



Drug Information Bulletin

Drug Information Centre (DIC)

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Editorial

Practice in Pharmacy is existing in India since long back, with a different name and structure and it has got a regulated structure since implementation of Pharmacy Act 1948. Engagement of Pharmacist in serving the prescription of a registered practitioner has been made mandatory by an amendment of sec 42 of Pharmacy Act 1940, in the year of 1984 and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year. Publication of "The Role of the Pharmacist in the Health Care System" by World Health Organization in the year of 1990 has given a solid platform to create more conducive environment for growing Pharmacy Practice in India. Dispensing by pharmacists is mandatory world wide for better health care services.

Recent demand by AIOCD to scrape this regulation is not only unjustified, but against the interest of the country as it will severely hamper the health care system. All the health care professional association especially pharmaceutical professional organizations should protest this unjustified demand.

USP opens second china site

The ever-expanding market in China has plenty of room for 3rd party pharmaceutical distribution and logistics companies says UPS as it opens a new facility in Zhejiang Province.

<http://www.outsourcing-pharma.com/Commercial-Services/UPS-Opens-Second-China-Site-to-Support-Growing-Healthcare-Market>

The first USP-China, office and laboratory facility, opened in Shanghai in 2007. It may be noted that first USP-India office and laboratory was opened at Hyderabad in the year of 2005.

J&J Birth Control Pill under recall in three countries

Reuters reports Johnson & Johnson on Tuesday issued a voluntary recall for its birth control pill, Cilest (ethinylestradiol and norgestimate), in Asia, Europe and Latin America. J&J spokesperson Michelle Romano said the 179 batches of Cilest, which were manufactured by the company's Janssen unit, were placed under recall after an internal quality test revealed there was no defined specification for one of the active ingredients in the drug.

Use of Statins associated with strains and sprains

MedPage Today reports, "Muscle pain has been associated with statin use, but" a study published online in JAMA Internal Medicine "suggests a link with skeletal adverse events as well." Researchers found that "the chances for any musculoskeletal disease diagnosis in those taking statins were significantly higher when compared with nonusers (odds ratio 1.19)." In addition, "statin users had a higher chance of being diagnosed with musculoskeletal adverse events in two out of three musculoskeletal subgroups based on ICD-9-CM codes: Dislocation/strain/sprain: OR 1.13 (95% CI 1.05-1.21) [and] musculoskeletal pain: OR 1.09 (95% CI 1.02-1.18)."

According to Cardio Source, "These findings are concerning because starting statin therapy at a young age for primary prevention of cardiovascular diseases has been widely advocated. Moreover, the numbers needed to be exposed for one additional person to be harmed were 37 to 58 individuals for various outcomes," the study authors wrote.

Testosterone prescriptions triple over past decade, but risks unclear

Sales of testosterone treatments have reached \$2 billion, but ABC World News (6/3, story 9, 2:10, Sawyer) asks "what about the risks?" Researchers in Texas are concerned that ads for testosterone prescriptions "may be driving a potentially worrisome amount of overtreatment. Between 2001 and 2011, they say testosterone prescriptions tripled among men over 40. But they say a full quarter of them were put on testosterone without even having their levels checked first to see if they really needed it." According to Dr. Edmund Sabanegh of the Cleveland

Clinic, the increase in treatments has become "a near epidemic portion." Additionally, the New England Journal of Medicine has said "only about 2% of men over 40 should be getting any boost at all," because while it can elevate muscle mass and boost sex drive, some doctors believe too much testosterone "much raises the risk of prostate cancer and liver damage."

The New York Times "Well" health blog reports that although "testosterone replacement therapy is approved specifically for the treatment" of hypogonadism, a study in the journal JAMA Internal Medicine notes many men who obtain testosterone prescriptions do not have evidence of a deficiency. "The medical group that sets clinical guidelines for testosterone replacement therapy, the Endocrine Society, recommends treatment only in men who have unequivocally low testosterone levels," but the report states a quarter of men did not have a blood test prior to receiving the hormone. Dr. Jacques Baillargeon, an associate professor of epidemiology at the University of Texas Medical Branch at Galveston, warned, "I think these relatively healthy men who are starting testosterone at age 40 are potentially going to be exposed for a very long time, and we don't know what the risks are."

HealthDay notes that one study from the University of Alabama "presented last month at the annual meeting of the American Urological Association suggests that use of testosterone might be an underappreciated cause of male infertility." The study found that the men's sperm production returned to normal after they ceased using testosterone supplements. Another study by the University of Washington in Seattle found "looked at 70 websites from companies across the United States,

found that just 27 percent of the online vendors described potential side effects, which experts say can include liver problems, male breast growth, increased male pattern baldness, possible harm to prostate health, raised risks for blood clots, congestive heart failure and a worsening of urinary symptoms.”

Walmart fined more than \$100 million for illegal disposal of chemicals

The largest retail chain in the United States, Walmart, has been found guilty of disposing of toxic waste in court cases filed by the cities of Los Angeles and San Francisco. Walmart, which is also the largest U.S. employer, will have to pay a fine of more than \$100 million for breaching environmental regulations across the country.

According to the [San Francisco Chronicle](#), the company pleaded guilty to dumping toxic chemicals such as fertilizer, pesticide and bleach in sewage systems. Walmart admitted a total of six counts of violations of the Clean Water Act by disposing of hazardous materials in garbage receptacles and sewage systems at more than 4,000 retail outlets across the United States. In addition, the U.S. Department of Justice found the retailer guilty of breaching federal laws by blending pesticides at a Missouri recycling facility and then reselling the end product, which was against the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Arkansas-based company also agreed to settle a civil case suit brought by the U.S. Environmental Protection Agency. In total, the retailer has agreed to pay over \$110 million in penalties, the Department of Justice announced.

The state of California started an investigation into the company in 2005,

following a report from a San Diego County Health Department inspector who had witnessed a Walmart employee pouring bleach into a sewer drain. The lengthy investigation involved more than 20 prosecutors and 32 environmental groups, the San Francisco Chronicle noted.

Melinda Haag, U.S. Attorney for the Northern District of California, commented that in its capacity as a major employer with numerous sites located across the country, the retailer is not just responsible for the products it has on its shelves but also for large quantities of hazardous materials coming from damaged products returned by customers. Documents presented to the court stated that illegal disposal of chemicals took place in at least 16 California counties in the period between 2003 and 2005. Federal investigators found that Walmart did not provide training to its employees on the proper handling, storage and dumping hazardous chemicals.

Ignacia Moreno, assistant attorney general for the Justice Department's Environment and Natural Resources Division, said that Walmart has failed to comply with regulations regarding the proper handling of such materials and waste and has potentially put public health and the environment at risk. Moreno even suggested that by violating federal regulations Walmart has gained an unfair advantage over its competitors.

Brooke Buchanan, a spokeswoman for the company, stated that the chemicals were in fact household items that could be found in every home, such as detergents, hairspray and deodorants. Some employees would dispose of broken bottles of bleach in the trash can instead of dumping them in the designated

container, she explained. Buchanan added that Walmart staffs are now trained every year on how to dispose of chemicals found in stores.

Developing nations to introduce resolution on access to medicines at UN Human Rights Council

The developing countries including India, Brazil, South Africa, Egypt and Thailand are set to introduce a resolution on access to medicines at the United Nations Human Rights Council (UNHRC) whose 23rd regular session is currently on in Geneva and the draft resolution is expected to come up for consideration next week. The current session will end on June 14.

The draft resolution requests States, the UN and other intergovernmental organisations to address the existing challenges with regard to access to medicines in the context of the right to health, and the ways to overcome those challenges.

The report of the Special Rapporteur on access to medicines, which was introduced at the Council meeting on May 27, "identifies and analyses challenges and good practices with respect to access to medicines in the context of the right-to-health framework". It uses the key human rights framework on access to medicines, i.e. availability, accessibility, acceptability and quality to analyse the international and national determinants to access to medicines.

In the first section of the report, the Special Rapporteur reviews the international legal framework as it applies to access to medicines. In the second section, he identifies key determinants of access to medicines and discusses challenges and good practices with respect to each aspect. The key determinants identified in the report are: local production of medicines, price

regulations, medicines lists, procurement, distribution, rational and appropriate use and quality of medicines.

The Special Rapporteur clearly states that, "access to affordable and quality medicines and medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central elements for the enjoyment of the right to health". Further, he "calls upon States to shift from the dominant market-oriented perspectives on access to medicines towards a right-to-health paradigm in promoting access to medicines".

According to the report, there are four key measures to be carried out by a State to fulfill its obligation with regard to access to medicines within the right-to-health framework. These are: (i) availability of medicines in sufficient quantities in public health facilities based on list of essential medicines selected to meet the priority health needs of the population; (ii) measures to ensure economic and physical access to the medicines on a non-discriminatory basis; (iii) measures to ensure that medicines that are determined are culturally and ethically acceptable to the people; and (iv) a strong regulatory mechanism coupled with transparent process to ensure quality, safety and efficacy of medicines.

The report urges States to adopt a national health policy with a national plan of action to ensure access to medicines. Further, it encourages States to ensure that national plans should adhere to the "central principles of non-discrimination, transparency, accountability, and multi-stakeholder participation, particularly of affected communities and vulnerable groups."