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OPIUM DERIVATIVES

**GOVERNMENT RESPONSE TO
OFT'S REVIEW OF
UNDERTAKINGS BY
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Introduction

1. The Government welcomes the OFT's recommendation that Government should consider competition when setting licensing policy for the import of opium derivatives. This recommendation was contained in the report *Opium Derivatives: A review of undertakings given by Macfarlan Smith*¹.
2. In the 2001 White Paper "*Productivity and Enterprise – A World Class Competition Regime*", the Government gave the OFT a formal role to advise where regulations may have an impact on competition issues. Until now, the OFT has used market studies to highlight examples of regulations; however, this is not the only avenue open to them to draw information to the Government's attention.
3. As part of their statutory role, the OFT regularly reviews undertakings given by organisations following earlier competition investigations. In this case, the OFT reviewed the undertakings by MSL following a report from the Monopolies and Mergers Commission (MMC)², and concluded that Government policy in respect of the licensing of imports for opium derivatives was having a negative effect on competition.

Background to the market

4. The principal opium derivatives used within the UK are codeine, dihydrocodeine, morphine and diamorphine. Of these, codeine is produced in the highest volume, and sold downstream to be incorporated by pharmaceutical companies in a wide range of products, many of which are available commercially. At the other end of the scale, diamorphine is a marginal product, used almost exclusively by the NHS. MSL is the world's sole manufacturer of diamorphine.
5. Opium derivatives – especially morphine and diamorphine – are highly prized on the illicit market and actively sought by misusers. It is important that such products cannot be diverted into the illicit market, but also that the guaranteed purity of pharmaceutical products is not jeopardised.
6. The Government therefore recognises the importance of the international licensing control system, which permits legitimate production and use, while at the same time preventing diversion. These controls restrict the use of drugs to purely medical and scientific purposes whilst at the same time ensuring that such drugs are available

¹ OFT 834

² MMC Report Cm 630: *A report on the matter of the existence of a monopoly situation in relation to the supply in the United Kingdom of opium derivatives*

in sufficient quantities to meet legitimate global scientific and medical needs.

7. The licensing system, and current Government policy, is rooted in a number of multilateral drug treaties³ which rest on the concept of national control by individual states within the limits of their jurisdiction. These deal with the licensing and inspection of cultivation, production, manufacture and trade (including import and export) in the controlled drugs. There is therefore a control equation, monitored by the International Narcotics Control Board (INCB), which ensures a balance between legitimate production with legitimate requirements. To enable the functioning of this, the UK Government must provide estimates of our requirements for narcotic drugs to the INCB for confirmation on an annual basis. The UK must not exceed these estimates without good reason and the prior knowledge and acceptance of the INCB.

8. As a result, import quotas are carefully applied to ensure that the combined use by the UK (through both import and UK production) does not exceed this estimate. In 1995 the European Court of Justice⁴ ruled that restrictions on importation were only justified to the extent that they are necessary for the protection of human health. As a result of this judgement imports of opium derivatives into the UK were permitted from 1997. However, since 2004 the Government has restricted the importation of some of the opium derivatives. The UK currently operates a system that allows 10% of codeine supplies to be obtained through import. This figure has not been robustly tested or reviewed since its inception.

The recommendation – Government should consider competition when setting licensing policy.

9. The OFT recommendation is in line with the Government's commitment to encourage and enhance the competitive process to bring the wider benefits to the UK economy. Preventing abuse of market power is a key element of this, and it is important to ensure that regulation which affects such market power is operated in a transparent manner. It is therefore clear that Government should regularly review policy decisions such as this to ensure that the detrimental impact to competition is prevented, or, where other objectives intervene, limited. The OFT report has provided an excellent catalyst for such a review, and the Government will commit to repeating the process of review every five years.

³ The 1961 Single Convention of Narcotic Drugs (which was strengthened by the 1972 protocol amending that Convention); the 1971 Convention on Psychotropic Substances and the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The UK is a party to all three conventions.

⁴ Case C-234/93 Rv Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith

10. Diamorphine is a powerful opioid analgesic which is used for the treatment of acute and chronic pain. The UK is unique in being the only country in the world to use it for palliative care, for example in cancer patients. It has advantages over other painkillers; in some cases it may cause less nausea and hypotension than morphine. It is also more soluble than morphine, which means that effective doses can be injected in smaller volumes, and this is important in emaciated patients. Injectable diamorphine is also used as an opiate substitution treatment for a small number of otherwise treatment-resistant cases of severe opiate addiction. It has a vital place in current clinical practice in the UK, and this has been illustrated by the degree of concern exhibited by doctors and other healthcare professionals during a recent shortage of the finished injectable product. Any failure in supply of these products could put at risk access to necessary pain relief. Additionally, the UK is one of the major producers of codeine products, exporting to a number of countries, and the continued success of the entire supply chain is an important consideration.

11. Given the importance of ensuring these objectives, in particular the supply of diamorphine, the Government recognises that there will, inevitably, be some impact on competition and the normal commercial functioning of the market. However, we recognise that within the framework, any detrimental effect should be minimised. We note that the Office of Fair Trading has not conducted a full assessment of the potential effect on supply of either an exit from the market by MSL or of a significant drop in market share as part of this exercise given the principal focus of its work was a review of undertakings.

12. Following further discussion and analysis of information provided by MSL the Department for Health has been able to make a judgement on this issue. There remains a real risk that MSL's ability to supply diamorphine in the UK could become unsustainable if import quotas were to be increased at this point in time. This analysis takes into account likely future developments in security considerations as well as looking at the potential risk of lost opium crop.

13. Nevertheless, the Government recognises that a lack of competition may continue to have a knock-on effect on both downstream prices and the ability of competitors to enter into the market. We will therefore undertake to analyse the effect of MSL's position as sole supplier on customers and competition, contrasting this with the positions of customers in other countries (both those who impose significant restrictions and those who do not).

Single European Market for Opium Derivatives.

14. During discussion with MSL and other parties while developing the response, a consistent complaint was the lack of a level playing field between the UK and other European countries (something recognised in the original MMC report). Currently, the UK is the only major European producer to allow imports.

15. There has been limited discussion of this at European level, and the Government is committed to raising this issue again with the European Commission, to develop options for the creation of a single market for these products.

16. The Government will present the findings of the full market analysis to the European Commission as background information.

End
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