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Commercial Bulletin

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Inside this issue:

Government must curb exports as stock shortages harm patients

MPs have slammed those responsible for the medicines supply chain, saying they have an "air of resignation" about stock shortages and have dismissed the problem as "either inevitable, or as having been inherited from the previous government".
There must be a "renewed sense of urgency" from the government and Department of Health (DH) in tackling shortages to protect patients from harm and free up pharmacists' time, the All-Party Pharmacy Group (APPG) reported this morning (May 15), following its six-month inquiry into the matter.
The group has made several recommendations that it believes would help to sort the problems out, with the most radical being a suggestion to prevent the free movement of UK medicines around Europe by exempting medicines from EU law on public health grounds.
While exporting medicines to other countries is legal under EU law, the APPG has urged the government to consider following France's example by taking advantage of a provision in an EU treaty that lets governments restrict the free movement of certain goods if it poses a risk to public health.
"The question is whether the UK government has the right order of priorities and whether it is obliged at all times to put the free movement provisions before the best interests of UK patients," said the Report of the APPG inquiry into medicines shortages.
Although the APPG said it had "no objection to the export of medicines in principal", this was on the condition that it did not harm patients. But it concluded that shortages were being caused "principally by the export of medicines" and that "patients are suffering and pharmacists' time and resources are being diverted away from patient care as a result of medicines being in short supply".

Pharmacists' efforts and patient harm

The report was supportive of the work pharmacists were doing to source medicines for patients, saying that without their efforts "the problem would be even worse". The MPs cited the results of the C+D Stocks Survey 2011 - which C+D submitted as evidence to the inquiry - saying it had shown that some pharmacists were spending more than five hours every week sourcing medicines.
The issue of patient harm proved to be highly contentious throughout the inquiry, with the MPs noting that the DH had disputed that there was any "hard evidence" to prove that patients were being harmed. "However, we heard evidence from a wide range of parties that seems to contradict this position," they said.
Although the group conceded that this evidence supplied by pharmacists and patient groups was "anecdotal in nature", it concluded: "We find it difficult to reconcile this evidence, anecdotal though it may be, with claims that there is nothing to suggest patients are having difficult or being harmed as a result of supply shortages."
The inquiry discovered that a lack of data about medicines shortages was hampering the DH's ability to manage the situation and also meant that those who exported medicines "do not have any way of knowing that they are contributing to a medicine shortage".
The APPG called on the government to make sure that research was "undertaken quickly" on shortages, meaning within "months rather than years" and warned that "without good information, the department's ability to bring this problem under control is compromised".

Quota review needed

The MPs were also critical of DH measures introduced so far to tackle the problems, including the publication of best-practice guidance and the establishment of a supply chain forum. "None of these steps has proved effective in mitigating the problem," they said. Existing guidance "must be adhered to", the MPs stressed, calling on the DH to explore sanctions for unjustified non-compliance.
On the subject of quotas, the APPG said that although these had "no doubt been introduced in good faith" by manufacturers, the committee had received a wealth of evidence suggesting they had "aggravated the underlying problem, rather than resolving it".
Quotas were not preventing exporting, instead "causing daily problems for many pharmacies who are not engaging in exporting", it concluded. And it called for a review of quota systems, with a task force to be set up to complete this work.
The MHRA was criticised for being "poorly positioned" to enforce obligations and duties regarding wholesale dealer licences (WDL) to make sure licence-holders were "taking their responsibilities to patients seriously".
"When pressed on this point, the MHRA's lead enforcement official explained to us that such activity would be out of the organisation's jurisdiction", a response that the APPG found "surprising and disappointing". The group suggested that the MHRA could consider working with HMRC to examine VAT returns to "identify the source of parallel exporting activity".
Other suggestions from the MPs included increasing buffer stocks held by wholesalers and having "better and more regular collaborative working" between supply chain stakeholders. "Occasional meetings with few outputs are not adequate," they concluded.
The group also warned that supply chain players were succumbing to the temptation to "blame each other" for stock shortages and called on all involved to work together on the matter.

Chemist & Druggist 15/05/12

‘businesseast’ venture seeks to create science and business park

Proposals for the regeneration of a 108-acre manufacturing plant in East London into a business, science and retail park have received the crucial support of the Government and the Mayor of London’s office.

Situated on prime land in Dagenham, the site has been a manufacturing and research centre for leading pharmaceutical company Sanofi for more than 76 years – producing oncology drugs for distribution around the world.

Sanofi ceases operations at Dagenham in 2013. As part of its legacy, the company has planning approval to transform the location – aimed at creating 2,500 new jobs and new business opportunities under the brand of ‘businesseast’.

Central to the plans is the retention of specialist high-spec laboratory, sterile manufacturing, technology and associated support services – ideal for use by other science-based or technology businesses.

The businesseast scheme also includes:

- Provision of existing assets towards a health facility for GPs with a dental school
- A training centre
- A supermarket with a petrol station
- An 80-bedroom hotel and restaurant
- Warehousing
- Manufacturing

Tim Metson, property expert for SOG Ltd, the regeneration specialist appointed by Sanofi to oversee the process, says: “There are thousands of square feet of specialist manufacturing and laboratory facilities on the Dagenham site that would cost millions of pounds to recreate at today’s prices. Our plan is to retain these buildings and offer them to other scientific businesses where they can be adapted for a multitude of R&D projects.

“The site has sterile manufacturing facilities, chemical and microbiology laboratories and warehouses with specialist utilities including water for injections, deionised water, clean steam, medical-grade compressed air as well as state-of-the-art air-conditioning systems. These sophisticated science buildings can act as a magnet to create a high-profile centre of technology.”

For more information visit: www.business-east.co.uk

Drugmakers crafting emergency plan for Greece

Drugmakers are putting together a plan for how to keep medications flowing to Greece if the economy collapses and payments become uncertain.

With the possibility of a financial default escalating there, drugmakers are working with European authorities to avoid a crisis, according to Reuters in an exclusive report. They are said to be studying the 2002 default in Argentina as a blueprint.

Because Greece is a small market, it is believed that most drugmakers can work with the country on delayed payment basis for awhile. But something has to be done, because the country has almost no domestic production, importing nearly everything and also buying mostly branded, not generics. As a result, its drug costs per capita are substantial, Reuters reports.

"There's a moral obligation to continue to supply," said Simon Friend, global pharmaceutical leader at PricewaterhouseCoopers. "Greece is not a big market, so most drug companies can absorb it … the reputational damage would, I think, more than outweigh the economic cost."

Novo Nordisk found that out last year, when it withheld insulin from the market for about a month after the government slashed its payment rate 25%. Still Novo got the government to settle for a smaller reduction. It is reportedly now on c.o.d. with the country's state-run hospitals. Others, like GlaxoSmithKline ($GSK), have not changed payment policies. Roche, which makes most of the world's cancer drugs, requires payment upfront from slow-pay hospitals but does not require that for drugs like CellCept, or its HIV medication, a spokesman told Reuters.

Still, there have been some drug shortages in the market and drug manufacturers are reportedly owed about €1.21 billion ($1.5 billion), the story says. And in a country where bribery and corruption are prevalent, drugmakers worry that if they keep supplying on credit, drugs might get diverted and sold in markets that can afford full rates

FiercePharma 18/05/12

Watson to pay EUR4.5 bn for Actavis

Watson has agreed to pay up to EUR4.5 billion (US$5.9 billion) for Actavis in a move that will create the world's third-largest generics company with combined generics sales of around US$5.7 billion last year. The two companies expect to complete the transaction – which represents around 2.45-times Actavis' 2011 turnover of US$2.45 billion and nearly 15-times adjusted earnings before interest, tax, depreciation and amortisation (EBITDA) of US$406 million – in the fourth quarter of this year, subject to antitrust approval.

"In a single, commercially-compelling transaction," commented Paul Bisaro, Watson's president and chief executive officer, "we will more than double Watson's international access and strengthen our commercial position in key established European markets, as well as in exciting emerging growth markets, including central and eastern Europe and Russia." Whereas Watson's generics operations outside of the US – largely acquired through taking over Arrow – last year accounted for less than a sixth of total Generics turnover that expanded by 44% to US$3.37 billion (Generics bulletin, 17 February 2012, page 26), buying Actavis would take that proportion up to around two-fifths, Bisaro said.

Western Europe and the Americas each accounted for 29%, or US$710 million, of Actavis' group turnover last year. Central and eastern Europe contributed another 23% or US$565 million, while another 5% or US$125 million came from the Middle East, North Africa and the Asia-Pacific region. The remaining 12% or US$295 million was generated by Actavis' Medis third-party operation, which is similar to the Specifar business for which Watson paid EUR400 million last year (Generics bulletin, 10 June 2011, page 1).

The deal will not only strengthen Watson's position in the US – where Actavis has 70 abbreviated new drug applications (ANDAs) pending approval – and the UK, it will also give the US firm a fast-growing business in Russia and a sizeable presence in emerging markets including Bulgaria, Indonesia, Romania, Serbia and Turkey.

Watson will also fill a strategic gap by taking control of Actavis' oncology injectables facilities in Italy and Romania. Actavis' plants in Bulgaria and the US will give the group capacity for liquids and semi-solids, while other Actavis sites produced 22 billion tablets and capsules last year. The deal also includes certain brands as well as Actavis' recently-agreed joint venture with Poland's Bioton to develop and market biosimilar insulins (Generics bulletin, 3 February
Generics Bulletin

Anti-Counterfeiting Measures
EGA fears anti-counterfeiting costs

Implementing anti-counterfeiting features required as a result of European Union Directive 2011/62/EU on falsified medicines could cost Europe's generics industry EUR1 billion (US$1.3 billion), the European Generic medicines Association (EGA) warned today. Such money, it insists, "could be far better used elsewhere" such as to develop new formulations or indications of existing products, increase the competitiveness of the EU's generics industry, or ensure EU citizens had access to lower-cost medicines.

"Anti-falsification technologies and the massive changes required to production lines – if applied to our sector – would place an unjustifiable burden on the sustainability of a part of the EU pharmaceutical industry which is a cornerstone of healthcare provision in Europe," insisted the EGA's director-general Greg Perry. "Moreover," he cautioned, "it will reduce patient access to affordable treatments as prices will increase or companies will reduce their portfolios to adjust for increased production costs".

Perry urged the European Commission to ensure its delegated implementing act clearly reflected the directive's explicit exemption for low-risk medicines, such as generics. Technological solutions, he stressed, should be targeted primarily at the high-priced products that were at risk of counterfeiting and enjoyed high profit margins that could absorb the costs of such measures.
Generics Bulletin

PRICE WATCH ..... UK
Simvastatin's price sinks to a new low

In a relatively quiet month for price changes, the latest offer in the UK for 28-tablet packs of simvastatin 20mg stands out. A 42% price decrease sounds enormous, but was actually only a few pence. But it is difficult to think of what else can be bought for as little as £0.11 (US$0.13), which was the product's lowest trade price in April. Not even the lower 10mg strength of simvastatin was cheaper, as its lowest price remained steady at exactly a halfpenny a tablet

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

WaveData

DRUG SHORTAGES

The drug shortages reported on are caused by drug companies imposing quotas to stop speculators from "profiteering" from price differentials in same brand drugs in the EU. For years, the exchange rates dictated that the UK was one of the most costly countries in the EU for drugs. Thus, parallel trade saw some same brand drugs coming from EU member states at lower prices. This was sanctioned by the UK government who introduced a parallel import licensing scheme for such products. It can even be said that government action encouraged parallel trade by adjusting reimbursement to chemists to allow for such products.

Now, the exchange rate dictates that the UK is one of the cheapest countries in the EU. Therefore same brand products will often be cheaper than the equivalents in other EU member states. So, it is quite natural to expect speculators to take advantage of this situation, ie, buy at the lowest price and sell at the highest. This is normal business practice and is encouraged by the EU as representing cross border free trade activity.

A government all-party Pharmacy Group, chaired by Keith Barron has been set up to examine the shortages. It would appear that steps taken to mitigate the problem have been to impose quotas. This, in my view, is a significant contribution to the problem, not the solution. The medicines in short supply are all patent protected single source products. Therefore alternative products are not available.

In normal market conditions manufacturers confronted with increased volume requirement, for whatever reason, would deal with it by increased manufacture and supply. However, in this situation the increases have been brought about by possible parallel exportation to EU member states. These products would be replacing those locally available that would have otherwise been sold at the higher price. This would result in a reduction of profits generated by these products which the industry generally finds unacceptable. .

So, it all boils down to profits, irrespective of the problem it may cause to the ultimate user. There has been no published estimate of the loss in revenue of this practice to the industry, but I suspect that it is relatively small. There will be no volume loss to the manufacturers; just a switch from one EU member state to another.

The action by speculators is not illegal, immoral or even unacceptable. However, one may question the imposition of quotas as a restriction of trade at the very least and the real cause of the shortages. The manufacturers are in a monopolistic situation and can dictate what action taken. So, who are the profiteers? After all, anything that impinges upon the profitability of the industry is going to evoke a reaction.

Martin Paltnoi
CEO
MPA Business Services Limited
www.mpasearch.co.uk

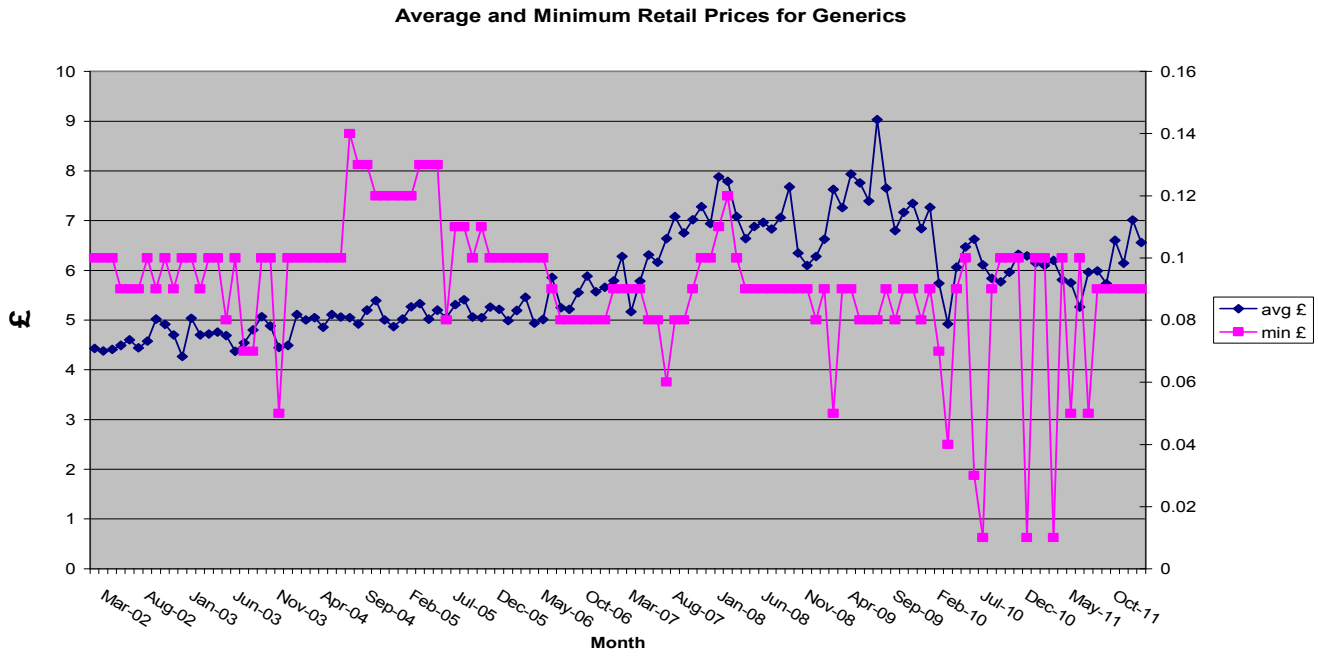
France's Afssaps becomes ANSM

France has overhauled its medicines agency, Afssaps, and from 1 May renamed it the National Agency for the Security of Medicines (ANSM). The changes – which aim to enhance the transparency and independence of the agency, as well as its ability to monitor the safety of medicines – come as part of a "major reform" of France's medicines system that was outlined by the country's health minister, Xavier Bertrand, last year.
Generics Bulletin

Average generic prices (Wavedata)

There has been some discussion recently as to whether generic prices are falling or rising in the long term. Using the prices offered to chemists and dispensing doctors by wholesalers and generic companies, wavedata have been able to see that over the last 10 years average prices have risen as brands have lost their patents and new generics have been launched. However looking at the minimum prices there are some signs of an overall decrease.

The sudden downward spikes in the minimum price are due to short-dated stock, with the overall trend in minimum prices being from about £0.10 in 2002 to £0.09 today. The average generic price on the other hand has risen from £4.43 in March 2002 to £6.36 in April 2012, a rise of £1.93!



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 April 2012

Galantamine XL Caps 8mg 28

Pioglitazone Tabs 30mg 28

Bendroflumethiazide Tabs 2.5mg 28

Galantamine XL Caps 24mg 28

Pioglitazone Tabs 15mg 28

Avodart Caps 0.5mg 30

Galantamine XL Caps 16mg 28

Pioglitazone Tabs 45mg 28

Quetiapine Tabs 100mg 60

Donepezil Tabs 10mg 28

This bulletin now goes out to 2300 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 13th June 2012, as I will be issuing the next one on the 20th June 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

Jackie Moss
WaveData Ltd

E-mail: Jackie@wavedata.co.uk
07968 815192