

Pricing & Reimbursement

Ratiopharm dominates AOK awards

Ratiopharm has captured almost half of all supply contracts for 76 molecules that have so far been awarded by the major German statutory health insurance fund, the AOK. The two-year supply contracts will begin on 1 April this year.

The German generics specialist – comprising the Ratiopharm, CT and AbZ labels – secured nationwide awards to supply 33 ingredients, and has also won contracts for the proton-pump inhibitor lansoprazole in four of the five German regions into which the tender has been split. The AOK has yet to award a contract for lansoprazole in the fifth region.

Furthermore, Ratiopharm has split the contract for sulpiride with its main German rival, Sandoz. Ratiopharm will supply the schizophrenia drug in three of the five regions, while Sandoz – through its 1A Pharma affiliate – is the AOK's exclusive partner in the other two regions.

Sandoz and 1A also divided the supply contract for calcipotriol, winning in one region while the originator, Leo Pharma, took the other four regions. For all other molecules, the same bidder won in all five regions, even though splitting the contracts into these regions had been intended to ensure a diversity of suppliers.

Excluding the split awards, Sandoz and 1A secured 11 supply contracts, while Torrent's Heumann captured five. Teva – including its Gry affiliate – won four molecules, while Mylan Dura and Winthrop/Sanofi each captured three. A dozen bidders won a supply contract for a single ingredient.

The AOK had initially launched a tender process for 87 molecules with an annual turnover of €1.4 billion (US\$2.0 billion) in August last year (*Generics bulletin*, 4 September 2009, page 18). However, the original 1 January 2010 starting date was pushed back by three months (*Generics bulletin*, 13 November 2009, page 13).

For seven of the 87 molecules, the fund said it had not received any appropriate bids, while a handful of awards were being held up by legal disputes. Whereas the AOK had initially forecasted a total saving of €800 million over the contracts' two-year term, it has now revised that down to about €300 million per year. **G**

Mergers & Acquisitions

Teva takes control of Japan's Taisho

Teva has acquired a majority stake in Japanese generics player Taisho Pharmaceutical Industries through its local Teva-Towa Pharma joint venture. A definitive agreement saw Teva-Towa obtain at least 66.7% of Taisho's outstanding shares for an undisclosed fee.

Privately-owned Taisho manufactures a portfolio of 120 generic molecules in more than 200 presentations which it markets to pharmacies, clinics, hospitals and wholesalers through a well-established sales and marketing force. The Japanese firm expanded its finished-dosage manufacturing facility in 2006, a year after it built a research and development centre.

Taisho – which is separate from Japan's leading OTC player of a similar name – has annual revenues of around ¥12 billion (US\$130 million) and employs almost 400 people. According to Teva, it is Japan's seventh-largest generics manufacturer.

Commenting on the transaction, Teva's president and chief executive officer Shlomo Yanai said it would “serve as a springboard for Teva-Kowa's operations in Japan”. “Taisho will bring invaluable local expertise and know-how to support our growth plan in Japan,” he insisted. Teva created a joint venture with Japanese pharmaceuticals firm Kowa in September 2008, with each party taking a 50% stake (*Generics bulletin*, 3 October 2008, page 1). **G**

Antivirals

Actavis launches valaciclovir in Europe

Actavis has launched the antiviral agent valaciclovir upon patent expiry in several of Europe's major markets on 20 and 21 December. The Icelandic firm introduced equivalents to GlaxoSmithKline's Valtrex and Zelitrex herpes treatments under its own label in France, Norway and the UK, while its Medis unit is also supplying third-party customers in France as well as in Italy. **G**

Biogenerics

US industry slams Senate bill

Healthcare reform legislation passed by the US Senate on Christmas Eve “amounts to a treasure trove for brand drug companies”, according to Kathleen Jaeger, president and chief executive officer of the US Generic Pharmaceutical Association (GPhA). “This bill is a missed opportunity to expand access to affordable medicine while also reducing drug costs,” she argued.

Senators voted along party lines by 60 to 39 votes on 24 December in favour of a wide-ranging bill that includes a regulatory pathway for bio-similar drugs. As with the House of Representatives bill that was narrowly passed some weeks earlier (*Generics bulletin*, 13 November 2009, page 13), original biotech drugs will be eligible for 12 years of market exclusivity – including four years of data exclusivity – plus another six months as a reward for paediatric trials.

The first biosimilar that is deemed to be interchangeable with a reference product will qualify for one year of market exclusivity.

The GPhA had called for the biosimilars provisions to be dropped from the healthcare reform package, but the Senate voted to debate the bill comprising more than 2,000 pages that is known as the ‘Patient Protection and Affordable Care Act’ (*Generics bulletin*, 27 November 2009, page 13). **G**

Mergers & Acquisitions

Zydus grabs all of Simayla

Zydus Cadila has acquired the outstanding 30% stake in South Africa’s Simayla Pharmaceuticals from the latter’s co-promoters, who include the firm’s founder, Ben Classen. The Indian company had bought a 70% stake in Simayla 18 months ago (*Generics bulletin*, 19 June 2008, page 3). **G**

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Manufacturing

Ranbaxy's Ohm gets warning letter

Ranbaxy Laboratories is in further trouble with the US Food and Drug Administration (FDA) after the agency issued a warning letter regarding the Indian group's Ohm Laboratories liquids manufacturing facility in Gloversville, New York. Inspections at the site conducted in July and August last year discovered violations of good manufacturing practice (GMP).

In a statement, Ranbaxy noted that the Gloversville plant was one of three manufacturing sites Ohm had in the US. Ohm's two other plants had passed inspections during 2009, the firm said, adding that most of the private-label OTC products made by Ohm were supplied from the two approved sites. The company recently launched valaciclovir tablets from Ohm's facility in New Brunswick, New Jersey (**Generics bulletin**, 11 December 2009, page 13).

Ohm has enlisted consultants PRTM to advise on the issues identified by the FDA.

In 2008, the FDA identified GMP deficiencies at Ranbaxy's Indian facilities in Dewas and Paonta Sahib, which resulted in an import alert (**Generics bulletin**, 3 October 2008, page 5). **G**

Management Reshuffles

Korea's Hanmi changes top man

South Korean generics player Hanmi Pharmaceuticals has promoted Sun-Min Lim to the position of chief executive officer. He replaces An-Soo Jang, whose term of office ended on 31 December 2009.

Gwan-Sun Lee has stepped up to head of research and development and global business. Like Lim, Lee also holds the title of president. **G**

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Generic Substitution

UK explores generic substitution

Three possibilities have been proposed by the UK's Department of Health (DoH) as it explores whether it should introduce generic substitution for the first time.

The possibility favoured by the British Generic Manufacturers Association (BGMA) is the use of a positive list of branded medicines for which pharmacists would be allowed to dispense the equivalent generic product.

The other two alternatives proposed in a public consultation announced by the DoH today are introducing a negative list of branded medicines which may not be substituted and maintaining the current ban on generic substitution.

Overriding the two options for introducing substitution would be the possibility for prescribers to refuse substitution "where they do not think it appropriate". "Patients can continue to receive a specific manufacturer's product when their treating clinician judges that this is necessary to meet clinical need," the DoH said in a statement.

However, health minister Mike O'Brien made clear that: "Where clinically appropriate, it is only sensible to allow more expensive branded products to be substituted with the same generic medicines which are just as effective as the branded version."

BGMA director Warwick Smith said a positive substitution list offered the "perfect balance" between maximum value and "the unfounded fears expressed by a number of stakeholders". Noting that generic prescribing had already reached 83% penetration in the UK, he said: "The vast majority of generics are interchangeable, and [there are] specific arrangements to cater for the few that are not. For patients to receive the branded versions of these products achieves nothing but to waste scarce National Health Service (NHS) resources."

The 12-week consultation period for the DoH to receive views from the public, patients, the NHS and stakeholders will close on 30 March 2010. **G**

Cholesterol-Lowering Drugs

Mylan expects sole Vytorin exclusivity

Mylan expects to be the sole recipient of 180-day market exclusivity for a generic version of Merck & Co's Vytorin (ezetimibe/simvastatin) cholesterol-lowering blockbuster. The generics firm has filed an abbreviated new drug application (ANDA) for tablets combining ezetimibe 10mg with simvastatin 10mg, 20mg, 40mg and 80mg.

According to Mylan, US sales of Vytorin tablets in these strengths were approximately US\$1.6 billion in the year ended September 2009.

Merck & Co responded to Mylan's ANDA submission by filing parallel patent-infringement lawsuits in district courts in New Jersey and West Virginia. They allege infringement of US ezetimibe patent RE37,721 and the combination patent 5,846,966, which expire on 25 April 2017 and 21 March 2014 respectively, each after a six-month period of paediatric exclusivity. **G**

Joint Ventures

Ranbaxy pulls out of Chinese venture

Ranbaxy has transferred its entire shareholding in a Chinese joint-venture operation to a state-owned firm. The Indian company made no comment on the commercial aspects of the transfer, but remarked that it now wanted to focus its Chinese endeavours on marketing value-added pharmaceutical formulations and consolidating its manufacturing operations.

Ranbaxy (Guangzhou China) had been a joint venture between Ranbaxy, Guangzhou Baiyunshan Pharmaceutical and Hong Kong New Chemic. Ranbaxy's entire shareholding is now held by HNG Chembio Pharmacy, which is part of the state-owned Hunan Nonferrous Metals Holding Group.

Ranbaxy noted HNG was in the pharmaceutical ingredients business as well as in distributing drug products. It said the transaction would give HNG entry into pharmaceutical dosage forms "in which HNG plans substantial further investments in the near future". **G**