

WHOLESALE BULLETIN

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Restricted List medicines and exporting

Wholesale dealers of medicines may not see all the publications that community pharmacists receive, so they may be unaware that the problems that community pharmacists experience in obtaining certain medicines for prescriptions remains a significant problem.

For that small percentage of pharmacies that have obtained a wholesale dealers licence, and are selling medicines for export, then some thought needs to be given to written procedures that will demonstrate to an MHRA inspector how products that are listed on the current months shortage list in the PSNC newsletter are being handled.

For wholesalers of medicines the challenge of exporting restricted list medicines is no easier, particularly for those wholesalers who do have community pharmacy customers. Whilst legal action is yet to be taken against an exporting wholesaler or pharmacy, it would be wise for those involved in exporting to consider what written proof they could provide, if challenged, as to how their actions could be proved not have compromised supply to UK patients.

For example, things that could be considered that may go some way towards showing regard for the restrictions upon exporting certain medicines, if challenged, could include:

* which products are exported, what are they used to treat, and how unique are they. The more serious the condition treated and the more unique the product, perhaps the more serious the breach if exported?

* what records are kept on each sale for export occasion to prove that checks have been undertaken upon stock availability from at least main wholesalers and manufacturers?

* are some buffer stocks retained for the UK market, of products in short supply, and appropriate detailed records kept to prove such?

The current situation is clearly unsatisfactory, and it remains to be seen whether 2012 is the year when this issue is taken more seriously by all actors. In the meanwhile wholesale suppliers should consider carefully their actions and how they would prove that they have not exacerbated the UK supply problems.

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Special points of interest

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Separate pharmacy wholesaling and dispensing, MPs told

Pharmacy wholesaling and dispensing activities need to be legally separated, so that pharmacies who serve NHS patients directly prioritise the UK patient over and above wholesaling activities which effectively divert medicine supplies, MPs have been told

A legal separation would ensure there is a clear audit trail of transactions between the pharmacy's wholesaling and pharmacy activities, permit suppliers to the pharmacy to know which entity they were supplying and therefore invoicing, and allow the regulator to see a clear audit trail of transactions, if and when required at inspection, according to the Association of the British Pharmaceutical Industry.

Suppliers would then be able to prioritise which part of the business they will supply when a product is in short supply, the research-based industry group has told the parliamentary All-Party Pharmacy Group's inquiry into medicines shortages.

The ABPI also expresses concern at the level of regulatory oversight and inspection of the trade in medicines. There are currently around 1,800 wholesaler dealer licenses in the UK - apart from Germany, the highest number in Europe by a significant margin - and the Medicines and Healthcare products Regulatory Agency does not have the resources to inspect the premises of 1,800 wholesale dealers, it says.

There needs to be a change in regulation, the industry group has told the MPs. It welcomes the proposed repeal

of Section 10(7) of the Medicines Act 1968, an exemption which currently allows pharmacy to trade up to 5% of its turnover without a wholesaler dealer licence, but calls for the change to go further, with a restriction on the exemption which permits pharmacies to be able to hold a wholesale dealer license and thus, to wholesale trade.

The ABPI also tells the inquiry that it does not support calls for the adoption of a Public Service Obligation, to include a 24-hour requirement to supply medicines, in the UK. "This would only increase the quantity of medicines into the system - and therefore being diverted into Europe - whilst also introducing unnecessary red tape," it warns.

Moreover, there is no data to show that PSOs work in other EU member states to solve the medicines shortages which they have suffered when they were net exporters, says the ABPI. It also cautions that an Obligation would be a challenge to enforce, given that demand then becomes short-term and more unpredictable, and the lead time on medicines is several months.

"To be effective, the 24-hour obligation would also need to be on all elements of the supply chain - pharmacies, wholesalers, repackers and manufacturers," it says.

The ABPI calls on wholesalers to support its position on the repeal of Section 10(7) of the Medicines Act, and urges Minister to "lead a shift in perception about the acceptability of sup-

ply diversion and demonstrate a willingness to take the necessary regulatory steps through the MHRA to address the challenge."

So far, the government has indicated that it does not feel the situation justifies a change in regulation and prefers the various stakeholders to find a solution amongst themselves, without the need for regulation, but the Department of Health Supply Chain Forum set up to tackle the problem in England has not yet found a solution, and there is scepticism among stakeholders as to whether the best practice guidance issued by the Forum will have any real impact, says the ABPI.

The industry group also tells MPs that it has recently convened a Pharmacy Advisory Group to "build a forum around which everyone involved in this highly-concerning issue can convene to find mutually-agreeable solutions." The exemption in Section 10(7) is being removed because it is not compatible with the European Union Falsified Medicines Directive, which must be implemented by January 2 next year.

Pharmatimes 02/02/12

Price watch UK

Tolbutamide takes a downturn after highs

Having topped the 'biggest risers' table in December (Generics bulletin, 13 January 2012, page 27), 28-tablet packs of tolbutamide 500mg were to be found astride the 'biggest fallers' table in January (see Figure 2). A modest average price decline of 13% last month, however, compared with a 295% rise in December.

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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'Truly shocking' patient harm from stock shortages uncovered

Almost half of pharmacists have known a patient whose health has suffered in the past year because of medicines shortages, the C+D Stocks Survey 2011 has found.

More than 140 pharmacists said they had seen a patient harmed because of medicines shortages, with incidents including mental health patients seeing their conditions worsen, a diabetic patient having a hyperglycaemic episode, and patients being referred to hospitals and other specialists (see Patient case studies, below).

"If pharmacists are finding that they can't get hold of the medication patients need when they need it, and that NHS guidelines are ignored, that should be sufficient for the government to take action," agreed Joyce Robins, co-director of Patient Concern. "We should not have to wait for a death list to prove patient harm," she said.

And mental health charity Mind said it was "very concerned" to see medicines delays affecting vulnerable patient groups. "It is very concerning that patients with mental health problems are being forced to wait longer than the recommended 24-hour time period for their medication, as this can have the effect of forcing people into withdrawal," explained Katherine Darton, information officer at the charity. "It is advisable people taking psychotic drugs should only stop taking them gradually," she added.

Pharmacy organisations also expressed concern about the findings. The Royal Pharmaceutical Society (RPS) called some of the accounts "truly shocking". "No one should have to experience trauma and further ill-health because of medicines shortages," said RPS spokesperson Neal Patel.

Rob Darracott, chief executive of Pharmacy Voice, said that the focus now must be on ensuring supply to patients.

"Thankfully pharmacists nearly always succeed in getting medicines promptly to patients despite the difficulties, but these examples are truly appalling," he said. "No patient wants to be told they cannot have their medicine, and no pharmacist wants to be in a position where they are powerless to help."

Patient case studies

Patient dies after week-long shortage

A Staffordshire pharmacist saw a patient die after it took one week to get the medication he needed.

"The patient was very ill with an immune disorder, and it took about a week to get his medication. By the time we got the drug, he had died," the pharmacist says. Although he can't be sure whether the shortages were the only cause of death, the pharmacist does see supply issues as a serious problem.

"We have manufacturers saying they can send us five packets of a drug when we need 11, and we have no idea when they're going to turn up," the pharmacist adds.

Schizophrenic patient self-harms

Hertfordshire contractor Graham Phillips, owner of the Manor Pharmacy (Wheathampstead) Ltd chain, tells C+D that a schizophrenic patient harmed himself after being unable to get hold of his medication for four or five days.

"The drug was unobtainable and no other pharmacy had it," he reports. "By the time we got it, the patient had self-harmed."

"You could say that he shouldn't have left it until the last minute, but people who suffer from schizophrenia often don't plan their lives in that way. The NHS should be built around the lives of patients, not the other way around," he argues.

Patient left with severe emotional trauma

A patient living in Surrey who had recently received a transplant was left suffering from severe emotional trauma after being left waiting days for her medicine, a pharmacist reports.

"In this case the patient had let her tablets run down before she came in, and she ran out before the new meds had arrived in. She was standing in front of me in tears – terrified that her body would reject the new kidney transplant she had just received. She was really scared," the pharmacist says.

Asthmatic patient told to go elsewhere

An elderly asthmatic patient in Havering was advised by a manufacturer to go elsewhere for an inhaler, despite being barely able to walk, one pharmacist reports.

"She's a regular patient of mine," the pharmacist explains. But a manufacturer quota left them unable to source the product.

"I rang the manufacturer, they suggested the patient went elsewhere and that's what frustrated me – she can barely walk a few steps, and they expect her to go around to other pharmacies? I don't think [manufacturers] understand that there's a person at the end of the line suffering," the pharmacist says.

Chemist & Druggist 10/02/12

Wavedata online developments

Wavedata Live Enhanced View

Earlier in February we added an enhanced view to our Wavedata live retail pricing website at <http://www.wavedata.net>

This now allows reports to be filtered and sorted to suit the user.

The advantage is that long reports can be quickly slimmed down to just the relevant information, saving both time and effort.

Users can switch between Classic and Enhanced views on the Menu page (the first page you see when you login.)

Basket Report

This report (which compares the prices of a basket of products sold by two separate suppliers) is available on the Pharma TouchStone CD. However we have been working recently to create an online version and hope to launch this later this year.

Pharma TouchStone

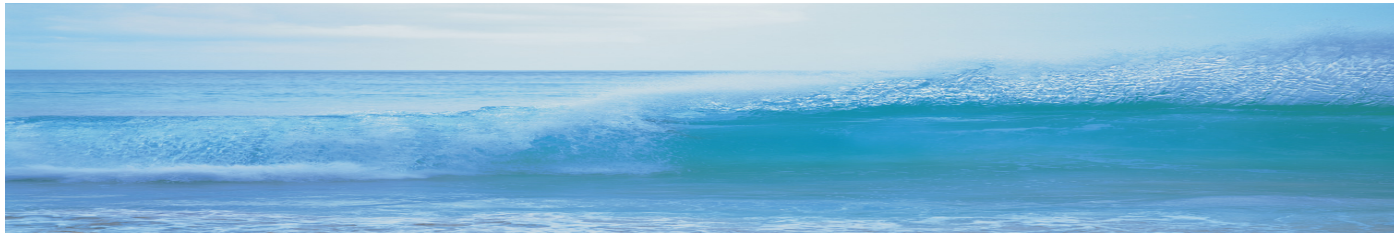
This database, which typically includes between three and six months of historical data, is sent to customers as a Microsoft Access database on CD.

However a couple of companies have recently told us that they no longer support Access and so we are now building an online version.

This will work in much the same way as the CD, but include some modifications where we can do things better on the web than on the CD.

For example drill-down can be done on the web but not in Microsoft Access.

If you would like to ask any questions please contact Charles Joynson on 01702 425125 or email info@wavedata.co.uk



Specific Mechanism – Ambiguity, Confusion and Unspoken Conflict

The Accession Treaty of 2003 sought to protect pharmaceutical IP rights in an expanding EU, but in so doing has created a legacy of confusion and unaddressed conflict in parallel trade.

The so-called “specific mechanism,” described in the treaty, permits the holder or beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a member state at a time when such protection could not be obtained in one of the new member states for that product, to rely on the rights granted by that cover to prevent the import of that product in the member state or states where the product in question enjoys patent protection or supplementary protection.

However, the paucity of the treaty’s drafting has left it open to interpretation and ambiguity, which has not been helped by the absence of case law precedent, largely resulting from the general imbalance in resources between rights holders and prospective importers.

For example: The treaty does not specify whether the specific mechanism encompasses formula and process patents; While the passing of relevant patent laws in new member states are identifiable, the treaty does not state whether these must be compared with a patent’s filing or priority dates. It seems unlikely to be the latter, but nevertheless such an interpretation can be lodged.

Unfortunately, we are unlikely to see such matters resolved until the issue entirely disappears in the future. In the meantime, while this does create opportunity for vigilant importers, it also means industry players operate in an uncertain landscape that was surely not the intention of the original treaty.

Greece announces compromise on pharma spending

Greece's state spending on pharmaceuticals will total no less than 2.8 billion euros this year, despite demands from the European Union (EU), the European Central Bank (ECB) and the International Monetary Fund (IMF) that it should spend no more than 2.1 billion euros, Health Minister Andreas Loverdos has said.

Announcing the compromise reached with the EU-ECB-IMF "troika" to industry representatives, he also said that the Health Ministry is aiming for national drug spending next year to total around 3.1 billion euros, according to local reports.

However, the Minister has also warned that the country is still spending too much on unnecessary medicines, with 1 billion euros-worth of unused drugs being thrown away per year. In 2011, when the country's drugs bill totalled

4.1 billion euros - against a target of 3.8 billion euros - doctors were still prescribing more "when they should have been prescribing less," he said. In 2010, Greece's public spending on medicines had soared to 5.6 billion euros.

The crisis is also affecting availability of medicines, with the national pharmacy association reporting that, out of the country's 500 most widely-used medicines, almost half are in short supply. Public insurance bodies still owe pharmacies around 300 million euros for medicines purchased since last April, it adds.

Meantime, Business Monitor International (BMI) has announced further downward revisions in its growth expectations for the Greek pharmaceutical market this year.

"It is beyond doubt that drugmakers in

Greece - particularly domestic producers primarily exposed to their home market - are faced with the most challenging operating environment in Europe. Our view that Greece's pharmaceutical market is set for a decade of decline remains firmly in play," it says.

BMI estimates that the Greek pharmaceutical market fell 10.1% in local currency terms to 6.48 billion euros in 2011, from 7.20 billion euros in 2010, and that healthcare spending overall dropped 5.4% from 22.87 billion euros to 21.64 billion euros, a reduction on the forecast which it made in fourth-quarter 2011 because of worsening macroeconomic conditions.

Pharmatimes 09/02/12

Compensate pharmacists for sourcing medicines, says APPG chair

Pharmacists should receive compensation for the time they spend sourcing medicines because of stock shortages, all-party pharmacy group chair (APPG) Kevin Barron has said.

Speaking exclusively to C+D at the Sigma Conference in Thailand, Mr Barron told C+D there was "no silver bullet" to resolving stock shortages and pharmacists should be paid for the time they spend sourcing stock.

"It isn't recognised in the financial arrangements pharmacies have with the NHS and it seems to me that it should be," the Labour MP said.

Mr Barron added that the government had now acknowledged stock shortages were an issue and would look to draw a solution from the APPG medicines shortages inquiry.

However, Mr Barron was "not convinced" by proposals from manufacturer body the Association of the British Pharmaceutical Industry (ABPI) to the inquiry, which called for pharmacy wholesaling and dispensing activities to be split to prevent exporting.

"If the solution was simple, I'm sure the government would have done it in 2008," he explained, adding that there was "no way of telling" which part of the supply chain was primarily responsible for exporting medicines. "If manufacturers decided to export for profit that would be totally within the law."

The APPG will publish a report on its findings in the first quarter of this year.

Chemist & Druggist 21/02/12

Sainsbury's opens its first hospital pharmacy

Sainsbury's has opened its first hospital pharmacy in a move that heralds the beginning of the supermarket's expansion into outpatient dispensing.

The pharmacy, which opened on Monday (February 20) at St James Cook University Hospital, Middlesbrough, will have improved opening hours and provide "an additional range of pharmacy services to visitors", said South Tees Hospital NHS Foundation Trust director of service for pharmacy Alan Hall.

"In the near future Sainsbury's will be

extending weekday hours and open at weekends for the dispensing of outpatient prescriptions," he said.

"In addition to this the pharmacy will sell over-the-counter medicines and offer a community service that will enable staff and visitors to have prescriptions from their GP dispensed."

Sainsbury's, which already has more than 250 pharmacies across the UK, was chosen by the South Tees Hospitals NHS Foundation Trust to work in collaboration with Healthcare at Home - a clinical homecare company - to provide outpatient dispensing.

Sainsbury's professional services manager David Gilder called it a "very exciting day for Sainsbury's" and said that the hospital pharmacy represented "an exciting new direction for Sainsbury's pharmacy operation".

"We are confident that our widespread experience in supermarket pharmacy puts us in a great position to not only deliver fantastic treatment for the patients at the hospital but also excellent value for money for South Tees NHS Foundation Trust," he said.

Chemist & Druggist 21/02/12

Concern grows over Europe's unpaid pharma bills

The unpaid debts of European healthcare systems owed to pharmaceutical companies reportedly stands at about 12 billion euros, and half of that is a result of Spain having problems in paying its bills.

The problem was addressed by Bruno Strigini, president of Europe/Canada at Merck & Co at The Economist's Pharma Summit summit in London last week. He said that 6 billion euros is outstanding in Spain and a further 4 billion euros is owed to medical device firms.

Mr Strigini claimed that the Spanish government was trying to resolve the situation but added that "it's clearly an issue. How are we going to recover the money that is owed"? He went on to say that "we're right in the middle of these discussions [but] I can't see how we can get to a solution that satisfies us without the help of international institutions", such as the International Monetary Fund and the European Union.

"Things are getting rapidly worse," said Richard Bergstrom, director general of the European Federation of Pharmaceutical Industries and Associations, who told Reuters that his organisation puts the total outstanding European debt for medicines at between 12-15 billion euros, up from around an earlier estimate of 10 billion euros.

Mr Bergstrom told the news agency that nearly all of those unpaid bills are in four countries - Greece, Portugal, Italy and Spain. The latter's government has pledged to pay the money owed by its regional governments to pharma.

Last week in Paris, Sanofi chief executive Chris Viehbacher told PharmaTimes World News that his firm has not seen any significant deterioration in payments from southern Europe since the problem of non-payment emerged in Greece last year. That problem was partly resolved when the Greek authorities tried to clear some debts by issuing pharma companies with government bonds and this could be a path taken by Spain.

Pharmatimes 13/02/12

Assogenerici applauds Italian substitution

Legislation passed this week requiring Italian pharmacists to substitute the cheapest available equivalent product when dispensing prescriptions "does not affect the freedom of choice" of prescribing doctors, according to the country's generics industry association, Assogenerici. Instead, the requirement – which is included as part of Italian Prime Minister Mario Monti's 'liberalisation decree' aimed at boosting the country's economy – offers the potential for Italy's healthcare system and patients to save EUR1 billion (US\$ 1.32 billion) annually, the association claimed.

Pointing out that the legislation allows doctors to mark prescriptions as 'non-substitutable' for specific medical reasons, Assogenerici said the substitution requirement "fully reflects the principle of the freedom of the prescribing doctor, whilst promoting the affirmation of a generic drug culture in Italy". Furthermore, the association claimed, the measures would allow Italian citizens to save around EUR600 million annually, whilst the country's health service would save around EUR400 million.

News@Genericsbulletin 26/01/12

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 January 2012

- Levetiracetam Tabs 500mg 60
- Levetiracetam Tabs 1g 60
- Levetiracetam Tabs 250mg 60
- Olanzapine Tabs 10mg 28
- Olanzapine Tabs 7.5mg 28
- Pioglitazone Tabs 15mg 28
- Hydrocortisone Tabs 10mg 30
- Lamotrigine Tabs 100mg 56
- Losartan Tabs 100mg 28
- Olanzapine Tabs 2.5mg 28

This bulletin now goes out to 2100 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 14th March 2012, as I will be issuing the next one on the 21st March 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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