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Cryo-Save India gets AABB accreditation

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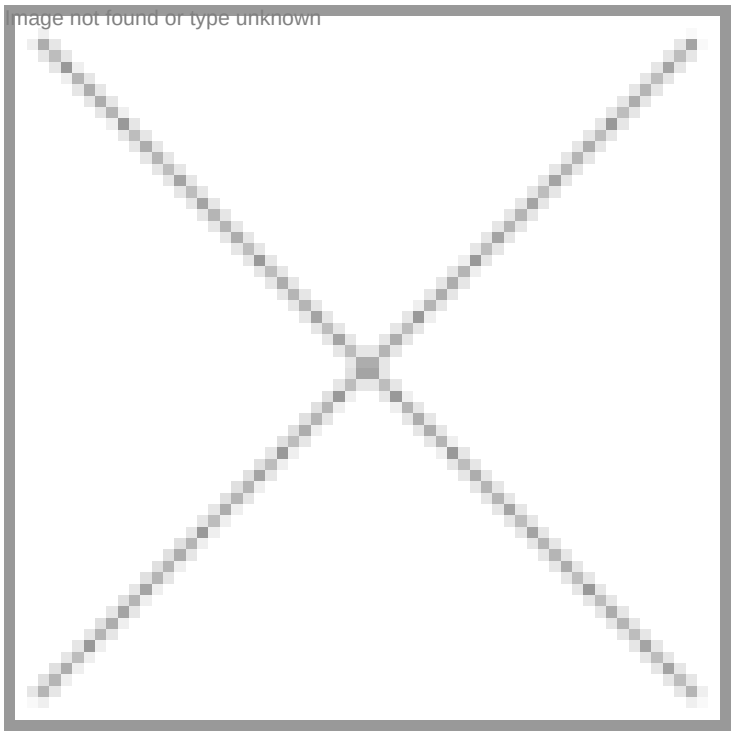

Cryo-Save India has received the prestigious American Association of Blood Banks (AABB) accreditation. The AABB accreditation follows an intensive on-site assessment by specially trained AABB assessors and establishes that the level of technical and administrative performance within the facility meets or exceeds the standards set by the AABB.

It qualifies the viability of the sample processed and stored at the Cryo-Save lab to be used in a transplant any time in the future. The AABB is an international non-profit body dedicated to developing the highest standards in blood and cord blood banking, transfusion medicine and cellular therapy.

Napo secures dismissal of legal action

In a new development in the Napo-Salix crofelemer legal issue, Napo Pharmaceuticals won a legal dispute with Salix Pharmaceuticals in which Salix had sought access to Napo's financial books and records. Napo had argued the action was completely without merit.

The motion to dismiss seeks a dismissal of Salix's own lawsuit with prejudice and, therefore, will bar Salix from pursuing the same claims in the future against Napo.

Napo also filed an amended law suit against Salix, which is pending in the Supreme Court of the state of New York. The complaint claims Salix breached its contract with Napo and seeks damages for the alleged failure of Salix to use â€œcommercially reasonable efforts to develop and commercialize crofelemerâ€?, a first-in-class novel drug compound.

The lawsuit seeks tens of millions of dollars in damages. On November 4, 2011, Napo terminated its collaborationagreement

with Salix to commercially develop crofelemer. The compound is a treatment for diarrhea, a life-threatening ailment, which impacts millions of people across the world.

Span MD gets ET NOW-IndiaMART award

Mr Veeral Desai, managing director, Span Diagnostics, recently received the 'ET NOW IndiaMART Leaders of Tomorrow' award in Mumbai.

Mr N R Narayana Murthy, chairman emeritus, Infosys Technologies, presented the award to the winner under pharmaceuticals and medical category and appreciated his contribution to fortify the MSME ecosystem with relentless efforts and creativity.

Mr Veeral Desai said he believed in strategic management processes that revolve around the main focus of the company, including innovation and creativity. The company develops and manufactures a comprehensive range of indigenous ready-made diagnostic products that are needed by various segments of healthcare.

CPL Biological facility in 4 months

CPL Biologicals, a joint venture between Novovax and Cadila Pharmaceuticals, has begun construction of a state-of-the-art manufacturing facility that will be used to produce pandemic and seasonal influenza vaccines.

The CPL Biologicals facility is expected to be operational within four months and should be capable of producing over 60 million doses annually at full capacity.

Novavax retains rights to products developed for markets outside India. CPL also expects to develop the pandemic H1N1 influenza vaccine candidate in India that Novavax is developing in the US.

Microbix, Zydus enter deal

Microbix Biosystems and Zydus Cadila have signed a letter of intent to market the thrombolytic drug, Urokinase, in the North American markets. The anticipated timeline for approval is late 2014. Microbix will receive a milestone payment upon reaching a certain sales target, will get a margin and also earn a royalty fee based on sales. Zydus will receive an option on the rights to all future indications, including in the areas of oncology and ophthalmology.

The estimated market size for Urokinase use in the US is expected to touch $400 million by 2020 between three indications, pulmonary embolism, catheter clearance and catheter prophylaxis. Zydus Pharmaceuticals US is ranked 12th among the top generic companies in the US.

Barcoding to reduce counterfeit drugs

Close on the heels of the Drugs Controller General India's (DCGI) notification on mandatory barcoding for export of pharmaceutical products, Activecubes, an analytics driven company, will soon introduce a service to pharmaceutical companies to enable them and the consumer to differentiate counterfeit drugs from authentic ones. It has been estimated that up to 30 percent of the drugs sold in the domestic market could be spurious. Furthermore, the counterfeit drug market said to be more than $75 billion worldwide. This not only presents a significant health hazard but also spells a major revenue loss to pharma companies, not to mention the hit that the brand takes.

Mr Rajesh Varrier, founder and CEO of Activecubes, said, â€œWe have developed a proprietary platform to generate a unique identification number at the strip or vial of the drug. On purchasing the drug, the end user can send an SMS of that unique number to a telephone number specified on the pack. The user would then be informed immediately if the drug purchased was genuine or not.â€?

Conservative estimates state that there are over 700 million mobile users in India, which makes this solution accessible to a large population in our country. In addition to the unique identification number, Actrivecubes also hopes to make use of QR codes, which can be read by mobile applications in advanced phones in the future.

Bharat Biotech's vaccine supply suspended

As a part of the evaluation of new pre-qualification applications of two vaccines types, the World Health Organization (WHO) after conducting a site audit in September 2011 at the Bharat Biotech production plant in Hyderabad, found deficiencies in the implementation of good manufacturing practices and in the quality management system of the company.

The observations had potential implications beyond the directly audited products for the hepatitis B vaccine (Revac-B+) and three formulations of oral polio vaccines (OPV) that are already on the list of vaccines prequalified by WHO for supply to countries through UN procurement.

As the manufacturing locations for the currently pre-qualified products hepatitis B and OPV vaccines were not audited in September 2011, the WHO has been requested by the ad hoc expert committee to conduct another site audit before making a final decision on all these products.

In the interim, the WHO has suspended supply of hepatitis B vaccine from the company through United Nations (UN) procuring agencies. The WHO has not recommended recall of Revac-B+ already distributed, since the suspension is precautionary. For OPV, Bharat products remain pre-qualified, as a risk-benefit assessment by the WHO took into account that the vaccine bulks are supplied by another prequalified manufacturer for formulation and filling by Bharat and that the vaccine is administered by the oral route.

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mAb trial: Biocon gets positive results

Biocon announced positive results from its double blind, placebo-controlled, phase III, TREAT-PLAQ study with Itolizumab in chronic plaque psoriasis. Itolizumab, the first humanized anti CD-6 monoclonal antibody, successfully met the pre-specified primary endpoint of significant improvement in Psoriasis Area and Severity Index (PASI-75) score after 12 weeks of treatment in patients with moderate to severe psoriasis compared to placebo.

It also met multiple secondary endpoints after 12 and 28 weeks of treatment. This 52-week study conducted in India had a12-week placebo controlled phase, 16-week consolidation and 24-week randomized withdrawal phase. It enrolled over 200 patients across placebo and two active treatment regimens.

Stemade to expand services in Asia

Stemade, a pioneer player in dental stem cell banking, is looking to offer its services in other countries in the Asia Pacific region, including Australia and Singapore.

The technology for extracting pluripotent mesenchymal stem cells was sourced from the Institute Clinident Biopharma, a French company. It allows people to store their stem cells obtained from their extracted teeth, which would have been discarded otherwise. With over 100 collection centers across India and one opened in Chandigrah recently, Stemade hopes to offer the technology to the masses.

This patent has been licensed for the Middle East and Asia Pacific.

Plan to increase thyroid awareness

Abbott and the Indian Thyroid Society have announced a commitment to improve thyroid disease awareness in women in India with the 'Make a Difference to Life - Think Thyroid, Think Life' program. Actor Ms Juhi Chawla has been named ambassador for this awareness initiative.

The initiative is a first-of-its-kind in India. Since 2010, 10 lakh individuals have been screened at the diagnostic andeducation camps held in India through the program. In 2012, the effort will expand to reach out to more than 10 lakh women. It is estimated that approximately 40 million Indians suffer from thyroid related disorders, of which 60 percent are women.

India to launch supplement program

The Ministry of Health and Family Welfare, Government of India, will soon launch a weekly iron and folic supplementation program. The program, implemented across the country in both rural and urban areas will cover nearly 12 crore adolescents. The ministry has suggested to the states that a fixed day in a week be earmarked for providing tablets to adolescents.

Out of the 12.2 crore adolescents in India (according to census 2011 projected population) in the age group of 15 to 19years,

approximately 5.7 crore are girls, of which 3.2 crore are anaemic. To address this, the states have been advised to project their fund requirements.

AXP gets ministry's nod in India

India's Ministry of Health has approved the AutoXpress System (AXP), a product of Thermogenesis, used for the processing of stem cells from cord blood, enabling the company to initiate commercial sales of the product in India.

Mr J Melville Engle, chairman and chief executive officer of ThermoGenesis, noted that the AXP approval in India comes even as the company awaits approval of the product in China. He said they were hopeful of getting regulatory approval in China in early 2012.

Plan for complete immunization

Declaring 2012 as the year of intensification of routine immunization, India has stepped up its efforts to achieve complete immunization. Under this initiative, the government has also expanded the Universal Immunization Programme by introducing second dose of measles, hepatitis B and pentavalent vaccination. With the present full immunization coverage of children being 61 percent, the target is to vaccinate more than 12 crore children through supplementary immunization activity in 14 states.

A web-enabled name-based tracking system has been put in place with a database of more than 10 million children. Parents are being sent SMS alerts before the due date of vaccination and health workers are also receiving the list of children due for vaccination through SMS.

NRHM reports released

Union Minster of Health and Family Welfare Mr Ghulam Nabi Azad released reports of the 5th Common Review Mission and the 8th Joint Review Mission of the National Rural Health Mission (NRHM) at a workshop in New Delhi.

He congratulated the NRHM team of the Centre and the states for the hard work that has led to notable improvement in the health indicators of the country. He said achievements of the NRHM have been endorsed by independent surveys. As per the latest Sample Registration Survey (SRS), country's infant mortality rate (IMR) has reduced to 47 (SRS 2010) from 58 in 2005 and maternal mortality rate declined from 254 during 2004-06 to 212 in 2007-09. In high focus states such as Orissa, Rajasthan and Bihar, the IMR has dropped by 13 or more points since 2005. Fall in rural IMR has been consistently more than urban IMR for last three years. Assam, Uttar Pradesh, Uttarakhand and Rajasthan have recorded the largest fall in maternal mortality ratio of 90, 81, 81 and 70 points respectively.

He asserted that Janani Shishu Suraksha Karyakram will provide free services to pregnant mothers and children and further reduce out-of-pocket expenditure by improving institutional delivery. He also said provision of essential drugs free-of-cost, standard treatment guidelines and basic minimum set of diagnostics at all the facilities is being planned in the 12th Plan to reduce financial stress on the poor patients.

Merck Millipore to install water purifier in schools

Merck Millipore, the life science division of Merck KGaA of Darmstadt, Germany, has selected two educational institutes in North India who will receive their new water purification system Aquelix. Jawahar Navodaya Vidyalaya, Ahmadpur, Uttar Pradesh and Government Medical College, Srinagar, were picked through a lucky draw during celebrations to mark the International Year of Chemistry 2011.

Six more such systems will be distributed to schools and colleges in Ahmedabad, Mumbai, Bangalore, Hyderabad, Kolkata and Chennai over the next three months. Merck Millipore's Lab Water division, which provides water solutions for laboratory applications, is part of the campaign commemorating IYC 2011.

Waters, Tecan sign agreement for assay platform

Waters and Tecan Group have entered into an agreement to combine Tecan's Freedom EVO liquid handling platform with Waters ACQUITY TQD liquid chromatograph-mass spectrometer to automate sample preparation. Waters will combine the technologies from both companies into a single, fully-supported analytical system solution.

The technology will help laboratories increase assay throughput and efficiency, improve profitability, and drive down overall assay costs. The firms announced the agreement at the annual Mass Spectrometry: Applications for the Clinical Laboratory meeting. Tecan is a leading global provider of laboratory instruments and solutions in biopharmaceuticals, forensics and clinical diagnostics.

Ind-Swift to promote Roche test in India

Roche Diagnostics entered into an agreement with Ind-Swift to promote its test for detecting heart attack, TROP T rapid assay, in India. Roche Diagnostics' TROP T rapid assay is a point-of-care test that can detect whether a patient is having a heart attack through a simple whole blood test.

Troponin â€“T is used to measure damage to the heart muscle and to differentiate between non-cardiac chest pain and heart attacks. The TROP T rapid assay gives a reliable qualitative result within 15 minutes. Ind-Swift will promote TROP T among cardiologists, diabectologists, consulting physicians and general practitioners all over the country with its 225-people strong field force.

â€œThis will give ISL a big chance to develop a strong presence in the cardiac field,â€? said Dr Gopal Munjal, MD & CEO, Ind-Swift Group.

TAKE announces global release of PharmaReady 5.0

TAKE Solutions, a life sciences and supply chain management company, announced the availability of PharmaReady 5.0, a web-based regulatory compliance solution suite for life sciences organizations to ensure faster approvals for their new products. The latest version introduces new document management features, and delivers technology framework upgrades to enhance scalability, response time, and ease-of-use.

PharmaReady 5.0 supports submissions to Swissmedic in addition to US FDA, Heath Canada and EMEA. It comes with an improved dashboard for easier navigation and management of documents from a centralized location, provides more visibility and control e-document or e-submission processes, and introduces new functionalities, including drag and drop for quicker document uploads. PharmaReady 5.0 includes an enhanced, highly scalable technology framework.
