

# Commercial Bulletin

May 2011

## Govt is not seeking to roll out OFT's model of VBP, says Minister

The government's plans to introduce a value-based pricing (VBP) scheme for NHS drugs from January 1 2014 do not include rolling-out the system proposed by the Office of Fair Trading (OFT), Health Minister Earl Howe has said.

The model put forward by the OFT in 2007 - when it declared that the Pharmaceutical Price Regulation Scheme (PPRS) was not fit for purpose and that the NHS was paying too much for branded drugs - would be "a recipe for driving drug prices down and down," said the Minister, speaking at the National Institute for Health and Clinical Excellence (NICE)'s annual conference in Birmingham.

**What** Ministers are seeking are new arrangements to encourage the development of drugs to address areas of unmet need and bring prices and benefits into line, and its priority is improving access to effective innovative medicines, he said.

**"We've** got to think about moving away from the drugs budget and towards a health budget," Earl Howe told the conference. Under the proposed new arrangements, there would be scope for the price of a drug to come down if it failed to add significant value but, on the other hand, Ministers "are not too afraid of increasing the drugs budget, as such," he added.

**The** Minister also cautioned that "we must be very careful" about the reference pricing position of the UK, as many other countries base their price-setting decisions on levels here, and also that pharmaceutical manufactures must not be discouraged from selecting the UK as a market for early launches of their products.

**Establishing** a system which defines value "won't be easy, but we have time," said the Minister, and he added that, under the new arrangements, the role of NICE "will inevitably evolve."

NICE is "self-evidently a world leader," he said, and the plans included in the Health and Social Care Bill to re-establish it as a non-departmental public body (NDPB) will put the Institute on a firmer footing and prevent the possibility of it being abolished by the government "on a whim." The primary legislation will allow NICE's role to evolve over time and ensure that it remains as relevant as it is now, he said.

Links

[www.nice.org.uk](http://www.nice.org.uk)

[www.dh.gov.uk](http://www.dh.gov.uk)

[www.of.gov.uk](http://www.of.gov.uk)

Pharmatimes 12/05/11

### *Ciprofloxacin suffers from price volatility*

Ciprofloxacin prices were somewhat volatile in the UK last month, with double-digit fluctuations in both directions compared with a month earlier. Meanwhile, prices for one of the UK's market's more recent entrants, pramipexole, took another downward lurch. The average price for 10-tablet packs of ciprofloxacin 500mg increased by 15% in April, compared with a month earlier (see Figure 1).

To see more go to <http://www.wavedata.co.uk/newinfo.asp> and view our article from this month's Generics Bulletin.

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## ***NCSO (no cheaper stock available)***

### ***Gabapentin tests reimbursement scheme***

Gabapentin capsules have been in short supply in the UK for the past year. Ever since May 2010, the anti-epileptic drug has appeared on the list of products granted special reimbursement status by the Department of Health.

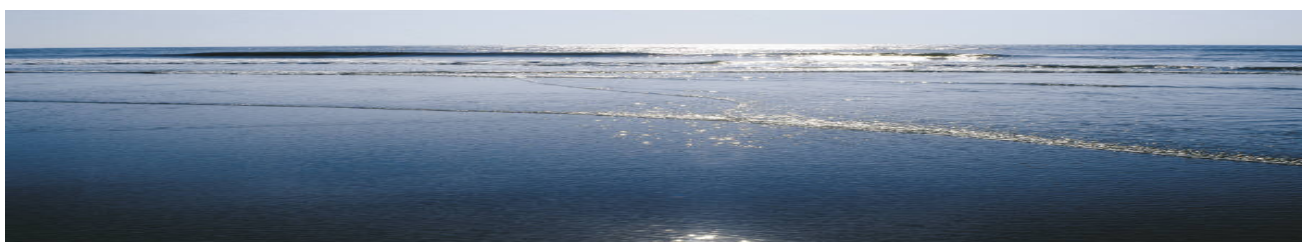
Firstly it was gabapentin 300mg capsules that were granted 'no cheaper stock obtainable' (NCSO) status by the department, but gabapentin 100mg capsules were added in August 2010 and 400mg capsules a month later. Figure 1 is typical of the rollercoaster pricing of gabapentin capsules since they were launched, and the efforts of the department to keep pace with the changes through Drug Tariff reimbursement prices.

The 300mg strength was the only generic product in November 2010 to be given the newly-introduced 'concessionary price increase' by the department as an alternative to granting NCSO status, which was the case for gabapentin 100mg and 400mg capsules. Price concessions are fixed at more than Drug Tariff reimbursement prices and, like NCSO status, only apply for the month in which they are granted. Their benefit to pharmacists and dispensing doctors is that they apply automatically without special endorsement by the dispenser.

Endorsement is required when dispensers supply an equivalent, more expensive proprietary drug instead of the prescribed NCSO product

To see more go to <http://www.wavedata.co.uk/newinfo.asp> and view our article from this month's **Generics Bulletin**.

#### **Generic Bulletin**



## **Teva transforms generics offering**

**Teva** UK Limited is transforming its offering to its independent pharmacy and dispensing doctor customers with the launch of a brand new generics buying scheme.

**Teva**, which was the first generics house to introduce a generics buying scheme back in 2003, says it has consulted its customers to find out exactly what they want from a generics scheme and has incorporated this into a brand new offering.

**The** company says that all customers have to do is to make a simple choice: TevaOne or TevaTwo.

Whichever one best suits their business. This will depend on whether they would prefer base monthly rebates combined with a bonus quarterly rebate (TevaOne), or whether they can commit to a minimum spend of £2,500 per month to earn Nett Price and incremental levels of rebates (TevaTwo).

**Said** Kim Innes, Teva's Commercial Director: "We've taken a long, hard look at our customer buying schemes. We asked our customers what they wanted, what they valued most from their generic medicines provider, and we listened. We've used their feedback to form the backbone of the change in our generic buying schemes – keeping them simple, reliable, and competitively priced."

**TevaOne** and TevaTwo will launch on 1 May 2011, replacing the current offerings. Teva's dedicated team of Account Managers is there to support the company's customers every step of the way and will be in touch shortly to discuss which of the new schemes is right for them.

**More** information is also available online at [www.tevauk.com/tevascheme](http://www.tevauk.com/tevascheme). Any questions can be directed to the freephone helpline 0800 085 8621.

**To** find out more about Teva UK Limited, visit [www.tevauk.com](http://www.tevauk.com)

Teva

Chemist & Druggist 21/04/11

## The European pharmaceutical supply chain is set for significant changes in the light of new European legislation on falsified medicines

Graham Smith of Aegate told members of the Small Pharma Industry group in early April that new European legislation will require medicines to have unique identifiers and tamper evidence as part of the requirements to combat falsified medicines in the EU. It is understood that all prescription medicines will be included in the requirements unless a risk assessment determines that the product is not in danger of being counterfeited.

It will then be down to wholesalers and pharmacists to validate the authenticity of the medicines in their possession to ensure any falsified medicines can be identified and be prevented from being dispensed to patients.

The plan is to also introduce strict requirements on repackagers to ensure that parallel traded packs are handled in the same way as medicines from the original manufacturer and any safety features removed are subsequently replaced with equivalent features. The costs of applying the safety features and the cost of the repository used to authenticate the medicines will be borne by manufacturing authorisation holders.

Although the legislation was passed at the European Parliament in February, the fine detail of exactly how the legislation will be implemented is currently being decided at the European level by the Commission. This is a different approach than is normal for European legislation that is traditionally passed to individual member states to implement. With the Falsified medicines directive the Parliament has enacted Article 290 (Delegated Acts) which requires the Commission to detail the modalities of operation. The acts will provide for a consistent approach to be implemented across Europe. The duration of the Delegated Acts is still unknown, but once the details are finalised industry will have only 36 months to implement the legislation on a pan-European basis.

Graham can be contacted on [graham.smith@aegate.com](mailto:graham.smith@aegate.com) or 07785 748 970

### Italian 40% price cuts threaten firm's futures

Reference-price reductions of up to 40% unveiled by Italy's regulatory agency, AIFA, threaten to drive several local generics players out of business, according to Giorgio Foresti, President of Italian generics industry association Assogenerici. The reimbursement price cuts introduced from 15 April also slashed profit margins on certain products to the extent that there is no incentive to market them, Foresti has warned.

According to AIFA, the new reference prices – or maximum reimbursement prices – it has set will save Italy's regional health authorities "not less than €600 million (US\$860 million) this year". Citing IMS Health data, Assogenerici said Italy's total generic market was valued at just under €1.4 billion at retail selling prices last year. This equated to €733 million at ex-factory prices.

The price cuts affect 4,188 off-patent products that were included in AIFA's transparency list' as of February 2011. In calculating the new prices, AIFA referenced Italian prices for off-patent medicines against those in "the pharmaceutical markets that most closely resemble that of Italy – France, Germany, Spain and the UK". The regulatory agency used IMS Health data for the year ended September 2010 to make European price comparison of products with the same active ingredients, delivery forms and strengths.

Most products face reimbursement cuts of between 10% and 40%, although for around 1,700 products that were already priced in line with the average in France, Germany, Spain and the UK, the reduction is 8%. With the aim of protecting the "operating sustainability of pharmaceutical companies", AIFA set the maximum reimbursement price cut at 40% and said it would not reduce prices for products that already had reference prices of €2.00 or lower.

But Foresti insisted smaller players would be forced to withdraw from Italian generics market. Many of Assogenerici's member companies had been unable to match the reference price, so patients were having to make up the difference through co-payments. Industry simply could not sustain the prices AIFA had set, Foresti stressed. While making a few cents per pack might be acceptable in countries such as Germany and the UK where generics volume penetration was over 50%, he said, it was not viable for Italy, where volume penetration was just 12.4%.

# Roche, Novartis "set to be leaders in personalised medicine:" study

Roche and Novartis are the only two out of a group of 10 leading pharmaceutical companies with at least one targeted drug therapy on the market which are likely to become leaders in the field of personalised medicine, says a new study.

The report classifies the two companies as "disruptors," ie, those able to competitively reshape therapy areas via personalised medicine. Both Roche and Novartis have the capacity to "upset normal competitive dynamics in a specific therapy area by shaping payers', regulators' and physicians' expectations of value," according to Peter Keeling, chief executive of change management and consulting firm Diaceutics, which carried out the research.

The firm's review of the 10 leading drugmakers, which classifies them according to their potential to capitalise on opportunities in personalised medicine, sees at Roche an excellent capacity for personalised medicine innovation and a robust strategy in the field, while Novartis has more recently focused on building its internal molecular diagnosis unit and has developed a clinical pipeline with a focus on personalised medicine, it says.

The next rank after the "disruptors" are "breakaway" companies, ie those positioned - based on the carefully selected, proactive investments which they have made - to migrate their operating models and corporate structures in order to successfully commercialise targeted therapies.

Diaceutics finds four such "breakaway" firms - AstraZeneca, Eli Lilly, Bristol-Myers Squibb and Pfizer - which, it believes, are likely to accelerate their activities and improve their commercial infrastructure for targeted therapies over the next 24-36 months. It judges all four companies as having roughly equal potential to commercialise targeted therapies, but believes that AstraZeneca, Lilly and Bristol-Myers Squibb, with their internal personalised medicine strategy teams, will likely be better organised internally to develop potential therapies and companion diagnostics. Pfizer, on the other hand, has a promising clinical pipeline for personalised medicine, it adds.

Whether these four attain "disruptor" status depends on whether their boards and senior management decide to migrate to a future culture and infrastructure based predominantly on personalised medicine, says the study.

The four remaining companies - GlaxoSmithKline, Sanofi-Aventis, Amgen and Merck & Co - are rated as "followers," ie, most likely to respond to the actions of other companies.

"Followers" have few commercial successes in this space and thus little commercial experience, and are more likely to strive to maintain their existing business models, rather than adapt them for personalised medicine, says the report.

Most drugmakers say they are ready for personalised medicine, and their development pipelines are filling up with opportunities, says Diaceutics, whose report finds that 46% of all new therapies currently in Phase III R&D could benefit from a personalised medicine strategy. Other studies have suggested that only 10% of such therapies are potential personalised medicine/targeted therapies, but the firm believes that the standard definition being used in the industry is narrow.

"In fact, any therapy that will directly benefit from a new or reshaped diagnostic approach should be considered personalised medicine," according to Mr Keeling. Moreover, the analysis finds that, in contrast to the belief held by many firms that personalised medicine will create smaller markets or less revenue, about half of the companies assessed in the report have a personalised therapy currently on the market that is near or above blockbuster-level sales of \$1 billion.

Links

[www.diaceutics.com](http://www.diaceutics.com)

Pharmatimes 12/04/11

## WaveData — Top ten products

According to WaveData, these were the most commonly investigated products in searches of the online pricing data at [www.wavedata.net](http://www.wavedata.net)

Both uk and pi prices were viewed for each product, giving some indication of where the focus was in April 2011

Simvastatin Tabs 40mg 28

Peppermint Oil

Co-Codamol Caps 8mg/500mg 100

Gabapentin Caps 300mg 100

Omeprazole Caps 20mg 28

Peppermint Oil E/C Caps 0.2ml 84

Simvastatin Tabs 20mg 28

Gabapentin Caps 100mg 100

Hydrocortisone Tabs 10mg 30

Metformin Tabs 500mg 28

This bulletin now goes out to 1400 plus people, and it is growing each month.

If you would like to add or suggest any articles/comments, please let me know by the 15th June 2011, as I will be issuing the next one on the 22nd June 2011.

If you have any colleagues who would like to receive this, please let them know about it. You can view all copies of the Bulletin at [www.wavedata.co.uk](http://www.wavedata.co.uk)

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