

No. B.17011/223/13/DHS/DRUGS/ 64
GOVERNMENT OF MIZORAM
DIRECTORATE OF HEALTH SERVICES
(Food & Drugs Administration Wing)
MIZORAM : AIZAWL

Dated Aizawl, the 13 June, 2025

OFFICE ORDER

Whereas, a written complaint received by FDA Wing, DHS against M/s R.Z.Pharmacy (SRHF-ZMC Canteen) was duly investigated and the Investigation Report found a prima-facie violations of the law. A show cause notice was accordingly issued to M/s R.Z.Pharmacy under Rule 66(1) of the Drugs Rules, 1945 vide letter no. B.17011/2/2024/DHS/DRUGS/51 dated 25.2.2025 requiring the licensee to explain why action shall not be taken for contravention of the provisions of Pharmacy Act, 1948 and the Drugs Rules, 1945. Detail situation of the case is as follows :-

1. The pharmacist being employed by M/s R.Z.Pharmacy is a working pharmacist at Civil Hospital, Aizawl and was not able to give regular supervision to the pharmacy operations at SRHF- ZMC Pharmacy Canteen while the daily routine work of the canteen is the dispensing of prescription drugs against the prescription of the doctors. Dispensing of prescription drugs in absence of a registered pharmacist is illegal as it is unsafe and harmful for the patients. Following are relevant provisions :-

Section 42 of Pharmacy Act, 1948 : No person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a registered medical practitioner.

Rule 65 (2) of Drugs Rules, 1945 : Any drug supplied on the prescription of a registered medical practitioner shall be affected only by or under the personal supervision of a registered pharmacist.

Regulation 3.4(a) of Pharmacy Practice Regulation, 2015 : The owner of a pharmacy business shall appoint a registered pharmacist, otherwise the owner shall be deemed contravening section 42 of Pharmacy Act, 1948

Regulation 9.1(a) of Pharmacy Practice Regulation, 2015: The various activities of dispensing (*prescription assembly*) like removal of drugs from the packing, filling the prescription etc. may be performed under the supervision of a registered pharmacist by any person who has been trained to performed these activities. However, the actual dispensing of drugs to patients shall only be performed by the registered pharmacist after due verification of the prescription filled by others.

It is therefore, quite evident that a pharmacy operated under a license in form 20&21 should be run only under the direct or personal supervision of a registered pharmacist and to this effect Mizoram FDA had issued circulars on July 13, 2018, May 21, 2024 and August 26, 2024. The August 26, 2024 circular directed pharmacist with other jobs to withdraw from their supervision as they are not able to manage the pharmacy properly.

However, M/s R.Z.Pharmacy does not employ or take steps to employ a full-time pharmacist and in his reply to the show cause notice he said he believed that the non-

pharmacist employee he had been engaging for more than 10 years were qualified to provide prescription services. And for being hospital canteen occupant, M/s R.Z.Pharmacy was warned about 5 years ago to employ a pharmacist on full-time basis but paid no attention to engage suitable registered pharmacist till today, thereby breaches the provisions of Sec.42 of Pharmacy Act, 1948 and Rule 65(2) of Drugs Rules, 1945.

2. M/s R.Z.Pharmacy is also engaging another firm namely M/s R.R.Pharmacy, Falkawn to manage the hospital canteen without prior approval of Hospital Authority. This is clearly evident in PM-JAY benefits from the hospital where payment is made to M/s R.R.Pharmacy who does not have any legal right to function in the management of SRHF-ZMC Canteen and thereby violate Section 18(c) of the Drugs & Cosmetics Act, 1940.

And whereas, the reply submitted by M/s R.Z.Pharmacy on 13.3.2025 has been duly considered and found unsatisfactory and inconclusive.

And whereas, after due consideration of the facts and circumstances, the licensing authority was satisfied that M/s R.Z.Pharmacy has violated Section 42 of the Pharmacy Act, 1948, Section 18 (c) of the Drugs and Cosmetics Act, 1940 and Rule 65(2) of the Drugs Rules, 1945 **warranting cancellation of drugs license.** However, it was decided to withhold cancellation and wait for improvements in compliance, with an understanding that the licensee would take immediate corrective measures.

And whereas, upon a **re-inspection conducted on June 12, 2025** by a team led by the Asst.Director (F&D), who had conducted the previous inspection, it has been reported that **no corrective actions** have been taken by the licensee and that **all earlier violations remain unrectified**, clearly indicating continued non-compliance and disregard to the provisions of the Pharmacy Act, 1948 and Drugs Rules, 1945.

Now, therefore, in exercise of powers conferred under Rule 66(1) of the Drugs Rules, 1945, the undersigned hereby **cancels** the Drug Licence No. 01/01/13/0517 & 01/01/13/0518 (form 20&21) granted to Lalrozara, M/s R.Z.Pharmacy, Falkawn with **immediate effect.**

M/s R.Z.Pharmacy is directed to immediately cease all activities pertaining to the sale, distribution and storage of drugs under the licence forthwith.

The licensee may, if aggrieved by this order, submit an appeal to the State Government within the prescribed period as per the provisions of Rule 66(2) of the Drugs Rules, 1945.

Sd/- F.LALLIANTLUANGA
Jt.Director (F&D)
Controlling & Licensing Authority
Directorate of Health Services
Mizoram : Aizawl

Copy to :

1. PS to Hon'ble Minister, H&FW
2. PPS to Commissioner & Secretary, H&FW
3. Principal Director, H&FW
4. Director of Health Services
5. Director of Hospital & Medical Education
6. Director, ZMC & H
7. The Medical Superintendent, ZMC & H for information *with a request to ensure uninterrupted supply of essential medicines to patients and to make suitable alternative arrangements for drug procurement and distribution at the earliest*
8. M/s R.Z. Pharmacy (Prop : Lalrozara) Contact : 9862366305
9. The AD (F&D), Sr.CMO Office, Aizawl West for information an necessary action
10. The Registrar, Mizoram State Pharmacy Council, DHS Old Building, Dinthar
11. Guard file



Jt. Director (F&D)

Controlling & Licensing Authority
Directorate of Health Services
Mizoram Aizawl