



News on Generics

1) US drug company **Par Pharma** has released a generic version of *Provigil*. The treatment aims to make patients suffering from sleeping disorders such as narcolepsy and obstructive sleep apnoea feel more alert and awake. Par Pharma secured the generic rights to the drug, originally developed by **Cephalon**, in the US in 2011.

2) US pharmaceuticals company **Akorn** plans to release a generic drug based on US healthcare giant **ViroPharma's Vancocin**. The treatment is intended to reduce clostridium difficile-associated diarrhoea. Akorn is based in New Jersey and is also established in the Indian market.

3) Finnish healthcare company **Orion** has issued a statement relating to **Mylan Pharmaceutical's** decision to file an abbreviated new drug application (ANDA) to release a generic drug based on Orion's patented drug *Stavelo* in the US. Orion said it does not believe that generic competition will be imminent. The ANDA has been sent to the US Food and Drug agency.

4) US pharmaceuticals company **Mylan** will release a generic version of *Boniva* (ibandronate sodium) tablets. Its pharmaceuticals unit secured approval from the US Food and Drug Administration for the product, which is intended to treat postmenopausal females who have, or at risk from, osteoporosis.

5) Indian pharmaceutical company **Dr Reddy's Laboratories** has launched ziprasidone hydrochloride capsules, a generic version of *Geodon*, an atypical antipsychotic developed by US pharmaceutical company **Pfizer**, in the US. The capsules are available in 20mg, 40mg, 60mg and 80mg strengths in 60-count bottle size

6) The US Food and Drug Administration has said seven lots of birth control pills have been withdrawn from the market by **Glenmark Generics Inc USA**. The recall follows a packaging error that would make the pills ineffective and leave women without sufficient contraception,

putting women at risk for unintended pregnancy. **Glenmark Generics Ltd India** produced and packaged the packets of generic norgestimate + ethinyl estradiol tablets. The distribution of the tablets to wholesalers and retail pharmacies across the US occurred between September 21 2011 and December 30 2011.

7) Canadian generic pharmaceutical company **Apotex** has paid US\$422,209,362 to **Sanofi** and **Bristol-Myers Squibb** (BMS) in damages related to the Plavix (clopidogrel bisulphate) patent infringement case. The payment, which is in accordance with a decision the US court of appeals for the federal circuit made in October 2011, is the final stage of the Plavixpatent litigation between the companies, which started on March 21 2002. Sanofi and BMS were also awarded US\$1,258,682 in post-judgement interest and US\$900,000 in costs, on top of the damages.

8) US specialty and generic pharmaceutical company **Mylan** has released levetiracetam in sodium chloride injection for intravenous use. The new product, which has already gained US Food and Drug Administration approval, is the first time multiple strengths of premixed levetiracetam have been available in ready-to-use bags of sodium chloride injection. The product is an antiepileptic drug to treat particular types of seizures

9) News: Commercial production of the first locally manufactured antiretroviral treatments in Tanzania will begin in the next few months, with a goal that the country will eventually produce enough drugs for half of all Tanzanians with HIV, reports All Africa. A pharmaceutical facility has been constructed near Arusha, in the north of Tanzania, using a US\$6.6mn grant from the EU, US\$963,000 from **Tanzania Pharmaceuticals Industry** (in which the governments holds a 40% stake) and US\$660,000 from German medical aid organisation Action Medeor. The HIV prevalence in Tanzania is roughly 5%, but HIV levels are as high as 15% in certain areas in the south, and, according to data from 2010, only 21.5% of HIV-infected Tanzanians had access to treatment.

Industry Brief - Supreme Court Rules In Favour Of Generic Drugmakers

News: A ruling by the US supreme court will allow generic drug manufacturers to challenge attempts from pharmaceutical firms to extend the remit of existing patent descriptions. The

ruling overrides a decision by the court of appeals in 2010. It follows **Novo Nordisk's** efforts to amend the phrasing of a patent covering its *Prandin* drug.

Company Brief - Par Pharma Launches Generic Provigil

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Finnish healthcare company Orion has issued a statement relating to **Mylan Pharmaceutical's** decision to file an abbreviated new drug application (ANDA) to release a generic drug based on Orion's patented drug Stavelo in the US. Orion said it does not believe that generic competition will be imminent. The ANDA has been sent to the US Food and Drug agency.

Actavis has released a generic version of **AstraZeneca's** anti-psychotic drug Seroquel (quetiapine) in Europe. The company launched quetiapine after AstraZeneca lost patent protection on its drug in Denmark, the UK, Germany, Italy, Ireland, the Netherlands and Romania. It has also released its generic drug in Sweden. Quetiapine is indicated for the treatment of schizophrenia and depressive and bipolar disorders.