



COMMERCIAL BULLETIN

Monthly service

December 2011

Pressure mounts on ministers to take more action on shortages

Health ministers are coming under increasing pressure from MPs and pharmacy leaders to take action over stock shortages, despite promising that the government is "not prepared to be complacent" about the problems.

Ogmore MP Huw Irranca-Davies promised to push for further government action on medicines shortages after claiming that minister Simon Burns failed to answer "fundamental questions" during a parliamentary debate on the topic on November 24.

"The minister didn't seem to recognise that this issue has been going on for a number of years and seems to be worsening," the Labour MP told C+D after the debate.

Mr Irranca-Davies used the debate to outline the problems medicines shortages were causing. He cited preliminary results from the C+D Stocks Survey, which continues to uncover incidents of patients being harmed by stock shortages and has found that some pharmacists are spending more than five hours a week sourcing medicines, as part of his evidence to parliament.

In his response, Mr Burns told parliament that the government would keep a "watchful eye" on the situation and pledged: "This is not an issue that will be discussed just once and then forgotten."

He also stressed that manufacturers and distributors were already duty-bound to ensure the continuous supply of medicines and could face regulatory action or criminal prosecution if they failed to do so.

"Some other EU member states have a very precise definition of how soon medicines should be received, but we are cautious about going down that road. It would vastly increase regulation on the industry and drive up costs across the board," he argued.

But his comments came under fire from pharmacy leaders, who questioned his assertion that supply chain best practice guidance had been "very successful in minimising the impact of shortages".

"The guidance has not been successful – patients and pharmacists have seen no improvement in the situation," said PSNC chief executive Sue Sharpe.

This week the committee revealed that 84 per cent of respondents to its survey on shortages had seen patients going without medicines because of delays in dispensing, and 89 per cent felt the problems had not improved in the past three months.

Mr Irranca-Davies also argued that the measures brought in so far were not working, and he expressed concern that Mr Burns had told parliament the government did not want to bring in additional regulation to resolve the matter.

"That's the crux of the matter – the government seems minded not to bring in any additional regulation no matter what the necessity or how strong the support," Mr Irranca-Davies told C+D.

Mr Irranca-Davies now hopes to secure a longer debate on the matter so that he can go into more detailed discussion and, where relevant, challenge the minister on his responses. He has also written to health boards in Wales and to PCTs in England to gather their views on the matter, and he hopes to be able to confront the government with evidence of the impact stock shortages are having.

Last chance to help!

If your patients and staff are being affected by medicines shortages, complete the C+D Stocks Survey by December 16 and we'll submit your evidence to the APPG inquiry and to the DH, and enter you into a prize draw to win £150 of John Lewis vouchers:

<http://www.chemistanddruggist.co.uk//supply-chain>

Chemist & Druggist 09/12/11

Special points of interest:

This bulletin is free to interested people in Pharma & Healthcare

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NHS Direct app helps one million patients

Health advice has now been given to more than one million NHS patients through their smartphones after an app was launched by the health service just six months ago.

The free NHS Direct app, available to patients with Android and iPhone devices, was launched in May to provide health and symptom checkers on a range of problems including dental pain, diarrhoea and vomiting, abdominal pain, rashes, back pain and burns.

The app also gives advice on relieving symptoms for conditions like flu, and can give more specialist advice on issues including mental health, contraception, sexual health matters and pregnancy.

Patients using the app have been able to get instant self-care advice,

which can be saved and accessed at a later date. And the service has been linked to the NHS Direct phone service, with patients given the option of submitting their details to be called back by a nurse adviser.

NHS Direct chief operating officer Ronnette Lucraft said the volume of users had shown the popularity of accessing healthcare remotely.

"More people now access NHS Direct's services online than they do over the phone and it is our aim to continue to provide our services in places that patients and the public will find useful and convenient," she said.

"The mobile app is a more discreet and less embarrassing way of seeking health advice for sensitive issues in public or crowded places. We

know that people also value the ability to request a call-back from a nurse if it is required, which is why the app is fully integrated with our phone service."

The app has received a number of positive review from users. One said: "The idea behind this app is fantastic. It will offer a lot of reassurance to those who need it and hopefully make some impact upon waiting times in A&E and GPs."

And another patient said: "Great app; I like the way you can store the advice or email it. It's good to know you can get reliable health information from a credible source."

http://www.publicservice.co.uk/news_story.asp?id=18008
14/11/11

Ireland's exports set to fall off the patent cliff

The patent cliff is like a yurt. It has many sides. To Big Pharma, it's been a looming threat for years. To generics makers, it's a multibillion-dollar boon. To India, with its generics-heavy pharma industry, it's a once-in-a-lifetime economic development opportunity. But to Ireland, which produces some of the world's biggest-selling branded drugs, it could be an economic sinkhole.

As *Bloomberg* reports, 5 of the globe's 12 top selling medicines are made in Ireland, including Pfizer's Lipitor, Eli Lilly's Zyprexa, and Merck's Singulair. Those 5 meds accounted for \$27 billion in 2010 sales. By 2013, those same 5 drugs will generate less than half that amount—\$13 billion. As those sales decline, so do Ireland's exports.

And if you look beyond the dozen best-sellers, the impact only grows. An economic geography expert at the National University of Ireland tells *Bloomberg* that about €19 billion, or \$26 billion, of Ireland's exports could be at risk as drugs lose patent protection. To put this in perspective, Ireland exported €49 billion of chemicals and pharma products last year, the news service says, and that's 55% of the country's merchandise exports.

The threat to exports comes at a bad time for Ireland. The country has more than its share of economic challenges, and exporting has been one of the few bright spots. The real question now is whether drugmakers will actually stick around after the blockbusters lose exclusivity. Pfizer has already put its Lipitor-formulation site in Cork up for sale, although it plans to continue making the drug's active ingredient in Ireland. "Will the pharma companies keep producing the drugs in Ireland as they come off patent?" was the question Matt Moran, director of PharmaChemical Ireland, posed to *Bloomberg*. He noted that this was a big issue for the country.

Fiercepharma 22/11/11



Pfizer cuts discounts from January 1

Pharmacists will have to pay more for Pfizer's patent products next year as part of the manufacturer's new discount scheme.

From January 1, the manufacturer will put its products into three categories, with the standard discount for patent-protected products reduced from 8.5 per cent to 7.5 per cent.

There will be no significant changes to products falling into the manufacturer's off-patent and discount not given categories, so the net effect on those medicines would be "negligible," said Pfizer's commercial account director Paul Wilson.

PSNC said it was "extremely concerned" about any moves that would reduce margins after clawback available on branded medicines, warning that they could distort the fair delivery of funding.

"PSNC has made these concerns known forcibly to the company concerned and will ensure this is raised in negotiations with the Department of Health," the committee said. It added that any impact of the Pfizer changes would be reflected in its margins survey.

However, despite the reduction in product discounts, Mr Wilson said Pfizer believed the impact of the changes on most community pharmacists would be "minimal" and that the revised scheme was competitive. "While we appreciate there is a reduction in the discount, we believe this is a generous scheme," he said.

Pfizer's top-up discount scheme will still apply to patent protected medicines, and while off-patent medicines will be invoiced at the full NHS price, products available under the Pfizer enhanced discount scheme will continue to achieve retrospective discount, the manufacturer confirmed.

Mr Wilson also stressed that the company was "committed to continuing to support community pharmacy". "Since 2008, when we started investing in community pharmacy, we've trained over 10,000 pharmacists in such programmes as Building Confidence in MURs," he said.

He added that the business had recently launched a similar course, due to be rolled out over the next few months, to help pharmacists address the challenges of the new medicine service.

Mr Wilson said Pfizer had decided to alter its discount scheme after conducting a review of its products portfolio. During the past four years this portfolio had changed significantly with the acquisition of pharmaceutical company Wyeth, and the launch of a small generics portfolio, he explained. A number of products had either recently lost their patent protection or were due to lose them shortly, he added.

For more information, pharmacists can contact Pfizer's customer contact centre on 0845 608 8866.
Chemist & Druggist 06/12/11

Pramipexole prices offer discounts of 90%

Both strengths of Pramipexole in figure 1 experienced dramatic falls in their average prices last month. Nearly a third was cut from the average prices of 30-count packs of Pramipexole 180mcg and 700mcg tablets in November. This left them both offering more than 90% discounts to Boehringer Ingelheim's Mirapexin brand that had lost its exclusivity less than a year earlier in December 2010.

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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Healthcare at home report

Earlier this month, the Department of Health's Commercial Medicines Unit published the final report 'Homecare Medicines Report - 'Towards a Vision for the Future.

This report, written by Mark Hackett, CEO at the University Hospital Southampton NHS Foundation Trust begins:

The importance of homecare medicines for patients cannot be underestimated. There are up to 200,000 people in England who receive this service, which has helped to transform their lives whilst they suffer from chronic or stable conditions that require regular treatment and monitoring. Since 1995, the NHS has been able to provide these home-care services at patients' homes and in the last four years there has been a rapid development of services which now incur around £1 billion expenditure each year.

The Chief Pharmaceutical Officer at the Department of Health asked me to undertake a review of the homecare medicines supply and associated services in England to establish what are the current challenges and issues and what should occur in the future. The review was commenced in November 2010 and has sought to address this

The rest of this report can be found at: <http://cmu.dh.gov.uk/files/2011/12/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf>

Boots opens 14th in-store GP surgery in Derby

A Derby GP practice has opened a satellite surgery via a [Boots](#) pharmacy, bringing the number of in-store GP surgeries operating in Boots stores in the UK to 14.

The latest opening in the Boots' Westfield centre branch in Derby will provide primary medical care services and is run by the city's long-established Wilson Street surgery. The surgery will be open Monday to Friday, a Boots spokesperson said.

GPs were looking forward to offering patients their services "at an even more convenient location", said practice manager Sue Altoft.

Boots director of pharmacy Peter Bainbridge said the company's aim was to "work alongside other health-care professionals to provide quality, convenient healthcare services to our customers".

Boots now has 24 partnership schemes with the NHS, including

dental practices in Manchester and London.

The opening of the GP surgery follows Sainsbury's opening its fourth in-store GP surgery last week.

Morrisons supermarket has also voiced plans to launch GP surgeries at its stores.

Chemist & Druggist 21/11/11

Generic drug companies to create private-sector drug shortage warning system

The generic drug industry's major trade group will develop a private-sector system that would warn about medicine shortages, even as the government threatens to step in and officially mandate similar action.

Generic drugmakers would create an advance warning system of sorts by working with distributors, wholesalers and other parts of the system that brings drugs to the marketplace, Ralph Neas, head of the Generic Pharmaceutical Association, told Reuters after a Senate hearing on drug shortages. He has suggested such a process should not solely involve the FDA, though said industry and regulators can, and should work together to make such a process succeed.

"They just don't have the analytical background with respect to the private sector," Neas told Reuters.

Maybe so, but government efforts to address the problem are increasing. At least one Senate bill is pending that would compel companies to inform the FDA when shortages are likely, Reuters notes. In October, President Obama also issued an executive order calling on the agency to get better advance notice when there are supply issues. And on Dec. 15, in response to another executive order, the FDA issued an interim final rule requiring manufacturers to report any interruptions in production for critical drugs. But the Government Accountability Office recently concluded that the FDA didn't have enough systematic data, resources or performance measures to respond to drug shortages on its own under existing regulations.

A solution to the drug shortage problem is crucial. FDA says early notification helped it prevent 137 shortages over the previous two years by working with other companies, Reuters reports. But drug shortages this year have now reached 220, up from 56 5 years ago.

FiercePharma 16/12/11

Introduction to the NHS Commercial Medicines Unit (CMU)

Arrangements for pricing and supply of medicines are complex and medicines shortages and product discontinuations have become increasingly prevalent for a number of reasons.

There is significant national interest and leadership in the most appropriate and cost effective use of medicines with the National Institute for Health and Clinical Excellence (NICE) to be put on a firmer statutory footing. The QIPP medicines use and procurement workstream is seeking to achieve additional potential savings of £475million a year by 2013-14.

The NHS Commercial Medicines Unit (CMU) provides the nationally accepted route for contracting of medicines for secondary care and has established strategic leadership in medicines procurement areas considered important to the NHS. Significant supporting structures have been developed at regional/ local level with highly effective pharmaceutical networks established. Specialist procurement pharmacists play a key role in co-ordinating local trust decisions and ensuring they are aggregated locally, thereby ensuring that the NHS CMU frameworks meet the requirements of pharmacists and clinicians within the NHS.

[Department of Health](#)

AAH lands exclusive Merck Serono fertility drug distribution deal

Manufacturer Merck Serono has struck an exclusive deal with AAH to distribute its fertility products to community pharmacies from January 9, next year.

The move will extend an existing deal for hospitals and fertility clinics and see AAH distributing Merck Serono's fertility range to community pharmacies and dispensing doctors as well as hospitals and clinics in the UK, excluding Northern Ireland.

AAH managing director Mark James said the arrangement would ensure "universal coverage" as well as "a robust and resilient supply chain."

"We are pleased that Merck Serono has chosen AAH Dextrous Solutions as its distribution partner," he said. "As we have with other pharmaceutical manufacturers, AAH worked closely with Merck Serono to develop a proposal that will ensure universal coverage and retain a robust and resilient supply chain."

AAH stressed that the deal would not represent any changes for existing pharmacy customers. Merck Serono's fertility range includes Cetrotide, Crinone, Gonaf, Luveris, Ovitrelle and Pergoveris.

Chemist & Druggist 06/12/11

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 November 2011

Esomeprazole Tabs 20mg 28
Levetiracetam Tabs 250mg 60
Levetiracetam Tabs 500mg 60
Abilify Tabs 15mg 28
Anastrozole Tabs 1mg 28
Aricept Tabs 10mg 28
Levothyroxine Tabs 25mcg 28
Adalat LA Tabs 20mg 28
Clopidogrel Tabs 75mg 28
Esomeprazole Tabs 40mg 28

This bulletin now goes out to 2000 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 11th January 2012, as I will be issuing the next one on the 18th January 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 www.wavedata.co.uk

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Season's greetings and a happy new year