DRUG SAFETY ALERTS 2012

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DSA

- Drug Safety Alerts are meant to provide information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products.
- One component of Drug Safety Alerts is ‘’product recalls’’. The FDA defines a product recall as actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm’s own initiative or by FDA request.

FDA issues MedWatch Regarding Various Endo Pharmaceuticals Products (09/01/2012)

- Issue: Tablets from one product may have carried over into packaging of another product resulting in a stray pill of one medicine ending up in the bottle of another product
- This issue affects following products:

1. Opana (Oxymorphone Hydrochloride) ER tablets CII
2. Percodan(Oxycodone Hydrochloride and acetaminophen)tabs
3. Endocet tablets CII
4. Morphine Sulphate ER tablets CII
5. Zydone (hydrocodone bitartarate/acetaminophen tablets) CII

- Production temporarily suspended to implement manufacturing process improvements, short term distruption of supply to be expected.

Novartis Consumer Health Issues Patient Level Recall on Over the Counter products(09/01/12)

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- Audience: Consumer, Pharmacy
- Issue: Reports of chipped and broken pills and inconsistent bottle packaging clearance practices resulting in bottles containing foreign tablets and capsules.
- Novartis Consumer Health Inc. is voluntarily recalling all lots of over the counter products Exedrin, Bufferin, Gas-X, Prevention and NoDoz.

Vitaflow Issues Patient-Level Recall on Renastart (30/01/2015)

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- Voluntary recall of Renastart 14.11 oz(400g) cans
- Issue: incorrect labelling
- Renastart is a powdered medical food used in the dietary management of pediatric renal disease, for patients one year and older in the United States.
- Immediate consequences- hyperkalemia and hypernatremia, can result in serious significant health consequences potentially leading to death.

FDA Issues Patient-Level Recall on Acetyl cysteine Solution 20%, 30 ml Vials (02/02/12)

- Voluntary recall after the discovery of a single visible glass particle in a vial.
- Acetyl cysteine for inhalation is usually delivered via direct instillation into a tracheostomy, or into the bronchial pulmonary tree during bronchoscopy.
- Glass particles can cause airway obstruction resulting in symptoms of choking, wheezing, difficulty breathing, coughing and potentially hemoptysis.

FDA Issues MedWatch on Proton Pump Inhibitors (08/02/12)

- Issue: The use of PPI's may be associated with an increased risk of Clostridium Difficile- associated diarrhea(CDAD).
- A diagnosis of CDAD should be considered for patients taking PPI's who develop diarrhea that does not improve.
- C.difficile is a bacterium that can cause diarrhea that does not improve.
- Working on including information in drug labels.

FDA Issues MedWatch on Avastin Due to Possible Counterfeit Product (14/02/12)

- Issue: counterfeit version of Avastin 400mg/16ml, labelled as Avastin, manufactured by Roche and does not contain the medicine's active ingredient- bevacizumab.
- Batch number: B6010, B6011 or B86017.
- Avastin is an injectable medicine used to treat cancer
- Approved version- do not include Roche Logo.

FDA approves MedWatch Regarding Statins and HIV or Hepatic C Drugs (01/03/12)

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- Issue: drug-drug interactions.
- Protease inhibitors and statins taken together may raise the blood levels of statins and increase the risk of muscle injury(myopathy). The most serious form of myopathy, called rhabdomyolysis can damage the kidneys and lead to kidney which can be fatal.
- Drug labels have been updated with information regarding drug-drug interaction and dosing recommendations of statins to safely co-administer with HIV or HCV protease inhibitors.

FDA Clarifies Dosing and Warning Recommendations for Celexa (28/03/12)

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- Issue: a potential risk of abnormal heart rhythms with high doses.
- Celexa, an antidepressant (citalopram hydrobromide) should no longer be used at doses greater than 40mg per day because it could cause potentially dangerous abnormalities in the electrical activity of the heart.
- Avoided in patients with heart complications.
- Maximum recommended dose is 20mg per day for patients above 60 years.

FDA Issues MedWatch on Birth Control Pills Containing Drospirenone (10/04/12)

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- Issue: Risk of blood clots in women taking birth control pills containing drospirenone
- Drospirenone is a synthetic version of the female hormone, progesterone, also referred to as progestin
- HCPs must consider risks and benefits of drospirenone containing birth control pills and a women's risk of developing a blood clot before prescribing these drugs.

Hospira, Inc Issues User-level Recall on Morphine Sulfate Injection 4mg/ml (07/04/12)

- Voluntary recall of Morphine Sulphate Injection, USP 4 MG/ML,(C-II) 1 ML Fill in 2.5ml Carpuject, that may contain more than the intended fill volume.
- Opioid pain medications such as morphine have life-threatening consequences if overdosed, which include respiratory depression and low blood pressure.

FDA Issues Drug Safety Communication On Victrelis and Ritonavir-Boosted HIV Protease Inhibitor Drugs (26/04/12)

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- Issue: drug-drug interaction
- Co-administration of hep c virus protease inhibitor, along with certain ritonavir-boosted human immunodeficiency virus protease inhibitors reduces the effectiveness of medicines, permitting the amount of HCV or HIV in the blood to increase.
- HCPs treating patients with both chronic HCV and HIV should closely monitor patients for potential HCV or HIV virologic rebound

FDA Issues Drug Information Update on Revlimid (lenalidomide) (07/05/15)

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- Increased risk of second primary malignancies in patients with newly- diagnosed multiple myeloma who received Revlimid.
- Information added to Revlimid Drug label

FDA Issues Drug Information Update regarding Gilenya (fingolimod) (14/05/12)

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- Report of a patient who died after the first dose of multiple sclerosis drug Gilenya.
- Contraindicated in patients with pre-existing or recent heart conditions or stroke or who are taking anti-arrhythmic drugs because of the drugs heart rate lowering effect.
- Hourly pulse and blood pressure measurement, heart rate obs upto 6 hrs after drug consumption and ECG monitoring prior dosing and after obs period.

B.Braun Issues Patient-Level Recall on Various Ambulatory Administration Sets (24/05/12)

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- Recall was issued as a result of reverse pump segment found in three administration sets.
- Use of affected sets may cause blood loss, under delivery of prescribed medication/fluid, or a potential delay in therapy.
- Continued use can cause potential risk of serious injury or death.

Caraco Pharmaceutical Lab Issues Patient –Level Recall on Nimodipine 30 (04/09/12)

- Recall issued as a precautionary measure due to the presence of crystals of nimodipine within the capsule solution.
- The product may no longer be bioequivalent and may potentially affect patients who are being treated for a medical emergency.

Ranbaxy Issues Voluntary Recall on Various Atorvastatin Products (09/11/12)

- Retail-level recall of multiples lots of atorvastatin 10mg, 20mg and 40mg tablets. Issued because of the potential for the affected lots to contain a foreign substance (small glass particles of less than 1mm).
- Risks associated with this defect could include injuries in the oral and gastrointestinal mucosa such as abrasion, pain, ulcerations, bleeding and local immune reactions.

Recall Hydrocodone Bitartrate and Acetaminophen 10mg/500mg tablets (29/11/12)

- Manufactured by Qualitest Pharmaceuticals Class I
- Recall issued because a small number of tablets exceed the weight requirement and could be super-potent for the ingredients of hydrocodone bitartrate and acetaminophen.
- Recall affects lot number C1440512A exp. 12/13 only. No other lots affected.

FDA Issues MedWatch on Chantix (Varenicline) (12/12/12)

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- Patients using Chantix can be at increased risk of major cardiovascular events (cardiovascular related death, nonfatal heart attack and nonfatal stroke).
- Chantix is a prescription medicine used to help adults quit smoking that works by blocking the effects of nicotine from smoking on the brain.
- HCPs- weigh the risks of Chantix against the benefits of its use.

CENTRAL DRUGS TESTING LABORATORY, CHENNAI

Drug Alert for the month of November,2012.

S.NO.	Name of Drugs / Cosmetics/Condoms	Batch No.	Date of Mfg.	Date of Expiry	Manufactured by	Received from
1	Hobby Hand Wash Spring Freshers	2418	May,2012	May,2015	M/s.Hobi Kozmetik A.S.,Merkezi K:2/6, Made in Turkiye.	ADC(I), CDSCO , IGI, AIR CARGO , New Delhi.
2	Ranitin -152 Tablets	CD981025	March,2011	February,2015	M/s. Torrent Pharmaceuticals Ltd, Baddi-173205. Solan(H.P). India.	DDC(I), CDSCO, South Zone, Chennai
3	Kohinoor Pink Pleasure Condoms	P x 2054	April,2012	March,2015	TTK LIG Limited, Pallavaram, Chennai-43.	ADC(I), CDSCO , Port, Chennai

Drug Alert for the Month of December, 2012

S. No.	Name of Drugs/cosmetics/condoms	Batch No./Date of Manufacture/Date of Expiry/Manufactured By	Reason for failure	Sample Received from	Declared by
1	Ranitin-150 Tablets	B. No. 1D 982012,D/Mfg. Jan,2012, D/Exp. Dec, 2015 Mfg. By. M/s Torrent Pharmaceuticals Ltd, 32, Middle Camp, NH 31 A, East District, Gangtok, Sikkim	Test for Description	CDSCO, South Zone, Chennai	CDTL, Chennai
2	Amlodipine & Atenolol Tablets (AMLI+AT)	Batch No -T1-12075 D/Mfg. -01/12 D/Exp. - 12/13 Mfd. By- M/S. RHYDBURG Pharmaceuticals Ltd., C-2 & 3, S.I.E.L., Selaqui, Dehradun-248197	Assay (content of Amlodipine)	CDSCO, Sub- Zone, Jammu	RDTL, Chandigarh
3	Cefixime Dispersible Tablets (Grix DT 100)	Batch No - RB12842T D/Mfg. -08/12 D/Exp. - 07/14 Mfd. By- M M/S. Rescuers Life Sciences Ltd. 131-132, EPIP, Phase-1, Jharmajri, Baddi, Distt.Solan (H.P.) 173205	Assay (content of Cefixime)	CDSCO, Sub - Zone, Chandigarh	RDTL, Chandigarh
4	Salbutamol Tablets IP 4 mg (SALBUTAMOL-4)	Batch No - 1331 D/Mfg. - AUG./2012 D/Exp. - JUL./2014 Mfd. By- M/S MINIL LABORATORIES PVT. LTD.,	Assay (content of Salbutamol)	CDSCO, Sub-Zone, Jammu	RDTL, Chandigarh

Reference

- www.fda.gov/Drugs/DrugSafety/default.html
- www.cdsco.nic.in/forms/list.aspx?lid=2041&ld=33
- https://www.caremark.com/wps/portal/!ut/p/c4/04_SB8K8xLLM9MSSzPy8xBz9CPMGdLA09-2JFw!/

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Thank you