July 2012

Monthly Service

Commercial Bulletin

Inside this issue

Anti-counterfeit deal fails to become EU law

Irish drug price cut deal enables new product listings

Walgreen's, Alliance Boots merge to create world's largest pharmacy chain

Do you require specialist science facilities? Sanofi has the answer!

PSNC hits out at Olympics medicine export claims

FREE DRUGS FOR THE INDIAN POPULATION

'Fast movers' reflects noisiest newcomers
PRICE WATCH ..... UK

80% of NHS trusts experiencing drug shortages

Pharmacists face financial strain under new drug tariff

Manufacturers slam government's new medicines spend squeeze

WaveData — Top ten products

Special points of interest:

This bulletin is free to Interested people in Pharma & Healthcare

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

If you have articles, comments or story ideas, please send them to the email above

www.wavedata.co.uk

Anti-counterfeit deal fails to become EU law

The European Parliament has rejected the international Anti-Counterfeiting Trade Agreement (ACTA) put before it by the European Commission, which means that it cannot become law in the European Union (EU).

The vote, on July 4, represented the first time that Members of the European Parliament (MEP) have exercised their power to reject an international trade agreement, and 478 of them did so, with 39 voting for it and 165 abstaining.

Parliament's striking down of the agreement was welcomed by international aid agency Medecins Sans Frontieres (MSF), which said that ACTA could have limited access to quality generic medicines.

"The way it was written, ACTA would have given an unfair advantage to patented medicines and restricted access to affordable generic medicines, to the detriment of patients and treatment providers alike," said Aziz ur Rehman, intellectual property adviser for the MSF Access Campaign.

MSF emphasises that it strongly supports efforts to ensure that generic medicines meet accepted international standards. However, it also says that ACTA's over-broad definition of "counterfeiting" and its excessive enforcement provisions left too much room for error. Legitimately-produced generic drugs could have been seized and detained, hindering access for people who rely on these medicines to survive, says the agency.

Moreover, the agreement's stringent provisions would have targeted third parties, including treatment providers such as MSF, by exposing them to the risk of punitive action in trademarked and patient infringement allegations, it points out.

The vote was also welcomed by David Martin, Scotland's senior MEP and author of the ACTA report to the Parliament's International Trade Committee, which had found the agreement to be too vague and open to misinterpretation, and that it could therefore jeopardise citizens' liberties.

"ACTA was wrong from the start. It was negotiated in secret, and tries to put together incomparable elements in the same treaty," said Mr Martin, who welcomed the Parliament's first-ever vote to reject an international trade deal as "a historic day in terms of European politics."

"The Commission and the Council will now be aware that they cannot expect blind support from the Parliament, which represents and defends citizens' rights. This vote represents true democracy in action and the coming of age of the European Parliament," he said.

Following the vote, MSF says that the European Commission should now review other "similarly harmful" intellectual property provisions being pursued in other agreements, including free trade negotiations such as the agreement currently being negotiated with India, one of the world's biggest exporters of generic medicines.

Mr ur Rehman calls on EU Trade Commissioner Karel de Gucht to "take heed - the vote on ACTA has shown that these harmful policies are unacceptable to European parliamentarians and some EU member states."

"The Commission should rethink its approach on intellectual property enforcement measures in free trade and other agreements," he said.

"We need to learn from this sorry mess," added Mr Martin. 'We need to listen to the people, we need to start again from scratch. We want to fight counterfeiting and we are willing to start working as soon as possible on a good solution, one our voters are comfortable with," he said.

* **ACTA** was negotiated by the EU and its member states, plus the US, Australia, Canada, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea and Switzerland, to improve the enforcement of anti-counterfeiting law internationally. It has been signed by 22 EU members, including the UK, but the vote in Parliament means that neither the EU nor its individual member states can join the agreement.

Links
www.europarl.europa.eu
www.msf.org

Pharmatimes 05/07/12

Irish drug price cut deal enables new product listings

The Irish government and the country's drugmakers have agreed interim drug price cuts which, they say, will deliver savings totalling 20 million euros in a full year and allow new products to be supplied through state drug schemes.
The new agreement extends the recently-expired deal between Ireland's Health Service Executive (HSE) and the Irish Pharmaceutical Healthcare Association (IPHA), under which, when a generic equivalent of an off-patent drug came onto the market, the price of the original product was reduced by 20% immediately and by a further 15% after 22 months.
Health Minister James Reilly has accepted the IPHA's proposal that, when such a generic equivalent comes to market, the price of the original product will be reduced immediately by 30% instead of 20%. In the case of products that have already been reduced 20% under the IPHA/HSE agreement but have not yet had the 15% reduction, the industry association has agreed to provide an immediate reduction of 10%, rather than having to wait for the expiry of the 22-month period provided for under the expired deal.
The price cuts are expected to deliver sayings of around 10 million euros in 2012, rising to as much as 20 million euros in a full year. And, as part of the agreement, the HSE says it will give its approval to drugs "which, in the normal course of events, would have been approved for reimbursement."
The IPHA has welcomed Dr Reilly's acceptance of its proposals which will, it says, deliver savings in the immediate short term and also allow for the full and proper implementation of the existing supply agreement by ensuring that new medicines can be reimbursed.
This will also now make sure that full negotiations on a new agreement between the state and IPHA can recommence, the group adds.
"This is a good day for Irish patients who will now have broad universal access to new innovative therapies restored," said IPHA president, David Gallagher.
"A key strength of the Irish healthcare system over many decades has been early access to the full range of modern, therapeutically-advanced medicines to all patients, regardless of income, and we are delighted to have been able to work with the Department of Health to ensure that this access can be restored," he added.
Speaking on the RTE Radio News at One programme, Mr Gallagher had pointed out that while there are currently eight or 10 new medicines which have been proven to be cost-effective and which ordinarily would have been added to the reimbursement scheme, no additions to the scheme have been made since last September.
According to local reports, these products include AstraZeneca's antiplatelet drug Brilique (ticagrelor), Novartis' multiple sclerosis treatment Gilenya (fingolimod) and Lundbeck's antipsychotic Sycrest (asenapine). Delayed budget decisions and other problems are also affecting access to other products including Janssen Cilag's Incivo (telaprevir) and Merck & Co's Victrelis (boceprevir), both for hepatitis C, and Boehringer Ingelheim's blood-thinner Pradaxa (dabigatran).
The Department of Health comments that Dr Reilly has accepted the industry's offer of interim price cuts "in advance of further discussions with IPHA which are expected to deliver more significant savings to the Irish patient and taxpayer."

Links

www.ipha.ie
www.hse.ie
www.dohc.ie

Pharmatimes 27/06/12

Walgreen's, Alliance Boots merge to create world's largest pharmacy chain

Alliance Boots will merge with Walgreens, the US-based drug retail chain, in a £4.3 billion ($6.7 billion) deal to create the world's largest pharmacy business.
Walgreen's plans to invest £2.54 billion and the rest in shares to buy the rest of Alliance Boots it does not own within three years. Both the companies have mutually agreed to create a global leader in pharmacy-led, health and well-being retail with over 11,000 stores in 12 countries.
The new company will be have the largest global pharmaceutical wholesale and distribution network with over 370 distribution centers delivering to more than 170,000 pharmacies, doctors, health centres and hospitals in 21 countries. It will also be the world's largest purchaser of prescription drugs and many other health and well-being products.
Stefano Pessina, the chairman of Alliance Boots, and the private equity house KKR, who between them own 70% of the business, have each sold 45% of their stakes. The remaining investors, a collection of private equity backers and funds, have also sold down.
Walgreens will not, for now, take on any of Alliance Boot's £7 billion debt. It has the right to acquire the remaining 55% over the next two to three year for about $9.5 billion (£6.03 billion), plus the debt, which it hopes will have fallen to about £5 billion by then.
All parties intend a full merger to go ahead to create the world's largest pharmacy chain with 11,000 shops in 12 countries, as well as the world's biggest pharmaceutical wholesaler.

http://www.thefinancepages.co.uk/companies/walgreens-alliance-boots

Do you require specialist science facilities? Sanofi has the answer!

Science and technology businesses looking to grow their operations have the opportunity to access state-of-the art R&D and manufacturing facilities which will become available next year following pharmaceutical company Sanofi's decision to close a plant in Dagenham, east London.

Sanofi has secured planning permission for a major regeneration programme on the 108-acre site aimed at generating up to 2,000 new jobs through the creation of "businesseast" – a science, business and retail park.
For more than 76 years the Sanofi site has been at the forefront of medical drugs research and manufacture. Its oncology products help thousands of sufferers from diseases including breast, lung and prostate cancers.
Although Sanofi announced that the plant is closing in 2013 for commercial reasons, the company has instigated an innovative regeneration programme revolving around the sale of vacant land for business and retail. The plan also involves the retention of existing sophisticated research & development and manufacturing facilities which could be sold or leased to support smaller pharmaceutical or science-based companies.
Mark Bass, Sanofi's Land Development and Partnership Leader – Dagenham, who has been responsible for overseeing the regeneration process, says retention of the multi-million pound science facilities are an integral part of the site regeneration. Mr Bass says the aim is to encourage other science and technology-based businesses to buy or lease some of the existing facilities to create a new science environment in east London.
He hopes that associated highly-skilled jobs would be generated benefiting the company's existing workforce as well as people in the wider region. However, Mr Bass stresses that Sanofi is working to an extremely tight time-frame and that businesses interested in the facilities need to move quickly.
"Retention of the science facilities is central to our plans for businesseast but we need to secure new occupants for these specialised buildings by the time Sanofi exits the site towards the middle of 2013," he says.
For more information on the regeneration programme visit www.business-east.co.uk or contact Dominic Whitfield at Savills Commercial Division on + 44 (0) 20 7409 8846.

PSNC hits out at Olympics medicine export claims

PSNC has hit out at claims that pharmacists may take advantage of relaxed medicines quotas during the Olympics to boost their exporting businesses.
Chief executive Sue Sharpe urged manufacturers to agree to lift quotas during the games, despite the Health Service Journal reporting that one manufacturer believed London pharmacists would "stockpile" medicines for export.
The manufacturer, which was not identified, reportedly said it was concerned that a "large number" of pharmacists who exported medicines were based in East London.The company argued that this could create shortages following the games.
But Ms Sharpe stressed that pharmacists worked "very hard" to ensure patients received their medicines on time. And she warned against abandoning NHS London's plans for the Olympics, which saw the trust write to manufacturers asking if they could lift medicines quotas for the period.
"In order for the agreed plans to work, everyone from pharmaceutical companies to wholesalers to pharmacies has to work very closely together," she said. "Interventions that could alarm the public unnecessarily are not helpful and risk undermining the positive spirit of collaboration we have established."
Wholesaling and manufacturer bodies today issued a statement suggesting they would continue with the agreed plans to ease supply chain delays.
"Manufacturers and wholesalers have been preparing for this situation and are working hard to ensure the necessary medicines reach pharmacists as normal throughout the Olympics," said Association of the British Pharmaceutical Industry and British Association of Pharmaceutical Wholesalers in a joint statement.
"Whenever pharmacists have difficulty obtaining a specific medicine from wholesalers they should contact the medicine's manufacturer as soon as possible – this remains the case during the Olympics."
In March, C+D reported that East London pharmacies could suffer "serious disruption" to medicines supply during the games.

Chemist & Druggist 10/07/12

FREE DRUGS FOR THE INDIAN POPULATION

The recent announcement that the Indian government is intending to give free generic drugs to its population and to ban the use of branded prescriptions in certain circumstances. The plan is to provide essential drugs free to patients in government run hospitals and clinics and is estimated to cost nearly $5billion over five years. This is part of a five year plan covering the government's big spending programme from 2012 to 2017. It is expected to be approved in August.

This has been greeted with alarm and scepticism among the pharmaceutical fraternity. Alarm from USA and European producers who are looking to India and China to shore up flagging profitability in Western markets. This decline in products is not because of any economic drop in the industry, but because of a natural evolution in the market. A expected decline in new chemical entities being discovered coupled with the patent expiry of some major drugs will result in an automatic drop in profits. The biggest growth area is the industry at present is generics which incorporates much lower levels of profit margins. But this is nothing that could not have been foreseen; the industry has tended to expect the loss of a "blockbuster" to be replaced by the creation of another. However, this has not been the case largely through the success of the industry who are running out of new areas to cover.

So, the announcement by the Indian government may raise some concern, but on the other hand it is being treated with a degree of credulity, particularly by some major Indian producers. It has been said that the proposed plan is not workable or feasible in view of the absence of adequate infrastructure to cope with this plan. It has been suggested that possibly public sector drug companies may provide an answer, but the lack of consultation with indigenous Indian pharmaceutical companies for practical solutions may undermine the credibility of the plan. It has also been suggested that this is nothing more than a political move and vote-catcher and has disregarded the possibility of drugs for the needy being stolen by officials involved in their distribution, as is the case in the distribution of wheat and rice by Indian States to the poor.

Only time will establish whether alarm or scepticism is applicable.

Martin Paltnoi
MD
MPA Business Services Limited
http://www.mpasearch.co.uk

'Fast movers' reflects noisiest newcomers

PRICE WATCH ..... UK

With more new generics coming onto the UK market, and many rapidly switched to category M of the Drug Tariff of pharmacyreimbursement prices, we have decided to overhaul our 'fast movers' table and set new rules for how we use the limited space available. Firstly, we have decided to prioritise recent launches. This has had the effect of restricting the selection to those launched since September 2004. The product basket has then been further refined by restricting it only to generics in category M as of 1 July 2012. This reflects not only the most recent newcomers to the category, but also gives an indication of the popularity of these products.

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

Subscribe to the industry's comprehensive source of news and analysis.
www.generics-bulletin.com

80% of NHS trusts experiencing drug shortages

Eighty percent of 60 National Health Service trusts in England and Wales are experiencing delays in obtaining medicines for their patients, freedom of information requests by Labour MP Huw Irranca-Davies have revealed.

Around 70 to 80 drugs are still on the danger list, including lifesaving medicines for serious illness such as cancer, heart conditions and Alzheimer's disease, as parallel traders continue to cash in despite the fact that patients are suffering as a result.

Speaking to BBC Wales, Irranca-Davies called on the UK government to take a harder stance on the issue as, he stressed, the voluntary route taken to date just isn't working. "Patients are having to wait weeks for drugs and it's not good enough".

If anything, he argues drug shortages are actually getting worse, despite a quota system operated by drug manufacturers to provide extra flexibility and limit pharmacists from submitting excessive orders, and numerous attempts by the government and other parties to rectify the situation over the last three or four years.

Some drugmakers say they are already producing more than 150% of what's needed, while chemists and doctors are spending an average of five hours a week ringing around trying to source drugs, and some are spending up to 20 hours a week on the phone, he claims.

Irranca-Davies is calling on the government to introduce tighter regulation in the shape of a Patient Service Obligation, which, he says, are already used by around three-quarters of countries in Europe to protect medicine supply to patients.

Enforcing obligations?

Health Minister Simon Burns said last month that the Medicines and Healthcare products Regulatory Agency is currently reviewing the patient service obligations introduced by other European member states, but added that the government "is cautious about increasing the regulatory burden on the supply chain".

Last week the British Association of Pharmaceutical Wholesalers said the Department of Health must "stop sticking its head in the sand" over the issue of medicines shortages, and in May, the All-Party Pharmacy Group's inquiry called on the Medicines and Healthcare Products Agency to "improve its efforts to enforce obligations on those with licenses to conduct wholesale activities," and to "consider carefully whether it is in the best interests of patients to see further growth in the number of Wholesale Dealer Licenses."

Also this week, an article in *The Daily Telegraph* laid much of the blame for shortages at the door of pharmaceutical companies, claiming that the quota system is to blame for waning drug stocks.

The Association of the British Pharmaceutical however was quick to refute this. "Quotas are a legitimate means of ensuring that UK patients receive the medicines they need", it said.

Sticking plaster

Conceding that the system is "a sticking plaster and not a cure", the ABPI stressed that it is essential to curb excessive orders, citing occasions where "manufacturers have received orders for medicines which represent more than the entire UK's requirement for one particular medicine in one go".

In a statement to *PharmaTimes* UK News, a spokesman for the Department of Health said "the government does maintain a buffer stock of certain essential medicines that can be released in emergencies," and stressed that it will "take any action necessary in the event of disruption to supply and distribution of medicines that causes serious risk to patients".

Pharmatimes 26/06/12

Pharmacists face financial strain under new drug tariff

More than 80 per cent of pharmacists expect to be worse off under July's changes to the drug tariff, a C+D straw poll has suggested.

The poll of 43 readers revealed that only 2 per cent thought they would be better off under the new payment arrangements, while 16 per cent said their finances would be roughly the same.

The tariff, which aims to simplify reimbursement, will see changes to methadone payment that some contractors estimate will cost them thousands of pounds a year. Out-of-pocket expenses will have a minimum threshold of 50p, while broken bulk claims in categories A and M will only be valid in cases where the reimbursement price of the smallest pack size listed in the drug tariff is at least £50.

Contractors will also receive a 10p container allowance for dispensing split packs where odd quantities have been prescribed.

PSNC told C+D the drug tariff changes should not represent a drop in overall income and said it would monitor their impact "very closely". The negotiator's head of pricing Harpreet Chana also stressed that the new tariff would reduce the amount of endorsing pharmacists needed to do.

But the NPA confirmed that it was still receiving calls regarding drug tariff changes. "The most popular query about the drug tariff continues to be around changes to the fee structure with methadone payments," said NPA head of information services Leyla Hannbeck. Ms Hannbeck added that there was "limited awareness" of changes to broken bulk reimbursement and urged pharmacists not to be "left in the dark and out of pocket".

Contractors talking to C+D said the new tariff could "chisel away" at overall income and criticised PSNC for not discussing the changes with contractors.

Jignesh Patel of Rohpharm Pharmacy, Plaistow, London, said he had mixed feelings over the new reimbursement arrangements. "In some aspects it will be quite good. But the basic dispensing fees every year have gone down, the profit margins have gone down, and now they're starting to chisel away at the other bits and pieces of remuneration."

The comments were echoed by Graham Phillips, owner of Manor Pharmacy Group (Wheathampstead) Ltd, Hertfordshire. "I understand what PSNC is trying to achieve, but what they're not doing is [asking] contractors what the effect will be,'" he said. "We've checked within our own group and the so-called simplification of methadone payments will cost us about £10,000. If you've modelled your business around methadone, it's catastrophic."

Chemist & Druggist 28/06/12

Manufacturers slam government's new medicines spend squeeze

Manufacturers have hit out at NHS plans to slow growth in new medicines spend over the next three years, stressing that this could jeopardise research into lifesaving medicines.

In a report it commissioned from the Office of Health Economics, the Association of the British Pharmaceutical Industry (ABPI) found that spend on branded medicines is set to rise just 1.3 per cent a year between 2011 and 2015. This compares to an annual hike of 2.5 per cent in NHS spend overall.

ABPI chief executive Stephen Whitehead criticised the plans as "bad news for the discovery of new lifesaving medicines", arguing that the government had already achieved "huge savings" from medicines coming off patent. The report found that patent expiries over the next three years would save the NHS £3.4 billion.

"I am deeply concerned that these savings are not being reinvested back into the system because these figures show our spending on the newest and most advanced medicines is declining in real terms," Mr Whitehead said.

The news came after the NHS This Year report revealed the health service had made £700 million of savings in prescribing in 2011-12. The savings will contribute to the government's target of saving £20bn across the NHS by 2015.

Speaking on BBC Radio Four's Today programme last week, Mr Whitehead argued that the drop in new medicines spend "stored up problems for the future", as the effective use of medicines could limit hospitalisations.

On the same programme, independent health policy analyst Roy Lilley defended the decision not to reinvest the money into medicines research. "The reason the drugs bill has gone down is because the NHS has gone out of its way to bring the drugs bill down," he said. "I think it's a bit rich for the pharmaceutical industry to say 'give us back the money you've saved so we can reinvest it'."

Amish Patel, managing director at Hodgson Pharmacy in Kent, said medical research was "crucial", but that the NHS may have other priorities. "It could be there's a need for it in other areas," he told C+D.

Last week, C+D reported that GPs were facing pressure to prescribe drugs according to cost, with a survey revealing that 93 per cent had been told to switch a patient's dyslipidaemia medication to a cheaper alternative.

Chemist & Druggist 11/07/12

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 June 2012

Atorvastatin Tabs 10mg 28

Atorvastatin Tabs 20mg 28

Atorvastatin Tabs 80mg 28

Losartan Tabs 50mg 28

Omeprazole Caps 20mg 28

Candesartan Tabs 4mg 28

Candesartan Tabs 16mg 28

Ibandronic Acid Tabs 150mg 1

Lansoprazole Caps 30mg 28

Losartan Tabs 100mg 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 15th August 2012, as I will be issuing the next one on the 22nd August 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