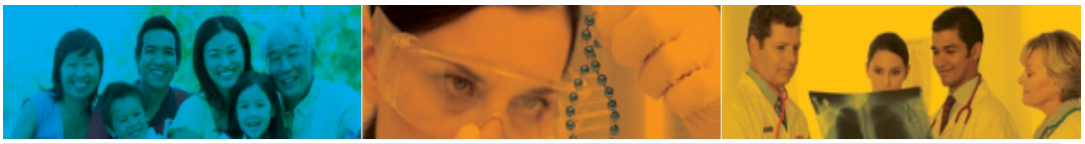

Clinical Research Update Volume - 4, April 2012

LAMBDA

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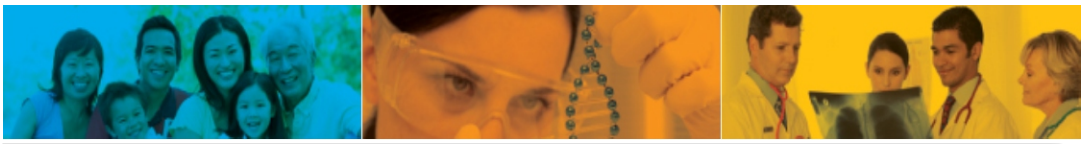


LAMBDA

GLOBAL NEWS

1.1. European Commission announced to speed up Drug Pricing and Reimbursement Decisions

March 2, 2012

- The European Commission has announced plans to speed up national drug pricing and reimbursement decisions in 120 days for innovative drugs and just 30 days for generics instead of 180 days.

1.2. Drug Makers Sued in US over "illegal" Rx Drug Coupons

March 12, 2012

- Eight drugmakers are being sued by US labour union health funds for offering their members co-pay discount cards and coupons on their prescription drugs, claiming that these constitute "an illegal kickback" and "a form of insurance fraud."
- Federal government health plans like Medicare consider these coupons kickbacks and have banned them; they are also prohibited in Massachusetts under an anti-kickback law.

1.3. Pfizer and Biocon End Insulin Biosimilar Pact

March 13, 2012

- Pfizer and India's Biocon have called off their collaboration signed 18 months ago to develop the latter's biosimilar versions of insulin. Both the firms now concentrate on their individual priorities for their respective biosimilars business.

1.4. Astra Zeneca Sues FDA in Generic Seroquel Dispute

March 13, 2012

- AstraZeneca is suing regulators in the USA in a bid to delay the entry of generic versions of its antipsychotic blockbuster Seroquel.

1.5. Survey Shows Significant Adoption of Web-based RTSM Systems by Clinical Sites

March 16, 2012

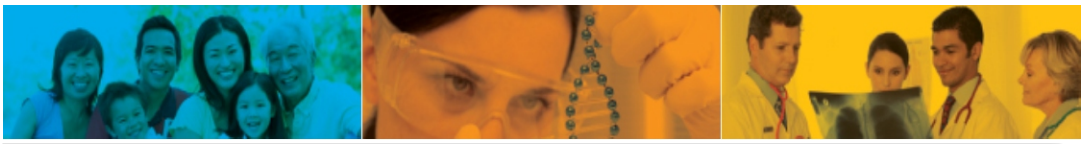
- Perceptive Informatics, an eClinical Solutions Provider, has reported results of its Randomization and Trial Supply Management (RTSM) Survey.
- The survey polled professionals at nearly 300 investigative sites across the Americas, Europe and Asia. The analysis showed that 65% of respondents worldwide use web-based RTSM systems to support clinical study execution. Results revealed a significant level of adoption of web-over voice-based versions of these technologies.

DOMESTIC NEWS

2.1. Patent Office Issues First Compulsory License to Natco to make Nexavar Drug

March 2, 2012

- The Patents Office granted compulsory license to Natco Pharma to make Nexavar Drug under section 84 (1) (b) of the Patents Act, 1970 that was against Bayer. The patented invention Nexavar by Bayer was not available to the public at a reasonably affordable price which was against the provision of Section 84 (1) (b) of the Patents Act.



- Patent office held that Bayer is found guilty of absolute neglect and delay as the company despite launching the product in the world in 2006 did not launch it in India till 2009 though the patent was granted in 2008 causing delay in the launch for no logical reason.

2.2. CSIR - OSDD Partners with TB Alliance to bring New TB Drugs to India March 24, 2012

- The Council of Scientific and Industrial Research (CSIR) announced a Memorandum of Understanding between its Open Source Drug Discovery (OSDD) initiative and the TB Alliance, an international non-profit organization which develops new, faster-acting, and affordable TB drugs to hasten the development of urgently needed new therapies for Drug-Resistant TB.

REGULATORY UPDATES

3.1. Update Of Eudralex Volume 2B - Presentation And Content Of The Dossier March 12, 2012

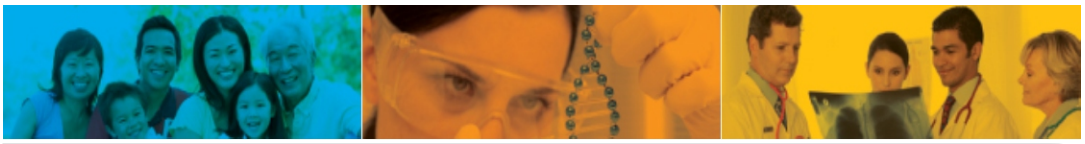
- The European Medicines Agency announced today of the possibility to submit initial marketing authorisation applications for human medicines, variations and renewal applications for human and veterinary medicines using electronic application forms.
- These forms, resulting from the collaboration of the EMA, the European Commission services and the National Competent Authorities, can be used for the centralised procedure, mutual recognition or decentralised procedures.
- Furthermore the following documents have been updated by more recent versions:
  - eCTD EU Module 1 (version 1.4, August 2009) - zip file
  - Change Control Process for European eCTD Standards - v1.1 (December 2006)
  - Change Control Form - v1.1 (December 2006)

3.2. US FDA hearing seeks input on modernising Clinical Trial Framework March 13, 2012

- The US FDA has scheduled a public hearing next month to gather views on whether and how it can do more to modernise and streamline its approach to Regulation and Good Clinical Practice (GCP) in the Clinical Research.
- The purpose of the hearing is to solicit public input from a broad group of stakeholders on the scope and direction of this effort, including encouraging the use of innovative models that may enhance the effectiveness and efficiency of the clinical trial enterprise.

3.3. FDA Issues Guidance for Benefit-Risk Determinations in Medical Device Premarket Approval March 28, 2012

- FDA has developed this guidance document to provide greater clarity for FDA reviewers and industry regarding the principal factors FDA considers when making benefit-risk determinations during the premarket review process for certain medical devices. FDA believes that the uniform application of the factors listed in this guidance document will improve the predictability, consistency, and transparency of the premarket review process.



3.4. First Generic Versions of Boniva gets US FDA Approval

March 21, 2012

- The US FDA has approved the first generic versions of Boniva (ibandronate) tablets, a once-monthly product to treat or prevent osteoporosis in women after menopause.
- Apotex Inc., Orchid Healthcare, and Mylan Pharmaceuticals Inc. are the manufacturers that have gained FDA approval to make generic 150 mg ibandronate tablets.

DRUGS IN DEVELOPMENT

4.1. HemaQuest Raises $13 mn for Phase II b study of Sickle Cell Disease

March 12, 2012

- HemaQuest Pharmaceuticals, a biotechnology company focused on developing small molecule therapeutics to treat hemoglobin disorders, has closed a $13 million extension of its Series B financing. HQK-1001 has been shown to stimulate fetal hemoglobin expression and red blood cell production in the laboratory, reducing the frequency of pain crises and hospitalizations of patients with sickle cell disease. It has received Orphan Drug designation in the U.S. and Europe for both sickle cell disease and beta thalassemia.

4.2. Provectus Reports Top-line Data in Phase II Psoriasis Study

March 19, 2012

- Provectus Pharmaceuticals, a development-stage oncology and dermatology biopharmaceutical company, reported top-line data for the company's randomized controlled trial of PH-10, a topical aqueous hydrogel, for mild-to-moderate plaque psoriasis.

4.3. BioSante Pharma's Pill-Plus gets Positive Phase II Trial Data

March 21, 2012

- BioSante Pharmaceuticals Inc. has released the data from studies of the Pill-Plus "triple component" oral contraceptive. The United States patents for oral use of the Pill-Plus are licensed by BioSante to Pantarhei Bioscience, a Netherlands-based pharmaceutical company, for development and marketing in the United States. BioSante retains rights to the Pill-Plus for transdermal development and marketing.

DRUG APPROVALS

5.1. US FDA Approves First and Only Oral Contraceptive to Treat Heavy Menstrual Bleeding

March 14, 2012

- Bayer HealthCare Pharmaceuticals Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved a new indication for Natazia® (estradiol valerate and estradiol valerate/dienogest) tablets for the treatment of heavy menstrual bleeding (HMB) that is not caused by any diagnosed conditions of the uterus (womb), in women who choose an oral contraceptive (OC) for contraception. With this approval, Natazia is the first and only oral contraceptive indicated for the treatment of HMB.

5.2. US FDA Approves First and Only Effervescent Osteoporosis Treatment in a Buffered Solution

March 14, 2012

- EffRx Pharmaceuticals SA announced that the U.S. Food and Drug Administration (FDA) has approved BINOSTO™ (alendronate sodium) Effervescent Tablets, previously known as EX101, for the treatment of osteoporosis in postmenopausal women, and as a treatment to increase bone mass in men with osteoporosis. EffRx anticipates that BINOSTO™ will be commercially available in the United States in the third quarter of 2012.

DRUG RECALLS

6.1. Shire Withdraws Replagal in USA as FDA wants More Trials

March 15, 2012

- Shire has withdrawn its Biologics License Application for Replagal (agalsidase alfa) with the US Food and Drug Administration to get approval for its Fabry disease . Shire says that recent interactions with the latter led the company to believe that the agency will require additional controlled trials for approval of the drug in the USA market.

6.2. Sun Pharma Recalls 1,55,000 Bottles of Eye Solution from the US Market

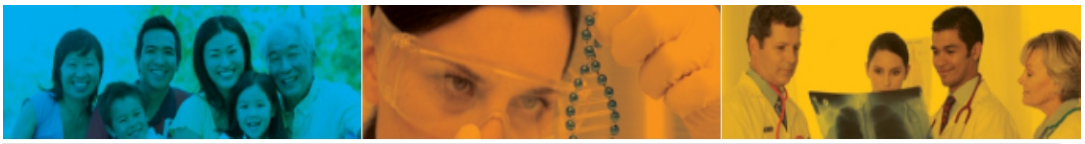
March 29, 2012

- Sun Pharmaceuticals is recalling 1,55,000 bottles of an eye solution from the US prescribed for relief in conjunctivitis last month after the impurities in the medicine were found to be "out of specification".
- Sun's recall falls under the FDA's Class III category, which means the use of the drug is not likely to have any adverse effects on the health of the patients. Such recalls are common in the US and does not necessarily mean that there is a problem with the quality of the drug.

6.3. Cipla Recalling drugs made for its foreign partners - Teva and Eagle Pharmaceuticals

March 29, 2012

- The FDA report said Teva Pharmaceuticals and Eagle Pharmaceuticals, partners of Mumbai-based Cipla, are withdrawing two medicines from the US market.
- Teva is calling back 7,260 bottles of flutamide capsules after another medicine was discovered in some of the vials. Flutamide is prescribed to patients of advanced prostrate cancer. (Recall comes under Class II, which means the use of the drug may cause temporary or reversible adverse effects.)
- Eagle Pharmaceuticals, Cipla's American partner, is also recalling an undisclosed quantity of argatroban injection after crystalline particulates were found in the vials. (Recall falls under FDA's Class III category)
- Both flutamide capsules and argatroban injection were made at Cipla's plant in Goa.



LAMBDA

MERGER AND ACQUISITIONS

7.1. Dainippon Sumitomo Pharma to acquire Boston Biomedical March 1, 2012

- Dainippon Sumitomo Pharma (DSP) of Osaka, Japan, plans to acquire Norwood, Mass.-based Boston Biomedical (BBI). DSP will make an upfront payment of $200 million to BBI shareholders, and will make development milestone payments of up to $540 million related to compounds BBI608 and BBI503 currently in development. It will also pay up to $1.9 billion in sales milestones.
- Once the acquisition closes in April, BBI will become a 100% owned subsidiary of DSP and continue its operation in the Boston area.

7.2 Quintiles hooks up with Malaysia's BiotechCorp for Clinical Research Support March 22, 2012

- US-based biopharmaceutical services company, Quintiles, is collaborating with the Malaysian Biotechnology Corporation (BiotechCorp), the lead development agency for the biotech industry in Malaysia, as part of BiotechCorp's efforts to foster a supportive national environment for clinical research.
- A memorandum of collaboration was signed by BiotechCorp with Singapore's Quintiles East Asia Pte Ltd during the 5th BioPharmaAsia Convention in the island state.

7.3 Icon Signs Partnership Agreement with Roche March 7, 2012

- ICON has been selected by Roche as its Technology Partner for storing and managing medical images collected during the company's clinical research programs after one year Pilot Program.
- Roche is using ICON's MIRA (Medical Image Review and Analysis) software as the company's central repository for medical images.

MEDIFACTS

8.1. Medication Leading Cause of Child Poisoning in US March 21, 2012

- Roughly 165 young children (Ages 5 yr and under) in the US are treated in the emergency departments every day after getting into medications, who unintentionally take a medicine or overdose on it, says a new report from Safe Kids Worldwide. The report suggests that 95% of unintentional medication overdose visits to emergency departments are caused by a young child who got into a medicine while a parent or caregiver wasn't looking. While 5% are due to dosing errors made by caregivers.

8.2. Frequent Chocolate Consumption Linked to Lower BMI March 26, 2012

- A recent study showed that frequent chocolate consumption was associated with lower body mass index (BMI), even when adjusting for calorie intake, saturated fat intake, and mood. The relationship between chocolate consumption frequency and BMI was calculated in unadjusted models, in models adjusted for age and sex, and in models adjusted for activity, satfats, and mood.