International Universal Health Day is being celebrated today throughout the globe with a theme “Leave No one behind when it comes to Health: Invest in Health Systems for all”. About half of the global population has no access to essential health services, about 100 million populations are going beyond the poverty line because of out of pocket expenditure on health. In order to improve the situation United Nations has adopted a resolution in its 67th session on global Health and Foreign Policy on 12th December 2012 recognizing the responsibility of Governments to urgently scale up efforts to accelerate the transition towards Universal access to affordable and quality health-care services.

In order to its proper implementation “Universal Health Coverage Coalition” has been formed comprising of 1000 organizations from 120 countries in the year of 2014. United Nations officially designated 12 December as International Universal Health Coverage Day in 2017. Government of India is also adopted some mechanisms to ensure UHC by 2030 like- Ayushman Bharat (PMJAY).

Pharmacists are also celebrating International Universal Health Day throughout the globe. Hope like all other stakeholders pharmacists will try their best to accelerate the process to achieve Universal Health Care.

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New Drug: Niraparib for ovarian cancer
Approved indication: ovarian cancer
Zejula (GlaxoSmithKline)
100 mg capsules

Ovarian cancer often presents late and tends to recur despite chemotherapy. This has led to a search for maintenance treatments for women with recurrent cancer. One approach is to inhibit the enzymes involved in the repair of DNA in tumour cells. In vitro, inhibition of the poly (ADP-ribose) polymerase (PARP) enzymes is cytotoxic and reduces tumour growth. Olaparib is a PARP inhibitor that has been used in ovarian cancer, but its efficacy is in tumours with mutations of the BRCA genes. Niraparib is a PARP inhibitor that may have efficacy in a wider range of tumours.

Patients start treatment within eight weeks of completing a course of chemotherapy. The recommended dose of niraparib is 300 mg once daily. Food does not significantly affect absorption. Most of the dose is metabolised with the metabolites being excreted in urine and faeces. This metabolism does not involve the cytochrome P450 system and there have been no drug–drug interaction studies. The half-life of niraparib is 36 hours, but it is unknown if this and other pharmacokinetic parameters are affected by severe kidney disease or moderate–severe hepatic impairment.

An open-label phase II treatment trial enrolled 463 women who had received a median of four chemotherapy regimens for ovarian, fallopian tube or primary peritoneal cancer. Most of these relapsed cancers had become resistant or refractory to platinum therapy. The patients took niraparib 300 mg daily with a median follow-up of 12.2 months. There was a response to treatment in 8% (38/456) of the women. The response rates varied with the genetics of the tumours. Overall survival was 17.2 months, but it was 26 months if there was a BRCA mutation.\(^1\)

The phase III NOVA trial of maintenance therapy enrolled 553 women with cancer of the ovary, fallopian tube or peritoneum. Despite sensitivity to platinum-based chemotherapy, the cancer had progressed. A BRCA mutation was present in 203 women. The patients were randomised in a 2:1 ratio to daily niraparib or a placebo and followed up for a median of 16.9 months. In the women who had BRCA mutations, the median progression-free survival was 21 months with niraparib and 5.5 months with placebo. The corresponding figures were 9.3 months and 3.9 months for the 350 women without a mutation. The actions of niraparib are not confined to cancer cells so all patients will experience adverse effects. In the NOVA trial 14.7% of patients given niraparib had to stop treatment because of adverse effects compared with 2.2% of the placebo group.\(^2\) As niraparib suppresses bone marrow, patients are at risk of anaemia, thrombocytopenia and neutropenia. These adverse effects may require treatment to be reduced or stopped, so the blood count should be regularly checked. In the NOVA trial 1.4% of the women taking niraparib developed myelodysplastic syndrome. Regular monitoring should also include pulse and blood pressure. Severe hypertension, including hypertensive crisis, affected 8.2% of the patients in the NOVA trial compared with 2.2% of the placebo group. Other adverse effects that are more frequent with niraparib than placebo include nausea, vomiting, constipation, fatigue, dyspnoea, mucositis and insomnia. Despite these common problems, the NOVA trial reported that the quality of life was similar for patients given niraparib or placebo.\(^3\)

On the evidence to date, niraparib has been approved as maintenance therapy for women with platinum-sensitive, relapsed high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who have had a complete or partial response to platinum-based chemotherapy. However, it is currently uncertain if the advantage of niraparib over placebo in progression-free survival will lead to a confirmed improvement in overall survival. When the NOVA trial was published, 16.1% of patients given niraparib had died compared with 19.3% of the placebo group.\(^2\) Further research will be needed to identify which women are most likely to benefit from a PARP inhibitor. A phase II trial has reported that progression-free survival is greater if niraparib treatment is combined with bevacizumab, compared to niraparib alone.

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Niraparib maintenance therapy has also been found to improve progression-free survival compared to placebo (median 13.8 vs 8.2 months) in a phase III trial involving women with newly diagnosed advanced ovarian cancer.\(^3\)

References:

Ref. Australian Prescriber

Status in India: It is available in India.

SEC Asserts COVID Booster Shots Shouldn’t Be Recommended Without Proper Clinical Trials
In the wake of the COVID-19 pandemic and never-ending speculations over vaccines against it, the Subject Expert Committee (SEC) under Central Drugs Standard Control Organisation (CDSCO) has stated COVID-19 booster doses should not be recommended without clinical trials. The observation arose while the SEC was reviewing the application of the Serum Institute of India (SII) for the COVID-19 booster dose in a meeting that took place on December 12.

The panel has sought additional data from SII and would evaluate the contention upon deliberations in person. Amid the emergence of the new COVID-19 variant Omicron, the SII has been seeking approval to administer the booster dose of its Covishield vaccine on the basis of adequate stock of the jab and rising demand for the booster shots.

Omicron Now Has Three Sub-Variants, Say Experts
The variant of concern, Omicron, has now three siblings – one up from two sub-lineages discovered last week.
According to Phylogenetic Assignment of Named Global Outbreak Lineages (PANGOLIN) that assigns lineages under ‘Pango lineage’ system to various viruses including the novel coronavirus that causes Covid-19, the third outlier of Omicron was found from a sample collected from England on December 3. The new outlier of Omicron variant is temporarily named England/MILK-2D24AC9/2021.
Dr Vinod Scaria of Institute of Genomics and Integrative Biology (IGIB), New Delhi, confirmed the development by tweeting late on Sunday about the new outlier of Omicron lineage with some shared mutations.
Omicron variant or B.1.1.529 split into two sub-lineages BA.1 and BA.2 earlier this month. These two variants have some shared mutations, besides some mutations that are unique to them. “A new diverse genome has appeared within the B.1.1.529 lineage that has all of the shared mutations of B.1.1.529, some of the mutations unique to BA.1 and some unique to BA.2 plus a few of its own,” PANGOLIN announced in its website.
Experts say though Omicron has been spreading faster than previous variants, most cases are mild.
Colchicine Risk of fatality if overdose
The Medsafe has issued a warning reminding the public of the high risk of fatality with colchicine overdose and that there are no effective treatments available for severe colchicine poisoning. Colchicine is indicated for the treatment of acute gout when nonsteroidal anti-inflammatory drugs are contraindicated, ineffective or not tolerated. Although colchicine has a narrow therapeutic index with the well-defined separation between therapeutic and toxic doses, some clinical guidelines may refer to unapproved dosing schedules for colchicine. From January 2016 to January 2021, the National Poisons Centre (NPC) received 56 cases related to colchicine poisoning. The main reasons of the poisoning were child exploratory behavior, therapeutic error and intentional self-poisoning. Health-care professionals should communicate with patients about the importance of storing medicines out of sight and reach of children and ensure patients know when and how to take colchicine.
Reference: Prescriber Update, Medsafe, June 2021 (www.medsafe.govt.nz/)

Remdesivir Risk of sinus bradycardia
The PRAC has recommended a change to the product information for remdesivir (Veklury®) to include sinus bradycardia as an adverse drug reaction. Remdesivir is indicated to treat COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen. The PRAC reviewed available data on rare reported cases of bradycardia in patients treated with remdesivir as well as data from clinical trials and the scientific literature. The PRAC concluded that a causal relationship between the use of remdesivir and the event is reasonably possible and recommended the revision of the product information. The majority of the events of sinus bradycardia resolved a few days after the treatment with remdesivir was discontinued.

Prednisone Risk of steroid withdrawal symptoms
The Medsafe has warned of cases of steroid withdrawal symptoms, such as, shaking, sweats, fatigue, puffy face and swollen legs, after taking high-dose prednisone for infective exacerbations of asthma. Prednisone is a corticosteroid that is indicated for treatment of several conditions such as arthritis, blood disorders, breathing problems and severe allergies. Prednisone dosing should be determined on a case by case basis taking into consideration the condition being treated and its severity. Generally, prednisone should be used at the lowest effective dose and for the shortest duration. Prolonged use of prednisone can result in suppression of the hypothalamic-pituitary-adrenal axis. Abrupt cessation or a too rapid withdrawal of prednisone may cause symptoms of adrenal insufficiency such as abdominal pain, nausea, diarrhea and hypotension.
Reference: Prescriber Update, Medsafe, June 2021

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