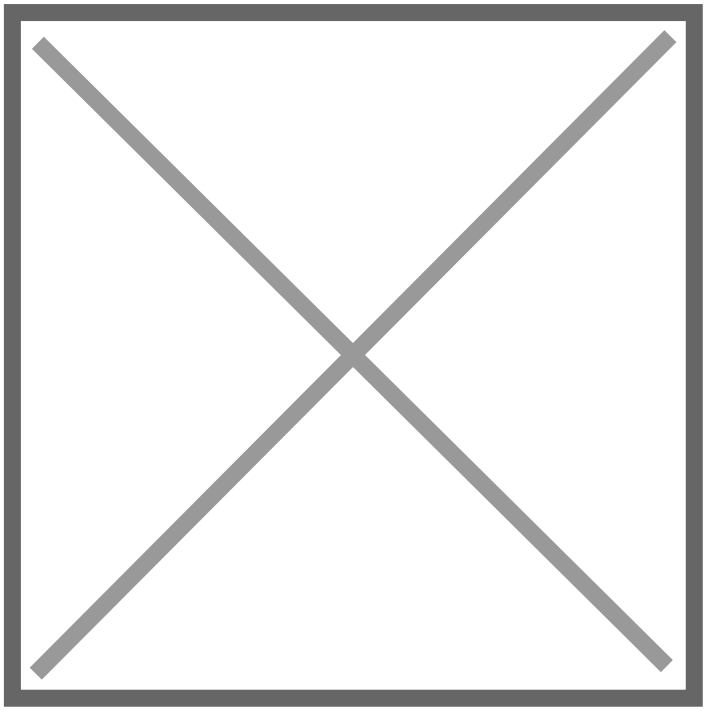
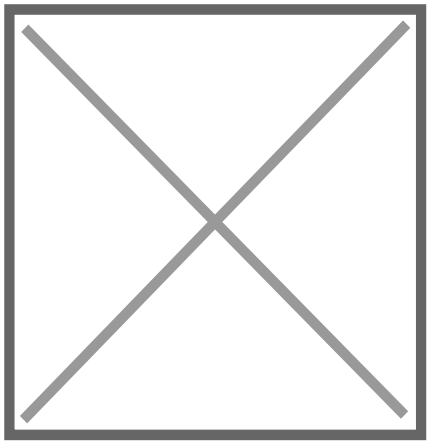


Pharma Round-up

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Dr Reddy's is first participant in USP's ingredient verification program

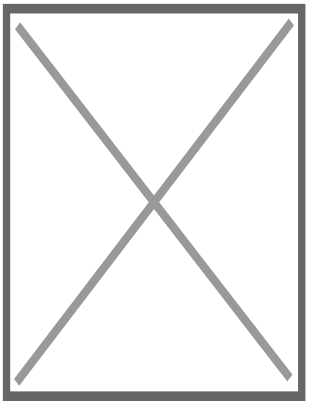


The United States Pharmacopeia (USP) has announced that Dr Reddy's Laboratories has signed on as the first participant in USP's pharmaceutical ingredient verification program. "Participating in this program shows that Dr Reddy's Laboratories shares USP's commitment to good pharmaceutical care throughout the world," said Dr Roger Williams, chief executive officer and executive vice president of USP. "We look forward to participating in this program so that we can show manufacturers, regulatory authorities and consumers our dedication to producing pharmaceutical ingredients and excipients that are of consistently high quality," said Satish Reddy, chief operating officer and managing director of Dr Reddy's Laboratories.

USP created the pharmaceutical ingredient verification program in response to increasing concerns throughout the pharmaceutical industry about the quality and consistency of pharmaceutical ingredients. The program enables manufacturers to show the quality and integrity of their ingredients with a recognizable "USP Verified" mark. As a participant in the pharmaceutical ingredient verification program, Dr Reddy's will submit ingredients to USP's verification process, which includes evaluation of an ingredient manufacturer's quality systems through an audit for compliance with Good Manufacturing Practices (GMPs); Review of manufacturing and quality control documents for the ingredients; Laboratory testing of ingredient samples from USP-selected lots for compliance with USP's FDA-enforceable standards for purity, potency and quality; And post-verification surveillance testing of ingredients bearing the USP Verified mark Once each ingredient or excipient passes the verification process, Dr Reddy's will receive a Certificate of Standards Compliance. They will then be permitted to post the "USP Verified" mark on the shipping container, and certificate of analysis demonstrating that it meets USP's world class

quality standards.

Zydus Cadila acquires Nippon Universal in Japan



Ahmedabad-based Zydus Cadila, having a turnover of over Rs 1,800 crore, has acquired 100 percent stake in Nippon Universal Pharmaceutical, a privately held company headquartered in Tokyo, Japan. This marks Zydus Cadila's second overseas acquisition, the first being Alpharma France in 2003.

The acquisition will strengthen its presence in Japan. It is expected to provide critical access to a ready manufacturing and marketing base. Nippon reaches out countrywide to more than 4000 hospitals and clinics. The generics market in Japan is valued at $3 billion has a tremendous growth potential as it currently stands at just five percent of the total pharma market in Japan in value terms and 17 percent by volume.

Zydus which set up Zydus Pharma Inc in 2006 to spearhead its foray in the generics market of Japan, will now be able to jumpstart its operations. Zydus will be looking to leverage Nippon's strong relationship with key wholesalers, which spans over three decades.

Pankaj R Patel, chairman and managing director, said, "We had announced our intentions of being a long term player in this market when we set up our subsidiary last year. Going forward, I believe this acquisition will unlock value for us as generic market in Japan is just opening up and post 2010 we expect this market to be a major growth driver for our global business.

Glenmark to acquire Medicamenta

Glenmark Holdings SA, a wholly owned Swiss Subsidiary of Glenmark Pharmaceuticals Ltd (India) (Glenmark), has concluded a deal to acquire a majority shareholding (>90 percent) of the company Medicamenta, giving Glenmark its first commercial foothold into the strategically important market of Europe. Under the Czech Law, a holding of more than 90 percent shares in a company will trigger a mandatory takeover bid for the remaining shares.

Glenmark's acquisition of Medicamenta, which has sales and marketing operations in both the Czech Republic and Slovakia, is for an undisclosed consideration. This acquisition provides Glenmark with a strategic entry point into two of the fastest-growing and attractive markets in Europe.

Medicamenta's projected revenues for the calendar year 2007 are $ 8 million. Medicamenta has 60 employees and brings along a basket of 29 solid dose and semi-solid products. These products are manufactured at its plant in Vysoke Myto, Czech Republic that spreads over 13,000 sm and is approved by the Czech Regulatory Agency (SUKL). Glenmark plans to make use of Medicamenta's plant capacity to support its broader operations, by providing additional manufacturing, packaging, quality release and warehousing for its European business.

Glenn Saldanha, managing director and CEO, Glenmark, commented, "The purchase of Medicamenta is another part of our long-term strategy to emerge as a speciality/brand company marketing novel drugs, by acquiring front-ends in key branded generics markets. Glenmark was advised by Nomura International plc, the European arm of the Japan based global investment bank, on the acquisition of Medicamenta.

Ranbaxy launches Osovair for treatment of asthma

Ranbaxy Laboratories has launched Osovair (Formoterol + Ciclesonide) inhalation capsules in a branded segment in India for treatment of asthma. This unique combination has been launched for the first time in the world combining the fastest acting Long Acting Beta 2 Agonist Formoterol and the new inhaled corticosteroid Ciclesonide. Osovair is available in rheocaps as Osovair 160 mcg, Osovair 320 mcg, depending on the severity of asthma patients.

Orchid to foray into Canadian generic formulations market

Orchid Chemicals & Pharmaceuticals has received a formal approval from the Canadian TPD (Therapeutic Product Directorate) for two of its ANDS (Abbreviated New Drug Submission) applications. These approvals correspond to two generic formulations, Cefoxitin and Ceftriaxone. These products are covered under the exclusive marketing arrangement that the company has with the leading Canadian generics major, Apotex.

Commenting on this development, K Raghavendra Rao, managing director, Orchid Chemicals & Pharmaceuticals, said, We are happy to foray into the Canadian generic segment with these approvals. With limited competition and a niche injectable product offering, we are confident of a sustainable revenue base from Canada. Given the track record of Apotex in garnering a major market share in the generic antibiotic injectable market in the US, we are optimistic that they would be able to replicate the same in the Canadian market too.

Going forward, Orchid would be enhancing its market presence further in Canada by launching other generic formulations in the cephalosporin and other product segments based on specific product filings and approvals.

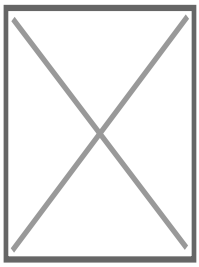
Lupin receives Ã¢â??Â¬20 m for patent sale

Lupin has received Ã¢â??Â¬20 million from Laboratoires Servier of France for the sale of certain patent applications and other related intellectual property for Perindopril for multiple countries.

Dr Kamal Sharma, managing director, Lupin, said, "The income from this sale significantly boosts our performance for the previous quarter. It obviously goes a long way to demonstrate our research and IP capabilities.

Lupin, a leading pharmaceutical company with strong research focus, has a program for developing New Chemical Entities (NCEs) with a state-of-the-art R&D center in Pune. It has significant presence in anti-TB, cephalosporins (anti-infectives) and cardiovascular drugs (prils and statins) and has a notable presence in the areas of diabetology, NSAIDS and asthma.

WHO move to include PCV in NIP lauded



Wyeth Pharmaceuticals, a division of Wyeth, has welcomed the World Health Organization's (WHO) decision to support the inclusion of pneumococcal conjugate vaccine (PCV) in national immunization programs worldwide. In view of the demonstrated vaccine efficacy and high disease burden, WHO notes that PCV can help substantially reduce mortality and morbidity. Pneumococcal disease is a significant concern to children's health, estimated by WHO to result in up to one million deaths each year in young children around the world.

Bernard Poussot, president, chief operating officer and vice chairman, Wyeth said, "Reducing the burden of pneumococcal disease is a vital step toward achieving the United Nations' Millennium Development Goal of reducing child mortality by two-thirds by 2015. Broad adoption of the WHO position has the potential to save millions of children's lives around the world. Wyeth is dedicated to doing its part, in collaboration with the GAVI Alliance, other international agencies and local governments, to bring Prevenar (Pneumococcal Saccharide Conjugated Vaccine, Adsorbed) to the world's most vulnerable populations through an affordable and sustainable plan that is reflective of global economic and market conditions.

Wyeth recently applied to WHO for pre-qualification status for Prevenar. If accepted, this status will enable international agencies to include the vaccine in mass immunization programs in the world's least developed countries. The pre-qualification process is expected to be completed by early 2008. In addition, Wyeth is developing a 13-valent pneumococcal conjugate vaccine that targets additional serotypes. This investigational vaccine currently is undergoing clinical development and potentially would offer broader coverage against pneumococcal disease for both infants and adults.

ISP Investco picks up 14.9 percent stake in Granules India

Granules India, a pharmaceutical formulation intermediates company with complete vertical integration, announced the issue of 22.11 lakh equity shares of Rs 10 each, fully paid-up at Rs 105.50 per share (including premium), to ISP Investco LLC., on a preferential basis, subject to the approval of the shareholders of the company at an extraordinary general meeting.

New Jersey-based investment advisor ISP Investco LLC will invest around Rs 23.33 crore in the company and hold 14.9 percent stake in the company.

Recently, Granule's Board of Directors approved the allotment of 14.9 per cent stake to US- based private equity firm Ridgeback Capital Investment LLC. The company also recently entered into an outsourcing agreement with Matchland Pty Ltd of Australia.

Granules India posted 13 percent rise in net turnover at Rs 50.21 crore for the second quarter ended December 31, 2006, compared to Rs 44.44 crore in the corresponding quarter in 2005.

Granules India manufactures several strategic Active Pharmaceutical Ingredients (APIs) and multiple Pharmaceutical Formulation Intermediates (PFIs), which are distributed in 35 countries. It is foraying into manufacturing of tablets with a capacity of six billion tablets per annum. This facility will strengthen its presence in the pharma outsourcing space as it will have capabilities of offering a wide range of products beginning from APIs to finished dosages (coated/uncoated).