

महाराष्ट्र राज्य औषध व्यवसाय परिषद

(भारत सरकारच्या औषध व्यवसाय अधिनियम १९४८ चा ८ वा अंतर्गत घटित)

MAHARASHTRA STATE PHARMACY COUNCIL

(Constituted under The Pharmacy Act, 8 of 1948 of Government of India)



Ref :-P-17/3/ 21217 /2019

Date :-

To,
The Under Secretary (Drugs)
Ministry of Health and Family Welfare
Govt. of India
Room No.414 A, D Wing
Nirman Bhawan
New Delhi - 110 011

19 NOV 2019

Sub: - Objections on Draft Rules to Amend the Schedule K of Drugs and Cosmetics Rules, 1945.

Ref: - Draft Notification G.S.R.827 (E) dated 6th November,2019, Ministry of Health and Family Welfare.

Respected Sir,

Maharashtra State Pharmacy Council is a statutory body constituted by the Government of Maharashtra under the provisions of Pharmacy Act -1948, a central Act enacted by the Government of India to regulate the practice and profession of pharmacy. This office grants registration to eligible applicants complying with provisions of section 32(2) of Pharmacy Act and issue registration certificates so that they can practice profession of pharmacy in Maharashtra State. Also, for implementation of section 42 of the Act (Dispensing by registered Pharmacist) this office has appointed Pharmacy Inspectors in our state with sanction of State Government.

It is learnt that the Amendment to Schedule K of the Drugs and Cosmetic Rules 1945 against serial number 23, for the entries under the column "Class of Drugs", where following are going to be substituted namely: -

" 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."

In this context, we seek your kind attention on following facts.

1) Section 42 of Pharmacy Act,1948 runs as below –

"No person other than a registered pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner. Whoever contravenes the

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provisions shall be punishable with imprisonment for a term which may extend to six month or with fine or with both."

- ✓ Kindly note that as per inspection reports of pharmacy inspectors, necessary communications were sent by this office to defaulting doctors or establishments for necessary implementation of this section. Also, in some cases, where dispensing of medicines was done by un registered persons, and cases were filed for contraventions of section 42 of Pharmacy Act by this office, honourable **Metropolitan Magistrate, Mulund court has charged fine to the said doctors and unregistered persons, upholding section 42 provisions.**
- ✓ In another case in which an appeal was filed by this office, **honourable high court of judicature at Bombay, Aurangabad bench had held the concerned persons guilty for contravention of provisions of section 42(1) of Pharmacy Act and thus upheld section 42 of the Act**

It is contention of this office, if subject mentioned proposed amendments are implemented it will be in contravention of provision of section 42 of Pharmacy Act -1948 which is a Central Act

- 2) We would also like to draw your attention to following facts regarding registration as pharmacists in our state -
 - ✓ Presently minimum registerable qualification is completion of Diploma in Pharmacy along with training (D Pharm- after 10+2 science stream) from PCI approved institute.
 - ✓ Total number of Registered Pharmacists in **Maharashtra state** as on today - **2,64,245**
 - ✓ The number of Pharmacy Colleges approved by PCI, New Delhi are increasing over last few years
 - ✓ As on today,
 - a) Number of Diploma Colleges in Maharashtra approved by PCI –**278**
 - b) Number of Degree Colleges in Maharashtra approved by PCI –**168**
 - c) Number of Pharm D Colleges in Maharashtra approved by PCI –**03**
- 3) As per information received by this office, Exit Examination for D Pharm. students before registration as a pharmacist is also under consideration by PCI, New Delhi which is Education Regulatory body as per Pharmacy Act provisions.
- 4) Also considering the knowledge level required to work as registered pharmacist, in many advanced countries registerable qualification is pharmacy course with

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minimum 4 years duration or more and in our country also bridge course is started by PCI, New Delhi for those who completed D Pharm.

Thus, registered pharmacist during academic years is already equipped with knowledge on manufacture of dosage forms, analysis, pharmacological properties and interactions of drugs, legal aspects of drugs, storage conditions etc. **With the implementation of subject mentioned proposed amendment there is high risk of these medicines turning into dangerous form if not handled by competent person.**

Hence this office is of the opinion that there is no dearth of qualified registered pharmacists in this state as well as medicines must be dispensed and handled through competent person only

Also considering importance of upgradation of knowledge for registered pharmacists, following Training programs are conducted by Maharashtra State Pharmacy Council for them and thousands of registered pharmacists are being trained who render quality services like counselling during dispensing of medicines

- ✓ Online Refresher Courses
- ✓ One day refresher course -Classroom type Courses
- ✓ Patient Counselling courses -Workshop type Courses

5) Further important point is implementation of Pharmacy Practice Regulations-2015 in all states of India via gazette Notification by PCI, New Delhi

- ✓ Accordingly, Registered Pharmacist has important role in review of patient prescription, record maintenance, identifying drug-drug, drug food interaction, etc and counsel patients. Pharmacists help in **adherence** to dosage regimen by patient which is utmost important in treatment like Tuberculosis. **This is evident from participation of Registered pharmacists in DOTS project for TB patients by Government**
- ✓ Pharmacists play important role in promotion of rational use of drugs. **To site an example, Menace of antibiotic resistance can be controlled by effective counselling by Registered pharmacists regarding completing course of antibiotics by patients even though they get symptomatic relief (or "feel" good) during dispensing and selling of medicines**

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- ✓ Pharmacists help patients in understanding the proper use of medicine and precaution taken which is vital in specialised dosage forms like inhaler, etc Medication errors can be avoided by proper information given by Registered pharmacists to patients during dispensing .To name a few, where proper information was not received by the end user , there have been examples like pessaries are taken orally by some patients .Also rota caps which need to be broke open through rota haler device and contents are to be taken through inhalation route are gulped with water by patients ,this leads to "No therapeutic result" with said medications .

A recent Johns Hopkins study claims more than 2,50,000 people in USA die every year from Medication Errors and Medication error is third leading cause of death all over the world

Minimising or ruling out these type of medication errors is possible only if person dispensing medicines is qualified Registered Pharmacist

In March 2014, World Health Organisation has introduced the concept of "Seven Star Pharmacist" considering scope of pharmacy practice and patient centred care to be given by Registered Pharmacist. Also taking into consideration, the pharmacists work to protect and promote the health, safety and wellbeing of patient and the public making them more resilient to infection, in the year 2015, WHO and FIP has jointly published handbook named "Fighting Antimicrobial Resistance: The contribution of Pharmacists."

- ✓ There is also important role of Registered Pharmacists in pharmacovigilance where reporting Adverse Drug Reactions can be done by them which will build strong data base, helpful in avoiding such type of incidences in future

We strongly believe the possibilities of following unwanted incidences in case said proposed amendments are implemented –

1. Existing issue of unemployment of qualified Registered pharmacists will reach detrimental levels.
2. Health of public at large will be in danger as medicines will be given by un competent person.
3. Medication error will rise as proper information related to drug, dosage form, how and when to take, etc will not be communicated to patient.

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In the year 2019, WHO has released facts sheet on the occasion of Patient Safety day, in which fact no 6 states that "Unsafe medication practice and medication errors harm millions of patients and costs billions of US dollars every year. This represents almost 1% of global expenditure on health."

4. Due to incompetency of staff handling medicines, there will be loss of potency for vaccines, insulin, etc which require specialised storage conditions and maintenance of cold chain to retain potency till reach final consumer
5. Overall health scenario will head to disastrous conditions.

Just like it is the right of every citizen to get right medicines, it also warrants that right medicines should be supplied by right, competent and learned person with effective counselling.

Therefore, Maharashtra State Pharmacy Council on behalf of more than 2 lacs 60,000 registered pharmacists in this state, proactively and strongly objects the Draft Rules and requests to revoke the proposed amendment in Schedule K in the interest of health of public at large.

Yours faithfully,

SAILI SWARNIL MASAL
Registrar
Maharashtra State Pharmacy Council

VIJAY PANDURANG PATIL
President
Maharashtra State Pharmacy Council