GENERICS bulletin
THE BUSINESS NEWSLETTER FOR THE GENERIC MEDICINES INDUSTRY

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Regulatory Affairs

User fees are no 'magic bullet'

The decision by President George Bush's administration to include user fees for generics in its budget for the 2008 financial year will not bring generics to market faster unless market barriers such as authorised generics and citizen petitions are tackled, according to the US Generic Pharmaceutical Association (GPhA). "Simply put, user fees alone are not the magic bullet for speeding up drug approvals," insisted the GPhA's president and chief executive officer Kathleen Jaeger.

The budget proposal unveiled earlier this week includes the US Food and Drug Administration (FDA) raising US$15.7 million during the year ending 30 September 2008 from user fees levied when companies submit generic drug applications. The proposals also include US$5.6 million in state funding to conduct more – and more timely – generic drug reviews.

During the 2008 financial year, the FDA estimates that it will receive 857 generic applications, compared to 793 in the year ended 30 September 2006. Implementing user fees, the FDA believes, will let it increase its approvals by 50% in the first full year of operation.

A further US$5.6 million in state funding will allow the Office of Generic Drugs (OGD) to grant final or tentative approvals for up to 550 drugs during the 12-month period, the FDA maintains. The agency hopes to raise the percentage of generic applications it acts on within 180 days from 55% at present to 75% by the end of the 2011 financial year. G

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Biogenerics

Ranbaxy plans European biosimilar

Ranbaxy Laboratories is aiming to enter the European Union market for biosimilar products by striking a deal for granulocyte-colony stimulating factor (G-CSF) with Zenotech Laboratories, the Indian injectables specialist in which Ranbaxy holds a strategic stake.

While the two firms have signed a global development and marketing agreement, they will initially focus on developing the filgrastim product in the European Union, where a clear regulatory pathway for biosimilars is already in place. However, Zenotech's chief executive officer Dr Jayaram Chigurupati said the product would "eventually" also be filed in the US.

"This agreement," commented Chigurupati's counterpart at Ranbaxy, Malvinder Mohan Singh, "signals Ranbaxy's foray into biosimilars by pooling Ranbaxy's significant regulatory and front-end infrastructure with Zenotech's expertise in the development and manufacture of biosimilar products." Zenotech – which already has an oncology alliance with Ranbaxy for oncology drugs (**Generics *bulletin***, 30 June 2006, page 14) – will produce G-CSF at its facility near Hyderabad, India.

Anticoagulants

Amphastar and Teva win Lovenox case

Amphastar Pharmaceuticals and Teva Pharmaceuticals have today emerged victorious in their long-running patent-infringement dispute with Sanofi-Aventis over the Lovenox (enoxaparin sodium) anticoagulant blockbuster. But the brand company said it was "evaluating its options for further legal recourse".

The case in a California district court had centred on Sanofi-Aventis' reissue patent RE38,743, which expires on 14 February 2012. Amphastar had obtained a summary judgement of inequitable conduct against Sanofi-Aventis, but that ruling was overturned by the US Court of Appeals, which remanded the case back to the California district court to decide on the validity, enforceability and infringement of the '743 patent (**Generics *bulletin***, 21 April 2006, page 10).

Lovenox is Sanofi-Aventis' best-selling brand with US sales in the first nine months of 2006 ahead by 16.6% to €1.12 billion (US$1.46 billion).

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Business Strategy/Second-Quarter Results

Aceto pushes into US dosage forms

Aceto has launched its first finished-dose generic in the US market by introducing isoflurane under its own label. According to Aceto, the inhalable anaesthetic has a US market size of over US$75 million and limited competition.

"We continue to make progress towards acquiring additional products to distribute under the Aceto brand," commented chairman, president and chief executive officer Leonard Schwarz. Agreements for another two abbreviated new drug applications (ANDAs) – one of which has been approved, while approval for the other is expected soon – are in place. And Aceto is negotiating with another supplier for four approved ANDAs.

Aceto is targeting older products with limited competition where prices have stabilised, but it will not market drugs for which it supplies active pharmaceutical ingredients (APIs) to third parties.

Pricing & Reimbursement

FeBelGen looks for more public support

Belgium faces three immediate threats to the long-term stability of its generics market, according to Joris Van Assche, secretary general of FelBelGen, the country's generics industry association. Apart from the continuing confusion about the government's plans to introduce a 'Kiwi' tender model – similar to that employed in New Zealand – there are also threats to pharmacists' margins for dispensing generics, and to generics prices through the statutory links between prices for brand originators and those for generics.

Talking to **Generics *bulletin*** before a press conference in Brussels today to publicise FelBelGen's arguments, Van Assche said that as far as he was aware, no generic companies – whether FelBelGen members or not – had participated in the second round of tendering for amlodipine and simvastatin that had closed in mid-January (**Generics *bulletin***, 12 January 2007, page 11).

Companies had been no clearer about the legal conditions of the tender scheme, he said, and the minister had compounded the confusion by stating that two unnamed companies would participate in the scheme although they had not been included last September in the original tender list. Moreover, a civil court in Brussels had confirmed there was a total lack of transparency surrounding the proposed legal framework.

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Annual Results

Exports keep Richter on growth track

A 28.2% increase to US$643 million in total export sales during 2006 more than compensated for the double-digit decline Hungary's Gedeon Richter suffered in its domestic market due to government cost-cutting policies and the end of a distribution deal.

The strongest export growth was in the Commonwealth of Independent States (CIS), where Russian sales rose by 38.6% to US$218 million. The European Union excluding Hungary contributed US$176 million, a rise of 20.7%. US sales climbed by 26.6% to US$88.5 million, largely due to supplying active pharmaceutical ingredients (APIs) for Barr's contraceptives. Turnover of US$80.0 million from other markets included sales up almost a fifth to US$16.8 million in Romania.

In its home market, Gedeon Richter lost around HuF2.8 billion (US$13.3 million) in sales from stopping distribution of Wyeth's OTC range, while price cuts from 1 July last year wiped off more than HuF1 billion.

Pricing & Reimbursement

Slovakia's GENAS combats price cuts

The viability of the generics industry in the Slovak Republic will be cast into doubt if the country's health minister persists with plans for price cuts of 5%-7% for all drugs, according to Christian Wieser, chairman of the Slovak Generics Association GENAS.

Wieser insisted that further price reductions after three years of cuts every quarter would mean generics firms would struggle to maintain the salesforces they needed to persuade doctors to prescribe their branded generics. The quarterly cuts, he pointed out, had reduced the price per defined daily dose (DDD) for risperidone from SKK180 (US$6.80) in November 2003 to less than SKK20 by October 2005. This was indicative of Slovakia having some of the lowest generics prices in Europe.

However, following a recent GENAS press conference that gathered widespread media coverage, health minister Ivan Valentovic has signalled that he may be ready to reconsider. Valentovic told a state broadcaster that he would discuss a compromise with those manufacturers that could prove they had cut their prices noticeably over the past year.

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Antidepressants

Sertraline floods US market

Almost 20 companies can now market sertraline hydrochloride tablets in the US after the 180-day market exclusivity granted to Teva Pharmaceutical Industries expired earlier this week. Among the firms announcing immediate launches of 25mg, 50mg and 100mg tablets following approvals on 6 February were Actavis, Lupin, Mylan, Barr's Pliva, Ranbaxy and Roxane.

Teva had obtained final approval for sertraline tablets equivalent to Pfizer's US$3 billion antidepressant Zoloft at the end of June last year, but it did not launch until mid-August, triggering the 180-day exclusivity period (**Generics *bulletin***, 18 August 2006, page 21). Pfizer reacted by marketing an 'authorised generic' through its Greenstone subsidiary.

Many of the new market entrants are among the firms that Teva is suing for alleged infringement of four sertraline process patents (**Generics *bulletin***, 2 February 2007, page 17).

Pricing & Reimbursement

Spanish firms will maintain supplies

Members of Spain's generics industry association, Aeseg, have pledged to ensure adequate supplies throughout the country, even though they face major difficulties once a new reference-price system comes into effect from 1 March this year.

"Historically generic medicines manufacturers have shown their ability to adapt to market conditions," Aeseg pointed out, stressing that there was no chance of supply shortages for generic drugs.

The reference-price system formed part of a medicines law that was passed last year (**Generics *bulletin***, 14 July 2006, page 7). All drugs that have been reimbursed for at least 10 years – or 11 years if they have gained a new indication – will be placed into a reference-price group of products with the same active ingredient and delivery form.

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Regulatory Affairs

BGMA makes sure leaflets are consistent

British patients who are dispensed the same generic product, but from a different manufacturer, will receive a similar patient information leaflet in future, thanks to a new scheme introduced by the British Generic Manufacturers Association (BGMA).

The scheme has been introduced in response to Europe's new requirement for user testing of patient information leaflets, which has the potential to produce different leaflets for the same generic medicine, depending on the test results.

All manufacturers of generic products supplied in the UK will be able to participate in the scheme, which will allow companies access to a library of user-tested patient information leaflets. These can be used both for the same generic medicine in their applications to the Medicines and Healthcare products Regulatory Agency (MHRA), and in a 'bridging' capacity for "closely-related" products.

Pricing & Reimbursement

German fund agrees generics tender

A leading statutory health insurance fund covering 25 million Germans – almost a third of the population – has for the first time negotiated purchasing discounts for generics drugs. The tender contracts with 11 undisclosed generics firms cover 43 active ingredients such as omeprazole, or combinations of ingredients, with prices up to 37% below current pharmacy retail prices.

The AOK fund estimated its savings through the agreements with "smaller generics firms" at "double-digit millions" of euros. A spokesperson for the fund declined to give a more precise figure, but said that the AOK planned to tender for more ingredients. The fund had initially sought offers for 89 active ingredients.

But Germany's leading generics players – through their industry association, Pro Generika – have accused the AOK of unsettling doctors, pharmacists and patients. Only the fund's finances would benefit, Pro Generika argued, adding that the AOK had failed to offer any incentives to potential partners, such as guaranteed volumes.