DIRC Newsletter

Vol. 23 | No. 1 | January – June 2021

Newsletter of Drug Information and Research Center, KSPC

Member of International Society of Drug Bulletins (ISDB)

Official Desk

Dear Pharmacists,

Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT)

Sri. Gangadhar V. Yavagal
President
Karnataka State
Pharmacy Council

Karnataka State Pharmacy Council had started a social welfare scheme called Karnataka Pharmacy Council Registered Pharmacist Welfare Trust (KPCRPWT) during 1998 which is a unique scheme established for the first time in India with a concern on the welfare of the pharmacist and his/her family.

The scheme is extended to the ailing pharmacists suffering from diseases such as Cancer, Kidney Failure, Bypass Surgery and other ailments of serious nature (in case the scheme is well responded by the members) as decided by the trust.

Majority of the Pharmacist have enrolled in the Trust. During the 2nd wave of Covid many of our pharmacists have expired due to corona in Karnataka as they were serving as frontline warriors.

The Trust has released an amount of Rs.2,00000/- per nominees for those Pharmacists who were enrolled in the Trust. Many families were very thankful for this support, and they appreciated the President, Managing Trustee and the members of this Trust for this support.

We also observed that many Pharmacists has not enrolled to Trust but after the death of the pharmacist, our Trust office has received several enquiries for the claims. But unfortunately, Trust was unable to support the nominee since the Pharmacist has not enrolled for the Trust even after several reminders and advertisements.

Once again, I wanted to remind you that, if you or your fellow pharmacists has not enrolled and are interested to enrol, kindly enrol to this Trust at the earliest. ❑

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Guest Column

Community Pharmacist: The Frontline Healthcare Professional

Abstract

Community Pharmacists are frontline primary health care provider. They are easily accessible to the public and extend plethora of advice relating to health, hygiene, nutrition, vaccination and comprehensive medication management in chronic diseases. Services provided by Community Pharmacists contribute in a big way to meeting and achieving national health care goals and needs of society. Advance practice models in

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community pharmacy services are gaining fast acceptance across the globe. These include patient-centred services like immunization and administration of vaccines, management of minor ailments and referrals, screening, prevention and health care support for self-care, home care, geriatric care etc. In therapeutics, patient compliance is most important factor affecting ultimate outcomes of therapy. Patient counselling by community pharmacist considerably improves compliance and thus efficacy of prescription. This leads to reduction in medication errors and untoward effects of medicines. Proper demonstration of administration techniques in case of self-administration of medicines is very important, especially for medicines meant for insertion into body cavities - eye, ear, nose, rectum, vagina, buccal and sublingual spaces etc. The preventive services specially include screening for diabetes, cholesterol, hypertension, and osteoporosis. The management of minor ailments at appropriate time helps in reducing the burden on health care infrastructure and cost. This goes very well with the English proverb 'a stitch in time saves nine'. Thus, Community Pharmacists effectively improve the efficiency of total health care landscape of a nation. In nutshell, the pharmacist enhances efficacy and safety of the prescription as a result of which burden of medication errors and iatrogenic diseases reduces.

Introduction

Professional capability of any individual depends on the quality of education and training imparted. How current is the curriculum, how up to date are the practical and how authentic are the resource materials utilized for acquiring knowledge, besides the depth and extent of exposure to real time practice environment during internship are the major factors responsible for producing a professional par excellence or a mediocre or a worse than below average professional. No professional can acquire skill without appropriate internship. No profession can do justice to its clients unless education and training are up to mark and knowledge is continuously updated based on practice based research, not text book content.

In 1994, WHO[1] described community pharmacists as follows:

> *"Community pharmacists are the health professionals most accessible to the public. They supply medicines in accordance with a prescription or, when legally permitted, sell them without a prescription. In addition to ensuring an accurate supply of appropriate products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health professionals, patients and the general public, and participation in health-promotion programmes. They maintain links with other health professionals in primary health care."*

In 2011, International Pharmaceutical Federation (FIP) adopted strategic objectives for advance pharmacy practice and WHO adopted standards for quality of pharmacy services. Good Pharmacy Practice (GPP)[2] guidelines mandated observance of three major types of activities-

(i) related to the compounding, preparation and dispensing of medicines, medical devices and other health products.

(ii) associated with treatment monitoring - Medication therapy management (MTM);

(iii) aiming to promote health and well-being of patients and the population, and to reach health objectives including immunization, personal and social hygiene, health education, preventive care, management of minor ailments etc.

In 2012, the International Labour Organization[3] (ILO) developed a set of norms for pharmacists in its International Standard Classification of Occupations which defines Pharmacist as follows:

> *"Pharmacists store, preserve, compound, and dispense medicinal products and counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors and other health professionals. They contribute to researching, testing, preparing, prescribing, and monitoring medicinal therapies for optimizing human health."*

As per this ILO document[3] the tasks of Pharmacists include-

(a) receiving prescriptions for medicinal products from medical doctors and other health professionals, checking patients' medicine histories, and ensuring proper dosage and methods of administration and drug compatibility before dispensing.

(b) preparing or supervising the preparation and labelling of liquid medicines, ointments, powders, tablets, and other medications to fill prescriptions.

(c) providing information and advice to prescribers and clients regarding drug interactions, incompatibility and contra-indications, side effects, dosage, and proper medication storage.

(d) collaborating with other health care professionals to plan, monitor, review, and evaluate the quality and effectiveness of the medicine therapy of individual patients, and the effectiveness of particular drugs or therapies.

(e) maintaining prescription files and recording issue of narcotics, poisons, and habit-forming drugs in accordance with legal and professional requirements.

(f) storing and preserving vaccines, serums and other drugs subject to deterioration.

(g) advising clients on and supplying non-prescription medicines and diagnostic and therapeutic aids for common conditions.

(h) supervising and coordinating the work of pharmacy technicians, pharmacy interns and pharmacy sales assistants.

(i) conducting research to develop and improve pharmaceuticals, cosmetics and related chemical products.

(j) conferring with chemists, engineering professionals and other professionals about manufacturing techniques and ingredients.

(k) testing and analysing drugs to determine their identity, purity and strength in relation to specified standards.

(l) evaluating labels, packaging, and advertising of drug products.

(m) developing information and risks of particular drugs.

In March 2016, the **Board of Pharmaceutical Practice** of the FIP [4] adopted the following definition of a "pharmacist":

> *"A pharmacist is a scientifically-trained graduate healthcare professional who is an expert in all aspects of the supply and use of medicines. Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and healthcare systems."*

FIP also asserted that 'Responsible use of medicines' can be assured by integration of health-system stakeholder activities and capabilities to ensure that patients receive the right medicines at the right time, use them appropriately, and benefit from them. Bringing the right medicines to patients who need them requires the coordinated efforts of health care team. In fulfilment of this task commitment of government, and a vision on how to integrate public and private interests and mobilise resources plays important role.

Pharmacy Vision 2020

The FIP Pharmacy Vision 2020 edifice is founded on three pillars, which include –

(i) Pharmacists providing value.

(ii) Inter-professional teams and collaborative care; and

(iii) New technologies (e-health and m-health)

The importance of professional ethics has been adequately emphasized in this document. The first pillar of providing value relies on adopting improved models of services which must be evidence-based, outcome oriented and patient-centred. The second pillar emphasizes collaborative teamwork with other health care providers to ensure access to affordable quality medicines. Finally, the third pillar of the edifice supports application of cutting-edge technologies to enhance health care information for encouraging personal wellness and prevention of diseases. Facilitating communication between patient and other health care providers is an aspect of telehealth (e-health) and telemedicine (e-medicine) especially useful for remote and rural areas. Assessment and validation of effectiveness of applied technologies is integral part of this strategy.

Thus, the objectives of the Pharmacy Vision 2020 are very loud and clear. It is for the practicing pharmacists to train and equip themselves for effective achievement of the goal and establishment of emerging global roles of pharmacist in the society for attaining better social image and status. Society definitely recognises those whose services are useful and irreplaceable for collective, individual or personal wellbeing of its members.

Ownership of Community Pharmacy

In many countries across Europe and even in Africa ownership of Community Pharmacy is restricted to registered pharmacist and in many countries more than 50 percent share of registered pharmacist in the firm is a must. Moreover, registered pharmacist is invariably manager of the Pharmacy. The purpose behind ownership restriction is very pious and the objective is to avoid conflict of interest. It ensures [5] –

(i) restricting the number of pharmacies.

(ii) full time services of registered pharmacist for every prescription dispensed.

(iii) adequate and sustainable business to the pharmacist; and

(iv) exhaustive counselling to the patients.

The ownership restriction favours and promotes impartial professional judgement and expert approach in dispensing prescription. It completely nullifies the risks of corporate ownership, which is likely to be influenced by corporate greed and profit motive instead of patients' clinical and economic interests. In Germany, France, Hungary, Estonia and Poland only a registered pharmacist can establish and own a community pharmacy. Many countries across Europe do not even allow owning more than one Pharmacy by the registered pharmacist. Few to mention for example are Denmark, Finland, France, Germany, Malta, Monaco, Spain and Turkey.

Community Pharmacy in India

Retail Sale

Community Pharmacy in India is still popular as retail pharmacy or chemist and druggist shop. Of course, it is a health care facility that is most easily accessible destination for public at large. In these licensed establishments medicines are legally required to be dispensed on the prescription of medical practitioner by a registered pharmacist [6] or OTC medicines are made available along with all necessary information about such medicines. The legal framework that regulates this important health care facility is the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Part VI of these rules covers sale of drugs applicable to allopathic medicines. Licensing Authority appointed by the State Government under rule 59(1) of the rules, grants licence to sell, stock, exhibit or offer for sale or distribute drugs. There are 3 types of retail sale licences for the specified Schedules of drugs as depicted in Table 1.

Table 1. Details of retail sale licences [*See rule 59(2)*].

S. No.	Category of drugs	Application Form No.	Licence Form No.	Licence Fee (₹)	Retention Fee before every five years (₹)*	Fees for duplicate copy of Licence. (₹)
1	Other than Schedule C & C (1) and Schedule X	19	20	1500	1500	150
2	Schedule C & C (1) excluding Schedule X	19	21	1500	1500	150
3	Schedule X	19C	20F	500	500	150

***** *Late fee after expiry up to 6 months @ 2% p.m. or part thereof [rule 63(3)].*

Conditions of licence (*See rule 65*)

- The supply, by retail, of any drug supplied on the prescription of a RMP shall be affected only by or under the personal supervision of a **registered Pharmacist**.
- the supply of a Schedule H1 drug shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied, and such records shall be maintained for three years and be open for inspection.
- Schedule H and Schedule H1 or Schedule X drugs shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.
- Supply of Schedule H and Schedule H1 or Schedule X drugs to RMPs, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.
- Records of purchase of a drug intended for sale or sold by retail shall be maintained by the licensee.
- Purchase bills including cash or credit memo shall be serially numbered by the licensee and maintained by him in a chronological order.
- The person dispensing a prescription containing a drug specified in Schedule H and Schedule H1 and Schedule X shall comply with the following additional requirements.
  - *(a)* the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once.
  - *(b)* if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions.
  - *(c)* at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.
- No person dispensing a prescription containing substances specified in Schedule H and Schedule H1 or X, may supply any other preparation, whether containing the same substance or not, in lieu thereof.

Conditions for Sale of Schedule X drugs

Substances specified in Schedule X kept in retail shop or premises used in connection therewith shall be stored—

(*a*) under lock and key in cupboard or drawer reserved solely for the storage of these substances; or

(*b*) in a part of the premises separated from the remainder of the premises and to which only responsible persons have access.

Loose supply of medicines

The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a Registered Pharmacist and such supply shall be made under the direct supervision of the Registered Pharmacist in an envelope or other suitable wrapper or container showing the following particulars on the label:

(a) name of the drug,

(b) the quantity supplied,

(c) the name and address of the dealer.

Inspection Book

The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.

Expired Stock

No drug shall be sold or stocked by the licensee after the date of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper except as provided in rule 65(17) and reproduced here.

"Provided that any such drugs in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, reimbursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks 2[and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "Not for sale".

Wholesale of drugs

There is also provision for three types of Wholesale licences in Form 20B for drugs other than those specified in Schedule C & C (1) and Schedule X**,** in Form 21B for Drugs specified in Schedule C & C (1) but excluding those specified in Schedule X and Form G for Drugs specified in Schedule X. As per clause (ii) of further proviso to rule 64(2)(ii) wholesale of drugs is to be done under the charge of a competent person, who—

(*a*) is a Registered Pharmacist, or

(*b*) has passed the matriculation examination or its equivalent examination from a recognised Board with four year' experience in dealing with sale of drugs, or

(*c*) holds a degree of a recognised University with one year's experience in dealing with drugs:

The detailed process for wholesale licence is depicted in Table 2.

Requirement of Premises

As per rule 62(2) and 64 (2)(ii) further proviso clause (i) of the Drugs and Cosmetics Rules, 1945:-

1. Minimum floor area required for a retail licences in Form 20, 21 and 20F is 10 m^2 ;
2. Minimum floor area required for a wholesale licences in Form 20B, 21B and 20G is 10 m^2 ; and
3. Minimum floor area required for both (wholesale and retail) licences is 15 m^2.

The premises must be equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies. The conditions of licence are mentioned in the Licence itself.

Discussion

The facts, rules and documents discussed above demonstrate that Community Pharmacists are specifically educated and trained health professionals who are charged with the management of the distribution of medicines to consumers and to engage in appropriate practices to assure safe and efficacious use of medicines dispensed by them. There is also increasing recognition that providing consumers with medicines alone is not sufficient to achieve the treatment goals. To address the medication-related needs, pharmacists' shoulder much greater responsibilities for the outcomes of medicines use and evolve their practices to provide patients with enhanced medicines-use services. The ultimate success of the prescription entirely depends upon how accurately it is dispensed, how precisely counselling has been done and how effectively the patient realises that strict compliance of the dosage regimen holds key to optimum outcomes of therapy. India needs Community Pharmacy not medicine shop! Indians need Community Pharmacy owned by Pharmacists not by mercantile barons. Every patient has the basic right to know everything about his medicine and intricacies of rational & safe use of his medicines. Section 42 of the Pharmacy Act, 1948 [7] and rule 65(2) of the Drugs and Cosmetics Rules, 1945 guarantees dispensing of prescription by registered pharmacist only.

Conclusion

Community Pharmacist ensures ease of access to affordable medicines of assured quality at competitive price along with professional services of diversified dimensions to achieve the goal of health and wellness for all citizens. It provides one stop solution for a myriad of health care needs. Community Pharmacy ownership should be restricted to registered Pharmacists, minimum distance restriction between 2 premises and minimum population restriction per Pharmacy (retail outlet) must be imposed to ensure adequate business and sustainability of the entrepreneur Pharmacist. Strict implementation of Good Pharmacy Practice (GPP) is another must in the interest of patients.

Table 2. Details of Wholesale licences (*See rule 65*)

S. No.	Category of drugs	Application Form No.	Licence Form No.	Licence Fee (₹)	Retention Fee before every five years (₹)*	Fees for duplicate copy of Licence. (₹)
1	Other than Schedule C & C (1) and Schedule X	19	20B	1500	1500	150
2	Schedule C & C (1) excluding Schedule X	19	21B	1500	1500	150
3	Schedule X	19C	20G	500	500	150

***** *Late fee after expiry up to 6 months @ 2% p.m. or part thereof [rule 63(3)].*

References

1. World Health Organization. The Role of Pharmacist in the Health Care System. WHO/PHARM/94.569, page 30-31.
2. Good Pharmacy Practice. Joint FIP/WHO Guidelines on GPP: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011 Available at: https://www.fip.org/file/1476 Accessed July 09, 2020.
3. International Standard Classification of Occupations ISCO-08. International Labour Office. Geneva: 2012; Vol 1: p 133-134. (https://www.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/---publ/documents/publication/wcms_172572.pdf accessed 10 August 2020).
4. Board of Pharmaceutical Practice. International Pharmaceutical Federation (FIP); The Hague: 2016. (https://www.fip.org/pharmaceutical-practice-and-the-fip-sections, accessed 10 August 2020).
5. World Health Organization Regional Office for Europe. The legal and regulatory framework for community pharmacies in the WHO European Region. ISBN 9789289054249, World Health Organization 2019.
6. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Government of India, Ministry of Health and Family Welfare, (Department of Health), New Delhi. (https://cdsco.gov.in/opencms/opencms/en/Acts-Rules/, accessed 11th August 2020).
7. The Pharmacy Act, 1948 (VIII of 1948). Government of India, Ministry of Law, Justice and Company Affairs. 1978: p 18-19.

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Drug of the Quarter

Drug : **Avanafil**

Class : Phosphodiesterase type 5 (PDE-5) Inhibitor

Dosing Form : 50mg/100mg/200mg

Strength : Tablet

DCGI Approval : 26.02.2021

USFDA Approval : 27.04.2012

Indication: Avanafil is approved for the treatment of erectile dysfunction.

Dosing Information:

Adult:

1) Usual dose: 100 mg orally as needed; take as early as 15 minutes prior to sexual activity; maximum once daily.
2) Titration: Based on efficacy and tolerability, may decrease to 50 mg 30 minutes prior to sexual activity or increase to maximum 200 mg; use lowest dose to provide benefit.

Pharmacokinetics

Absorption

- Tmax: 30 to 45 minutes
- Tmax, Oral, Korean patients: 20 to 30 minutes
- Effects of food: delay in Tmax of 1.12 to 1.25 hours; AUC and Cmax not clinically insignificant

Distribution

- Protein binding: 99% plasma protein bound.

Metabolism

- Hepatic: extensive via CYP3A4; minor extent by CYP2C isoforms
- Metabolite, M4: active, 4% of the pharmacologic activity

Excretion

- Fecal: 62%
- Renal: 21%

Elimination Half Life

- 5 hours

Contraindications:

- Concomitant use of nitrates (any form) either regularly or intermittently; if nitrate required for a life-threatening situation, allow 12 hours or more to elapse after last dose of avanafil before administering nitrate only under close medical supervision with appropriate hemodynamic monitoring.
- Hypersensitivity to avanafil or any component of the product.
- Concomitant use with a guanylate cyclase stimulator (eg, riociguat).

Cautions:

➢ **Cardiovascular**

- o Sexual activity or vasodilatory effects of avanafil could aggravate conditions of preexisting cardiovascular disease.
- o Congestive heart failure (NYHA Class 2 or greater); use not recommended.
- o Coronary revascularization, myocardial infarction, stroke, life-threatening arrhythmia, or coronary revascularization within last 6 months; use not recommended.
- o Angina occurring during sexual intercourse or unstable angina; use not recommended.
- o Hypotension (resting blood pressure less than 90/50 mmHg) or hypertension (resting blood pressure greater than 170/100 mmHg); use not recommended.

- **Hematologic:** May increase risk of bleeding in patients with bleeding disorders or active peptic ulceration.
- **Ophthalmic**
  - History of non-arteritic anterior ischemic optic neuropathy (NAION); increased risk for recurrence.
  - Non-arteritic anterior ischemic optic neuropathy (NAION) leading to permanent vision loss may occur; discontinuation recommended in the event of any sudden vision loss.
- **Otic:** Sudden hearing decrease or loss may occur; discontinuation recommended.
- **Reproductive:**
  - Priapism or prolonged erections lasting greater than 4 hours may occur and could result in permanent penile tissue damage if not treated immediately.
  - Use caution in patients with anatomical deformation of the penis (eg, angulation, cavernosal fibrosis, or Peyronie disease).
  - Use with caution in patients with conditions which may predispose them to priapism, such as sickle cell anemia, multiple myeloma, or leukemia.

Drug-Drug Interactions

Category	Drug/s (Examples)	Interaction Effect	Management
Antimalarial*	Nitroglycerin	May result in risk of potentiation of hypotensive effects.	Contraindicated for concurrent use.
Antimalarial*	Hydroxychloroquine	May result in decreased avanafil clearance and increased avanafil plasma concentration.	Contraindicated for concurrent use.
Antianginal*	Isosorbide Dinitrate/ Mononitrate	May result in risk of potentiation of hypotensive effects.	Contraindicated for concurrent use.
Antiretroviral**	Lopinavir/Ritonavir/Indinavir	May result in decreased avanafil clearance and increased avanafil plasma concentration.	Avoid concomitant use.
Antifungal**	Ketoconazole/ Voriconazole	May result in decreased avanafil clearance and increased avanafil plasma concentration.	Avoid concomitant use.
Antibiotic***	Clarithromycin	May result in reduced avanafil clearance and increased avanafil plasma concentrations.	Use caution if concomitant use is required.
Adrenergic blocker***	Tamsulosin	May result in increased risk of hypotension.	Use caution if concomitant use is required.
Antitubercular***	Rifampin	May result in potential for decreased avanafil exposure.	Use caution if concomitant use is required.
Anticonvulsant***	Carbamazepine	May result in potential for decreased avanafil exposure.	Use caution if concomitant use is required.

Severity: *The drugs are contraindicated for concurrent use. **The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects. ***The interaction may result in exacerbation of the patient's condition and/or require an alteration in therapy.

Mechanism of Action

Nitric oxide increases levels of cGMP, which relaxes smooth muscles in corpus cavernosum to allow inflow of blood to achieve and maintain penial erection. Avanafil, a selective inhibitor of cGMP-specific phosphodiesterase type 5 (PDE-5), enhances the effect of nitric oxide by inhibiting PDE-5, which degrades cGMP in the corpus cavernosum. Sexual stimulation is required to initiate the local release of nitric oxide.

Adverse Effects

Common

- **Dermatologic:** Flushing
- **Musculoskeletal:** Backache
- **Neurologic:** Headache
- **Respiratory:** Nasal congestion, Nasopharyngitis

Serious

- **Ophthalmic:** Non-arteritic ischemic optic neuropathy, Anterior (Rare)
- **Otic:** Sudden hearing loss
- **Reproductive:** Priapism, Prolonged erection of penis

Effects in Pregnancy

Severity	Management
Moderate	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when Avanfil is used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug treatment against potential risks before prescribing Avanfil during pregnancy.

Effect in Lactation

Severity	Management
Major	Infant risk cannot be ruled out. Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when Avanfil is used during breast-feeding. Weigh the potential benefits of treatment against potential risks before prescribing Avanfil during breast-feeding.

Patient Education: Advise patient to report symptomatic hypotension.

References:

1. http://www.micromedexsolutions.com/
2. http://www.cdsco.nic.in/

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Drug Safety Alerts - Pharmacovigilance Programme of India (PvPI)

The preliminary analysis of Serious Unexpected Serious Adverse Reaction (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below.

Sl. No	Suspected Drug/s	Category	Indication/Use	Adverse Reaction/s Reported
			March 2021	
1	Hydroxyzine	Antihistamines	For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine -mediated pruritus.	Photosensitivity Reaction
2	Salicylic Acid	Keratolytic agents	For the treatment of acne vulgaris.	Photosensitivity Reaction
			February 2021	
3	Cefpodoxime	Cephalosporin Antibiotics	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis.	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome
4	Clarithromycin	Macrolide Antibiotics	Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	Burning Sensation
			January 2021	
5	Fexofenadine	Antihistamines	Treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria.	Blurred Vision
6	Ambroxol	Anti-tussive	Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma.	Fixed Drug Eruption

Healthcare professionals, Patients / Consumers are advised to closely monitor the possibility of the above adverse events associated with the use of above drugs.

If such events are encountered, please report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (http://www.ipc.gov.in) or by PvPI Helpline No. 1800-180-3024.

Meaning: Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) - A symmetrical erythematous rash on the flexures after systemic exposure to a drug.

Reference: www.ipc.gov.in ❑

Serious Risks/Safety Information – USFDA

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) – USFDA

The USFDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products.

The appearance of a drug on this list does not mean that conclusive of the risk. It means that FDA has identified a ***potential safety issue*** but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines whether the drug is associated with the risk or not and it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS) or gathering additional data to better characterize the risk.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information
April - June 2020				
Antimigraine	Fremanezumab, Erenumab-aooe Galcanezumab Eptinezumab	Subcutaneous	Stevens-Johnson syndrome (SJS)	Evaluation in progress.
Dihydroorotate Dehydrogenase Inhibitor	Teriflunomide	Oral	Drug reaction with eosinophilia and systemic symptoms	Evaluation in progress.
Antineoplastice Agent	Daratumumab, Daratumumab and Hyaluronidase-fihj	Intravenous	Listeriosis	Evaluation in progress.
Antineoplastice Agent	Apalutamide	Oral	Toxic epidermal necrolysis	Evaluation in progress.
Antihyperlipidemic	Fenofibrate, Fenofibrate, Fenofibric acid, Choline fenofibrate	Oral	Drug-induced liver injury	Evaluation in progress.
Antidiabetic	Lixisenatide, Exenatide, Semaglutide, Semaglutide, Liraglutide, Insulin glargine and Lixisenatide, Albiglutide, Dulaglutide, Insulin degludec/liraglutide	Subcutaneous	Hypoglycaemia	Evaluation in progress.
Antineoplastic Agent	Palbociclib	Oral	Stevens-Johnson syndrome	Evaluation in progress.
Antineoplastic Agent	Ribociclib, Letrozole	Oral	Stevens-Johnson syndrome	Evaluation in progress.
Antihyperlipidemic	Atorvastatin	Oral	Drug interaction between atorvastatin and hepatitis C virus (HCV) NS5A/NS5B inhibitors	Evaluation in progress.
Gastrointestinal Agent	Obeticholic acid	Oral	Liver disorder	Evaluation in progress.
Immune Modulator	Ocrelizumab	Intravenous	Hepatitis B reactivation	Evaluation in progress.
Anti-Infective Agent	Hydroxychloroquine sulfate, Chloroquine phosphate Generic products containing hydroxychloroquine and chloroquine	Oral	Cardiotoxicity	Evaluation in progress.

Therapeutic Class / Category	Drug (Examples)	Route of Administration	Potential Signal of a Serious Risk / New Safety Information	Additional Information
Proton Pump Inhibitors	Rabeprazole sodium, Dexlansoprazole, Esomeprazone strontium, Esomeprazole magnesium, Lansoprazole, Omeprazole, Pantoprazole sodium, Esomeprazole magnesium and naproxen, Aspirin and omeprazole, Omeprazole and sodium bicarbonate	Oral	Hypocalcemia and parathyroid hormone disorders	Evaluation in progress.
Opioid agonist-antagonists	Buprenorphine	Intradermal	Injection site necrosis	Evaluation in progress.
Immune Modulator	Natalizumab	Intravenous	Neonatal thrombocytopenia	Evaluation in progress.
Antineoplastic Agent	Vincristine sulfate, Vinblastine sulfate, Vinorelbine tartrate	Intravenous	Incorrect route of product administration	Evaluation in progress.
Antineoplastic Agent	Enzalutamide	Oral	Severe cutaneous adverse reactions	Evaluation in progress.
Musculoskeletal Agent	Onasemnogene abeparvovec-xioi	Intravenous	Thrombotic microangiopathy	Evaluation in progress.

References:

1. http://www.fda.gov/
2. www.micromedexsolutions.com, Micromedex (R) 2.0, 2002-2020, IBM Corporation 2020.

Drug News – Around the Globe

1. Drugs: Nivolumab** **Country: USA**

Nivolumab is an antineoplastic drug.

Approved Indication: Nivolumab is approved in combination with certain types of chemotherapy, for the initial treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer and esophageal adenocarcinoma. This is the first FDA-approved immunotherapy for the first-line treatment of gastric cancer.

Approved Dosage Form: Intravenous.

Side-effects: Peripheral neuropathy (damage to the nerves outside of the brain and spinal cord), nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation and musculoskeletal pain [1].

2. Drugs: Alirocumab* **Country: USA**

Alirocumab is an Antihyperlipidemic agent.

Approved Indication: Alirocumab is approved for adult patients with homozygous familial hypercholesterolemia (HoFH), a genetic condition that causes severely high cholesterol.

Approved Dosage Form: Subcutaneous.

Side-effects: Nasopharyngitis, injection site reactions and influenza [1].

3. Drugs: Mirabegron** **Country: USA**

Mirabegron is an adrenergic agonist.

Approved Indication: Mirabegron is approved to treat neurogenic detrusor overactivity, a bladder dysfunction related to neurological impairment, in children ages three years and older. Mirabegron is also indicated for overactive bladder in adult patients.

Approved Dosage Form: Oral.

Side-effects: Urinary tract infection, nasopharyngitis (common cold), constipation and headache[1].

4. Drugs: Bamlanivimab and Etesevimab* **Country: USA**

Bamlanivimab and Etesevimab is an immune modulator.

Approved Indication: Bamlanivimab and Etesevimab is approved to administer together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms) who test positive for SARS-CoV-2 and who are at high risk for progressing to

severe COVID-19. The authorized use includes treatment for those who are 65 years of age or older or who have certain chronic medical conditions.

Approved Dosage Form: Intravenous.

Side-effects: Nausea, dizziness, pruritus and rash[1].

5. Drugs: Relugolix* **Country: USA**

Relugolix is a nonpeptide gonadotropin-releasing hormone (GnRH) receptor antagonist.

Approved Indication: Relugolix is approved for the treatment of adult patients with advanced prostate cancer.

Approved Dosage Form: Oral.

Side-effects: Hot flush, increased glucose, increased triglycerides, musculoskeletal pain, decreased hemoglobin, fatigue, constipation, diarrhea and increased levels of certain liver enzymes [1].

Note – *Not available in India.

**Available in India

Reference: https://www.fda.gov/

Continuing Pharmacy Education (CPE)

Dispensing Instructions to the Pharmacists

Asthma-Drug Therapy - Continuation from the previous newsletter issue

(Inhalation/Nasal spray)

Drugs/ Category	Use	Warnings	Less serious side effects	Advice
Ciclesonide **Dosage forms:** Inhalation/Nasal spray	Indicated for maintenance treatment of asthma.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding or have osteoporosis, cataracts, glaucoma or any type of infection, especially a lung infection such as tuberculosis.	Headache, nasal discomfort or nosebleed.	Advise patient that the inhalation aerosol is not indicated for acute asthma attacks. Advice patients to use the medicine exactly as directed by their physician. Advice patient to rinse mouth with water without swallowing after use to reduce risk of oral candidiasis. Advise patient against sudden discontinuation of drug. Advice patient on proper administration technique. Avoid direct contact with nasal septum or eyes.
Fluticasone **Dosage forms:** Inhalation/Nasal spray	Indicated for maintenance treatment of asthma.	Prescription to be reconfirmed in case of patient is pregnant or breastfeeding, or if you have liver disease, osteoporosis, cataracts, or glaucoma.	Headache, cough, pain in throat.	Advice patient to seek immediate medical attention if their symptoms get worse or if they need more inhalations from their rescue inhaler than usual. Advice the patient to take drug at the same time every day and not use it more than once every 24 hours. Advice the patient to take next dose of oral inhalation at the same time they normally do if a dose is missed.

(to be continued.....)

Storage: Advice the patient or caretaker to store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Ensure to keep all medicine out of the reach of children.

References:

1. Handbook of Pharma SOS, Educational Series-I, 9th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.
2. www.micromedexsolutions.com, Micromedex® 2.0, 2002-2021, IBM Corporation 2021.
3. www.mayoclinic.org

❑

Drug Usage in Special Population - Pediatrics and Geriatrics

(From KSPCDIRC publication)

Anticoagulants

Drug	Usage in Children (Pediatrics)	Usage in Elderly (Geriatrics)
Acenocoumarol	Use only if there is accessibility to an adequate facility to perform regular coagulation tests to guide dosage adjustments.	Dose adjustment based on daily evaluation of coagulation time until a maintenance dosage is achieved.
Apixaban	Safety and efficacy have not been established.	No dosage adjustment required.
Ardeparin	Safety and efficacy have not been established.	No dosage adjustment required. Caution in severe renal and liver impairment.
Dalteparin	Safety and efficacy have not been established.	Dose adjustment required particularly in geriatric patient.
Enoxaparin	Safety and efficacy have not been established.	No dosage adjustment required.
Heparin	Safety and efficacy have been well established.	No dosage adjustment required.

Reference: Drug Usage in special Population-Pediatrics and Geriatrics, Educational Series-II, 9thEdition 2020, published by Karnataka State Pharmacy Council, Bengaluru.

❑

Drug Usage in Special Population - Pregnancy and Lactation

(From KSPCDIRC publication)

Anticoagulants

Drug	Usage in Pregnancy (Teratogenicity)	Usage in Breastfeeding (Lactation)
Acenocoumarol	Fetal risk has been demonstrated. Evidence has demonstrated fetal abnormalities or risks when used during pregnancy or in women of childbearing potential. An alternative to this drug should be prescribed during pregnancy or in women of childbearing potential.	Infant risk cannot be ruled out. Use with Caution.
Apixaban	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women of childbearing potential. But it is an essential vitamin and requirements are increased during pregnancy.	Infant risk cannot be ruled out. Not recommended.
Ardeparin	Fetal risk cannot be ruled out. Use only during pregnancy if the potential benefit justifies the potential risk to the fetus.	Infant risk cannot be ruled out. Use with Caution.
Dalteparin	Fetal risk cannot be ruled out. Administer only if the potential benefit justifies the potential risk to the fetus.	Infant risk cannot be ruled out. Use with caution.
Enoxaparin	Fetal risk cannot be ruled out. Available evidence is inconclusive or is inadequate for determining fetal risk when used in pregnant women or women of childbearing potential. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy.	Data not available. Caution.
Heparin	Fetal risk cannot be ruled out. Use only during pregnancy if the potential benefit justifies the potential risk to the fetus.	Infant risk is minimal. Safe to use.

Reference: Drug Usage in special Population-Pregnancy and Lactation, Educational Series-I, 8th Edition 2020, published by Karnataka State Pharmacy Council, Bangalore.

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ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015 (Pharmacy Practice Regulation, 2015)

(ಅಧ್ಯಾಯ–3)

8. ತಮ್ಮ ರೋಗಿಗಳೆಡೆಗೆ, ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರ ಕರ್ತವ್ಯಗಳು:

8.1 ಅಸ್ವಸ್ಥರಿಗೆ ನೆರವಾಗುವುದು:

(ಎ) ತನ್ನ ಸೇವೆಯನ್ನು ಬಯಸುವ ಪ್ರತಿಯೊಬ್ಬ ವ್ಯಕ್ತಿಯನ್ನು ಸೇವಿಸುವ ನಿರ್ಬಂಧಕ್ಕೆ ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಒಳಪಟ್ಟಿಲ್ಲದಿದ್ದರೂ ಸಹಾ, ಆತನು ಅನಾರೋಗ್ಯ ಪೀಡಿತರ ಮತ್ತು ಗಾಯಾಳುಗಳ ಕರೆಗೆ ಓಗೊಡಲು ಸದಾ ಸಿದ್ಧರಾಗಿರತಕ್ಕದ್ದು ಮಾತ್ರವಲ್ಲ, ತನ್ನ ಉನ್ನತ ಗುರಿಯ ಉನ್ನತ ಗುಣ ಮತ್ತು ತನ್ನ ವೃತ್ತಿಪರ ಕರ್ತವ್ಯಗಳ ನಿಭಾವಣೆ ಸಂದರ್ಭದಲ್ಲಿ ತಾನು ನಿರ್ವಹಿಸತಕ್ಕ ಜವಾಬ್ದಾರಿಗಳನ್ನು ಸದಾ ಜ್ಞಾಪಿಸಿಕೊಂಡಿರತಕ್ಕದ್ದು. ಆತನ ಆರೈಕೆಗೊಪ್ಪಿಸಲಾದವರ ಆರೋಗ್ಯ ಮತ್ತು ಜೀವಗಳು ಆತನ ಕುಶಲತೆ ಮತ್ತು ಗಮನಿಸುವಿಕೆಯ ಮೇಲೆ ಅವಲಂಬಿತವಾಗಿದೆ ಎಂದುದನ್ನು ಆತನು ಎಂದಿಗೂ ಮರೆಯತಕ್ಕದ್ದಲ್ಲ.

(ಬಿ) ರೋಗಿಗೆ ಮಾರಕವಾಗಬಹುದಾದ ಯಾವುದಾದರೂ ದೌರ್ಬಲ್ಯ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರಲ್ಲಿದ್ದರೆ ಅಥವಾ ಅದು ರೋಗಿಯೆದುರು ಆತನ ಕೆಲಸದ ನಿರ್ವಹಣೆಯ ಮೇಲೆ ವ್ಯತ್ತಿರಿಕ್ತ ಪರಿಣಾಮ ಉಂಟು ಮಾಡುತ್ತಿದ್ದರೆ, ಅಂತಹ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರನ್ನು ಆತನ ವೃತ್ತಿಪರ ಪರಿಕರ್ಮ ಅನುಷ್ಠಾನಗೊಳಿಸಲು ಅನುಮತಿಸತಕ್ಕದ್ದಲ್ಲ.

(ಸಿ) ಈ ಕೆಳಗಿನ ಪ್ರಬಂಧಗಳನ್ನು (ಔಷಧಗಳು ಮತ್ತು ಕಾಂತಿವರ್ಧಕಗಳ ನಿಯಮಾವಳಿ 1945 ಮತ್ತು ಆ ನಿಯಮಗಳ ಅನುಬಂಧ "ಎನ್"ಗಳ ಪ್ರಬಂಧಕಗಳಲ್ಲದೇ ಹೆಚ್ಚುವರಿಯಾಗಿ) ಭೈಷಜ್ಯೀಯ ಆರೈಕೆಯಲ್ಲಿ ಅಳವಡಿಸತಕ್ಕದ್ದು:–

- ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರನ್ನು ಹೊರತುಪಡಿಸಿ ಬೇರೆ ಯಾವುದೇ ಅನ್ಯವ್ಯಕ್ತಿಯು, ಒಬ್ಬ ನೋಂದಾಯಿತ ವೈದ್ಯ ಪರಿಕರ್ಮಿಯ ವೈದ್ಯಲಿಖಿತದ ಮೇಲೆ, ಯಾವುದೇ (ಶೆಡ್ಯುಲ್ H ಮತ್ತು X ಔಷಧಗಳು) ಔಷಧವನ್ನು ಸಂಯುಕ್ತಗೊಳಿಸುವುದು, ತಯಾರಿಸುವುದು, ಮಿಶ್ರಗೊಳಿಸುವುದು ವಿನಿಯೋಗಗೊಳಿಸುವುದು ಅಥವಾ ಸರಬರಾಜು ಮಾಡುವುದನ್ನು ಮಾಡಕೂಡದು.
- ಶುಶ್ರೂಷಾ ಸೂಕ್ತತೆಯನ್ನು ವೃದ್ಧಿಸುವ ಉದ್ದೇಶಕ್ಕಾಗಿ ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಔಷಧ ಸರಬರಾಜಿಗಾಗಿ ಹಾಜರುಪಡಿಸಲಾದ ಪ್ರತಿಯೊಂದು ವೈದ್ಯಲಿಖಿತವನ್ನು ರೋಗಿಯ ದಾಖಲೆ ಜೊತೆಗೆ ಈ ಕೆಳಗಿನವುಗಳನ್ನು ಗುರುತಿಸುವಿಕೆಯ ಮೂಲಕ ವಿಮರ್ಶಿಸತಕ್ಕದ್ದು.
  1. ಅಧಿಕವಾಗಿ ಉಪಯೋಗಿಸಿರುವುದು ಅಥವಾ ಕಡಿಮೆಯಾಗಿ ಉಪಯೋಗಿಸಿರುವುದು.
  2. ಇಮ್ಮಡಿಯಾಗಿ ಶುಶ್ರೂಷೆ ಸೂಚಿಸಲ್ಪಡುವುದು.
  3. ಔಷಧಿ ಖಾಯಿಲೆಗಳ ಅಂತರ್ ಪ್ರತಿಕ್ರಿಯೆ.
  4. ಔಷಧಿ – ಔಷಧಿಗಳ ಅಂತರ್ ಪ್ರತಿಕ್ರಿಯೆ.
  5. ಔಷಧದ ಪರಿಮಾಣ ಸರಿಯಾಗಿಲ್ಲದಿರುವುದು ಅಥವಾ ಔಷಧ ಶುಶ್ರೂಷೆಯ ಅವಧಿ ಸರಿಯಾಗಿಲ್ಲದಿರುವುದು.
  6. ಔಷಧಿ ತಡೆಯಲಾರದೇ ಬಾಧೆ ಪಡುವುದು (Allergy) ಇವುಗಳ ಅಂತರ್ ಪ್ರತಿಕ್ರಿಯೆ.
  7. ಔಷಧಗಳ ಲಭ್ಯತೆಯ ಪರಸ್ಪರ ಸಂಬಂಧ ಕಲ್ಪಿಸುವುದು (ಔಷಧಗಳ ಕೃತಕ ಅಭಾವ ಉಂಟಾಗುವುದನ್ನು ತಪ್ಪಿಸಲು).
  8. ವೈದ್ಯಕೀಯವಾಗಿ ತಪ್ಪು ಉಪಯೋಗ / ದುರುಪಯೋಗ.

ಸೂಚನೆ: ಮೇಲೆ ಹೇಳಿದವುಗಳಲ್ಲಿ ಯಾವುದನ್ನಾದರೂ ಗುರ್ತಿಸಿದಲ್ಲಿ, ಅದನ್ನು ತಪ್ಪಿಸಲು ಅಥವಾ ಸಮಸ್ಯೆಯನ್ನು ಪರಿಹರಿಸಲು, ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಅಗತ್ಯಬಿದ್ದರೆ, ನೋಂದಾಯಿತ ವೈದ್ಯ ಪರಿಕರ್ಮಿಯೊಡನೆ ಸಮಾಲೋಚಿಸುವುದೂ ಸೇರಿದಂತೆ, ಸೂಕ್ತ ಕ್ರಮ ಕೈಗೊಳ್ಳತಕ್ಕದ್ದು.

8. DUTIES OF REGISTERED PHARMACISTS TO THEIR PATIENTS

8.1 Obligations to the Sick:

a) Though a registered pharmacist is not bound to attend each and every person asking his services, he shall not only be ever ready to respond to the calls of the sick and the injured but shall be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. He shall never forget that the health and the lives of those entrusted to his care depend on his skill and attention.

b) Registered pharmacist having any incapacity detrimental to the patient or which can affect his performance vis-à-vis the patient shall not be permitted to practice his profession.

c) Pharmaceutical care (in addition to the provisions of Drugs and Cosmetics Rules 1945 and Schedule N of the said Rules) the following provisions shall be included :-

- No person other than a Registered Pharmacist shall compound, prepare, mix, dispense or supply of any medicine on the prescription of a Registered Medical Practitioner (Schedule H & X drugs);
- A Registered Pharmacist shall review the patient record and each prescription presented for supply for the purpose of promoting therapeutic appropriateness by identifying:
  1. Over utilization or under utilization
  2. Therapeutic duplication
  3. Drug-disease interactions
  4. Drug-drug interactions
  5. Incorrect drug dosage or duration of drug treatment
  6. Drug-allergy interactions
  7. Correlation of availability of drugs (to avoid artificial shortage of drugs)
  8. Clinical abuse/misuse

Note: upon recognizing any of the above, the Registered Pharmacist shall take appropriate steps to avoid or resolve the problem that shall, if necessary, include consultation with the Registered Medical Practitioner.

8.2. ತಾಳ್ಮೆ, ಸೂಕ್ಷ್ಮತೆ ಮತು ಗೌಮ್ಯತೆ:

ತಾಳ್ಮೆ ಮತ್ತು ಸೂಕ್ಷ್ಮತೆಗಳು ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರಿಗೆ ಅನ್ವರ್ಥ ನಾಮಗಳಾಗತಕ್ಕದ್ದು. ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರಿಗೆ, ಆತನ ರೋಗಿಗಳಿಂದ ತಿಳಿಸಲ್ಪಟ್ಟ ಒಂದು ವ್ಯಕ್ತಿಗೆ ಸಂಬಂಧಿಸಿದ ರಹಸ್ಯಗಳನ್ನು ಅಥವಾ ಗೃಹಜೀವನದ ಅಂತರಂಗದ ವಿಚಾರಗಳನ್ನು ಮತ್ತು ವೈದ್ಯಕೀಯ ಶುಶ್ರೂಷೆಯ ಸಮಯದಲ್ಲಿ ತಿಳಿದು ಬಂದ ಆ ರೋಗಿಗಳ ಸ್ವಭಾವ ಅಥವಾ ಗುಣ ನಡತೆಗಳಲ್ಲಿನ ದೋಷಗಳನ್ನು, ದೇಶದ ಕಾನೂನುಗಳಿಂದ ಹಾಗೆ ಬಹಿರಂಗಗೊಳಿಸುವುದು ಅಗತ್ಯ ಎಂದು ಆಜ್ಞಾಪಿಸಲ್ಪಟ್ಟ ಹೊರತು, ಬಹಿರಂಗಗೊಳಿಸಲೇಬಾರದು. ಆದಾಗ್ಯೂ ಸಹಾ ಒಬ್ಬ ಆರೋಗ್ಯವಂತನು, ಯಾವುದೇ ಒಂದು ಸಾಂಕ್ರಾಮಿಕ ರೋಗಕ್ಕೆ ಸದ್ಯದಲ್ಲೇ ಬಲಿಯಾಗುವಂತಿದ್ದರೆ, ಅಂತಹ ರೋಗದಿಂದ ಆತನನ್ನು ರಕ್ಷಿಸಲು, ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ವಿಶ್ವಾಸದ ಮುಖಾಂತರ ತಾನು ಕಲೆಹಾಕಿದ ಮಾಹಿತಿಗಳನ್ನು ಉಪಯೋಗಿಸಿಕೊಳ್ಳಬಹುದೇ ಎಂಬ ನಿರ್ಧಾರವನ್ನು ಕೆಲವು ಸಂದರ್ಭಗಲ್ಲಿ ಸಮಾಜಕ್ಕೆ ತನಗಿರುವ ಬದ್ಧತೆಯ ಮೇರಿಗೆ ಆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ತೆಗೆದುಕೊಳ್ಳತಕ್ಕದ್ದು. ಅಂತಹ ಪ್ರಕರಣದಲ್ಲಿ, ಆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಅಂತಹದ್ದೇ ಸನ್ನಿವೇಶದಲ್ಲಿ, ತನ್ನ ಸ್ವಂತ ಕುಟುಂಬದ ಸದಸ್ಯರೊಬ್ಬರ ಬಗ್ಗೆ, ಇನ್ನೊಬ್ಬರು ಯಾವ ರೀತಿಯಲ್ಲಿ ಪ್ರತಿಕ್ರಿಯಿಸಬೇಕೆಂದು, ತಾನು ಆಶಿಸುತ್ತಾನೆಯೋ ಅದೇ ರೀತಿಯಲ್ಲಿ ಪ್ರತಿಕ್ರಿಯಿಸತಕ್ಕದ್ದು.

8.3. ಅವಲೋಕನ:

ಒಬ್ಬ ರೋಗಿಯ ಪರಿಸ್ಥಿತಿಯ ವಿಷಮತೆಯನ್ನು ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು, ಉತ್ಪ್ರೇಕ್ಷೆಯಿಂದ ಅಥವಾ ಕನಿಪ್ಠತೆಯಿಂದಾಗಲೀ ಅವಲೋಕಿಸತಕ್ಕದ್ದಲ್ಲ. ಆ ರೋಗಿಯ ಬಗ್ಗೆ ಆತನ ಅತ್ಯುತ್ತಮ ಏಳ್ಗೆ ಮತ್ತು ಆತನ ಕುಟುಂಬಕ್ಕೆ ಹಿತಕಾರಿಯಾದಂತಹ ತಿಳುವಳಿಕೆಯನ್ನು ಆ ರೋಗಿ, ಆತನ ಸಂಬಂಧೀಕರು ಅಥವಾ ಜವಾಬ್ದಾರಿಯುತ ಹಿತಚಿಂತಕರು ಹೊಂದುವಂತೆ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಖಾತ್ರಿಪಡಿಸಿಕೊಳ್ಳತಕ್ಕದ್ದು.

8.4. ರೋಗಿಯನ್ನು ಉಪೇಕ್ಷಿಸಲೇಬಾರದು:

ತಾನು ಯಾರು ಸೇವೆ ಮಾಡುವುದು ಎಂಬ ಆಯ್ಕೆಯು ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರಿಗೆ ಮುಕ್ತವಾಗಿ ಇದೆ. ಆದಾಗ್ಯೂ ಒಂದು ಆಕಸ್ಮಿಕ ಸಂದರ್ಭದಲ್ಲಿ ಆತನ ಸಹಾಯ ಯಾಚಿಸಿ ಬರುವ ಯಾವುದೇ ಬೇಡಿಕೆಗೆ ಆತನು ಸ್ಪಂದಿಸತಕ್ಕದ್ದು. ತನ್ನ ರೋಗಿಯನ್ನು ಅಥವಾ ರೋಗಿಗಳನ್ನು, ಅಗತ್ಯವಾದ ವೈದ್ಯಕೀಯ ಸೇವೆಯಿಂದ ವಂಚಿತನನ್ನಾಗಿಸಬಹುದಾದ ಒಂದು ತಿರಸ್ಕಾರದ ಯಾವ ಕ್ರಿಯೆಯನ್ನು, ಉದ್ದೇಶಪೂರ್ವಕ ಮುಕ್ತ ಮನಸ್ಸಿನಿಂದ ಒಬ್ಬ ನೋಂದಾಯಿತ ಭೇಷಜಜ್ಞರು ಎಸಗತಕ್ಕದ್ದಲ್ಲ.

8.2 Patience, Delicacy and Secrecy:

Patience and delicacy shall characterize the registered pharmacist. Confidences concerning individual or domestic life entrusted by patients to a registered pharmacist and defects in the disposition or character of patients observed during medical attendance shall never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a registered pharmacist shall determine whether his duty to society requires him to employ knowledge, obtained through confidence as a registered pharmacist, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the registered pharmacist shall act as he would wish another to act toward one of his own family in like circumstances.

8.3 Prognosis:

The registered pharmacist shall neither exaggerate nor minimize the gravity of a patient's condition. He shall ensure himself that the patient, his relatives or his responsible friends have such knowledge of the patient's condition as will, serve the best interests of the patient and the family.

8.4 The Patient must not be neglected:

A registered pharmacist is free to choose whom he will serve. However, he shall respond to any request for his assistance in an emergency. Registered pharmacist shall not willfully commit an act of negligence that may deprive his patient or patients from necessary medical care.

KSPC News

1. PharmaDisha 2020

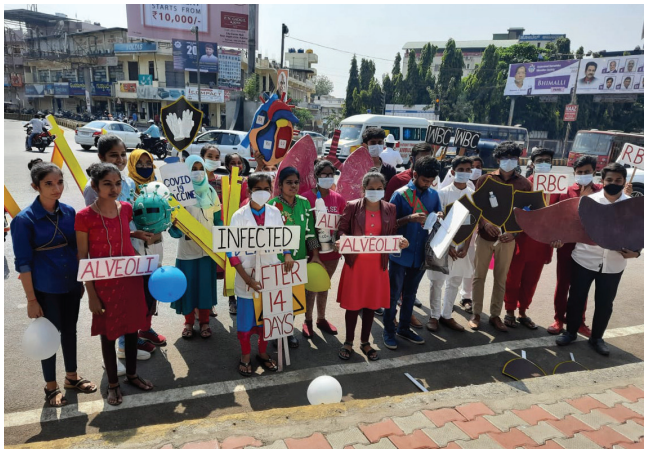
The second session of PharmaDisha 2020 was conducted on 14th February 2021 for those students who missed attending the session during February 2020.

Going by the pandemic situation, the same was conducted online.

2. Rajiv Memorial Education Society's College (RMES) of Pharmacy, Kalburgi

Rajiv Memorial Education Society's College (RMES) of Pharmacy, Kalburgi conducted Covid 19 vaccine Awareness rally on 25th February 2021.

Dr. Kishore Singh Chatrapathi, Director, Rajiv Memorial Education Society's College of Pharmacy, Kalaburagi and Executive Committee Member, Karnataka State Pharmacy Council arranged the rally along with other colleagues from their college.



3. Hoskote Taluk Drug Dealers Association

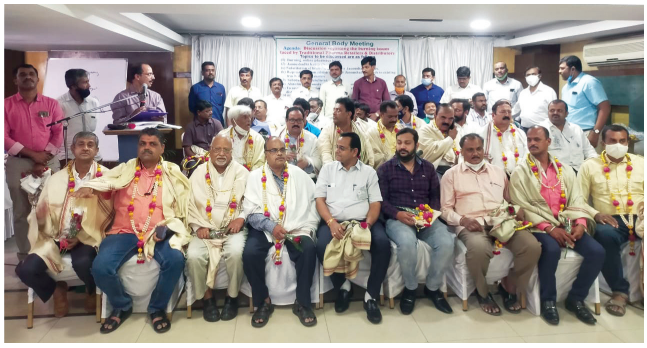
Sri. Gangadhar V. Yavagal, President, Karnataka State Pharmacy Council inaugurated a Pharmacy training program at Hoskote Taluk Drug Dealers Association on 14-03-2021.

Sri.D.A.Gundu Rao, Vice President,KSPC and Sri.Y.Veeranarayana Gowda, Member, KSPC attended the program.

4. Bruhath Bengaluru Chemists and Druggists association

Bruhath Bengaluru chemists and Druggists association has organised a meeting to discuss regarding the issues faced by traditional Pharma Retailers and Distributors.

Sri. Gangadhar V. Yavagal, President and Sri.D.A.Gundu Rao, Vice President from the Karnataka State Pharmacy Council attended the meeting.



5. Felicitation

Sri. Gangadhar V. Yavagal, President, Karnataka State Pharmacy Council was felicitated by the Sri. Ashokswamy Herur at Gangavathi on 28-02-2021.

At this event a State Register Pharmacist Address book was launched at an event held at the Pharmceutical House, Pharma Palace, Gangavati where the family of the deceased pharmacist received a KPCRPWT welfare amount of Rs.200000/-.

Sri. Gangadhar V. Yavagal highlighted the activities of Council such as digitalization of Registration system, scholarship, Gold medal award, Trust benefits and various online services provided by the Council for the information of the Pharmacists and public.

He also highlighted advantage for enrolling to KPCRPWT and he encouraged the Pharmacists who have not enrolled under the KPCRPWT to enroll at the earliest to avail the benefit for the Pharmacist or the nominee.

ಫಾರ್ಮಸಿ ಕೌನ್ಸಿಲ್‌ನಿಂದ ಸಿಗುವ ಸೌಲಭ್ಯಗಳನ್ನು ಪಡೆದುಕೊಳ್ಳಿ : ಯಾವಗಲ್

ಸುವರ್ಣಗಿರಿ ವಾರ್ತೆ

ಗಂಗಾವತಿ: ಕರ್ನಾಟಕ ರಾಜ್ಯದ ಫಾರ್ಮಸಿ ಕೌನ್ಸಿಲ್ ನಿಮ್ಮದು ಆ ಸಂಸ್ಥೆಯಿಂದ ಸಿಗುವ ಸೌಲಭ್ಯಗಳನ್ನು ಪಡೆದುಕೊಳ್ಳಿ ಎಂದು ರಾಜ್ಯದ ರಿಜಿಸ್ಟರ್ಡ ಫಾರ್ಮಾಸಿಸ್ಟಗಳಿಗೆ, ಕೌನ್ಸಿಲ್ ಅಧ್ಯಕ್ಷ ಗಂಗಾಧರ ವಿ.ಯಾವಗಲ್ ಕರೆ ನೀಡಿದರು.

ನಗರದ ಔಷಧೀಯ ಭವನದಲ್ಲಿ ನಡೆದ ರಾಜ್ಯ ರಿಜಿಸ್ಟರ್ಡ ಫಾರ್ಮಾಸಿಸ್ಟಗಳ ವಿಳಾಸದ ಪುಸ್ತಕ ಬಿಡುಗಡೆ ಕಾರ್ಯಕ್ರಮದಲ್ಲಿ ಮುಖ್ಯ ಅತಿಥಿಯಾಗಿ ಅವರು ಮಾತನಾಡುತ್ತಿದ್ದರು.

ವೈಯಕ್ತಿಕ ಫಾರ್ಮಾಸಿಸ್ಟಗಳ ಕುಟುಂಬಕ್ಕೆ ಎರಡು ಲಕ್ಷ ರೂಪಾಯಿಗಳ ಸಹಾಯಧನ ಮತ್ತು ಗಂಭೀರ ಖಾಯಿಲೆಗಳ ಚಿಕಿತ್ಸೆಗೆ ಕೌನ್ಸಿಲ್‌ನಿಂದ ಸಹಾಯ ಧನ ದೊರೆಯುತ್ತದೆ ಎಂದರು.

ಫಾರ್ಮಾಸಿಸ್ಟಗಳ ಮಕ್ಕಳು, ಅಣ್ಣ ತಮ್ಮಂದಿರು ಫಾರ್ಮಸಿಯಲ್ಲಿ ಉನ್ನತ ಶ್ರೇಣಿಯಲ್ಲಿ ಉತ್ತೀರ್ಣರಾದರೆ ಪ್ರೋತ್ಸಾಹ ಧನ ಮತ್ತು ಆರ್ಥಿಕ ಸ್ಥಿತಿಯಲ್ಲಿ ಹಿಂದುಳಿದ ವಿದ್ಯಾರ್ಥಿಗಳ ವಿದ್ಯಾಭ್ಯಾಸಕ್ಕೂ ಹಣಕಾಸಿನ ನೆರವು ಕಲ್ಪಿಸುವುದಾಗಿ ತಿಳಿಸಿದರು.

ಡಿಜಿಟಲ್ ರಿಜಿಸ್ಟರ್ಡ ಸರ್ಟಿಫಿಕೇಟ್, ಐಡೆಂಟಿ ಕಾರ್ಡ್, ಆನ್ ಲೈನ್ ಸಂಪರ್ಕ ಮುಂತಾದ ಸೌಲಭ್ಯಗಳನ್ನು ಕೌನ್ಸಿಲ್ ನಲ್ಲಿ ಕಲ್ಪಿಸಲಾಗಿದೆ. ಮುಂದಿನ ದಿನಗಳಲ್ಲಿ ಎಲ್ಲಾ ಫಾರ್ಮಾಸಿಸ್ಟಗಳಿಗೂ ಪಿಪಾನ್ ಮತ್ತು ರಿಜಿಸ್ಟರ್ ಸಂಖ್ಯೆ ಇರುವ ನೇಮ್ ಪ್ಲೇಟ್ ಗಳನ್ನು ಉಚಿತವಾಗಿ ವಿತರಿಸಲಾಗುತ್ತದೆ ಎಂದು ಹೇಳಿದರು.

ಅಧ್ಯಕ್ಷತೆ ವಹಿಸಿದ್ದ ರಾಜ್ಯ ಫಾರ್ಮಾಸಿಸ್ಟಗಳ ಸಂಸ್ಥೆಯ ಅಧ್ಯಕ್ಷ ಆಶೋಕ ಸ್ವಾಮಿ ಹೇರೂರ ಮಾತನಾಡಿ ಮೆಡಿಕಲ್ ಕೌನ್ಸಿಲ್, ಡೆಂಟಲ್ ಕೌನ್ಸಿಲ್ ಮತ್ತು ವಕೀಲರ ಕೌನ್ಸಿಲ್ ನಲ್ಲಿರುವ ಡಿಜಿಟಲ್ ಪ್ರಮಾಣ ಪತ್ರ ಹಾಗೂ ಗುರುತಿನ ಪತ್ರಗಳನ್ನು ನೀಡಲಾಗುತ್ತಿಲ್ಲ.ಆದರೆ ಈ ಎಲ್ಲಾ ಕೌನ್ಸಿಲ್ ಗಳಿಗೂ ಮುಂಚಿತವಾಗಿ ಫಾರ್ಮಸಿ ಕೌನ್ಸಿಲ್ ಡಿಜಿಟಲ್ ವ್ಯವಸ್ಥೆಗೆ ಒಳಪಟ್ಟಿದ್ದು ಶ್ಲಾಘನೀಯ ಎಂದರು.

ಗುರುತಿನ ಪತ್ರಕ್ಕೆ ಆಧಾರ್ ವಿಳಾಸವನ್ನು ಜೊತೆಯಾಗಿರಿಸಬೇಕು ಎಂದು ಕೌನ್ಸಿಲ್ ಅಧ್ಯಕ್ಷರನ್ನು ಹೇರೂರ ಒತ್ತಾಯಿಸಿದರು.

ನಗರದ ಸೇಂಟ್ ಫ್ರಾಲ್ಸ್ ಡಿ.ಫಾರ್ಮಸಿ ಕಾಲೇಜ್ ಪ್ರಿನ್ಸಿಪಾಲ್ ಮಂಜುನಾಥ ಹೀರೆಮಠ, ಉಪನ್ಯಾಸಕರಾದ ಅಫೀದ ಹುಸೈನ್, ಶ್ರೀಮತಿ ರಾಘವಗಲ್, ನ್ಯಾಂಪುವಾದಿ ಸಂದ್ಯಾ ಹೇರೂರ, ಕೊಪ್ಪಳದ ಶರಣಪ್ಪ ಬೆಟಗೇರಿ, ರಾಜ ಶೇಖರ ಪಾಟೀಲ್ ಹುಲಗೇರಿ, ಕುಷ್ಟಗಿಯ ರಾಜಶೇಖರ ಕಮಾಡಿ, ಗಂಗಾವತಿಯ ಹನುಮರೆಡ್ಡಿ ಮಾಲಿ ಪಾಟೀಲ್, ಗಣೇಶ ಸುಳೇ ಕಲ್, ಕನಕಗಿರಿಯ ಪಶುಪತಿ ಪಾಟೀಲ್ ಮತ್ತು ಕಾರಟಗಿಯ ವೀರಣ್ಣ ಕಾರಂಜಿ ವೇದಿಕೆಯ ಮೇಲೆ ಉಪಸ್ಥಿತರಿದ್ದರು.

ಕನಕಗಿರಿ, ಕಾರಟಗಿ, ಗಂಗಾವತಿ ತಾಲೂಕಿನ ಔಷಧ ವ್ಯಾಪಾರಿಗಳು ಮತ್ತು ಫಾರ್ಮಾಸಿಸ್ಟಗಳು ಸಮಾರಂಭದಲ್ಲಿ ಭಾಗವಹಿಸಿದ್ದರು.

❑

ಭೇಷಜೀ ಪರಿಕರ್ಮ ನಿಬಂಧನೆಗಳು, 2015
(Pharmacy Practice Regulations, 2015)

4.2. ನೋಂದಾವಣೆಯ ನವೀಕರಣ:

ನೋಂದಾವಣಿ ನವೀಕರಿಸಲು ಆ ಭೇಷಜಜ್ಞರು ಐದು ವರ್ಷಗಳ ಅವಧಿಯೊಳಗೆ ಈ ಕೆಳಗೆ ಹೇಳಿದ ಸಂಸ್ಥೆಗಳಲ್ಲಿ ಯಾವುದಾದರೂ ಒಂದು ಸಂಸ್ಥೆಯು, ಭೇಷಜೀ ವಿಷಯದ ಬಗ್ಗೆ ಸಂಘಟಿಸಿದ, ಕನಿಷ್ಠ ಪಕ್ಷ ಒಂದು ದಿನ ಅವಧಿಯ, ಕನಿಷ್ಠ ಪಕ್ಷ ಎರಡು ಪುನ:ಶ್ಚೇತನ ಪಠ್ಯಕ್ರಮಗಳಲ್ಲಿ ಭಾಗಿಯಾಗಿರತಕ್ಕದ್ದು.

1. ಭಾರತದ ಭೇಷಜೀ ಪರಿಷತ್ತು
2. ರಾಜ್ಯದ ಭೇಷಜೀ ಪರಿಷತ್ತುಗಳು
3. ಕೇಂದ್ರ ಸರಕಾರ / ರಾಜ್ಯ ಸರಕಾರ
4. ಪರಿಷತ್ತಿನಿಂದ ಮಾನ್ಯತೆ ಪಡೆದ ವೃತ್ತಿಪರ ಸಂಸ್ಥೆಗಳು

Attention - Registered Pharmacists

Lending of Registered Pharmacist Certificate to any Chemist and Druggist shop / Hospital / Nursing Home /Wholesale Distributors / Clinics without physical presence will be guilty of such infamous conduct and will be liable to have his/her name removed from the register under u/s 36(1) (ii) of the Pharmacy Act 1948. Such Registered Pharmacists are directed to withdraw their Certificate lent without physical present to avoid legal action under intimation to this office.

Additional Information on any article is available on request

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Drug Information and Research Center

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Printed & published by: Registrar on behalf of Drug Information and Research Center (DIRC), Karnataka State Pharmacy Council