

Evaluating the impact of the OFT's 2001 abuse of dominance case against Napp Pharmaceuticals

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1 EXECUTIVE SUMMARY

- 1.1 The Office of Fair Trading (OFT) has a public commitment to evaluate each year at least two of its previous interventions. These evaluations help us to understand whether and how our projects have achieved the desired impact, and whether the outcomes could be further improved. The OFT relies on findings from such evaluations to learn lessons that can be applied to future comparable interventions.
- 1.2 In this context, the OFT's evaluation team has evaluated the impact of the abuse of dominance decision made against Napp Pharmaceuticals in 2001 for its conduct in the sustained release morphine (SRM) market. This is the first time that the OFT has conducted an in-depth evaluation of an abuse of dominance case. Additionally, this is the first time the OFT has conducted an in-depth evaluation 'in-house'. This research has been carried out by OFT economists and independently reviewed by Professor Steve Davies. The final report incorporates a number of comments received from the independent review on preliminary drafts.
- 1.3 The aim of this evaluation was to understand the extent to which the SRM market has changed as a result of the 2001 decision and to estimate the impact of OFT's intervention in terms of monetary savings to the NHS. In order to do so, we have examined trends in SRM prices, SRM market structure and total cost to the NHS of procuring SRM drugs.

Background

- 1.4 Napp Pharmaceutical Holding Ltd (Napp) supplies SRM in the UK to hospitals and to the community segment. Napp launched SRM products into the UK in 1980. Its patent expired in August 1992.
- 1.5 Following a complaint against Napp's conduct in this market, in July 1999, the OFT launched an enquiry under the Competition Act 1980. An investigation began under the Competition Act 1998 (CA98) following its entry into force on 1 March 2000.

This was the OFT's first abuse of dominance case under CA98. The OFT found that Napp had used heavy discounting, often in excess of 90 per cent of the list price, when bidding for hospital contracts to supply SRM against other competitors. This type of exclusionary behaviour in the hospital segment enabled Napp to charge excessive prices in the larger community segment and retain a very significant share of the market (well over 90 per cent).

- 1.6 A smaller proportion of SRM tablets were sold via the hospital segment (10-14 per cent) than the community segment. However, this segment was considered 'an important, or even indispensable, 'gateway' to community sales'.¹ Any new entrant had to establish itself in the hospital segment before it could penetrate the much larger and profitable community segment, with doctors in primary care preferring patients to remain under the same drug regime once they leave the hospital.
- 1.7 In its decision, published in March 2001, the OFT found that Napp abused its dominant position in both the hospital and community segments (of the SRM market), and imposed a fine of £3.21m. Additionally, Napp was required inter alia to reduce the NHS list price of MST tablets by at least 15 per cent and to sell MST tablets to hospitals in the UK at a price of not less than 20 per cent of the (reduced) NHS list price. Napp appealed the OFT's decision to then Competition Commission Appeal Tribunal (CCAT); the OFT's infringement finding was substantially upheld², though the fine was amended to £2.2 million.

¹ From the Court of Appeal judgment of Buxton LJ (paragraph 5) in *Napp v Director General of Fair Trading* [2002] EWCA Civ 796, available at www.catribunal.org.uk/files/NappCAJudge.pdf

² The CCAT unanimously confirmed the OFT's finding of infringement, with one 'minor exception'. See paragraphs 346 and 563 of the CCAT's judgment.

Methodology

- 1.8 This evaluation has relied on both quantitative and qualitative analysis and data from a variety of sources including the NHS Health and Social Care Information Centre, the NHS Commercial Medicines Unit (CMU), the Department of Health, stakeholder interviews and desk research.
- 1.9 We have interviewed a number of stakeholders including the CMU, hospital pharmacists, and firms producing SRM in the UK market. We also engaged with GPs in primary care to understand their views on prescribing practices in the UK – in particular of SRM drugs. Additionally, we carried out desk research and interviewed a number of relevant academics and policy analysts familiar with the regulation of the pharmaceutical industry in other jurisdictions, to inform our view on international markets for specialised drugs (such as SRM).
- 1.10 We analysed price and market share (volumes) data over time using data on the community and hospital segments. We also used this data, together with cost information, to conduct some econometric analysis.

Factors influencing the choice of SRM product

- 1.11 We looked at procurement and prescribing practices within the UK to help inform our analysis. There are three factors that interact with each other to influence the procurement of specialised drugs such as SRM; these are procurement regulations, prescribing decisions made by clinicians and dispensing decisions made by pharmacists.
- 1.12 As such, we have found that aspects of the procurement system have affected the impact of the OFT's 2001 intervention.
- 1.13 In 2001, the OFT found that there was significant 'clinical inertia' when it came to prescribing decisions. In addition to the 'brand effect' identified in the OFT decision (especially as MST is more than 30 years' old), the short brand name (instantly

recognisable and easy to prescribe) played a role in enhancing clinical inertia and limiting clinicians (in both primary and secondary care) from prescribing alternative SRM products.

- 1.14 Additionally, the OFT (in 2001) found that specialist doctors and hospital pharmacists attached a significant cost to the risk of (administering) mistakes that might result from switching products. Thus, in the past, hospital trusts may have been willing to pay more for a familiar product (like MST), rather than risk using a cheaper, lesser known product.
- 1.15 Given its longevity in the market, MST was thought of by clinicians as a 'quasi-generic product', with the brand name frequently associated with or used to designate the category. In the absence of 'generic substitution' in the community segment, Napp's brand name and its reputation (when combined with its anticompetitive conduct) acted as a barrier to competition in the community segment. However, there have been changes in the right direction since 2001, particularly in the community segment.
- 1.16 The Department of Health has proactively sought to influence the way in which GP's prescribe for a number of years; particularly, they have encouraged generic prescribing. There has been a sharp increase in generic prescribing of SRM products since 2004. Generic SRM prescriptions accounted for 30 percent of all SRM prescriptions in 2004 and approximately 50 per cent of all SRM prescriptions in 2010.
- 1.17 When a prescription is written generically, then a pharmacist must decide which version of the drug is the most clinically appropriate for the patient. Where there are no clinical issues the pharmacist may decide to dispense the version that offers the greatest margin. The increase in generic prescribing of SRM may therefore have led to increased competition in this market; however, our assessment of the impact of our 2001 intervention is limited to changes in proprietary (branded) prescriptions made by clinicians. In the current procurement framework, doctors (consultants and GPs) are the decision makers, as they are the

individuals who decide which products to prescribe. Patients taking the medication are the 'consumers'. The NHS is the 'purchaser' who pays the final bill. We find that under this set-up there is a misalignment of incentives which gives rise to substantial potential inefficiencies.

- 1.18 Although our engagement with hospital pharmacists and consultants already indicates a certain amount of interaction between them (especially through the provision of formal guidance), the NHS Commercial Medicines Unit is currently in the process of updating its strategic framework for procurement, aiming to bridge the gap between clinicians and pharmacists, such that decisions can be made in an informed way and cost efficiencies can be maximised.

Empirical findings

- 1.19 We analysed prices and market shares in the SRM market on the basis of information provided by the NHS Information Centre and the NHS Commercial Medicines Unit.
- 1.20 We found that the discounts offered by Napp to the hospital segment have fallen following the OFT's 2001 intervention. Napp's discounts have fallen, on the whole from approximately 90 per cent to 40 per cent of list price, going beyond the directions imposed on it by the OFT. As a result, the price of Napp's SRM products has risen substantially in the hospital segment since the OFT's 2001 intervention. The price of a 10mg MST tablet has gone from less than £0.01 in 1999, to over £0.04 in 2010, representing a price increase of approximately 400 per cent. This contrasts with a constant or downward trend in prices of rival products.
- 1.21 Our limited data on market shares in the hospital segment showed that there has been a substantial change in Napp's position in this segment since the OFT's 2001 intervention. Napp's market share (across all twice daily SRM products) has fallen from approximately 95 per cent to approximately 50 per cent.

- 1.22 Our analysis shows a clear downward trend in the list price of Napp's SRM products (MST) in the community segment. The list price of a 10mg MST tablet has gone from approximately £0.12 in 2001 to approximately £0.09 in 2009, representing a decrease of approximately 25 per cent, in excess of the 15 per cent price decrease stipulated in the 2001 OFT's decision. As such, Napp's prices in the hospital and community segment have moved closer together. Despite the reduction in Napp's prices to the community segment, its SRM products are still more expensive than the products of its rivals.
- 1.23 The data shows that NAPP's market share (based on proprietary prescriptions) in the community segment has reduced substantially since the OFT's 2001 intervention. Its market share has gone from approximately 95 per cent in 2001 to 65 per cent in 2010. However, it is still the biggest supplier in the SRM market. Napp's main competitor in the community segment has seen a substantial increase in their market share (of proprietary prescriptions), from approximately three per cent in 2001 to 30 percent by 2009. There is evidence to suggest limited entry into the SRM market since 2001; however the market still remains concentrated, with two major players.
- 1.24 We also used our data to investigate the relationship between Napp's prices and its market shares in the community segment. We used econometric analysis to model Napp's price as a function of its market share. Although our model did not enable us to make inferences about statistical significance and causality, we found that high market shares tend to be correlated with high prices, after controlling for dosage and time effects. This econometric analysis confirmed the analysis conducted via descriptive statistics. We did not conduct a similar analysis for the hospital segment due to the lack of available data on this segment.
- 1.25 We estimated the impact of our intervention in terms of the cost savings delivered to the NHS. To calculate savings, we estimated the change in cost of procuring SRM drugs in both hospital and community segments, comparing the actual annual cost of

procuring SRM drugs with the hypothetical cost (that is, how much it would have cost the NHS to procure SRM drugs had the OFT not intervened). In doing so, we assumed that real prices and market shares would have remained at their 2001 levels, and the aggregate quantity of SRM demanded would have been the same as actual level observed between 2001 and 2009.

- 1.26 Our savings estimates are based on proprietary prescriptions – those prescriptions where a clinician states the branded product to be dispensed (for example, MST 30mg or Zomorph 30mg). Proprietary prescriptions accounted for approximately 50-80 per cent of all prescriptions in the time period under consideration.
- 1.27 We estimated total savings to the community segment (from our 2001 intervention) to be approximately £15 million between 2001 and 2009, which equates to an annual saving of approximately £1.7 million. We found an increase in the cost of procuring SRM in the hospital segment of approximately £200,000 per year. Thus, we found that the net annual saving to the NHS as a whole (that is, to both hospital and community segments), is approximately £1.5 million.
- 1.28 We consider this figure as a conservative estimate for cost savings. We do not expect the increase in cost to the hospital segment to persist in the long run. We would expect savings in the hospital segment to increase over time as price competition (in both hospital and community segment) intensifies, thus further reducing prices to the competitive level. We have also assumed that demand for SRM products is completely inelastic (that is, prices do not impact upon the quantity demanded), thus our estimate might not capture all of the savings resulting from our intervention.
- 1.29 The OFT's 2001 intervention may have contributed to the increase in generic prescribing of SRM but our conservative savings estimate does not claim impact for this increase. Furthermore, our savings estimates do not account for the deterrent effect of our intervention. Stakeholders have told us that the Napp decision had a significant impact in terms of

detering other firms from engaging in predatory pricing in the hospital segment. As such, we expect the actual magnitude of savings to be substantially higher than our estimates.

2 INTRODUCTION

Background

- 2.1 Napp Pharmaceutical Holding Ltd (NAPP) supplies sustained release morphine³ in the UK to hospitals⁴ and to the community segment.⁵ NAPP launched sustained release morphine products into the UK in 1980. Its patent expired in August 1992.
- 2.2 Following a complaint against NAPP's conduct in this market, in July 1999, the OFT launched an enquiry under the Competition Act 1980. An investigation began under the Competition Act 1998 (CA98) following its entry into force on 1 March 2000. This was the OFT's first abuse of dominance case under CA98. The OFT found that NAPP had used aggressive discounting, often in excess of 90 per cent of the list price, when bidding for hospital contracts to supply sustained release morphine against other competitors. This type of exclusionary behaviour in the hospital segment enabled NAPP to charge excessive prices in the larger community segment where it had a significant share of the market (over 95 per cent).
- 2.3 In its decision, published in March 2001, the OFT found that NAPP abused its dominant position in both the hospital and

³ Chapter 3 provides further details on the characteristics of the sustained release morphine market.

⁴ The end-users in this segment are patients in hospitals or hospices, that is, secondary care patients. Sustained release morphine is prescribed by hospital doctors or specialists. This segment accounts for 10-14 per cent of the market, with supply purchased directly from manufacturers by hospitals (the hospital segment).

⁵ The end-users in this segment are patients in community pharmacy care, with GPs issuing prescriptions. This segment accounts for the majority of the market (86-90 per cent), with supply distributed by pharmaceutical wholesalers for resale to community pharmacies (the community segment).

community segments and imposed a fine of £3.21m.⁶ Additionally, Napp was required inter alia to reduce the NHS list price of MST tablets by at least 15 per cent and to sell MST tablets to hospitals in the UK at a price of not less than 20 per cent of the (reduced) NHS list price. NAPP appealed the OFT’s decision to the then Competition Commission Appeal Tribunal (CCAT); the OFT’s infringement finding was substantially upheld, though the fine was amended to £2.2 million.⁷

FIGURE 2.1: INFRINGEMENT FINDING

Abuse of dominance finding for the supply of sustained release morphine in the UK, by NAPP in two segments:

Hospital Segment (10-14%)	NAPP offered high discounts in this segment. NAPP offered highest discounts on those products for which it faced a directly competing product from Boehringer Ingleheim- (BIL). This created strategic barriers to entry (that is, exclusionary pricing), preventing other suppliers from getting a foothold in this market.
Community segment (86 – 90%)	NAPP charged excessive prices in this segment, by exploiting lack of competition. Competition was weak in this segment due to demand side barriers to entry such as the strength of the NAPP brand in this segment, risk aversion to using substitute drugs alongside price insensitivity of GPs (spend on this drug represented a small proportion of their overall budget).

⁶ The OFT’s infringement decision and directions can be viewed at the following link - www.of.gov.uk/OFTwork/competition-act-and-cartels/ca98/decisions/napp

⁷ The CCAT judgment of January 2002 amended the fine from £3.21m to £2.2m, see para 564, Napp Pharmaceuticals v Director General of Fair Trading [2002] CAT 1, which can be found at www.catribunal.org.uk/files/JdgNapp150102.pdf

- 2.4 Although, a smaller proportion of Sustained Release Morphine (SRM) tablets were sold via the hospital segment (10-14 per cent), this segment was considered 'an important, or even indispensable, 'gateway' to community sales'.⁸ Any new entrant had to establish itself in the hospital segment before it could penetrate the much larger and profitable community segment of the market.
- 2.5 When making prescribing decisions, the reputation of the brand (for instance, the reputation of MST; Napp's most popular product) was found to play a key part in hospitals and there has historically been a lot of reluctance to switch between brands.⁹ Additionally, the OFT's 2001 report found that Doctors in community care prefer patients to remain under the same drug regime once they leave the hospital.¹⁰ It is for this reason that the hospital segment is seen as a 'gateway' to the community segment.
- 2.6 Napp ensured that it won hospital contracts by offering very high discounts to the hospital segment. Given that community segment prescribing takes its direction from the hospital segment and the fact that this segment is relatively price inelastic, Napp was able to maintain excessive prices and a very high market share. In 2001, the majority (86-90 per cent) of sustained release morphine was supplied through the community

⁸ See Para 5 of the Court of Appeal's judgment on permission to appeal, [2002] EWCA Civ 796, which can be found at www.catrribunal.org.uk/files/NAPPCAJudge.pdf

⁹ Our conversations with stakeholders (particularly firms competing with Napp in the SRM market) have confirmed this view; given the product specific characteristics of sustained release products, there is a reluctance to switch between brands.

¹⁰ Hospital pharmacists indicated that the reverse effect is also true (to a limited extent though as usually SRM would be introduced in secondary care) with hospital consultants continuing to prescribe the same drug that the patient was under while in community care.

segment.¹¹ The OFT (in 2001) found that Napp could charge excessive prices in the community segment because of the absence of competition due to demand side entry barriers.^{12,13} Excessive pricing in this segment provided Napp with a strong incentive to price low in the hospital segment in order to ensure that other firms did not enter this market. NAPP was thus able to use strategic pricing to create barriers to entry in the hospital segment.

2.7 The price of SRM charged in the community segment at the time of the decision was described as 'significantly higher than the price charged to hospitals, in the case of some higher strength tablets the community wholesale price being in excess of 1,000 per cent higher than the average hospital price'.¹⁴

2.8 At the time of the decision, direct savings as a result of the infringement decision (excluding impact of increased competition), were estimated at £2m per year,¹⁵ while Link

¹¹ In 2009, 92 per cent of sustained release morphine was supplied through the community segment and eight per cent was supplied through the hospital segment.

¹² GPs in the community segment are price insensitive to sustained release morphine (SRM), due to spend on this drug as a proportion of their overall budget being small. Other factors include the fact that Napp's brand of SRM has a strong reputation for performance, the perceived risk of trying substitute drugs is high, and the need for considerable promotional expenditure in order to dislodge Napp's position. This makes it difficult for other suppliers to enter this segment. Para 2688 of the CCAT's Judgment www.catribunal.org.uk/files/JdgNapp150102.pdf summarises some of these demand side barriers.

¹³ NAPP argued the PPRS (Pharmaceutical Price Regulation Scheme) offered a constraint on their behaviour, however, this was not accepted by the OFT. See decision paragraphs 122-137. The CCAT judgment noted that it was 'common ground that the PPRS principally controls a company's overall ROC and does not, in that connection, concern itself with individual products' (paragraph 408).

¹⁴ See paragraphs 218 and 252 of the OFT's decision

¹⁵ See John Vickers 'Competition is good for consumers', in Fair Trading magazine, 2002 - www.offt.gov.uk/shared_offt/fair_trading/ft32.pdf

Pharmaceuticals¹⁶ (producers of Zomorph capsules), claimed that Zomorph capsules would save the NHS over £5m if used instead of MST (Napp's main SRM product).

Objectives

2.9 The aim of this evaluation is to assess the success of the 2001 OFT intervention against its objectives,¹⁷ In doing so, we hope to understand the extent to which the SRM market has changed since the 2001 decision. We also aim to quantify the impact of OFT's intervention in terms of the cost to the NHS of procuring SRM products. In order to do so, we have examined trends in the following three areas:

- Prices –how the price of SRM products (of Napp and its competitors) have changed in both the hospital and community segments since the OFT's 2001 decision and whether the hospital and community prices have moved closer to each other.
- Market structure – we analyse how the structure of the SRM market has changed since the OFT's 2001 decision and whether NAPP has been able to maintain its significant market share. Particularly, we are interested in the scale of entry and exit within the market and the extent to which new players have been able to establish themselves.
- Total cost to the NHS – we estimate the change in total cost to the NHS of procuring SRM drugs. Particularly, we would

¹⁶ Link Pharmaceuticals Group was acquired by Archimedes Pharma in 2006.

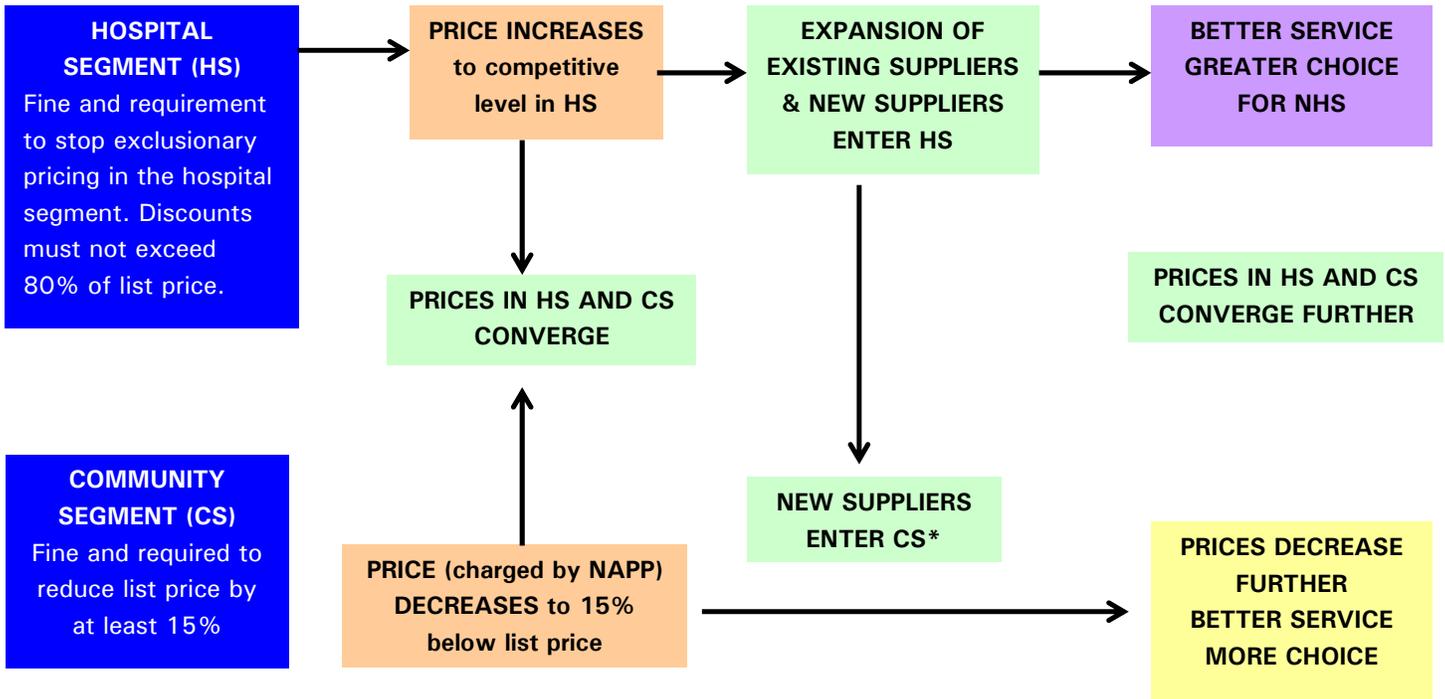
¹⁷ The aim of the intervention was to prevent the exclusionary behaviour which Napp was engaging in. In doing so, it was hoped that competition would be stimulated, which would result in new entry and subsequently lower prices of the SRM products, particularly in the community segment, which accounts for approximately 90 per cent of the SRM market.

like to see whether the OFT's 2001 decision has led to cost savings for the NHS.

- 2.10 In order to evaluate the impact of our 2001 intervention, it is important to define a clear counterfactual. That is, we must try and ascertain what would have happened (and how the SRM market would have evolved) had the OFT not intervened in 2001. This process is explained in further detail in Chapter 4, where we present our quantitative savings estimates.
- 2.11 Figure 2.2 is a decision tree of the expected impact of the 2001 OFT decision. The direct impact of the decision was likely to be through the removal of exclusionary discounts offered by Napp to hospitals enabling new entry in this segment, which in turn would stimulate competition and entry in the community segment. It was expected that increased price competition in the community segment would in turn lead to lower prices in this segment, and eventually to a greater alignment of hospital and community prices.¹⁸

¹⁸ Given that the hospital segment acts as a gateway to the larger community segment, firms will always have an incentive to loss lead and as such we did not expect to see absolute convergence in prices between both segments. However, we expected the difference in prices between both segments to decrease. In the short run, (immediately after the OFT's 2001 intervention) we expected hospital segment prices to rise. However, once competition had been stimulated in the community segment, it was expected that prices in the hospital segment would fall to the competitive level and thus there would be greater alignment of prices across both segments.

FIGURE 2.2: INTERVENTION LOGIC MODEL



* There is a brand or reputation effect. New suppliers in the HS will be able to build up their reputation, possibly spilling over into the CS. The result could be that GPs will be more willing to consider prescribing sustained release morphine supplied by manufacturers, other than NAPP.

Methodology

2.12 We have relied on both quantitative and qualitative analysis in this evaluation. Most of the data required for the evaluation was provided to us by the NHS and was complemented by additional information gathered through primary research. The analysis is summarised below.

i. Quantitative analysis

- We analysed price and market shares (volumes) data over time (1990-2009) using data provided to us by the NHS Health and Social Care Information Centre¹⁹ (on the SRM market in the community segment) and the NHS Commercial Medicines Unit²⁰ (on the SRM market in the hospital segment).
- We carried out econometric analysis using the NHS data and (some) data on the cost of manufacturing SRM products obtained from a company that (similarly to NAPP) produces and supplies SRM in the UK. The aim of this analysis was to understand the relationship between price and market share in the SRM market.

ii. Qualitative research

- We engaged with hospital pharmacists and GPs in community care to understand their views on prescribing practices in the UK – in particular of SRM drugs.²¹ In addition, we interviewed a number of stakeholders including

¹⁹ Referred to as the NHS Information Centre for the remainder of this report.

²⁰ Referred to as CMU for the remainder of this report.

²¹ Please see Annexe C for the surveys which were sent to GPs and hospital pharmacists.

the CMU, hospital pharmacists, and firms producing SRM in the UK market.

- We carried out desk research and interviewed a number of relevant academics and policy analysts familiar with the regulation of the pharmaceutical industry in other jurisdictions to inform our view on international markets for specialised drugs (such as SRM).

Structure of the report

2.13 The rest of this report presents our findings on the SRM market, examines the impact of the 2001 decision and sets out our conclusions and learnings:

- Chapter 3, on 'The market for Sustained Release Morphine in the UK', provides a broad description of SRM products and the key players in the market at present. It also discusses procurement of specialised drugs (such as SRM) in the UK and the factors which influence prescribing choices. The concluding section compares the UK market to other international markets.
- Chapter 4, on 'The impact of the 2001 OFT decision', contains the core empirical analysis, analysing price trends and market concentration since 2001. This section also summarises the qualitative evidence gathered and aims to quantify the impact of our intervention (in terms of total savings or additional costs to the NHS).
- Chapter 5, on 'Conclusions and lessons', summarises the evaluation findings and looks to draw useful lessons for future OFT work.
- Annexe A – Graphs and charts presents some additional graphs and charts on prices and market shares which have not been presented in the main report.

- Annexe B – Econometrics presents a more detailed explanation of the econometric analysis conducted as part of this evaluation.
- Annexe C – Surveys contains the full surveys which were sent to hospital pharmacists and GPs.

3 THE MARKET FOR SUSTAINED RELEASE MORPHINE IN THE UK

Introduction

- 3.1 This section describes SRM products and features of the SRM market in the UK including procurement and prescription practices in the UK.

Product description

- 3.2 Morphine is a strong opioid analgesic²² used to treat moderate and severe pain (particularly in cancer patients) – it is a controlled drug, only available on prescription. The oral route is considered the optimal route for the administration of analgesics, including morphine.²³
- 3.3 There are two different types of oral morphine formulations on the market – sustained (sometimes called slow, modified or controlled) release and immediate release. Immediate release preparations provide short acting, but immediate pain relief for use primarily where the pain is unstable. Sustained release morphine extends the duration of action of a morphine preparation and is used when the pain is fairly constant. Its use reduces the number and frequency of tablets that need to be administered.

Suppliers of SRM in the UK

- 3.4 Napp was the first company to launch a sustained release morphine product (MST) in the UK in 1980. Prior to the launch of MST, only immediate release morphine products were available

²² Analgesics are painkillers: non-opioid analgesics, such as aspirin or paracetamol, are generally used in the treatment of mild pain, while opioid analgesics (that is, those have an opium base) are used in the treatment of moderate to severe pain

²³ Based on the 2001 OFT decision document, paragraph 10.

for the treatment of cancer pain and other severe pain. MST was a new sustained release formulation of an existing chemical entity, morphine sulphate.

3.5 At present, the following companies manufacture and supply SRM in the UK:

- Napp, which supplies MST²⁴ and MXL (its current market share in the community segment is approximately 65 per cent)²⁵
- Archimedes Pharma,²⁶ which supplies Zomorph (its current market share in the community segment is approximately 30 per cent).
- Amdipharm, which supplies Morphgesic SR (its current market share in the community segment is approximately three per cent)
- Teva Pharma, which supplies Filnarine SR (its current market share in the UK community segment is less than one per cent)
- Sanofi Winthrop, which supplies Morcap SR (its current market share in the UK community segment is less than one per cent), and
- Sovereign medical, which supplies Rhotard Morphine SR (its current market share in the UK community segment is less than one per cent).

²⁴ MST is available in tablet form and as a suspension.

²⁵ These market shares are based on 2009 data on proprietary prescriptions, we do not have data on how generic prescriptions are allocated between various products. If generic prescriptions have gone to Napp's competitors then we expect these figures to underestimate the market shares of Napp's competitors.

²⁶ Archimedes Pharma acquired Link Pharmaceutical Group in 2006

- 3.6 Sustained release morphine (SRM) is supplied in many different presentations (that is, tablets, capsules, suspension) and in different pack sizes. The brands are also sold in different strengths. Napp's MST tablets are offered in seven different strengths and MST is the only product which offers 5mg and 15mg tablets. There are two different types of SRM products, those which must be taken once daily (once every 24 hours) and those which must be taken twice daily (once every 12 hours). Napp's MXL and Sanofi Winthrop's Morcap SR are the only once daily (24 hour) sustained release products. The others all need to be administered twice daily.
- 3.7 Firms that want to manufacture or market sustained release morphine in the UK must be properly authorised to do so. To manufacture medicinal products in the UK, a firm must have a manufacturers' license under the Medicines Act 1968. To market SRM in the UK a firm must obtain a specific marketing authorisation for that product under the Medicines for Human Use Regulations 1994 (SI 1994/3144). Manufacturers' licenses and marketing authorisations are granted by the MHRA.

Procurement of SRM in the UK

- 3.8 In order to evaluate the impact of our intervention in 2001, it is important to understand the way in which specialised drugs (such as SRM) are procured and prescribed in both the hospital and community segments in the UK. The procurement regulations influence prescribing decisions made by clinicians and the dispensing decisions made by pharmacists. In doing so, the procurement mechanism will also influence the impact of our 2001 intervention.
- 3.9 At the outset it is worth mentioning that procurement of specialised drugs is very different across both segments, with

very little interaction between hospital and community segments in relation to drug prices.²⁷

- 3.10 Prices of branded pharmaceuticals supplied to the NHS are controlled indirectly by the Pharmaceutical Price Regulation Scheme (PPRS), a non-contractual scheme between the Department of Health and the Association of the British Pharmaceutical Industry (ABPI). The PPRS covers sales of branded medicines into both primary and secondary care.
- 3.11 Under the PPRS,²⁸ companies have a target profit, usually expressed as a return on capital, and set prices accordingly. On market entry, companies have freedom of pricing for major new products, that is, new active substances within the constraint of their profit target. This regulation of profits is effected by the indirect control of price levels across a company's portfolio of medicines: individual prices are not managed so much as overall price levels.

Hospital segment²⁹

- 3.12 In the hospital segment, supply is purchased directly from manufacturers by individual hospitals. Products dispensed in the hospital segment are intended for patients in a hospital or hospice (secondary care) and is usually prescribed by hospital doctors or specialists.

²⁷ There is a very little interaction between those who are involved in procurement in each segment. Hospital pharmacists we engaged with told us that they have no contact with the Prescription Pricing Authority (PPA) with regards to discussing/aligning the prices of drugs in the hospital and community segments.

²⁸ For further details on the PPRS, see - www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/DH_494 and www.offt.gov.uk/OFTwork/markets-work/completed/pprs

²⁹ This section draws on information provided to us by the NHS Commercial Medicines Unit (CMU).

- 3.13 There are different ways in which hospital trusts can purchase drugs. Trusts can make use of a network of regional collaborative procurement hubs, and a national supplies and distribution organisation, NHS Supply Chain,³⁰ but there is no requirement for them to do so, and they are free to buy directly from suppliers.³¹
- 3.14 Hospital pharmacy procurement groups work together on a geographical basis to aggregate demand and seek opportunities to create savings on both branded and generic products. There are currently a total of 10 groups operating at strategic health authority (SHA) level, each supported by one of seven category specialists employed by the NHS Commercial Medicines Unit.
- 3.15 When the NHS Commercial Directorate introduced the Supply Chain Excellence Programme (2003) it was agreed that (1) the pharmacy procurement groups would be maintained for contracting for branded products; (2) for generic products the groups would be placed into six geographical 'divisions' so that contracts could be awarded either nationally or on a 'divisional basis'.
- 3.16 The procurement mechanism in the hospital segment is fairly complex and works through a number of key organisational structures and networks:
- Hospital Pharmacists – they provide prescribing advice to clinicians and deliver clinical services, and they manage hospital purchasing and dispensing activities on a day to day

³⁰ The Supply Chain Excellence Programme introduced collaborative procurement hubs, owned by trusts, that are responsible for the strategic management of all commercial non pay spend within their health economy.

³¹ Taken from NAO report – 'The procurement of consumables by NHS acute and Foundation trusts'. This can be viewed at the following link:
www.nao.org.uk/publications/1011/nhs_procurement.aspx

basis.

- SHA Pharmacy Procurement Groups – each NHS trust is represented on a SHA pharmacy procurement group by a pharmacist or technician. Representing the interests of the trusts’ budget holders, clinicians and relationships with PCTs, these pharmacists meet regularly to align procurement standards and approaches.
- NHS Commercial Medicines Unit (formerly NHS PASA) – SHA pharmacy procurement groups are supported by a dedicated NHS CMU category specialist and Quality Assurance and Technical Pharmacists. Business identified by the groups is competitively tendered on their behalf by the NHS CMU. The NHS CMU also awards and manages the resulting contracts on behalf of the groups.
- National Pharmaceutical Supply Group (NPSG) – operating at the national level, NPSG is accountable to the Department of Health Pharmacy Non-Executive Board on strategic matters relating to the procurement and supply of medicines to the NHS. NPSG is the strategic focus in the relationships between the NHS CMU, the Department of Health, NHS Trust Chief Pharmacists and the SHA pharmacy procurement groups.
- Pharmaceutical Market Support Group (PMSG) – operating at the national level, PMSG is accountable to the Department of Health Pharmacy Non-Executive Board on tactical operational matters relating to the procurement and supply of medicines to the NHS. The PMSG brings together a national overview of commercial and pharmaceutical expertise to assist the NHS CMU to coordinate pharmacy purchasing group activity and to advise the SHA pharmacy procurement groups on the most appropriate award decisions.

3.17 Regional contracts which are awarded by hospital trusts are framework contracts only and as such do not create a binding

commitment on the part of the individual NHS trust to purchase exclusively from the contracted supplier(s). An individual hospital may choose either to purchase drugs under the terms of their regional NHS CMU contract, or to negotiate an individual contract, which may be on different terms. For example - one of Napp's competitors told us that it had won an exclusive contract to supply SRM products to a number of hospital trusts, however, 18 months after the contract had been awarded, they had received minimal orders for their SRM product. The trusts had continued to purchase Napp's MST off-contract.

- 3.18 The variety of approaches and complexity of the hospital procurement system was confirmed by the information received from hospital pharmacists. Whereas some hospital pharmacists referred to exclusive agreements with specialised drug providers, others said they try to use more than one provider. There appeared to be no standard approach adopted by all trusts.
- 3.19 There are differences in prescribing practises between the hospital and community segments. Whereas community pharmacists cannot use 'generic substitution', hospital pharmacists can. So for example, if a specialist in a hospital prescribes MST, a hospital pharmacist can dispense a therapeutically equivalent product (such as Morphgesic SR). One caveat here is that the therapeutically equivalent product dispensed by the hospital pharmacist should be the same formulation as the original product prescribed by the hospital specialist. So, tablets will generally be substituted with tablets, and not capsules.³² This, in effect puts a limit on the range of substitutes available to a hospital pharmacist.

³² This is important because Zomorph (MST's biggest rival product) is produced in capsule form and not tablet form. However, hospitals have their own operating procedures with regard to what they can and cannot substitute or use as interchangeable.

Community segment

- 3.20 Products supplied in the community segment are intended for patients in primary care and are prescribed by GPs. In the community segment, pharmaceutical companies distribute supply through a limited number of pharmaceutical wholesalers, who in turn sell products on to community pharmacies.³³ Wholesalers are able to obtain a discount from pharmaceutical companies when purchasing drugs in bulk.³⁴ Additionally, in recent years there has been growth in Direct to Pharmacy schemes, with manufacturers selling directly to pharmacies.
- 3.21 Pharmacies are reimbursed for the cost of dispensed items as follows. The total value of the prescription medicines dispensed by a pharmacy is calculated on the basis of a reference price for each drug. For branded drugs this reference price is the manufacturers' NHS list price (as provided under PPRS), while for generics it is the price as determined by the Secretary of State and set out in Part VIII of the Drug Tariff published monthly. Prices in Part VIII of the Tariff are listed in five categories A, B, C, M and E with most being in A, C or M. Category M lists prices of commonly used items and the price is based on quarterly data of transaction prices between manufacturers, wholesalers and pharmacies. Category A uses a 'basket' of four suppliers' prices to obtain a weighted average price. Category C is commonly used when an item is frequently supplied but does not fulfil the criteria for category A. This is most often seen when a product is only available as a proprietary. The price will be based on a particular brand or supplier that is shown in the tariff. The value of the medicines at these reference prices is known as the Net Ingredient Cost (NIC).

³³ Based on information provided to us by Department of Health.

³⁴ Based on OFT's evaluation report: 'Evaluating the impact of the 2003 study on the Control of Entry regulation in the retail pharmacies market' (Annexe 2). Please see www.of.gov.uk/shared_of/reports/Evaluating-OFTs-work/OFT1219a.pdf - 2010-04-06 for further details.

- 3.22 The pharmacy is then reimbursed for its NIC less a deduction or 'clawback' of part of the discount at which it is assumed to have purchased the medicines from manufacturers and wholesalers. The rate of deduction is larger for higher values of monthly NIC, to in theory reflect the greater discounts available to pharmacies purchasing larger quantities of medicines.
- 3.23 The overall deduction scale is set annually so that the total retained buying profit across all pharmacies is expected to equal a target amount. Variances between the target profit margin and the actual profits achieved are taken into account in setting the remuneration and drug reimbursement rates in subsequent periods.
- 3.24 There is no system of 'generic substitution' for specialised drugs in the community segment in the UK.³⁵ Thus a community pharmacist must follow the prescription which is written by the GP³⁶. In the UK community segment, if MST is prescribed, then MST must be dispensed. If, however, the GP prescription refers to a product in generic terms (for example, if a GP wrote '30 mg sustained release morphine tablets'), then a community pharmacist could choose which brand to dispense.³⁷

Key factors influencing choice of branded SRM

- 3.25 The 2001 OFT decision found that the hospital segment is extremely price sensitive when it comes to purchasing branded drugs. This is generally true but there are a number of

³⁵ See section below on Pharmaceutical markets in other countries.

³⁶ Many other countries have introduced generic substitution, so that, for example, if a GP were to prescribe a pack of MST 30mg tablets, a community pharmacist could dispense a therapeutically equivalent alternative. Under such a scheme, the pharmacist would dispense the product that is most profitable for him to dispense (assuming that there are no special clinical factors which must be considered).

³⁷ When a GP writes a prescription in generic terms, we refer to this as a 'generic prescription' throughout this document.

characteristics of SRM drugs which make price a secondary factor when clinicians make prescribing choices.

Clinical inertia and reputational effects

- 3.26 In our discussions with hospital chief pharmacists, we were told that, in addition to the brand effect identified in the OFT decision (especially as MST is more than 30 years old), the short brand name, which is instantly recognisable, and the associated ease of prescription plays a role in enhancing clinical inertia and preventing clinicians (in both primary and secondary care) from prescribing alternative SRM products.³⁸
- 3.27 In addition, it appears that, given its longevity in the market, MST is thought of by clinicians as a 'quasi-generic product', with the brand name frequently associated with or used to designate the category.³⁹ As community pharmacists cannot use 'generic substitution', Napp's brand name and its reputation acts, in itself, as a barrier to competition in the community segment.
- 3.28 Academic literature also supports the importance of reputational effects in influencing prescribing decisions. Judith Hellerstein (1994)⁴⁰ examined why physicians continue to prescribe branded drugs when cheaper generic substitutes are available. The results of her work are consistent with an explanation of physicians' prescription behaviour based on habit persistence. She notes that 'given that none of the important observable determinants of the prescription behaviour are patient specific, and given that physicians do not appear to respond to the pecuniary incentives of state legislation or moral hazard, habit seems the more likely

³⁸ All controlled drugs must be written out in full form (words and numbers), making MST a very attractive (short and easy to remember) brand name.

³⁹ Similar examples from other industries are 'sellotape' and 'hoover'.

⁴⁰ 'The demand for post patent prescription pharmaceuticals', Judith K Hellerstein, NBER working paper no. 4981, (1994), please see <http://ideas.repec.org/p/nbr/nberwo/4981.html> for further details.

explanation for the persistence of prescription behaviour'. She goes on to say that 'when physicians make prescription decisions based on their idiosyncratic habits or the habits of others around them, they do not make cost-effective decisions'.⁴¹

- 3.29 Despite the existence of clinical inertia and reputational effects in this market, there has been a significant increase in the rate of generic prescribing of SRM products in the last 10 years.^{42, 43} According to data provided to us by the Department of Health, the rate of generic prescribing for 10mg SRM tablets⁴⁴ has gone from 23.6 per cent of all prescriptions in 2002 to 51.1 per cent in 2009. This increased rate of generic SRM prescribing is likely to have had a substantial impact on the SRM market; when a generic prescription in the community segment, a pharmacist can decide which product to dispense, based on the relative profitability of competing products. Thus, we would expect this change to have led to a change in the competitive dynamics of the SRM market.
- 3.30 The OFT's 2001 intervention may have contributed towards the increase in generic prescribing of SRM products; if the intervention led to greater competition and new entry in the SRM market and clinicians were aware of this, it might have led them to issue more generic prescriptions. However, when we quantify the benefit of our intervention (in Chapter 4) we do not consider

⁴¹ See page 34 of 'The demand for post patent prescription pharmaceuticals', Judith K Hellerstein, NBER working paper no. 4981, (1994), please see <http://ideas.repec.org/p/nbr/nberwo/4981.html> for further details.

⁴² We were not able to obtain data on generic prescribing rates which goes back beyond the last 10 years.

⁴³ The Department of Health has proactively sought to influence prescribing decisions for a number of years. Particularly, they have sought to increase the level of generic prescribing in order to generate cost savings to the NHS.

⁴⁴ 10mg tablets are used as an example, the generic prescribing rates are quite similar across different drug strengths.

the increase in generic prescriptions. This is because we do not have data on what was actually dispensed when a generic prescription was written and also because we calculate a conservative savings figure.

‘Switching costs’

3.31 Whilst there has been an increase in the rate of generic SRM prescribing over the last 10 years (to approximately 50 per cent), it is still considerably lower than the level of generic prescribing for other pharmaceutical products⁴⁵. This is due to the nature of the product and the associated ‘switching costs’ of moving between SRM products.

3.32 Specialist doctors and hospital pharmacists attach a significant cost to the risk of (administering) mistakes that might result from switching products. As there is a great deal of familiarity with MST, hospital pharmacists believe there is a very low chance of mistakes being made.⁴⁶ Thus, hospital trusts may be willing to pay more for a more familiar product (such as MST), rather than risk using a cheaper, lesser known product that they might believe might be associated with higher risks when being administered by nurses in hospitals or care homes.⁴⁷ And, despite the price sensitive nature of the hospital segment and the drive for efficiency, the relatively small amount spent on SRM does

⁴⁵ The generic prescribing rate in England for 2007/08 was 83 per cent.

⁴⁶ Some SRM products are once daily, some are twice daily.

⁴⁷ One of Napp’s rivals told us that features such as colour of the tablet are also very important. Given that Napp has been in the market for so long, the people administering its products will be used to the colour of its tablets. For example, they may have instructions to take one red tablet in the morning and one purple tablet in the evening. Switching to a different product (with potentially different tangible characteristics) therefore brings the risks of mistakes as it takes time to familiarise oneself with the new tablets or capsules.

not create a strong incentive for switching, especially in the context of (perceived) risks.⁴⁸

3.33 The extent to which (perceived) switching costs might lead to product differentiation is supported by the academic literature in the area. Merino Castello (2003)⁴⁹ notes that when the buyer knows more about the quality of one good the longer he has consumed it, the option to switch is not an attractive one because of the risk it involves. Consequently, in order to switch, buyers may have to be compensated for this uncertainty. In the present context, clinicians will continue to prescribe drugs that they know have already worked on patients they have treated (for example, MST), in preference to taking the gamble of trying drugs that they have not tested before on patients. Klemperer (1987)⁵⁰ found that the existence of switching costs can mean that ex-ante identical and homogenous products become ex-post heterogeneous. Consequently, switching costs lead to a form of 'artificial' product differentiation, which has implications for firms' strategy and consumer behaviour.

3.34 This perceived switching cost might limit the impact of the OFT's 2001 intervention (given the product specific characteristics of SRM). We should bear this in mind when assessing the overall effectiveness of the intervention.

Misaligned incentives

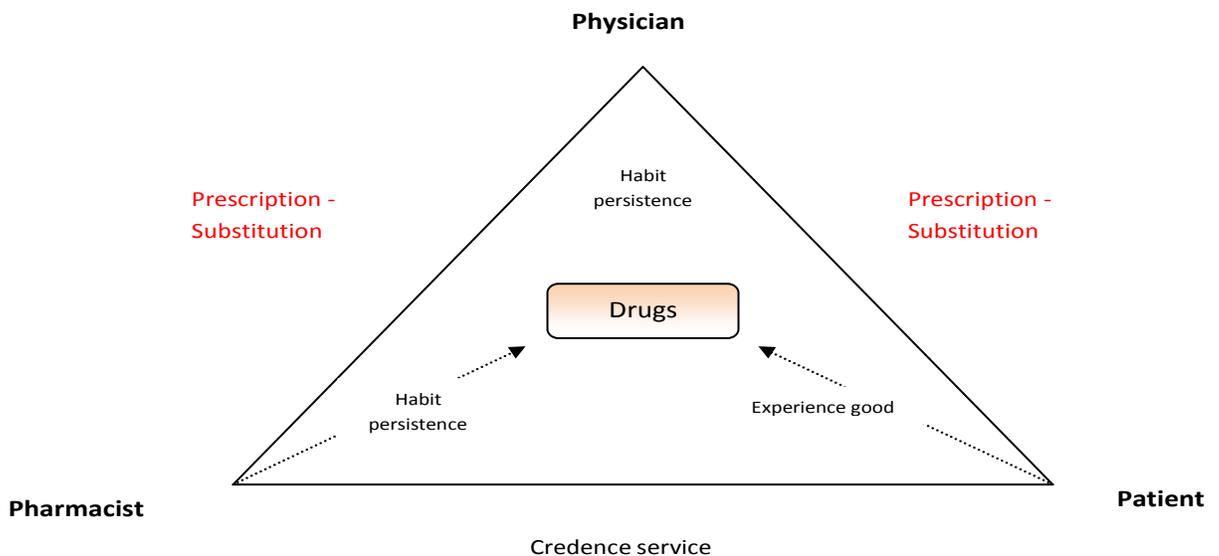
⁴⁸ One hospital pharmacist told us that the annual amount spent on SRM products is less than 0.5 per cent of total trust drugs budget. Thus an increase in spending on SRM products would not substantially alter their total annual spend. So, while hospital pharmacists do seek to use the most cost efficient drugs where possible, in the case of SRM, the savings would be quite small compared to the risk of procuring new products (as discussed above).

⁴⁹ 'Demand for Pharmaceutical Drugs: a Choice Modelling Experiment, Anna Merino-Castello', June 2003

⁵⁰ Markets With Consumer Switching Costs Quarterly Journal of Economics, 1987, Paul Klemperer.

- 3.35 Incentives play a key role in making markets work efficiently. Under the current procurement mechanisms for specialised drugs such as SRM, outlined above, there is a misalignment of incentives which can result in inefficient outcomes in these markets.
- 3.36 In the current procurement framework, doctors (consultants and GPs) are the decision makers, as they are the individuals who decide which products to prescribe. Patients taking the medication are the 'consumers'. The NHS is the 'purchaser' who pays the final bill. The diagram below summarises the bilateral relationships which exist in pharmaceutical markets.

FIGURE 3.1: BILATERAL RELATIONSHIPS IN PHARMACEUTICAL MARKETS⁵¹



⁵¹ Based on diagram in 'Demand for Pharmaceutical Drugs: a Choice Modelling Experiment, Anna Merino-Castello, June 2003

- 3.37 As noted by Merino-Castello (2003),⁵² demand for pharmaceutical drugs is unusual in the sense that the consumer is typically not the one deciding which product to consume and often not the one paying for it. Merino-Castello (2003) also notes that the drug purchasing process is characterised by the existence of information asymmetries between physicians and patients and uncertainty about drug effectiveness. Because medical knowledge is so complicated, the information held by the physician regarding the consequences and possibilities of treatment is necessarily much greater than that of the patient, or at least, so it is believed by both parties.
- 3.38 In the **current** system, the decision makers do not have explicit and clear incentives to consider price when making prescription choices. Despite the fact that there may be a substantial difference in price between two therapeutically equivalent branded products, a doctor prescribing the product will not be directly affected by the cost of the choice he makes (as the cost will be incurred by the NHS). The doctor will make his decision based on other factors (such as brand reputation, ease of prescribing, etc.).⁵³
- 3.39 The presence of the misalignment of incentives gives rise to substantial potential inefficiencies. In markets where incentives are not misaligned, once a product comes off patent and there is a cheaper equivalent, consumers (or consumer representatives) will choose this equivalent. In this way, firms compete on price in order to gain market share (see following section on international markets). In the UK, the structure and workings of

⁵² 'Demand for Pharmaceutical Drugs: a Choice Modelling Experiment, Anna Merino-Castello', June 2003

⁵³ However, we note that GPs do have a duty to the tax payer and will be monitored by their PCT with regard to their prescribing costs and trends. There has been an increased emphasis on monitoring the drug spend on GP prescriptions in recent years and price is becoming an increasingly important factor for GPs.

market for specialised drugs such as SRM, by not reflecting or rewarding price incentives, may hinder entry into the market.

- 3.40 Although our engagement with hospital pharmacists and consultants already indicates a certain amount of interaction between them (especially through the provision of formal guidance), the CMU is currently in the process of updating its strategic framework for procurement, aiming to bridge the gap between clinicians and pharmacists, such that decisions can be made in an informed way and cost efficiencies can be maximised.

Pharmaceutical markets in other countries

- 3.41 This section compares and contrasts the UK pharmaceutical market with international markets, particularly the US market. This section highlights the extent to which incentives and market workings are dependent on the policy structures in place.
- 3.42 We spoke with a number of academics and policy officers to build up an understanding of specialised drugs markets in the USA. The procurement and prescription of specialised drugs in the USA can be characterised as follows:
- State laws govern the procurement systems in the US – however, automatic substitution is in place across all states. If a generic product is available, unless the prescribing doctor has specifically stated that a particular product must be dispensed (they can do this by checking a box called 'Dispense as written' on the prescription) then the pharmacist can choose which product to dispense (that is, branded or generic).
 - The pharmacist will make his decision based on the profit he will make from particular products – it is almost always more profitable for a pharmacist to dispense a generic and therefore generic take up is very rapid.

- Another difference between the US and the UK is in the ‘bill-payer’. Whereas in the UK the NHS is the eventual bill-payer, the US system is much more fragmented with a number of individual, ‘managed health care plans’. These managed health care plans have a co-paid element which means that the patient will pay for a proportion of the cost of the drugs they consume.
- Most of these health care plans work on the basis of a formulary – a formulary might consist of three tiers, for example i) generic drugs, ii) preferred branded drugs, iii) other branded drugs. Depending on the tier of the drug which a patient is prescribed, the co-payment will differ. The co-payment incentivises the patient to opt for the generic product – unless the doctor has stated otherwise, there is an element of choice here.
- In the USA, within six months of a generic entering the market, absorption rates are approximately 80 per cent. There are some cases where generic substitution is not as widespread, for example in the case of oral contraceptives, here generics accounted for approximately 50 per cent of the market after six months.
- One well known example of a big name drug which was largely replaced with a generic is Prozac (produced by Eli Lilly) – Barr Pharmaceuticals was involved in a law suit against Eli Lilly and eventually proved that the patent on Prozac was invalid. Within six weeks of the generic being introduced to market, it accounted for 80 per cent of sales.

3.43 We were not able to obtain any detailed information about the SRM market in another jurisdiction. This was one of the main problems we faced when trying to define the counterfactual, that is, what would have happened in the UK SRM market had the OFT not intervened. Had we been able to obtain data on SRM markets in other countries we might have been able to make

inferences about what would have happened absent the OFT intervention.⁵⁴

⁵⁴ Although it might be difficult to compare the UK SRM market with an international SRM market given differences in regulatory system and structure.

4 IMPACT OF THE 2001 OFT DECISION

- 4.1 This chapter looks at the impact of the 2001 OFT decision, particularly the extent to which the prices of SRM products have changed in the hospital and community segments and the level of competition in the SRM market. Additionally we try and compute a figure for the change in the total bill to the NHS (for procuring SRM products) since the 2001 intervention.⁵⁵
- 4.2 In order for our intervention to achieve maximum impact, it is necessary for community segment doctors to change their prescribing practices. This is because there is no generic substitution in the community segment (as discussed in chapter 3), and because this segment accounts for the vast majority of SRM product demand (approximately 93 per cent in 2010, according to data provided to us by one of Napp's competitors). However, changes in community segment prescribing practices are driven, in turn, by changes in hospital segment prescribing practices. Therefore it is important to look at trends in both segments and the extent to which changes in the hospital segment have translated into changes in the community segment.
- 4.3 We looked at the price trends in SRM products for both community and hospital segments. We can split our data into three distinct time periods: the period where Napp's SRM products were still under patent and it was therefore the only SRM producer in the market (1980 – 1992), the period after Napp's patent expired but before the OFT's investigation (1992-2001) and the time since the OFT's decision (2001 onwards). We are most interested in the price trends following OFT's intervention (2001 onwards).

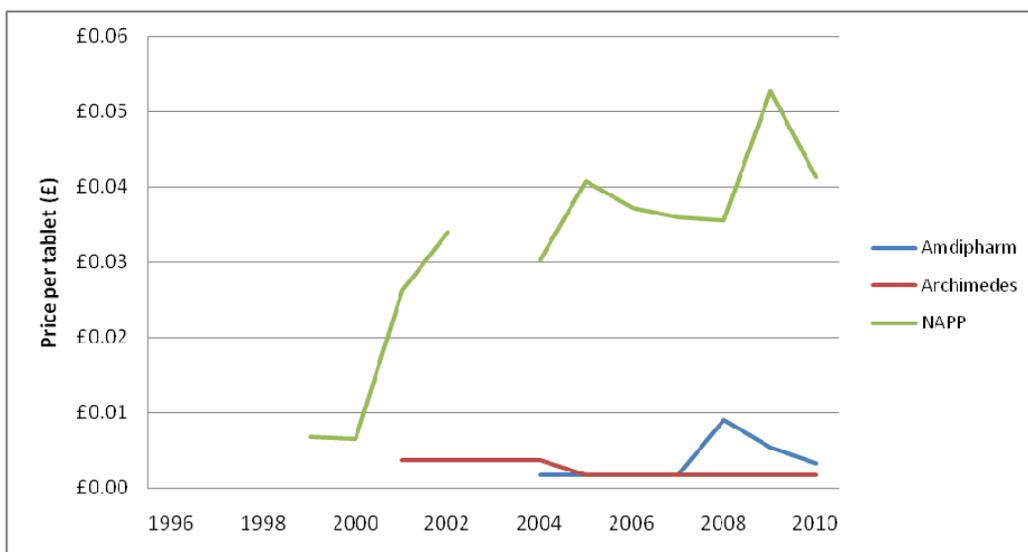
⁵⁵ The community segment market shares presented in this section are based on data relating to proprietary prescriptions. We do not have data on the product dispensed when a generic prescription is written. Given that our analysis of market shares is based on proprietary (branded) prescriptions only, our analysis covers approximately 50 – 70 per cent of the market over the period under consideration.

- 4.4 As discussed in chapter 2, we expect that as a result of the OFT's intervention, Napp will have removed its exclusionary discounts in the hospital segment – our 2001 decision stated that Napp must not offer discounts of more than 80 per cent of their NHS list prices. Thus, in the period following OFT's intervention, we would expect to see an increase in the price of Napp's SRM products to the hospital segment. If the removal of exclusionary discounts has facilitated entry into the hospital segment and subsequently stimulated competition in the wider community segment, we would expect to see a reduction in the price of Napp's SRM products in the community segment.

Hospital segment

- 4.5 Data on the hospital segment was obtained from the NHS Commercial Medicines Unit (CMU). This data covered the period 1996 – 2009 and provided us with the list prices and actual contract prices awarded by hospitals across 10 different NHS buyer groups. We were able to obtain data on the quantity of SRM products dispensed in the hospital segment (across England) for the years 2005 and 2006.
- 4.6 The graph below looks at the prices charged to hospitals for SRM products. The graphs show the prices (in terms of price per tablet) charged by the three biggest SRM producers (Napp, who produce MST; Archimedes Pharma, who produce Zomorph; and Amdipharm, who produce Morphgesic SR). The graphs cover the time period 1996 to 2009 and, though the data is not comprehensive across all years, they provide a strong indication of market trends. Figure 4.1 provides the analysis for 10mg tablets as these are the most frequently dispensed tablets. The analysis of other drug strengths (30 mg, 60 mg, 100 mg and 200mg) is presented in Annexe 1.

FIGURE 4.1: ACTUAL PRICE OF 10MG SRM PRODUCTS (PER TABLET) IN THE HOSPITAL SEGMENT, 1996 – 2009



Source: Data provided by CMU, OFT analysis.

Notes: There is a gap in the line for NAPP due to missing data.

4.7 The graph above shows that the price (per tablet) of NAPP's SRM products (MST) has risen substantially since the OFT's 2001 intervention. The price of a 10mg MST tablet has gone from less than £0.01 in 1999, to over £0.04 in 2010, representing a price increase of approximately 400 per cent. This contrasts with a relatively constant or slight downward trend in prices of rival products. As a result, the price of NAPP products now exceeds the price of rival products in the hospital segment by a substantial margin, they are approximately five times more expensive. The trend is fairly consistent across drug strengths.⁵⁶ The prices of Amdipharm and Archimedes' products have remained fairly close to one another since Amdipharm entered the market in 2003. Hospital pharmacists have confirmed that Napp's rivals offer very high discounts to the hospital segment,

⁵⁶ Please refer to annexe 1 to see graphs for alternative drug strengths.

sometimes in excess of 95 per cent.⁵⁷ We can see from this that despite Napp's substantially higher prices (than those of its competitors) in the hospital segment, its rivals still have to price very aggressively in this segment to compete. This finding is consistent with the idea that the hospital segment is a gateway into the community segment and that firms' losses lead in this segment.⁵⁸

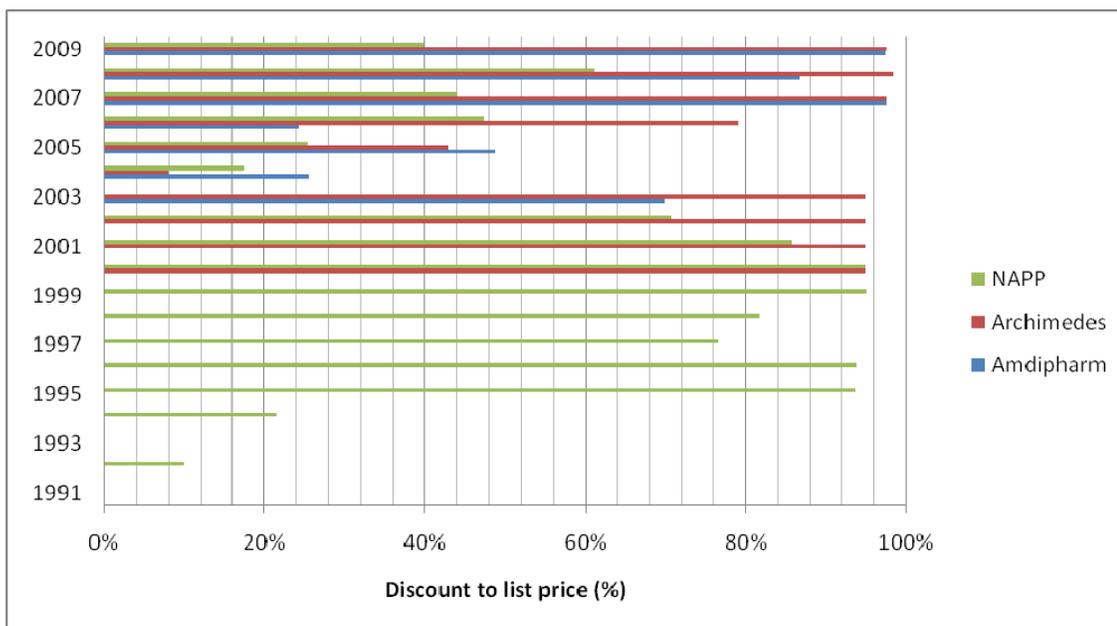
4.8 The findings above are corroborated by the data we have on discounts.⁵⁹ As a result of the 2001 intervention, Napp was restricted in the level of discounts it could offer to hospitals for its SRM products; Napp was required to charge the hospital segment at least 20 per cent of its community list price. In effect this meant that Napp could not offer discounts in excess of 80 per cent. The chart below shows the discounts offered (as a percentage of list price) by Napp, Archimedes Pharma and Amdipharm on their respective SRM products.

⁵⁷ One hospital pharmacist told us that 'Archimedes are currently discounting Zomorph so that it costs less than 1p per capsule. This corroborates our data showing a decrease in prices offered by Napp's rivals to the hospital segment. Another pharmacist told us that current hospital prices are as low as about five per cent of the list price. One of Napp's competitors told us that 'in the secondary care market we have had to progressively tender below cost of goods to be successful'.

⁵⁸ This implies that even if prices in the hospital segment and community segment do move closer together, we would not expect to see absolute convergence.

⁵⁹ It was possible to calculate discounts as we had data on list prices and actual contract prices – the percentage difference between these two prices is the discount. For example, if the list price is £1, and the actual contract price is £0.10, this would represent a discount of 90 per cent on the list price.

FIGURE 4.2: AVERAGE DISCOUNTS ON PACKS OF 10MG SRM TABLETS OFFERED IN THE HOSPITAL SEGMENT, 1991 – 2009



Source: Data provided by CMU, OFT analysis

4.9 The graph above shows that the discounts offered by NAPP to the hospital segment have fallen following the OFT’s 2001 intervention. Napp’s discounts have fallen, on the whole from approximately 90 per cent to 40 per cent. However, discounts offered by rivals (Amdipharm and Archimedes) have not fallen – they have remained higher, over or above 80 per cent. In some cases, discounts offered by Napp’s rivals have been in excess of 95 per cent. This is consistent with Napp’s actual prices in the hospital segment being considerably greater than the prices of its competitors (as shown in Figure 4.1).

4.10 We also analysed the (somewhat limited) data we have on market shares in the hospital segment.⁶⁰ This data shows us that there has been a substantial change in Napp’s position in the

⁶⁰ We obtained monthly data on volumes of SRM products dispensed in the hospital segment for the years 2005 and 2006. This data gave us the volume of Napp products dispensed and the volume of non Napp products dispensed. We have used this data to compute market shares.

hospital segment since the OFT's 2001 intervention. Napp's market share (across all twice daily SRM products) has fallen from approximately 95 per cent to approximately 50 per cent.⁶¹ This finding is corroborated by (anecdotal) data obtained through our engagement with market players, including one of Napp's competitors (whose market share in the hospital segment of the SRM market has increased tenfold), and references by hospital pharmacists to contracts gained by NAPP competitors.

- 4.11 Thus, limiting Napp's ability to offer excessive discounts in the hospital segment appears to have brought about a change in the competitive dynamics of this segment, with competitors able to gain market share. However, despite the fact that Napp's prices in the hospital segment are higher than those of its competitors (as shown in figure 4.1 above), it is still the biggest supplier in the hospital segment. This would confirm that price is not the only determinant of drug choice, and whilst hospitals tend to be price sensitive, they do also attach a clinical risk to switching from one product to another. This 'inertia' may be limiting, or delaying the immediacy of the impact of price restrictions such as those imposed by the OFT in 2001.

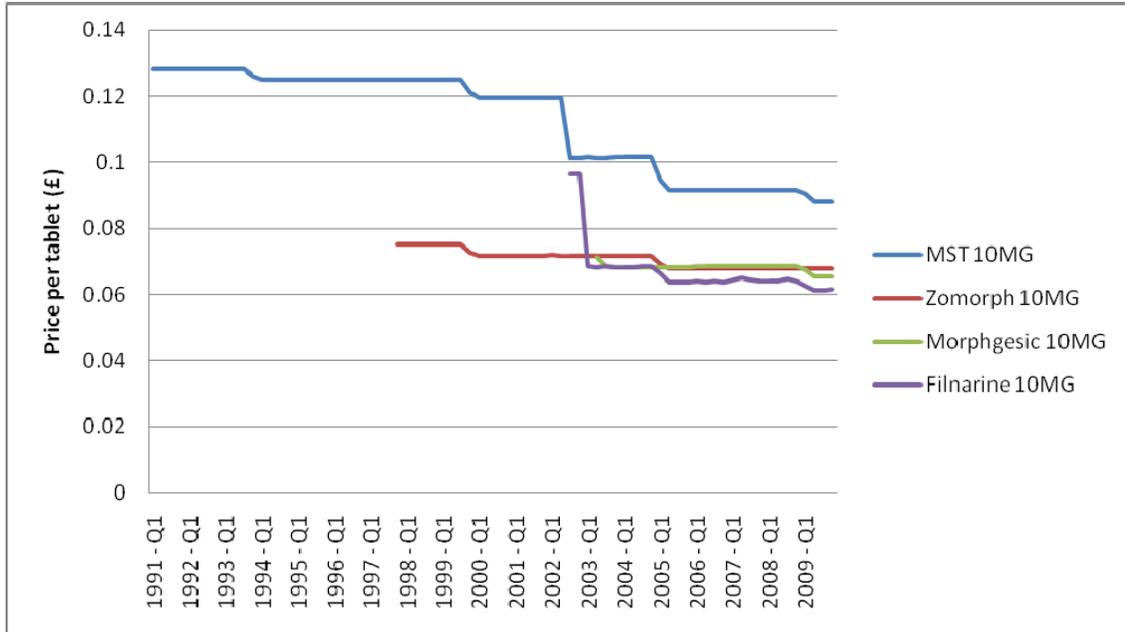
Community segment

- 4.12 Data on the community segment was obtained from the NHS Information Centre. This data covered the period 1991 – 2009 and provided the list price of SRM products and the quantity of SRM products dispensed across England. While we were not able to obtain realised prices in the community segment, list prices should give a good indication of how prices changed in this segment since our intervention.⁶²

⁶¹ Our calculations find that in 2005 Napp's market share in the hospital segment was 42 per cent and in 2006 its market share was 52 per cent.

4.13 The graph below shows our analysis of prices in the community segment. We looked at prices for the four major SRM products, MST (produced by Napp), Zomorph (produced by Archimedes Pharma), Morphgesic (produced by Amdipharm) and Filnarine (produced by Teva Pharma).

FIGURE 4.3: LIST PRICE OF 10MG SRM PRODUCTS (PER TABLET) IN THE COMMUNITY SEGMENT, 2001 – 2009



Source: Data provided by NHS Information Centre, OFT analysis

Notes: Community segment data is based on list prices and thus these graphs do not take account of discounts negotiated by pharmacies.

4.14 The graph above shows a clear downward trend in the list price of Napp’s SRM products (MST) in the community segment. The list price of a 10mg MST tablet has gone from approximately £0.12 in 2001 to approximately £0.09 in 2009, representing a decrease of approximately 25 per cent, in excess of the 15 per

cent price decrease stipulated in the 2001 OFT's decision.⁶³ We observed a similar trend across all drug strengths.⁶⁴

- 4.15 As in the hospital segment, the prices of Napp's rivals tend to be very close to one another, with the exception of Filnarine (produced by Teva Pharma) in 2003, whose price was temporarily higher than other rivals prices in 2003, before falling in line with them in 2004. The prices of rival products have stayed relatively constant over time, with a slight decrease. However, movements in Napp's prices and those of its rivals seem to be more correlated in the community segment than in the hospital segment.⁶⁵
- 4.16 Despite the reduction in Napp's prices to the community segment, its SRM products are still more expensive than the products of its rivals. Table 4.1 illustrates the differences in prices between MST and Zomorph.

⁶³ The directions given to Napp by the OFT (in 2001) also said that the actual price charged should be not more than 87.5 per cent of list price. However, we do not have data on actual prices charged in the community segment and as such our analysis is confined to list prices.

⁶⁴ See annexe A for further detail

⁶⁵ This correlation may result from the fact that we have not taken account of discounts, although we do not believe that substantial discounts are offered in the community segment

TABLE 4.1 COMPARISON OF NAPP AND ARCHIMEDES PHARMA PRICES IN THE COMMUNITY SEGMENT⁶⁶

	10mg	30mg	60mg	100mg	200mg
MST	£5.29	£12.72	£24.80	£39.92	£78.16
Zomorph	£4.08	£9.69	£18.93	£30.18	£57.18
Napp's 2009 premium (%)	30%	31%	31%	30%	37%
Napp' 2001 premium (%)	33%	41%	43%	43%	67%

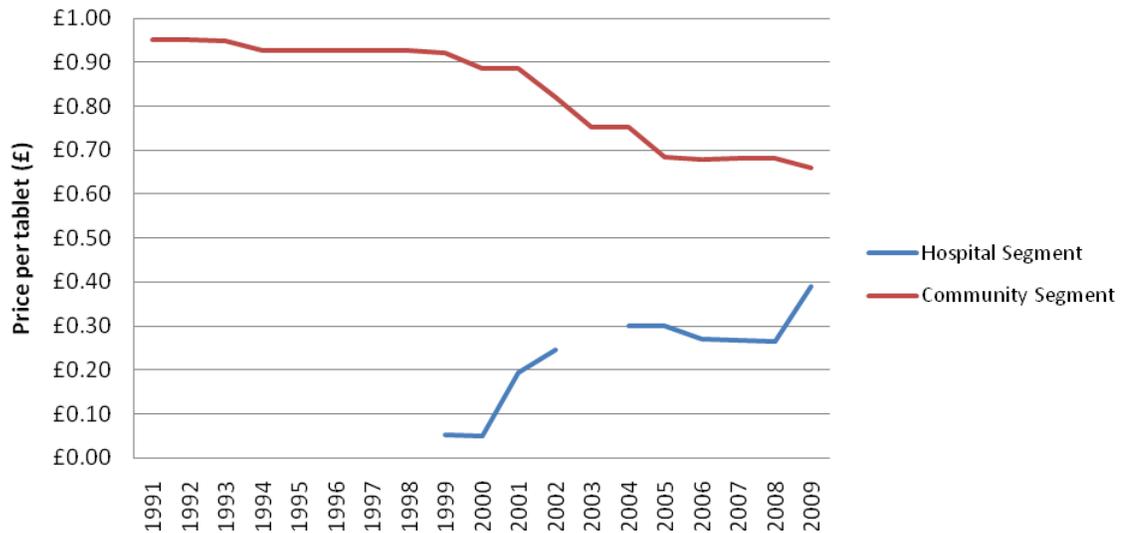
4.17 Table 4.1 shows us that Napp's prices are still at least 30 per cent higher than Archimedes' in the community segment in 2009, compared to a premium of some 40 per cent in 2001. As such, despite some convergence in prices, Napp appears to be able to maintain a significant price premium. Such an outcome, reflecting that, with (more effective) price competition, Napp may still be able to achieve a premium (albeit reduced), was somewhat anticipated in the OFT decision.⁶⁷

⁶⁶ These prices are list prices and refer to the price of a pack of 60 SRM tablets.

⁶⁷ In the 2001 OFT decision (paragraph 211) it was noted that 'branded products are often priced at a premium to other products. It is notable that in the hospital segment Napp is unable to sustain a premium price since, in effect, MST has lost its brand value. It is only in the community segment where buyers are less price sensitive and where there is an absence of effective price competition, partly as a consequence of Napp's conduct that Napp can sustain a premium of 40 per cent over competitors. The Director

4.18 Figure 4.4 shows that Napp's prices in the hospital and community segments have moved closer together.

FIGURE 4.4: COMPARISON OF PRICES IN HOSPITAL AND COMMUNITY SEGMENT FOR NAPP'S MST (100MG) TABLETS, 1991 - 2009



Source: Data provided by CMU/NHS Information Centre, OFT analysis

4.19 Given the fact that our hospital data is based on realised prices and community segment data is based on list prices, it is likely that the actual difference in prices between hospital/community segments is slightly smaller than the difference depicted above. In 2001, it was found that Napp's community prices were sometimes 1000 per cent greater than its hospital prices. Looking at the 2009 data, Napp's community segment prices appear to be approximately 75 per cent greater than its hospital segment prices.

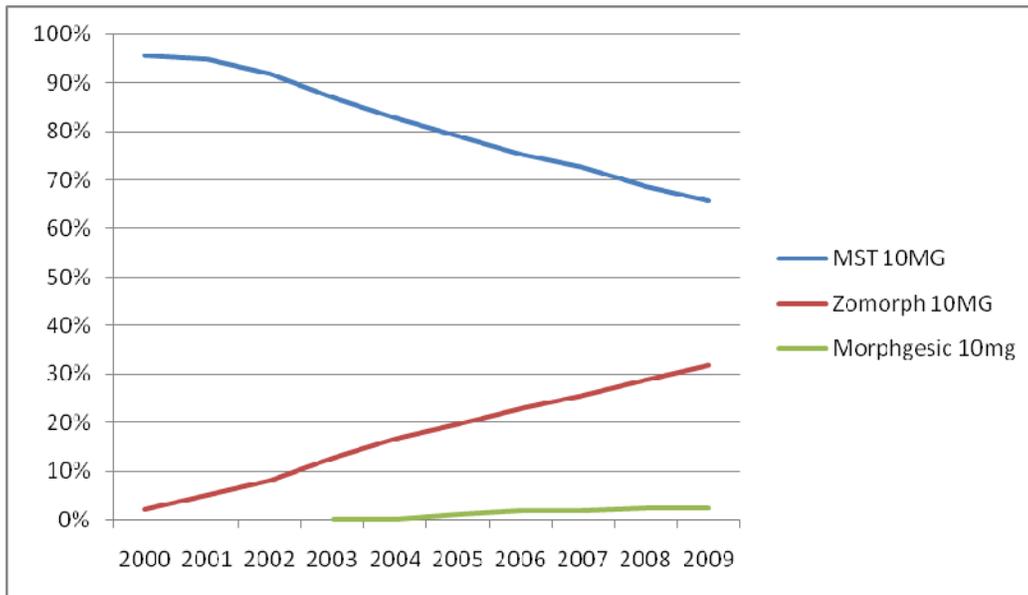
accepts that even with effective price competition Napp may be able to achieve a premium over competitors' prices, but he does not accept that the premium would be as high as 40 per cent.'

Entry and Exit/Market Concentration

- 4.20 We also analysed market shares in the community segment of the SRM market to understand the impact of our intervention on market structure and whether it had facilitated entry of new firms and products. We calculated market shares by looking at volume data (that is, the number of tablets dispensed by each company). However, it is important to note that our market shares relate to proprietary (branded) SRM prescriptions. Proprietary prescriptions account for between 50 and 80 per cent of the market for the time period under consideration.⁶⁸
- 4.21 The graph below shows the market shares of supply for the three largest producers in the SRM market, Napp, Archimedes and Amdipharm from 2000 to 2009. The three of these firms combined account for approximately 98 per cent of market supply for SRM in England.

⁶⁸ We must rely on proprietary prescriptions to analyse market shares in the community segment because we do not have data on the drugs dispensed when a generic prescription is written. Whilst we cannot comment on the whole market based on our data set, we are nevertheless able to comment on the effectiveness of our 2001 intervention with regard to the impact of our intervention on proprietary prescriptions.

FIGURE 4.5: MARKET SHARES OF SUPPLY FOR 10MG SRM TABLETS IN THE COMMUNITY SEGMENT, 2000 – 2009



Source: Data provided by CMU/NHS Information Centre, OFT analysis

Notes: market shares based on volume data

4.22 The data shows that Napp’s market share in the community segment has reduced substantially since the OFT’s 2001 intervention (based on proprietary prescriptions). Its market share has gone from approximately 95 per cent in 2001 to 65 per cent in 2009. However, it is still the biggest supplier in the SRM market. Archimedes Pharmaceuticals (formally Link Pharmaceuticals) have seen a substantial increase in their market share in the community segment, from approximately three per cent in 2001 to 30 percent by 2009. Thus, the market still remains concentrated, with two major players. Amdipharm entered the market with Morphgesic SR after the OFT’s 2001 intervention (they entered in 2003) but have not been able to gain a sizeable share of the market since entry. In 2009 they accounted for less than three per cent of market supply. The trends observed for 10mg tablets are also observed for other tablet strengths (see annexe A).

- 4.23 We can see that Zomorph's position has changed substantially since our 2001 intervention. Zomorph entered the market in 1997.- The fact that only it has been able to build up its market share over time would support the view that reputation effects remain important in specialised drugs markets, even if they are open to generic competition such as the market for SRM. The OFT's intervention has led to greater price competition and a strengthened position of one of Napp's pre-existing rivals, and an increased (albeit limited) entry in the market.
- 4.24 This analysis is supported by qualitative evidence from our engagement with hospital pharmacists, that referred to the increase in the range of SRM products available since the 2001 decision. New entrants into the SRM market include Teva Pharma (producers of Filnarine SR), Amdipharm (producers of Morphgesic SR) and Sovereign Medical (producers of Rhotard Morphine SR). Since our 2001 intervention, there have been new entrants in the SRM market, however these entrants have faced challenges in establishing themselves as significant market players, with demand barriers mostly arising from brand inertia still appearing as significant.⁶⁹
- 4.25 Hospital pharmacists have also referred to the increase since 2001 in non morphine substitutes for SRM, including Oxycontin (also produced by Napp). Additionally, hospital pharmacists told us that since 2001, Napp has invested more into other markets than SRM, which are less competitive, such as the market for non-morphine opiates.

⁶⁹ Our engagement with new entrants in the SRM market seems to confirm the reluctance to switch one high-end modified release morphine for another, even when secondary care contracts are awarded on a joint basis with MST.

Econometric analysis of price and market shares data

- 4.26 As well as our trend analysis, we have also used the data to conduct an econometric analysis of Napp's prices and market shares in the community segment. We have modelled Napp's price as a function of its market share. Although our model does not enable us to make strong inferences about statistical significance and causality, we do find that high market shares tend to be correlated with high prices, after controlling for dosage and time effects. This econometric analysis confirms the analysis conducted via descriptive statistics. We did not conduct a similar analysis for the hospital segment due to the lack of available data on this segment.
- 4.27 Annexe B outlines the methodology used to conduct the econometric analysis along with the results obtained from various regressions.

Estimated cost savings

- 4.28 We have tried to quantify the impact of our intervention in terms of the cost savings delivered to the NHS when procuring SRM drugs. We anticipated substantial cost savings in the community segment of the market as prices of Napp's products have come down by approximately 25 per cent. Moreover, Archimedes has been able to increase its market share to approximately 30 per cent, and its prices are lower than those of Napp's. However, these savings had to be offset against a potential increase in the cost of procuring SRM in the hospital segment; Napp's prices in this segment increased substantially (since 2001), and although their market share has decreased, is it still approximately 50 per cent.
- 4.29 The OFT's 2001 intervention may have contributed towards the increase in generic prescribing of SRM products; if the intervention led to greater competition and new entry in the SRM market and clinicians were aware of this, it might have led them to issue more generic prescriptions.

- 4.30 An increase in generic SRM prescriptions could have led to three different scenarios: i) all generic prescriptions go to Napp, ii) all generic prescriptions are allocated to other brands, iii) generic prescriptions are allocated on a pro-rata basis. On the basis of economic incentives we would expect the second scenario to be most realistic.⁷⁰ If the second scenario were in fact true, then we would expect to see substantial cost savings to the NHS as a result of increased generic prescribing.
- 4.31 However, when we quantified the benefit of our intervention we did not consider the increase in generic prescriptions. This is because we did not have data on what was actually dispensed when a generic prescription was written and also because we calculated a **conservative** savings figure. Our savings estimates are based on proprietary prescriptions – those prescriptions where a clinician states the brand to be dispensed (for example, MST 30mg or Zomorph 30mg). Proprietary prescriptions accounted for approximately 50-80 per cent of all prescriptions in the time period under consideration.
- 4.32 Our savings estimates therefore capture changes in prescribing practices (when a branded SRM drug is dispensed) resulting from increased competition in both hospital and community segments, following the OFT's 2001 intervention.
- 4.33 When trying to compute a quantitative savings estimate resulting from the OFT's 2001 intervention, it was very important to have a clearly defined counterfactual. That is, we had to make assumptions about what would have happened in the SRM market had the OFT not intervened. This could have potentially been done by looking at the SRM market in another country (in

⁷⁰ However, we are aware that there are other factors beyond economic incentives which may determine prescribing decisions made by pharmacists.

which there had not been an intervention). However, we were unable to obtain data on the SRM market in another jurisdiction.⁷¹

Community segment

- 4.34 Firstly, we calculated savings in the community segment.
- 4.35 We used data (on prices and volumes in the community segment) to calculate the actual cost of procuring SRM drugs in this segment. We compared this actual procurement cost with the hypothetical procurement cost (that is, how much would it have cost to procure SRM drugs in the community segment, had the OFT not intervened in 2001).
- 4.36 In order to generate a hypothetical cost of procuring SRM in the community segment, we made some simplifying assumptions. We looked at Napp's prices and market shares in the community segment (of the SRM market) in the years prior to our intervention – they had been relatively stable for a number of years⁷². On this basis, we assumed that absent the OFT's 2001 intervention, Napp would have been able to maintain its high market share in the community segment (approximately 95 per cent) as well as its high prices in this segment.⁷³
- 4.37 Additionally, we assumed that the aggregate quantity of SRM demanded would not have changed, had the OFT not

⁷¹ Moreover, given the regulatory specific nature of pharmaceutical industries, considering an alternative jurisdiction may not have been useful in terms of understanding how the UK SRM market would have evolved, absent the OFT's 2001 intervention.

⁷² Looking at real prices (Annexe B) shows a slight downward trend over time, but this is gradual. Assuming constant real prices may slightly overestimate savings from the community segment, but this is offset by

⁷³ Absent the OFT's intervention, we assumed (for the purpose of this calculation) that Napp would have continued to engage in anti-competitive behaviour and this would have allowed it to maintain its position in the community segment.

intervened.⁷⁴ This is based on the assumption that demand for SRM in the community segment is price inelastic (that is, demand for SRM in the community segment does not respond significantly to changes in price).

4.38 To summarise; to estimate the hypothetical cost of procuring SRM in the community segment (absent OFT intervention), we assumed that market shares of Napp and Archimedes (its largest competitor)⁷⁵ remained at their 2001 level between 2001 and 2009; we assumed that Napp's real price in the community segment remained constant between 2001 and 2009; we assumed that the hypothetical quantity of SRM products demanded in each year between 2001 and 2009 was equal to the actual quantity of SRM demanded in each of those years.

4.39 Using these assumptions and our data (on prices and volumes in the community segment), we calculated the difference between the actual cost and the hypothetical cost of procuring SRM drugs in the community segment, for each year between 2001 and 2009. We estimated total savings from the community segment to be £15.1 million between 2001 and 2009, which equates to a roughly £1.7 million annual saving.

Hospital segment

4.40 Next we looked at the change in cost of procuring SRM products in the hospital segment. The limited data we had on this segment showed that demand for SRM products had remained constant over time. Given that the aggregate quantity of SRM dispensed

⁷⁴ There has been an increase in the quantity of SRM demanded in the community segment since our intervention, however, we assume that this increase is not driven by price, but rather by other factors such as demographics and increased emphasis on palliative care, with more people being treated with SRM in primary care. Our engagement with clinicians and pharmacists has confirmed our view that demand for SRM is in fact inelastic in the community segment.

⁷⁵ For simplicity, we did not account for the other smaller SRM producers as they accounted for a very small proportion of the market at the time of the intervention.

in the hospital segment remained constant (after the OFT's 2001 intervention), we assumed that it would have remained constant, even if the OFT had not intervened.⁷⁶ Given that the quantity of SRM demanded stayed the same, we can compare like for like, the cost of procuring SRM in this segment.

- 4.41 We used our limited data on market shares (of Napp and Archimedes) in the hospital segment (for 2005 and 2006) to calculate the cost of procuring SRM in the hospital segment for each of these two years.⁷⁷ We compared these costs with the cost of procuring SRM in 2001 (in the hospital segment).
- 4.42 We found that the cost of procuring SRM in the hospital segment increased by approximately £200,000 per year (using 2005 data, relative to 2001) and by £225,000 per year (using 2001 data, relative to 2001).

Overall savings

- 4.43 To look at the overall change in the cost (to the NHS) of procuring SRM products, we compared the savings which resulted from the community segment and offset them against the increased costs estimated in the hospital segment.
- 4.44 We estimated annual savings of approximately £1.7 million in the community segment. We assumed an annual increase in cost of approximately £225,000 to the hospital segment (we took the higher of our two figures, to be conservative). This provides a net annual saving estimate (to the NHS as a whole) of £1.5 million.

⁷⁶ Again, we assume that demand for SRM is inelastic and does not respond to changes in price.

⁷⁷ We applied the market shares to the total quantity of SRM demanded (assuming that demand split between different strength SRM products remained constant over time) and multiplied the relevant quantities by the relevant prices of Napp/Archimedes.

4.45 We believe that this is a lower bound savings estimate as we would not expect increased costs in the hospital segment to persist in the long run.⁷⁸ Additionally, as prices continue to fall in the community segment (due to increased competition in this segment), we expect savings in this segment to grow. Finally, this savings estimate does not take account of the deterrent effect of our intervention⁷⁹ and it does not account for the fact that our intervention may have contributed to an increase in generic prescribing of SRM, which in turn may have generated additional cost savings to the NHS.

⁷⁸ Following the OFT's 2001 intervention, as price competition intensifies in the community segment, we expect that prices in the hospital segment will fall to the competitive level.

5 CONCLUSIONS

Concluding remarks

- 5.1 This report concludes that the OFT's 2001 intervention has had a substantial impact and has brought about a significant change in the UK SRM market.
- 5.2 Napp have adjusted their pricing policy in line with the directions imposed by the OFT – list prices in the community segment have fallen by more than the stipulated 15 per cent, and discounts in the hospital segment have not exceed the stipulated 80 per cent.
- 5.3 Since 2001 Napp's prices in the community segment have fallen by 25 per cent. During the same period Napp's market share in the community segment (based on proprietary prescriptions) has fallen from 95 per cent to approximately 65 per cent.
- 5.4 Since 2001 Napp's prices in the hospital segment have risen by up to 400 per cent. During the same period Napp's market share in the hospital segment has fallen from **95 per cent to approximately 50 per cent.**
- 5.5 The original decision found that in 2001, Napp's prices in the community segment were 1000 per cent higher than those in the hospital segment. Since 2001, there has been some convergence in prices across both segments, and now Napp's prices in the community segment are approximately 75 per cent greater than its hospital segment prices.
- 5.6 **Annual benefits** to the NHS from reduced spending on SRM procurement are conservatively estimated at **£1.5 million. It should be noted that this estimate does not take into account the wider 'deterrent' effect of our intervention.**
- 5.7 The floor imposed on Napp's prices in the hospital segment has allowed entry by competitors into the hospital segment. Given the price sensitive nature of the hospital segment, competing firms (by offering substantial discounts) have been able to gain

market share. Napp's market share has fallen from approximately 96 per cent to 50 per cent in the hospital segment. However, although the hospital segment is price sensitive, it does not appear to be as price sensitive as the 2001 OFT decision found. Despite the fact that Napp's SRM products are significantly more expensive than those of its rivals in the hospital segment, it is still the biggest SRM supplier to hospitals.

- 5.8 This insensitivity appears to be due to a number of factors: 1) nature of product, given that its used to treat chronic pain in terminal patients means that there is a clinical risk of switching, 2) habit persistence on the part of doctors and pharmacists, they prefer to stick with the tried and tested, Napp has been around for 30 years and has established a very strong reputation, 3) the procurement system allows hospitals to purchase drugs off contract; so even if a contract is won through competitive tender, it does not prevent hospital pharmacists remaining with a particular brand by going directly to other pharmaceutical companies to purchase products.
- 5.9 Given the strong reputation effect in the SRM market, it is not surprising that the main beneficiary of OFT's intervention has been Archimedes (formerly Link) – they have been in the market since 1997 and thus have been able to build up a brand reputation/value. Other than Archimedes, we have not seen a substantial increase in the range of products on offer and other entrants have found it very difficult to gain a foothold in the market. Thus although there has been an impact, it has taken a substantial amount of time to occur.
- 5.10 However, there has been an increase in **generic prescribing** of SRM since 2004, indicating that clinical inertia may not be as important a factor in determining SRM prescribing choices now as it was in- 2001. The OFT's intervention may have contributed to the increase in generic prescribing of SRM, however this is not accounted for in our conservative quantitative savings estimate.
- 5.11 The evaluation has provided interesting insights into the current working of prescribing and procurement processes in different

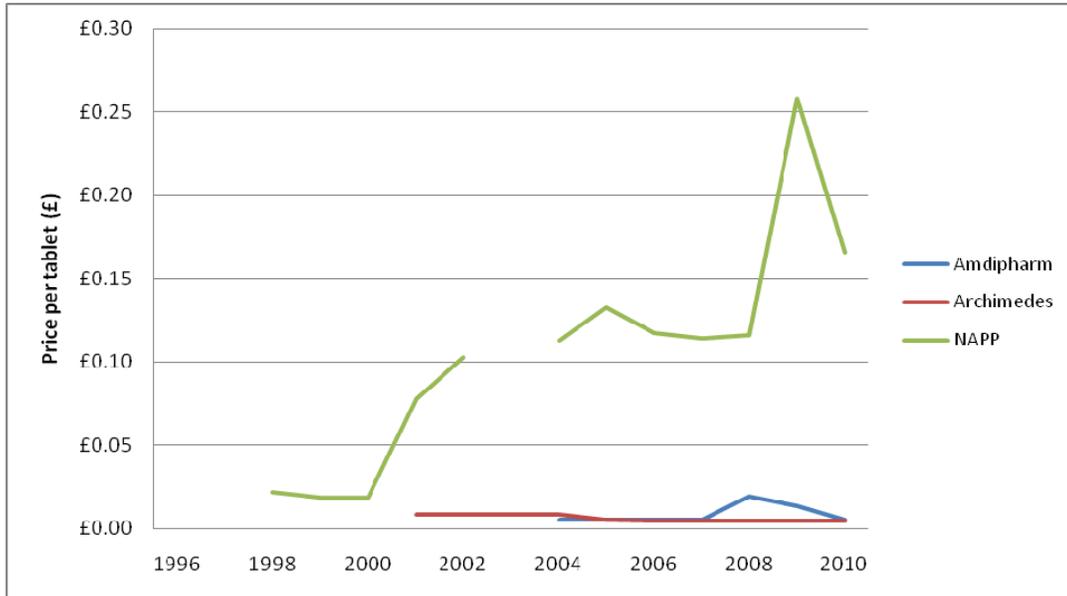
segments of the health provision market (including on the existing gap between clinicians and pharmacists and initiatives to bridge it). During the course of the project, we have shared these insights with colleagues in other parts of the office and will continue to do so in the future.

5.12 As the first evaluation which has been carried out 'in-house', we have learnt a number of valuable lessons that would be of use on future evaluation work, including on

- planning and resource implications of running such a project within a wider evaluation programme
- engagement with internal and external stakeholders (most notably on the challenges arising from reliance on other government department and bodies for data collection and analysis), and
- processes for quality assurance, including on how to optimise the combined input of internal quality assurance (including Steering Committee) and of external auditing. In addition to liaising with DH, we have engaged with Professor Steve Davies (our independent academic adviser) and his review of the report will be available on our website.

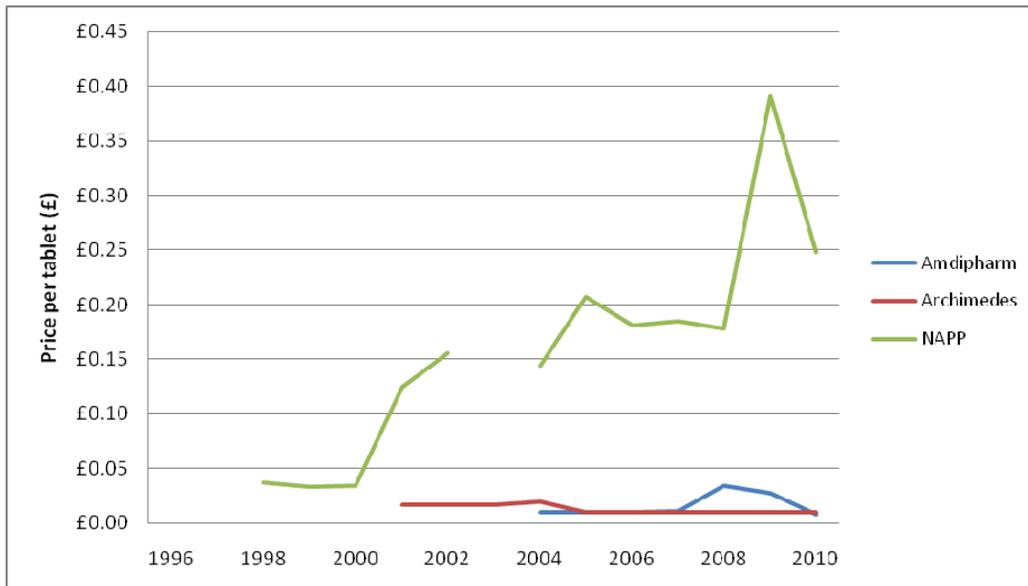
ANNEXE A: GRAPHS AND CHARTS

FIGURE A.1: PRICE OF 30MG SRM PRODUCTS (PER TABLET) IN THE HOSPITAL SEGMENT, 1996 – 2009



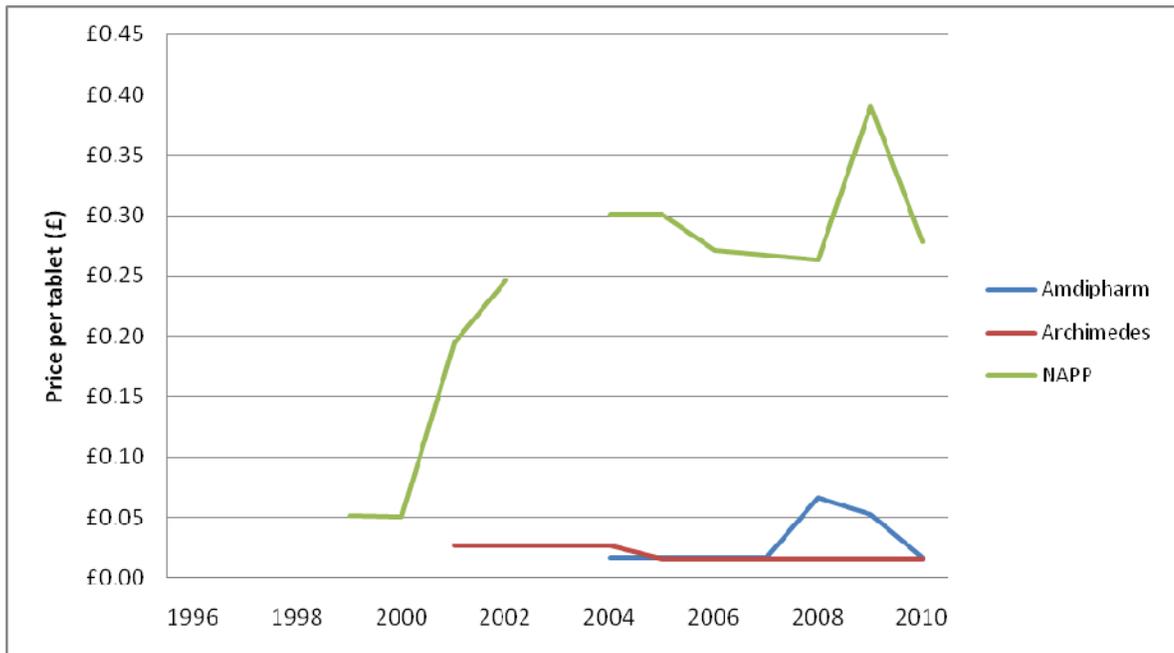
Source: Data provided by CMU, OFT analysis.

FIGURE A.2: PRICE OF 60MG SRM PRODUCTS (PER TABLET) IN THE HOSPITAL SEGMENT, 1996 – 2009



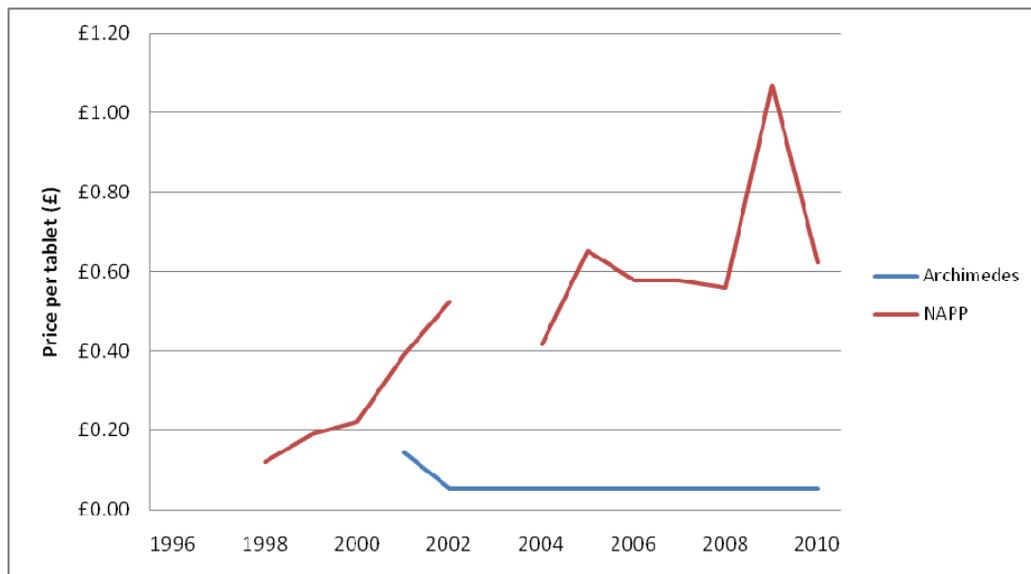
Source: Data provided by CMU, OFT analysis.

FIGURE A.3: PRICE OF 100MG SRM PRODUCTS (PER TABLET) IN THE HOSPITAL SEGMENT, 1996 – 2009



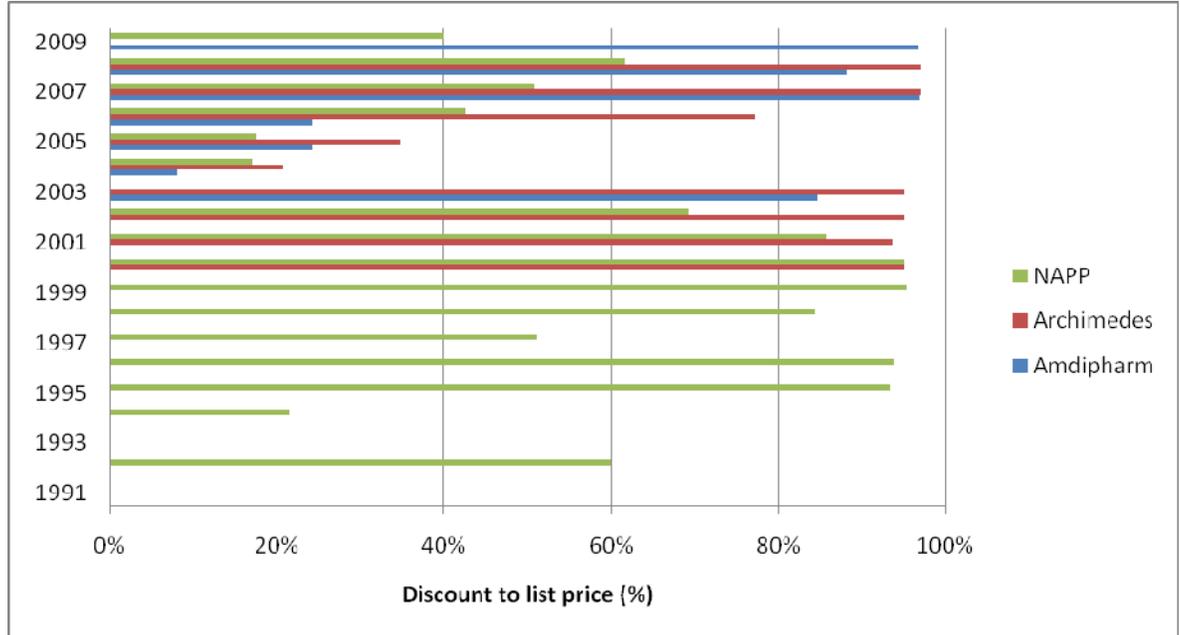
Source: Data provided by CMU, OFT analysis.

FIGURE A.4: PRICE OF 200MG SRM PRODUCTS (PER TABLET) IN THE HOSPITAL SEGMENT, 1996 – 2009



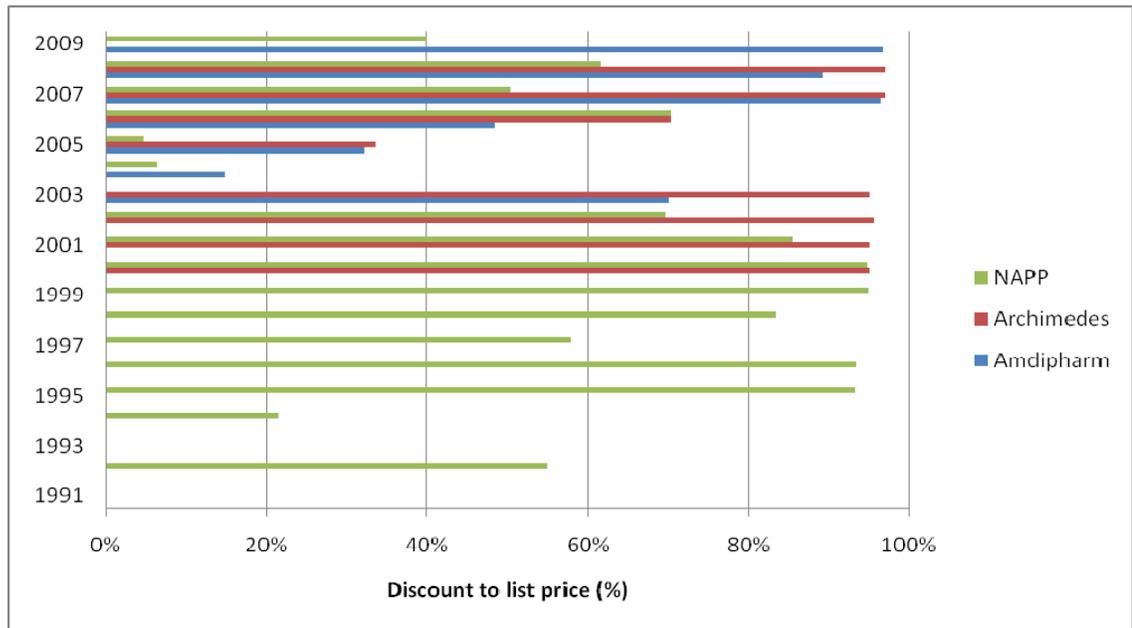
Source: Data provided by CMU, OFT analysis.

FIGURE A.5: AVERAGE DISCOUNTS ON PACKS OF 30MG SRM TABLETS OFFERED IN THE HOSPITAL SEGMENT, 1991 – 2009



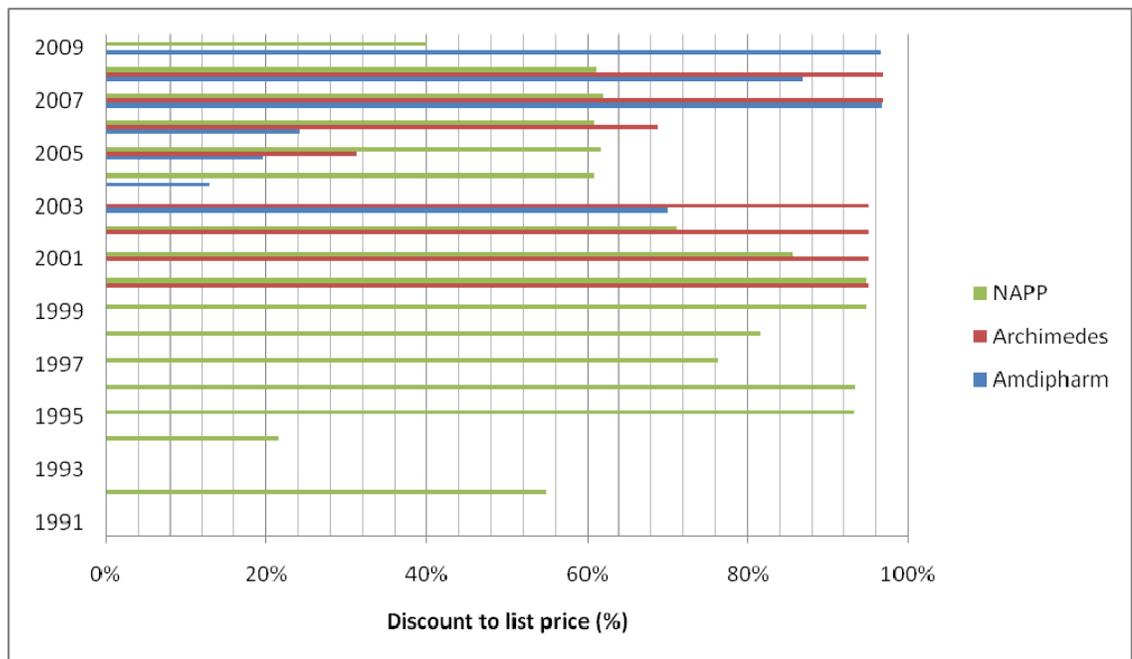
Source: Data provided by CMU, OFT analysis

FIGURE A.6: AVERAGE DISCOUNTS ON PACKS OF 60MG SRM TABLETS OFFERED IN THE HOSPITAL SEGMENT, 1991 – 2009



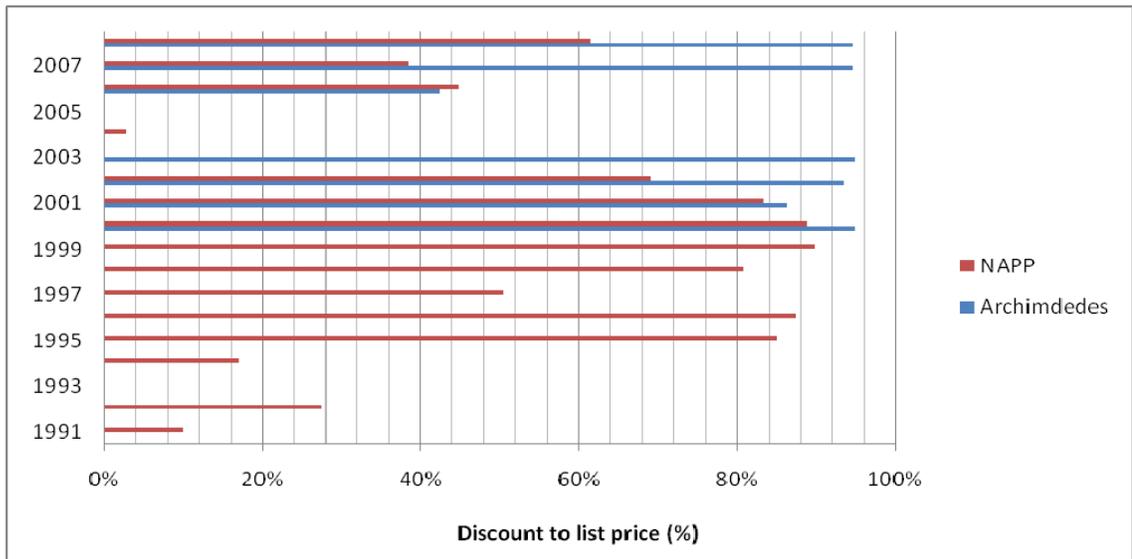
Source: Data provided by CMU, OFT analysis

FIGURE A.7: AVERAGE DISCOUNTS ON PACKS OF 100MG SRM TABLETS OFFERED IN THE HOSPITAL SEGMENT, 1991 – 2009



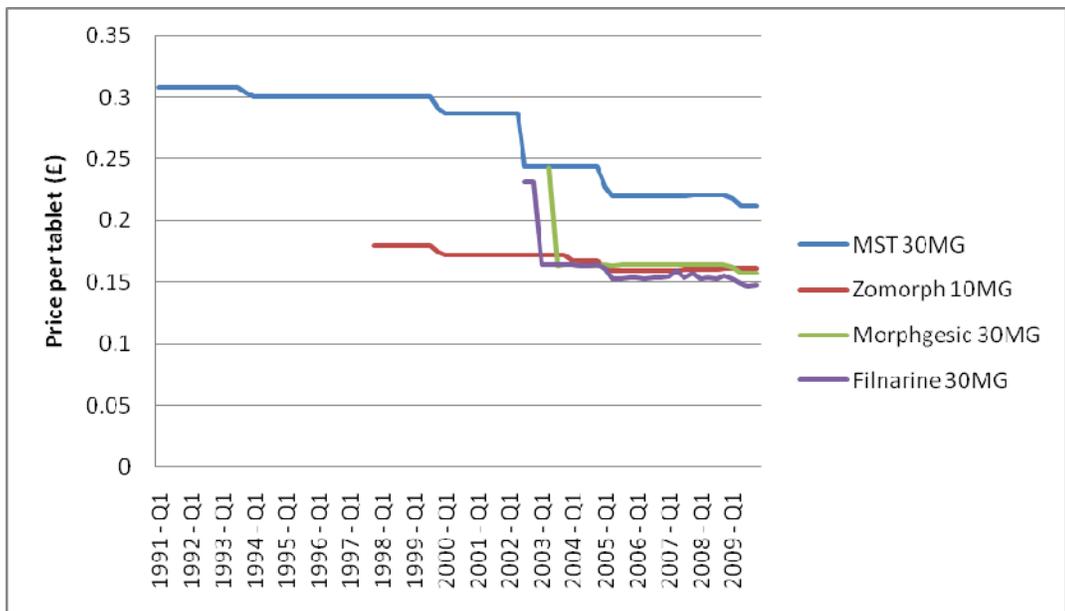
Source: Data provided by CMU, OFT analysis

FIGURE A.8: AVERAGE DISCOUNTS ON PACKS OF 200MG SRM TABLETS OFFERED IN THE HOSPITAL SEGMENT, 1991 – 2009



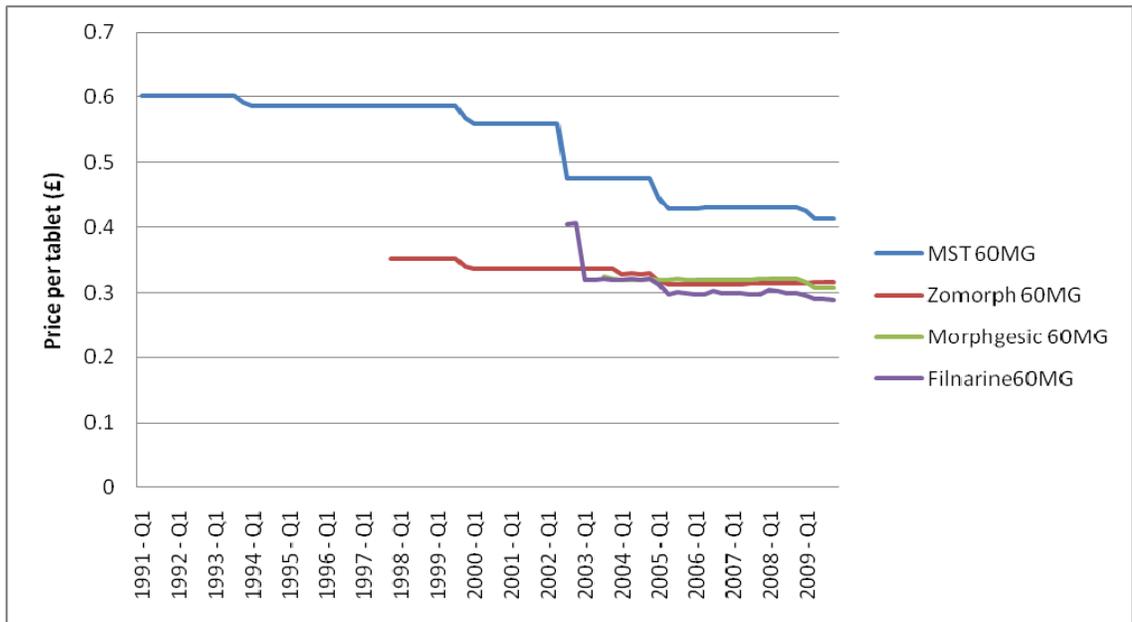
Source: Data provided by CMU, OFT analysis

FIGURE A.9: PRICE OF 30MG SRM PRODUCTS (PER TABLET) IN THE COMMUNITY SEGMENT, 2001 – 2009



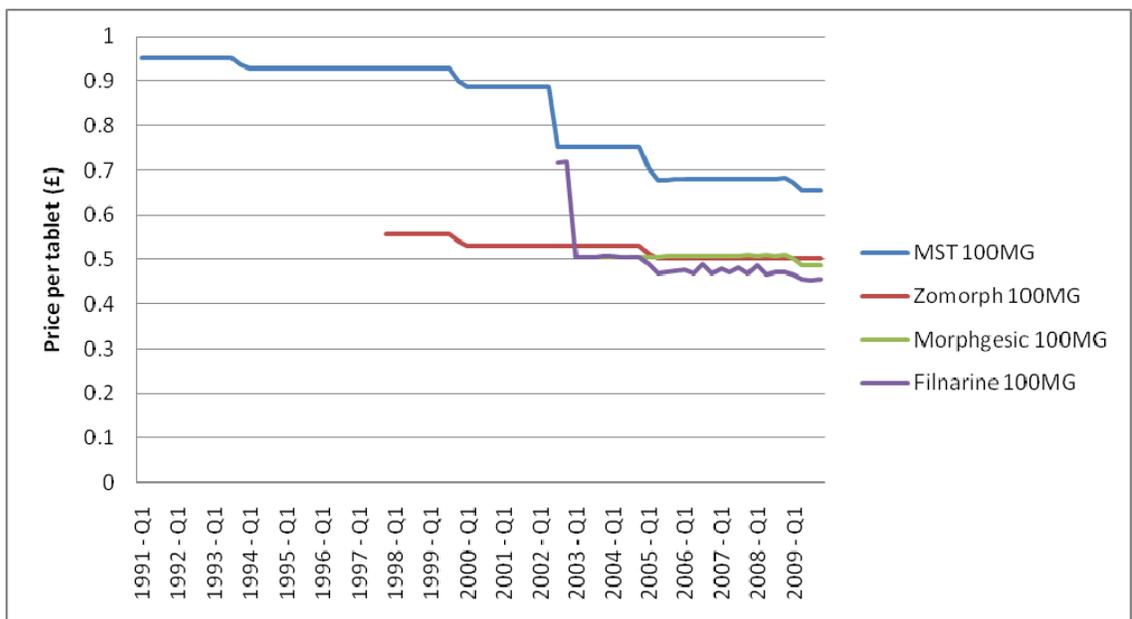
Source: Data provided by NHS Information Centre, OFT analysis

FIGURE A.10: PRICE OF 60MG SRM PRODUCTS (PER TABLET) IN THE COMMUNITY SEGMENT, 2001 – 2009



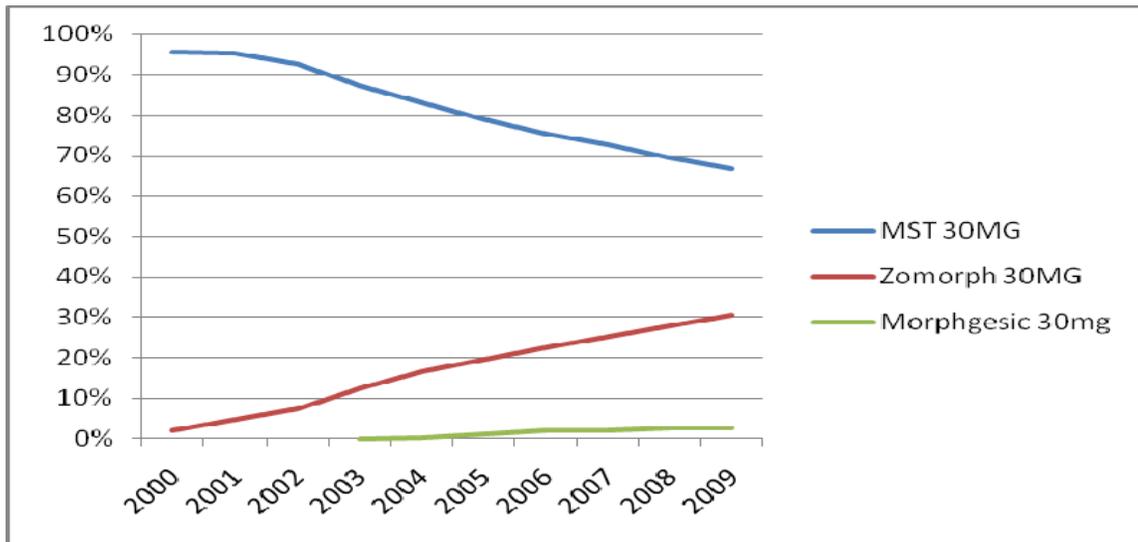
Source: Data provided by NHS Information Centre, OFT analysis

FIGURE A.11: PRICE OF 100MG SRM PRODUCTS (PER TABLET) IN THE COMMUNITY SEGMENT, 2001 – 2009



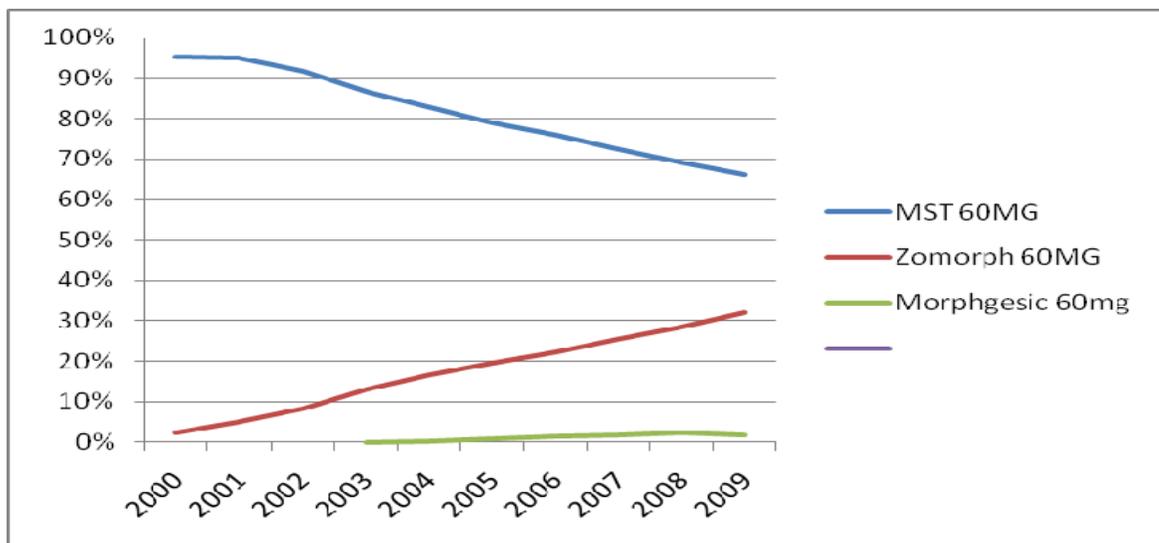
Source: Data provided by NHS Information Centre, OFT analysis

FIGURE A.12: MARKET SHARES OF SUPPLY FOR 30MG SRM TABLETS IN THE COMMUNITY SEGMENT, 2000 – 2009



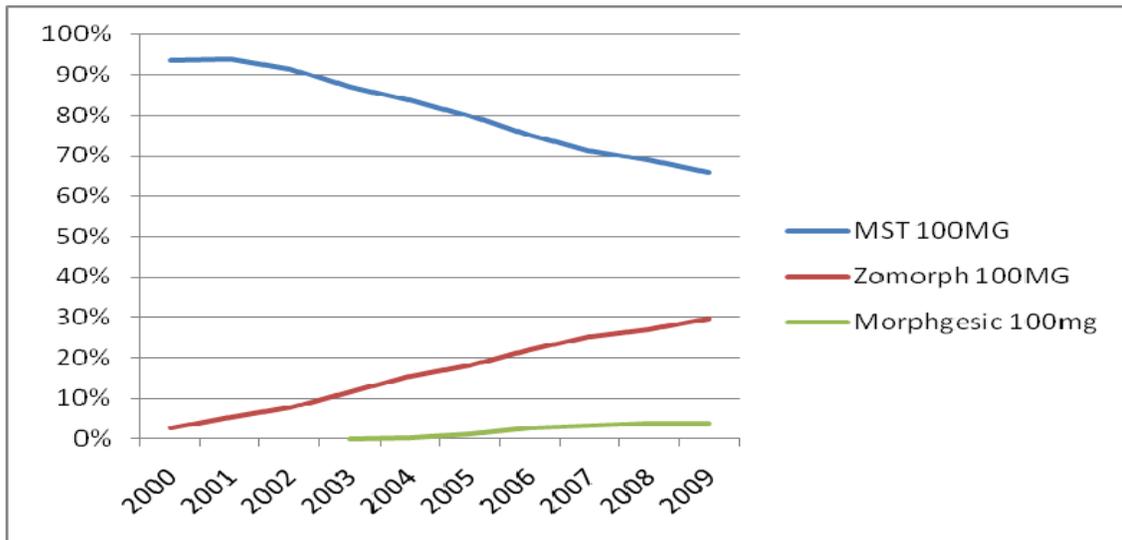
Source: Data provided by CMU/NHS Information Centre, OFT analysis

FIGURE A.13: MARKET SHARES OF SUPPLY FOR 60MG SRM TABLETS IN THE COMMUNITY SEGMENT, 2000 – 2009



Source: Data provided by CMU/NHS Information Centre, OFT analysis

FIGURE A.14: MARKET SHARES OF SUPPLY FOR 100MG SRM TABLETS IN THE COMMUNITY SEGMENT, 2000 – 2009

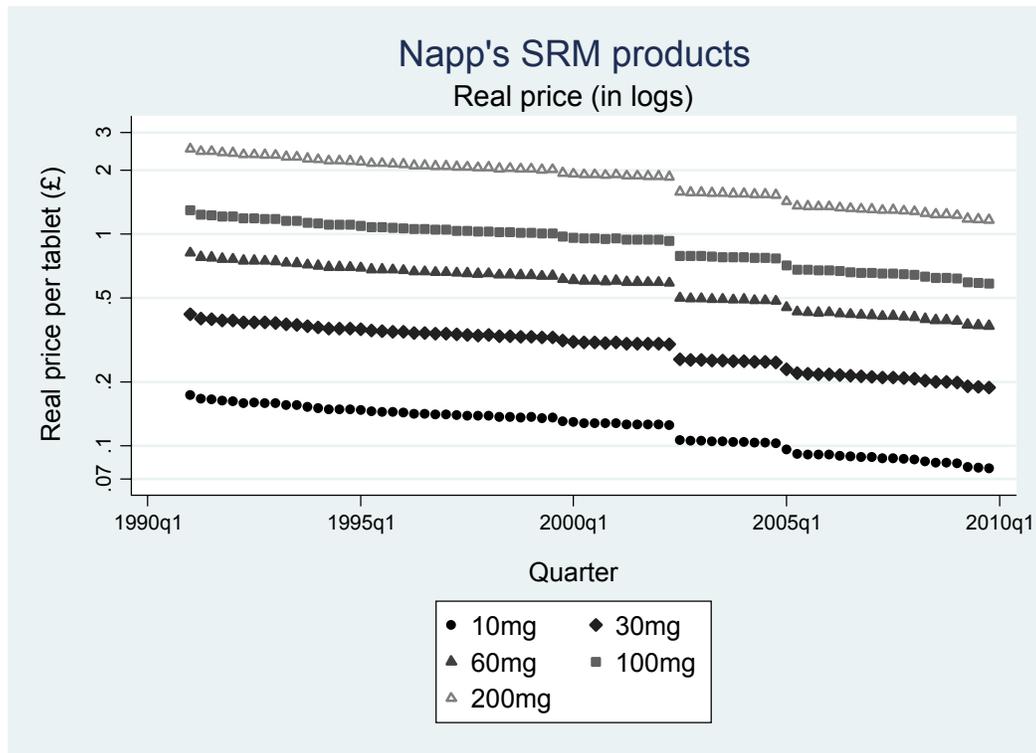


Source: Data provided by CMU/NHS Information Centre, OFT analysis

ANNEXE B – Econometric analysis of price and market shares data

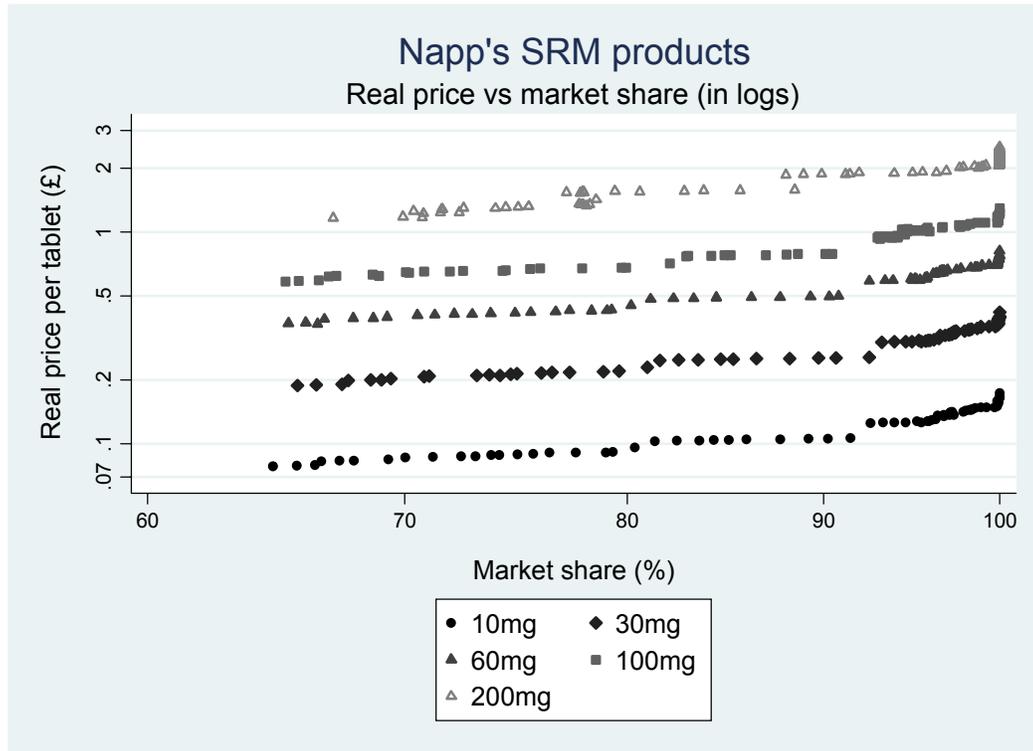
- B. 1 We have also used our data to conduct an econometric analysis of Napp's prices and market shares in the community segment. The aim was to explore in greater detail the relationship between price and market share for Napp's SRM products.
- B. 2 Although the model does not enable us to make inferences about causality and statistical significance (this is explained in more detail below), the analysis shows that lower market shares are correlated with lower prices, after controlling for dosage and the post CCAT judgement time period.
- B. 3 We obtained price and market share data for the community segment for the time period 1991 – 2009 for five of Napp's SRM products (five different dosages - 10mg, 30mg, 60mg, 100mg and 200mg). Thus, the analysis used data over time for five different dosages of Napp's SRM products. The price data reflected the price per tablet. We were unable to obtain cost data for the same time period and thus could not control for cost explicitly, but evidence from Napp's competitors indicates that costs of producing SRM have not changed significantly since 2001.
- B. 4 We used quarterly data from the ONS on the Consumer Price Index (CPI) to deflate the nominal price data, in order to obtain data on real prices. Figure B1 below plots the natural logarithm of real price per tablet over time, for the five different dosages.

Figure B1: Real price per tablet (in logs)



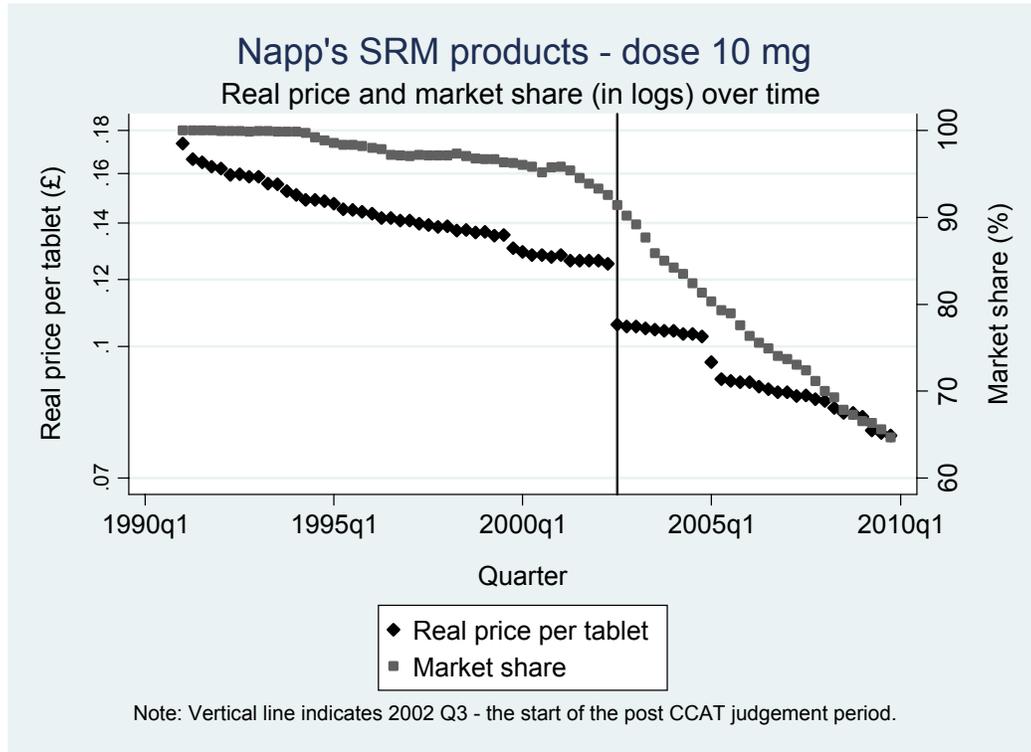
B. 5 Figure B2 shows the natural logarithm of real price per tablet plotted against the natural logarithm of Napp's market share for each of the five dosages. The figure shows that the natural logarithms of real price and market share are positively correlated.

Figure B2: Real price vs market share (in logs)



B. 6 Figure B3 shows the natural logarithm of real price and the natural logarithm of market share for the 10 mg dosage, over time. Similarly to Figure B2, Figure B3 shows that the natural logarithms of real price and market share are positively correlated.

Figure B3: Real price and market share (in logs) over time, for 10 mg dosage



- B. 7 We have modelled Napp's real price as a function of Napp's market share, a dummy variable for the post-CCAT judgement period, and dummy variables for drug dosage.
- B. 8 We have used a log linear specification for the regression, with the exact specification noted below.⁸⁰ The regression was estimated using ordinary least squares. However, once again it is important to note that we should be cautious not to draw conclusions regarding causality and statistical significance, due to the potential bias and inconsistency resulting from potential endogeneity. These issues are explored in greater detail below.

⁸⁰ In this specification t indicates quarter and d indicates dosage.

$$\ln(\text{real price}_{t,d}) = \alpha + \beta_1 \ln(\text{market share}_{t,d}) + \beta_2 \text{post CCAT judgement dummy} + \delta_1 * 30\text{mg dummy} + \delta_2 * 60\text{mg dummy} + \delta_3 * 100\text{mg dummy} + \delta_4 * 200\text{mg dummy} + \varepsilon_{t,d}$$

- B. 9 The coefficient on $\ln(\text{market share})$, β_1 , is the elasticity of real price with respect to market share, holding the other factors in the regression constant; on average, a one per cent decrease in market share is associated with a β_1 per cent decrease in real price, holding the other factors in the regression constant. The log-linear specification allows the prices for different dosages to have the same elasticity with respect to the market share for different dosages. This is what we would expect since the different products differ only in terms of their dosage.
- B. 10 We have included a dummy variable for the post-CCAT judgement period, as there was a large one off decrease in prices immediately following this judgement. The CCAT judgement stipulated a 15 per cent price decrease in the community segment, and so the dummy variable accounts for this. The dummy variable for the post CCAT judgement period is equal to one if the time period is 2002 Q3 or later, and it is equal to zero if the time period is 2002 Q2 or earlier.⁸¹
- B. 11 We have included four dummy variables for 30 mg, 60 mg, 100 mg, and 200 mg dosages (the 10 mg dosage is the default category). These dummy variables have been included to account for the fact that different dosages have different prices. For example, the dummy variable for the 30 mg dosage is equal to one if the dosage is 30 mg and is equal to zero otherwise. The other dosage dummy variables have been defined in a similar way.
- B. 12 The table below shows the results of the regression:

⁸¹ The CCAT judgement was delivered on 8 May 2002.

Table B1: Regression results

Dependent variable: Natural logarithm of real price	
Explanatory variable	Coefficient (p-value in parentheses)
Natural logarithm of market share	1.18 (0.00)
Post CCAT judgement dummy variable	-0.15 (0.00)
Dummy variable for 30 mg	0.87 (0.00)
Dummy variable for 60 mg	1.54 (0.00)
Dummy variable for 100 mg	2.01 (0.00)
Dummy variable for 200 mg	2.70 (0.00)
Constant	-7.34 (0.00)
Number of observations	380
R-squared	0.9967
Adjusted R-squared	0.9967

- B. 13 On first inspection of the regression output, it appears that the estimates of the coefficients are all statistically significantly different from zero (at the 99 per cent level of confidence). However, as discussed in more detail below, we should be cautious not to interpret the regression results as indicating causality or statistical significance. Hence, we can only interpret the results in terms of correlations.
- B. 14 The coefficient of 1.18 on market share (β_1) implies that, on average, a one per cent decrease in market share is associated with a 1.18 per cent decrease in real price, holding the other

factors constant. The coefficient of -0.15 on the post CCAT judgement dummy (β_2) shows that the CCAT ruling was associated with an approximately 15 per cent decrease in real price, holding the other factors constant.

- B. 15 The dummy variables $\delta_1 - \delta_4$ are included to account for the fact that different dosages have different prices. For example, the dummy variable for 30 mg indicates that, on average, the difference in the natural logarithm of the real price between the 30 mg tablet and the 10 mg tablet is estimated to be 0.87, holding the other factors constant. This is equivalent to the real price for the 30 mg tablet being $100 * (e^{0.87} - 1) = 139$ per cent more expensive than the 10 mg tablet, holding other factors constant, or in other words about 2.4 times more expensive, which is very similar to the actual ratio of the nominal prices. The interpretation of the other dosage dummies is similar.
- B. 16 The model has an R-squared value of 0.99, implying that 99 per cent of the variation in the natural logarithm of real price can be explained by the model. However, we should not draw any conclusions from the high R-squared value. It is possible that the seemingly high R-squared is driven by the trending nature of the dependent variable.⁸² Moreover, as discussed in more detail below, the model may suffer from bias and inconsistency as a result of potential endogeneity, due to potential simultaneity of price and market share and due to potentially omitted variables. Thus, we cannot infer that changes in market share cause changes in price, and the results of the model should only be interpreted as descriptive rather than explanatory.

⁸² Estimating a similar regression specification to the one in Table B1, but adding a linear time trend as an additional explanatory variable yields qualitatively similar results. The coefficient on the natural logarithm of market share is smaller but still positive, indicating that a positive correlation between the natural logarithms of real price and market share is still observed after including a linear time trend. The R-squared in this specification is very high, similarly to the R-squared reported in Table B1. However, since the dependent variable (the natural logarithm of real price) is trending over time, the usual R-squared may overstate the explanatory power of the model.

- B. 17 As mentioned above, the regression specification may suffer from simultaneity bias. Whilst market share probably influences price in any static relationship, it is possible that price also influences market share in a more dynamic relationship. If firms are purely statically pricing then one might expect firms with higher market power to price at higher levels. Given one might expect higher market power to be associated with high market shares, this implies a positive correlation between price and market share. However this relationship may not hold over time. With limited barriers to entry and/or expansion one may expect high prices to lead to entry or expansion from rivals, this in turn would lead to lower market shares implying a negative correlation over time.
- B. 18 As a result of the potential simultaneity of market share and price, the estimates of all the coefficients (including the estimate of β_1) may be biased and inconsistent. In order to be able to identify the effect of market share on price, we need to specify both an equation for price and an equation for market share, and we also need to have at least one exogenous variable that is in the market share equation but not in the price equation and that has a nonzero coefficient in the market share equation. Such a variable (or variables, if more than one) could be used as an instrumental variable for market share in the price equation because it would be correlated with market share; we would also need to assume that the instrumental variable is uncorrelated with the error term ε in the equation for price. Having such an instrumental variable would allow us to obtain consistent estimates of the coefficients. However, we do not have any instrumental variables available and thus cannot alleviate the potential bias and inconsistency.
- B. 19 In addition to simultaneity, the regression specification may also suffer from the potential problem of omitted variables bias. There may be additional factors we have not been able to control for that may both influence price and be correlated with market share. Unobserved demand shifts might be one such factor. Given that we have not been able to control for this and other potential omitted variables, it may be that all the estimates (and in particular the estimate of β_1) are biased and inconsistent.

- B. 20 Thus, given the potential presence of simultaneity and omitted variables, the estimate of β_1 in particular may be biased and inconsistent. As a result, the findings of the regression need to be interpreted as descriptive rather than explanatory. We cannot infer causality but we can observe a correlation between market share and price, holding other factors in the specification constant. Namely, lower market shares of Napp's products tend to be correlated with lower prices of Napp's products, having controlled for different dosages and the post-CCAT judgement period.
- B. 21 The results from our econometric analysis are consistent with the analysis conducted via descriptive statistics (and summarised in the main body of the report).

ANNEXE C – SURVEYS SENT TO GPs AND HOSPITAL PHARMACISTS

SURVEY SENT TO HOSPITAL PHARMACISTS

1. Do you provide consultants with any formal guidance on prescribing specialised drugs (for example on price), or do you not?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

If yes, please provide details:

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2. Do you have a mechanism in place to ensure you have up-to-date information on the price of branded drugs, or do you not?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

If yes, please provide brief details:

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3. Please rate the changes which, in your view, have occurred in the following aspects of the sustained release morphine (SRM) drug market since 2001

Range of SRM drugs available

substantial increase	<input type="checkbox"/>
some increase	<input type="checkbox"/>
very little change	<input type="checkbox"/>
some decrease	<input type="checkbox"/>
substantial decrease	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Price of products

substantial increase	<input type="checkbox"/>
some increase	<input type="checkbox"/>
very little change	<input type="checkbox"/>
some decrease	<input type="checkbox"/>
substantial decrease	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Please provide any further details:

4. Since 2001, have any non SRM drugs been introduced to the market as effective substitutes for SRM drugs (that is, can be used to treat the same conditions/symptoms)?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

If yes, please list and indicate when they were introduced and whether you consider them to be effective substitutes for SRM products:

5. Please rate movements in average prices (taking account of discounts) of SRM products since the OFT's case against Napp in 2001?

substantial increase	<input type="checkbox"/>
some increase	<input type="checkbox"/>
very little change	<input type="checkbox"/>
some decrease	<input type="checkbox"/>
substantial decrease	<input type="checkbox"/>
don't know	<input type="checkbox"/>

6. Have the discounts on the various SRM products narrowed since the OFT's case against Napp in 2001, or not?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Please provide further details:

--

7. How do the discounts (to list price) offered on SRM products compare to discounts offered on other types of drugs?

larger discounts	<input type="checkbox"/>
similar	<input type="checkbox"/>
smaller discounts	<input type="checkbox"/>
don't know	<input type="checkbox"/>

8. Typically, how many bids do you receive per contract you award when procuring specialised drugs (such as sustained release morphine)?

--

9. Specifically for SRM drugs, has the number of bids you receive per contract you award changed since 2001, or not?

--

10. Do you typically enter into exclusive agreements with pharmaceutical companies for specialised drugs, or do you procure from more than one provider?

--

11. Do you have access to information on patents on popular drugs and when they are set to expire, or do you not?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

If yes, please provide brief details:

--

12. Do you discuss with the Prescription Pricing Authority (PPA) any differences in prices of specialised drugs (for example, SRM) between the hospital and community segments, or do you not?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

13. Please add any additional points you would like to make:

--

14. Would you be willing to speak with us in greater detail about any of these issues?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

15. If you have answered yes to Q14, please provide contact details OR email us at rohan.sawhney@oft.gsi.gov.uk.

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Thank you very much for your participation in our survey.

SURVEY SENT TO GPs

1. When deciding between prescribing two therapeutically equivalent drugs, how important are the following factors in your decision?

a) Length of time the drug has been on the market

very important	<input type="checkbox"/>
fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

b) Price of the drug

very important	<input type="checkbox"/>
fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

c) Reputation of brand/company manufacturing the drug

very important	<input type="checkbox"/>
Fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

d) Previous treatment patient has received

very important	<input type="checkbox"/>
fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

e) Recommendation from colleagues

very important	<input type="checkbox"/>
fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

f) Your experience of prescribing to previous patients

very important	<input type="checkbox"/>
fairly important	<input type="checkbox"/>
of little importance	<input type="checkbox"/>
unimportant	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Other factors (please specify nature and relevance):

--

2. Do you view the following sustained release morphine (SRM) drugs as therapeutically equivalent to MST tablets (produced by Napp) or not?

Morphgesic SR tablets (produced by Amdipharm)

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Zomorph capsules (produced by Archimedes Pharma)

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Oramorph tablets (produced by Boehringer Ingelheim)

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Filnarine SR tablets (produced by Teva Pharmaceuticals)

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

3. When a patient is discharged from secondary care and still requires SRM, do consultants recommend a particular brand to GPs?

always	<input type="checkbox"/>
sometimes	<input type="checkbox"/>
never	<input type="checkbox"/>
rather not answer	<input type="checkbox"/>

4. Please rate the changes which, in your view, have occurred in the following aspects of the SRM market since 2001

Range of SRM drugs available

substantial increase	<input type="checkbox"/>
some increase	<input type="checkbox"/>
very little change	<input type="checkbox"/>
some decrease	<input type="checkbox"/>
substantial decrease	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Price of products

substantial increase	<input type="checkbox"/>
some increase	<input type="checkbox"/>
very little change	<input type="checkbox"/>
some decrease	<input type="checkbox"/>
substantial decrease	<input type="checkbox"/>
don't know	<input type="checkbox"/>

Please provide any further details:

5. Since 2001, have any non SRM drugs been introduced to the market as effective substitutes for SRM drugs (that is, can be used to treat the same conditions/symptoms)?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>
don't know	<input type="checkbox"/>

If yes, please list and indicate when they were introduced and whether you consider them to be effective substitutes for SRM products:

6. Please add any additional points you would like to make:

7. Would you be willing to speak with us in greater detail about any of these issues?

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

8. If you have answered yes to Q7, please provide contact details OR email us at rohan.sawhney@oft.gsi.gov.uk.

Thank you very much for your participation in our survey.