Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Recently Government of India has instructed all state Government & UTs to ensure that " Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs" as per Notification No. MCI-211(2)/2016(Ethics)/131118 dtd. 08.10.2016 vide recent D.O.Letter No. 7(13) 2014-NHM-1 dtd. 18th April 2017. This instruction has further supported by a notification by MCI vide No. MCI-211 (2) (Gen.)/2017-ethics dated. 21.04.2017 amending clause 1.5 of the MCI (Professional Conduct, Etiquette and Ethics) Regulations 2002, which is -
"Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs".
The notification instructed all Registered Medical Practitioners under the MCI Act to comply this instruction. This notification also warned if any doctor found violating this instruction concerned State Medical Council (SMC) / Medical Council of India (MCI) will take suitable disciplinary action against the offender as per the provision under clause 1.5 of Ethics Regulation.
This step is one step ahead towards improving access to medicines. In addition to this Standard Treatment Guidelines require to be developed by the Country / State / individual health care set up and a rational price control mechanism require to be adopted for improving access to Medicines.
Health care activists are happy with this development and expect some more stringent steps by the Govt. and regulatory agencies to improve access to medicines.

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Andrographis paniculata Potential risk for allergic reactions

The Medsafe has reminded that products containing andrographis have the potential to cause serious allergic reactions. Andrographis paniculata is a herb included in some natural health products. These products are used by consumers to support a healthy immune system, support recovery from the common cold and help with symptoms of the cold. In New Zealand, a number of cases have been identified by CARM which reported allergic reaction in consumers taking andrographis-containing products. The reported reactions include dyspnoea, flushing, urticaria and anaphylaxis.

Similar reports have been noted internationally. Between December 2002 and April 2014 the TGA in Australia received 43 reports of anaphylaxis and 78 reports of other allergic-type reactions associated with products that contain andrographis. WHO Global ICSR database, VigiBase® contains 198 reports related to andrographis. Of these reports, 147 reports involved hypersensitivity reactions such as urticaria, pruritus, anaphylactic reactions, eyelid oedema, face oedema and angioedema. These reports were submitted by countries participating in the WHO Programme for International Drug Monitoring (PIDM).

Reference: Safety Information, Medsafe, 24 March 2017 (www.medsafe.govt.nz/)

Vemurafenib Risk of acute kidney injury

The MHLW and the PMDA have announced that the package insert for vemurafenib (Zelboraf®) has been updated to include the risk of acute kidney injury as a clinically significant adverse reaction. In addition, the company core datasheet (CCDS) has also been updated. Vemurafenib is indicated for BRAF mutation-positive radically unresectable malignant melanoma. A total of two cases associated with acute kidney injury have been reported in Japan. A causal relationship could not be excluded in both cases.

Reference: Revision of Precautions, MHLW/PMDA, 14 February 2017 (www.pmda.go.jp/english/)

Warfarin Risk of calciphylaxis

The NPRA has reviewed the risk of calciphylaxis with warfarin and issued a directive to update the local package inserts of warfarin-containing products with this safety issue. Warfarin is an oral anticoagulant which acts by inhibiting the synthesis of vitamin K-dependent clotting factors II, VII, IX, and X. Since the year 2000, the NPRA has received 341 warfarinrelated ADR reports with a total of 563 adverse events in Malaysia. Most of the adverse events were reported as skin and subcutaneous tissue disorders (111 cases, 19.7%), nervous system disorders (92 cases, 16.3%) and gastrointestinal system disorders (63 cases, 11.2%). At present, no reports of calciphylaxis have been received locally. One report described a female patient who developed pain and skin necrosis after taking warfarin, however it was not confirmed whether this was calciphylaxis or warfarin-induced skin necrosis (WISN), as no skin biopsy was done.

Reference: MADRAC Newsletter, NPRA, Volume 21, December 2016 (See WHO Pharmaceuticals Newsletter No.4, 2016: Reports of calciphylaxis in the US)

Tramadol-containing products Risk of serious respiratory depression in children and adolescents

Health Canada has updated the product information for tramadolcontaining products to further manage the risk of serious

breathing problems. Health Canada has also reminded that tramadol is not recommended for use in patients under 18 years of age. Tramadol is an opioid prescription drug to treat moderate to moderately severe pain in adults. Health Canada has carried out safety review on tramadol, after a safety review of codeine and the risk of serious breathing problems in children. At the time of the review, Health Canada had not received any reports of serious breathing problems related to the use of tramadol in children and adolescents in Canada. This safety review found one international report of respiratory depression in the published literature, linked to the use of tramadol in a 5-year old child. The child was an ultra-rapid metabolizer and this may have played a role. Many studies suggest that differences in how the liver works could affect the risk of side effects experienced by patients using tramadol. These studies help to confirm that ultra-rapid metabolizer patients may be more at risk of developing respiratory depression with the use of tramadol.

Reference: Summary Safety Review, Health Canada, 22 February 2017 (www.hc-sc.gc.ca) (See WHO Pharmaceuticals Newsletters No.6, 2015: Risk of slowed or difficult breathing in children in the US and No.5, 2015: Tramadol oral drops not for children under the age of 12 years in Australia)

US FDA approves drug to treat Duchenne muscular dystrophy

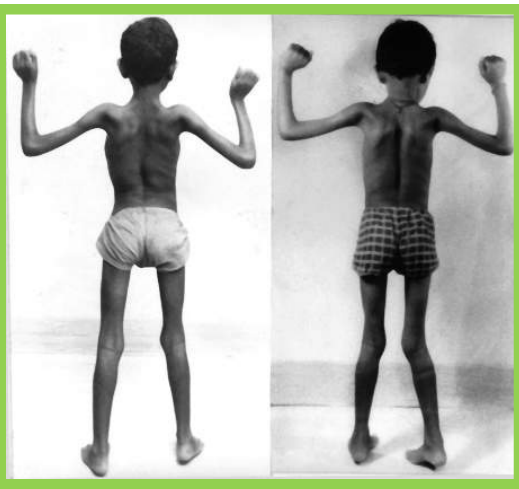
The U.S. Food and Drug Administration approved Emflaza (deflazacort) tablets and oral suspension to treat patients age 5 years and older with Duchenne muscular dystrophy (DMD) on 9th February 2017, a rare genetic disorder that causes progressive muscle deterioration and weakness. Emflaza is a corticosteroid that works by decreasing inflammation and reducing the activity of the immune system.

Corticosteroids are commonly used to treat DMD across the world. This is the first FDA approval of any corticosteroid to treat DMD and the first approval of deflazacort for any use in the United States.

"This is the first treatment approved for a wide range of patients with Duchenne muscular dystrophy," said Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "We hope that this treatment option will benefit many patients with DMD."

DMD is the most common type of muscular dystrophy. DMD is caused by an absence of dystrophin, a protein that helps keep muscle cells intact. The first symptoms are usually seen between 3 and 5 years of age and worsen over time. The disease often occurs in people without a known family history of the condition and primarily affects boys, but in rare cases it can affect girls. DMD occurs in about one of every 3,600 male infants worldwide.

People with DMD progressively lose the ability to perform activities independently and often require use of a wheelchair by their early teens. As the disease progresses, life-threatening heart and respiratory conditions can occur. Patients typically succumb to the disease in their 20s or 30s; however, disease severity and life expectancy vary.



Child suffering from Duchene Muscular Dystrophy DMD)

The effectiveness of deflazacort was shown in a clinical study of 196 male patients who were 5 to 15 years old at the beginning of the trial with documented mutation of the dystrophin gene and onset of weakness before age 5. At week 12, patients taking deflazacort had improvements in a clinical multiple comparisons, patients on deflazacort appeared to lose the ability to walk later than those treated with placebo.

The side effects caused by Emflaza are similar to those experienced with other corticosteroids. The most common side effects include facial puffiness (Cushingoid appearance), weight gain, increased appetite, upper respiratory tract infection, cough, extraordinary daytime urinary frequency (pollakiuria), unwanted hair growth (hirsutism) and excessive fat around the stomach (central obesity).

Other side effects that are less common include problems with endocrine function, increased susceptibility to infection, elevation in blood pressure, risk of gastrointestinal perforation, serious skin rashes, behavioral and mood changes, decrease in the density of the bones and vision problems such as cataracts. Patients receiving immunosuppressive doses of corticosteroids should not be given live or live attenuated vaccines.

The FDA granted this application fast track designation and priority review. The drug also received orphan drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The sponsor is receiving a rare pediatric disease priority review voucher under a program intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. A voucher can be redeemed by a sponsor at a later date to receive priority review of a subsequent marketing application for a different product. This is the ninth rare pediatric disease priority review voucher issued by the FDA since the program began.

Emflaza is marketed by Marathon Pharmaceuticals of Northbrook, Illinois.

Ref. FDA News Release

placebo. An overall stability in average muscle strength was maintained through the end of study at week 52 in the deflazacort-treated patients. In another trial with 29 male patients that lasted 104 weeks, assessment of muscle strength across a number of muscles compared to those taking deflazacort demonstrated a numerical advantage over placebo on an assessment of average muscle strength. In addition, although not statistically controlled for

Reader Speak….

Excellent Dr. Mandal. This is a significant achievement in any parameter.
Congratulation to all of you and very specific to you as an individual who puts all efforts to have its continuity.
With regards,

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