

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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Subject: Objections of Pharmacy Council of India to proposed amendment in Schedule K against serial number 23 of the Drugs and Cosmetics Rules, 1945.

Reference: Notification No.G.S.R. 827 (E) dated 6th November, 2019 published in Part II - SEC. 3(i) of the Gazette of India : Extraordinary seeking comments on proposed amendment in the Drugs and Cosmetics Rules, 1945 in Schedule K, against serial number 23, for the entries under the column "Class of Drugs".

Sir,

1. The Pharmacy Council of India (PCI) is a statutory body working under the Ministry of Health and Family Welfare, Government of India, New Delhi. It is constituted under the Pharmacy Act, 1948 with a mandate to regulate pharmacy education & practice of profession in the country.
2. Reference to the amendment proposed in serial No.23 of schedule K of Drugs and Cosmetic Rules 1945, the PCI submits its objections and prayers with justification as under -

PCI's objections to proposed amendment in schedule K against Serial No.23	Prayer
1. Extension of exemptions to Urban Areas.	It is prayed that - a) While structuring the human resource needs for not only urban areas but also for rural areas in line with NHP 2017, a registered Pharmacist may be made a required human resource in these Wellness Centers in Urban areas and exemption granted under serial No.23 of Schedule K to other cadres in the Wellness centers be set aside.

PCI's objections to proposed amendment in schedule K against Serial No.23	Prayer
	b) This will also contribute to the Key Policy Principles of NHP 2017 wherein government is committed to provide quality healthcare to the Indian population without any discrimination on caste, creed, financial status and geographical location.
2. Inclusion of ASHA workers. The class of drugs to be dispensed / supplied by health functionaries is not defined.	It is prayed that addition of "ASHA WORKERS" under serial No.23 of Schedule K be deleted.
3. Applicability of exemptions to Wellness centers.	No exemptions under S.No23 of Schedule K be provided in Health and Wellness Centers as proposed in the amended clause.

Justification

1. Section 42 of the Pharmacy Act clearly states that no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner and whosoever contravenes it shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees or with both.
2. Under section 10 and 18 of the Pharmacy Act, the PCI has notified the Pharmacy Practice Regulations, 2015 with a basic objective to -
 - improve quality of health care.
 - ensure that Pharmacists maintain high standards in their duty.
 - reduce cost of health care.
 - inhibit criminal abuse of medicines.

As per the said Regulations dispensing, pharmaceutical care and patient counseling are defined as under -

- "Dispensing" means the interpretation, evaluation, supply and implementation of a prescription, drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.
- "Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the care or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, as defined by the Pharmacy Council of India.
- "Patient counseling" means the oral communication by the pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.

3. Reference to the amendment proposed in serial No.23 of schedule K of Drugs and Cosmetic Rules 1945, the PCI submits its objections as under -

A. Preface

The principle serial No.23 of schedule K and the proposed amendment along with extent and conditions of exemptions is reproduced below:

Principle Serial No.23	Extent and conditions of Exemption	Proposed amendment in serial No.23
40[23. Drugs supplied by (i) Multipurpose Workers attached to Primary Health Centres/Sub-Centres, (ii) Community Health Volunteers under the Rural Health Scheme, (iii) Nurses, Auxiliary Nurses, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/Primary Health Centres/Sub- Centres and 41 [(iv) Anganwadi Workers].	All The provisions of Chapter IV of the Act and Rules thereunder, which require them to be covered by a sale licence, provided the drugs are supplied under the Health or Family Welfare Programme of the Central or State Government.]	23. Drugs supplied by (i) Health functionaries including Community Health Officers , Nurses,Auxiliary Nurse Midwives and Lady Health Visitors attached to Primary Health Centres/ Sub-Centres/Health &Wellness Centres in rural and urban areas, (ii) Community Health Volunteers such as Accredited Social Health Activists (ASHAs) under the National Health mission, and (iii) Anganwadi Workers.

The PCI understands that the objective of the Government while bringing out this amendment is based on the National Health Policy 2017. The relevant objectives of National Health Policy 2017 (NHP 2017) are quoted below -

2.3 Objectives

Improve health status through concerted policy action in all sectors and expand preventive, promotive, curative, palliative and rehabilitative services provided through the public health sector with focus on quality

2.3.1 Progressively achieve Universal Health Coverage

A. Assuring availability of free, comprehensive primary health care services, for all aspects of reproductive, maternal, child and adolescent health and for the most prevalent communicable, non-communicable and occupational diseases in the population. The Policy also envisages optimum use of existing manpower and infrastructure as available in the health sector and advocates collaboration with non-government sector on pro-bono basis for delivery of health care services linked to a health card to enable every family to have access to a doctor of their choice from amongst those volunteering their services.

2.3.2 Reinforcing trust in Public Health Care System: Strengthening the trust of the common man in public health care system by making it predictable, efficient, patient centric, affordable and effective, with a comprehensive package of services and products that meet immediate health care needs of most people.

(Source: National Health Policy released by Ministry of Health and Family Welfare, GoI, Objectives, page 3)

V. **Patient Centered & Quality of Care:** Gender sensitive, effective, safe, and convenient healthcare services to be provided with dignity and confidentiality. There is need to evolve and disseminate standards and guidelines for all levels of facilities and a system to ensure that the quality of healthcare is not compromised.

(Source: National Health Policy released by Ministry of Health and Family Welfare, GoI, Key Policy Principles, page 2)

B. The PCI's major Objections to the proposed amendment are –

1. Extension of exemptions to Urban Areas.
2. Inclusion of ASHA workers. The class of drugs to be dispensed / supplied by health functionaries is not defined.
3. Applicability of exemptions to Wellness centers.

PCI objection No. 1 : Extension of exemptions to Urban Areas.

The PCI strongly opposes this amendment. The rationale in support of the PCI's key objections is as under -

- a) Reproduced below is a table from a WHO report on Healthcare workforce in India (reference year 2001). The Pharmacists shown in the table are the Pharmacists who are employed in community health services i.e. they are employed in a dispensary or a hospital or any other similar settings. The Pharmacist workforce engaged in the retails distribution and sales of drugs is not included.

Table 2.2. Health workers by urban-rural stratum and gender

HEALTH WORKER CATEGORY	URBAN			RURAL			RATIO OF URBAN DENSITY TO RURAL DENSITY	MALE		FEMALE		MALE-FEMALE RATIO
	Number	% of all urban health workers	Density per lakh urban pop'n	Number	% of all rural health workers	Density per lakh rural pop'n		Number	% of all male health workers	Number	% of all female health workers	
Allopathic doctors	381 980	31.2	133.5	250 454	29.7	33.7	4.0	525 945	41.0	106 489	13.6	4.9
Ayurvedic doctors	63 564	5.2	22.2	46 719	5.5	6.3	3.5	94 040	7.3	16 243	2.1	5.8
Homeo. doctors	35 984	2.9	12.6	30 432	3.6	4.1	3.1	55 784	4.3	10 632	1.4	5.3
Unani doctors	6 993	0.6	2.4	3 349	0.4	0.5	5.4	9 479	0.7	863	0.1	11.0
Dental pract.	19 315	1.6	6.8	5 088	0.6	0.7	9.9	18 648	1.5	5 755	0.7	3.2
Nurses & midwives	380 611	31.1	133.0	249 795	29.6	33.6	4.0	104 609	8.1	525 797	66.9	0.2
Pharmacists	127 172	10.4	44.5	104 266	12.4	14.0	3.2	208 559	16.2	22 879	2.9	9.1
Ancill. health	205 156	16.7	71.7	146 022	17.3	19.7	3.6	255 415	19.9	95 763	12.2	2.7
Trad'l & faith heal.	4 606	0.4	1.6	8 034	1.0	1.1	1.5	11 341	0.9	1 299	0.2	8.7
All health workers	1 225 381	100.0	428.3	844 159	100.0	113.7	3.8	1 283 820	100.0	785 720	100.0	1.6
All doctors & nurses	869 132	70.9	303.8	580 749	68.8	78.2	3.9	789 857	61.5	660 024	84.0	1.2
All doctors	468 521	39.9	170.7	330 954	39.2	44.6	3.8	685 248	53.4	134 227	17.1	5.1
AYUSH doctors	106 541	8.7	37.2	80 500	9.5	10.8	3.4	159 303	12.4	27 738	3.5	5.7

Notes: All doctors comprise allopathic plus AYUSH doctors. AYUSH doctors include ayurvedic, homeopathic, and unani doctors. The urban population was 2,861 lakhs and the rural population was 7,425 lakhs. Urban (or rural) density is defined as the number of urban (or rural) health workers divided by the urban (or rural) population.

(Source : THE HEALTH WORKFORCE IN INDIA ,Human Resources for Health Observer Series No. 16, Sudhir Anand and Victoria Fan, WHO, table 2.2, page 17, https://www.who.int/hrh/resources/16058health_workforce_India.pdf)

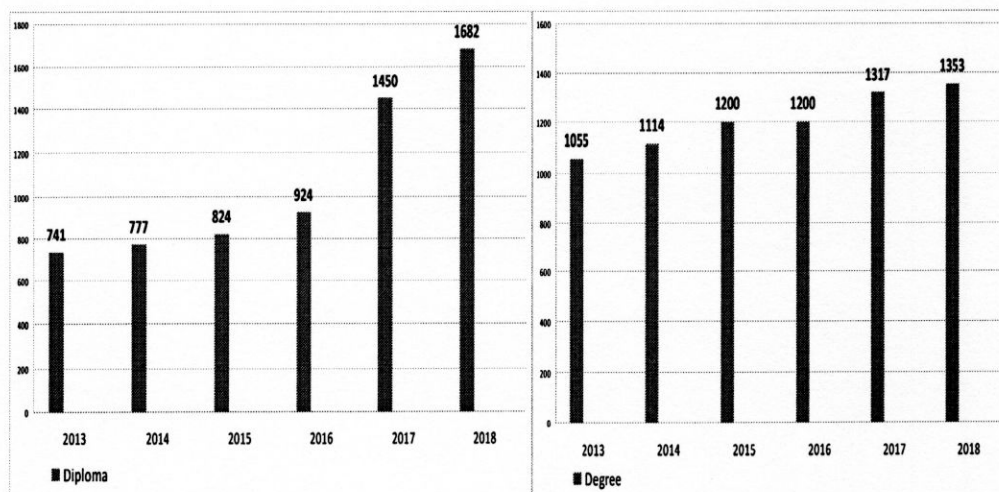
- b) As per the data shown in the table, there are 133 allopathic doctors per lakh population in Urban areas and 44 Pharmacists per lakh population in the similar setting of healthcare. However, the Rural India had 33.7 doctors per lakh population and 14.00 Pharmacists per Lakh population. The inference derived from the above table can be summarized as under -

Health Worker	Density per Lakh Urban	Density per Lakh Rural	Ratio Urban to Rural	Doctor to Pharmacist ratio (Urban B)	Doctor to Pharmacist ratio (Rural B)
Allopathic Doctor	133.5	33.7	4	3 : 1	2.4 : 1
Pharmacist	44.5	14	3.2		

Going by the above data, it is apparent that Rural density in case of both Doctor and Pharmacist is lower as compared to Urban areas, but still Pharmacist density is better than doctor on per Lakh population even in Rural India.

Secondly, Doctor to Pharmacist ratio in Urban India is 3:1, hence there is one Pharmacist for every three doctors whereas in Rural areas there is One Pharmacist on every 2.4 doctors.

- c) However, this data being almost two decades old, there is a substantial increase in the availability of Pharmacist due to the major expansion in educational institutions imparting Pharmacy education as is evident from the growth chart of pharmacy institutions with annual intake as mentioned below –



(Number of institutions imparting Diploma in Pharmacy and Degree in Pharmacy from 2013 to 2018 in India)

The progression of approved Institutes imparting Diploma and Degree in Pharmacy in India has shown a consistent increase over the past 5 years period from 2013 to 2018. The growth in case of institutions imparting Diploma in Pharmacy is more than 120% and degree in Pharmacy is around 30%. Hence India is creating sufficient trained human resource in Pharmacy to cater the needs of Indian population and contribute to the objectives of Universal Health Coverage as envisioned under NHP 2017.

At present, the current statistics with regard to number of pharmacy institutions is as under -

Course	Number of Institutions	Intake / per annum
D.Pharm	3,022	1,80,770
B.Pharm	1,961	1,25,524
Pharm.D	267	8,010
Total	5,250	3,14,304

The above data clearly depicts that approx. 3 lakh pharmacists are passing out per annum from the pharmacy institutions.

Conclusion:

While country is having sufficient trained and competent human resource available for dispensing and handling of drugs, there seems no need to extend the exemptions of having untrained workforce for handling the dispensing and distribution of the drugs to Indian population. This amendment of allowing cadres other than a Pharmacist to dispense and distribute the drugs will lead to

1. Erosion of quality of pharmaceutical services provided to the Indian population thus creating further challenges to health care like -
 - a) Antibiotic resistance
 - b) Over utilization or under utilization of drugs
 - c) Therapeutic duplication
 - d) Drug-disease interactions
 - e) Drug-drug interactions
 - f) Incorrect drug dosage or duration of drug treatment
 - g) Drug-allergy interactions
 - h) Clinical abuse/misuse etc.
2. Make the trained workforce unemployed leading to unrest amongst already existing 1.2 million qualified pharmacy professionals besides around 3 lakh pharmacists passing out per annum.

PCI Prayer:

It is prayed that -

- a) While structuring the human resource needs for not only urban areas but also for rural areas in line with NHP 2017, a registered Pharmacist may be made a required human resource in these Wellness Centers in Urban areas and exemption granted under serial No.23 of Schedule K to other cadres in the Wellness centers be set aside.
- b) This will also contribute to the Key Policy Principles of NHP 2017 wherein government is committed to provide quality healthcare to the Indian population without any discrimination on caste, creed, financial status and geographical location.

PCI objection No. 2. : Inclusion of ASHA workers for supplying the drugs.

- a) ASHA workers have been a part of National Health Missions of the previous National Health Policies of Government of India.

- b) As per the policy document of National Health Mission,

(download from <http://nrhm.gov.in/communitisation/asha/about-asha.html>)

“One of the key components of the National Rural Health Mission is to provide every village in the country with a trained female community health activist ASHA or Accredited Social Health Activists. Selected from the village itself and accountable to it, the ASHA will be trained to work as an interface between the community and the public health system. Following are the key components of ASHA”

- i) The qualification requirements as per NHM document are as under -

- ASHA must primarily be a woman resident of the village married/ widowed/ divorced, preferably in the age group of 25 to 45 years.
- She should be a literate woman with due preference in selection to those who are qualified up to 10 standard wherever they are interested and available in good numbers. This may be relaxed only if no suitable person with this qualification is available.

ii) And, as per the NHM document, their primary responsibilities are as under -

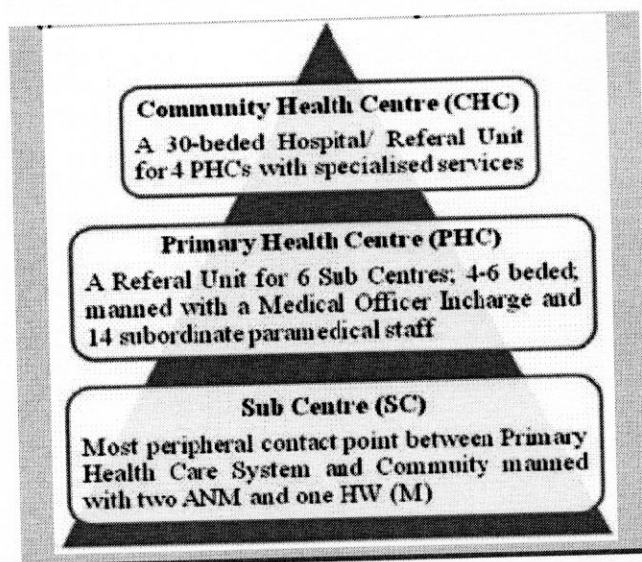
- Empowered with knowledge and a drug-kit to deliver first-contact healthcare, every ASHA is expected to be a fountainhead of community participation in public health programmes in her village.
- ASHA will be the first port of call for any health related demands of deprived sections of the population, especially women and children, who find it difficult to access health services.
- ASHA will be a health activist in the community who will create awareness on health and its social determinants and mobilise the community towards local health planning and increased utilisation and accountability of the existing health services.
- She would be a promoter of good health practices and will also provide a minimum package of curative care as appropriate and feasible for that level and make timely referrals.
- ASHA will provide information to the community on determinants of health such as nutrition, basic sanitation & hygienic practices, healthy living and working conditions, information on existing health services and the need for timely utilisation of health & family welfare services.
- She will counsel women on birth preparedness, importance of safe delivery, breast-feeding and complementary feeding, immunization, contraception and prevention of common infections including Reproductive Tract Infection/Sexually Transmitted Infections (RTIs/STIs) and care of the young child.
- ASHA will mobilise the community and facilitate them in accessing health and health related services available at the Anganwadi/sub-centre/primary health centers, such as immunisation, Ante Natal Check-up (ANC), Post Natal Check-up supplementary nutrition, sanitation and other services being provided by the government.
- She will act as a depot older for essential provisions being made available to all habitations like Oral Rehydration Therapy (ORS), Iron Folic Acid Tablet(IFA), chloroquine, Disposable Delivery Kits (DDK), Oral Pills & Condoms, etc.

- c) From the above responsibilities assigned to ASHA workers, the basic reason was to use these cadres to motivate the oppressed society to -
1. motivate inhabitants of her village to use the available healthcare facilities and programs of the Government.
 2. act as a interface between the health care system and people.

3. inculcate the habits of sanitation which is a biggest driver towards disease prevention.
4. motivate pregnant ladies to register with the Primary Health Centers, Community Health Centers or other government facilities to drive the mother and child care programs of the Government.
5. provide a first aid and manage limited number of drugs like ORS, Iron Folic, Chloroquine and contraceptive drugs and devices.

Hence, the cadre which comes with a minimum criteria of being only a literate person and having no set qualification or training in any healthcare domain can be limited to its already set responsibilities only. They should continue to motivate people to use best sanitation and life style habits and bring them to healthcare facilities for any healthcare needs other than the limited supplies which they are already doing for ORS or contraceptive methods etc.

d) Indian Primary Healthcare Services are based on a hierarchy as under -



e) The manpower allocations for sub-centre, which are the first contact point as per IPHS guidelines is as under -

Type of subcentre Staff	Sub-centre A		Sub-centre B (MCH Sub-centre)	
	Essential	Desirable	Essential	Desirable
ANM/Health Worker (Female)	1	+1	2	
Health Worker (Male)	1		1	
Staff Nurse (or ANM, if Staff Nurse is not available)				1**
Safai-Karamchari*	1 (Part-time)		1 (Full-time)	

*To be outsourced.

** if number of deliveries at the Sub-centre is 20 or more in a month

(Source: [http://health.bih.nic.in/Docs/Guidelines/Guidelines-Sub-Centers-\(Revised\)-2012.pdf](http://health.bih.nic.in/Docs/Guidelines/Guidelines-Sub-Centers-(Revised)-2012.pdf) page 15)

- f) There is a provision of an ANM and Staff nurse as desirable. A sub-center typically is planned for a population of 5000-6000 as per guiding document.
- g) The next level of Primary health Care is a PHC, for which the manpower as mentioned in IPHS guidelines for PHCs is as under -

Manpower: PHC

Staff	Type A		Type B	
	Essential	Desirable	Essential	Desirable
Medical Officer- MBBS	1		1	1*
Medical Officer -AYUSH		1*		1*
Accountant cum Data Entry Operator	1		1	
Pharmacist	1		1	
Pharmacist AYUSH		1		1
Nurse-midwife (Staff-Nurse)	3	+1	4	+1
Health worker (Female)	1*		1*	
Health Assistant. (Male)	1		1	
Health Assistant. (Female)/Lady Health Visitor	1		1	
Health Educator		1		1
Laboratory Technician	1		1	
Cold Chain & Vaccine Logistic Assistant		1		1
Multi-skilled Group D worker	2		2	
Sanitary worker cum watchman	1		1	+1
Total	13	18	14	21

* For Sub-Centre area of PHC.

* If the delivery case load is 30 or more per month. One of the two medical officers (MBBS) should be female.

* To provide choices to the people wherever an AYUSH public facility is not available in the near vicinity.

Source (<http://health.bih.nic.in/Docs/Guidelines/Guidelines-PHC-2012.pdf>
page 16)

- h) As per the standard manpower requirement document of IPHS-PHC-2012 released by Ministry of Health and Family Welfare, there are 1 position essential for a Pharmacist and 1 additional as desirable along with a Nursing staff requirement at 3. These PHCs are typically meant for a population of 25-30 thousand and hence will be around 6000-7000 households in the community.

Conclusion

Based on the above facts and figures

- Due to already availability of trained registered Pharmacists in PHCs and trained ANMs in sub-centres of healthcare pyramid, allowing ASHA workers to supply drugs is detrimental to health of the population.
- The qualification of ASHA workers does not prepare them adequately to handle the complex drug regimens in the current periods.
- With the increase in the registered Pharmacist workforce in the country, even allowing some minimum drugs to an ASHA worker needs to reviewed by the Government on the basis of merits and challenges in the patient safety.

- Further availability of Registered Pharmacists on the retail shops available throughout the country (at present count as per AIOCD data, the number of retail Pharmacies in India is around 8,00,000) could be leveraged by government in driving the health programs right upto the last mile.

Prayer

It is prayed that addition of "ASHA WORKERS" under serial No.23 of Schedule K be deleted.

PCI objection No. 3. : Applicability of exemptions to Wellness centers as proposed in NHP 2017

- a) Health and Wellness Centers are poised to be the center of Universal Primary Healthcare as per NHP 2017. As per the policy, the scope of care by these centers is reproduced below -

3.3.1 Primary Care Services and Continuity of Care:

This policy denotes important change from very selective to comprehensive primary health care package which includes geriatric health care, palliative care and rehabilitative care services. The facilities which start providing the larger package of comprehensive primary health care will be called 'Health and Wellness Centers'. Primary care must be assured. To make this a reality, every family would have a health card that links them to primary care facility and be eligible for a defined package of services anywhere in the country. The policy recommends that health centres be established on geographical norms apart from population norms. To provide comprehensive care, the policy recommends a matching human resources development strategy, effective logistics support system and referral backup. This would also necessitate upgradation of the existing sub-centres and reorienting PHCs to provide comprehensive set of preventive, promotive, curative and rehabilitative services. It would entail providing access to assured AYUSH healthcare services, as well as support documentation and validation of local home and community based practices. The policy also advocates for research and validation of tribal medicines. Leveraging the potential of digital health for two way systemic linkages between the various levels of care viz., primary, secondary and tertiary, would ensure continuity of care. The policy advocates that the public health system would put in place a gatekeeping mechanism at primary level in a phased manner, accompanied by an effective feedback and follow-up mechanism.

(Reproduced from National Health Policy 2017 released by Ministry of Health and Family Welfare, Government of India page 8 & 9)

13.6.3 For achieving the objective of having fully functional primary healthcare facilities- especially in urban areas to reach under-served populations and on a fee basis for middle class populations, Government would collaborate with the private sector for operationalizing such health and wellness centres to provide a larger package of comprehensive primary health care across the country. Partnerships that address specific gaps in public services: These would inter alia include diagnostics services, ambulance services, safe blood services, rehabilitative services, palliative services, mental healthcare, telemedicine services, managing of rare and orphan diseases.

(Reproduced from National Health Policy 2017 released by Ministry of Health and Family Welfare, Government of India page 20 & 21)

- b) These Health and Wellness Centers are the backbones of the healthcare delivery system for the Indian population and are supposed to manage the -
1. Care in Pregnancy and Child-birth.
 2. Neonatal and Infant Health Care Services.
 3. Childhood and Adolescent Health Care Services.
 4. Family Planning, Contraceptive Services and other Reproductive Health Care Services.
 5. Management of Communicable Diseases: National Health Programmes.
 6. General Out-patient Care for Acute Simple Illnesses and Minor Ailments.
 7. Screening, Prevention, Control and Management of Non-communicable Diseases.
 8. Care for Common Ophthalmic and ENT Problems.
 9. Basic Oral Health Care.
 10. Elderly and Palliative Health Care Services.
 11. Emergency Medical Services including Burns and Trauma.
 12. Screening and Basic Management of Mental Health Ailments.

(Source https://nhm.gov.in/New_Updates_2018/NHM_Components/Health_System_Stregthening/Comprehensive_primary_health_care/Day_1/Overview_of_CPHC_and_Operationalization_of_HWCs_JS_P.ppt)

- c) Thus, Health and Wellness centers are expected to be the guardians of the health of Indian population. The preventive and curative disease management of both communicable as well as non communicable diseases makes it a herculean task for this sector of healthcare pyramid and hence this needs trained and skilled human resource for each and every delivery which such centers are supposed to give to the general public whether it is for preventive care or for curative care and NCD management.

- d) Drugs, though are not the only tool to achieve these desired objectives, but are one of the key factors in achieving the health objectives of population of our country. The challenge here is not only providing the drugs but providing complete Pharmaceutical Care to the patient and general public. The Pharmaceutical Care is an essential responsibility which has been assigned to a trained and Registered Pharmacist under the "Pharmacy Practice Regulations 2015" framed under the Pharmacy Act of India 1948.

The duties and responsibilities of a Practicing Pharmacist as per Pharmacy Practice Regulations 2015 are listed below for your ready reference;

Key care Drivers in Pharmacy Practice Regulations 2015

The Regulations for the first time define the key care drivers updated to the current practice like practice of pharmacy, patient counselling, pharmaceutical care, pharmacy practitioners etc. besides dispensing, compounding, distribution etc.

a. Practice of Pharmacy as per these Regulations means:

- i. Interpretation, evaluation and implementation of medical orders: dispensing of prescriptions and drug orders.
- ii Participation in Drug and Device selection, drug administration, Drug regimen review and drug or drug related research.
- iii. Provision of Patient Counselling and provision of those acts or services essential to deliver Pharmaceutical Care in all the areas of patient care including primary care.
- iv. Responsibility for the compounding and labeling of drugs and devices (except for the labeling of non-prescription drugs and commercially produced legendary drugs and devices by a manufacturer, re-packer or retailer), correct and secure storage of drugs and devices and adequate record keeping for them.

b. Pharmacy Practitioner: A Pharmacy Practitioner has been defined as well as his role has been classified based on patient care & healthcare needs. This classification needs separate set of competencies to be possessed by a Pharmacist to justify that assigned role. These are as under:

- i. Community Pharmacist: A registered Pharmacist who is responsible for ensuring correct and safe supply of medical products to the general public.

- ii. Hospital Pharmacist: These professionals work in a hospital setting responsible for safe, appropriate and cost effective use of medicines. They also closely work with other healthcare professionals to devise the most appropriate drug treatment for the patients. Sometimes they are also engaged in the manufacturing of some drugs required for some specific treatments.
 - iii. Drug Information Pharmacist: Can work in any setting including community, hospital, teaching hospital and other healthcare settings and provide information and guidance to patients / physicians / dentists / other healthcare practitioners on drug interactions, side impacts, dosage and adequate medication storage.
 - iv. Clinical Pharmacist: Provides patient care that optimizes medication use and encourages health well-being and prevention of diseases.” They care for the patient and population in all sort of healthcare settings and often collaborate with Physician and other healthcare professionals.
- c. **Pharmaceutical Care**: It is defined as a provision of drug therapy and other patient care services intended to achieve outcome related to care or inhibition of a disease, elimination or decrease of patient’s indicators, or arresting or slowing down of a disease development. This role is a completely new role assigned to a Pharmacist in these Regulations where a Pharmacist becomes an integral part of therapy rather than only providing medicines as instructed. A Pharmacist is supposed to provide his expert services which may start with identification of right and the most appropriate therapy to the complete care during the administration and diseased state of the patient.

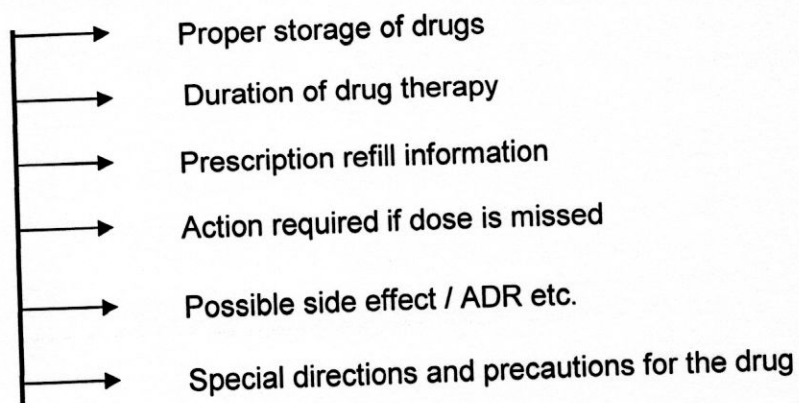
By including Pharmaceutical care as a duty, a Pharmacist is entrusted with the responsibility of reviewing the patient records and each prescription presented for dispensing. A pharmacist is now mandated to promote therapeutic appropriateness by identifying:

- Over Utilization / under utilization
- Therapeutic duplication
- Drug- disease and drug-drug interaction & drug allergies
- Incorrect dosage and duration of treatment
- Clinical abuse or misuse etc.

The above issues are to be resolved, if required, in consultation with the treating physician.

- d. Patient Counselling:** This has been included for the first time in the Regulations providing a legal frame work for the Pharmacist to counsel the patients as a “ Oral communication of information to the patient or caregiver, in order to ensure proper use of the drug or device. This means that a Pharmacist has to have an extensive knowledge on the proper use of the drug which includes storage, administration and precautions which has to be implemented for consumption of a particular drug. A Pharmacist is required to understand the leaflet insert of each drug being dispensed to a patient so that he can fulfil the desired role.

He is expected to counsel the patient / caregiver on



- e. Renewal of Pharmacist registration:** Pharmacist for renewal of registration once in 5 years has to undergo two refresher courses of minimum one day duration for making himself eligible for remaining in the register. These refresher courses are to be conducted by approved bodies in the Regulations. This will ensure that a Practicing Pharmacist will remain updated about the innovations or new techniques introduced in the profession and will help them to service the society better. The incorporation of this provision will strengthen the spirit of lifelong learning as envisaged in the Pharmacy Act 1948.

The Practice Regulations for Pharmacist was an outcome of challenges being faced in the current healthcare delivery and drugs and disease management becoming more and more complex everyday.

The extent of medical errors, which are defined as a damage to the health of a patient or person which are not related to his disease or state of health, but are caused by errors encountered during the treatment and cure is immense. As per the latest information available, occurrence of medical errors in India are to the extent of 5.2 Million per year. A major portion of these medical errors are Medication errors.

The medication errors are defined as -

- Definition as mentioned in WHO paper on Medication errors “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use”.
- Definition as per Encyclopedia of Medical Concepts : Erros in prescribing, dispensing, or administration medication with the result that the patient fails to receive the correct drug or the indicated proper dosage.

The Medication Errors are the ones which happen during the drug to patient interface which is only a part of the patient care in healthcare setting. Some of the examples of medication errors could be

- Wrong drug dispensed in LASA (Look alike Sound alike) formats like ADRenaline and ATROPine, DOPamine and DOButamine etc
- Wrong dose calculation in ICU setting of Ionotopes or Insulin
- Wrong route of administration like IV injection instead of IM injection.
- Wrong dose calculation in case of some of the chemotherapeutic drugs which are calculated based on weight or surface area of the patient.
- Administration of incompatible drugs at the same time.
- Mistakes in selection of multi drug therapy.
- Illegible handwriting leading to dispensing of wrong drugs.
- Dosage adjustment etc.

However, with the introduction of Pharmaceutical Care within the Pharmacy Practice Regulations 2015 and making counseling as compulsory responsibility of a Practicing Pharmacist, these medication errors can be substantially reduced if not possible to eliminate.

Conclusion

Going by the above rationale and data, it is all the more necessary to utilize the services of a Registered Practicing Pharmacist in the management of Drug and Disease interface. Non-communicable diseases (NCDs) require prolonged use of prescribed drugs and hence, a proper and qualified Pharmaceutical Care, time to time counseling and prescription monitoring of the patient by a registered Pharmacist can help to manage the status of these diseases to sub critical level and help in reducing the need for hospitalization or pre mature mortality.

With the abundant Pharmacist human resource availability, this workforce may be judiciously utilized not only to achieve the Universal Health Coverage Objectives of the NHP 2017 but also to fulfill the supplementary objectives like quality of care.

Prayer

No exemptions under S.No23 of Schedule K be provided in Health and Wellness Centers as proposed in the amended clause.

4. Other Submissions

The Pharmaceutical workforce of India has been the backbone of our country's self sufficiency in the provision of required drugs for cure of almost all the diseases for which a cure is available anywhere in the world and at the most affordable cost.

However, a qualified Practicing Pharmacist can contribute much more in downstream healthcare management for the better health of Indian public. With the available number of workforce and the competency, the Pharmacist workforce can contribute as mentioned under to achieve the national objective of Quality Universal Health Coverage.

The suggestions are as under:

1. There are new opportunities in the healthcare delivery value chain which have been duly identified in the current NHP of India 2017 and a Pharmacist has been included in the list of candidates for complementary cadre in the healthcare delivery and government's Universal health Coverage objectives.

Pharm.D graduates, who has qualified the 6 years clinical oriented course including one year internship in a tertiary care hospital alongside the clinicians can be given restricted prescription rights may be under the supervisory control of a medical doctor. These graduates are trained for clinical management along with Pharmaceutical Care and can effectively manage the less critical diseases like diarrhoea, simple fever, continuity or stop of an infection drug therapy, management of chronic diseases etc once a specialist has already diagnosed the patient. This will reduce the load of repeat calls on the Physician or specialist and they will be in a position to handle the critical patients more effectively.

2. The Pharmacist next door, who is operating a community pharmacy commonly known as Chemist and Druggist, generally holds a Diploma in Pharmacy as a minimum qualification. The spread of around 700K to 800K such Pharmacies across the length and breadth of India is a resource which policy planners have not thought of utilizing still. The Pharmacy Practice Regulations giving a legal status to these Pharmacists for practicing Pharmaceutical Care, Patient Care and Primary Care can be roped in to drive the national objectives on

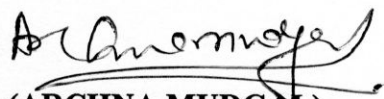
- Mother and Child related health programs
- Universal Vaccination Plans
- Family Planning and Sexual Health
- Monitoring of non communicable diseases like Coronary arterial diseases, Diabetes, Hypertension etc thereby reducing the risk of aggravating these diseases leading to hospitalization etc.

With almost 700K to 800K such Pharmacies operating in India, there is an average of one pharmacy on around 2000 people in India so is the availability of number of Pharmacists. If these pharmacists are incentivized, they can provide personal healthcare management to the society. Assuming that a Pharmacy operates 14 hours a day, 325 days a year, the time a Practicing Pharmacist can spend is 2.27 hours per year or almost 3 minutes per week. Assuming that only 50% of the population needs regular care, the time available will double. This much of time is sufficient for regular blood pressure or blood glucose monitoring for chronic care patients or executing a regular immunization to children or elders if required. Based on this calculation and competency potential of community pharmacist which is readily accessible, this workforce can really be useful for preventive and promotive care in alignment with the NHP 2017 goals under various schemes like.

- **Mission Indradhanush:** Vaccination scheme covering 528 districts with 3.15 crore children & pregnant women.
- **Ayushman Bharat scheme:** Health insurance program for comprehensive health coverage to 10 crore poor families.
- **Pradhan Mantri Jan AushadhiYojna:** Affordable quality medicines.
- **Pulse Polio Programme:** Covering more than 17 crore Children below 5 years of age across the country.

In view of above facts, the PCI strongly opposes the proposed amendment in serial No.23 of schedule K of the Drugs and Cosmetics Rules 1945 and requests to withdraw it in the interest of public health and society at large.

Yours faithfully




(ARCHNA MUDGAL)
Registrar-cum-Secretary

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