Adoption of a Cost-Saving Innovation:
Germany, UK and Simvastatin

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Abstract
We examine how the UK and German health care systems responded to a major cost-saving innovation: the availability of generic simvastatin, a cholesterol-lowering drug. In the German Social Health Insurance, the generic's entry reduced sales volumes for both branded simvastatin (Zocor) and a close substitute, branded atorvastatin (Lipitor/Sortis). In UK, only the sales of branded simvastatin fell whereas the sales of atorvastatin were mostly unaffected. We trace these experiences to institutional differences in the two health care systems and to the structure of patient cost-sharing in particular.

Zusammenfassung
Wir untersuchen die Reaktionen des britischen und des deutschen Gesundheitssystems auf eine der bedeutendsten kostensparenden Innovationen: die Verfügbarkeit von generischem Simvastatin, einem cholesterinsenkenden Medikament. Die Zulassung des Generikums senkte bei den gesetzlichen Krankenkassen in Deutschland die Verkaufsvolumen sowohl bei dem Markenprodukt Simvastatin (Zocor) als auch bei einem sehr ähnlichen Ersatzwirkstoff, dem Markenprodukt Atorvastatin (Lipitor/Sortis). In Großbritannien führte die Zulassung nur bei dem Markenprodukt Simvastatin zu geringeren Verkaufszahlen, wohingegen der Verkauf von Atorvastatin kaum betroffen war. Wir führen dies auf institutionelle Unterschiede beider Gesundheitssysteme und besonders auf die Struktur der Kostenbeteiligung des Patienten zurück.

Published as: McGuire, Thomas, and Bauhoff, Sebastian. "Adoption of a Cost-Saving Innovation: Germany, UK and Simvastatin" In: *England and Germany in Europe – What Lessons Can We Learn from Each Other?*, edited by Klusen, N., F. Verheyen and C. Wagner, p. 11-26. Baden-Baden, Germany: Nomos Verlag, 2011

Introduction

Health care systems can be compared in terms of costs (spending per capita, share of GDP devoted to health care, spending growth), outcomes (longevity, maternal death rates), and fairness (solidarity in financing, disparities in services), all system metrics determined by many factors. Working with such aggregates has some limitations. A finding, for example, that Germany spends more per capita than the UK on health care, calls attention to an issue, but, by itself, has no direct implication for health policy. Furthermore, an overall measure, like spending, averages many activities. It is unlikely, comparing two health care systems, that one will be superior to another in all components of the average. For identification and exchange of productive approaches – for mutual learning – specific comparisons are more likely to uncover instances where one system solves a problem more effectively than another.

This paper compares the German and UK health care systems as they respond to a particular cost saving innovation: the availability in 2004 of the generic statin, simvastatin, previously sold as Merck's branded Zocor. Statins, a widely used and effective class of cholesterol-reducing drugs, were developed based on research on cholesterol synthesis at the Max Planck Institute in the 1950s. Statin drugs, while effective, are costly to health payers. In 2004, another branded statin, Lipitor (atorvastatin, sold as Sortis in Germany) was the largest selling drug, with world-wide sales of US$12.0bn; in the same year, Zocor was the second largest selling drug with sales of US$5.9bn (OFT 2007: 39).

Simvastatin was the first widely used statin to be available as a generic. How did the health care systems in Germany and the UK respond to this opportunity? Specifically, how quickly was the generic version available in each country? At what price to the national health system (and to consumers)? How rapidly did simvastatin displace Zocor? Finally, and here is where Germany and UK will diverge the most: to what degree did simvastatin substitute for Lipitor?

In the following sections we first outline the coverage and pricing practices for pharmaceuticals in Germany and the UK.[1] We highlight key differences between the systems in the managing of generic entry with regards to regulatory processes and consequences for the patented drug. We then turn to the experience with generic simvastatin, which had large impacts on an important segment of the prescription drug market in both countries. The differential impact in Germany and the UK reflects the regulatory and institutional variations that underlie the adoption of cost-saving technology in these contexts.

Drug review, coverage and pricing

German Social Health Insurance

In the German Social Health Insurance (SHI), coverage and pricing decisions are made by a joint federal committee (*Gemeinsamer Bundesausschuss*).[2] Most covered drugs are subject to reference pricing, whereby the joint committee determines the drug groupings and the

1 Kanavos, Costa Font and McGuire (2007) compare the markets for and regulation of drug policies in UK, Germany, Netherlands and France in relation to branded statin products over the period 1991-2002.
2 The committee consists of physician, dentist, hospital and sickness fund representatives. In this section we focus on outpatient prescribing.

reference price as maximum reimbursement through the funds.[3] There are three forms of reference groups, depending on the included drugs. The reference price is set within the lower-third of the included drugs' market prices since 2006; at least a fifth of prescriptions and packages must be at or below the reference price (§ 35 SGB V). In addition to the SHI-wide reference price, individual funds can negotiate rebates with manufacturers in exchange for exclusivity in generic supply.

Until recently, manufacturers were free to set the prices for new, patented drugs. The November 2010 health reform (*Arzneimittelmarktneuordnungsgesetz*, active from January 2011) constrains the price-setting ability depending on whether a new molecule provides additional benefits. Under the new regulations manufacturers remain free to set initial prices. However, this price is revisited in the first 3-12 months as the joint committee assesses whether the drug provides benefits relative to existing treatments. If the committee recognizes no additional benefit, the reference price applies. If the manufacturer can demonstrate additional benefits, the firm and sickness funds (as a group) negotiate a reimbursable price. An independent arbiter will determine a price if the funds and manufacturer do not come to a resolution within 12 months.

Physicians are only subject to weak incentives regarding pharmaceuticals. Physician associations and sickness funds agree on regional targets for pharmaceutical expenditures, which are then applied to individual practices. In principle, practices were responsible for costs exceeding prescribing budgets yet these fines have rarely been imposed (Brandt, 2008; Kanavos *et al*., 2008). An additional but short-lived *bonus-malus* rule for specific groups of drugs created financial incentives for individual physicians to limit (over-) prescribing. However, this rule was abolished in the 2010 reforms (BMG, 2010).

Pharmacies play a central role in the German system. First, they are responsible for collecting copayments, which are described below. Second, pharmacists are required to substitute toward cheaper drugs with the same chemical, concentration and package size, unless the prescription precludes substitution (*aut idem* rule). Pharmacies are also responsible for dispensing according to any rebate contracts that individual funds may have negotiated with generic manufacturers.

Finally, patients are subject to copayments of 10% of the sales price and between 5 and 10 Euro per prescription; this copayment is transferred to the sickness funds.[4] The sales price is the price paid by consumers in the pharmacy and consists of the manufacturer's price plus margins for wholesalers and the pharmacy. In cases where the reference price applies, patients are also responsible for any costs beyond this price: since the reference price determines the reimbursement by the sickness funds, patients must self-finance the difference between the reference and sales prices. Conversely, all copayments are waived for drugs that are at least 30% below the reference price. Copays may also be reduced for medications purchased under a rebate contract. Because the reference price plays an important part in determining patient copays, physicians must inform patients when prescribing a drug that is priced above the reference price.

Table 1 illustrates the current structure of patient copayments for Lipitor, and branded and generic simvastatin in Germany. These drugs are subject to the same reference price but have substantially different sales prices. In particular, Lipitor is priced substantially above than

3 The distribution via wholesale and pharmacies adds an additional cost to pharmaceuticals. Both institutions receive a regulated flat fee and percentage of the drug's price. Manufacturers must offer a mandatory discount to all sickness funds; this discount been temporarily modified several times.

[4] Children below the age of 18 are exempt from these copays, and pharmaceutical expenditures count toward an income-related cap on total out-of-pocket costs.

the reference price, leading to high patient copays. The generic simvastatin hits the floor of the statutory copay of 5 Euro.

Table 1: Example of copayments for selected statins (Euro)

	Sortis / Lipitor (Atorvastatin)	Zocor (Simvastatin)	Generic (Simvastatin)
Sales price	57.36	22.66	13.34
Reference price	13.36	13.36	13.36
Diff. sales – reference price, if positive	44	9.30	n/a
Regular copay	5 (min copay)	5 (min copay)	5 (min copay)
Total patient copay	**49**	**14.30**	**5**

Notes: example for fourth quarter of 2010 and package of 30 film tables of 20mg active ingredient. The generic simvastatin is produced by ratiopharm. Prices from DIMDI, 2010.

United Kingdom National Health Service

The UK National Health Service (NHS) uses separate pricing schemes for branded and generic drugs. The Pharmaceutical Price Regulation Scheme (PPRS) applies to patented drugs. The Scheme determines list prices indirectly by setting profitability and is negotiated between the Department of Health and the pharmaceutical industry association for a period of about 5 years. Manufacturers are free to set initial prices for New Active Substances but subsequent price increases are subject to approval.[5] In practice, these price controls are more binding than the profit controls (OFT, 2007).

Reimbursement rates for generics under the Drugs Tariff are based on volume-weighted average ex-factory prices across available generics in the UK. Since the amount paid to the pharmacy is not tied to the pharmacy's actual cost, this procedure has led to sharp declines in generic prices: in 2005, the average annual decrease in generic prices in the UK was nearly 5 times higher than Germany (32.4 and 6.9% respectively; see OFT, 2007-A: 62).

As in Germany there are weak controls on prescribing at the physician-level. While the National Institute for Clinical Excellence (NICE) offers guidelines that include considerations for cost-effectiveness and the British National Formulary points to generic prescribing for each drug entry, GPs are free to choose among therapeutically equivalent medicines. Moreover, financial incentives for GPs to prescribe cost-effective medications are limited: the key contracting arrangements are between the Primary Care Organizations (PCO) and GP practices rather than individual physicians, and the contract specifies mostly clinical targets that may not align with cost-containment considerations (OFT, 2007-A). PCOs may use local incentive structures to manage prescribing, but overall GPs have been found to "have weak knowledge of the prices of some of the most widely-prescribed drugs in the UK" (OFT, 2007: 2) and are presumed to be relatively insensitive to drug prices in their prescribing decisions.[6]

[5] The profit and price controls apply at the level of the manufacturer rather than specific drugs. The PPRS updates may include temporary, across-the-board price cuts. Manufacturers can "modulate" prices of individual drugs in their portfolio to achieve these savings. The repeated use of these cuts has led to concerns about strategic behavior by manufacturers as they anticipate future adjustments (e.g. OFT, 2007).

[6] The practice-level incentive schemes and, from 2004, the Quality Outcomes Framework may have increased price sensitivity, but the available evidence is mixed (Walley *et al*., 2005).

Prescriptions are issued for a specific brand or written generically using the chemical's name, and dispensing and reimbursements at the pharmacy-level vary accordingly. When the physician explicitly prescribes the brand, or when the physician writes the chemical and no generic is available, pharmacists must dispense the brand and the associated reimbursement is based on manufacturers' list prices as governed by the PPRS.[7] For a generically written prescription the reimbursement is based on the average price of generics in the market plus a dispensing margin which represents a financing arrangement between the NHS and pharmacies.[8] The two parallel approaches to determining reimbursements imply that dispensing margins on generics are higher than margins on branded drugs.

Patients contribute flat-fee copayments (of £7.40 in England as of April 1, 2011) for medication purchases, the same for brand or generics. Many exemptions (young, old, unemployed) imply that the majority of prescriptions are free. Overall patients in England pay only 5.6% of drug costs (OFT, 2007: 14).

Table 2 summarizes the key features from this and the previous section. Overall the pricing for generics in the UK is more aggressive than in Germany since it is constructed as volume-weighted average, and pharmacies have a strong incentive to shop for the lowest cost source. The default substitution in the pharmacy and variable patient copayments in Germany imply there is likely to be a greater response to high manufacturer prices for a brand in the presence of generic alternatives.[9]

[7] The reimbursements are based on predetermined price schedules (list and ex-factory prices) rather than actual prices paid, so that pharmacies have incentives to procure from the cheapest source, including parallel imports. Since pharmacies may receive discounts from manufacturers of branded and generic drugs, the NHS shares potential profits through a variable clawback payment (the average payment is 9.2% of total monthly reimbursements; OFT, 2007: 30). The clawback creates a wedge between the list price and actual reimbursement.

[8] As procurement agents for PCOs, pharmacies receive a guaranteed level of income that is operationalized through contractual dispensing margins. This retained profit margin is achieved mainly through manipulation of the reimbursement rates of generics in Category M of the Drugs Tariff (OFT, 2007: 32; OFT, 2007-A: 52).

[9] The Office of Fair Trading (OFT, 2007: 15) was critical of incentives to substitute in the UK. "As these brief descriptions suggest, demand for drugs within the NHS (particularly in primary care) is characterised by a complex set of principal-agent relationships, in which:

• the person who consumes the drug (the patient) neither decides nor, in most cases, pays
• the person who decides which drug should be used (the prescribing doctor) neither pays nor consumes, and
• the institution that pays for the drug (the NHS / Government) neither consumes nor decides."

Table 2: Key features of pharmaceutical policies in the UK and Germany

	UK	Germany
Supply-side measures		
Generic firms allowed to complete regulatory requirements prior to patent expiry (Bolar provisions)	Y	Y
Price cap	Y	
Reference pricing		Y
Proxy demand-side policies		
Promoting generic prescribing	Y	Y
Compulsory generic prescribing		
Prescribing monitoring and audit	Y	Y
Default generic substitution at pharmacy		Y
Flat fee combined with regressive margin for pharmacy		Y
Flat fee for pharmacy		
Discounting allowed for pharmacy	Y	
Clawback of pharmacy profits	Y	
Demand-side policies		
Differential co-payments		Y
Flat fee	Y	

Source: based on Kanavos (2008) and Kanavos et al (2008), with modifications. Y=yes.

Managing generic entry in Germany and the UK

How do the German and the UK institutions outlined above handle the introduction of a generic drug? In Germany, the entrant would fall into a reference group with an associated price that represents the maximum reimbursable cost for sickness funds. Individual sickness funds could negotiate rebate contracts with the manufacturer, triggering default substitution in the pharmacy and lower copayments for their patients. Physicians must inform patients if a prescribed drug is priced above the reference price and hence generates higher patient copays. As result, physicians may be price responsive agents for patients who are at risk for cost-sharing.[10]

In the UK, the generic would be priced under the Drug Tariff, i.e. as function of ex-factory prices and market shares of other generics. GPs are not required to switch patients to the cheaper medication. Any updates in prescribing guidelines by NICE are not binding and the financial incentives to substitute are weak for individual physicians. Substitution yields no savings in copayments for patients that could outweigh any transaction costs from switching.[11] As consequence, there is little cause to switch patients to the generic, or to write the prescription with the chemical's name so as to allow substitution in the pharmacy. The potentially rapid decline in generic prices under the Drug Tariff's pricing formula increases pharmacy margins for generics but are not transmitted to either physicians or patients.

A comparative perspective from the United States

In the U.S., drug coverage and pricing is decentralized to private managed care plans and public purchasers. Most private payers use three-tier formularies, with generic drugs on the first

[10] Direct-to-consumer advertising of prescription drugs is not allowed in Germany, possibly further increasing the cross-price elasticity.

[11] In addition, the different approaches for pricing branded and generic drugs (particularly the dispensing margins) can mitigate the price differential from the GP perspective.

tier requiring a small copayment from the patient, "preferred brand" drugs on the second tier requiring a moderate copayment, and other branded drugs on the third tier requiring the highest copayment (KFF, 2009).[12]

A drug formulary encourages use of lower-priced generics when these are available, and more generally, encourages, by favorable tier placement, medications the plan regards to be more cost-effective (Grabowski and Mullins, 1997). A formulary also puts a plan in good bargaining position with manufacturers, especially in the presence of therapeutic alternatives among branded drugs for treating particular conditions. Plans do not put all drugs for some conditions on the formulary. By choosing the drug or drugs for favorable formulary placement, the plan can offer a manufacturer favorable tier placement – which translates into higher sales volume – in exchange for rebates (Huskamp *et* al, 2003; Grabowski and Mullins, 1997; Frank, 2001).[13]

A typical drug formulary in a managed care plan covers only some of the many available statins. Duggan *et al.* (2008: 77-78) examined the inclusion on formularies of 20 of the top-selling brand name statin drugs in three large private Part D plans serving Medicare beneficiaries in California in 2007.

> "The formulary status and prices of each drug vary substantially across plans. In the AARP plan, for example, five of the 20 drugs were preferred, eight were nonpreferred, and the other seven were off-formulary [no coverage]. In the WellCare plan, three were preferred, on nonpreferred, and 16 off-formulary. In the Sierra plan, four were preferred and 16 were off-formulary…There was little overlap between these plans in formulary placement; for example, only one drug (Zetia) was on the preferred tier in all three plans. This latter finding suggests that statin manufacturers were selective in providing discounts to these plans in exchange for better (or exclusive) formulary placement."

Generic drugs, like simvastatin, are always first-tier in formularies. (One of the authors of this paper gets his 90-day supply of simvastatin by mail for a US$15 copay.)[14]

Once a generic version of a drug becomes available in the U.S., state-level regulations lead to aggressive and immediate substitution for the brand. Even if the physician writes "Zocor" on the prescription, pharmacies dispense a generic. Formulary coverage policies reinforce the substitution, so that within about two months of generic entry, brand sales fall to less than 10% of the pre-generic level.[15]

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[12] Danzon and Ketcham (2004) discuss differences between formularies and therapeutic reference pricing.

[13] Huskamp *et al.* (2003: 154) find savings of about 30% by the Veterans' Administration when it established closed classes in its national formulary.

[14] The website for Medco (a pharmacy benefit manager) for Harvard employees indicates that the branded statins on Tier 2 are Lescol, Lipitor, Altoprev, Livalo, Crestor, Mevacor and Pravachol. Comparing Simvastatin and Liptior, the website reports:

	Annual Costs		
	You pay	Plan Pays	Total
Simvastatin	$60	$168.71	$228.71
Lipitor	$140	$1445.04	$1585.04

There is also the following disclaimer: "The cost that is displayed, however, does not include any additional discount or other incentives your plan may receive from your use of this medication."

[15] For a recent review, see Berndt and Newhouse (2010). The drug patent regulations in the U.S. were reformed in 1984, extending in some cases, patent life for new drugs, but encouraging generic entry and legal challenges to patents. The upshot is that in some cases drugs go off patent in the U.S. later than in other countries. This was true for Zocor which didn't have generic competition in the U.S. until 2006. Berndt and Newhouse (2010) also discuss U.S. patent policy.

Simvastatin Experience

Statins are a major drug class of cholesterol-reducing medications and include a variety of active ingredients, most importantly in terms of sales, atorvastatin and simvastatin. Atorvastatin is still under patent by Pfizer and sold under the brand name of Lipitor (Sortis in Germany). Simvastatin is the active ingredient in Zocor, a product of Merck. When used in their standard dosage, atorvastatin and simvastatin have similar clinical outcomes (e.g., Zhou et al, 2006) and are considered close substitutes for the majority of patients. Statins represent a large share of prescription drug expenditures worldwide.

The expiration of Merck's patent on simvastatin in May 2003 in Germany and the UK, and the subsequent emergence of generic simvastatin were associated with large shifts in the prices and use of statins in both countries. Generic simvastatin provides a useful case study of a potentially disruptive cost-saving technology that the German and UK institutions translated into different outcomes for the health systems. In this section we chronicle the impact of generic simvastatin on the branded Zocor and the therapeutic substitute Lipitor.[16] While generic simvastatin led to a precipitous drop in market share for Lipitor in Germany, it did not have corresponding impact on Lipitor sales in the UK. The market share of Zocor declined steeply in both countries as generic competitors entered. We trace these experiences to institutional differences in the two health care systems.

Prices and market shares

Zocor lost patent protection in Germany in May 2003, leading to the immediate entry of generic producers and a rapid switch from branded to generic simvastatin.[17] This may be due to the *aut idem* substitution in the pharmacy, which encourages lower priced products.

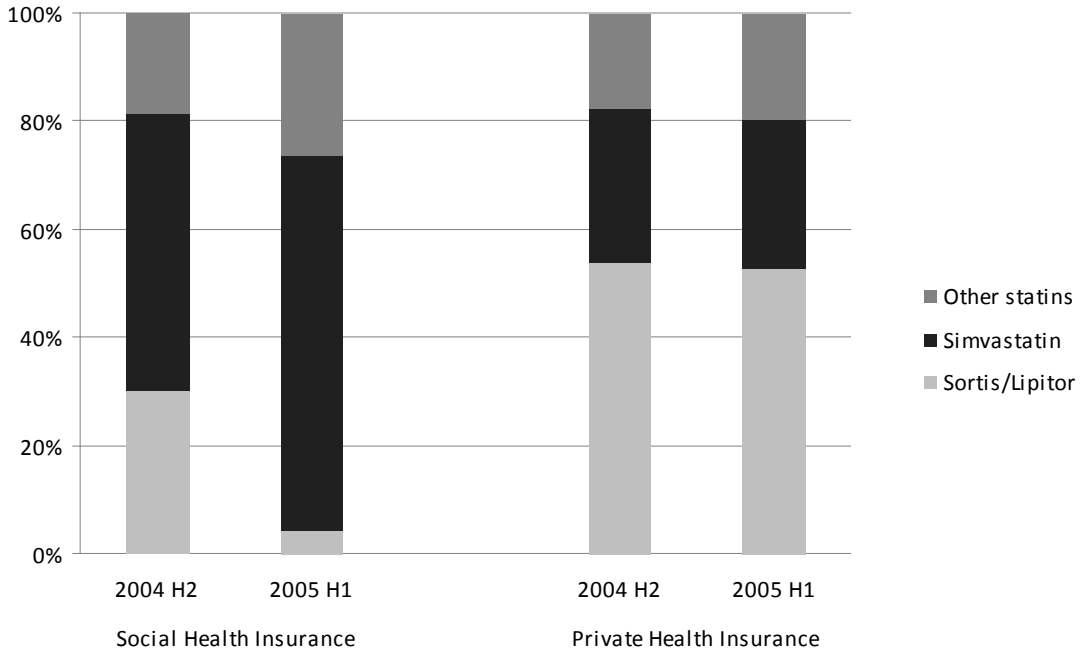
In addition, the expiration of Zocor's patent impacted the market for its close but patented substitute, Lipitor. The joint federal committee created a single reference group for all statins in 2004, with a common reference price from January 2005. The reference group includes drugs that are on-patent and therapeutically similar, making Lipitor subject to the reimbursement ceiling. Pfizer mounted a legal challenge against the application of the reference price but lost in the first and appeals instances (G-BA, 2010).

Figure 1 shows the evolution of market shares by molecule in the German statin market before and after the introduction of the reference pricing in January 2005. Despite the significant gap between the sales and reference prices for Lipitor, Pfizer did not reduce Lipitor's price, leading to a significant increase in patient copayments for Lipitor. The consequence was a sharp drop in Lipitor's market share from the second half of 2004 to the first half of 2005, mostly to the benefit of simvastatin. Lipitor maintained its market share in the private health insurance, which was not subject to the copay shock.

[16] Throughout we compare atorvastatin and simvastatin of similar package sizes, delivery modes and strength. Although the potency of these two ingredients differs somewhat, we adopt OFT's (2007-A: 41) view that adjusting for potency does not lead to different substantive conclusions because of the very large price differences.

[17] Prior to patent expiration, Merck introduced its own "fighter brand" Zocor MSD and sold early-entry rights to a generics producer. As result, the market share of branded Zocor started declining from early 2003 (Raasch, 2006).

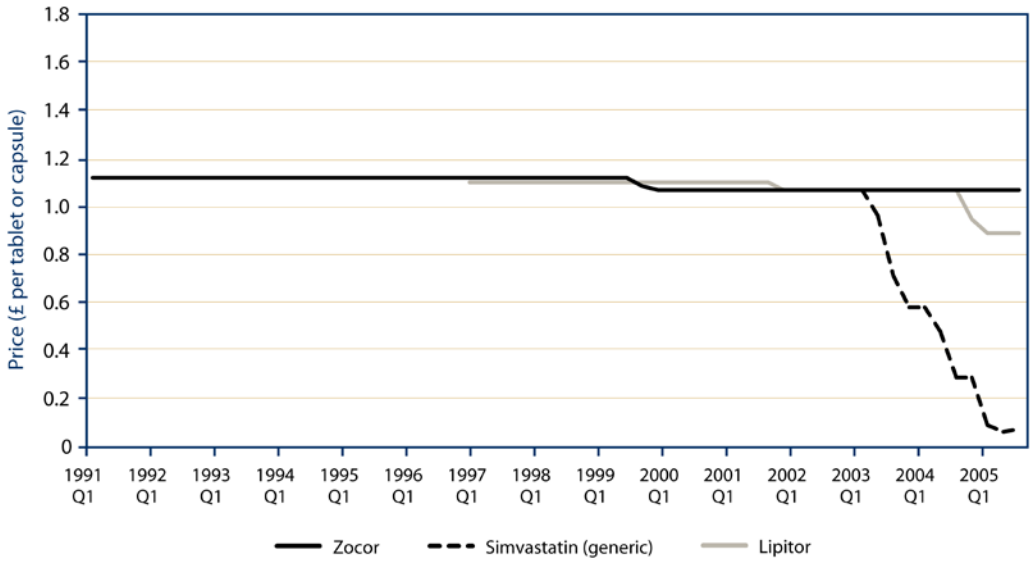
Figure 1: Market share of statins before and after reference pricing in Jan 2005



Notes: H1 and H2 refer to the first and second half of the year, respectively. Reference pricing is only used in social health insurance. Adapted from Wild (2006).

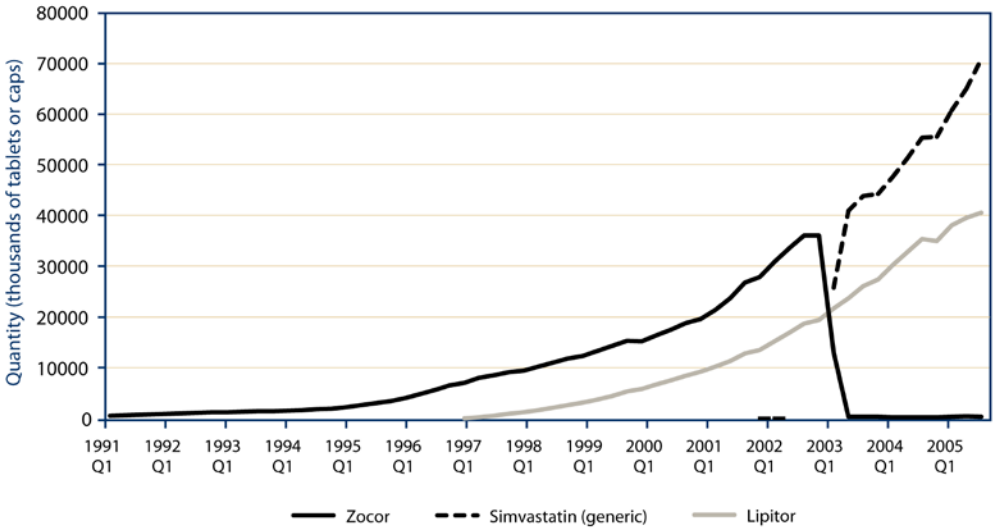
Merck's patent on simvastatin in the UK also expired in May 2003, leading to entry and a rapid decrease in prices for generic simvastatin (Figure 2a). In this context, the substitution was almost entirely from Zocor to generic simvastatin: Figure 2b shows that the decrease in sales for Zocor is recovered by its generic competitors. Lipitor's sales trend remains unaffected, indicating the lack of switching away from the on-patent statins despite a very substantial price advantage. This strikingly low cross-price elasticity has raised concerns over foregone savings to the NHS (OFT, 2007).

Figure 2a: Prices of selected statins in the UK



Notes: Tablets with 20mg active ingredient; adapted from OFT (2007).

Figure 2b: Sales volume of selected statins in the UK



Notes: Tablets with 20mg active ingredient; adapted from OFT (2007).

Discussion

The impact of generic entry in Germany and the UK highlights how variations in health systems can affect outcomes. Both countries limit reimbursements as generics appear and encourage, but do not strictly require, physicians to prescribe such that pharmacists can substitute. The pharmacy-level substitution policies can explain the switch across drugs with the same molecule, i.e. from Zocor to generic simvastatin. In the German case, this substitution operates through the default *aut idem* requirement. In the UK, pharmacies may dispense generics when the prescriber indicated the chemical's name.

However, active intervention by physicians is required to switch patients across molecules, i.e. from the still-patented Lipitor to generic simvastatin. This suggests that prescribing behavior is critical to the different experiences in Germany and the UK. German physicians may be more effective agents for their patients because of the impact of drug choice on copays. The flat copayment and many exemptions in the UK imply that price differences are not transmitted to patients and, indirectly, physicians. Officials in the UK are aware of the ineffectiveness of the NHS in transmitting incentives for substitution down to the level at which action can be taken:

> *"Competition between manufacturers did not lead to significant reductions in the price of substitute products, such as the other statins. Moreover, these substitute products retained significant volume and market shares despite the very significant change in relative price following simvastatin going off-patent. Given the very low prices at which generics are available, sustained prescribing of high-priced brands that may be therapeutic substitutes for many patients, raises potentially very significant concerns about the cost effectiveness of prescribing behaviour."* (OFT, 2007: 26).

Developments in the US statin market also suggest the importance of coverage policy and patient cost-sharing to encourage switching across molecules by physicians. Zocor lost patent protection in the US in June, 2006, later than in Germany or the UK. With simvastatin available generically, formularies moved Lipitor to higher tiers.[18] One pharmacy benefit manager moved Lipitor to tier 3 in January, 2006 in anticipation of generic simvastatin, and saw more than 40% of patients switch from Lipitor to a lower-tier statin (Cox *et al.*, 2007). Among those with copayment differences of $21 or more, 80% switched.[19]

Such decentralized efforts at substitution aggregated to a major effect on statin sales. As Aitken *et al.* (2008) report, the loss of Zocor's protection led to a rapid displacement of the branded drug with generic simvastatin. Moreover, Lipitor sales fell by 12 percent overall and 26 percent for new prescriptions.

The expiration of Zocor's patent and the subsequent changes in Germany and the UK provide a useful case study to how these health care systems adapt to cost-saving innovations.[20] In this instance the potential cost saving was transmitted into incentives to decision-makers (physicians and patients) more effectively in the German than in the UK system. At least in the case of drugs, there is considerable patient cost sharing in the German system with a mechanism to leverage physician agency and encourage substitution. This seems to be largely absent in the UK, leading to costly prescribing patterns and a slower adoption of lower-cost treatments.

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[18] See Aitken *et al.* (2008). U.S. state generic substitution laws do not apply to simvastatin-Lipitor substitution.
[19] See also Sy *et al.* (2009) who find a 40% switching from Lipitor in a group of physicians.
[20] OFT (2007: 25) concurs that the experience with Zocor is common in the UK, making it a good example for related innovations.

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