

Pregabalin's release produces price peak

Pregabalin finally arrived unencumbered onto the UK generics market on 17 July this year, ending a long saga of court appearances, warning letters and 'carved out' indications. It soon made its mark. Hurriedly transferred by the authorities on 1 August to category M of the Drug Tariff of pharmacy reimbursement prices, pregabalin's appearance was greeted within a matter of weeks by its first price concession (**Generics bulletin**, 15 September 2017, page 10). Pregabalin's trade price had risen so rapidly that what pharmacists were paying for the epilepsy and neuropathic pain drug soon overtook pregabalin's reimbursement price, thereby leaving pharmacists out of pocket.

When the Drug Tariff price of pregabalin 150mg capsules was slashed from £64.40 (US\$85.05) in July to £2.29 in August, the product's average trade price responded by increasing by 20% to £14.93. Moreover, its lowest price, which had been less than half of its new Drug Tariff price, increased by 232% to £3.35. Such volatility immediately obliged the Department of Health to grant pharmacists a price concession of £19.95 on the same product they had only just listed at £2.29.

Charles Joynson, WaveData's managing director, maintained that doctors were holding off from prescribing the drug until its Drug Tariff price came down. "When the Drug Tariff changed, doctors increased their usage. This led to shortages, price increases and hence to price concessions," he commented.

Pregabalin's journey to market began as long ago as the beginning of 2015 when Justice Richard Arnold ruled in a legal battle between Actavis and Pfizer that England's National Health Service (NHS) must issue guidance to the country's 211 clinical commissioning groups and to the NHS Business Services Authority instructing them that pregabalin should only be prescribed for neuropathic pain under Pfizer's Lyrica brand name. He insisted that this was "the most efficacious, dissuasive and cheapest solution" to Pfizer's fears that its patent would be infringed if pharmacists dispensed generics for the patented indication (**Generics bulletin**, 13 March 2015, page 19).

Later that year, Arnold ruled that six key claims of the UK part of Pfizer's method-of-use patent 0,934,061 that protected Lyrica until July this year were invalid for insufficiency (**Generics bulletin**, 2 October 2015, page 27). The decision was upheld on appeal a year later (**Generics bulletin**, 21 October 2016, page 11). Arnold also issued an interim injunction in 2015 that barred Sandoz from marketing and supplying pregabalin with the same label indications as Lyrica (**Generics bulletin**, 20 November 2015, page 17). Sandoz subsequently failed in an attempt to lift the injunction (**Generics bulletin**, 13 January 2017, page 11).

The legal wranglings do not seem to have had much effect on the trade prices of the three most popular strengths of pregabalin, judging by Figures 1, 2 and 3. Price decay was relatively fast after launch, despite the usage restrictions. However, Joynson pointed out that "a wide range of suppliers" were making additional efforts to sell stock in October 2015 – coinciding with Arnold's ruling – and in April 2017, which may have had more to do with manufacturing or delivery cycles.

December 2016's little peak in average trade prices, he added, was due to "a large increase in the number of prices of over £30 per pack". There were five such offers in November, he noted, but 28 in December. Total monthly price offers for pregabalin have fluctuated in number over the 30 months since launch, with noticeable peaks around October 2015 and when NHS England withdrew its usage guidance in June 2017, ahead of the July patent expiry (see Figure 4).

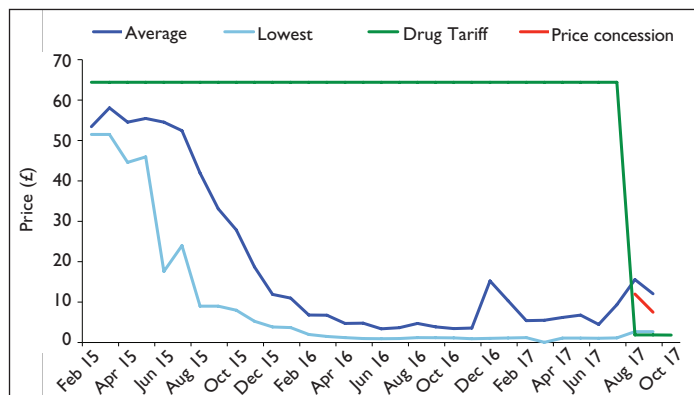


Figure 1: Monthly prices since launch for 56-capsule packs of pregabalin 25mg: lowest and average trade, Drug Tariff and concessionary (Source – WaveData)

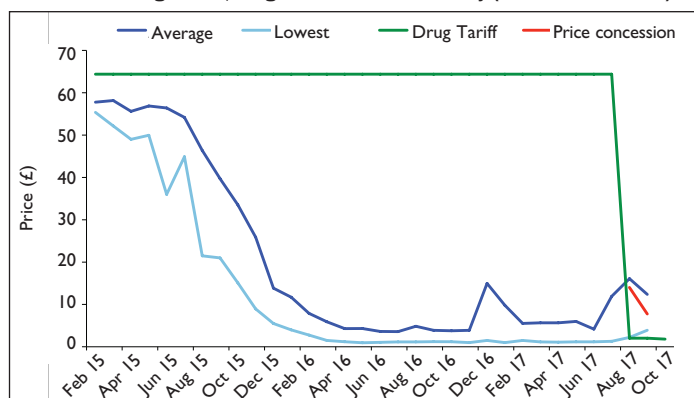


Figure 2: Monthly prices since launch for 56-capsule packs of pregabalin 75mg: lowest and average trade, Drug Tariff and concessionary (Source – WaveData)

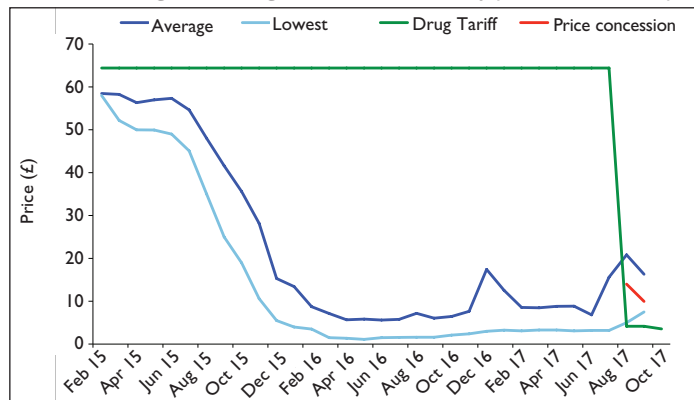


Figure 3: Monthly prices since launch for 56-capsule packs of pregabalin 300mg: lowest and average trade, Drug Tariff and concessionary (Source – WaveData)

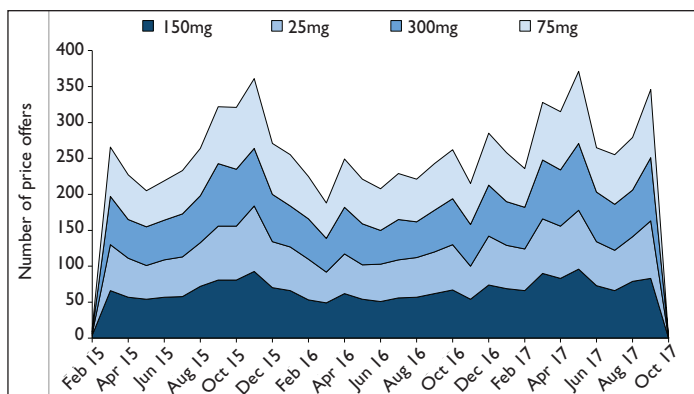


Figure 4: Number of monthly price offers for pregabalin made to independent pharmacists and dispensing doctors since launch (Source – WaveData)

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