Commercial Bulletin

Monthly Service **August 2012**

New UK drug pricing system will 'stifle innovation'

The ABPI has attacked the UK government's new drug pricing policy, saying it will not benefit the pharma industry.

Value-Based Pricing is set to come into place on 1 January 2014, and will replace the 50-year old PPRS pricing system, which allows pharma to set its own prices and then have its treatments assessed by NICE.

This looks set to change in 18 months' time, with a new VBP-based system seeing the government set prices for new treatments based on how it values a drug.

As part of this proposal, NICE's role in issuing guidance to the NHS will be downgraded.

Value in this context includes whether a drug can ease the burden of illness, has a societal benefit and/or is a step change in innovation.

The ABPI is expected to start negotiations with the government next month, and its chief executive Stephen Whitehead is now publicly setting out his stall.

He said: "Whilst we support a broader definition of value for the assessment of medicines, we are not convinced that value-based pricing will encourage innovation or reward the most effective medicines.

"In fact, we are concerned that value-based pricing could in fact stifle innovation because it will struggle to accurately reflect the inherent gradual and incremental nature of innovation."

He also said that the ABPI was unclear if VBP will reward the industry enough in order to allow the research and development of new medicines.

"We believe promoting innovation would be better served by developing a pricing scheme that is flexible, holistic, negotiated in a single agreement and which rewards the discovery of new medicines," he said.

Whitehead added that the issue of patients being able to access medicines should be addressed through the government's Innovation, Health and Wealth review, something it is currently working on with the Department of Health.

This review was published in December and looks to increase access to medicines and better support the life sciences industry.

Whitehead makes it clear that the ABPI does not want to see the secondary legislation of VBP replace the voluntary PPRS system, but would rather sort out the issues of access with the Department of Health via the IHW.

Ultimately the ABPI wants the PPRS to remain, but would like to see new definitions of value for drugs, with the aim of getting more medicines to patients that have not been deemed cost-effective by NICE.

Open for business

Whitehead was reacting to the British Prime Minister David Cameron's speech to the Global Health Summit this week, where he discussed his desire to implement VBP.

The PM was also lauding the success of the life sciences industry, adding that the UK was 'open for business' for pharma and biotech companies.

Outside of his VBP discussion, Whitehead said he echoed the Prime Minister's call to investors that the UK is open for business, and it allowed an opportunity for him to also applaud his members.

"The life sciences industry here is a world leader and this event was a great success," he said, adding that it is "showcasing to an international audience the pre-eminent science base we have to develop new medicines and life saving treatments.

"The government's continued support for industry is highly valued and a range of initiatives such as the Patent Box have persuaded companies to research and develop ideas here in the UK," he concluded.

Comment

The ABPI will now argue that in order to have them stay here, they will ultimately need to drop VBP, or risk a similar situation to Germany, where pharma is protesting against new price controls and barriers to reimbursement.

The government, however, needs to show that it is increasing access to new medicines whilst also getting the best deal – wedded to this is the need to keep the pharma industry in the UK, meaning it will need to make some tough decisions in the coming months.

The negotiations begin in earnest from September – expect more public statements and political manoeuvring from both sides as they come toward a deal.

http://www.inpharm.com:8080/news/173711/new-uk-drug-pricing-system-will-stifle-innovation

02/08/12

Special points of interest:

This bulletin is free to Interested people in Pharma & Healthcare

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www.wavedata.co.uk

Inside this issue

Patent Expiry

There has been much talk in the press recently about savings that can be made when branded pharmaceutical patents expire and are then available generically. The recently published Prescribing Cost Analysis for 2011 shows the following costs of dispensing in primary care of branded products which are, or will soon be, available generically:

Atorvastatin £310.9m, Pregabalin £153.2m, Olanzapine £120.8m, Quetiapine £103.8m, Candesartan £86.2m, Donepezil £72.3m and Pioglitazone £65.8m

Often following patent expiry, the Drug Tariff takes some time to catch up with the actual purchase price of these patent-expired molecules. During this time the profitability of dispensing these medicines is much higher than normal, as Drug Tariff price remains high, but purchase price falls dramatically due to competition within the market place. Interestingly Atorvastatin is moving from Category C to Category M only weeks after patent expires in May 2012.

The impact on the original brand sales is dramatic as dispensing contractors substitute the new generic for the original brand at the point of dispensing. In most cases original brand sales fall to less than 10% of previous sales.

What can pharma do to prevent this catastrophic event? The answer is to start planning early for patent expiry and to decide on a strategy which minimises the impact on brand sales.

Very often when a product comes off patent, whilst existing brands will suffer from fierce price competition, previous experience with the patent expiry of proton pumps, ACE inhibitors, sartans and statins shows that the market expands dramatically as a whole. Whilst market share will drop in absolute terms, existing brand sales may very well increase if the pharma company's post patent strategy and marketing efforts are handled correctly.

Surelines are acknowledged experts on the Drug Tariff, remuneration of dispensing contractors and the general prescribing/dispensing interface and have historical reimbursement prices and data going back over fifteen years. This historical data includes Drug Tariff prices and market prices of generics. Begin your patent expiry strategic planning by talking to them first. Either email nigel@surelines.com or telephone him on 01604 859000.

Surelines 10/08/12

PRICE WATCH ..... UK

Atorvastatin prices continue downwards

The average trade price of 28-tablet packs of atorvastatin 20mg dropped by a fifth last month. It has now reached £1.83 (US$2.83), although prices as low as £1.23 were on offer in July (see Figure 1). Already in category M of the Drug Tariff of reimbursement prices, the product is worth £6.16 to pharmacists when they dispense it. In terms of dispensing margin, this represents an average profit of over 70%.

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

WaveData

Irish bailout warning over health overspend

The Irish government has been told to show how it plans to cut health spending, after the Health Service Executive (HSE) revealed that its financial deficit hit 281.6 million euros in the first five months of this year.

The requirement has come from Ireland's bailout "troika" - the European Commission, the European Central Bank (ECB) and the International Monetary Fund (IMF) - following their seventh review of the government's compliance with the bailout programme, half-way through its four-year run. They have given Ministers until the end of September to present measures aimed at rectifying the HSE's runaway deficit.

According to the Executive, reasons for its overspending - which increased by 80 million euros in one month alone - include slow progress in implementing savings of more than 100 million euros on pharmaceutical costs and 140 million euros from health insurers. And the Minister for Public Expenditure, Brendan Howlin, has pointed out that the deficit accounts for just 2% of the HSE's annual budget of 13.4 billion euros.

Following a meeting of the cabinet subcommittee on health, held to discuss the HSE's overspend, Minister for Health James Reilly said that all doctors employed by the state, and pharmacists, were being asked to supply patients with generic drugs.

"As a result of the financial pressures that we are experiencing and will experience in the future, more cost-effective prescribing by doctors and pharmacists is clearly in the patient's interest and the national interest," The Irish Times reports Dr Reilly as stating.

Also, the government has now published its Health (Pricing and Supply of Medical Goods) Bill 2012, which provides for the introduction of a system of generic substitution and reference pricing,

The bill would permit pharmacists to substitute cheaper generic versions for prescribed branded drugs, if they have been designated as interchangeable by the Irish Medicines Board (IMB) and if it is safe to do so. It would also set reference prices for groups of interchangeable medicines, and require patients who want a particular brand that costs more than the reference price to pay the additional cost out of pocket.

Official estimates put potential savings to the state resulting from the introduction of reference pricing as high as 100 million euros a year.

"Generic substitution coupled with reference pricing provides patients with an incentive to opt for the cheapest available product, but does not impose any unavoidable additional costs on patients," says the Department of Health.

The bill also sets out statutory procedures governing the supply, reimbursement and pricing of medicines and other items to patients under the General Medical Services (GMS) and community drugs schemes. It would allow the HSE to attach conditions to the supply of certain items, provided that any restrictions are evidence-based and in the interests of patients and ensuring value for money, the Department adds.

The bill has been introduced into the Seanad, the upper house of the Irish Parliament (Oireachtas) this week, and is expected to become law by the end of the year.

Also this week, the cabinet approved the Health Service Executive (Governance) Bill 2012, which will abolish the HSE board structure and replace it with a directorate as the new governing body. The aim is to make the Executive more directly accountable to the Minister for Health and the Oireachtas and help prepare for the next phase of the country's health reforms and, ultimately, the introduction of universal health insurance.

"This government inherited a two-tier health system which is inherently unfair to many citizens," said Dr Reilly. The bill "is a significant step on the road to the abolition of our two-tier health system and its replacement with a system that responds to our needs and not our financial means," he added.

HSE chief executive Cathal Magree has announced that he plans to step down from his post "at the appropriate time of transition to the new governance structure."

Links

www.dohc.ie

www.hse.ie

www.imb.ie

Pharmatimes 20/07/12

Per capita income-linked reference pricing planned for India

The Indian government is considering the proposal to introduce a per capita income-linked reference pricing mechanism for drugs, which could see the prices of some medicines being cut by up to a third.

Based on recommendations from an inter-ministerial committee, the proposal recommends fixing the price of patented drugs by comparing the prices granted in the UK, Canada, France, Australia and New Zealand. The retail price would be fixed by adjusting to the per capita income of the country, the committee advises.

In the report, the committee notes the price of Roche's lung cancer drug Tarceva, which costs the equivalent of 121,000 rupees in Australia and France but costs 35,450 rupees in India. Adjusted to per capita income would drop the price of the drug in Australia and France to 10,309 and 11,643 rupees respectively, which, the committee says, should be the level for the retail price in India.

These calculations would only apply to drugs that have no therapeutic alternatives on the market.

The move comes at an interesting time for pharma in India as the country looks to shakeup drug procurement and review the intellectual property process.

In June, the country announced plans to make medicines free for everyone from October. Under the proposal the government would fund 75% of the costs and would be based on a central procurement agency that would buy the drugs in bulk. Meanwhile, in February, Natco Pharma was granted a compulsory licence to make and sell a copy of Bayer HealthCare's patented cancer drug Nexavar for a fraction of the cost – a move that could become more common in a bid to reduce drug prices.

The Indian industry trade body, the Indian Pharmaceutical Alliance, believes the reference pricing proposal has value based on how governments in developed countries, which tend to pay the majority of healthcare costs, are able to negotiate prices. In India, by comparison, up to 79% of patients foot the bill for their own healthcare.

However, the Organisation of Pharmaceutical Producers of India, the body that lobby's industry, called the proposal "fundamentally flawed" and planned to fight it.

"To apply the ration of per capita income of India and a developed country to arrive at the in-market price of an imported patented product manufactured in a developed country with a totally different cost structure will be highly irrational and construed as comparison between apples and oranges," said OPPI director-general Tapan Ray.

The report is to be reviewed by the department of pharmaceuticals and then will be open for consultation.

Pharmatimes 17/08/12

Reduced wholesaler distribution model

Following an internal review of the company's processes for distributing medicines, Servier is introducing new arrangements to simplify and improve the distribution of its branded medicines in the UK.

On the basis of objective, transparent and non-discriminatory criteria, Servier has selected two companies to work as partners in a reduced wholesaler distribution model for a period of two years: Alliance Healthcare (Distribution) Ltd and AAH Pharmaceuticals Limited. Under the new model, which will become effective as of 1 September 2012, the two selected companies will distribute Servier's branded medicines to hospital pharmacies, community pharmacies and dispensing doctors in England, Wales, Scotland and Northern Ireland.

Servier is confident that the new model will improve the quality of supply for Servier branded products to the market in the most effective manner without impacting on NHS budgets.

The new model will ensure better access to medicines for patients. It will maintain appropriate and continued supply of |Servier's branded medicines to pharmacies and persons authorised to supply medicinal products, so that high levels of service are provided to our customers and that needs of patients in the UK are met.

We will be working closely with Alliance Healthcare (Distribution) Limited, and AAH Pharmaceuticals Limited to enable a smooth transition to the new distribution arrangements ahead of 1 September 2012. This will hopefully ensure there is no disruption to the supply of Servier branded medicines.

Servier Laboratories Ltd 06/08/12

www.servier.co.uk

CCGs already improving patient care

Clinical Commissioning Groups - the new structures set up under the Health and Social Care Act to control most of the NHS's budget - are already improving patient care, says their representative body.

NHS Clinical Commissioners (NHSCC), a group billing itself as 'an independent collective voice' for CCGs, has published 12 case studies in 'Clinical Commissioning in Action', a report it describes as a 'valuable snapshot'.

From April next year 212 CCGs, run largely by GPs and other health professionals, will replace the existing 152 primary care trusts.

In essence, it means local clinicians are leading on local health services with a view, for example, to taking pressure off A&E services in their area.

The NHSCC report says sharing best practice on improvements to patient care and experience will help but it insists: "None of these schemes are rocket science. Very often they are simple solutions to obvious problems."

It cites Nene CCG near Kettering's investment in additional training for practice nurses so they can treat patients with minor injuries in their surgeries and order X-rays without going through a doctor.

South Devon and Torbay CCG is attempting to reduce costs for outpatient appointments, many of which did not result in any treatment, by providing safe follow-up for men with raised prostate specific antigen levels.

They usually need monitoring, even if they have not had treatment for prostate cancer, and this means an outpatient visit, a wait for blood test results - and a repeat of the process in six months' time.

Now patients can have blood tests locally and be contacted with the results, saving an estimated 1,500 outpatient appointments a year.

Meanwhile West London CCG has developed an integrated programme providing a single point of access to a range of mental health services for patients in Kensington and Chelsea.

And the report describes how the CCG for Great Yarmouth and Waveney sought to understand why many people with long-term conditions were bypassing local health facilities and going to A&E - and has ended up asking them for help in redesigning the system to encourage better use.

"This is just a glimpse of what's possible," said NHSCC interim president Dr Michael Dixon. "Clinical commissioning has a huge potential to bring real transformation to the NHS and better outcomes for patients."

The organisation's interim chair, Dr Charles Alessi, said there was a "need to celebrate the successes, however small, as these will encourage and inspire others to achieve more for their patients".

There was significant opposition from health professionals to the creation of CCGs and suspicions as to their effectiveness remain.

Last month a survey published by Labour's Shadow Health Team showed that 125 separate treatments, previously provided free by the NHS, have been restricted or stopped by NHS bodies including CCGs in the last two years.

Despite the NHS having to make £20 billion in efficiency savings by 2015, health minister Simon Burns said the government would not stand for restrictions coming from the need to save costs.

The NHSCC's findings mirror those from a report by the government last February which demonstrated ways in which emerging CCGs were already benefiting patients.

Examples then included work by a Newcastle CCG which had led to the number of patients admitted to hospital with emergency respiratory problems falling by 70%, and a Wigan CCG's redesign of stroke services which cut the average hospital stay for patients from 56 days to 12 days.

NHSCC encompasses the NAPC and the NHS Alliance and works with the NHS Confederation. The work of CCGs is overseen by the NHS Commissioning Board Authority.

http://www.inpharm.com:8080/news/173524/ccgs-already-improving-patient-care

27/07/12

Talking labels boost compliance in patients with poor eyesight

Electronic medicines labels that talk to patients with poor eyesight are helping to boost compliance in a small pilot in Scotland.

David Hunter, from Trossachs Pharmacy in Callander, Scotland, has been testing the labels with two patients in a trial funded by NHS Forth Valley's health board.

Pharmacists can record a 10- to 15-second voice message on the credit card-sized labels that can be activated by patients pressing a large button. The messages typically name the medication and provide information on the correct dose. Where appropriate, the label messages can also include warnings such as the need to avoid alcohol or to contact a doctor if side effects are experienced.

Mr Hunter told C+D that he had already seen an improvement in medicine compliance from both patients included in the pilot. "We're on first name terms and they are regularly contacting me and asking about their medication, which they would probably never have done before," he said.

Mr Hunter advised pharmacists interested in the scheme to contact their local health board for funding. Each label costs around £5, but Mr Hunter said the cost was offset by long-term savings from the improvements made to patient compliance. "You're going to get a patient who's more interested in compliance," he said. "You get more one-on-one contact."

NHS Forth Valley telehealthcare lead Ann Allison said the talking labels offered "the antidote to dangerous mistakes". "An inability to read medicine instructions can lead to people taking the wrong pill at the wrong time or at the wrong dose," she said

Chemist & Druggist 23/07/12

WaveData — Top ten products

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

Both uk and pi prices were viewed for each product, giving some indication of where the focus was in July 2012

Atorvastatin Tabs 10mg 28

Serevent Evohaler 25mcg 1 (120 Doses)

Atorvastatin Tabs 20mg 28

Seroquel XL Tabs 200mg 60

Betahistine Tabs 16mg 84

Perindopril Tabs 2mg 30

Adalat LA Tabs 30mg 28

Betahistine Tabs 8mg 84

Crestor Tabs 5mg 28

Domperidone Suspension 1mg/1ml 200ml

This bulletin now goes out to 2300 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 12th September 2012, as I will be issuing the next one on the 19th September 2012.

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

http://www.wavedata.co.uk

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