

# Commercial Bulletin

## UK consultation on value-based pricing begins

The UK government has now put its plans to introduce value-based pricing (VBP) for medicines supplied through the NHS from 2014 out for consultation.

**VBP** "will ensure that the price the NHS pays for medicines are based on an assessment of its value, looking at the benefits for the patient, unmet need, therapeutic innovation and benefit to society as a whole," Health Secretary Andrew Lansley said yesterday as he announced the consultation, which will run to March 17.

The VBP system will replace the Pharmaceutical Price Regulation Scheme (PPRS) when it expires at the end of 2013, and apply to New Active Substances (NAS) placed on the market from January 1, 2014, according to the consultation document setting out the government's plans. Subject to discussion with industry, some existing medicines could be included within the system, it says; generics are not expected to be included.

For branded medicines already covered by the PPRS at the end of 2013, a successor scheme will be developed.

**Discussing** the case for change, the document notes that, while the PPRS has provided "some" stability over time, it does not sufficiently promote innovation or access. "In particular, freedom of pricing for new drugs puts the NHS in the position of either having to pay high prices that are not always justified by the benefits of a new drug or having to restrict access," it says and, while initiatives such as patient access schemes (PAS) and the Cancer Drugs Fund have helped, these are not long-term solutions.

**Pharmaceutical** companies need a pricing system that is more stable, transparent and gives clear signals about priority areas so that research efforts are directed to maximum effect, while a better way is also needed for dealing with new drugs whose benefits are more limited, it adds. "For example, product line extensions, which are comparable to, or offer only small benefits over existing treatments may not add much for patients. The NHS should not have to choose between paying over the odds or restricting access," the document says.

The key principle of VBP is to ensure that NHS funds are used to gain the greatest possible value for patients; therefore, the government is proposing a range of thresholds or maximum prices reflecting the different values that medicines offer. Its proposed price threshold structure would be determined thus: a basic threshold, reflecting the benefits displaced elsewhere in the NHS when funds are allocated to new medicines, plus higher thresholds for:

- medicines that tackle diseases where there is greater "burden of illness" - the more the product is focused on diseases with unmet need or which are particularly severe, the higher the threshold;
- products that can demonstrate greater therapeutic innovation and improvements compared with other products; and
- medicines that can demonstrate wider societal benefits.

**Turning** to the role of the National Institute for Health and Clinical Excellence (NICE) under the new system, the document says that "there is no scope for NICE in England, or its parallel bodies in the rest of the UK, to enter into pricing negotiations or to recommend an NHS price."

**NICE** is a world leader in pharmacoeconomic evaluation of drugs and a centre of excellence, it says, and points to the "significant future expansion" of the Institute's work, as set out in the NHS White Paper, on the development of quality standards for health and social care, along with tools and guidance to support commissioners in delivering them.

"**Subject** to parliamentary approval, NICE itself will be re-established in the forthcoming Health and Social Care Bill, to guarantee its status and ensure it is fit for purpose," it says.

The consultation was welcomed by Dr Richard Barker, director general of the Association of the British Pharmaceutical Industry (ABPI), who said he looked forward to representing the industry in co-creating the new system with the government.

Dr Barker agreed that the priority in any new system must be rapid and consistent patient access to new medicines – "value is meaningless without consistent access," he said.

**Also**, innovation and investment in R&D must be fairly recognised and rewarded, he said, pointing out that UK continues to lag behind Europe in the uptake of innovative medicines despite having amongst the lowest prices, "so price alone is clearly not the main driver of access in the NHS."

**Nevertheless**, pharmaceutical companies agree "fully that the government and the NHS should seek value for money from medicines, and expect NICE to continue to play a key part in the process. Our industry must demonstrate the full value of its medicines, it is for government to put in place processes which assess that full value, and then secure access to that value for NHS patients," said Dr Barker.

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### 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 December 2010

**Risedronate Sodium Tabs 35mg 4**  
**Sertraline Tabs 50mg 28**  
**Alendronate Tabs 70mg 4**  
**Glipizide Tabs 5mg 56**  
**Metformin Tabs 500mg 28**  
**Mycophenolate Caps 250mg 100**  
**Mycophenolate Tabs 500mg 50**  
**Prednisolone E/C Tabs 2.5mg 28**  
**Requip XL Tabs 8mg 28**  
**Citalopram Tabs 40mg 28**

### Drugmakers “aggressively changing the way they do R&D”

With dozens of prescription medicines due to lose patent protection over the next few years, and company pipelines currently containing few likely blockbusters with the potential to replace declining revenues, developers are aggressively changing the way they do R&D, says a new study.

“The research-based drug industry, in the United States and globally, is not sitting still, but the question remains whether developers can bring enough new drugs to market at the pace needed to remain financially viable,” according to Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development (CSDD).

Speaking yesterday at the release of the Tufts Center's Outlook 2011 report on pharmaceutical and biopharmaceutical trends, Dr Kaitin noted that pharmaceutical developers are looking to reduce development times, cut costs and improve operating efficiency.

At around \$1.3 billion, the cost of developing a new drug is now higher than ever, according to Tufts CSDD. Mr Kaitin acknowl-

edged the difficulty of predicting which new products could become blockbusters, ie, yielding annual revenues of at least \$1 billion, and said that the challenge to create such products is expected to become increasingly daunting in the next few years.

According to advice from the Center, actions that will help improve R&D productivity include: - greater reliance on translational science to help identify the right disease targets for new molecules; - greater use of partnering with external service providers to share risks, reduce cycle times, lower costs and improve resource management; and - greater use of sophisticated portfolio management techniques.

Among the near-term trends highlighted in the Tufts CSDD latest Outlook report are that:

- the US Food and Drug Administration (FDA) will exercise its new activism in order to confront a serious public health problem reaching critical mass. Such issues include shortages of antibiotics, emergency drugs, anesthetic agents, treatments for

cognitive disorders, and newer and better pain medications;

- although more than half of all FDA-regulated clinical trials in 2010 were conducted outside the US, sponsors will seek to decrease the number of countries hosting development activity in an effort to reduce global logistical and regulatory complexity;

- the pharmaceutical and biotechnology industries will continue to dedicate resources to the development of monoclonal antibodies (mAbs), as annual global sales of these products currently approach \$40 billion; and

- among private payers in the US, risk-sharing agreements to manage uncertain outcomes and costs (where pharmaceutical companies and payers agree to share the risk regarding a newly-approved product's cost effectiveness in clinical practice) will become more common.

Pharmatimes 08/01/11



### Price Watch UK

#### Extended data reveals quiet December

With important new generics entering the marketplace all the time, our 'fast movers' table was beginning not to reflect accurately what was going on in the market. As we start the New Year, this has been corrected with an overhaul of the table. Six new generics have been included for the first time, while room has been made for fluoxetine. The new products are 'Clopidogrel, Finasteride, Losartan, Pantoprazole, Topiramate, Venlafaxine, Pramipexole and Risedronate

**To see more go to**  
<http://www.wavedata.co.uk/news2a.asp>  
**and view our article from this month's Generics Bulletin.**

**WaveData**

### Pharmacists say: "don't change our wholesaling arrangements"

**Pharmacy** leaders have urged the Medicines and Healthcare Products Regulatory Agency (MHRA) not to change the current arrangements regarding pharmacy wholesale dealing, which the Agency says have become "complicated."

**Section 10** of the Medicines Act exempts pharmacists in specific healthcare settings from some manufacturer and wholesale dealing provisions, but the number of amendments introduced over the years means these arrangements have become complicated, says the MHRA, in its recent "informal consultation" on streamlining and reducing regulatory burdens, conducted as part of its project to consolidate and review UK medicines legislation.

"We will generally review Section 10 to ensure that it is compatible with [EU legislation] and reflects current professional practice," says the Agency in its consultation document.

**But** pharmacy leaders are urging the regulator to leave the arrangements as they are.

"Far from being complicated, the provisions are straightforward and have allowed community pharmacies to provide a service that benefits patients in the UK," says a joint response submitted to the MHRA by Pharmacy Voice, the Pharmaceutical Services Negotiating Committee (PSNC) and Community Pharmacy Wales.

"It is in the interests of patients that community pharmacists continue to be permitted to carry out limited amounts of activities that some would describe as wholesale dealing. This includes selling medicines to other community pharmacies in the UK, or to healthcare professionals in the UK who require modest quantities of medicines to meet the needs of their patients," say the pharmacist leaders.

"Pharmacies are also the source of medicines in limited quantities to those persons or groups of persons identified in the sale or supply exemptions. In practical terms, healthcare providers and those mentioned in the sale or supply exemptions require small quantities, and would not usually be in a position to open wholesaler accounts at reasonable costs to obtain these stocks," they add.

**While** emphasizing that they do not support the export of medicines that are in short supply, the pharmacists state that they "do firmly believe that limited 'wholesaling' for use in the UK, to support patient care, is a vital role for pharmacies."

**As** they stand, the Section 10 exemptions provide the right framework to ensure that patients receive the right medicine, at the right time, from a pharmacy premises that are convenient to access, the groups' submission concludes.

"The existing provisions are straightforward and have allowed community pharmacies to provide a service that is in the best interests of patients," said Rob Darracott, chief executive of Pharmacy Voice.

"Changing regulations around wholesale dealing will obstruct pharmacists in getting patients their medicines quickly and safely," added Sue Sharpe, chief executive of the PSNC. "At a time where pharmacists are experiencing serious supply issues as a result of the indefensible supply problems with many important medicines, responsible professional-to-professional selling can inject much-needed flexibility into the local medicines supply chain," she said.

**The** Royal Pharmaceutical Society has also strongly urged the Agency to retain the exception for pharmacists to hold a wholesale dealer's licence. "The prospect of pharmacies routinely having to pay for and comply with the conditions of a wholesale dealing licence would be disproportionate to its safeguarding benefits, and would effectively increase the regulatory burden to pharmacies at a time when government policy intent is about right-touch regulation," says the Society, in its response to the consultation.

Links

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

[www.npa.co.uk](http://www.npa.co.uk)

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

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

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

Pharmatimes 11/01/11



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## Wavedata Live now even livelier

We've made some changes to our WaveData Live service at <http://www.wavedata.net> to make it more up to date and easier to use.

Over the last couple of years we've been adding invoice prices collected from chemists and dispensing doctors to the existing price list and telesales information.

Example 1:

Product Name	Qty Sold	Supplier Name	Country	Date	Price
Simvastatin Tabs 20mg 28	5	<a href="#">Cordia Healthcare (Paid Prices) (Retail)</a>	Eng.	09/12/2010	£0.24

So the example above shows that 5 packs of Simvastatin Tabs 20mg 28 were bought by a retail chemist in England on the 9th of December from Cordia and £0.24 was paid for each pack.

Example 2:

Product Name	Qty Sold	Supplier Name	Country	Date	Price
Aricept Tabs 10mg 28	1	<a href="#">Phoenix (Paid Prices) (Retail)</a>	PI to Eng.	08/12/2010	£74.58

In the second example a single pack of Aricept Tabs 10mg 28 was purchased by a chemist in England from Phoenix on the 8th of December for £74.58. However this time the product was an import (PI).

To make these invoices (paid prices) easier to see we've highlighted them in green, and now show the quantity bought on the invoice as a new column. [Note; Parallel Imports are highlighted in brown]

You can also see contact details for wholesalers by clicking the name.

Please let us know if you have any thoughts on further improvement by emailing us on [info@wavedata.co.uk](mailto:info@wavedata.co.uk) or phoning on 01702 425 125.

This bulletin now goes out to 1100 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 9th February 2011, as I will be issuing the next one on the 16th February 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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