Home Office

RESPONSE TO THE GOVERNMENT CONSULTATION ON THE IMPORT POLICY FOR OXYCODONE

SEPTEMBER 2015

Contents

Introduction

This document is the Government's response to the consultation paper, *Oxycodone Import Policy Second Consultation, September 2014*.

It will cover:

- the background to the consultation
- a summary of the responses to the consultation
- the policy decision

Background

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

https://www.gov.uk/government/consultations/oxycodone-import-policy

1.1 Views were invited on the options set out in that document, which were framed in broad and general terms.

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

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

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

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

1.3 The Home Office conducted a first consultation in 2009. It did not find the responses to the four options presented (Options 2 to 5 as set out in the table below) sufficiently compelling to adopt any of them at that time. As part of its response in 2009 one respondent suggested a further option. That suggestion forms the basis of Option 6, one of two additional options developed for this second consultation exercise. Option 7 was developed by the Home Office to take account of as wide a range of interests as possible. The Home Office has also included an option (Option 1) to maintain the current interim system – effectively no change.

1.4 Given the passage of time and changing market conditions since publication of the first consultation, respondents were asked to indicate if their original response still stands or whether they wanted to submit further and additional comments.

1.5 At the point of the issuing of the consultation paper (and subject to the consultation) it appeared to the Government that option 7 represented the best balance between the benefits of increased competition and the risks from diversion of oxycodone.

1.6 The consultation ran from 20 September to 20 November 2014. As well as notifying trade bodies and generally informing all importing and exporting companies active in September and October 2014, the Home Office gave specific notification of the consultation to respondents from the 2009 consultation and to holders of Home Office domestic controlled drugs licences.

1.7 A summary of the options covered in the consultation paper is shown in the table overleaf.

Option	Description	Effect
1	No change – maintain interim policy (see 1.8 below)	• Imports of oxycodone will only be allowed in accordance with the current interim policy.
2	Restrict imports from outside the EEA	• Imports of oxycodone will be allowed from within the EEA for any purpose (subject to INCB estimates). • Only if oxycodone is not available from within the EEA will imports from outside the EEA be allowed for re-export or any other purposes (on a temporary basis to address the shortfall and subject to INCB estimates).
3	Allow limited imports from outside the EEA under a UK defined quota system (to be determined)	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will be allowed from outside the EEA in addition (subject to a UK defined quota) and will not be limited to re-export.
4	Allow unrestricted imports from outside the EEA	• Imports of oxycodone will be allowed from anywhere in the world for any purpose; and • The INCB approved estimate will be the only limit on imports.
5	Allow imports from outside the EEA for re-export	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). Imports from outside the EEA will be allowed from outside the EEA for re-export purposes only. There will be no restriction on quantities
6	Allow imports from outside the EEA only if there is inadequacy of supply or suppliers within the EEA	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports from outside the EEA will be allowed for any purpose, including for re-export, but only if there is inadequacy of supply or supplier in the EEA.
7	As option 6 but imports will also be allowed from outside the EEA where those imports are for re-export purposes only	• Imports from within the EEA will be allowed for any purpose (subject to INCB estimates). • Imports will only be allowed from outside the EEA for any purpose other than for re-export, if there was inadequacy of supply or competition within the EEA. • Imports from outside the EEA for the sole purpose of re-export outside of the EEA will be allowed irrespective of whether there are adequate supply or suppliers within the EEA. Imports for consumption within the UK, whether all or part of a shipment, would not be permitted.

1.8 The existing 'interim' oxycodone policy is as published in response to an FOI request of 15 March 2002 and is set out in section 6 of the consultation paper. The details of that policy are as follows:

- Imports for re-export purposes can be made 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 may be allowed. This provision only applies to a handful of companies in respect of which 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 for personal use in line with the pre-existing personal import policy (less than three months supply and/or travel of three months duration).

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

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

Summary of responses

2.1 We received a total of 21 responses. The responses came mostly from British based pharmaceutical companies. Two respondent companies were based overseas. The overseas companies have UK interests either through affiliates or sister companies.

2.2 Most companies used the formal response format on the consultation website though some put forward additional submissions to provide further context to their responses.

2.3 A qualitative review of responses was undertaken. Consultees were given the opportunity to provide substantive quantitative data, but unfortunately such data was not submitted. Therefore, an evaluation attributing monetary values to all impacts of any proposed policy and an assessment of the costs and benefits for relevant options could not be carried out. The appraisal of responses and the following impact assessment therefore represent our best efforts to evaluate and monetise impacts, using both the information provided in responses and that subsequently obtained from other government departments.

2.4 Although there was no single option amongst the listed options that was favoured by most respondents, two thirds of respondents considered there to be a need for change from the current (interim) policy, with many expressing (a) a desire to place oxycodone on a similar footing to other substances (i.e., no specific “restrictive” import control); and (b) a need to remove the current link between oxycodone and diamorphine.

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

2.6 Overall there were many strong arguments articulated against option 1.

2.7 One response stated:

> "The manufacture of oxycodone and the granting of licences should, in no way be linked to another product. We are concerned that Macfarlan Smith's products should not be bundled together. As a result of this bundling, the restrictions on the import and export of oxycodone appear in isolation to how other controlled drugs are treated. We reiterate that other products with the same classification as oxycodone do not carry the same restrictions and the markets for these products work well: the natural downward pressure of competition lowers their overall costs and there are no issues with the integrity of the supply chain. The geographical length of a supply chain has no correlation with its security and the way in which products are held." – Consultation response[2].

2.8 Others were similarly direct:

i) "It is not clear why oxycodone is treated differently from other controlled substances and it should not be bundled with diamorphine for this purpose." – Consultation response.

ii) "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." – Consultation response.

iii) We do not feel there is a requirement to consider oxycodone API separately vs. other opiates/controlled API substances. The current system to manage the importation of controlled (API) substances appears to work very well and we feel that oxycodone API should be managed in a similar way. - Consultation response

iv) "Opening the UK market up to imports from the EEA/outside the EEA would enable access to alternative formulations and competition might

[2] All respondents are listed at the end of the document. Comments are quoted anonymously.

support further development by domestic producers." – Consultation response.

v) "There is room to encourage more UK manufacturers of the finished dosage form and novel dosage forms however there is a concern that the restriction on the limited sources of the API is preventing more work/interest in this area." – Consultation response.

vi) "We believe that the interim policy of the Home Office acts against the interests of the UK patients, the taxpayer, the government and industry, and serves only to protect UK companies with a market dominant position." – Consultation response.

vii) "By opening up the oxycodone market to competition, the NHS will benefit from lower costs, which could offset any increase in the cost of diamorphine. We note that with limited competition, oxycodone prices have come down. This is likely to grow when a greater level of competition is enabled. We are concerned about the principle of the Home Office intervention in the marketplace." – Consultation response.

2.9 A small number of companies asserted, however, that there was currently sufficient competition to drive manufacturing process innovation, and that more generally:

"the nature and functioning of the worldwide oxycodone API market already drives competition that benefits the UK market." – Consultation response

2.10 As many companies did not align with a 'favoured' option, but instead concentrated their responses around the two 'themes' in paragraph 2.4 above, the analysis of the responses below shall primarily focus on an evaluation of whether to maintain the 'status quo' position (option 1). We consider this appropriate, as if there is to be a change of policy, the case for change, and by contrast the case for maintaining the current position, should be carefully considered.

Evaluation of responses in favour of maintaining option 1[3]

2.11 Only two respondents indicated a preference to maintain option 1. Of these, one respondent submitted a detailed response which highlighted four main reasons for potentially maintaining option 1. These reasons are discussed in turn and are as follows:

- the risk of diversion;
- the economic benefits of policy change;
- the supply of pain relieving drugs to the NHS; and
- compliance with International conventions.

2.12 Having fully assessed the evidence presented, we do not think that the issues raised here are intractable or justifiable barriers to change. Our reasoning is set out below.

Risk of diversion

2.13 With any movement of controlled drugs, there is a risk of diversion to the illicit market. However, we regard this risk as well controlled. In addition to this, we do not consider that there is a direct link between an increase in imports and wider societal harm. Each country in the world is different and has different health systems. Therefore the experience of other countries is not directly comparable to the UK. There is no recorded evidence of oxycodone abuse in the UK on the same scale as occurs in the USA, for example, and no evidence of diversion either within the UK or in import-export transactions. Our licensing regime is effective at managing the risk of diversion.

2.14 Furthermore, we do not believe that any proposed change in policy will lead to over-supply with the UK, with an associated risk of diversion. Prescribing practice will not ultimately be influenced by any change in an oxycodone import policy. The availability of a drug from domestic stocks at manufacturers or

[3] Option 1 is shown at paragraph 1.8.

wholesalers does not drive prescribing, which should be determined by clinical and patient needs.

2.15 The robustness of the UK licensing regime in (a) managing domestic licensees and (b) dealing with import/export applications for the international movement of controlled drugs can be cited as mitigating any potential risks. There is a notable lack of reported losses of controlled drugs and psychotropic substances during import, export, or domestic movement. Accordingly, there is no evidence to suggest that drugs are at any greater risk of diversion because their 'imports' are determined solely by the INCB 'estimates'.[4]

2.16 Some respondents also suggested that we had over-stated the diversion risk.

> "We consider that [since the 1961 convention], taking into account the major improvements in transport and border security that have taken place, this alleged risk factor needs to be re-assessed." – Consultation response

2.17 To quantify any risk, however, we can look at diversion in two contexts; first in import-export transactions and secondly in domestic supply. We can also look at diversion in terms of the risk in respect of oxycodone individually, and then at diversion of all drug material, to assess whether there is an abundance or paucity of evidence of diversion and whether this is significant.

2.18 First, looking at diversion within the import-export transactions and international shipments, because of the restrictive nature of the interim policy, we necessarily have to be informed by patterns or evidence of diversion of other

[4] The United Nations International Narcotics Control Board (INCB) is an independent, quasi-judicial expert body established by the Single Convention on Narcotic Drugs of 1961. For more information, see: http://www.incb.org/incb/en/index.html. The 'estimates' are the quantities of individual controlled drugs a country estimates it will require each calendar year- These are 'approved' by the INCB and cannot be exceeded, but can be amended in-year, with sufficient justification, with the approval of the INCB. For more information, see http://www.incb.org/documents/Narcotic-Drugs/Training-Materials/English/PART_II_English.pdf

drug materials (if that exists) in order to determine whether there is a significant risk in respect of oxycodone.

2.19 We have no evidence of diversion in the international supply chain for oxycodone or any other substances. Similarly, we have no significant unexplained imbalance in our statistical reporting to the International Narcotics Control Board (INCB) to indicate there is an unreported lost in transit risk. In summary, and noting the consultation respondents' comments, as there appears to be neither unreported nor reported loss of oxycodone or other substances, we do not consider there is significant a risk of diversion. If transactions or shipments were to increase as a result of a change of policy, the risk is well managed through the execution of the licensing regime.

2.20 The UK is held to operate a robust and effective control system in respect of drug control; this has been subject to domestic and international scrutiny. There is no evidence that, during the existence of the present oxycodone import policy, other materials have been diverted or that the system is ineffective. The present oxycodone policy, which partially restricts imports, does not seem to have highlighted (on a comparative basis) any such vulnerability in respect of other drug materials.

2.21 Secondly, and turning to the potential for domestic (intra-UK) diversion, as a competent authority we issue domestic controlled drug licences specific to schedules of controlled drugs and activities (e.g. possess, supply, produce). These are valid for one year and inherent to these is a condition to report any thefts or losses of product, regardless of their size, to the Police and Competent Authority (the Home Office). Accordingly, we are well informed of any possible diversion in-country. Incidents are very small in number and size. The most common reasons for any such incident is a miscount or mis-pick of single boxes of finished product. Other reasons for loss can include theft by employees of small quantities, often for personal use. There is no record of any reported thefts

or suspicious losses from domestic licensees concerning oxycodone products in the last 5 years.[5]

2.22 We are aware of only one recent reported incident of diversion of medicines at the wholesale level into the illicit trade in the UK (Medicines and Healthcare products Regulatory Agency (MHRA) Operation PANGEA)[6]. This is a case where the business was set up purposely to divert these medicines to illicit use and should therefore be distinguished from legitimate wholesalers, for which there is no report of such diversion activity taking place. The probability of any risks of diversion from legitimate wholesale sources materialising is therefore assessed as very low.

2.23 The robust licensing system, supported by annual renewals and periodic compliance inspections, and the lack of evidence of diversion of materials in country together indicate that the risk of diversion is very low. As oxycodone products have been subject to domestic movements and no vulnerabilities detected, the risk of diversion as a result of an increased number of domestic movements appears very low and the risk is well-managed through existing reporting structures.

2.24 The requirements placed on organisations under the Misuse of Drugs Regulations (MDR) 2001, including licensing and safe custody requirements etc., have a downward effect on the risks of diversion of drugs in transit in the UK. This ensures, through the licensing regime, that there is oversight of goods in transit, with a clear audit trail showing who is in possession at any point in time, who is supplying, etc. Oxycodone's controlled status as a schedule 2 (MDR 2001) drug will be unchanged by any new policy. This means that the robust reporting and statutory record keeping requirements imposed in respect of these drugs will remain at the highest levels of control and audit to which any medicinal drugs are subject.

[5] This is based on unpublished management information.
[6] See http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea for more information.

2.25 We do not consider that there is any reason to believe that there is any new or additional risk consequent on any proposed policy change which is not mitigated by the control systems already in place. As noted above, it does not follow that increased availability of a prescription drug leads to an increase in its availability to society as a whole. We have no evidence of diversion in the supply chain. There is no causal link between an increase in imports and an increase in harm. We think that the linking of experiences in other countries to the UK is misleading. The increase in misuse of opioids in the US, for example, is mirrored by an increase in the prescribing of opioids over the last quarter of a century. Similar increases in such prescribing in the UK have not led to US levels of misuse, harm and death.[7]

2.26 The UK has one of the most effective regulatory frameworks on drugs considered to be harmful or otherwise dangerous. This system is quite different from that encountered in other countries such as the US where manufacturers are freely able to advertise drugs and 'doctor shopping' (where patients source medication from various practitioners or clinics at the same time) can easily occur.

2.27 There is no evidence that any over-supply of a drug will necessarily lead to over prescribing with a consequential increase in dependence or addiction, and the two must be separated. Doctors make a clinical decision based on patient need rather than the increased availability of a drug at wholesale level.

2.28 The MDR places specific requirements on the movement of these potent drugs, including licensing of organisations dealing in these drugs, recording of stocks and destruction requirements in the wholesale chain. These requirements,

[7] Weisberg, D., et al 2014, 'Prescription opioid misuse in the United States and the United Kingdom: Cautionary lessons', *International Journal of Drug Policy,* Volume 25, Issue 6, Pages 1124–1130.

bolstered following the Shipman Inquiry[8], are considered to be effective to prevent over supply at wholesale level filtering into the illegal market through diversion, or other misuse.

2.29 Additionally, since 2007, a system of local Accountable Officers for controlled drugs (CDAOs), also introduced in response to the Shipman Inquiry, ensures adherence to the regulatory requirements in designated facilities, such as NHS and private hospitals, at a local level. In addition, CDAOs are responsible for convening local intelligence networks. These bring a range of local interests (including regulators, health providers, local authorities and the police) together to share information and intelligence on problems concerning controlled drugs and to take appropriate action.

2.30 These regulatory assurances, coupled with the high standard of practice by NHS professionals, mean that there is comparatively safer prescribing practice in the UK when compared to other countries. Any over-supply of oxycodone at wholesale level in the short term is therefore unlikely to have any impact on prescribing. Even if over supply impacts on prescribing levels, the systems described above would ensure this is picked up and addressed immediately.

2.31 Furthermore, interim findings from the Advisory Council on the Misuse of Drugs (ACMD) inquiry on diversion and illicit supply of medicines suggest that:

- There is no evidence for diversion and illicit supply of medicines of a magnitude similar to that in the US;
- Diversion of medicines mainly occurs after a drug has been prescribed in the community;

[8] See https://www.gov.uk/government/publications/amendments-to-the-misuse-of-drugs-regulations-2001-the-2001-regulations-to-implement-key-elements-of-the-action-programme-published-in-safer-management-of-controlled-drugs-december-2004 for more information.

- There is no evidence of major diversion from wholesale stocks for illicit use, neither is there a correlation between wholesale supplies and levels of prescribing.

The interim conclusion is that "wholesale stock levels have little impact on prescribing, diversion and misuse of medicines in the UK."[9]

2.32 For the reasons above, the prescribing, dispensing and use of controlled drugs, more particularly those listed in Schedule 2 (like oxycodone) are subject to the strictest requirements in the UK. Prescribing is a clinical decision made by doctors based on patient needs and irrespective of wholesale stock levels. The NHS systems for prescribing and patient record systems means doctor shopping, as occurs in other countries, occurs in the UK, if at all, on a much lower scale.

2.33 In summary, the risk of potential diversion, whether within the UK or in international movements appears overstated. Having considered all the evidence, there is therefore no reason to believe that there is any new or additional risk with any proposed policy change which is not mitigated by the control systems in place.

Economic benefit

2.34 As noted above, the opportunity to provide a range of quantitative data to help support a full economic analysis was not taken up by those responding to the consultation.

2.35 This is likely to be partly as a result of concerns about submitting commercially sensitive data (which would potentially be liable to public disclosure) and partly because any economic future is uncertain. This is the second consultation on this subject; and we consider that further research in this

[9] A letter from the ACMD to the Minister of State for Policing, Criminal Justice and Victims may be found here: https://www.gov.uk/government/publications/acmd-interim-advice-diversion-and-illicit-supply-of-medicines

area is unlikely to produce sufficient extra information to help inform our decision, or to do so at a proportionate and reasonable cost. Our view, therefore, is that this consultation is the vehicle to (i) obtain information in respect of the impact of any changes in policy,(ii) inform a decision stage impact assessment, and (iii) ensure that any impacts are monetised as fully as possible. We consider it reasonable to apply standard economic principles in the absence of cogent quantitative data specific to the subject matter in hand. The basic theory is clear: there is, in general, a link between competition, an unrestricted market and declining product price.

2.36 Working on these standard economic principles and assumptions, the desire for a freer, less restrictive market appears to have influenced the following comments. These responses suggest a reflection of the position in the wider pharmaceutical industry:

i) "By opening up the market to foreign imports it keeps the UK manufacturers price competitive and protects the NHS from paying inflated costs". – Consultation response

ii) "There is room to encourage more UK manufacturers of the finished dosage form and novel dosage forms. However, there is a concern that the restriction on the limited sources of the API is preventing more work/interest in this area." – Consultation response

2.37 The following comments are more concerned with the current link between diamorphine and oxycodone:

i) "By opening up the oxycodone market to competition, the NHS will benefit from lower costs, which could offset any increase in the cost of diamorphine (if Macfarlan Smith's assertions are valid). We note that with limited competition, oxycodone prices have come down. This is likely to grow when a greater level of competition is enabled". - Consultation response.

ii) “A less restrictive alternative to the prohibition on imports of oxycodone would be for the NHS to pay a market (rather than cross-subsidised) price for diamorphine, thereby ensuring that MSL continues to produce it”. – Consultation response.

iii) “We are concerned about the principle of the Home Office intervention in the market place.” - Consultation response.

2.38 One respondent, however, was concerned about the feasibility of other companies entering the market. They stated “the Home Office does not explain what, in its view, is the mechanism by which Options 2 to 7 would trigger the entry of a new supplier of Oxycodone API in the UK”.

2.39 We accept there is a possibility that no new entrants to the oxycodone market may emerge. Our general intention was to consult on the future of the oxycodone importation policy. We have no interest in specific companies; our wider intention is to ensure that any policies we have comply with international drug control obligations, and, whilst being consistent with those obligations, encourage competition sufficiently as not to affect security of supply to the NHS, and facilitate the growth of the UK pharmaceutical sector. Furthermore, if there is no new entrant to the oxycodone API market and the existing supplier’s business is unchanged, it would seem unlikely that the profitability of that oxycodone API production would be adversely affected, all other facts being equal.

2.40 As it stands, the current policy prevents even the opportunity for new entrants to enter the market. If the policy was changed to remove the current restrictions, it does not necessarily follow that more companies would enter the market, demand for oxycodone would increase or a preference for a non-UK based API supplier would occur. An unrestricted policy allows the potential for new entrants into the market but does not guarantee it. As with any product, our assumption is that market itself will decide as potential companies assess viability for themselves. There is nothing particular about the oxycodone market to suggest that normal company economic behaviour within the pharmaceutical sector would not happen.

2.41 One respondent was also concerned that any changes to the policy might affect its own profitability.

> "Oxycodone API is still key to [our] business... any impact of a change in import policy on [our] sales of oxycodone API can therefore be expected to have a considerable effect on its global profits." - Consultation response.

2.42 In addition to this, there was the suggestion that, given the respondent's own chosen structure, any lifting of the current restrictions would disproportionately affect it.

> "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." - Consultation response.

2.43 While we accept that this is possible, we have evaluated this as far as is practicable given the information provided and balanced this against our stated needs. Overall, if one single company's business model impedes flexible responses to regulatory or market changes, this should not be a driver of policy which affects a whole business sector and has important ramifications for the national interest. Furthermore, even if the price of oxycodone does not fall - for example because of other factors like a raw material price increase or secondary production costs (e.g. energy) - it seems highly unlikely to increase on account of a policy to relax restrictions.

2.44 From an international perspective, the observation was made that other countries in the world operate selective restrictions on certain substances, be that as an API or a medicinal product. Whether these restrictions exist or not - in whatever form -, we do not consider this is to be a justification for operating a similarly restrictive approach for a single drug, when no such other restrictions are in place in respect of other potentially dangerous drugs, and there does not

appear to be evidence of an imperfect market on account of that ‘free’ and enabling policy.

2.45 One company stated in its consultation response that:

> “The Home Office should only reach a final policy decision after appropriate consultation with the European Commission and its international trading partners on reciprocal relaxation of trading barriers.” - Consultation response.

2.46 The Home Office does not consider that protection for one particular company is beneficial to the industry as a whole, even if there are wider issues at play relating to trade reciprocity, as there will be other markets and opportunities which are open to business exploitation. Even without reciprocal liberalisation, there could be significant benefits to British consumers and finished dose manufacturers, both of whom will benefit from lower prices. These manufacturers may well argue that they are being unfairly penalised by the presence of the interim policy. It is recognised that, as a principle, reciprocal liberalisation is sound, and relevant Government departments will continue to engage bilaterally on this issue as appropriate, where reciprocity may not be fully implemented.

2.47 It is worthy of note, however, that our (unpublished) licensing records indicate that since 2011 exports of significant quantities of oxycodone API occur from the UK to some countries where it is claimed restrictive import policies are in operation. There does not appear to be significant evidence to suggest the availability of any of existing ‘export’ markets would decrease in response to any change to UK oxycodone import policy.

2.48 In summary, lifting import controls should deliver a more competitive market within the UK, both now and in the future; there is inadequate evidence to support limiting competition by controlling imports. The presumption should be not to restrict those as the benefits of competition may be dynamic and unpredictable in magnitude. We reiterate that the policy should of course comply with

international drug control requirements and should protect public health and security.

2.49 The impact assessment, as far as is practicable, further explores the economic impact of policy changes.

Supply of pain relieving drugs

2.50 The INCB report on Narcotic Drugs: Estimated World Requirements for 2015; Statistics for 2013 published 17 March 2015 states:

> "The available data indicate that the amount of opiate raw material available for the manufacturing of narcotic drugs for pain relief is more than sufficient to satisfy the current level of demand as estimated by Governments. In addition, both production and stocks continue to increase."[10]

2.51 The Home Office estimates that the UK, in primary and secondary care, uses no more than 75kgs of diamorphine per year. Based on data collected from all contributing countries, the INCB estimates that the stock of opiate raw materials for 2013 was 546 tons. These stocks are considered to be sufficient to cover 14 months of expected global demand at the 2014 level of demand. Indicative, and provisional, data suggests that 2014 and 2015 stocks of opiate raw material are 721 and 956 tons respectively.

2.52 It is our view, therefore, that there is no shortage of the raw materials to make this specific pain relieving drug. However, there is currently only one stated supplier of diamorphine API for pain relief. This, in itself, is a potential weakness in terms of security of supply as this makes the NHS, and its patients, overly reliant on one company for this particular drug. The current policy maintains this

[10] INCB report on Narcotic Drugs: Estimated World Requirements for 2015; Statistics for 2013. Part 3, page 107, paragraph 32, published 17 March 2015: http://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/2014/narcotic-drugs-technical-report-2014.html

situation which, in effect, suggests that the Government is content with the level of risk and uncertainty in the supply of an essential controlled-drug containing medicine, in this case diamorphine. As we are in fact not so content, further work is required to manage this current risk. This is explained in more detail in section 3.

Compliance with International conventions

2.53 The UK has obligations under the 1961 Convention: namely to prevent the accumulation of excess controlled drugs in the possession of manufacturers, traders, distributors and others, and minimising, as far as is reasonably possible, international movements of controlled drugs in order to reduce the risk of diversion. The Convention does not seek to prevent legitimate and free trade, however. We are conscious of these twin aims and the proposed importation policy of oxycodone will reflect both.

2.54 One respondent said that the Convention does not tolerate a diversion risk even if the state identifies competitive benefits that accrue form a particular approach to drug control. It was suggested that the Convention state's economic considerations are not to be taken into account. That respondent argued that the Home Office would be misdirecting itself if it adopted a policy on the basis that competitive benefits outweigh increased diversion risk.

2.55 There may, however, be some misunderstanding about the Convention and its scope. We consider that the effect of the Convention is to concentrate on opiate raw materials and their diversion, rather than any subsequent API or finished product. With this potential misunderstanding in mind, we sought clarification from the INCB. They stated:

> With respect to licit trade, this framework [the Convention] comprises a number of obligations which are incumbent upon States including the establishment and maintenance of a special administration for the purpose of applying the provisions of the conventions and the provision

> of annual estimates/assessments and quarterly and annual statistics to the Board. It also establishes a system of control governing international movements of narcotic drugs and psychotropic substances so as to facilitate access to these substances while preventing their diversion into illicit channels. This is done through administrative and regulatory controls including the issuance of import/export certificates with due regard to the estimates confirmed by the Board for each country.
>
> ... the international drug control conventions do not, in any way impose any geographical restrictions on the international movements of narcotic drugs and psychotropic substances beyond those described above. As such, so long as a State maintains an effective special administration which complies with its reporting obligations to the Board, diligently establishes its own estimates, controls imports/exports through the issuance of import/export and any other measures considered necessary to prevent diversion, it shall be deemed to be in compliance with its international obligations under the drug control conventions[11].

2.56 In summary, we consider that a correct understanding of the Convention (an understanding which is supported by the comments of the INCB), and the effectiveness of the UK's controlled drug licensing regime together mean that we fulfil the objective of compliance with our international obligations.

[11] Unpublished correspondence INCB ref INCB-CES UK 28/15 9 April 2015

Policy decision

3.1 The Home Office acts as the UK Competent Authority for Drug and Precursor Chemical domestic and import-export licensing, with one exception. Controlled Drug domestic licensing for premises in Northern Ireland is devolved to the Department for Health, Social Services and Public Security. This consultation has been conducted on that basis and, since this relates to an import policy, is applicable to import-export transactions by companies in both Great Britain and Northern Ireland.

3.2 For the reasons outlined above, we do not consider the arguments for maintaining option 1 are sufficiently persuasive to adopt that option. It is accepted that there may be impacts on business as a result of the change in policy, but we consider that the potential risks associated with the adoption of a new policy can be well managed. We acknowledge the economic benefits are potentially uncertain, but there is no reason to suggest a negative outcome is any more likely to occur than a neutral or positive outcome. Indeed, as the magnitude of any impacts of change are difficult to quantify because there are beyond Home Office control and depend entirely upon the behaviour of businesses, it is right that the regulatory conditions are created which provide the best possible foundation for the market as a whole to respond to any changes in supply and demand. This is subject always to compliance with international obligations and public health and security considerations.

3.3 As was stated above, there was no majority preference for any of the listed options. However, two thirds of responses did identify need for change from Option 1. For the reasons stated above, we conclude that there is no justification for maintaining the current restriction. Accordingly, the remaining options were evaluated, taking into account the views expressed in the consultation and the assessments made in respect of the ‘status quo’ option (1) in respect of :

- compliance with International conventions;
- the risk of diversion;

- the economic benefits of policy change, and,
- the supply of pain relieving drugs to the NHS.

3.4 Given the evaluations made in respect of these factors showed a generally poor justification for maintaining a restrictive import policy, the arguments for replacing option 1 with another which sought to restrict imports as policy for a (i.e. options 2, 3, 5, 6 and 7) were not compelling. As these options all involve varying degrees of restriction, they would perpetuate an anomalous policy position for a single drug to a greater or lesser extent. Given the intervention that would be necessary for the adoption of any of these policies, there is a strong likelihood that new inequalities in the market would be created or existing ones maintained. Our evaluations suggest there was not a good reason for replacing one anomalous policy with another.

3.5 A significant number of respondents gave a strong indication that oxycodone import policy should be set on a level footing with almost all other controlled drugs in the UK, namely that there should be no restrictive policy. Accordingly, and after balanced consideration and weighing of all relevant factors, option 4 appeared to offer the most sustainable solution which offered the greatest benefit to the sector as a whole, whilst being consistent with the other factors that must drive policy, as identified above.

3.6 Furthermore, when considering all of the responses, it was clear that there are no present grounds for maintaining a link between diamorphine and oxycodone. Strong arguments from some consultees suggested that a different policy for the API and finished product was necessary. The latter was something that had not been explicitly considered before and presents the Home Office with an opportunity to resolve these issues.

3.7 In respect of diamorphine, the Home Office recognises that there is a ‘link’ between oxycodone and diamorphine API on account of the material coming from the same supplier. This may, or may not, be perpetuated by the current ‘interim’ oxycodone policy, in so far as the production of diamorphine is either

subsidised or contingent on the current producer of diamorphine API ensuring a profit is made on other drug lines (oxycodone) to ensure the viability of diamorphine production. We accept that one product may be more profitable to a supplier than another and that a change in oxycodone import policy may inform wider business decisions made by that API manufacturer. However, it is equally possible that the manufacturer may, of its own volition, make a decision in respect of its continued production of diamorphine API, which may affect wider diamorphine availability within the NHS. Beyond purchasing agreements and any other contractual arrangements, that manufacturer is under no apparent obligation to continue to supply at a set price. One response may be for that manufacturer to increase its price for that product to ensure viability, if it previously cross-subsidised that product line with a more profitable one and negotiate with its customers. This is understood to be a normal business operational practice and there is no reason to believe this could not occur in respect of diamorphine supply. Any protection that option 1 currently affords the supply of diamorphine may simply serve to stifle new entrants to the market; maintaining a link between diamorphine production and oxycodone import policy is not sustainable for the reasons given above.

3.8 In short, the potential impact of a shortage of diamorphine on UK patients is understood and the importance of this recognised. However, this position could occur on account of a change in business practice or orientation by the single producer who exercises ‘market power’ in respect of this drug line. Furthermore, a change of this type would not be contingent upon a change to the ‘interim’ oxycodone import policy. It is accepted that a change in oxycodone import policy may trigger the manufacturer to make changes to its product line, but the likelihood of this cannot be readily quantified. Government policy in this regard cannot be based upon anticipating the behaviour of companies which rightly operate wholly independently of government as private businesses.

3.9 Given the potential consequence of a diamorphine shortage, whether that manifests on account of a change in oxycodone import policy, or for other reasons, it is appropriate, in the course of implementing the new policy, that the

current position is evaluated and actions taken to mitigate and manage any changes to the present supply of diamorphine and to ensure patients can continue to access this medicine, if there is a clinical necessity to prescribe or administer it.

3.10 The Home Office is the regulatory and licensing authority. We do, however, recognise that there are impacts beyond our immediate licensing remit. We intend to work collaboratively with other government departments, particularly the Department of Health (DH), the Department for Business, Innovation & Skills (BIS) and potentially the Foreign and Commonwealth Office as necessary during any transition periods, as the new policy is adopted. It has therefore been agreed that DH will lead work to evaluate the likelihood of a diamorphine shortage and actions to mitigate this, and consider what measures could be taken longer term to reduce indirect vulnerability to UK patients by virtue of having a single supplier of source material. Other government departments will support any potential international engagement, as appropriate. This work will ensure all or a combination of the following actions occurs to mitigate any threat to the disruption of diamorphine production.

3.11 The agreed initial actions to be undertaken in accordance with the above can be summarised as follows:

- engage with the current supplier of diamorphine API to ensure stocks of drug material are secured for short and medium term supply;
- engage with the current supplier of diamorphine API to establish the impacts, if any, on their medium to long-term production of diamorphine;
- examine and evaluate current prescribing practice to ascertain the essential clinical indications for which diamorphine is the preferred drug to be administered.
- consider and explore clinically satisfactory alternatives to diamorphine usage in primary and secondary care in the event of a shortage, or a catastrophic failure in the supply chain;

- engage with those in NHS procurement activities to support them and ensure they have the mechanisms in place to obtain best value for oxycodone products to take advantage of any pricing changes as a result of realising the benefits of completion;
- engage with industry to assess the viability and preparedness of other potential suppliers of diamorphine API to enter the market; and
- engage internationally to examine any restrictive policies in other countries with a view to reducing any barriers that may exist.

These are not exhaustive and other options may well present themselves during the engagement.

3.12 It is accepted that these actions will take time and the market similarly will need time for any adjustment to occur. It is important that any engagement with industry is open and collaborative. Furthermore, it is recognised that any new suppliers/producers need time to work up production lines or facilities. With this in mind, to immediately implement a new oxycodone policy could potentially cause disruption in the pharmaceutical sector and downstream to patients. For this reason we are proposing a phased implementation as outlined below which we consider provides the opportunity to minimise any disruption and mitigate the risks of diamorphine shortage. Whilst there are agreed actions during this period, this is not a good reason to delay publication of the new policy or its implementation dates.

Consultation outcome - new oxycodone policy

3.13 In short, the government intends to adopt ‘option 4’ and this can be broken down into the following policy responses.

3.14 As discussed, the present ‘interim’ policy contains ‘limbs’ which relate to API and finished products separately. It was clear from the consultation response, and the significant number of respondents that the ‘finished product’ market was

very eager for change to the presently restrictive policy and wished quickly to realise the benefits of any policy change. For this reason, whilst the ultimate policy response to this consultation may in essence be the same, there was little justification for delaying a change in respect of finished product imports whilst any adjustments to the API market occurred. For this reason changes will be implemented in two phases.

Imports of finished product

3.15 As there was a spread of representations but no consensus one way or the other, and no one option preferred, and with most respondents favouring a general opening of the market, it is logical to align oxycodone finished product imports with other substances. With this in mind, and taking note of the discussion above, subject to INCB estimates, we intend to allow imports of oxycodone finished product from any source for any purpose.

3.16 To be clear, parallel imports, imports for re-exports and imports for domestic use of finished products will be allowed from any country irrespective of the source of the original API. This will go some way to aligning oxycodone with other substances. We anticipate companies will initially source finished products from existing supply chains but in time they may switch to alternative sources should these be viable.

3.17 This will take effect from 3 months from the date of the consultation response.

3.18 For completeness, and with regards to exports, there would be no restrictions on exports to any destination country for any purpose (save for INCB estimates in those countries).

Imports of API

3.19 With reference to oxycodone API, we intend to allow imports from any source for any purpose. However, we propose a phased implementation.

3.20 This will take effect from 18 months from the date of the consultation response to allow the market time to adapt to the new environment and to allow the actions agreed above to take place to mitigate any risks to the supply chain of diamorphine.

3.21 The proposed 18 month lead in time is a rational and proportionate response to the historical complexity of the market and serves to mitigate any impacts, albeit placing the onus on licensees to review their positions and identify opportunities or responses to any changed market conditions. Given this notice, and clarity of intention, it is reasonable to expect a business to respond to changing market conditions in this time period. Our view is based on the benefits to all existing and new UK businesses in the sector. It would be inappropriate for the Government as regulator to adopt or maintain a policy on account of the profitability of a single UK (private) company when the market across the whole of the UK is in a position to respond to any changes in regulatory landscape.

3.22 We consider that the transition period is one that is mutually beneficial to both industry and government. It provides adequate time for business to respond to those changes, and for government departments to work with the industry to facilitate transition, thereby safeguarding the diamorphine supply to UK patients, if clinical use of this substance remains unchanged.

3.23 We would anticipate that in practice current and new manufacturers are likely to source their API from existing domestic sources, and subsequently from foreign sources if they so desired. It is acknowledged that, in the medium term, it is possible that if FDF manufacturers become ‘tied’ to an API supplier - for example within their group of companies - any FDF

manufacturers without 'tied' supplies may experience difficulty sourcing API. However, having considered all information available, it is not felt there is evidence to indicate there is a reasonable likelihood of this happening. As is the case now, we will consider import applications on a case by case basis.

3.24 For completeness, and with regards to exports, there would be no restrictions on exports to any destination country for any purpose (save for INCB estimates in those countries).

3.25 The effects of this policy will, in time, place oxycodone on the same footing as other controlled drugs imported into the UK for medicinal purposes. Although, this is a departure from our initial indicated preference in the consultation paper, based on the responses received we now believe that this is the most appropriate approach, because this offers the best balance to enable the UK to meet its wider healthcare needs and realise the benefits of competition without compromising the security or integrity of the supply chain, or placing the drug at a disproportionate risk of diversion. This meets all the intentions of the consultation document, and we believe shows the effectiveness of the consultation in informing our decision making.

3.26 At first sight this may appear a radical change, but it is noteworthy that when a number of substances were controlled[12] in June 2014, the default import policy was applied to these substances in the way all others were controlled before them. This was to allow, subject to INCB estimates where relevant, imports from anywhere in the world for any purpose. Oxycodone will be placed on the same basis as almost every other controlled substance[13] that is imported into the UK in 3 months for finished product forms and in 18 months for API material.

[12] See https://www.gov.uk/government/publications/circular-0082014-changes-to-the-misuse-of-drugs-act-1971 for more information.
[13] There are separate arrangements for codeine.

Imports on the person, clinical trials, research and reference standards

3.27 There was general agreement for imports for research and/or analytical purposes as this drives innovation and the development of new medicines. We intend to leave this, and imports of medicine on the person for personal use, unchanged and in line with other controlled drugs. Each application will be assessed on a case by case basis.

Conclusion

4.1 The Government welcomes the responses to the consultation and would like to thank all those who responded on this issue.

Consultation principles

4.2 The principles that Government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

https://www.gov.uk/government/publications/consultation-principles-guidance

Respondents

4.3 Responses were received from the following companies:

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

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