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NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH DEEMED UNIVERSITY

JAN-JUN 2022 Vol VIII Issue 1

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Managing Editors View

The goal of a Pharmacy newsletter's editorial team is to deliver valuable insights and knowledge to their readers, which they can use to improve their practice and patient care. We are here to provide timely and relevant information on the latest developments and trends in the pharmacy Industry, including news on drug approvals, new devices and clinical research.

This newsletter also includes articles on professional development, patient education, and practice management. Community programs organized by the Department of Pharmacy can play a vital role in improving awareness about various health-related issues, including medication safety, disease prevention, and overall health promotion. This Newsletter would be helpful to empower pharmacists with the skills and knowledge they need to provide better care and services to their patients.



Dr. Dipti Gohil
Associate Professor

NEW DRUG APPROVAL

1. Gimeracil bulk & Oteracil potassium bulk and Tegafur 15mg/20mg, Gimeracil 4.35mg/5.8mg and Oteracil 11.8mg/15.8mg capsules

Indication: Gastric cancer, Advanced, in combination with cisplatin:

- Pretreatment: Follow the European Medicines Agency (EMA)-approved pretreatment hyperhydration for cisplatin infusions, and provide antiemetic and antidiarrheal agents during therapy.
- Dosing: The dose for the treatment of advanced gastric cancer in adults is tegafur/gimeracil/oteracil monopotassium 25 mg/m² (expressed as tegafur content) orally twice daily, morning and evening, on days 1 through 21 of a 28-day cycle in combination with cisplatin 75 mg/m² IV infusion once every 28 days. Administer cisplatin for up to 6 cycles; continue tegafur/gimeracil/oteracil monopotassium until disease progression or intolerable toxicity.

Note: Do not substitute tegafur/gimeracil/oteracil monopotassium for other oral 5-fluorouracil products

Dosage in Renal Failure

- Initial Dose Modification: For patients with mild renal impairment (CrCl, 50 mL/min or greater), no dose adjustment is required. For patients with moderate renal impairment (CrCl, 30 to 50 mL/min), the recommended initial dose is 20 mg/m² orally twice daily (expressed as tegafur content) on days 1 through 21 of a 28-day cycle. Use in patients with severe renal impairment (CrCl, less than 30 mL/min) is not recommended
- Dose Adjustments During Therapy: Base renal dose adjustments on CrCl determined prior to initiating treatment on day 1 for every cycle.

Side effects: Hypertension, Hypotension, Peripheral edema, Alopecia, Hand-foot syndrome, Hyperpigmentation of skin, Pruritus, Rash, Xeroderma, Hyperkalemia, Hypoalbuminemia, Constipation, Diarrhea, Loss of appetite, Nausea, Anemia Grade 3 or higher, leukopenia, Neutropenia, Thrombocytopenia, Asthenia, Peripheral neuropathy, Lacrimal System disorder, Fatigue.

Contraindications & Caution:

- Concomitant use with other fluoropyrimidines.
- Dihydropyrimidine dehydrogenase deficiency.
- ESRD requiring dialysis.
- History of severe and unexpected reactions to fluoropyrimidine therapy.
- Hypersensitivity to tegafur, gimeracil, oteracil, or any component of the product.
- Pregnancy or breastfeeding.
- Severe bone marrow suppression
- Treatment within 4 weeks with dihydropyrimidine dehydrogenase inhibitors, including sorivudine or chemically related analogs (eg, brivudine)

Pregnancy: Avoid use of this drug during pregnancy and prescribe an alternative. Evidence has demonstrated fetal abnormalities or risks when

used during pregnancy. Advise women of childbearing potential of fetal risk.

Source: 1. List of new drugs approved in the year 2022

https://cdsco.gov.in/opencms/opencms/system/modules/CDSO.WEB/elements/download_file_division.jsp?num_id=ODg5Ng==

2. Vericiguat tablets 2.5mg/5mg/10mg

Indication: Heart failure, chronic, To reduce the risk of cardiovascular death and heart failure hospitalization in symptomatic patients with reduced ejection fraction:

- Initial Dosage: 2.5 mg orally once daily with food
- Dosage titration: Double the daily dose approximately every 2 weeks as tolerated
- Target maintenance dose: 10mg once daily.

Dosage in Renal Failure

- Estimated GFR (eGFR) 15 mL/min/1.73 m² or greater and not on dialysis: No dosage adjustment recommended
- eGFR less than 15 mL/min/1.73 m²: Not studied

Side effects: Hypotension Anemia.

Contraindications & Caution:

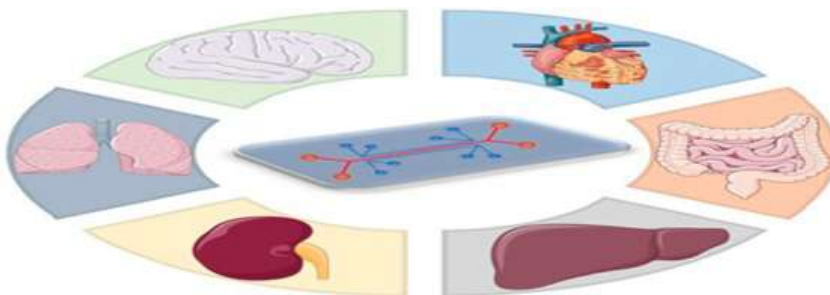
- Concomitant use of other soluble guanylate cyclase (sgc) stimulators.
- Pregnancy

Source: 1. List of new drugs approved in the year 2022

https://cdsco.gov.in/opencms/opencms/system/modules/CDSO.WEB/elements/download_file_division.jsp?num_id=ODg5Ng==



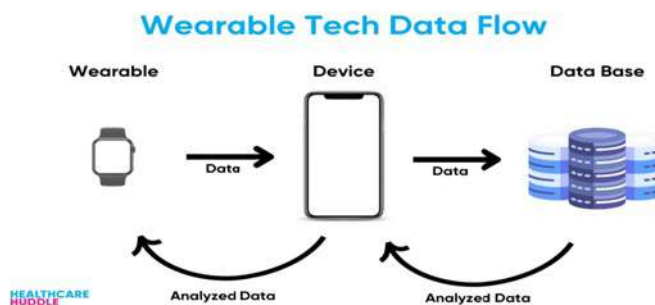
ORGANS-ON-CHIPS



- Organs-on-chips technology is a rapidly advancing area of research that has the potential to transform the way drugs are developed and tested.
- Organs-on-chips are microfluidic devices that mimic the structure and function of human organs, allowing researchers to test the safety and efficacy of drugs in a more accurate and efficient manner. This technology can help reduce the need for animal testing and speed up the drug development process.
- In pharmacy, organs-on-chips technology can be used to model the behavior of different organs in response to drugs and disease, providing insights into drug toxicity, efficacy, and mechanism of action. This can help identify potential drug candidates earlier in the development process and reduce the risk of adverse reactions in patients.
- Organs-on-chips technology can also be used to personalize medicine by testing drug responses in patient-specific tissues. This can help identify the best treatment option for individual patients, reducing the need for trial and error in prescribing drugs.
- It has the potential to revolutionize drug discovery and development by providing a more accurate and efficient way to test drugs. However, there are also challenges associated with implementing organs-on-chips, such as the need for standardization and scalability, as well as regulatory and ethical considerations.

Reference: Singh D, Mathur A, et.al. Journey of organ on a chip technology and its role in future healthcare scenario. Applied Surface Science Advances. 2022 Jun;9:100246.

WEARABLE TECH INTEGRATION



Wearable technology has the potential to revolutionize the pharmacy industry by enhancing patient care, improving medication adherence, and increasing efficiency. Here are some examples of how wearable tech can be integrated into pharmacy:

- **Smartwatches:** Smartwatches can be used to remind patients to take their medication at the right time. The watch can also track the patient's medication history and send alerts to the patient's healthcare provider if the patient misses a dose.
- **Activity trackers:** Activity trackers can help patients monitor their physical activity, sleep patterns, and other health metrics. This data can be used to tailor medication dosages or adjust treatment plans.
- **Health monitoring devices:** Wearable devices such as blood pressure monitors, glucose monitors, and heart rate monitors can help patients track their health and alert their healthcare provider if there are any significant changes in their health status.
- **Roche is another early adopter of wearable tech integration.** The company paired its mySugr app with the Accu-Chek Guide glucose meter, enabling people with diabetes to experience a different, more responsive way to manage the condition.
- **Electronic health records:** Wearable tech can integrate with electronic health records, allowing pharmacists to access real-time data on patients' health status and medication use. This information can help pharmacists make more informed decisions about patient care.

Reference: <https://www.cprime.com/resources/blog/advantages-of-integrating-wearable-health-technology-into-your-ehr-system>

A Case Report on Sub-Arachnoid Hemorrhage

Bleeding is a warning indication for many patients and persistent or recurrent hemorrhage leads to visit critical care facility. Brain computed tomography should be used to check for a ruptured aneurysm or an underlying SAH. The following are some of the methods for determining the underlying cause of SAH: Computed tomography angiography, magnetic resonance angiography and digital subtraction angiography are the 3 types of angiographies. Subarachnoid Hemorrhage (SAH) is a condition of bleeding in the space between the brain and the tissues covering the brain. A medical emergency is frequently caused by burst blood artery in the brain (aneurysm). If this condition not treated properly it may result into permanent damage to the brain or death. Arachnoid mater– the middle layer of the meninges inferior to the dura mater and superior to the pia mater. The term arachnoid is a reference to the spider web like appearance of the arachnoid mater fibres where they attach to the underlying pia mater. Sub-arachnoid space- it is located between the arachnoid mater and the underlying pia mater. It contains the arachnoid trabeculae. The arachnoid trabeculae are thin fibrous filaments that hold the two surfaces in place. The subarachnoid space is bounded by impermeable arachnoid and pia mater, it become full with CSF also provide pathway for the CSF circulation and absorption around the encephalon and vertebral column.

Case description: A 36-years-old male was referred to the critical care department of our tertiary care teaching hospital with a complaint of severe frontal headache and vomiting from past 2 days. He had history of HTN and was not on any medication. Brain CT-SCAN was performed. Radiological finding of CT-SCAN shows Acute Sub-arachnoid Hemorrhage (SAH) in the in the split between the hemispheres, basal cistern, prepontine cistern, ambient cistern and small extension into bilateral sylvian cisternal spaces and along the tentorium in posterior aspect. The patient deceased after 27 days of admission.

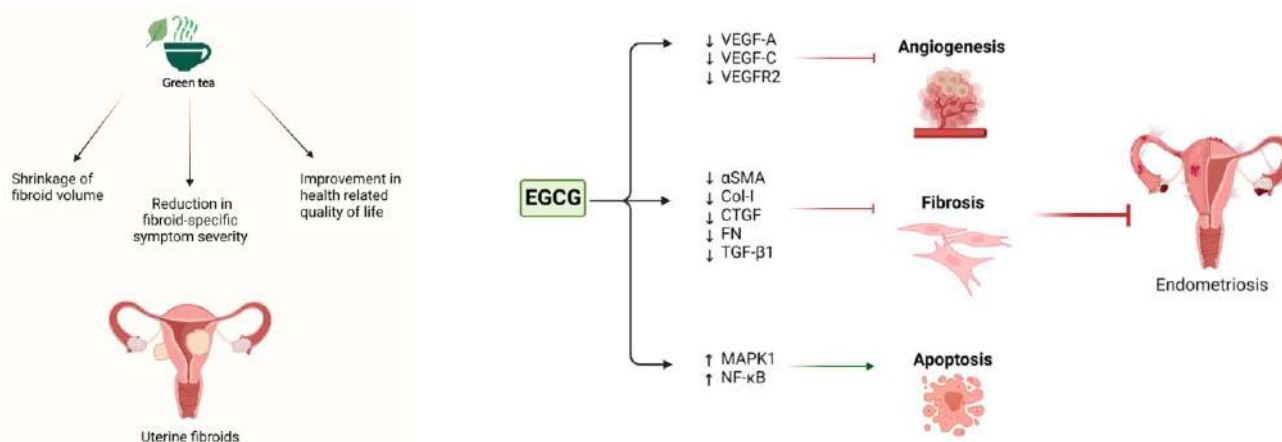
Treatment: Treatment focuses on stabilizing your condition, treating an aneurysm and preventing complications. If bleeding is caused by a ruptured brain aneurysm then Surgery is performed : The surgeon makes an incision in the scalp and locates the brain aneurysm. A metal clip is placed on the aneurysm to stop the blood flow to it. Endovascular embolization : The surgeon inserts a catheter into an artery and threads it to your brain. Detachable platinum coils are guided through the catheter and placed in the aneurysm. Other endovascular treatments : Certain aneurysms can be treated with endovascular embolization that uses newer technology such as stent-assisted or balloon-assisted coiling or devices that divert blood flow.

Conclusion: In this case report, a 36-year-old male patient who has a Sub Arachnoid Hemorrhage (SAH) which is not a infrequent condition but Subarachnoid hemorrhage may be caused by trauma or occur spontaneously. Even if diagnosed and treated early, it is a life-threatening situation that can result in death or serious disability. Observation for indicators of intracranial mass effect, medication, and early neurosurgical intervention are all a component of the therapy. Ten to Fifteen percent of folks with subarachnoid hemorrhage die earlier than arriving on the sanatorium, and only half of live on to clinic discharge. Physicians must recognise subarachnoid haemorrhage as soon as feasible, since early diagnosis of persistent headache reduces the risk of mortality and quality of life.

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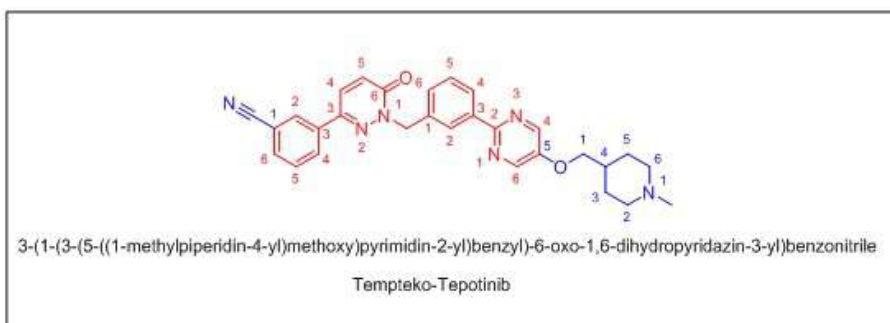
Green tea holds potential as treatment for uterine fibroids, PCOS, and menopausal symptoms

Tea is a beverage made from the leaves of the *Camellia sinensis* plant and is widely consumed across the world, and green tea is one of the popular varieties. Of the many antioxidant and polyphenolic compounds found in green tea, epigallocatechin gallate (EGCG) is one of the major active compounds. It has been widely explored as a chemotherapeutic agent against various forms of cancer. Millions of women worldwide experience benign reproductive disorders such as fibroids, endometriosis, polycystic ovarian syndrome (PCOS), adenomyosis, and dysmenorrhea. Properties of Green tea: The nutrients present in green tea include lipids, carbohydrates, a wide variety of vitamins, amino acids, carotenoids, chlorophyll, and alkaloids such as caffeine, theobromine, and xanthine. Additionally, trace elements such as zinc, calcium, copper, iron, magnesium, chromium, and manganese are also found in green tea. Benefits against gynecological disorders:



Source: <https://www.news-medical.net/news/20230321/Green-tea-holds-potential-as-treatment-for-uterine-fibroids-PCOS-and-menopausal-symptoms.aspx>

“Tempetko(Tepotinib): A Promising Targeted Therapy for MET-Overexpressing and Mutated Cancers”



Pharmacology:

- Tepotinib is an oral tyrosine kinase inhibitor targeted against MET for the treatment of metastatic non-small cell lung cancer in patients exhibiting MET exon 14 skipping mutations.
- Pharmacokinetics and pharmacodynamics:
 - The absolute bioavailability of tepotinib following oral administration is approximately 72%.^{7,3} At the recommended dosage of 450mg once daily, the median T_{max} is 8 hours and the mean steady-state C_{max} and AUC_{0-24h} were 1,291 ng/mL and 27,438 ng·h/mL, respectively.
 - Co-administration with a high-fat, high-calorie meal increases the AUC and C_{max} of tepotinib by approximately 1.6-fold and 2-fold, respectively
 - When Tepotinib is a highly selective inhibitor of MET kinase activity, requiring once-daily dosing. However, it has been associated with interstitial lung disease (ILD)/pneumonitis, which can be fatal. Patients must be monitored for respiratory symptoms and treatment immediately withheld if ILD/pneumonitis is suspected. If no other causes are identified, tepotinib should be discontinued indefinitely.

Mechanism of action:

- Tepotinib inhibits MET, a protein commonly overexpressed or mutated in tumors, to slow or stop cancer cell growth and movement. It also downregulates genes that promote aggressive cancer behavior and upregulates those that suppress it. Tepotinib also inhibits other proteins, though their relevance to its cancer-fighting mechanism is uncertain. Overall, tepotinib is a promising drug for targeting the MET pathway in cancer treatment.

Spectrum of Activity:

- For Metastatic no small cell lung cancer is a type of lung cancer that has spread beyond the lung to other parts of the body, such as the liver, bones, or brain. It is the most common form of lung cancer and often diagnosed at an advanced stage, making it more difficult to treat

Drug interactions:

- Tepotinib has the potential to interact with other drugs or substances, which can affect its efficacy or increase the risk of side effects. For example, the concomitant use of strong CYP3A inhibitors, such as ketoconazole or clarithromycin, may increase the exposure to tepotinib and lead to toxicity. Similarly, the concomitant use of strong CYP3A inducers, such as rifampicin or carbamazepine, may reduce the exposure to tepotinib and lower its effectiveness. Tepotinib can also interact with drugs that affect the QT interval, such as class IA or III antiarrhythmic agents or certain antipsychotics, and increase the risk of arrhythmias. Therefore, caution should be exercised when administering tepotinib in combination with these drugs.
- In addition, tepotinib can inhibit the activity of drug transporters such as P-gp and BCRP, which may affect the pharmacokinetics of co-administered drugs that are substrates of these transporters.

Conclusion:

- Tepotinib shows promise as a treatment for cancers with overexpressed or mutated MET, inhibiting cancer cell growth and promoting tumor suppression by regulating gene expression. However, its potential interactions with other drugs and uncertain efficacy for some cancers, such as nonsmall cell lung cancer, require further research. Nonetheless, tepotinib represents a promising avenue for targeted cancer therapy that warrants continued investigation.

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- https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214096s000lbl.pdf
<https://go.drugbank.com/drugs/DB15133>

WHO GUIDELINE on control and elimination of human schistosomiasis (14 Feb 2022)

WHO GUIDELINE on control and elimination of human schistosomiasis (14 Feb 2022)

RECOMMENDATION 1.

In endemic communities with prevalence of *Schistosoma* spp. infection $\geq 10\%$, WHO recommends annual preventive chemotherapy with a single dose of praziquantel at $\geq 75\%$ treatment coverage in all age groups from 2 years old, including adults, pregnant women after the first trimester and lactating women, to control schistosomiasis morbidity and advance towards eliminating the disease as a public health problem.

RECOMMENDATION 2.

In endemic communities with prevalence of *Schistosoma* spp. infection $< 10\%$, WHO suggests one of two approaches based on programmatic objectives and resources: (i) where there has been a programme of regular preventive chemotherapy, to continue the intervention at the same or reduced frequency towards interruption of transmission; or (ii) where there has not been a programme of regular preventive chemotherapy, to use a clinical approach of test-and-treat, instead of preventive chemotherapy targeting a population.

Routine induction of labour, for women with uncomplicated pregnancies, at less than 41 weeks is not recommended (low-certainty evidence).

RECOMMENDATION 3.

In endemic communities with prevalence of *Schistosoma* spp. infection $\geq 10\%$ that demonstrate lack of an appropriate response to annual preventive chemotherapy, despite adequate treatment coverage ($\geq 75\%$), WHO suggests consideration of biannual (twice yearly) instead of annual preventive chemotherapy.

RECOMMENDATION 4.

WHO recommends that health facilities provide access to treatment with praziquantel to control morbidity due to schistosomiasis in all infected individuals regardless of age, including infected pregnant excluding the first trimester, lactating women and pre-SAC aged < 2 years. The decision to administer treatment in children under 2 years of age should be based on testing and clinical judgement.

RECOMMENDATION 5.

WHO recommends WASH interventions, environmental interventions (water engineering and focal snail control with molluscicides) and behavioural change interventions as essential measures to help reduce transmission of *Schistosoma* spp. in endemic areas.

RECOMMENDATION 6.

In communities approaching the interruption of transmission (defined as having no autochthonous human cases reported for 5 consecutive years), WHO suggests a verification framework that consists of:

1. Testing for *Schistosoma* infection in humans with a diagnostic that has high sensitivity and specificity. This may require the use of a two-step diagnostic process starting with a high sensitivity test confirmed with a second, high specificity test.
2. Testing for *Schistosoma* infection in snails with a diagnostic that has high sensitivity and specificity. This may require the use of a two-step diagnostic process starting with a high sensitivity test confirmed with a second, high specificity test.

Source: <https://www.who.int/publications/who-guidelines>

DRUGS IN CLINICAL TRIAL

Zimura

Company: Iveric Bio

Disease: Geographic Atrophy

Treatment type: Oligonucleotide

Trial: Gather-2

Six years ago, a biotech named Ophthotech was among the industry's most closely watched companies. Wall Street viewed a prospective eye drug it was developing as a threat to top-selling medicines from Regeneron and Roche. Shares climbed as high as \$79 apiece before the treatment failed multiple Phase 3 tests, triggering layoffs, a strategic reset and a name change to Iveric Bio.

Though Iveric rebranded as a gene therapy maker, a biologic drug held over from the Ophthotech days remains its most valuable asset. Known as Zimura, the drug is in clinical testing for geographic atrophy, a form of blindness with no effective treatments. Phase 3 results are expected this fall.

Iveric is following a blueprint laid out by Apellis Pharmaceuticals. Both are developing drugs that tamp down the activity of the complement system, a part of the body's innate immune response. Apellis' medicine produced mixed results in late-stage testing that the company used to support an approval application in June. Now, Iveric aims to catch up.

Zimura already succeeded in one Phase 3 trial, the results of which were published in the journal of the American Academy of Ophthalmology in 2020. Success in a second study as well could set Iveric's drug apart from Apellis' medicine

Source: <https://www.biopharmadive.com/news/biotech-10-clinical-trials-watch-2022-second-half/625359/>

Sotatercept

Company: Merck & Co.

Disease: Pulmonary arterial hypertension

Treatment type: Fusion protein

Trial: STELLAR

Merck & Co. paid \$11.5 billion to buy Acceleron Pharma and its drug sotatercept in the industry's second-largest deal last year.

Sotatercept, once the focus of a partnership between Acceleron and Celgene, appeared to hit a dead end in 2016 when the research was deprioritized. But Acceleron breathed new life into sotatercept by testing it in pulmonary arterial hypertension, a rare and potentially deadly type of high blood pressure in the lungs. Posititanercept data reported in 2020 and later published in The New England Journal of Medicine sent Acceleron's shares soaring. Merck acquired the company less than two years later, betting on sotatercept's potential as a first-of-its-kind treatment for the disease.

Merck will soon see whether that gamble pays off. By the end of the year, Merck could report results from a study called STELLAR, the first of four Phase 3 trials of sotatercept. Merck is counting on sotatercept not only to justify its sizable investment, but to replace revenue it will lose when its top cancer drug Keytruda goes off patent in 2028.

Source: <https://www.biopharmadive.com/news/biotech-10-clinical-trials-watch-2022-second-half/625359/>

WORLD CANCER DAY-2022

Department of Pharmacy, Sumandeep Vidyapeeth organized awareness activity of Cancer at village 'Piparia' on the occasion of World Cancer Day-2022. The students from Department of Pharmacy, SVDU had prepared posters and pamphlets subjecting to awareness of Cancer. They explained about types of cancer, symptoms and preventive action to be taken to villagers and school students. This information was provided to audience in local language (Gujarati) for their better understanding. Pharmacy Students had a very good experience about communication with people and they also received a good response from local people of village and the school staff as they were happy and satisfied with the event.



INTERNATIONAL WOMEN'S DAY

On International women's day, awareness programme was conducted by Women welfare and Antisexual committee, Department of Pharmacy, SVDU in collaboration with Banaj Primary School, Banaj on 8th March 2022. International women day is a global day celebrating the social, economic, cultural and political achievements of women. The theme for International Women's Day (8 March), is "Break the bias," It marks the tremendous efforts by women and girls around the world in shaping a more equal future. So, empowering women, making them aware of their right and economically independence is playing an important role in development of nation. Faculties and Students travelled to Banaj village, Karjan, organized a rally and interacted with some villagers regarding Educating of Girl child and equality among for both genders at Banaj Primary School. Thereafter students of Sumandeep Vidyapeeth organized a Drama/Skit pertaining for Educating Girl Child. Also, three student of Department of Pharmacy presented speech regarding gender equality. Chief Guest Mrs. Archana K Kale (Social worker), gave speech to all students, villagers, children regarding Women Empowerment. Sumandeep Students also had organized some games for school children and their guardians.



"IT'S TIME TO REMOVE "L" FROM LEARN"

Department of pharmacy, Sumandeep Vidyapeeth organized It's time to remove "L" from Learn" seminar related to Financial management for teaching and non teaching staff. A Webinar was arranged on 23th June. Interactive speech was delivered by Mr. Rinkal Patel; Financial Planner, Shubh Wealth, Vadodara. He discussed Term Insurance, Health Insurance and Systemic Investment Planning. He also discussed the Amount of Investment, terms of Investment and frequency of Investment. He deliberated about professional asset management of various securities (shares, bonds and other securities/assets).





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