HIMACHAL PRADESH STATE PHARMACY COUNCIL

H.P. STATE PHARMACY COUNCIL

DRUG INFORMATION CENTER

DRUG AND THERAPY BULLETIN

Issue 3, December, 2017

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DRUG UPDATES

Ozempic for Type 2 Diabetes

On December 5, 2017, the US FDA approved Ozempic(R) (semaglutide) subQ injection as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes. Ozempic, which is administered one time per week, demonstrated efficacy in a clinical trial in which patients treated with semaglutide had significantly higher A1c reductions compared with those treated with placebo.

Prescribing information can be found at: http://www.novo-pi.com/ozempic.pdf.

Lonhala Magnair for COPD

On December 5, 2017, the US FDA approved Lonhala(TM) Magnair(TM) (glycopyrrolate) inhalation solution for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Lonhala Magnair, the first nebulized long-acting muscarinic antagonist to gain FDA approval, was shown to improve lung function compared with placebo in the GOLDEN trials.

Prescribing information can be found at: https://www.lonhalamagnair.com/LonhalaMagnair-Prescribing-Information.pdf.

Repatha for MACE prevention

On December 1, 2017 the US FDA approved a new indication for Repatha(R) (evolocumab) subQ injection to prevent heart attacks, strokes, and coronary revascularizations in adults with established cardiovascular disease. Repatha, the first and only PCSK9 inhibitor approved for this indication, was shown to reduce the risk of these major adverse cardiovascular events in the FOURIER clinical trial.

Prescribing information can be found at http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pdf.

Taltz now for PsA

On December 1, 2017 the US FDA approved a new indication for Taltz(R) (ixekizumab) subQ injection for treatment of adult patients with active psoriatic arthritis (PsA). Taltz, which is already indicated to treat patients with plaque psoriasis, may be

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administered alone or in combination with a disease-modifying antirheumatic drug (eg, methotrexate). The new indication comes after safety and efficacy trials showed a significant improvement in joint symptoms in patients treated with ixekizumab compared with those treated with placebo.

Prescribing information can be found at: http://pi.lilly.com/us/taltz-uspi.pdf.

Auvi-Q for Infants

On November 20, 2017, the US FDA approved a 0.1-mg strength of Auvi-Q(R) (epinephrine) IM injection to treat life-threatening anaphylaxis in infants and small pediatric patients weighing 7.5 to 15 kg (16.5 to 33 pounds) who have an increased risk for or a history of serious allergic reactions. Auvi-Q, the first

and only epinephrine auto-injector with a needle length and strength that provides dosing in infants and small children, was granted priority review for this expanded indication.

Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/201739s008s009lbl.pdf.

Faslodex with Abemaciclib for MBC

On November 15, 2017 the US FDA expanded the indication for Faslodex(R) (fulvestrant) IM injection to include use in combination with abemaciclib to treat hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2) advanced or metastatic breast cancer (MBC) in female patients whose disease has progressed after endocrine therapy. In the Monarch 2 trial, patients who were treated with fulvestrant plus abemaciclib had a significantly longer duration of progression-free survival compared with those who were treated with fulvestrant plus placebo.

Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021344s035lbl.pdf.

Fasenra for severe asthma

On November 14, 2017, the US FDA approved Fasenra(TM) (benralizumab) subQ injection for the add-on maintenance treatment of patients 12 years of age or older with severe asthma and with an eosinophilic phenotype. In about half of severe asthma patients, high eosinophil levels can result in elevated asthma severity and symptoms, decreased lung function, and an increased risk of exacerbations. Fasenra is the first and only respiratory biologic that depletes eosinophils directly, rapidly, and almost completely within 24 hours.

Prescribing information can be found at: http://www.azpicentral.com/pi.html?product=fasenra&country=us&popup=no.

Abilify MyCite with digital sensor

On November 13, 2017, the US FDA approved Abilify MyCite(R) (aripiprazole) oral tablets with a sensor for the treatment of schizophrenia, the acute treatment of manic and mixed episodes associated with bipolar disorder, and as an add-on treatment for depression in adult patients. The tablet is embedded with an ingestible sensor which is linked to a wearable patch that transmits the data to the patient's smart phone and a web-based portal allowing healthcare professionals and caregivers to track patient compliance.

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Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/207202lbl.pdf.

Sprycel for pediatric with Ph+ CML

On Friday, November 10, 2017 the US FDA expanded the indication for Sprycel(R) (dasatinib) oral tablets to include the treatment of children with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Previously approved to treat adults with different forms Ph+ CML and adults with Ph+ acute lymphoblastic leukemia, Sprycel becomes the first and only second-generation tyrosine kinase inhibitor approved for children. Safety and efficacy was evaluated in 2 pediatric studies; the largest to involve pediatrics with chronic myeloid leukemia in chronic phase. The approval was granted under priority review and received orphan designation.

Prescribing information can be found at: https://packageinserts.bms.com/pi/pi_sprycel.pdf.

Cinvanti for CINV

On November 9, 2017, the US FDA approved Cinvanti(TM) (aprepitant) IV emulsion to prevent acute and delayed chemotherapy-induced nausea and vomiting (CINV) following initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin and of moderately emetogenic cancer chemotherapy. Cinvanti, the first polysorbate-80 free IV formulation of an NK1 receptor, was approved based on bioequivalence data that showed efficacy of fosaprepitant (Emend(R) IV) and aprepitant in preventing CINV.

Prescribing information can be found at: https://www.herontx.com/sites/default/files/pdfs/CINVANTI_PI_11.9.17.pdf.

Adcetris for PCALCL and CD30 expressing MF

On November 9, 2017, the US FDA approved a new indication for Adcetris(R) (brentuximab vedotin) IV injection to treat adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) and CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy. This new indication for Adcetris was granted breakthrough therapy designation and priority review and is the fourth FDA-approved indication for the drug.

Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125388s094lbl.pdf.

Prevymis for CMV prevention

On November 9, 2017, the US FDA approved Prevymis(TM) (letermovir) oral tablets and IV injection for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). The efficacy of Prevymis was demonstrated in a clinical trial in which fewer patients treated with letermovir had clinically significant CMV infection by week 24 post-HSCT compared with those treated with placebo.

Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209939Orig1s000,209940Orig1s000lbl.pdf.

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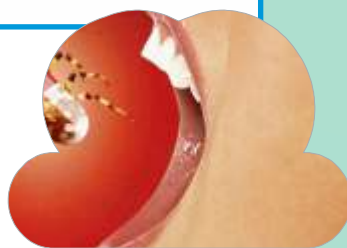

REGULATORY AMENDMENTS

Amendments in the drugs and cosmetics rules

Ministry of health and family welfare, Govt. of India has amended the drugs and cosmetics rules 1945 vide notification no. G.S.R. 1337 (E) dated 27-10-2017 providing that manufacturing license for drugs and cosmetics and approval of drugs/cosmetics testing laboratories shall remain valid if licensee deposits licence retention fee before the expiry of period of every succeeding five years from the date of issue, unless, it is suspended or cancelled by licensing authority. Amendments also provides that before grant of license in form 25 or form 25A or form 25B or form 25F or form 28 or form 28A or form 28B or form 28D or form 28DA to manufacture for sale and for distribution of drugs or in form 32 or form 32A or form 33 for manufacture of cosmetics, the state license authority shall cause the manufacturing premises to be inspected jointly by the central and state drug inspectors. Further premises licensed shall be inspected jointly to verify the compliance with the conditions of license and the provision of the act and rules not less than once in three years or as needed as per risk base approach.

Strict regulatory control over manufacture, distribution, sale of oxytocin

Ministry of health and family welfare took a meeting in 14-03-2017 to take stock of situation relating to strict and regulate manufacturing of oxytocin and to permit its manufacturing in compliance to the judgment of the High court of Himachal Pradesh. In regard to control over manufacture, sale and distribution of oxytocin it was decided in the meeting that cases of stoppage of production of oxytocin have been ordered for various reasons including non-compliance to GMP, GLP, GDP etc. should be monitored.

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PHARMA NEWS

Sun Pharmaceutical Recall Riomet® (Metformin Hydrochloride Oral Solution) due to Microbial Contamination

Sun Pharmaceutical Industries, Inc. (SPII), a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd is voluntarily recalling two lots of Riomet® (Metformin Hydrochloride Oral Solution), 500 mg/5mL, to the retail level (Class II Recall). The Riomet® (Metformin Hydrochloride Oral Solution) has been found to be contaminated (Scopulariopsis brevicaulis). The contamination was discovered during sample preparation for the Antimicrobial Preservative Effectiveness Testing (AMPET) being performed as part of the 12 month stability study interval.

FDA approves first two-drug regimen for certain patients with HIV

The U.S. Food and Drug Administration approved Juluca, the first complete treatment regimen containing only two drugs to treat certain adults with human immunodeficiency virus type 1 (HIV-1) instead of three or more drugs included in standard HIV treatment. Juluca is a fixed-dose tablet containing two previously approved drugs (dolutegravir and rilpivirine) to treat adults with HIV-1 infections whose virus is currently suppressed on a stable regimen for at least six months, with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.

Biocon launches KRABEVATM for treatment of Several Types of Cancer

Biocon Ltd, Asia's premier biopharmaceuticals company, has launched KRABEVATM, a biosimilar Bevacizumab for the treatment of patients with metastatic colorectal cancer and other types of lung, kidney, cervical, ovarian and brain cancers, in India. It is the world´s first and only Bevacizumab with a unique ´QualCheck´ mechanism, which will ensure that patients get a quality-ascertained product right upto infusion. Bevacizumab is indicated as a first-line treatment of patients with metastatic colorectal cancer (mCRC), and is accepted as a standard treatment option in combination with chemotherapy for patients with non-small-cell lung cancer (NSLC), metastatic renal cell carcinoma and recurrent ovarian cancer. KRABEVATM is the second key oncologic biosimilar product from Biocon´s global biosimilars portfolio to be launched in India, in order to address the unmet patient need for affordable biological therapies.

Astrazeneca's osimertinib is only approved in India

In last month, there was lot of hike about osimertinib is being sold illegally in the Hyderabad by private and government hospitals despite a ban by the Drug Controller General of India (DCGI). But, DCGI confirmed that only AstraZeneca Pharma India Limited, Bangalore has given permission for import and marketing of cancer drug.

Actually, this confusion occured with notice (F. No. 12-38/2017-DC) from CDSCO which states that, "Osimertinib mesylate is not yet approved for use in India. Quality, Safety and Efficacy of Osimertinib mesylate tablets is under review by CDSCO.

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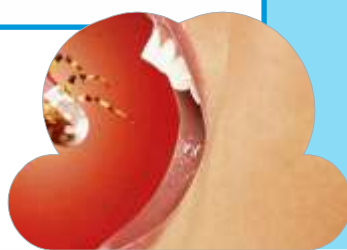

PHARMA NEWS

But as per CDSCO's recent notice CDSCO, itself gave permission to Astrazeneca India on 29th May, 2017 for import and market Osimertinib Film coated Tablets 40mg/80mg (as Osimertinib Mesylate).

Dr. Reddy's Laboratories announces the launch of generic Azacitidine for Injection in the Canadian Market

Dr. Reddy's Laboratories Ltd. is pleased to announce that generic Azacitidine for injection 100 mg/vial, a bioequivalent generic version of VIDAZA® (azacitidine for injection), is approved by Health Canada.

"Bringing Azacitidine for Injection to the Canadian market at this time is very important for us, as well as for our customers and their patients," says Alok Sonig, Executive Vice President and Head of the North America Generics business at Dr. Reddy's. "This launch represents Dr Reddy's commitment to make affordable injectable drugs available in Canada." Dr. Reddy's is first to market with this Azacitidine for injection in Canada.

HPV Vaccine Prevents Uncommon Childhood Respiratory Disease

The vaccine that protects against cancer-causing types of human papillomavirus (HPV) also prevents an uncommon but incurable childhood respiratory disease, according to a new study published in The Journal of Infectious Diseases. The findings suggest that the chronic and difficult-to-treat condition, recurrent respiratory papillomatosis, is disappearing in Australian children as a result of the nation's highly successful HPV vaccination program.

This is a world-first finding of evidence that the HPV vaccine has actually prevented recurrent respiratory papillomatosis cases," said study author Julia M.L. Brotherton, MD, PhD, MPH, of the Victorian Cytology Service in Melbourne, Australia. "It's really exciting that we finally have a way to prevent this terrible disease.

Note

If anyone would like to publish his/her article in the monthly bulletin of Drug Information Center regarding Pharma updates, they can send their articles with their full address and professional status on the following reference before 25th of the every month.

Mail ID: hpspcdic@gmail.com

Toll Free: 18001210443, Tel: 9218428042,
Whatsapp: 9459220253

Which kind of queries can be asked from Drug Information Center... ?

It is the matter of pride for all the population of Himachal Pradesh that there is **Drug Information Center** (DIC) in the state which is giving the services to promote the rational drug use. Maximum population of state knows that there is DIC, but they are unaware about the services of the DIC. They all are confused that which kind of queries they can ask.

There is no any restriction to take the drug query information by any one. Any person (physician, pharmacist, nurse, patient, people of community, old persons, students, researchers etc.) can come in or call in the DIC office to take drug information.

Following kinds of queries regarding drugs can be asked from DIC:

- If patient is administering two medicines at the same time then he/she before administering the medicine, can confirm from DIC that this combination is safe or not safe. If combination will be not safe then it may also be life threatening.
- If patient is administering a medicine then he/she can confirm which kinds of foods have to be avoided.
- Someone can confirm that use of any specific medicine in particular condition (like as pregnancy/ lactation) is safe or not safe.
- General information about drug identification can also be taken from the DIC, like as use and side/adverse effects, time of administration, duration of administration, dose in different age groups etc. about any drug.
- Information about substituted drugs with different prices can also be provided by DIC.
- Any updation about medicines can be confirmed from DIC.

DIC will provide the accurate information on request without any fear and favor.

In short, it can be say that DIC can provide any kind of information about any medicine to any one without any cost.

Personnel can assess directly, can call in the DIC office, sent the query by post, by E-mail on following address:

Drug Information Center, Run by Himachal Pradesh State Pharmacy council at Laureate Institute of Pharmacy Kathog, jwala ji, Distt. Kangra HP 177101

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