



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

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Editorial

Recent declaration of formation of National Medical Devices Promotion Council by the Minister of Commerce and Industry, Govt. of India under Dept of Industry Policy and Promotion (DIPP) will certainly give a fillip to the growth of Medical Devices manufacturing in India. It is expected to end the 70-90 percent import dependence of Indian medical devices industry and an import bill of about 31000 crores. Minister also announced establishing a Medical Devices Design Centre and assured as exports picks up by establishing a Medical Devices Exports Promotion Council like - Pharmexcil. This new body will act as a facilitating and promotion and developmental body for the Indian Medical Devices Industry.

It is expected that Medical Devices Development Council will help realize the expectation for India to be among the Top 5 Medical Devices manufacturing hubs worldwide as the Council will spearhead the policy needs to accelerate the manufacturing of medical devices in India. Experts are happy to find that the Govt. is taking serious steps to make India a global robust hub for medical devices manufacturing and fulfilling Govt's ambitious mission of making quality healthcare affordable for common masses.



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Trials started on breath test to detect multiple cancers early

A breathalyzer designed to detect multiple cancers early is being tested in the UK. Several illnesses are known to create signature smells from the body, including typhoid fever reported to smell like baked bread and the aroma of acetone, said to be similar to rotten apples, on the breath of diabetics. Recent research has also shown that a person's breath could also indicate the presence of cancer.

To test this theory, Cancer Research UK have launched a two-year trial into a clinical device, called the Breath Biopsy, to find out if exhaled airborne molecules can be useful for cancer detection.

In the body's normal metabolic processes, molecules called volatile organic compounds (VOCs) are produced. It's thought that cancer can create a different pattern of VOCs, which researchers hope to identify using the device. "Our goal is, can we spot these subtle differences?," Billy Boyle, co-founder and CEO at Owlstone Medical which developed the device, told CNN.

The trial, which is being run by the Cancer Research UK Cambridge Centre, is recruiting up to 1,500 participants, including healthy people to act as a control group.

Patients with stomach and esophageal cancers will initially be asked to try the test, before expanding to patients with prostate, kidney, bladder, liver and pancreatic cancers. Participants will be asked to breathe into the device for 10 minutes to provide a sample, which will be analyzed by Owlstone Medical's laboratory in Cambridge.

The idea is to identify if cancer signals are similar or different and how early any signals could be picked up. If some people go on to develop cancer, their samples will be compared to those who don't develop the disease.

Ref. CNN

Govt. sets up council to boost local manufacturing, export of medical devices

In a major fillip to medical devices industry, the Indian government has decided to set up a National Medical Devices Promotion Council under the Department of Industrial Policy and Promotion (DIPP) to boost domestic manufacturing and exports.

The Council will be headed by secretary, DIPP of the Ministry of Commerce and Industry. Apart from the concerned departments of the Central government, the Council will also have representatives from the health care industry and quality control institutions.

Andhra Pradesh MedTech Zone, Visakhapatnam, will provide technical support to the Council.

The council will be tasked to promote and facilitate exports of medical devices, act as a platform for networking and garner views on industrial and trade policies and practices, provide technical assistance to various departments to simplify the approval process and drive a dynamic Preferential Market Access (PMA) policy while discouraging unfair trade practices in imports.

Source: www.moneycontrol.com

Indian Firms Can Now Access China's Cancer Drug Market

In a move that might open up opportunities for Indian pharmaceutical firms, China has opened its vast market of government hospitals to foreign companies manufacturing cancer drugs.

The government has included 17 cancer drugs manufactured by foreign companies in its national basic insurance programme. Half of the thousands of government-run hospitals have been asked to use these imported drugs for treating cancer of the lungs, rectum and kidney.

This is a major opportunity for the Indian pharmaceutical sector, which has been seeking access to the Chinese market. India-made drugs are relatively cheap compared to those made in the West, giving Indian companies a clear edge.

But there are questions about whether Indian companies would make the best of the opportunity. They have been reluctant to invest funds and the time it takes to conduct trials and get approval from regulators before releasing a drug, while Western companies are eager to do so.

The move comes after a public outcry against the non-availability and extremely high prices of foreign-made cancer drugs, forcing patients and their relatives to use smuggled medicines. Government-imposed restrictions led to the creation of a vast black market for cancer medicines that were smuggled from other countries, including India.

The government recently allowed a movie, *Dying to Survive*, to be widely screened across China. The movie showed how cancer drugs smuggled from India had become widely popular in China despite regular police crackdowns. One character in the movie was seen bitterly criticising government policy, a rare occasion where the Chinese government has allowed criticism of its policies.

At least 129 cancer hospitals and 1,257 tertiary hospitals have already begun to take advantage of the government's decision, which was taken some months ago but publicly announced only now.

"Availability of cheap drugs has greatly eased the financial burden of some cancer patients," state media quoted National Health Commission spokesperson Song Shuli as saying.

Source: ET HealthWorld

Fentanyl (Transdermal patches): Life-threatening and fatal opioid toxicity from accidental exposure

The MHRA has reminded health-care professionals to give clear information to patients and caregivers about how to minimise the risk of accidental exposure to fentanyl patches, particularly in children, and the importance of appropriate storage and disposal of patches. Fentanyl is a potent opioid analgesic and its overdose could

cause: respiratory depression; tiredness; extreme sleepiness or sedation; inability to think, walk, or talk normally; and feeling faint, dizzy or confused. Despite issuing advice to health-care professionals in 2014, the MHRA continue to receive reports of unintentional opioid toxicity and overdose of fentanyl due to accidental exposure to patches. Since July 2014, five reports of fatal incidents specifying accidental exposure, accidental overdose, or product adhesion issues were received. Accidental exposure to transdermal fentanyl can occur if a patch is swallowed or transferred to another individual. Fentanyl patches should be stored out of sight and reach of children. Reference: Drug Safety Update, MHRA, 11 October 2018 (www.gov.uk/drug-safetyupdate) (See WHO Pharmaceuticals Newsletter No.4, 2014: Reminder of potential life-threatening harm from accidental exposure, particularly in children; No.6, 2013: Packaging changes to minimize risk of accidental exposure in USA)

Fluoroquinolones: Potential risk of aortic aneurysm and dissection

The MHRA has announced that fluoroquinolones should only be used after careful assessment of benefits and risks, and after consideration of other therapeutic options in patients at risk for aortic aneurysm and dissection. Fluoroquinolones are antibiotics authorized for serious, lifethreatening bacterial infections and four of them (ciprofloxacin, levofloxacin, moxifloxacin and ofloxacin) are available in UK. Data from epidemiologic and non-clinical studies indicate an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones. Health-care professionals are advised to inform patients, particularly those at risk (e.g. elderly), about rare events of aortic aneurysm and dissection. It is important that patients seek immediate medical attention in case of sudden onset severe abdominal, chest or back pain. Reference: Drug Safety Update, MHRA, 14

November 2018 (www.gov.uk/drug-safetyupdate)

Rivaroxaban: Increase in all-cause mortality

The MHRA has announced that rivaroxaban treatment in patients who undergo transcatheter aortic valve replacement (TAVR) should be stopped and the patient should be switched to standard care. Rivaroxaban is indicated for the prevention of venous thromboembolism and treatment of deep vein thrombosis. Preliminary analysis of a phase three trial shows that risks of all-cause death and bleeding post-TAVR were approximately doubled in patients assigned to a rivaroxaban-based anticoagulation strategy compared with those assigned to receive an antiplatelet-based strategy (clopidogrel and aspirin). Reference: Drug Safety Update, MHRA, 11 October 2018 (www.gov.uk/drug-safetyupdate)

Dolutegravir: Risk of neural tube defects

The EMA has announced that PRAC confirmed its precautionary advice issued earlier this year on the use of dolutegravir in pregnant women and women who can become pregnant. Women who can become pregnant should use effective contraception while taking dolutegravir. Additionally, women should undergo a pregnancy test before starting treatment and the medicine should not be used during the first trimester of pregnancy unless there is no alternative. Dolutegravir is an antiretroviral medicine used in combination with other antiretroviral medicines to treat human immunodeficiency virus (HIV). The evaluation assessed preliminary results from a study that found cases of neural tube defects in babies born to mothers who used dolutegravir during pregnancy. Reference: EMA, 5 October 2018 (www.ema.europa.eu)

Pic of Health camp



Gangasagar Health Camp organized by IPA Bengal Branch & IPA Bengal Pharma & Health Care Trust

Forthcoming Event:

Pharma Times Conclave

Theme:

Transforming Disruptors into Enablers: For Universal Health Care

Date:

24th January 2019

Venue:

Hotel Orchid, Mumbai

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