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MHRA ADVICE HIGHLIGHTS GENERIC SUBSTITUTION DANGERS, SAYS NORGINE

Recent MHRA advice on the treatment of patients with ciclosporin has highlighted the potential dangers of automatic generic substitution, according to European speciality pharma Norgine.

Late last year the UK regulator issued advice to doctors that the immunosuppressant ciclosporin must be prescribed and dispensed by brand name, as small differences in bioavailability between different formulations of the drug can alter blood concentrations in patients stabilised on a specific brand, leading to potentially serious complications such as transplant rejection in renal patients.

And because of potential fluctuating bioavailability between the different forms of ciclosporin patients taking the drug could be at risk under the government's proposals for automatic generic substitution, whereby pharmacists are required to dish out cheaper generic version of medicines even if doctors have specifically prescribed their branded counterparts, Norgine claims.

Government plans for automatic generic substitution are currently up for consultation until March, and if the scheme is ultimately given the go-ahead then all renal patients should be excluded from the policy, says Timothy Statham OBE, head of the National Kidney Federation.

"Treating renal patients is extremely complicated – some take up to 24 medications per day," he explained. "They have to take so many drugs that no substitution is safe; any changes to their treatment must be decided by the originating prescriber and no one else", he stressed.

The dangers of changes in bioavailability from switching between different versions of a medicine have also been highlighted by the National Patient Safety Agency, which has recently issued guidelines for the treatment of bipolar disorder with lithium to avoid such scenarios.

Negative impact

In addition, a group of multidisciplinary healthcare professionals and patient groups - funded by Norgine - published its fears over the risks of generic substitution last Summer in the paper *Automatic generic substitution — Clinical implications for patients*, claiming that the scheme could end up confusing patients, disrupting drug regimens and thereby affect compliance and treatment outcomes.

The DH, however, insists that increasing the proportion of generic prescriptions by just 5% could save the NHS some really big bucks which could be redirected into patient care. According to Health Minister Mike O'Brien, generic substitution will "deliver value for money and savings to the NHS which will go directly back into health services, ultimately benefiting patients and improving the care they receive."

Pharmatimes 01/02/10

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Special points of interest

This bulletin is free to interested wholesaler employees

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

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www.wavedata.co.uk

Alliance Pharma buys Cambridge Labs for up to £16.4 million

Speciality pharmaceutical group Alliance Pharma saw the value of its stock swell after unveiling plans to buy certain chunks of Cambridge Laboratories for between £14.3 million and £16.4 million. The move will see Alliance gain access to 18 prescription products covering various therapeutic areas, such as ImmuCyst, an immunotherapy for superficial bladder cancer, and procarbazine for Hodgkin's Lymphoma.

But the group has only bought the operations of Cambridge Labs' associated with trading, i.e. its

sales and administration divisions, and has not purchased anything linked with its development business, Alliance chief John Dawson told the Financial Times.

Under the terms of the deal, Cambridge Labs' offices in Dublin, Ireland, and Newcastle, including around 30 staff, will transfer to Alliance, but the company said it plans to incorporate incoming support functions into its existing offices in Chippenham, Wiltshire, which could put about 25 jobs at risk of redundancy.

The acquisition, which will be

funded by its existing credit facility and a share placing, is expected to close on February 22, and be "significantly earnings enhancing" to Alliance in the financial year ending December 31, 2010, the firm said.

Pharmatimes 10/02/10

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300 branded drug prices slashed in Ireland

Research-based drugmakers in Ireland cut the prices of almost 300 of their most widely-prescribed medicines by 40%, in a move aimed at saving the state 94 million euros over the next full year.

The Irish Pharmaceutical Healthcare Association (IPHA) said it had agreed the price cuts after being approached by Mary Harney, the Minister for Health and Children, with a request to create immediate savings on the state bill for medicines. As a result of the 40% reductions, the patented drugs on the list are now cheaper than their generic versions, and customers should save 3-4 euros each time their prescription is dispensed - potentially as much as 500 euros a year, said the Association, which has set up a website, www.checkthelist.ie, for consumers to check which products are now cheaper. They can also call 1890 876 700 for this information.

IPHA members have also agreed to pay an increased rebate to Ireland's Health Service Executive (HSE) in respect of the manufacturer price of all other medicines dispensed under the nation's Community Drug Schemes, the Association added.

However, pharmacists are under no obligation to pass on the new lower prices to consumers, and the Irish Pharmacy Union (IPU), which represents community pharmacists, has pointed out that pharmacists had not been permitted to start purchasing medicines at the new lower prices in advance of the reductions.

"This means that the medicines, which pharmacists stock on their shelves for patients on behalf of the HSE, will now be paid for by the HSE at the new lower rates, despite having been purchased by pharmacists at the high prices which were previously agreed between the HSE and the drug companies," said IPU president Liz Hoctor, who described this "discrepancy" as "yet another severe financial blow for pharmacists."

The price cuts may also hit the thriving border trade built up by pharmacists in Northern Ireland, who have been permitted to fill prescriptions for residents of the Republic who pay for their prescriptions since changes in European Union (EU) regulations took effect in November 2008.

Ms Harney has yet to secure a similar price-cutting undertaking from generics makers, which are represented by the Association of Pharmaceutical Manufacturers in Ireland (APMI). The Minister said she was disappointed that APMI members have "declined to offer any reductions," but warned them that it is her "firm intention to obtain savings from APMI of at least an equivalent level to those secured from IPHA," totaling a further 27 million euros in a full year.

The Irish government's current pricing agreement with the APMI runs out on September 1, while a new deal with makers of branded medicines is due to take effect in March 2012.

- Ms Harney has also confirmed that Ireland's controversial new 50-cent prescription charge, to be imposed on each prescription item dispensed to the Republic's 1.4 million medical card-holders under the Community Drugs Schemes, is expected to be introduced on April 1. Taoiseach (Prime Minister) Brian Cowen has defended the new charge, saying it will generate savings of some 30 million euros a year. Ireland's drugs bill is forecast to reach 3 billion euros for 2010.

Pharmatimes 02/02/10

BAYER ANNOUNCES DISTRIBUTION DEAL

Bayer Diabetes Care, the diabetes care division of Bayer HealthCare in the UK, has announced a new distribution deal.

Bayer Diabetes Care is to distribute selected products for patient and healthcare professional use with Alliance Healthcare, Phoenix and AAH from 1 April. **Products** affected include Breeze2 and Contour blood glucose test strips. **The** move follows a change in July 2009 to the distribution of Bayer Schering products, which are only supplied through AAH, Alliance Healthcare and Phoenix.

Arrangements for distribution of Bayer's Consumer Care and Bayer's Animal Health products remain unchanged.

Further information, including the list of products selected for the new model is on <u>Bayer's website</u>.

Chemist & Druggist

WaveData know of a number of commercial managers who are currently seeking new roles.

If you have vacancies, please let us know and we will put you in contact with each other.

(Free service)

UK drug prices bottom in Europe

In just four years prices of branded medicines in the UK have plummeted to among the lowest in Europe, according to a report by the Department of Health.

The study looked at the prices tags of 150 branded medicines in 13 different global markets last year and found the UK now ranks 12th, lagging behind countries such as France, Ireland and Germany, and beating only Australia.

A DH spokesperson stressed to Pharmatimes Magazine that the figures

should be "treated with caution" as the fall in the value of the pound between 2004 and 2008 "accounts for much of the change in the UK's position relative to other countries over this period". But the Association of the British Pharmaceutical Industry says the government's shock renegotiation of the Pharmaceutical Price Regulation Scheme last year – which further trimmed the list price of medicines sold to the NHS has also played a significant role in changing the UK's ranking.

Further analysis by the ABPI has found the UK to be well behind its European peers on medicine spend, equating to just 1% of its

gross domestic product, compared to the 2.32% spent by Greece. The UK figure is also two-thirds of the average spend in 15 European nations.

Pharmatimes Jan 2010



PFIZER KICKS OFF GENERICS RANGE WITH SIX DRUGS

Pfizer has launched a range of generic medicines in the UK.

The pharma giant said the move to widen its product offering would maximise the value it offered pharmacies.

The initial launch consists of six medicines: metformin, finasteride, ondansetron, paroxetine, mirtazapine and mirtazapine OD.

Further medicines will be added throughout the year, dependent on licensing.

The range would offer pharmacists more choice in the generics market, Pfizer commercial director Steve Poulton told C+D, and was part of the company's aim "to move closer to pharmacists, because we recognise that pharmacists are becoming a much more influential voice in the use of medicines".

"My aim is that where pharmacists have a choice, they purchase their medicines from Pfizer," he said.

The generics would be supplied through Pfizer's DTP (direct to pharmacy) scheme and count towards pharmacies' discounts", Mr Poulton said. This would offer pharmacists "logistical and financial benefits," he added.

"Pharmacists will get the same benefits of the proven, robust supply chain for branded medicines... they will need to talk to their Pfizer account managers to work out pricing," Mr Poulton advised.

The launch was prompted by the number of blockbuster drugs coming off-patent in the next few years.

The range will be manufactured in India by Aurobindo Pharma and Claris Lifesciences, with which Pfizer signed agreements last year.

Chemist & Druggist 04/02/10

To find out why Alendronate stands out in a quiet month, go to www.wavedata.co.uk/news and view our article from this months Generics Bulletin.

Supply deal renewed.

AstraZeneca has renewed its direct to pharmacy distribution deal with AAH and Alliance Healthcare for another four years.

Chemist & Druggist 23/01/10

Greek bailout deal reached at EU summit

The prime minister of <u>Greece</u> has appealed for "psychological and political support" as <u>Europe</u>'s leaders gathered in Brussels to try to hammer out a bailout for their debt-laden neighbour.

George Papandreou told Le Monde this morning that it was important that the eurozone acted together to address the crisis. Papandreou said he expected fellow European leaders to support his efforts to cut Greece's debt, which is expected to hit 120% of GDP this year.

The ongoing crisis has seen <u>financial traders take huge bets against the euro</u>, speculating that Greece will fail to solve its financial woes. Papandreou argued that this means it is particularly important the rest of Europe agrees a deal.

The euro rose slightly against the dollar and the pound today, reaching \$1.3747 and 88.2p. City experts, though, warn that the crisis will have a critical influence on bond markets as well as currency values.

Guardian 11/02/10

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

Both uk and pi prices were viewed for each product, giving some indication of where the focus was in January 2010

Gliclazide Tabs 80mg 28

Lercanidipine Tabs 10mg 28

Prednisolone E/C Tabs 5mg 30

Goserelin acetate Implant in Syringe Applicator 3.6mg 1

Lercanidipine Tabs 20mg 28

Actos Tabs 15mg 28

Bendroflumethiazide Tabs 2.5mg 28

Codeine Phosphate Tabs 30mg 28

Furosemide Tabs 20mg 28

Gabapentin Caps 300mg 100

This bulletin now goes out to 950 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 10th March 2010 ,as I will be issuing the next one on the 17th March2010

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

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Jackie Moss

WaveData Ltd

E-mail: jackie@wavedata.co.uk

07968 815192