NO.B.17011/24(B)/17/DHS/DRUGS/<u>9/</u> GOVERNMENT OF MIZORAM DIRECTORATE OF HEALTH SERVICES (FDA WING)

MIZORAM : AIZAWL

Dated Aizawl, 22 February, 2023

CIRCULAR (Self auditing of pharmacy)

Mizorama damdawi dawr (pharmacy/drug store)-te an lo felfai theih zawk nan mahnia damdawi dawr endik dan tur (Self auditing of pharmacy) ruahmanna siam a ni a, hei hian dan bawhchhiat theihna lakah damdawi dawr thui takin a veng thei dawn a ni. A tlem berah kum khatah vawi 3 tal mahni dawr endik theih a nih chuan damdawi dawrin hma a sawn ngei dawn a ni.

Chuvangin, damdawi dawr zawng zawngte chu hemi hmanga an dawr endik theuh thin tura ngen leh beisei an ni a, bialtu FDA Officer-te pawhin damdawi dawr an endik hunah hei hi an entel ngei thin tur a ni ang.

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

Dated Aizawl, the Representation of February, 2023

Memo No.B.17011/24(B)/17/DHS/DRUGS/<u>9/</u>

Copy to :-

1. PPS to Principal Secretary, Health & Family Welfare

2. Principal Director, Health & Family Welfare

3. All ADs (F&D)/DIs/ADIs

Mizoram for info & necessary action

4. Mizorama damdawi zuar zawng zawngte, an lo hman tangkai turin.

5. The Secretary, MCDA, Aizawl Headquarters

6. Guard file.

Jt.Director (F&D),

Controlling & Licensing Authority, Directorate of Health Services,

Mizoram: Aizawl.

GOVERNMENT OF MIZORAM HEALTH & FAMILY WELFARE DEPARTMENT

(FOOD & DRUG ADMINISTRATION WING)

SELF INSPECTION (AUDITING) OF A PHARMACY

Self Inspection date :
Conducted by :
1. Name of the Drug Store/Pharmacy:
2. Address of Drug Store/Pharmacy:
3. Licence Number :
4. Date of Issue of licence :
5. Validity of the licence :
6. Licence retention fee submitted (if due) : Yes / No (Submit licence retention fee within time)
7. Proof of licence retention fee submission (Retention Letter) kept: Yes / No (Retention Letter and copy of Challan must be kept in record)
8. Constitution of the firm : Proprietorship / Partnership / Pvt.Ltd.
9. Is there any change in the constitution? : Yes / No (If yes, apply for new licence)
10. Name(s) of Prop. / Partners / Directors of the firm :
11. Name of the responsible person of the firm :
12. Whether licences of the firm ever suspended or partially cancelled? : Yes / No (Obey the provisions of Drugs and Cosmetics Act/Rules)
13. Whether sign board of firm displayed? : Yes / No (Display sign board with name of the firm and such other particulars)
14. Whether "Drugs Store / Pharmacy" written on the sign board? ("Drugs Store/Pharmacy" must be written on the sign board)
15. Whether Drug Licence displayed at a prominent place? : Yes / No (Display drug licence at the prominent place)

16. Name of Regd. Pharmacist (RP) of the firm :				
17. Registration Number of Regd. Pharmacist :				
18. Validity of Regn. of Regd. Pharmacist (Validity of Regn. Certificate of RP must be up to date)				
19. Whether Regn. Certificate of RP/Supervision Agreement disj (You should display Regn. Certificate of RP/Supervision Agr	played. reement)	: Yes / No		
20. Joining date of Regd.Pharmacist :				
21. Whether any change in Regd. Pharmacist :	Yes / I	Yes / No		
22. Resignation date of Regd.Pharmacist (If resigned) :	y 17			
23. Whether new Regd.Pharmacist appointed (If resigned):	Yes / I	Yes / No		
24. If yes, date of appointment of new Regd.Pharmacist :	(1)			
25. Name of new Regd.Pharmacist :				
26. Regn. Number of Regd.Pharmacist :				
27. Validity of Regn. of Regd.Pharmacist :				
28. Whether dust free environment is maintained? (Keep your premises neat and clean)	:	Yes / No		
29. Whether purchase record of drugs is maintained properly? (Maintain purchase record of every drug properly)	:	Yes / No		
30. Whether purchase record is maintained in chronological ord (Maintain purchase record in chronological order)	ler?:	Yes / No		
31. Whether drugs are purchased from licenced dealers? (Purchase drugs from licenced dealers only)	:	Yes / No		
32. Whether purchase invoices bear all the mandatory details? (Purchase invoice should have all mandatory details of drug	: g)	Yes / No		
33. Whether drugs are being sold under the personal supervision (Sale of drugs must be done under the personal supervision	on of RP?	: Yes / No		
34. Whether drugs are being sold on the prescription of RMP? (Sell the drugs on the prescription of a RMP)	:	Yes / No		
36. The second s		,*		

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Yes / No 35. Whether substituting the prescription of RMP? (Do not substitute the prescription of RMP) 36. Selling of drugs on price more than MRP. Yes / No (Do not sell the drugs on the price more than MRP) Yes / No 37. Sale records of drugs maintained. (Maintain sale record of the drugs) Yes / No 38. Sale records maintained in legible manner. (Maintain sale record of the drugs in legible manner) Yes / No **39.** Name and address of prescriber mentioned. (Mention name and address of the prescriber) Yes / No **40.** Name and address of patients mentioned. (Mention name and address of the patient) Yes / No 41. Sale record is having all other mandatory details. (Sale record of drugs should have all mandatory details) 42. Sale invoice signed by Regd. Pharmacist. Yes / No (Sale invoices must be signed by RP) 43. Sale of Schedule H-1 drugs (Antibiotics etc) without prescription : Yes / No. (Never sell antibiotics without prescription) Yes / No 44. Sale of habit forming drugs. (Never sell habit forming drugs without prescription of a RMP) Yes / No 45. Schedule-H1 register maintained. (Maintain Schedule-H1 register) Yes / No **46.** Full time electricity supply. (Full time electricity supply must be ensured to maintain desired temperature of the drugs) 47. If not, generator maintained. (Full time electricity supply must be ensured to maintain desired temperature of the drugs) 48. Whether drugs are exposed to direct sun light? Yes / No (Drugs should not be exposed to direct sunlight) Yes / No **49.** Refrigerator is in working condition. (Refrigerator must be in working condition) Yes / No **50.** Whether temperature of refrigerator is maintained? (Temperature of refrigerator must be maintained)

51. Stocking the drugs in refrigerator which do not require storage (Do not stock drugs in refrigerator which do not require storage)		
52. Stocking the drugs requiring cold storage in refrigerator.(Only drugs requiring cold storage should be kept in refrigera	: itor)	Yes / No
53. Whether food items are stored in refrigerator? (Do not stock food items in refrigerator)	:	Yes / No
54. Whether oily injections are stored in refrigerator?(Do not stock oily injections in refrigerator)	:	Yes / No
55. Switching off the refrigerator in the night.(Do not switch off the refrigerator in the night and maintain d	: esired	Yes / No temperature)
56. Air conditioner installed. (Installation of air conditioner is advisable to maintain the roo	: om tem	Yes / No perature)
57. Stocking the drugs in its original containers.(Always stock the drug in the original container of that drug)	:	Yes / No
58. Stocking the drugs on floor. (Do not stock the drugs directly on the floor)	:	Yes / No
59. Homeopathic medicines stocked separately. (Stock the homoeopathic medicines separately)	:	Yes / No
60. "Homeopathic medicines" written on the rack. (Write "Homeopathic medicines" on the rack)	:	Yes / No
61. Ayurvedic medicines stocked separately. (Stock the Ayurvedic medicines separately)	:	Yes / No
62. "Ayurvedic medicines" written on the rack. (Write "Ayurvedic medicines" on the rack)	:.	Yes / No
63. Veterinary drugs stocked separately. (Stock the Veterinary drugs separately)	:	Yes / No
64. "Veterinary drugs Not for human use" written on the rack. (write "Veterinary drugs Not for human use" on the rack)	: •	Yes / No
65. Expiry drugs found stocked. (Stock Expired drugs separately away from the trade stock)	:	Yes / No
66. "Expired dated drugs Not for Sale" written on the rack. (Write "Expired dated drugs Not for Sale" on the rack)	: :	Yes / No

67. Schedule -X drugs found stocked. (Separate licence must be obtained for Schedule-	X drugs)	:	Yes / No
68. "Physician samples Not for Sale" found stocked (Do not stock and sell "Physician samples not for		: 0	Yes / No
69. "Hospital supply drugs not for sale" found stock (Do not stock and sell "Hospital supply drugs not		:	Yes / No
70. Drugs without invoice found stocked. (Invoice has to be properly kept)		:	Yes / No
71. Oxytocin Injection found stocked. (Sale of Oxytocin Injection through retail chemis	t is not allowe	: d)	Yes / No
72. "Banned drugs" found stocked. (Never stock and sell banned drugs)		:	Yes / No
73. Date of last inspection done by FDA Officer	:		~
74. Whether samples have been drawn by FDA Offi	cer?	:	Yes / No
75. What was the result of sampled drug?		:	Standard / NSQ
76. Copy of last self inspection kept.(Copy of all self inspection reports must be kept)		:	Yes / No
77. Whether CC Camera installed at the sale counter (CC Camera to be installed to cover the sale counter)		:	Yes / No
Determ	Signature		
Date :	Name		8

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