

Monthly service

# Commercial Bulletin

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## Supply chain guidance is 'not worth paper it is written on', experts warn

Department of Health (DH) guidance designed to ensure the smooth running of the medicines supply chain is "not worth the paper it is written on", pharmacy experts have warned.

[Numark](#) warned that the guidance, which states that pharmacists should receive medicines within 24 hours of ordering them, was "unenforceable", while others called for it to be made "more robust".

"The supply chain guidance is unenforceable [so] one might say 'it is not worth the paper it is written on'," said Gary Choo, Numark's head of information services.

Mr Choo said supply chain problems needed to be resolved, warning: "In a patient centric healthcare service, it is unfeasible that a pharmacist cannot dispense a medicine because of manufacturers' quotes."

[Avicenna](#) CEO Salim Jetha also called for more action to tackle stock shortages, saying "guaranteed supply" within 24 hours would help. And Doncaster LPC secretary Nick Hunter agreed the guidance was "not very effective" and needed to be made "more robust".

The guidance "had helped", said [Alliance Healthcare](#), although it warned that despite improvements, pharmacists were still facing "unacceptable" problems obtaining medicines. But rather than criticising the guidance, supply chain stakeholders should be encouraged to work together to enforce or promote it, the wholesaler suggested.

[AAH](#) warned that the guidance alone could not resolve stock shortages. "The 24 hour target [also] needs to be more clearly defined – the key aspect is the time which the patient has to wait before they can pick up the medicines they need," said head of corporate relations James Lindsay.

Wholesalers could meet the 24 hour target if they had stock and manufacturers would supply within a day when they received an emergency order, he said. "[But] by the time the pharmacist has tried unsuccessfully to order medicines from wholesalers and then had to resort to ordering direct from the manufacturer it can take several days to a week or more before patients actually get the medicines they need," he warned.

[PSNC](#) agreed the "serious problem" of stock shortages had not yet been solved, and said it continued to press for an effective resolution.

The comments followed a C+D investigation that revealed [DH officials had never believed the supply chain guidance would fully resolve stock shortages](#).

A [DH](#) spokesperson told C+D last week that the department had developed the guidance in collaboration with supply chain stakeholders, and stressed that it had been "extremely helpful" in clarifying the roles and responsibilities of all those involved in medicines distribution. The DH would continue to work to ensure effective implementation of the agreed arrangements, it said.

For your chance to win £150 worth of John Lewis vouchers and to help us push for a resolution to stock shortages, complete the [C+D Stocks Survey](#) online now at [www.chemistanddruggist.co.uk/supply-chain](http://www.chemistanddruggist.co.uk/supply-chain)

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### Special points of Interest

**This bulletin is free to interested people in Pharma & Healthcare**

**Please send names of new subscribers to Jackie@wavedata.co.uk**

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## Pharmacy should base specials decisions on more than price

Pharmacists must not waste time shopping around for the lowest specials prices and should consider factors such as quality of service and ordering flexibility as well as price, experts have warned.

Specials prices are expected to level out in line with those listed in the new specials tariff that came into force on November 1, industry leaders said. And this should enable pharmacists to concentrate on quality and patient needs, they stressed.

"Time spent shopping around is valuable time lost with patients, and will inevitably impact on patient care," said Raj Nutan, director of commercial operations at Numark. "It is essential that pharmacists choose a specials manufacturer that will provide quality products at a good price, with continuity of supply and consistency of pack."

Avicenna said pharmacists should still be wary of paying too much for specials, but agreed they might have other priorities.

"Pharmacists will need to look holistically at their entire business – three to four scripts of specials per month will in no way compensate for category M reductions and increases in operating overheads," said CEO Salim Jetha.

The tariff should make it easier for pharmacists to choose the right supplier, the Association of Commercial Specials Manufacturers (ACSM) argued.

"The tariff now provides a good benchmark of cost and so in many ways, pharmacists should be freed from concern about cost and be able to focus on fulfilling quality criteria and providing the product that best meets patients' needs," said ACSM chairman Alan Krol.

Specials manufacturer Nova Laboratories stressed pharmacists could stand to make a margin on "every single" special. The tariff put an onus on pharmacists to be more commercially minded, said John Seaton, Nova's commercial and financial director. But he argued this would not necessarily force them to shop around. "There are still margins to be made through professional procurement and partnering with a trusted supplier," he said.

### Specials: your say

"[The tariff] is a new chapter in the lexicon of endorsement confusion. Many of the calls received by Numark in the week following the introduction of the tariff were associated with queries on specials."

**Raj Nutan, director of commercial operations, Numark**

"We may see some short-term disruption, but in the long run I think [the specials tariff] will help protect pharmacy's reputation."

**Sue Moore, general manager, Alphega Pharmacy UK**

"If I happen to buy specials for less than the tariff price, that will be fantastic, but it won't force me to switch all my purchasing to a cheaper supplier. But I won't pay more than the drug tariff – that's the deal-breaker."

**Brian Deal, Ashwell Pharmacy, North Hertfordshire**

"[The introduction of the tariff] has left very little time for independent pharmacists to plan their business in the face of more red tape, more work, and more costs."

**Chris Barker, Spirit Healthcare (specials supplier)**

"Price must always be balanced against quality and service. Factors such as consistency of product and reassurance of product integrity need to be taken into account and are heavy responsibilities."

**Alan Krol, chairman, ACSM**

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### This month subscribers may find some changes in some of our services

- Wavedata Live now allows much faster downloading. This means you can download long lists such as the whole of the drug tariff, or the retail prices of Category C, A or M products in about 6 seconds
- We are in the process of adding new reports to our Pharma TouchStone product. A new tab has been created (Company) and new reports are being added to this which allow you to interrogate the pricing of your own products in much faster ways.
- Wavedata's 'Pharma TouchStone CD User Guide' has been rewritten and updated
- Wavedata have added a number of video tutorials to <http://www.youtube.com/user/wavedata> Any suggestions for new videos would be most gratefully received.

## Anti-counterfeiting measure now on the horizon

A 2D barcode authentication system, which is fully compliant with the new European legislation for falsified medicines, has achieved new milestones that substantially increase the level of patient protection for European consumers.

Aegate's 2D barcode system is now available to 88% of pharmacists in Belgium, 85% in Greece and 90% of pharmacists in Italy. In total this enables approximately 40,000 of the 160,000 pharmacists in Europe to be ready for the European Legislation once it is implemented.

Medicines authentication is a mechanism which utilises a unique code number affixed to an individual tamper-evident medicinal package. When the unique code is read by a scanner connected to the authentication database, important safety information, including verification that the pack is not a counterfeit or recalled, can be relayed back to the health professional connected to the system.

Commenting on these achievements Gary Noon CEO Aegate said "reviewing the most recent outcomes from Aegate's system there is no doubt that an authentication sys-

tem has significant patient safety benefits. In 2010, Aegate informed pharmacists of 48,571 individual packs that were recalled and 8820 packs that were soon to expire or had expired, demonstrating the clear benefits of rapid and real time mechanism to deliver this information to pharmacists immediately before dispensing".

The new European legislation for falsified medicines will mean adoption of an authentication system will soon become mandatory, which will without doubt limit the economic attractiveness of placing counterfeit medicines into the market. Given the rise in counterfeit medicines in Europe year on year, estimated by the European Commission as 10-20% per annum, Aegate urges the Commission to proceed to the next step of preparing the implementation acts without delay to ensure that pharmacists can start to install authentication barriers as soon as possible.

Rather like a safety deposit box in a bank, pharmaceutical companies deposit data files relating to the unique codes contained on the drug packaging, similar to those currently transferred to the government authorities in Belgium, Greece and Italy. These files are transferred to Aegate before products are released into

the market. When the product reaches the pharmacy, the product code is validated by the pharmacist through an on-line scanning process, integrated inside the pharmacy software. On dispensing, the validation process carried out by Aegate takes less than a second. Any safety notices associated with the product are delivered to the pharmacists before dispensing. This assists pharmacists and pharmaceutical companies to ensure the best quality medicines advice is being provided to patients.

Importers will have to re-box medicines destined for a second country, and will need to apply to Aegate to have the old codes deleted and new ones issued. Manufacturers will need to print these unique codes on individual packs and will have to bear the costs of not just changes to their own system, but the pharmacy's systems as well.

Barcodes will be different in each country, so German code cannot for example be scanned in France.

Aegate

### 95% discount on pramipexole in under year

*Another third came off the lowest price of 30-tablet packs of pramipexole 700µg last month, meaning the Parkinson's disease treatment has now been discounted by more than 95% since its launch in the UK less than a year ago. Boehringer Ingelheim's Mirapexin was available exclusively at £76.40 (US\$121.50) for 30-tablet packs of the 700µg strength last December. Now as Figure 1 shows, independent pharmacists and dispensing doctors can get a generic equivalent for just £2.60, after a price cut of 32% between September and October. The new low represents price erosion of nearly 97% in just 10 months.*

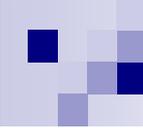
To see more go to <http://www.wavedata.co.uk/newinfo.asp> and view our article from this month's Generics Bulletin.

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## FDA: Drug shortages expected to increase

Although the causes of drug shortages--manufacturing problems, lack of API, a stricter FDA shutting down plants, industry consolidation and the thin margins of generics--are well known, regulators and legislators remain stymied on how to solve the problem. There are "multiple factors and it's very difficult to identify which one is most important," Peter Lurie, a senior FDA adviser, tells *Reuters*. Despite the standard list of causes, no one is able to explain fully why the shortages are escalating. The FDA expects reports of drug shortages to rise over the next few months to years, agency spokesperson Lisa Kubaska says in an email. Unfortunately, FDA and congressional proposals offer little hope of solving the long-term problem, *Reuters* reports. A widely acknowledged first step is better communication among manufacturers and the FDA, which has helped avert 99 shortages this year

as a result of advance notice from the drugmakers. Manufacturers aren't required to report shortages to the FDA, but when they do, the regulator asks about the cause, how long the shortage is expected to last and how it can help. "Sometimes there is a quality issue or other manufacturing issue that FDA is able to work with the firm on, and sometimes the company needs FDA assistance with expediting review to help prevent or address a shortage," Kubaska says in the email.

In Canada, where there's reluctance among some manufacturers to report shortages, officials are trying the "big stick" approach. Health Minister Leona Aglukkaq has told drugmakers and medical associations that unless they figure out a way to alert doctors about the growing number of shortages, she would impose a solution, reports *Edmonton CTV*. The companies have since agreed to pool information on shortages and post details

on two public websites.

U.S. Sen. Amy Klobuchar introduced a bill in February that would force drug companies to inform the FDA about looming shortages, but the bill does little to prevent shortages in the long-term. "People aren't in agreement on how to solve it in the long-term, and not a lot of bills are going through Congress," Klobuchar told *Reuters*.

The FDA's drug shortage program, run by Associate Director Valerie Jensen, consists of 5 scientific and regulatory experts, up from three a few years ago. They coordinate with other CDER personnel to conduct medical necessity assessments of the drugs, consider action on inspection reports, and assess the proposals of drugmakers as they attempt to avoid supply disruption or increase production.

FiercePharma Manufacturing 18/10/11

## Obama orders FDA action on drug shortages

The Obama administration is wading into the drug-shortage fray. The president plans to sign an executive order that aims to alleviate scarcity of many important drugs, including key cancer therapies, the *New York Times* reports. However, the question remains whether the directive--or any single directive--can actually do much to fight the shortages.

Obama's order will require the FDA to expand reporting on potential drug shortages, accelerate review of new applications to manufacture scarce meds, and share more information with the Justice Department to help fight price gouging, the *NYT* reports. Similar provisions are part of legislation that's been lagging in Congress since February.

"The president's action is a recognition of the fact that this is a serious problem, and we can and should do more to help solve it," an administration official told the *Times*. "We can't wait anymore."

The order stops short of several measures that some in the drug industry had advocated, such as a national drug stockpile. And it doesn't address the root causes of some shortages, such as a scarcity of particular raw materials. The administration is working to identify those causes and plans to release two analyses of the market for injectable drugs, which dominate the list of scarce meds.

FiercePharma 31/10/11

## Sainsbury's plans to double pharmacy revenue in three years

Sainsbury's aims to double its pharmacy revenue in the next three years, driving the expansion with "significant growth" in hospital outpatient pharmacies.

The supermarket giant has been awarded an outpatients contract at a hospital in Middlesbrough and is recruiting staff for the pharmacy.

Sainsbury's, which has pharmacies in 253 stores, saw a 4.5 per cent growth in its pharmacy business last year and plans to open 10 more pharmacies in 2012.

The multiple has reported strong growth in key service areas, with flu vaccinations up 230 per cent on last year already and cholesterol testing services expected to increase by 50 per cent in 2012. The move into hospital pharmacy came after successes in this area for other multiples.

In September, Lloydspharmacy reported that its [dispensing service at the Royal Cornwall Hospital](#) had "significantly" reduced patient waiting times and the [Co-operative Pharmacy revealed that it had moved into secondary care](#), after being awarded a seven-year outpatient dispensing contract with Doncaster and Bassetlaw Hospital NHS Foundation Trust.

Sainsbury's plans coincide with the launch of the company's [Wells Challenge](#), which will see 10 families using Sainsbury's pharmacy services to improve their health and wellbeing, with outcomes independently measured.

Get all the latest news on pharmacy multiples at <http://www.chemistanddruggist.co.uk/multiple-pharmacy-store>

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### Access to market to become more difficult in France

France is going through a major change in their legislation at the moment which will change the relationship between the pharmaceutical industry and French clinicians.

The bill replaces the current AFSSAPS (French Agency for the Safety of Health Products) with a new institution. The bill provides that the new agency (the French Agency of Health Products (AFSEP). ) may impose administrative fines, especially to companies that have not obeyed their legal transparency obligations.

Among the major amendments, the Senate forbade any links of interest to four leaders of health organizations: the High Authority of Health, the Public Safety, the Institute for Medical Research and the National Institute of cancer. However, the senators did not go far as to prohibit any link of interest to experts.

These changes may mean that getting access to clinicians and hence market access may be more complex.

<http://www.lequotidiendumedecin.fr/information/le-senat-adopte-le-projet-de-loi-sur-le-medicament>

### 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](http://www.wavedata.net)

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

Esomeprazole Tabs 20mg 28

Esomeprazole Tabs 40mg 28

Levetiracetam Tabs 250mg 60

Levetiracetam Tabs 500mg 60

Olanzapine Tabs 10mg 28

Olanzapine Tabs 2.5mg 28

Levetiracetam Tabs 1g 60

Levetiracetam Tabs 750mg 60

Bisoprolol Fumarate Tabs 2.5mg 28

Olanzapine Tabs 5mg 28

**This bulletin now goes out to 1900 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 December 2011, as I will be issuing the next one on the 20th December 2011.**

**If you have any colleagues who would like to receive this, please let them know about it.**

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