

Latest tariff brings more ups and downs

The UK's two generic statins experienced contrasting fortunes when the latest October edition of the quarterly Drug Tariff for England and Wales was released by the Prescription Pricing Authority. While the amount retail pharmacists and dispensing doctors were reimbursed for dispensing generic simvastatin increased, compared with the July-September tariff, the money they received for dispensing generic pravastatin on the National Health Service fell by a greater amount.

Both products are in the new category M of the Drug Tariff, introduced in April. Category M prices are based on a weighted average of a product's actual market price in the previous three months, derived from sales and volume data supplied voluntarily by generics suppliers.

The Department of Health is trying to lose £300 million (US\$530 million) from its annual drugs bill by introducing category M. What is less clear, however, is whether the change in calculating reimbursement prices has had a 'feedback' effect on actual generics prices in the marketplace. On the face of it, reimbursement prices follow actual prices, not the other way around. But it is also apparent that the UK generics market is currently at least £20 million a month smaller at market prices than it was a year ago, a figure that is in line with the amount the government is trying to save.

There is no consistent pattern to the simvastatin price rises in the latest October Drug Tariff. The reimbursement price for 28-tablet packs of simvastatin 10mg has risen by 6%, but the 20mg and 40mg strengths are now worth 21% and 16% more, respectively, to dispense than last month. Pravastatin, meanwhile, has seen its reimbursement price decline by as much as 43% for 28-tablet packs of the 20mg strength. The price fall by pravastatin 10mg is a less severe 33%, and the 40mg strength is 27% lower.

According to our Price Watch data, compiled by WaveData, the average market prices for 28-tablet packs of pravastatin 10mg, 20mg and 40mg were £1.01, £1.35 and £1.58 in September, approximately half the October Drug Tariff prices of £2.27, £2.39 and £3.33. The market prices had fallen between 25% and 30% since July, however, roughly in line with the latest Drug Tariff reductions.

Simvastatin in the same three strengths and pack sizes could be bought in the marketplace for £0.46, £0.54 and £1.57 on average during September. The July figures were £0.52, £0.62 and £1.87,

which indicated modest price falls, rather than the steep price rises allowed by the latest Drug Tariff. Moreover, the Drug Tariff prices of £1.75, £1.79 and £4.14 mean pharmacists are now being reimbursed at more than three-times the prices they are actually paying on average for the lower strengths of simvastatin.

It should be stressed, however, that WaveData only collects market prices. It has no ready access to volume data of the type analysed by Department of Health each quarter. However, it has been able to gauge the effect of the new category M by making use of the department's published 2004 market statistics.

When the new category M was introduced for about 450 generic medicines in the Drug Tariff in April, the intention was to reduce the generics drug bill by £300 million annually. This saving was to be channelled instead into paying for extra healthcare services provided by pharmacists under a new pharmacy contract.

The trick the Department of Health has been trying to manage over the past seven months – in the three quarterly tariffs to date – is to pitch the category M prices in the Drug Tariff at such a level as to achieve the £300 million saving. Any more, and they will have retail pharmacists, in the shape of the Pharmacy Services Negotiating Committee, crying "foul".

Thanks to a rapidly rising amlodipine market price in the weeks before the first April tariff, pharmacists would have been paying the UK government for the privilege of dispensing the antihypertensive when the revised tariff came out. As a result, the

| | 2004 (£ millions) | 2005 (£ millions) | Change (£ millions) |
|-----------|----------------------|----------------------|------------------------|
| August | 95.1 | 75.5 | 19.6 |
| September | 87.5 | 67.5 | 20.0 |

Figure 3: Changes in the market value of category M products in England and Wales in the months of August and September 2005, compared with the same months a year earlier. The figures are based on actual average monthly sales volumes in 2004, according to Department of Health statistics, and actual average market prices in the month in question. Only category M products for which published sales volumes are available have been included; 2005 market values are based on 2004 volume data (Source – WaveData)

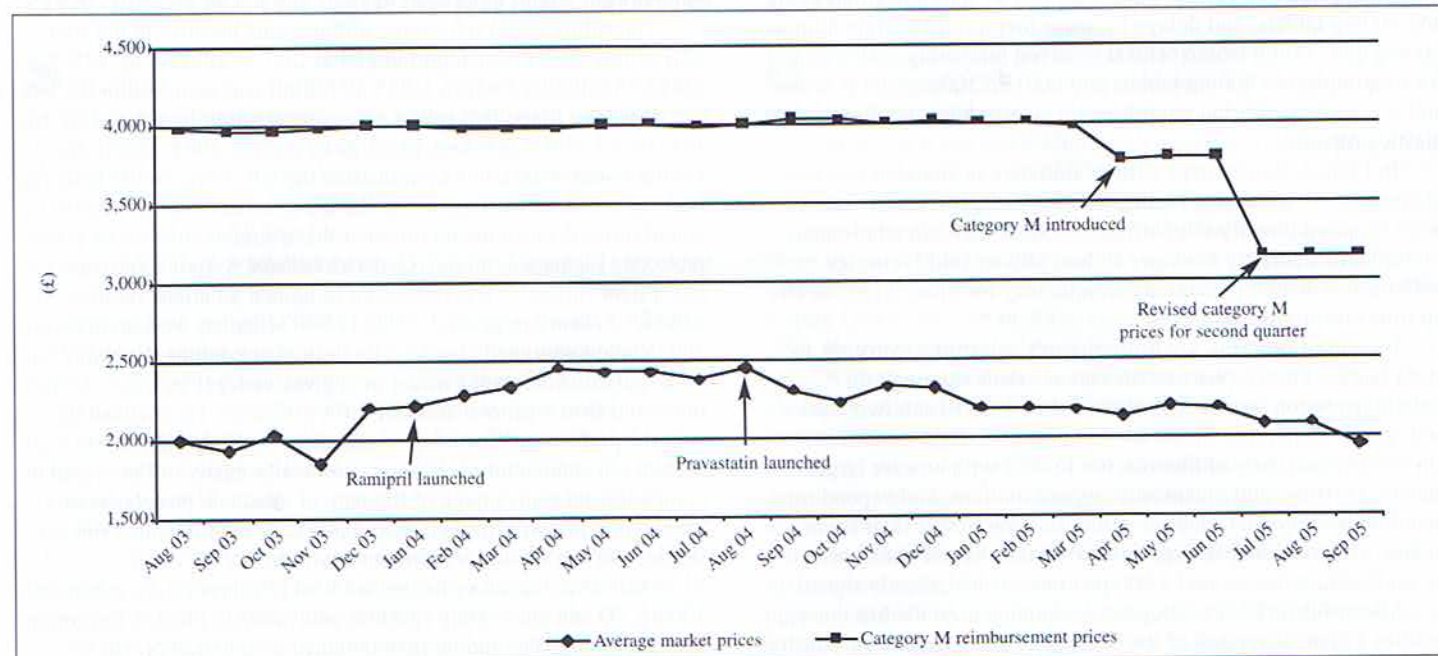


Figure 1: Comparison of the value of a basket containing every product now in category M, comprising one pack per product, according to Drug Tariff prices and actual average market prices for the months in question (Source – WaveData)

product was made an exceptional case. It was rapidly withdrawn from category M and returned to category A in the tariff, which is based on the price lists of wholesalers AAH and UniChem, plus those of Teva, Alpharma and Ivax.

When amlodipine was returned from category M to category A, its Drug Tariff prices were raised from £2.51 to £8.89 for 28 tablet packs of amlodipine 5mg and from £2.93 to £12.25 for the 10mg strength. At the time, average market prices were £4.47 and £6.64, respectively (*Generics bulletin*, 8 April 2005, page 14).

Now amlodipine has been returned to category M in the October tariff – this time to stay, according to the department – it is priced at £5.48 and £7.96. This compares with average market prices in September of £2.77 and £4.64. These tariff prices represent a much better mark-up than the 50% or so pharmacists enjoyed from dispensing generics during the most recent quarter, and they are more in line with the mark-ups of 75% or so available in the first quarter under the new tariff (see Figure 1).

Just how consistent reimbursement prices were for a basket of category A products before they were transferred to category M in April can be seen in Figure 1. The basket was consistently worth £4,000, calculated simply from the total reimbursement price of all products now in category M, on the basis of one pack per product.

The average monthly market value of the same basket of products was about £2,000. On the face of it, this value appears to have been unaffected by the recent changes to the Drug Tariff. The basket apparently was worth the same last month as it was two years ago.

However, Charles Joynson, managing director of WaveData,

PRICE WATCH UK highlights generics price changes in the UK market and appears exclusively in every issue of *Generics bulletin*, courtesy of the Pharma TouchStone service of WaveData.

WaveData collects and collates pricing information from a number of European countries. In the UK, pricing information about generics, brands and parallel imports is gathered from offers made to independent retail pharmacists and dispensing doctors by wholesalers and generic manufacturers. WaveData collates this data and publishes the results as its Pharma TouchStone service. This is designed to give customers of the service fast, accurate, real-time access to current generic prices.

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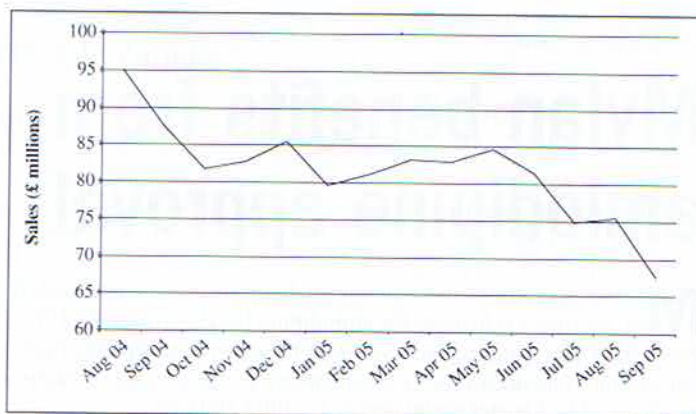


Figure 2: Market value of category M products in England and Wales, based on actual average monthly sales volumes in 2004, according to Department of Health statistics, and actual average market prices in the month in question. Only category M products for which published sales volumes are available have been included; 2005 market values are based on 2004 volume data (Source – WaveData)

points out that the basket has got bigger over the period with more category M products becoming available as generics. While these new additions did not affect reimbursement prices before April, products like pravastatin and ramipril – both in the UK top 10 selling drugs – grew the actual sales value of the basket, at least until about August 2004. However, falling generics prices since that time have brought the basket's value back to where it was two years ago, representing a sharp reduction in real terms.

The overall trend in market size when the Drug Tariff changes were introduced can be judged from Figure 2. This shows the value of the basket of category M products, calculated from actual average market prices for the month in question, weighted according to Department of Health published sales volumes for most of the lines.

As can be seen, the value of the generics market in England and Wales in category M products has been falling steadily from £95 million a month in August 2004 to less than £70 million a month in September 2005. What is less clear is whether the Drug Tariff changes since April have contributed to this decline.

A direct comparison for the months of August and September, shown in Figure 3, indicates a monthly shrinking in generic market size of about £20 million. Given increased volumes in 2005, this implies a fall in actual generic market size among category M products alone of at least £250 million annually.

ATTENTION DEFICIT HYPERACTIVITY DISORDER DRUGS

Shire files Adderall petition

Shire Pharmaceuticals is trying to block generic versions of its amphetamine-based Adderall XR drug for attention deficit hyperactivity disorder (ADHD) by filing a citizen petition with the US Food and Drug Administration (FDA). The petition filed on 12 October calls on the FDA to require rigorous bioequivalence testing or additional clinical trials for generic versions of Adderall XR.

Generic firms, the brand company insisted, should have to establish bioequivalence through "a study producing identical or superimposable plasma-concentration time curves and pharmacokinetic profile". Alternatively, Shire said, the FDA should require clinical trials demonstrating the safety and effectiveness of the generic version in treating ADHD.

Shire recently revealed that it was discussing a settlement of litigation relating to two patents expiring in 2018 with the first generic filer, Barr Pharmaceuticals (*Generics bulletin*, 9 September 2005, page 15).

The brand company is also suing the second generic filer, Impax, but has not yet taken similar action against Colony or Teva.

CHOLESTEROL LOWERING DRUGS

Japan hands Teva API win

The Japanese Patent Office has ruled in favour of Teva Pharmaceutical Industries in the Israeli firm's dispute with Sankyo over a patent on pravastatin. Teva manufactures the active pharmaceutical ingredient (API) for the finished-dosage form of pravastatin in several countries, including Japan.

Following a trial in August, the patent office found that Sankyo's patent 3,463,875 relating to pravastatin free from epipravastatin was invalid because of prior intellectual property applications filed by Teva in Japan.

The favourable ruling follows the Japanese Patent Office's decision in April this year to invalidate Sankyo's patent 3,236,282 relating to a pravastatin extraction process using iso-butyl acetate, again due to Teva's prior art filings. The Israeli firm said the Japanese patent examiners had noted at the time that Teva's request to invalidate the '282 patent had been the first time a generics firm had directly challenged a brand company's patent in Japan.

Meanwhile, Teva has gained tentative US approval for gatifloxacin 200mg and 400mg tablets equivalent to the antibiotic Tequin.