Editorial

It is my proud privilege to pen the editorial at a historical moment—the completion of 12 years of publication of this Drug Information Bulletin. The weekly bulletin started its journey in April 2007, brought out by the Drug Information Centre (DIC), IPA, Bengal Branch and is now a fortnightly bulletin jointly published by DIC, IPA-Bengal Branch and Regulatory Affairs Division (RAD), IPA. As far as my information goes, this is the first of its kind of bulletin serving its readers from all spheres of the society like Pharmacist, Doctors, Nurses, health workers, NGOs, and general public worldwide. It has received accolades and great appreciation from most of the readers due to its content and its regular publication. Initially it was started to serve IPA members then receiving request from other professional stake holders, as well as request from other countries the bulletin marched ahead. Presently we have readers from different countries all over the world and different strata of society.

Some hospitals and educational institutes are forwarding this Bulletin among their faculty members and keeping hard copies in their libraries with our prior permission so that students can read this. A number of Drug Information Centers are reproducing this with our permission both in Government and private sector. A few international agencies have extended recognition like-Commonwealth Pharmacists Association (CPA), HIFA, UK etc.

This is a free service to anybody and everybody, and any person / institute interested in drug information, and we have never accepted any donation or advertisement from anybody for this publication to keep our voice unbiased. This has been possible due to help and co operation from all of our readers and mentors. Hope this bulletin will continue its service to the society with help from all of you in future too.

Greetings to all!

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Price of 42 non scheduled anticancer Drugs (390 brands) reduced by 30-86 Percent as a result of a recent order by NPPA: Boon for the Patients

OFFICE MEMORANDUM

Subject : Trade Margin Rationalisation of select Non-scheduled Anti-Cancer Drugs under paragraph 19 of DPCO, 2013.

National Pharmaceutical Pricing Authority (NPPA) vide Order SO No. 1041(E) dated 27.02.2019 put a cap of 30% Trade margin on Selling Price for the non-scheduled Anti-Cancer formulations containing any of the 42 drugs listed therein by invoking paragraph 19 of DPCO, 2013.

2. The NPPA directed manufacturers to fix their retail price based on price at first point of sale of product (referred as Price to Stockist), as per formula in Table A of aforesaid Order, of the non-scheduled formulations containing any of the 42 Non-Scheduled anti cancer drugs listed in the aforesaid Order (whether individual or in combination, irrespective of dosage strength, dosage form and/or route of administration).

3. The NPPA also directed manufacturers to provide the revised MRP of their formulations in Annexure I (details of PTS and MRP arrived for formulations by using the formula prescribed) of Order dated 27.02.2019 in respect of all non-scheduled formulations containing drugs as per Table B, irrespective whether there was any change in MRP or not, by 6th March, 2019, under paragraph 9(2) of the DPCO, 2013.

4. Further, information was also sought from 10 hospitals regarding these 42 drugs, to capture institutional data.
5. The revised MRP in respect of formulations arrived from these 42 drugs as per data provided by manufacturers, is at Annexure-X.

6. The revised prices shall come into effect from 8th March, 2019.

7. The onus of providing correct information rests with the manufacturer. The manufacturer will be liable for any aberration arising out of incorrect information or withholding correct information from NPPA.

8. It is further reiterated that the trade margin cap notified by S.O. No. 1041(E) dated 27.02.2019 is applicable on all the brands containing any of the 42 drugs listed in aforesaid Order, irrespective of whether the brand/formulation is included in the Annexure attached herewith.

9. All other conditions for non-scheduled formulations as per the provisions of DPCO, 2013 shall be applicable to the 42 drugs under reference.

10. The manufacturers not complying with the price arrived at through S.O. No. 1041(E) dated 27.02.2019 and notes therein, are liable to be acted against, under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(Amarpal Singh Sawhney)  
Director (Pricing)

The complete list of 42 anti-cancer drugs under price control

Annexure : X:
Revised MRP of 390 formulations Non-Scheduled Anti-Cancer Medicines w.e.f. 08.03.2019 (Based on data received till 07.03.2019)
Details are available at:

Study tests efficacy, safety of Ivermectin in childhood malaria
Data from a study published in the journal Lancet showed that repeated mass administration of the drug Ivermectin, a treatment for parasite infections, resulted in a 20% reduction in the incidence of malaria in children age 5 and younger in Burkina Faso. The 18-week trial, conducted during the country's 2015 rainy season to assess ivermectin's safety and efficacy, was financed by the Bill & Melinda Gates Foundation. Ref.: OnMedica

Statin use tied to increased diabetes risk, study finds
Researchers studied 9,535 people without diabetes, ages 45 or older, and found that those who took statins had higher insulin resistance and blood glucose levels after 15 years, and they were 38% more likely to develop type 2 diabetes, compared with those who did not take the drugs. The findings in the British Journal of Clinical Pharmacology revealed an even greater risk among those who had an impaired glucose balance and were overweight or obese. Ref.: Diabetes (UK)

Hydrochlorothiazide Risk of non-melanoma skin cancer
The Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that the Summary of Product Characteristics and Patient Information Leaflets for hydrochlorothiazide containing products have been updated to include the risk of nonmelanoma skin cancer as an adverse effect. Hydrochlorothiazide is indicated for hypertension and oedema associated with cardiac or hepatic diseases. Pharmacoepidemiological studies have shown a dosedependent risk of nonmelanoma skin cancer with exposure to increasing cumulative doses of hydrochlorothiazide. Healthcare professionals are advised to inform patients taking hydrochlorothiazide of the risk of non-melanoma skin cancer, particularly when used long-term, and advise them to report and check regularly for new or changed skin lesions or moles. Patients are also advised to limit exposure to sunlight and UV rays, and use adequate protection to minimise the risk of skin cancer. Reference: Drug Safety Update, MHRA, 14 November 2018 (www.gov.uk/drug-safety-update)

Insulin-containing products: cartridges and pre-filled pens risk of medication errors from extraction of insulin
The Health Products Regulatory Authority (HPRA) has updated the product information for insulin cartridges for reusable pens and prefilled (disposable) pens to include a warning on the risk of potential medication errors when extracting insulin, which could lead to serious hyper and/or hypoglycaemic episodes. Insulin pens and cartridges for reusable pens are for single patient use only. Blood and biological matter can regurgitate into the insulin cartridge during injection. Reusing a cartridge or pen for another patient exposes the second patient to a risk of transmission of any blood borne pathogens. The HPRA provided advice on actions to take if a device is not working and emphasized that extraction of insulin containing product from cartridges and pre-filled pens via a syringe is not recommended. Reference: Drug Safety Newsletter, HPRA, November 2018 (www.hpra.ie)

DISCLAIMER:
The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.