

# Pregabalin fails to heed judge's forecast

Launching true generic pregabalin products may prompt moves to category M of the Drug Tariff of pharmacy reimbursement prices, Justice Richard Arnold commented last autumn in a 174-page ruling on claims contained in the UK part of Pfizer's European method-of-use patent 0,934,061 (**Generics bulletin**, 2 October 2015, page 27).

But, six months later, despite Arnold ruling that only prescriptions for pregabalin to treat peripheral neuropathic pain should carry Pfizer's Lyrica brand name – but all other uses of the painkiller, such as fibromyalgia, should be generic – not much has changed.

When Sandoz and Teva launched unbranded pregabalin generics last July, they effectively released the pregabalin market from the stranglehold put on it earlier by Arnold when he ordered the National Health Service (NHS) to issue guidance that pregabalin should only be prescribed for neuropathic pain under Pfizer's Lyrica brand name (**Generics bulletin**, 13 March 2015, page 19).

Starting in July, average generic pregabalin prices started to decay faster. But a glance at the Drug Tariff for April 2016 shows that pregabalin capsules in eight strengths from 25mg to 300mg are still in category C and should still all be reimbursed at the trade price of the equivalent Lyrica strength. For pharmacists, this means dispensing profit margins of between 90% and 98%, given that average prices have fallen to 10% of the brand's official trade price and lowest prices barely reach 2%.

Official dispensing data shows that when three branded generics were launched in February 2015 – Actavis' Lecaent, Consilient's Rewisca and Dr Reddy's Alzain – they immediately replaced Lyrica as pharmacists' products of choice, cutting brand sales down to almost zero (see Figure 1).

However, Arnold insisting that the NHS should issue guidance – “the most efficacious, dissuasive and cheapest solution” to Pfizer's fears that pharmacists would dispense generics for what was then the full patented indication – allowed Pfizer's Lyrica back into the market. So-called ‘brand equalisation’ measures, comments WaveData's managing Director Charles Joynson, also contributed to Lyrica's “fight back” as Pfizer equalised its prices with those of the generics. He adds that dispensing doctors were even more affected by the NHS guidance than pharmacists. Only 4% of generic pregabalin was handed out by dispensing doctors in the period between March and December 2015, with pharmacists responsible for the remaining 96%.

Market prices for pregabalin – however it was labelled and marketed – held remarkably steady during the months following generic launch in February 2015. Even after the entry of unbranded generics in July, market prices for Lyrica, as well as parallel imports of Lyrica, followed those of the generics downwards (**Generics bulletin**, 23 October 2015, page 31).

Today, however, pregabalin acts like a category M generic – with its reimbursement price dictated by actual market prices – despite its category C status. Figures 2, 3 and 4 all show the early slow price decline and the more rapid fall from last July. They also illustrate average generic prices today of £6.00 to £7.00 (US\$8.60 to US\$10.00) and lowest prices under £2.00.

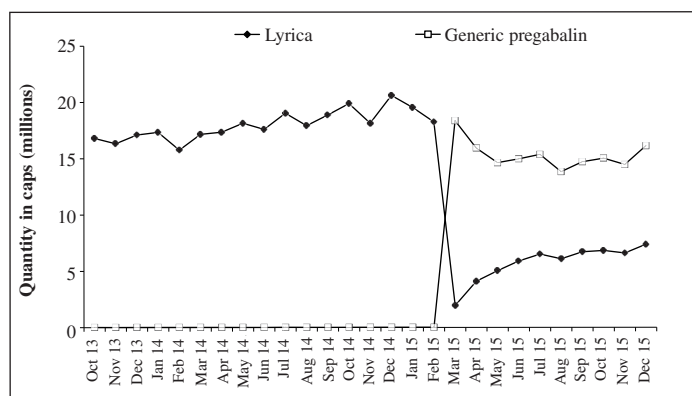


Figure 1: Monthly quantities of pregabalin dispensed in England and Wales, showing the distinct change on generic launch in February 2015 (Source – WaveData)

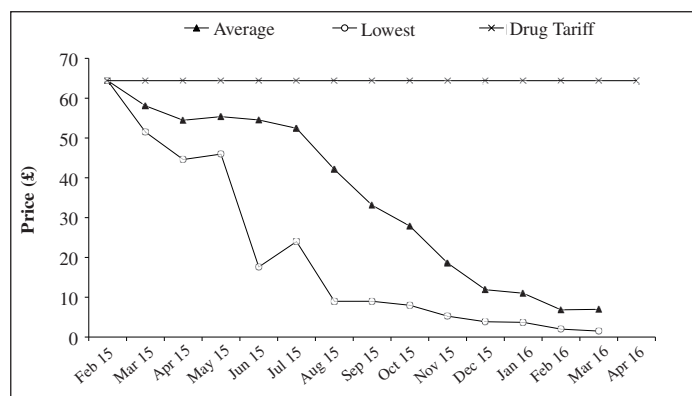


Figure 2: Lowest and average trade, and Drug Tariff prices for pregabalin 25mg capsules after generic launch (Source – WaveData)

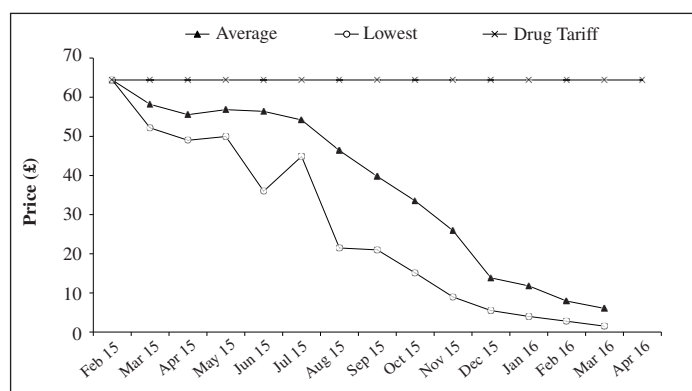


Figure 3: Lowest and average trade, and Drug Tariff prices for pregabalin 75mg capsules after generic launch (Source – WaveData)

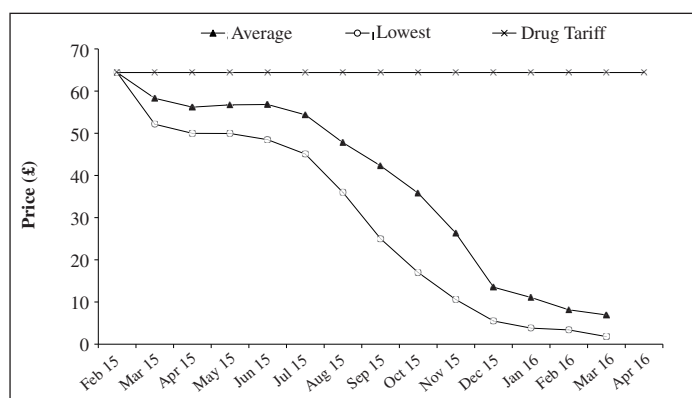


Figure 4: Lowest and average trade, and Drug Tariff prices for pregabalin 150mg capsules after generic launch (Source – WaveData)

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