

Opium derivatives

**A review of the undertaking given
by MacFarlan Smith Limited**

March 2006

OFT834

© **Crown copyright 2006**

This publication (excluding the OFT logo) may be reproduced free of charge in any format or medium provided that it is reproduced accurately and not used in a misleading context. The material must be acknowledged as crown copyright and the title of the publication specified.

CONTENTS

<i>Chapter</i>		<i>Page</i>
1	Executive summary	1
2	Introduction and background	6
3	Compliance with the undertaking	18
4	Effectiveness of undertaking	23
5	Conclusions and recommendations	31
 <i>Annexe</i>		
A	Summary of the Monopolies and Mergers Commission report on opium derivatives (1989)	36
B	Undertaking given by Macfarlan Smith Limited in relation to the supply of opium derivatives	39
C	Definition of small, medium and large customers	40

1 EXECUTIVE SUMMARY

Introduction

- 1.1 This report reviews the operation of the undertaking given by Macfarlan Smith Limited (MSL) in 1989, to publish and make generally available a list of maximum prices for certain opium derivatives, against the background of developments in the production and use of opium derivatives over the past 17 years.
- 1.2 The undertaking was given by MSL to the Secretary of State for Trade and Industry following a report¹ of the Monopolies and Mergers Commission (MMC).² This report and the subsequent undertaking were made under the monopoly provisions of the Fair Trading Act 1973 (FTA 1973).³ A summary of the MMC report is included at Annexe A and the full text of the undertaking is at Annexe B.

Summary of findings

- 1.3 There has been substantial growth in both the production and use of opium derivatives since 1989. This is likely to continue.
- 1.4 As in 1989, MSL (now part of Johnson Matthey plc) faces little competition to supply the UK market. Boots, the only remaining UK manufacturer of opium derivatives in 1989, withdrew from supplying

¹ Monopolies and Mergers Commission (1989), *A report on the matter of the existence or possible existence of a monopoly situation in relation to the supply in the United Kingdom of Opium Derivatives* Cm 630.

² The functions of the MMC were transferred to the Competition Commission from 1 April 1999, pursuant to section 45 of the Competition Act 1998.

³ Although the undertakings were originally given to the Secretary of State for Trade and Industry the undertakings were transferred to the Competition Commission in 2004 (The Enterprise Act 2002 (Enforcement Undertakings and Orders) Order 2004, SI No. 2181).

opium derivatives in 1990 leaving MSL as the only UK based supplier. MSL supplied approximately 91 per cent of the UK market for the reference opium derivatives in 2002, compared with 87 per cent in 1986/7. The remainder of the market is supplied by a number of importers based elsewhere in the European Economic Area (EEA).

- 1.5 The importation of opium derivatives into the UK is regulated through a licensing system which operates subsequent to the UN Convention on narcotic drugs ('the Convention'). In 1989 the Home Office, the government department responsible for the operation of the licensing system in the UK, did not permit any importation unless UK manufacturing capacity was unable to meet legitimate medical or scientific demand.
- 1.6 In 1997 the Home Office changed this policy and allowed imports of opium derivatives from elsewhere in the European Union (EU) and subsequently the EEA. This was subject to the level of importation remaining within an agreed estimate which is provided to the International Narcotics Control Board (INCB), which monitors the implementation of the Convention. However in 2004, as a result of increased levels of importation, the Home Office imposed limits on imports of codeine phosphate, the largest selling product, in order not to exceed the estimate and subsequently to protect UK production capability, with the policy objective of safeguarding reliability of supply.
- 1.7 In 1989 the MMC found that MSL was able to exploit its monopoly position by charging high prices and engaging in price discrimination at the expense of those customers buying smaller quantities. It also found that MSL achieved very high levels of profitability. It concluded that these practices were against the public interest.⁴ The Office of Fair Trading (OFT) finds that these practices continue to be features of

⁴ MMC (1989), paragraphs 9.58, 9.60.

MSL's supply. MSL's profits from the reference opium derivatives, as measured by return on capital employed, have fallen compared with 1980s levels, but are still high.

- 1.8 The OFT finds that MSL's undertaking to publish and make generally available maximum price lists has not been consistently complied with. The availability of a price list is unknown to the majority of MSL's customer base, contrary to what the MMC had intended, and has not substantially constrained price discrimination, particularly against customers buying smaller quantities.
- 1.9 In 1989 the MMC recommended the liberalisation of trade in opium derivatives within the then European Community, in order to increase competition in supply in the UK. This has not happened, although the Government has allowed some imports from within the EEA. The recent decision on the restriction of importation of codeine phosphate was taken without consideration of the resultant effects on competition and opiate prices, and consequently on customers and the taxpayer.

Conclusions and recommendations

- 1.10 The undertaking to publish maximum price lists has been ineffective in substantially constraining price discrimination against MSL's smaller customers. Notwithstanding this, and regardless of whether there has been a change of circumstance, the OFT recommends that the undertaking should remain unchanged at present. This is because the main reason for the competition problem in this sector is the trading restrictions on opium derivatives that are maintained by the UK Government through its licensing policy.

- 1.11 The OFT recognises it is a matter for the Government to determine whether or not import restrictions are justified under Article 30 of the Treaty of Rome⁵ (subject to review by the Courts), but when assessing whether or not there is a material risk to supply which justifies such protective measures it is important that it takes into account the consequent effects on competition, consumers and taxpayers. It is not clear to us that reliability of supply of opium derivatives in the UK would be jeopardised by a greater reliance on the EEA market. Indeed most of the member states of the EEA are reliant on importation as the source of opium derivatives. The OFT has not been informed of any concerns in those countries about shortages of supply of opium derivatives.
- 1.12 The OFT recommends that the Government takes into consideration competition issues for the purposes of devising future licensing policy.
- 1.13 The OFT has made the Government aware of its concerns relating to the operation of the import licensing regime and is willing to provide advice on devising licensing policy which considers the benefits of competition. The OFT will continue to monitor the situation and will consider the Government's response to our concerns, in order for us to be satisfied that a further market reference would be unnecessary. The OFT cannot rule out further action if the distortion to competition supported by the current policy continues unchecked.

⁵ Article 30 of the EC Treaty Permits the imposition of restrictions if they can be justified on grounds, inter alia, of protection of health and life.

1.14 As a supplementary measure, the OFT is taking steps to improve compliance and effectiveness of the undertaking in order that greater information on MSL's prices is available to its customers. MSL has reacted to our concerns about the lack of customer knowledge about the price list by agreeing to improve compliance and ensure that all bulk customers⁶ are kept informed of the maximum price list. This should bring a greater degree of transparency to the prices charged by MSL and provide customers with more information which they will be able to use for the purposes of price negotiations. The OFT shall monitor this to ensure that it happens.

⁶ This includes all customers, except those which buy single packs. This includes smaller pharmaceutical companies and NHS bodies.

2 INTRODUCTION AND BACKGROUND

Opium derivatives

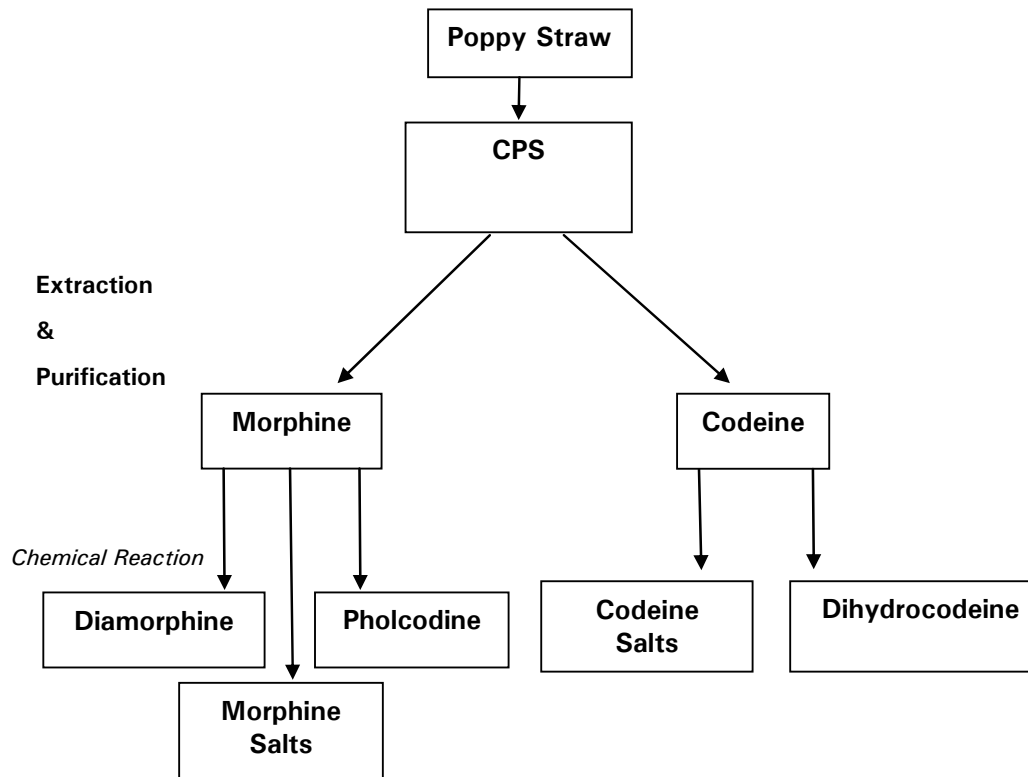
2.1 Opium derivatives are produced using concentrate of poppy straw (CPS) imported into the UK under a Home Office licence. The derivatives are used in the manufacture of a wide range of medicines or for scientific research. These include over-the-counter (OTC) pain killers (analgesics) and cough medicines (antitussives), known as 'formulated' products, which are used in the treatment of a range of medical conditions.

MSL's opium derivative production process

2.2 MSL, now part of Johnson Matthey plc,⁷ purchases CPS as the raw material for opiate products from suppliers based in Australia, Spain and Hungary. It has recently started to grow poppies in the UK to meet some of its needs. All downstream aspects of manufacture, processing, testing and packaging of opium derivatives are conducted by MSL in the UK. MSL's opium derivatives are then sold to customers, both within the UK and abroad, who use them to manufacture formulated medicines. Its customers are mostly pharmaceutical companies and research institutions, though some are NHS hospitals making special prescription drugs. The stages of production of opium derivatives are shown below in Chart 2.1.

⁷ In 1989, when the MMC reported, MSL was a subsidiary of Glaxo Group Limited. Since 2001 it has been part of Johnson Matthey plc.

Chart 2.1: MSL production processes



Source: Information provided by MSL

The UK market

- 2.3 The value of the total UK market for the sales of opium derivatives was just over £31 million in 2003/4,⁸ the last date for which figures are available.
- 2.4 The production and use of opium derivatives in prescription and non-prescription drugs has grown substantially in the UK since 1989.

⁸ Based on information provided by MSL.

- 2.5 MSL's UK sales of the reference products⁹ have increased from 13.3 tonnes in 1989 to 44.8 tonnes in 2004, an increase of over 236 per cent.¹⁰ In addition MSL has developed a range of new opium derivatives (for example, hydrocodone, oxycodone) since 1989. MSL also supplies opium derivatives for manufacture in the UK of drugs for export and manufacture abroad. Sales of these products have also grown significantly since 1989.
- 2.6 MSL is the UK's sole manufacturer and producer of opium derivatives. MSL's share of the UK reference opium derivatives market was 91 per cent by volume in 2002 (96 per cent for codeine phosphate, the largest selling opium derivative accounting for over two-thirds of MSL's UK sales of reference products) with the remainder of the market supplied by imports from other EEA countries.¹¹ This compares with 87 per cent in 1986/7.¹² At that time MSL faced competition from another domestic manufacturer, Boots,¹³ which exited the market in 1990.

⁹ The reference opium derivatives are codeine phosphate, codeine hydrochloride, codeine sulphate, codeine alkaloid, morphine alkaloid, morphine hydrochloride, morphine sulphate, morphine tartrate, ethylmorphine hydrochloride, diamorphine hydrochloride, pholcodine alkaloid and dihydrocodeine tartrate.

¹⁰ Based on INCB figures provided by MSL.

¹¹ Information provided by MSL.

¹² MMC (1989), table 2.1.

¹³ MMC (1989), paragraph 2.5

The regulatory framework

Medicines for Human Use Regulations 1994

- 2.7 The Medicines for Human Use Regulations 1994¹⁴ require a formulated product on the market to meet the safety, quality and efficacy standards prescribed by the Medicines and Healthcare Products Regulatory Agency (MHRA). The producer must have a licence for the manufacture of 'medicinal products' (that is, formulated products, not merely ingredients). The product licence includes not only the active pharmaceutical ingredient (such as the opium derivative), but also the name of the source, both must be approved by the MHRA before a licence is issued.
- 2.8 Licence holders proposing to change the formulation on a product licence, for example, to change an active ingredient such as the opium derivative, must seek a variation to the licence. The MHRA has informed us that the time taken and prices charged to obtain a product licence variation differ according to the complexity of the request. If the MHRA has assessed the active pharmaceutical ingredient from a manufacturer beforehand, the variation can take less than a month to complete. However, if the manufacturer of the new ingredient has not previously been approved, then the procedure is more protracted and can involve rigorous testing to ensure compliance with MHRA rules.

¹⁴ S.I. 1994/3144.

The UN Convention on Narcotic Drugs 1961

- 2.9 The cultivation of opium poppies and the manufacture and distribution of opium derivatives is subject to regulation throughout the world under the aegis of the INCB. The INCB was established by the Convention, which created a worldwide regulatory framework within which signatory countries must operate.¹⁵
- 2.10 The Convention requires signatory countries to provide an annual estimate of the narcotic drugs it expects to be consumed for medical and scientific purposes or used in the manufacture of other drugs to the INCB. In order to ensure that these estimates are observed, it also requires signatory countries to license all stages of the production, use and movement of narcotics. The purpose of these controls is to ensure that narcotics are used only for legitimate medical and scientific purposes and are not diverted into illicit channels.
- 2.11 The responsibility for overseeing the implementation of both the estimates system and the licensing system lies with the Home Office in the UK.

The estimates system

- 2.12 Each year the Home Office has a responsibility to provide the INCB with an annual estimate of the quantities of narcotics it expects to be consumed for medical and scientific purposes or used in the manufacture of other drugs. Thereafter, it is the Home Office's responsibility to agree with the INCB any upward or downward adjustments to the estimated requirements for the UK as the year progresses.
- 2.13 The Home Office bases its estimates on information obtained from licensed companies such as manufacturers, distributors and pharmaceutical companies at the end of the preceding year.

¹⁵ The UK ratified the Convention on 2 September 1964.

UK licensing system

- 2.14 In the UK any organisation wishing to possess, supply, produce, manufacture, import or export narcotics requires a Home Office licence.
- 2.15 Licence applications are currently made to the Home Office's drugs branch. The credentials of an applicant, including security arrangements, are checked. If the Home Office inspectors have no objections a licence may be issued.
- 2.16 MSL is the only company to currently hold a licence to manufacture opium derivatives in the UK. The Home Office has informed the OFT that it would be willing to issue a manufacturing licence to another company, which met the relevant security requirements. However it is not aware of any company which has attempted to gain a manufacturing licence in recent years or has indicated a desire to do so in the future. This limited prospect of new entry means that MSL is likely to be the sole domestic manufacturer of opium derivatives in the near future.
- 2.17 Applications to import opium derivatives are determined by the country of origin. The Home Office will not authorise imports of opium derivatives from outside the EEA. Home Office policy on imports from EEA countries is discussed in more detail below.
- 2.18 Importation licences can be issued provided that they will not cause the UK estimate of the particular drug to be exceeded. If so, the Home Office is responsible for agreeing, if appropriate, a modification of the estimate with the INCB. The Home Office will not issue a licence in such cases until such time as the INCB have agreed an increase to an estimate.
- 2.19 The OFT has been informed that the procedures for the shipment of controlled drugs are secure. Well established and rigorous procedures are in place at airports and ports to receive these goods. The OFT has not been informed of any instance in the recent past where legally imported opium derivatives have been diverted to illicit uses.

UK policy on imports of opium derivatives

- 2.20 Prior to and at the time of the MMC report in 1989, it had been Home Office policy for many years not to issue import licences unless UK manufacturing capacity was unable to meet legitimate medical or scientific demand.¹⁶
- 2.21 That policy changed in 1997 after a legal challenge by a pharmaceutical company seeking to import diamorphine from the Netherlands on the basis that the policy infringed Article 28 of the Treaty of Rome.¹⁷
- 2.22 Article 28 prohibits member states hindering, directly or indirectly, the free movement of goods and capital between member states. This prohibition is subject to the proviso in Article 30, which permits the imposition of restrictions if they can be justified on grounds, inter alia, of protection of health and life.
- 2.23 The Convention allows, but does not require, signatory countries to prohibit imports. The European Court of Justice (ECJ) concluded, in 1994, that, in these circumstances, member states must refrain from imposing such a ban, unless it can be justified under Article 30. The ECJ held that the need to ensure that a country has reliable supplies for essential medical purposes may justify a barrier to intra-community trade under Article 30 on the basis that the objective of such a ban is to protect the health and life of humans, provided that objective could not be achieved by measures less restrictive of trade within the European Union.¹⁸

¹⁶ MMC (1989), paragraph 8.20.

¹⁷ See Case C-324/93 *R v Secretary of State for Home Department, ex parte Evans Medical Ltd and Macfarlan Smith Ltd* [1994] ECR I-563.

¹⁸ *Supra*, paragraphs 37 and 38.

- 2.24 In the aftermath of the MMC report the Home Office recognised that its policy of not permitting any imports where domestic supply was available was likely to impede intra-community trade contrary to Article 28 and could not be fully justified under Article 30.
- 2.25 Since 1997 the Home Office has permitted imports of opium derivatives from EU, later extended to EEA, member states.¹⁹ Its decision not to grant licences to importers wishing to import opium derivatives from countries outside the EU was upheld by the High Court in *R v Secretary of State for the Home Office, ex parte Arthur H Cox Ltd.*²⁰
- 2.26 The European Commission attempted in the late 1990s to secure the co-operation of member states to the operation of a single market in opium derivatives. In the event some member states (but not the UK) invoked Article 30 of the Treaty of Rome to prevent a single market from coming into effect. The OFT is not aware of any ongoing attempts by the European Commission to revisit this issue.

Recent developments in licensing policy

- 2.27 In August 2004 the Home Office, in response to increasing levels of imports of codeine phosphate from suppliers within the EEA and a concern that the UK estimate to the INCB might be exceeded, adjusted its policy. It decided to apportion the estimate for 2005 between MSL and importers. The Home Office explained to the OFT that its key consideration in apportioning the estimate was to ensure reliability of supplies within the UK.

¹⁹ A scheme was also put in place to import diamorphine from 1992 but was not widely used.

²⁰ Judgment of 14 December 1998. In the matter of application for judicial review *Regina v the Secretary of State for the Home Office ex parte Arthur H Cox & Co Limited*. EWHC Admin 1137.

- 2.28 Accordingly, in December 2004 the Home Office reduced by about 10 per cent the volume of codeine phosphate that MSL was licensed to manufacture for the UK market (35.5 tonnes in total, cutting back MSL's 2003 figure by four tonnes). It did not expect this reduction to jeopardise MSL's codeine production and therefore a reliable domestic manufacturing capacity would be maintained. Importers, which had requested licences to import just over 9.7 tonnes of codeine base in 2005, were granted licences to import the remainder, in total, up to four tonnes, only about 40 per cent of the amount they requested.
- 2.29 The Home Office has indicated that it will adopt a similar approach in relation to other opium derivatives if there is a danger that the estimate will be exceeded as a result of increasing importation.

Imports not requiring a Home Office Licence

- 2.30 The most commonly used formulated products containing codeine, dihydrocodeine and pholcodine, contain only small quantities by weight of opium derivatives. As a consequence they can be freely imported without the need for a Home Office licence under schedule 5 of the Misuse of Drugs Regulations 2001.²¹ These formulated products have been imported into the UK, principally from the Republic of Ireland, in increasing amounts in recent years. These products directly compete with the formulated products produced by companies based in the UK.

Policy adopted by other countries in relation to opium imports

- 2.31 As noted above, the Convention does not require signatory countries to prohibit imports of opium. Countries have taken different approaches to the application of their obligations under the Convention and, if applicable, the Treaty of Rome.

²¹ SI 2001/3998.

- 2.32 Most of the remainder of the EU, measured both in terms of number of countries and share of EU population, operates on an open market basis, whereby importers may compete freely to supply customers. Canada and Switzerland are other examples of open markets. Other countries have a closed market and restrict imports of opium derivatives unless domestic supply is not available. These countries include the United States of America, France, Japan and Spain.
- 2.33 As explained above, the UK's approach is hybrid. A small volume of codeine phosphate imports is allowed – up to 10 per cent of the estimate – but the market is currently mainly reserved for supply by domestic producers: MSL is the only one at present. The other opium derivatives may be imported as long as there is no danger that the estimate may be exceeded.

The MMC report on opium derivatives (1989)

- 2.34 The MMC report found that MSL supplied 87 per cent of the UK market, faced little competition in the UK and that there was little prospect of new entry to produce opium derivatives within the UK.²² Imports were permitted only where domestic supply was not available. The MMC concluded that MSL had exploited its monopoly by engaging in price discrimination and had been able to charge high prices in the domestic market, leading to very high levels of profit. The MMC found that these aspects of MSL's behaviour were against the public interest. (See Annexe A for a fuller summary of the report).²³

²² MMC (1989), paragraph 1.3.

²³ MMC (1989), paragraphs 9.36,9.40.

- 2.35 The MMC believed it was of prime importance to increase competition in this market. It recommended that the Home Office, in conjunction with other Government departments, should work towards the creation of a single European Community (EC) market in the reference opium derivatives through the reciprocal opening up of trade between EC member states as soon as possible and no later than 1992.²⁴
- 2.36 The MMC also considered that in the interim a measure of price protection was appropriate for MSL's customers in the UK. They recommended that MSL should be required not to increase its maximum prices for reference products for a period of three years, except in the event of substantial and unavoidable increase in its costs.²⁵
- 2.37 To remedy the adverse effects arising from price discrimination, the MMC recommended the publication of maximum price lists by MSL. In addition the MMC concluded that the list would increase the transparency of MSL's pricing policy, an issue which the MMC expressed concern about.²⁶ It was expected that these lists would provide a constraint on price discrimination against smaller customers.²⁷ MSL undertook to publish and make 'generally available', on a 'continuing basis', a maximum price list.²⁸ The full text of the undertaking can be found at Annexe B.

²⁴ MMC (1989), paragraph 9.66.

²⁵ MMC (1989), paragraph 9.67. This recommendation was not accepted by the Secretary of State for Trade and Industry, although it was voluntarily adhered to by MSL for two years following the MMC report. It was discontinued by MSL on the basis that it was unworkable and did not reflect changes in the market.

²⁶ MMC (1989), paragraph 9.35.

²⁷ MMC (1989), paragraph 9.65.

²⁸ Refer to footnote 9 for details of the opium derivatives covered by the maximum price list.

2.38 It is the duty of the OFT to consider from time to time whether, by reason of any change of circumstances,²⁹ an undertaking should be varied, revoked or superseded by a new undertaking, and to give such advice to the Competition Commission (CC) as it may think proper in the circumstances.³⁰ This undertaking was last reviewed in 1997.³¹ It concluded that the liberalisation of trade in opium derivatives within the European Union still offered the best prospect of improving the market for supply of opium derivatives in the UK.

Current review

2.39 On 18 August 2004 the OFT announced a further review of the undertaking concerning the publication of maximum price lists by MSL.³² The review has been undertaken using statutory powers under the FTA 1973 and the Enterprise Act 2002 (EA 02).³³ This report sets out the findings of the review.

²⁹ Section 88 (4) of the FTA 1973. The relevant sections of the FTA 1973 are still in force by virtue of Schedule 24 of the EA 02.

³⁰ The OFT does not provide advice to the CC in the event that no recommendation is made to vary, release or supersede an undertaking.

³¹ Report by the Director General of Fair Trading to the Secretary of State for Trade and Industry concerning the undertaking given by Macfarlan Smith Ltd, 27 April 1997.

³² Refer to www.offt.gov.uk/news/press+releases/2004/128-04.htm

³³ s.88 Fair Trading Act 1973 and ss. 5 & 7 and paragraph 16 (3), Schedule 24 Enterprise Act 2002.

3 COMPLIANCE WITH THE UNDERTAKING

MMC findings

- 3.1 The MMC noted a 'lack of transparency' in MSL's pricing policy and found that there was little knowledge amongst MSL's customers as to the existence and nature of an internal price list and to the availability of volume based discounts.³⁴
- 3.2 The MMC considered the prices MSL charged for opium derivatives and how they varied according to category of customer. It found that 'unit prices were significantly lower for large volume customers than small volume customers and there was variation in the percentage price/quantity reductions given by MSL on different reference products'.³⁵ It concluded this gap in the prices charged by MSL to small and larger customers did not reflect differences in cost and had been increasing in the years before the MMC reported as prices to larger customers had decreased at a faster rate than prices to smaller customers.³⁶

³⁴ MMC (1989), paragraph 9.29.

³⁵ MMC (1989), paragraph 5.3.

³⁶ MMC (1989), paragraph 9.36.

- 3.3 MSL argued that that the principal reason for prices to larger customers falling faster than prices to smaller customers during the three years prior to the MMC's investigation was the greater buying power of the former.³⁷ MSL also argued that there was no discrimination in the treatment of customers which was not justified in terms of its relationship with those customers.³⁸
- 3.4 The MMC concluded that MSL's use of price discrimination operated to the disadvantage of its smaller customers. It concluded that it was a step taken by MSL for the purpose of exploiting and maintaining the monopoly position and constitutes a fact which operates against the public interest. The particular effect of the practice being that prices for MSL's smaller customers were higher than they would have been if MSL were not exploiting its monopoly position.³⁹ It expected MSL's publication of a list of maximum prices, which it agreed to in the later stages of the MMC's inquiry, to provide a constraint on its discrimination against its smaller customers.⁴⁰
- 3.5 As a consequence of the MMC report, MSL gave a statutory undertaking to the Secretary of State for Trade and Industry in 1989 to ensure that a maximum price list 'shall be published and made generally available on a continuing basis' and to provide the OFT with a copy of that list on every change in the prices stated in the list. The full text of the undertaking can be found at Annexe B.
- 3.6 This chapter examines MSL's compliance with its undertaking.

³⁷ MMC (1989), paragraph 9.32.

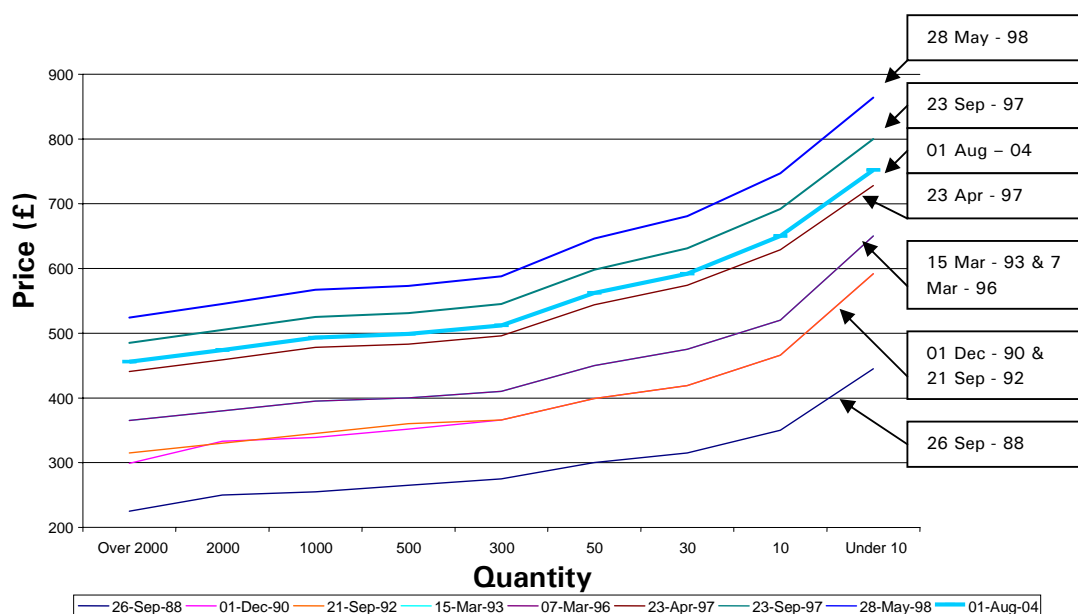
³⁸ MMC (1989), paragraph 7.26.

³⁹ MMC (1989), paragraph 9.36.

⁴⁰ MMC (1989), paragraph 9.65.

3.7 Chart 3.2 shows the list prices for codeine phosphate issued since 1988 by MSL. These prices specify the maximum amount per kilogram that MSL will charge for a particular quantity.

Chart 3.2: Maximum price list prices for codeine phosphate 1988 to 2004



Source: Information provided by MSL

3.8 Chart 3.2 shows that the price list was updated on eight occasions after 1988. Before 1998, the price list was updated frequently, though not generally annually. However over the period 1998 to 2004, no amendments to the price list were made. A provisional revised list was prepared, but not issued, in August 2004, as MSL felt that it might be inappropriate to issue the list while the review was in progress.

3.9 In addition, the list prices price list was updated only prices increased, the only decrease in list prices was in 1992, and that was slight and only for those customers buying more than 300 kilograms.

- 3.10 Chart 3.2 also shows that the price profile has remained very similar throughout the period. Prices per kilogram rise as the quantity purchased falls. They rise more steeply for purchases below 300 kilograms, and more steeply still when the quantity falls below 10 kilograms.
- 3.11 The OFT has been informed that that the cost of raw materials (CPS) makes up 80 per cent of the cost of producing the final product, making it the key determinant of MSL's costs. We would expect, in a competitive market, that variations in raw materials prices would be reflected in the prices charged and in the price list issued by MSL.
- 3.12 Between 2000 and 2003 we understand the price MSL paid for CPS declined, but there was no update of the price list to reflect this reduction in costs. In the same period the average price of codeine phosphate supplied by MSL fell by an amount that was about half the proportionate decrease in CPS prices. The infrequency of recent issuing of the price list and the lack of updating to reflect changes in costs raise queries about the extent to which the price list is an effective constraint. In order to assess this more fully we considered the views of customers about the maximum price list.

Customer survey

- 3.13 The OFT sent a customer survey to all of MSL's customers of which 37 out of 64 responded.⁴¹ Around 60 per cent of respondents were pharmaceutical companies.
- 3.14 The survey indicates that 84 per cent of respondents did not recall receiving any kind of price list from MSL. Indeed 78 per cent were not even aware of the fact that MSL publishes maximum price lists. These responses may reflect the lengthy period since the list was last distributed in 1998.

⁴¹ We received 40 responses but three failed to provide any information.

3.15 MSL have informed the OFT of a small number of occasions when it has charged customers in excess of the maximum price list. Upon discovery of this error MSL paid compensation to the companies involved. MSL has provided credit note evidence demonstrating this. In addition it has informed the OFT that it reviews all invoices to ensure that no company is charged over the maximum list price.

Conclusion on compliance

3.16 The OFT finds that MSL's record on compliance with the undertaking is disappointing. Although it has published maximum price lists at times of update and provided a copy to the OFT it has not made the price list 'generally available and on a continuing basis' to customers. As our survey has demonstrated a majority of MSL's customers did not recall receiving nor were even aware of such a maximum price list. In the absence of customer awareness about the issue of the price list it is unlikely that the intentions of the MMC, that the list should give greater transparency to MSL's pricing and act as a constraint on price discrimination against its smaller customers, could be realised.

4 EFFECTIVENESS OF UNDERTAKING

Introduction

4.1 In order to discover if the remedy proposed by the MMC had reduced price discrimination the OFT carried out an analysis of the prices which MSL charged for various opium derivatives, examining changes in the price of supply to UK customers since 2000. We looked first at prices charged to domestic customers for codeine phosphate and then domestic prices for some of the other opium derivatives. We also examined how prices charged to domestic customers compared to MSL's export prices and profitability levels being achieved by MSL.

Price discrimination

4.2 The OFT has considered MSL's pricing policy in relation to a number of opium derivatives it supplies in order to ascertain whether price discrimination is occurring. The methodology used to identify large, medium and small customers can be found at Annexe C.

Codeine phosphate

4.3 A statistical comparison of average prices paid by customers buying large, medium and small quantities of codeine phosphate revealed that the unit price charged by MSL generally falls as the quantity purchased increases. Thus, it showed that:

- small purchases cost more than medium sized purchases in the range of 15 to 51 per cent
- small purchases cost in the range of 22 to 87 per cent more than large purchases, and
- medium purchases cost in the range of five to 44 per cent more than large purchases.

- 4.4 The analysis also showed that the price paid per kilogram varies significantly within each purchase band. This is particularly pronounced for customers purchasing smaller quantities.
- 4.5 Furthermore, although the price for codeine phosphate generally falls as the quantity purchased increases, this is not always the case, in particular for those buying in small quantities. For this group of customers, the price paid by different customers for similar sizes of purchase can vary considerably. We conclude from this evidence that discounts are related to other factors in addition to quantity.
- 4.6 Our analysis suggests that the price paid for codeine phosphate is determined largely by bargaining, rather than cost, and this was confirmed by evidence the OFT received from customers (see below). Clearly those buying smaller quantities are likely to have less bargaining power than those buying in larger quantities.

Other opium derivatives

- 4.7 The supply of diamorphine hydrochloride and dihydrocodeine tartrate also shows significant variation in the prices charged, both between and within the groups of customers buying in small, medium and large quantities.

Supply arrangements

- 4.8 The OFT sent a questionnaire to all of MSL's customers (identified by MSL as having purchased opium derivatives recently). The responses indicated that:
- supply arrangements are normally one off or short term deals
 - about two-thirds of MSL's customers did not consider that they had a formal continuous supply contract with MSL
 - eight per cent had contracts of less than one year in duration

- 19 per cent had contracts of one to two years, and
- at the time of the survey only three per cent had supply contracts of greater than two years.

4.9 Most customers said that prices were arrived at by negotiation. As noted in paragraph 4.3, few customers were aware of the maximum price list and there is no evidence that it played any role in the negotiation for a majority of customers.

4.10 Several customers told us that they had no knowledge of any discount structure and were unaware of how much they would have to purchase to qualify for discounts. Transparency in pricing does not seem to have improved.

4.11 Our customer survey also showed that most customers in this market are very limited in their price sensitivity. Demand is inelastic. When asked whether, if the price in the UK were five to 10 per cent higher or lower, they would change the quantity purchased, 68 per cent said that they would not.⁴² Since there are no acceptable substitutes, they are vulnerable to the exercise of monopoly power.

4.12 From interviews conducted during the review, it also became apparent that the negotiating experience differs significantly by type of customer. Smaller purchasers indicated that MSL had been unprepared to negotiate on price.

⁴² This can be explained by the fact that they are an essential ingredient in products for which demand is fairly static at any one point in time. For example, one is unlikely to take more prescription and/or non prescription drugs just on the basis that they are either cheaper or more expensive at any one point in time.

- 4.13 Customer survey responses support the interview findings. Several of those purchasing in large or medium sized quantities said they were able to negotiate a discount, whereas none of those purchasing in smaller quantities were able to do so. For example, two medical institutions requested a discount and neither reported success.

Longer term contracts

- 4.14 The MMC indicated in 1989 that it was desirable for MSL to restrict contract lengths to two years in order that they may not be used to restrict market entry.⁴³ During the course of the review the OFT found one or two examples of longer term supply agreements, in excess of two years, with some larger buyers. These included buyers which had, to the knowledge of MSL, explored the option of sourcing from overseas.
- 4.15 A number of companies told the OFT that MSL's prices had led them to consider importing opium derivatives. This has coincided with increased activity by import agents in this market. These agents often offer a comprehensive service, taking responsibility for obtaining licences and for storage and delivery of the products. This service may explain the increase in imports planned for 2004/5 which the Home Office has noted, and which it has concluded places the UK at risk of exceeding its INCB estimate.

⁴³ MMC (1989), paragraphs 9.38 and 9.59.

Conclusions on price discrimination

- 4.16 As we have seen, there is some evidence that MSL is still able to discriminate by price between its customers in a way which does not seem to be cost-reflective. The evidence indicates price discrimination by MSL between customers purchasing similar quantities. This is particularly the case with respect to buyers of smaller quantities of opium derivatives.
- 4.17 It would seem that the price struck depends not only on cost savings for the supplier but also on the buyer power and negotiating skills of the customer, and this places smaller customers, in particular non-commercial institutions such as NHS hospital laboratories, at a disadvantage. This pattern of behaviour is similar to that reported by the MMC which found the price discrimination by MSL operated to the disadvantage of customers purchasing smaller quantities of opium derivatives.

Domestic prices compared to export prices

- 4.18 This section compares prices charged by MSL to UK customers with those it charges for supply to customers in other countries. Some of those countries are 'open' markets, that is, markets where licensing of imports is not restricted by the government in the interests of domestic producers or suppliers. The section also considers the price of offers to supply made to UK customers by overseas suppliers.
- 4.19 Some opium derivatives are traded much more than others: codeine phosphate is the largest, followed by dihydrocodeine tartrate and morphine sulphate. In each case home sales are about two to three times export sales by volume. Total sales of two other drugs, pholcodine and morphine hydrochloride, are much lower and they are more important as export products.

- 4.20 Evidence that has been provided to the OFT indicates that MSL is charging more in the UK market than in other, open market, countries where it exports opium derivative products. In many cases it appears that UK purchasers of opium derivative products are paying more than their foreign counterparts.
- 4.21 This pattern is similar, albeit much less pronounced, to that reported by the MMC in 1989. Responses from MSL's UK customers and the evidence of MSL's supply prices suggest that many smaller customers could save up to 30 per cent by sourcing codeine phosphate from other EEA member states. Several companies which the OFT contacted during the review have provided us with quotes they have received from opiate suppliers elsewhere in the EEA, which demonstrate that they were able to source opium derivatives more cheaply from abroad than at MSL's UK supply prices.

Profitability

- 4.22 MSL's UK prices are associated with high profits. While MSL's return on capital employed (ROCE) has fallen considerably from its level in the later 1980s, it is still nearly twice the minimum level of return MSL expects on its investments. Furthermore, the fall in MSL's ROCE to its current level may be a reflection of certain factors in MSL's accounts, including a sustained programme of capital expenditure to increase capacity. But for these factors, the rate of ROCE found may have been considerably higher and could be so in the future.
- 4.23 The comparison of UK and export prices and the continuing high level of MSL profitability both indicate that MSL's prices of supply in the UK remain higher than would be likely if supply was under conditions of effective competition.

Downstream effects

- 4.24 UK manufacturers of lower strength formulated analgesics face competition from overseas companies, which can import lower strength formulated products into the UK without a Home Office licence (see paragraph 2.30).⁴⁴ In such cases the UK manufacturers cannot readily pass on the higher costs of MSL opium derivatives to their customers. In theory such competition should act to constrain MSL's ability to charge high prices.
- 4.25 Several small and medium sized pharmaceutical companies, based in the UK, have informed us during the course of our review that they have found it difficult to compete with foreign based pharmaceutical companies. This is because the foreign based companies are able to manufacture formulated products, using lower cost opium derivatives sourced in open market countries, and import them into the UK. These companies therefore enjoy a competitive advantage over UK companies which are dependent on MSL for supplies of opium derivatives.
- 4.26 The OFT has also been told that one company may have relocated production of analgesics outside of the UK, in order to secure cheaper opiate prices. In these cases the OFT cannot say that price differences for opium derivatives are the sole explanation, but they do seem to have been an influencing factor.
- 4.27 A number of small and medium sized British pharmaceutical companies have also indicated that they have found it difficult to compete in export markets with companies sourcing cheaper materials from open markets. Two companies have told us that they have lost business as a result of their limited ability to source material from abroad and others have indicated that this has significantly constrained them.

⁴⁴ These overseas companies are still subject to the MHRA's regulatory system for assuring safety and quality of imported medicines.

- 4.28 MSL is able to point to a substantial growth since 1989 in exports of pharmaceutical preparations from the UK made with its opium derivatives, and may claim that its prices are not handicapping British exports. However our evidence indicates that most of this growth in exports is generated by the large purchasers of opium derivatives, many of whom enjoy favourable prices from MSL.
- 4.29 There are also a number of public sector bodies, such as hospitals, which purchase small quantities of opium derivatives from MSL in order to make customised medicines or for research. There is no alternative source of supply within the UK and their limited purchasing volumes make importation uneconomic. They pay amongst the highest prices to MSL for their opium derivatives. These higher prices must be met by public and private medical services, funded ultimately by the end customer, the public, through either taxation, or medical insurance or direct charges for medical services.

Conclusions on downstream effects

- 4.30 There are indications that price discrimination may distort the growth of exports by certain manufacturers, and inhibit the ability of medium and smaller sized manufacturers to export pharmaceutical products or compete effectively with foreign based companies which import opium based formulated pharmaceutical products into the UK. In addition it would seem that hospitals and research institutions which are dependent upon MSL for supplies of opium derivatives may be paying higher prices than would be the case in more competitive circumstances.

5 CONCLUSIONS AND RECOMMENDATIONS

- 5.1 The 1989 MMC report concluded that there was little competition in the UK to supply opium derivatives and that MSL exploited its monopoly by charging high prices and by discriminating on price against its smaller customers. The MMC recommended introducing more competition by removal of regulatory barriers to imports from elsewhere within the EU.
- 5.2 While sales of the reference opium derivatives in the UK have grown rapidly since 1989, by over 236 per cent, the structure of supply is essentially the same. MSL is now the only UK producer of the reference opium derivatives, and there seems little prospect of new entry. The Home Office allows only limited imports of codeine phosphate from EEA countries, and these take a modest share of the market. MSL's share of supply in the UK for codeine phosphate, the most important of the reference opium derivatives, is now around 96 per cent, and above the 1987 level of approximately 81 per cent.⁴⁵
- 5.3 Evidence before the OFT shows that MSL is able to discriminate between its UK customers, that smaller customers in particular may suffer from discrimination. The pattern of behaviour is not dissimilar to that reported by the MMC in 1989.
- 5.4 The OFT has also observed that MSL's average prices for supply in the UK for the more important opium derivatives, and for most of the others, are above MSL's average prices for supply for export.

⁴⁵ MMC (1989), table 2.1. The 1986/7 figure relates to codeine generally and not codeine phosphate specifically.

- 5.5 MSL put to the MMC in 1989 the argument that export prices concerned only residual production and that therefore domestic and export prices ought not to be compared. However, a significant minority of MSL's UK production of the reference opium derivatives is now for direct export. The OFT therefore considered it appropriate and reasonable to compare UK and export prices.
- 5.6 The comparison shows that MSL's export prices are on average lower than its UK prices. In many cases its exports are to customers in markets which are not subject to the import constraints the UK regime incorporates. Medium and larger UK buyers are well aware of the lower prices available in open markets abroad. Our survey showed that over half of MSL's UK customers would buy abroad at lower prices if they were able to do so. Information from our survey, backed up by details given at interview by pharmaceutical manufacturers, suggests possible savings in the range of 15 to 30 per cent for codeine phosphate and 10 to 25 per cent for dihydrocodeine tartrate.
- 5.7 There have been expressions of concern about MSL's UK prices by all categories of customer. However, larger purchasers of opium derivatives appear at least to have the bargaining power to negotiate more favourable terms than are available for small and medium customers.
- 5.8 There appears to have been a marked and continuing decline in the profitability of MSL's UK reference product business from the very high levels found by the MMC. However, the level of profitability MSL achieves is still high at almost double the cost of capital charge faced by MSL. Moreover, there are reasons to believe that the current and recent ROCE figures revealed by our analysis may understate the profitability of MSL's opiate business.
- 5.9 It is clear that the existing undertaking, which was anyway only intended to be interim pending liberalisation of the supply of the reference opium derivatives, has thus far been largely ineffective.

- 5.10 The requirement to publish and make generally available on a continuing basis a maximum price list has not been properly observed - most customers appear unaware of the price lists limiting their ability to constrain MSL's pricing.
- 5.11 However, the fundamental problem identified by the MMC in 1989 was a lack of effective competition in supply of the reference opium derivatives in the UK. That problem remains. The MMC recommended relaxation of controls on imports of opium derivatives from elsewhere in the EU. That remains the best option in economic terms, because it would allow market forces to bear on MSL's prices.
- 5.12 Recently, there have been signs of a potential increase in competition from EEA importers, with requests to increase the volumes of codeine phosphate imported to about 25 per cent of the UK's estimate. However, that potential has not been realised as fully as we would wish as a result of the UK's licensing policy, which has confined importers to codeine phosphate volumes amounting to no more than 10 per cent of the estimate out of concern that MSL's position might otherwise be jeopardised and hence reliability of supply in the UK. The Home Office, in applying the policy, has not had regard to the competition effects that this approach produces.
- 5.13 The OFT considers that this should change. We believe that the Government has discretion to liberalise its licensing policy and thereby increase the ability of importers to exercise competitive constraints on MSL.
- 5.14 It is not clear to us that reliability of supply of opium derivatives in the UK would be jeopardised by a greater reliance on the EEA market. Customers would be able to decide whether to rely on one supplier or to spread their demand across several suppliers, as is normal in other sectors of business.

- 5.15 The OFT has been told by an importation agent that its first hand experience provided no examples either here or abroad where a foreign supplier had failed to fulfil a supply contract, nor did they have hearsay knowledge of any such cases. A number of pharmaceutical companies which presently source opium derivatives from the EEA have also told us that they have experienced no disruptions to supplies. Moreover, we are have contacted licensing authorities in Ireland, Germany and the Netherlands, which operate an open market policy, which have confirmed that they are unaware of any concerns over reliability of supplies in these countries.
- 5.16 We recognise, nevertheless, that the Government has legitimate concerns about reliability of supply, and in particular they have expressed the view that opening up competition for the reference products has to be balanced against the importance of ensuring continuing supplies of diamorphine, of which MSL, we are informed, is the only reliable supplier.

Recommendations and conclusions

- 5.17 The OFT recommends that the Government take into consideration competition issues for the purposes of devising future licensing policy and gives weight to the impact of its policy on opiate prices, on the pharmaceutical sector and on the end consumer and taxpayer. Competitive supply will lower prices and can be expected to produce benefits overall for the economy. The OFT can see no clear legal obstacle to a revision of its licensing policy.
- 5.18 The OFT has written to the Government and highlighted the distortions on competition created by the current regime. The OFT is willing to provide assistance to the Government in considering future licensing policy in this area. The OFT will continue to monitor the situation and will consider the Government's response to our concerns. The OFT cannot rule out further action, including a market reference, if the distortion to competition supported by the current policy continues unchecked.

5.19 In addition, the OFT has prompted MSL to publicise its price list more widely and to increase transparency around its pricing. It has taken the following steps and the OFT shall be monitoring to ensure future compliance:

- it has issued its last updated price list to all bulk opiate customers and will reissue it to all customers each January, and
- it has asked customers to keep it informed of changes in personnel, to ensure that the list gets to the right person (this is significant given the limited period of time a pharmaceutical buyer typically remains in post).

5.20 This should ensure that all customers have greater knowledge of the maximum price list than they have had in the past. This should enhance price transparency and provide customers with more information that can be used as part of the negotiating process.

ANNEXES

A SUMMARY OF THE MONOPOLIES AND MERGERS COMMISSION REPORT ON OPIUM DERIVATIVES (1989)

Introduction

- A.1 In 1989 the MMC reported on the supply of opium derivatives in the UK following representations made to the Home Office by a pharmaceutical manufacturer that the price of codeine was higher in the UK than in other countries. MSL subsequently agreed an undertaking (see Annexe B for details) to address the adverse findings which the MMC reached.

Findings

- A.2 A monopoly situation was found to exist in favour of MSL, a manufacturer of opium derivatives. MSL supplied just over 87 per cent, by volume and by value, of the UK third party market for the reference opium derivative products.⁴⁶
- A.3 There were no imports of opium derivatives into the UK because for many years it had been Home Office policy not to issue import licences pursuant to the Home Office's interpretation of international obligations under the United Nations Single Convention on Narcotic Drugs 1961.⁴⁷
- A.4 New entry was considered unlikely because the costs of entry were high relative to the likely turnover of a new entrant.⁴⁸ The MMC found

⁴⁶ MMC (1989), paragraph 9.2.

⁴⁷ MMC (1989), paragraph 9.4.

⁴⁸ MMC (1989), paragraph 9.13.

that MSL exploited this monopoly position by engaging in price discrimination, to the detriment of smaller customers. This practice was found to be against the public interest.⁴⁹

- A.5 Furthermore the MMC also found that, due to the monopoly situation, MSL had been able to charge high prices in the domestic market, leading to very high levels of profit. The MMC concluded that this was also against the public interest.⁵⁰

Recommendations

- A.6 While the MMC investigation was in progress, MSL issued a maximum price list which incorporated reductions in price. The MMC concluded that the continued publication of a maximum price list should provide a constraint on MSL's discrimination against its smaller customers, and did not recommend further action.⁵¹
- A.7 The MMC recommended that MSL should be required not to increase its maximum prices to UK customers for reference products for three years, except in the event of a substantial and avoidable increase in costs.⁵² In addition the MMC recommended that the Home Office, in conjunction with other government departments, should work towards the creation of a single EC market in the reference products through the reciprocal opening up of trade between the EC member countries as soon as possible and not later than 1992.⁵³

⁴⁹ MMC (1989), paragraph 9.36.

⁵⁰ MMC (1989), paragraph 9.40.

⁵¹ MMC (1989), paragraph 9.65.

⁵² MMC (1989), paragraph 9.67.

⁵³ MMC (1989), paragraph 9.66.

The remedy

- A.8 The adverse findings led to MSL undertaking to publish, and make generally available on a continuing basis, a maximum price list for the opium derivative products and to report any changes in its maximum prices to the Office of Fair Trading.

B UNDERTAKING GIVEN BY MACFARLAN SMITH LIMITED IN RELATION TO THE SUPPLY OF OPIUM DERIVATIVES

- B.1 MSL agreed the following undertaking.
- B.2 In respect of the products specified in Appendix 5.3 of the MMC report on Opium Derivatives,⁵⁴ and for so long as it continues to supply the same to the UK market, the Company shall ensure that a maximum price list, in a form which is the same or similar to the list contained in that Appendix, shall be published and made generally available on a continuing basis, and that a copy of the list is sent to the Director General of Fair Trading (Director General) on the date of signing this undertaking and thereafter on every change in the prices stated in the list.
- B.3 The Company shall provide the Director General with such further information as he may reasonably require from time to time for the purpose of monitoring compliance with this undertaking.

Date of undertaking: 13 September 1989

⁵⁴ See footnote 9 for details of the products covered by the undertakings.

C DEFINITION OF SMALL, MEDIUM AND LARGE CUSTOMERS

- C.1 The companies chosen in the analysis were split between 'large', 'small' and 'medium' customers. Given that different goods are sold at different prices and in different quantities, the definition of a large, medium and small company is done differently for codeine phosphate than for the other drugs chosen in this analysis. The split was made to highlight the different 'treatment' of customers based on their historical purchasing record with MSL and the threshold levels/cut-off points are different for each drug because of the different aspects of the data in terms of price, sales, buyers etc.

Codeine phosphate

- C.2 For codeine phosphate, a small customer is defined as a customer whose revenue makes up to 0.6 per cent of total product sales. A medium customer is one whose revenue share is between 0.7 and 2.6 per cent of total product sales. A large customer is one whose revenue share is over 2.7 per cent of total product sales.

Diamorphine hydrochloride

- C.3 For diamorphine hydrochloride, a small buyer is defined as one that has a revenue share that is between zero to one per cent of total product sales. A medium buyer is defined as one that has a revenue share of one to 10 per cent of total product sales and a large buyer is defined as one that has a revenue share of over 10 per cent of total product sales.

Dihydrocodeine tartrate

- C.4 For dihydrocodeine tartrate a small buyer is defined as one that has a revenue share of up to one per cent of total product sales. A medium buyer is defined as one that has a revenue share of one to three per cent of total product sales. A large buyer is defined as one that has a revenue share of over three per cent of total product sales.