disruption in the market.
- The do-nothing option would have no impact on MSL's profits from oxycodone. As a result, there should be no subsequent effect on the production of diamorphine. There is however the possibility that subsequent changes in the market for oxycodone and the continuing link between the production of oxycodone and diamorphine will result in a disruption in the supply of diamorphine. For example if NAPP decides to import a greater share of API from its American subsidiary, or if MSL's business strategy shifts. It is not possible to ascertain the likelihood of this risk, given the lack of information about the long term plans of MSL or NAPP. Such a situation would result in increased costs to the NHS as they procured diamorphine from another, likely more expensive, source. Alternatively, the NHS could switch to the closest alternative, morphine, which would generate cost savings but potentially lead to a decline in patient welfare where morphine is not the most appropriate painkiller.
- Option 1 will not reduce competition, but it is possible that the competition issues identified in this impact assessment will become more egregious over time, leading to higher prices and reduced downstream competition. In particular, the potential rise of generics, discussed in paragraph 45, may erode NAPP's market share, reducing its buying power and in turn its ability to deliver low priced oxycodone FDF to the UK.

Option 2 - All barriers to the import of oxycodone FDF will be lifted within 3 months, restrictions on the import of the oxycodone API will be lifted after 18 months

112. There are two risks associated with Option 2:

- Option 2 carries a theoretical risk of increased diversion to the illicit market, although this risk is assessed to be minimal. There are tight controls surrounding the transit and sale of controlled drugs, with organisations needing to register with the Home Office, as well as clear each individual sale. All losses of controlled drugs must be immediately reported to the Home Office and records show that the amount of controlled drugs which go missing before prescription are negligible. The majority of diversion occurs post prescription.
- There is also a risk that MSL will exit the diamorphine market with no company stepping forward to provide diamorphine at a price reasonable to the majority of NHS hospitals and clinical commissioners. This risk is not assessed to be significant for two reasons: First, diamorphine is a high value drug to the NHS suggesting a low level of demand elasticity. This means that there would have to be a significant increase in price before demand began to decrease. Second, the production processes involved in producing diamorphine are well known and not unduly complex, suggesting that a company should be able to enter the market and provide diamorphine at a reasonable price. If production of diamorphine by MSL ceased, such a situation would result in increased costs to the NHS as they procured diamorphine from another, likely more expensive, source. Alternatively, the NHS could switch to the closest alternative, morphine, which would generate cost savings but potentially lead to a decline in patient welfare where morphine is not the most appropriate painkiller.

Option 3 – Imports of oxycodone from within the EEA will be allowed for any purpose. Imports of oxycodone from without the EEA will be allowed in the event of inadequacy of supply or for the purpose of re-export.

113. Both of the risks discussed above for Option 2 also apply to Option 3, although the reduced increase in competition expected from opening up trade with the EEA as opposed to the entire world as in Option 2, reduces these risks.

114. In addition to the above, a risk associated with Option 3 is that continuing to put in place any form of restriction on the importation of oxycodone will be vulnerable to a legal challenge. This is due to the policy being out of step with that for other controlled substances and generally not in keeping with the UK's commitment to free-trade. Companies within the market for oxycodone have indicated that they may consider legal recourse if they believe the Home Office's response to this issue is insufficient. It could result in the Home Office being forced to adjust its policy, generating reputational issues. Additionally, changes may not include an adjustment period, increasing the risk of disruption in the market.

G. Enforcement

115. Management of the controlled substances licensing system will continue to be managed by the Home office. Companies provide information necessary to identify clear lines of responsibility and effective control over the movement of controlled substances.

H. Summary and Recommendations

116. The government has selected option 2 as its favoured policy. This option represents the best opportunity to ensure UK consumers and companies receive the best possible prices for oxycodone, while simplifying the current regulatory system and having a negligible impact on UK businesses.

117. The best estimates for both options are a nil net impact. This is based on the conclusion that MSL's oxycodone API prices are currently competitive, which is supported by the available evidence. This means that MSL is unlikely to lose business as a result of import controls being lifted to either the whole world or the EEA. As a result, there will be no further impacts on the wider UK economy or the supply of diamorphine, nor any benefit from reduced API prices.

118. Neither of these assessments take into account the non-monetised benefits of options 2 and 3. Both options will result in a higher level of competition in the API and FDF markets, although the increase in competition, and therefore the potential gains, will be higher in option 2 than in option 3. There are well-recognised benefits of competition, and it is possible that the net effect on the UK economy will be positive. An increase in competition will help ensure that UK consumers and businesses obtain the best possible prices for oxycodone and potentially improve the competitiveness of the UK pharmaceutical industry. Option 2 will also simplify the current system of regulation for controlled substances by bringing the policy regarding the importation of oxycodone in line with that of almost all other controlled drugs[27].

[27] There are separate arrangements for codeine.

119. In comparison, option 3 would introduce a new anomalous policy out of step with that for almost all other controlled drugs. It also contains many of the risks associated with Option 2 without guaranteeing the same level of benefit. Increased competition from European producers of oxycodone could result in reduced prices and will increase competition in the UK oxycodone market; however these gains are unlikely to be as large as those associated with Option 2.

120. Finally, option 1 maintains an anomalous policy at odds with wider UK approaches to trade and controlled drugs and does not guarantee the continued supply of diamorphine. It also leaves open the possibility that UK consumers and companies may not obtain the best possible prices for oxycodone, with potential consequences for competition and the competitiveness of the UK pharmaceuticals industry.

I. Implementation

121. The Government plans to implement these changes in two stages:
    - For finished products, this will be implemented from 3 months after the consultation response.
    - For API, the policy is implemented 18 months after the consultation response.

J. Monitoring and Evaluation

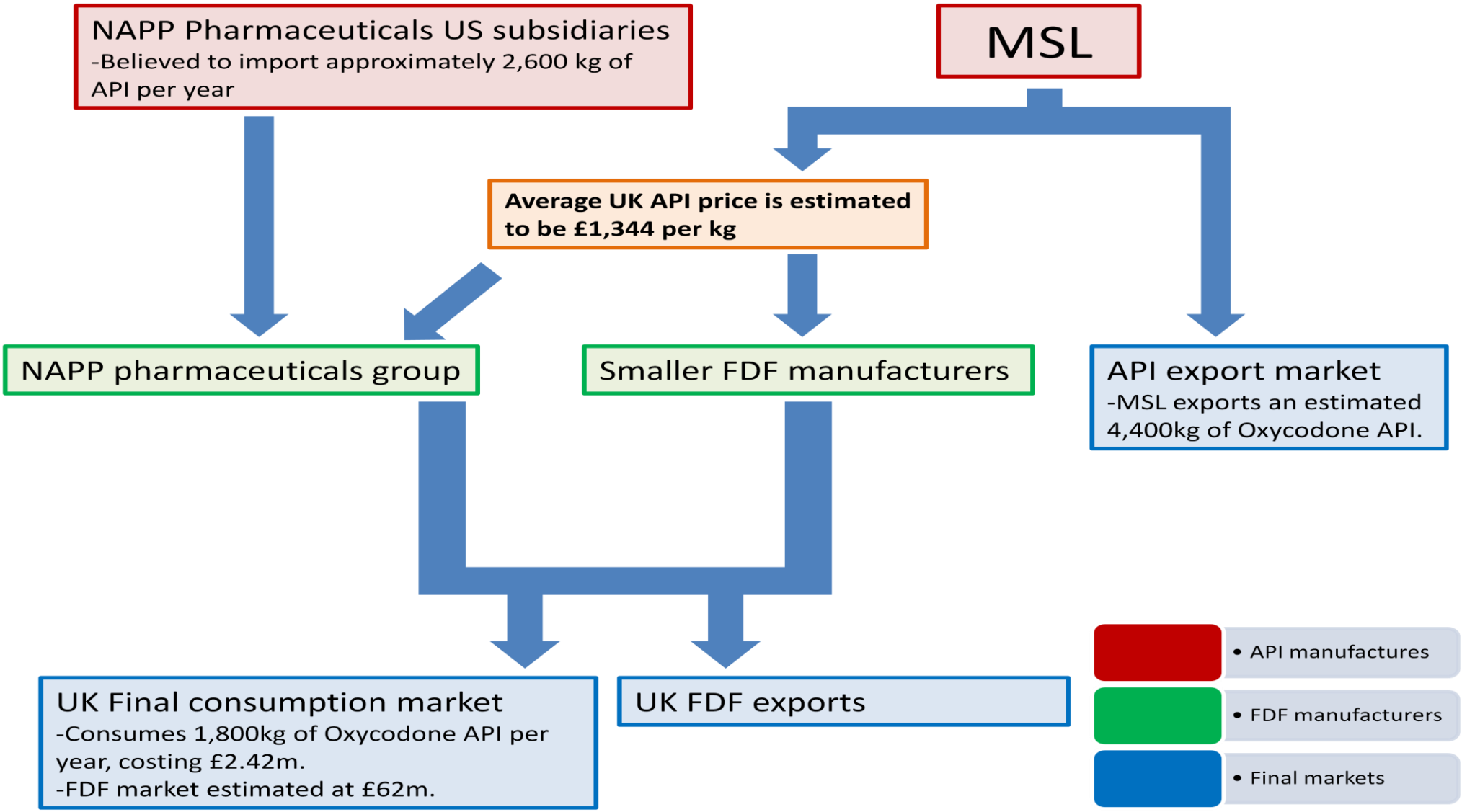
122. The key objectives of the proposed policies are to maintain an effective licensing regime for controlled drugs, ensure access for British consumers to the cheapest possible pharmaceuticals; and maintain the competitiveness of the UK pharmaceutical industry.

123. The first objective will be monitored by the Home Office using management information on the losses of controlled substances. No significant increase in such losses would suggest this objective is being met.

124. The Home Office will engage with the department of health in evaluating the success at ensuring access to the cheapest possible pharmaceuticals. Steady or falling prices would suggest that this policy objective is being met. Engagement with the NHS will also evaluate the extent to which the supply of diamorphine has continued.

125. The Home Office will engage with the Department of Business Investment and skills and potentially the Competition and Markets authority to ensure that the competitiveness of the UK pharmaceuticals industry is maintained.

Annex A:


NAPP Pharmaceuticals US subsidiaries
-Believed to import approximately 2,600 kg of API per year
MSL
Average UK API price is estimated to be £1,344 per kg
NAPP pharmaceuticals group
Smaller FDF manufacturers
API export market
-MSL exports an estimated 4,400kg of Oxycodone API.
UK Final consumption market
-Consumes 1,800kg of Oxycodone API per year, costing £2.42m.
-FDF market estimated at £62m.
UK FDF exports
• API manufactures
• FDF manufacturers
• Final markets