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○ ISSUE 7

○ March 2014

Brandspeak

AN E-UPDATE BY BRANDCARE

Med-ad Update

Regulatory Bodies:

The Indian Pharmaceutical industry



Ethically compromised, uncontrolled practices within the medical and pharmaceutical sectors may need a careful reappraisal and a regulatory restraint. Understanding the regulatory sketch of the pharma sector is important to get the grasp of the prompt change happening specially at global level, particularly considering the good manufacturing practices (GMP), good clinical practices (GCP), and good laboratory practices (GLP). It is these regulatory bodies that can ensure availability of healthy, affordable and good quality products to the commons. With Central Drugs Standards and Control Organisation (CDSCO) ensuring maintenance of standards of safety, efficacy approving for manufacturing license, the provisions of Drug Price Control Order

(DPCO) have been vested in National Pharmaceutical Pricing Authority (NPPA) that ascertains pricing - ceiling and non-ceiling. Ceiling price is the only maximum price fixed applicable throughout the country in case of each bulk drug, which is under price control. Non-ceiling price however is specific to a particular pack size of scheduled formulation of a particular company. Keeping up with the international standards, Indian pharmaceutical regulatory bodies have come up with major changes. GCP, GLP and GMP being more in line with the international standards after the proposed amendments, even drug registration and regulatory submission guidelines are being looked at. CDSCO has decided to adopt Common Technical Document (CTD) format for technical requirements for registration of pharma products for human use.

Embracing Drug Master File (DMF) and drug product dossier concepts CTD format in line with global requirements would contribute significantly in easing the entry to global markets also ensuring safe, good quality medicines to Indian patients. With the help of Ministry of health, CDSCO, Indian Pharmacopoeia commission (IPC); a pharmacovigilance program is under initiation. The pharmacovigilance program of India will collect, collate and analyse data to arrive at an inference which could be suggested as regulatory interventions, besides communicating risks to healthcare professionals. The focus of Indian pharmaceutical regulatory bodies is moving towards risk management and science based GMP regulations enhancing availability of quality products at affordable prices.

FDA Boosts Serving Sizes to Reflect Real Eating



Based on surveys done in 1978 and 1988 on the eating capacity of people, Food and Drug Administration (FDA), came up with the nutrition label in 1993. Then, it was different standards of eating that people had, a normal ice-cream scoop, eight ounces of soda at a time were supposed to be moderate consumption but off late, FDA notices that people's eating habits have changed. Americans specially seem to be consuming more now. Post the 21 years old nutrition label, the FDA deems it to be fit to relook into the serving size. Nutrition label once relooked would include changes in highlighting calories and added sugar to suit the context today.

The stats reflect the following changes in consumption:

Ice cream: 1/2 cup to 1 cup

Soda: 8 oz. to 12 oz.

Sugar: 4 g to 8 g

Bagels, toasters, pastries, muffins: 55 g to 110 g

The change to be incorporated is true too, since a bottle of soda is 2.5 servings of soda but we do consume a bottle in one go.

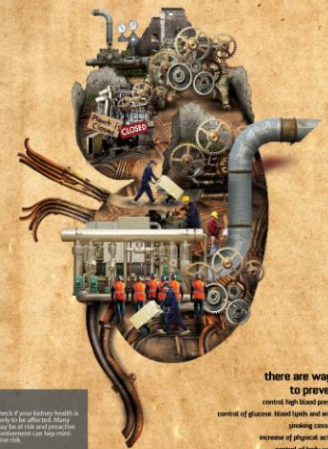
Not every food item is certain to increase; yogurt supposedly would reduce from eight oz. to six ounces.

Labeling would be dramatically affected too as increased quantity wouldn't then mean "low fat" serving, however the product might still claim to be "low fat" in terms of nutrition provided.

Though the FDA plans to incorporate such amendments, but surveys suggest that people don't pay that much attention to labels as they did earlier. Hopefully the attempt aids people realise their consumption.

WORLD KIDNEY
DAY, 13TH MARCH
2014

obsolescence can set in with age...



Focusing on chronic kidney diseases and aging, let us all join our hands to spread awareness about the kidney ailments that can start at any age but only go to increase with time. Let us take steps at an early age and combat this silent killer.

To download free poster, visit:

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