

# Commercial Bulletin

Monthly service

March 2012

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The Department of Health (DH) must take the lead on medicines supply problems and "referee" all those involved in the supply chain to resolve the issues, wholesalers have said.

Problems were being caused by "contradictory commercial incentives" in the supply chain that were leading some stakeholders to act in a "perfectly logical and understandable manner" that was not necessarily serving patients, the British Association of Pharmaceutical Wholesalers (BAPW) said.

"As the DH is responsible for the whole supply chain it needs to demonstrate leadership on this issue," Mark James, chair of the BAPW and group managing director of AAH told the all-party pharmacy (APPG) inquiry into medicines shortages yesterday (March 6).

"It could start by enforcing and managing the existing guidelines regarding best practice that it helped produce in 2010," he added.

Martin Sawyer, executive director of the BAPW, agreed: "The DH says it cannot act because there is no evidence of patient harm; but surely avoiding patient harm occurring in the first

place is the shared goal of all those involved in medicine supplies."

The BAPW also told MPs that "a fundamental cause" of medicines shortages was the "dysfunctional application of a single market within the EU on the medicines supply chain". "This problem will never go away while supply is dictated by the single market and price side is dictated by the national market," Mr James told the MPs' inquiry.

Jeremy Main, managing director of Alliance Healthcare, said emergency stocks should be controlled by wholesalers.

"The reality is that there is an export market pharmacists are using," he said. "As soon as the line they are hoping to export comes into stock they are ordering a very large amount of it to export."

Stephen Fishwick, head of external relations at the NPA, said the BAPW evidence showed the wide context of the problem, and added that in order to cut through the complexity "it would be helpful to harden up a straightforward commitment to a 24 hour maximum delivery time to pharmacies".

During the session, the BAPW outlined other proposals included in its submission to help ease the problems with the availability of certain medicines. The proposals include:

updating regulation through a new legally enforced patient service obligation that will help establish more resilient medicines distribution using the nationwide infrastructure of BAPW wholesalers' 54 depots to assist with emergency supplies by bringing stock closer to the pharmacy and patient, so that these can be rapidly distributed as required establishing independent third party monitoring of medicine deliveries so the facts and patient impact can clearly be assessed

a more stringent and transparent wholesale dealer's licence regime C+D's stocks Survey 2011 found that almost half of pharmacists had known a patient whose health had suffered in the past year because of medicines shortages.

Chemist & Druggist 07/03/12

## New Greek law says industry must cover pharma overspend

Greece's parliament has passed major new pharmaceutical cost-containment legislation which will require drugmakers to cover, each quarter, any overspending on the strict limits which the bill sets for the national drugs bill.

The new law - which passed on a 213-58 vote, with a number of deputies abstaining - states that overall drugs spending by Greece's social insurance funds must not exceed 2.88 billion euros for this year.

The legislation also mandates that, from April 1, clinicians must prescribe medicines from the 10 most-widely used therapeutic classes by generic name only, and from June 1 this requirement will apply to all products on Greece's positive reimbursement list. The funds will reimburse at the level of the cheapest product in each class, and any cost difference between this and the product supplied will have to be paid for by the patient.

Moreover, "inappropriate" prescribing - ie, of medicines by other than their generic name, and not of the cheapest product available - will now be classed as a criminal offence, according to local reports.

Generics currently account for just 18% of the pharmaceutical market in Greece, one of the lowest levels in the European Union (EU), and the latest measures aim to bring this up to the EU average of 50%. Health Minister Andreas Loverdos - who says he intends to slice a massive one billion euros off the nation's drug spending in a single year - has condemned a "coalition of interests" for allegedly attempting to cast doubts on the quality and safety of generics with the aim of hindering their wider uptake in Greece; however, counterfeit drugs are a significantly greater problem for Greece than for other EU nations.

The new law also seeks to save money by mandating the use of computerised prescriptions, with the imposition of a 1-euro fine on doctors for each handwritten prescription, and deregulation of pharmacy opening hours.

The legislation constitutes a requirement by the EU, the European Central Bank (ECB) and the International Monetary Fund (IMF) - Greece's "troika" of creditors - for agreeing a second bailout of 130 billion euros for Greece.

It is also reported that Yiannis Tounta, president of Greece's National Organisation of Medicines (EOF) has been in

talks with the troika concerning moves to delay the introduction into Greece of innovative new medicines until the products have been accepted for reimbursement by 8-10 other EU member states. Cancer drugs would be excluded from the proposals.

Commenting on the new legislation, analysts at IHS Global Insight say that the requirement for pharmaceutical companies to pay back any spending above the stated limit in each quarter is "very negative." This is especially so given that many multinational and Greek drugmakers are owed considerable amounts, by the public hospitals in particular, and that the multinationals which have been paid in Greek government bonds have seen their value plummet, they note.

- A number of decrees concerning implementation of some of the major measures contained within the cost-containment legislation are expected to be announced shortly.

Pharmatimes 04/03/12



### Lansoprazole prices undergo rapid rises

Lansoprazole is in short supply, judging by steep price rises for both the 15mg and 30mg strengths in February. As Figure 1 shows, the average price of 28-tablet packs of lansoprazole 30mg increased by 21% to £1.09 (US\$1.74) last month; while the average price of the equivalent 15mg strength rose by 45% to £0.61 (see Figure 3). Lowest prices for the two packs also saw double-digit increases.

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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## Shire announces new supply deal

Shire Pharmaceuticals has unveiled plans to further limit the number of full-line wholesalers supplying its products later this year.

From May 1, Shire will be dropping AAH from its supplier list, leaving only Alliance Healthcare and Pheonix Healthcare.

Shire said there would be "little or no disruption to customers or patients as a result of the change" and that the move was an extension of the supply chain review it undertook two years ago

The products affected are Calcichew, Fosrenol, Mezavant, Reminyl, Equasym, Resolor and Xagrid.

Nicola Massey, vice-president and general manager of Shire Pharmaceuticals, said she was "very pleased" with the outcome of the discussions with the two wholesalers.

"I am confident we will develop even stronger working partnerships with fewer wholesalers, enabling us to be more responsive to the ongoing changes in the NHS," she said.

James Lindsay, head of corporate relations for AAH Pharmaceuticals, told C+D that AAH was disappointed with the decision. "We believe we have delivered a highly effective operational and commercial service to Shire, our dispensing customers and ultimately patients," he said. "We still contend that including AAH would have been in the best interests of Shire, our customers and patients."

Mark Stephenson, commercial healthcare director for Alliance Healthcare, said the wholesaler was delighted to have been selected to continue to work with Shire.

"Alliance Healthcare is committed to maintaining the highest levels of service on these products, and we will be communicating full details of this latest supply chain change to all customers in preparation for go-live on May 1," he said.

In Northern Ireland, Alliance Healthcare has sub-contracted the delivery of Shire products to Sangers (NI). Alliance Healthcare and Sangers will be contacting customers directly in this region to confirm the specific ordering process.

Chemist & Druggist 13/03/12



### FDA moves to ease cancer drug shortages

The US Food and Drug Administration has stepped in to increase the supply of critically-needed cancer drugs, specifically shortages of Johnson & Johnson's Doxil and methotrexate, caused by manufacturing problems at Ben Venue Laboratories.

For Doxil (doxorubicin), used for ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma, the FDA has okayed temporary importation of a replacement drug, namely Sun Pharmaceutical Industries' Lipodox (also doxorubicin). The move is "expected to end the shortage and fully meet patient needs in the coming weeks", the agency noted.

For methotrexate, "a drug that is needed for

the treatment of many forms of cancer and other serious diseases", the FDA says it has "successfully engaged many firms to assist in maintaining supplies". First, FDA has prioritized review of and approved a preservative-free methotrexate generic manufactured by APP Pharmaceuticals which will become available in March and continue indefinitely.

Secondly, Hospira expedited release of additional supplies, resulting in 31,000 vials of new product, enough for more than one month's worth of demand, being shipped to hundreds of US hospitals and treatment centres. The FDA is also working with Mylan and Sandoz.

FDA Commissioner Margaret Hamburg said that "a drug shortage can be a frightening prospect for patients and President

Obama made it clear that preventing these shortages from happening is a top priority". In October, the president issued an executive order on drug shortages, and the FDA says this resulted in "a six-fold increase in voluntary notifications by industry of potential shortages".

In 2011, there were a total of 195 drug shortages prevented and since the executive order, the agency has prevented 114 of them.

Links  
[www.fda.gov](http://www.fda.gov)

Pharmatimes 22/02/12

## Northern Ireland pharmacies 'on their knees', Numark warns

**Northern** Ireland pharmacies are "on their knees" and the government has offered "nowhere near enough" compensation to address the impact of cuts it imposed on the sector last year, experts have warned.

**Pharmacy** groups branded the government's proposed £8 million compensation package – rejected by Community Pharmacy Northern Ireland (CPNI) last week – inadequate. They also criticised the government for wasting money on legal action against CPNI, which has cost £153,000 to date.

**The** comments came after the government argued that the latest judicial review, which ruled that last year's pharmacy funding cuts had been implemented illegally, should be subject to appeal. The judicial review was the second the government has lost on the subject.

**But** Wayne Harrison, Numark's membership services manager in Northern Ireland, hit out at the government's handling of the situation. "The Department of Health, Social Services and Public Safety states on the one hand that it wants to use taxpayers' money to get the best value from NHS spending. But it seems to have ignored the large financial cost to the taxpayer of two needless judicial reviews in less than two years, with even more money [potentially] being wasted on the department's appeal," he argued.

**Mr** Harrison slammed health minister Edwin Poots' comments in the Northern Ireland Assembly last week, when he said pharmacists would play a "much greater role in the future" in providing frontline care.

**"Well** Mr Poots, we are not in the future, we are in the now, and the very real threat of contractors having to close their doors for the last time might just mean that there is no pharmacy in the community to provide the level of care you have hinted at," he told C+D.

**He** added that the proposed £8m compensation figure would be "nowhere near enough" to counter the effect of the cuts on pharmacies. "Contractors are on their knees and cannot be left without immediate financial recompense that is equitable," he said.

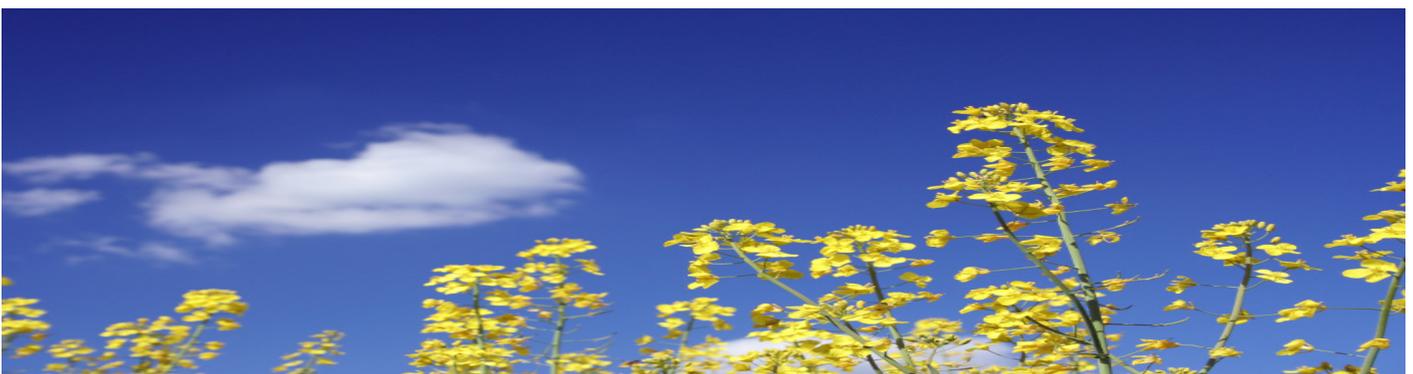
**The** comments were echoed by Anne McAlister, NPA representational manager in Northern Ireland, who also criticised the way the government had proposed distributing the £8m sum.

**Mr** Poots had intended to set aside £3m of the total figure for pharmacies in rural and deprived areas. But Ms McAlister argued that all contractors should receive equal compensation. "The stress on owners and employees has been felt universally, and that's why there's been such disappointment that the funding measures were targeted specifically at pharmacies in rural and deprived areas," she said.

**Ms** McAlister said a number of Northern Ireland contractors had reported working six days a week to make ends meet, during the NPA's business workshops held this month. "The reduction in remuneration has been applied equally throughout the pharmacy network, so any easing of that pressure should be equally applied," she told C+D.

**CPNI** revealed that 511 out of 532 contractors had voted against the government's proposed £8m compensation package in a vote held last week.

Chemist & Druggist 19/03/12



### **FDA may let Pharma sell more drugs OTC**

The FDA may let more drugs go OTC. Commissioner Margaret Hamburg says the agency is "trying to get feedback from various stakeholders" about improving access to medications. And one of those improvements could well be allowing more drugs to be purchased without a prescription, *The Wall Street Journal* reports.

Janet Woodcock, director of the Center for Drug Evaluation and Research, said the number of newly over-the-counter medications wouldn't be "vast." But it could include, for instance, hypertension drugs for patients who don't have acutely high blood pressure. Some drugs might be sold without a prescription, provided patients consulted with pharmacists on their proper use.

To win OTC status, drugmakers would still have to conduct consumer-use studies to prove customers could use the medications correctly. And that's not necessarily a picnic. As the *WSJ* points out, Merck has tried repeatedly to win OTC status for its statin drug Mevacor, but the FDA has yet to be convinced that consumers would properly evaluate their need for statin therapy.

A new openness could prompt more drugmakers that are mulling an OTC move--such as Pfizer with its newly off-patent cholesterol drug Lipitor--to go forward with the necessary research.

FiercePharma 08/03/12

#### **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 February 2012

Levothyroxine Tabs 100mcg 28  
Pioglitazone Tabs 15mg 28  
Donepezil Tabs 5mg 28  
Omeprazole Caps 20mg 28  
Donepezil Tabs 10mg 28  
Losartan Tabs 100mg 28  
Pioglitazone Tabs 30mg 28  
Latanoprost Eye Drops 0.005% 2.5ml  
Levothyroxine Tabs 25mcg 28  
Losartan Tabs 50mg 28

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