

Obama seeks a seven-year period

The data-exclusivity term for innovative biotech medicines should be cut from 12 years to seven, beginning in 2012, according to a deficit-reduction and job-creation package put forward by US president Barack Obama. Obama's plan also calls for a ban on 'pay-for-delay' settlements.

Obama insists that reducing the exclusivity period "strikes a balance between promoting affordable access to medications and encouraging innovation to develop needed therapies". The proposal – which includes banning evergreening by halting additional exclusivity periods for minor changes to branded biologic drugs – will result in savings of US\$3.5 billion to federal healthcare programmes such as Medicare and Medicaid over a 10 year timeframe.

On pay-for-delay deals, Obama proposes authorising the Federal Trade Commission (FTC) to stop companies entering into deals that would delay generic competition. It cites the FTC's finding that such litigation settlements on average delay generic entry by 17 months and cost US consumers US\$3.5 billion per year (Generics bulletin, 3 September 2010, page 16).

The same two measures were included in the 2012 budget proposals that Obama announced earlier this year (Generics bulletin, 4 March 2011, page 1). However, brand industry bodies have defended the 12-year exclusivity term, insisting it has broad support in congress. Several senators are also pushing to include 12-year exclusivity for biologic drugs in trade deals that the US is currently negotiating.

Generics Bulletin 03/10/11

GPs see "thousands of patients" at two Sainsbury's stores

GP surgeries at two Sainsbury's stores have seen "thousands of patients" since the in-store doctor scheme was first launched in 2008, the supermarket has revealed.

Patients value the service being offered and staff in the surgeries and pharmacies involved had enjoyed an "excellent" working relationship, a spokesperson said.

Sainsbury's pharmacist at the Colne store Iram Anwar said she had a good relationship with the in-store GP at her

branch, and felt the in-store surgery had helped "raise awareness" of the services pharmacy offered.

Sainsbury's will consider expanding the in-store surgery scheme, saying it would welcome GPs or PCTs approaching them to suggest opening further surgeries. However, the supermarket chain had not "set a firm target" for this, a spokesperson added.

Sainsbury's [became the first supermarket to launch an in-store GP service](#) in 2008, running

a surgery from the consultation room of its 100-hour pharmacy in Heaton Park, near Manchester.

It opened another GP surgery in July this year in Colne, Lancashire, and a nurse-led facility at the Newcastle under Lyme store.

The supermarket offered GPs [free use of its pharmacy consultation rooms](#) to run medical surgeries for up to 20 hours a week last year.

Chemist & Druggist 04/10/11

Special points of Interest

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Specials tariff details unveiled

Details of the new specials tariff, that comes into effect on November 1, have been unveiled by the NHS Business Services Authority (NHS BSA) and PSNC.

The specials prices, which are being introduced as a new section of the Drug Tariff, will replace category E in a move designed to create a "more transparent system for reimbursing specials".

Prices for 58 specials now appear under Part VIII B of the Drug Tariff, which NHS BSA says will "capture the majority of high cost, high volume specials prescribed".

The list of products in the tariff will be reviewed every six months, while prices will be reviewed quarterly. And the prices would be calculated using a "similar" system to category M, said NHS BSA.

Pharmacists buying specials at a higher price than that listed would not be reimbursed the extra cost, it warned.

"Pharmacy contractors are expected to shop around and negotiate lower prices in a similar way as they do for generics," NHS BSA said.

But contractors were advised to contact PSNC if they experienced "exceptional circumstances", when it would look at applying for an NCSO concession.

Specials that are not listed under the tariff will be reimbursed differently, depending on where the product was manufactured.

Products made by an MHRA-licensed manufacturer will be reimbursed at the invoice price, minus any discounts or rebates.

There will also be a flat fee of £20 to contribute to any out-of-pocket expenses.

But if the product is manufactured under the section 10 exemption in the Medicines Act, pharmacies will be reimbursed for the cost of the ingredients. And there will be a £20 extemporaneous dispensing fee for the cost of preparing or sourcing the product.

Pharmacists should endorse prescriptions 'SP' to claim out-of-pocket expenses and 'ED' to claim the extemporaneous dispensing fee.

Chemist & Druggist 14/10/11

Actavis slashes buying scheme prices

Actavis has relaunched its Accumulator buying scheme with higher discounts and lower trade prices for pharmacy customers.

The scheme, relaunched on October 1, now includes discounts of up to 30 per cent for pharmacies spending more than £4,000 a month. The generics manufacturer has also cut more than 180 trade prices.

The new rates should help pharmacies survive financial pressures, said Actavis director Michael Cann.

"It's very clear to us it's a challenging environment and pharmacies need to be sure their profit and income streams are maintained," he said. "We've relaunched the Accumulator scheme to show pharmacy that we're prepared to adapt our pricing to meet their needs as we go forward."

The scheme was designed to be "clear and transparent" to minimise the time pressure on pharmacists, he added.

"One of the key issues is that pharmacies find themselves under time pressure," he said. "We recognise that pharmacists don't have the time to scan every price list and ring every wholesaler."

Pharmacists interested in joining the Accumulator scheme can contact their Actavis sales representative or customer service team on 0800 731 0370 for more details.

Chemist & Druggist 04/10/11

U.K. pharma protests value-based pricing

It's no secret that Europe's austerity push has put the squeeze on drug-makers. Not surprisingly, troubled Greece, Spain and Italy have all gone after drug spending as a way to dig out of their financial holes. But so have the healthier countries, including AAA-rated Germany and the U.K.

It's not for lack of pushback from pharma. Eli Lilly CEO John Lechleiter went on a lobbying tour to persuade German officials that current price cuts--and forthcoming value-based pricing on new drugs--will end up hurting their country in the end by discouraging pharma investment and innovation. And no doubt plenty of arm-twisting from plenty of industry types has been going on behind

the scenes all over Europe.

The latest protest from pricing-pressured drugmakers comes from the U.K., where the CEO of the Association of the British Pharmaceutical Industry said new value-based pricing set to take effect in 2014 won't do anything to "encourage innovation" in the industry.

Keep the current Pharmaceutical Price Regulation Scheme, which is a profit-controlled model, ABPI's Stephen Whitehead told the *Telegraph*. Add elements of value-based pricing to the PPRS, by all means, he said. But don't switch altogether. "We would like there to be a single holistic scheme that is low on bureaucracy, efficient, patient-focused and reflects an element of freedom of pricing," Whitehead said.

It's those last three words that mean most. Losing pricing freedom right and left, pharma would like to hang onto it wherever it can. Unfortunately for the industry, the U.K. government has its own aims. "We need a much closer link between the price the NHS pays and the value that a new medicine delivers," a spokesman told the *Telegraph*.

Related Articles:

[In U.S. and Spain, pharma says price cuts will cost jobs](#)

[Spain's new rules shut out off-patent brands](#)

[Pharma faces bigger hurdles in Europe](#)

FiercePharma 21/09/11

MHRA and Interpol crack down on 600 illegal UK drugs web pages

The MHRA and the Metropolitan Police have shut down 600 UK web pages as part of a week-long international crackdown on the illegal internet drugs trade.

The drugs watchdog also worked with local police to carry out raids at 16 addresses and 13 arrests between September 20 and 27 during Operation Pangea IV.

The MHRA seized more than 1 million doses of illegal medicine worth approximately £2 million, including 52,000 doses of counterfeit pills, in conjunction with the UK Border Agency.

An estimated 13,500 illegal online pharmacy websites were shut down, 55 people arrested and £5m worth of counterfeit and illegal medicines were seized globally in the largest enforcement action of its kind.

Operation Pangea IV involved 80 countries and was co-ordinated by Interpol.

Drugs seized by the MHRA agency included epilepsy, asthma, acne, narcolepsy and erectile dysfunction medicines.

Chemist & Druggist 30/09/11



Fluoxetine capsules cost just a halfpenny

Thanks to a price cut of more than a fifth last month, independent pharmacists and dispensing doctors could have bought 20mg capsules of fluoxetine for just a halfpenny each. As Figure 1 shows, a 21% cut in the lowest price of the antidepressant meant that 30-capsule packs of fluoxetine 20mg were on offer for just £0.15 (US\$0.23). Such a steep price cut by one player, possibly due to short-dated stock, also affected fluoxetine's average trade price, pulling it down by 5% during the month.

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

WaveData

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Have you ever wished you had a list of drugs coming off patent?

Then a new service launched recently by MPA will help you.

MPA Pharma Patent Spotlight is a monthly report that identifies which products are due to lose their product patent protection in the next two years; which have supplementary protection certificates (SPCs) and whether any have been granted paediatric extensions.

The report, written by patent experts with over 40 years of pharmaceutical patent experience; is emailed to subscribers as an Excel spreadsheet. In addition, an email alert service notifies subscribers of any late changes affecting products.

The service costs £995 per annum for the UK Pharma Patent Spotlight. Coverage and pricing for other EU member states is available upon request.

Incentive

To help new subscribers Wavedata have agreed to offer new subscribers 250 free credits for the online Wavedata live service at <http://wavedata.net>

So please email us your contact details at info@wavedata.co.uk, we will then pass your name onto MPA and send you login details for the live pricing service.

Below is a sample, shown as it was reported on 1st January 2008:

MPA Patent Spotlight - Sample Data - As of 1st January 2008									
INN	Brand	Patentee	SPC Applicant	1st EU	Patent		SPC & Paediatric Expiry & Status		
				Authorisation	Expiry	Status	SPC	Paediatric	SPC Status
fordaparinsodium	Arixtra	Sanofi-Synthelabo	Sanofi-Synthelabo	21/03/2002	16/01/2008	Expired	16/01/2008	not applicable	Inforce
deferiprone	Feriprox	NFD Corporation	BIG International	25/08/1999	23/03/2008	Expired	23/03/2008	not applicable	Inforce
interferonalpha-n1	Interferon	Amgen Inc	Amgen Inc.	01/02/1999	24/04/2008	Expired	24/04/2008	not applicable	Inforce
imidapril Hcl.	Harleed	Tanabe Sanyaku	Tanabe Sanyaku	12/11/1997	19/05/2008	Expired	19/05/2008	not applicable	Inforce
bicalutamide	Bicaluplex	IC plc	Zeneca	23/02/1995	07/07/2008	Expired	07/07/2008	not applicable	Inforce
desflurane	Suprane	ECC Inc.	ChmadaPharm	19/07/1993	31/01/2008	Expired	18/07/2008	not applicable	Inforce
tiludronic acid (tiludronate)	Skelid	Sanofi	Sanofi	20/02/1995	25/07/2008	Expired	24/07/2008	not applicable	Inforce
lenograstim	Granocyte	Chugai Sanyaku KK	Chugai Sanyaku	28/07/1993	07/02/2008	Expired	27/07/2008	not applicable	Inforce
fluvastatin	Lescol	Sandoz	Sandoz AG	23/08/1993	21/11/2008	Expired	22/08/2008	not applicable	Inforce
cefdinir	Omnicef	Fujisawa	Fujisawa	16/06/1997	27/09/2008	Expired	27/09/2008	not applicable	Inforce
interferonbeta-1b	Betaferon	Gatus Corp	Gatus Corp.	30/11/1995	13/10/2008	Expired	12/10/2008	not applicable	Inforce
ropinride hydrochloride	Requip	SmithKline Beecham	SmithKline Beecham	02/07/1996	30/11/2008	Expired	29/11/2008	not applicable	Inforce
venlafaxine hydrochloride	Eflexor	American Home Products	American Home Products	05/05/1994	06/12/2008	Expired	06/12/2008	not applicable	Inforce
famridovir	Famvir	Beecham Group plc	Beecham Group	10/12/1993	08/09/2008	Expired	09/12/2008	not applicable	Inforce
atosiban	Tradolite	Ferring	Ferring	20/01/2000	14/12/2008	Expired	14/12/2008	not applicable	Inforce

Northern Ireland mulls new Rx charges to pay for life-saving drugs

Northern Ireland could re-introduce prescription charges as a way of paying for life-saving drugs, Health Minister Edwin Poots has suggested.

Prescription charges were abolished in April 2010 by the previous Health Minister, Ulster Unionist Michael McGimpsey, and Mr Poots' party, the Democratic Unionists, made no mention of re-introducing them in their manifesto issued before the May 5 elections this year.

However, Mr Poots has now said that reintroducing a charge of as little as 50 pence per prescription, or even less, would affect only 11% of the population but could raise millions to fund supplies of "life-changing and life-saving" drugs to treat conditions such as rheumatoid arthritis and cancer.

The minister told the BBC that he feels a "moral obligation" to supply these drugs, which are not currently being supplied to all patients in Northern Ireland who need them, and that he was looking at "various models" to address the issue.

"We are looking at a range of funding streams, but the one option which most definitely is not available to us is additional cash from the budget," he added, in comments made to the Belfast News Letter.

Mr Poots also said that if prescription charges were to be re-introduced, "it certainly will not happen within this financial year."

Nevertheless, he added that it was "simply unacceptable" that "life-changing and potentially life-saving" medicines "are available everywhere but here in Northern Ireland."

Mr McGimpsey had put the cost of abolishing the prescription charge at around £13 million, but Mr Poots says he believes the true cost is actually closer to £30 million.

- In late June, a public opinion poll conducted by Northern Ireland's Patient and Client Council found that most people considered that the re-introduction of a minimum prescription charge would be acceptable, provided the list of illnesses that exempt patients from charges was reviewed to ensure that the needs of people with long-term serious conditions could be adequately met.

Also, they said that individuals' economic and social situations and needs must be taken into account; for example, medication for pensioners, children and people on low incomes should remain free.

Pharmatimes 06/10/11

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

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

Anastrozole Tabs 1mg 28

Levothyroxine Tabs 100mcg 28

Levothyroxine Tabs 50mcg 28

Pioglitazone Tabs 15mg 28

Levetiracetam Tabs 250mg 60

Levothyroxine Tabs 25mcg 28

Citalopram Tabs 20mg 28

Levetiracetam Tabs 1g 60

Naftidrofuryl Caps 100mg 84

Pioglitazone Tabs 30mg 28

This bulletin now goes out to 1700 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 16th November 2011, as I will be issuing the next one on the 23rd November 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

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