

# RELINES GUIDELINES

GUIDELINES FOR PRESCRIPTION
WRITING AND HANDLING
OF PRESCRIPTIONS AND
PRESCRIPTION MEDICINES.

A Stakeholders' Initiative - Goa

# GUIDELINES FOR PRESCRIPTION WRITING AND HANDLING OF PRESCRIPTIONS AND PRESCRIPTION MEDICINES

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### THE VOLUNTARY HEALTH ASSOCIATION OF GOA

With inputs from the following stakeholders:-

- Allopathic doctors and hospitals as represented by The Goa Medical Council, The Indian Medical Association, The Association of Private Nursing Homes in Goa, The Goa Medical College and The Directorate of Health Services, Goa.
- 2. Pharmacists and pharmacies as represented by The Goa State Pharmacy Council, The Indian Pharmaceutical Association and The Chemists & Druggists Association, Goa.
- 3. Dentists as represented by The Goa Dental College, The Indian Dental Association, and The Goa Dental Council.
- 4. Veterinarians as represented by The Goa Veterinary Association, The Department of Animal Husbandry and Veterinary Services and The Goa Veterinary Council.
- 5. The Directorate of Food & Drugs Administration, Goa.
- 6. The Voluntary Health Association of Goa

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### 1. INTRODUCTION

Recent years have seen a significant shift of focus in healthcare from advances in technology to patient safety; to such an extent, that in 2002, the WHO passed a World Health Assembly Resolution on Patients Safety. This was prompted by the realization that countries were loosing up to \$29 billion due to health care errors annually. The General Medical Council, U.K., changed its stated role from "Registration of Doctors and Regulating Medical Education", to "Protecting Patients and Guiding Doctors". The U.K. now has a National Patients Safety Agency (NPSA). Australia has its Australian Patients Safety Foundation; and India has established the National Institute for Patients Safety (NIPS). In short, patients' safety has become the primary focus in therapeutic medicine.

Medication errors occupy a prominent place in the list of deficiencies resulting in adverse events. They accounted for 19.3% of all cases handled by the Medical Protection Society in the UK; an organization that functions like the Medical Indemnity Insurance in India. In the United States it is estimated that 7,000 deaths each year are caused by medication errors; with harmful effects in 1.8% of all hospital admissions. More worrying is the fact that medication errors rose 2.57 fold in the ten year period from 1983-1993 in the US, where attempts to computerize prescriptions still produced an error margin of 67%.

Regrettably in India we do not have the culture of recording/publicizing our mistakes much less analyzing them. Hence we have no data on this issue; but the causes appear to be multifactoral. A small prescription survey in Goa revealed that prescriptions rarely comply with the rules in all parameters. Further:

- In the public sector, providers are more likely to commit errors of omission they are less likely to exert effort compared with their private counterparts.
- In the private sector, providers are prone to errors of commission they are more likely to behave according to the patient's expectations, resulting in the inappropriate use of medications, the overuse of antibiotics, and increased expenditures.

(Jishnu Das & Jeff Hammer, World Bank Policy Research Paper No.3228)

NPSA defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of health professional, patient or consumer."

Medication errors carry human costs for the patient, their family and friends, and for the professionals concerned. They also impose a financial burden on the patient, as well as the healthcare system. Most available statistics allude to costs related to hospital in-patients. To this must be added the unknown cost of errors in primary and community care, and also indirect costs such as those arising from litigation. The potential savings from reducing serious medication errors are therefore substantial, both in terms of reducing human suffering as well as sheer economics.

At the heart of medication therapy, lies the prescription; a legal document governed by the following laws:-.

- The Indian Medical Council Act, 1956
- The Indian Medical Council (Professional Conduct, Etiquette & Ethics) Regulations, 2002
- The Drugs and Cosmetics Act, 1940 and Rules 1945
- The Pharmacy Act, 1948
- The Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules 1987
- Drugs (Price Control) Order, 1995
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and **Rules 1955**

Prescription writing used to be an art as well as a science. Unfortunately, times have changed. More often than not, we find incomplete and illegal prescriptions being handed over to patients, and, more unfortunately, honored at pharmacies. This has resulted in a disturbing trend of putting the patients safety at risk; and there is an urgent need to put things right.

In spite of existing laws, there is considerable confusion with regards to matters

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relating to a prescription at every stage of its journey from a doctor's prescription pad to the point where the medicine is to be used by the patient. Ground realities indicate that there are problems and difficulties faced by patients as well as the pharmacists; there are lacunae and ambiguities, which result in varying interpretations by different stakeholders.

This booklet on Guidelines for prescription writing and handling is a result of a series of round table meetings of the representative stakeholders in the state of Goa. The following were the meetings held:

- a. Round table meeting in 2006, at Hotel ALua, Merces
- b. Round table meeting in 2009 at Hotel Delmon, Panaji
- c. Round Table meeting in April 2011, at Hotel Atish, Ponda

The following stakeholders participated in the discussions

- Allopathic doctors and hospitals as represented by The Goa Medical Council, The Indian Medical Association, The Association of Private Nursing Homes in Goa, The Goa Medical College and The Directorate of Health Services, Goa.
- Pharmacists and pharmacies as represented by The Goa State Pharmacy Council,
   The Indian Pharmaceutical Association and The Chemists and Druggists
   Association, Goa.
- 3. Dentists as represented by The Goa Dental College, The Indian Dental Association, and The Goa Dental Council.
- 4. Veterinarians as represented by The Goa Veterinary Association, The Department of Animal Husbandry and Veterinary Services and The Goa Veterinary Council.
- 5. The Directorate of Food & Drugs Administration, Goa.
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The Guidelines for prescription writing and handling have been drafted based on existing laws. However, as the regulatory documents do not cover all the aspects, the stakeholders have drawn out guidelines based on legal implications, social and moral principles, and responsibilities of all those involved in prescription writing as well as prescription dispensing.

After each meeting, the draft Guidelines were circulated to the stakeholders, and

their opinions and suggestions canvassed. These final Guidelines are the recommendations of the 3<sup>rd</sup> Round Table meeting.

It is hoped that all the stakeholders, namely the doctors, dentists, veterinarians, hospital owners, nurses, pharmacists, pharmacy owners and their staff, drug regulatory authorities, the state medical, dental and pharmacy councils, health authorities, and even staff and students of medical, pharmacy, dental and nursing colleges will find these Guidelines useful, adopt them and most importantly, abide by them.



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# 2. WHO CAN WRITE A PRESCRIPTION FOR ALLOPATHIC MEDICINES

Only a Registered Medical Practitioner (R.M.P.) who is registered with the respective State Medical/Dental/Veterinary Council is authorized to prescribe allopathic medicines.

An R.M.P. includes an allopathic doctor (Minimum M.B.B.S), a Dentist (minimum B.D.S), a Veterinarian (minimum B.V.Sc).

- However, it is understood that a Dentist should prescribe only those medicines which are related to, and needed for his/her profession, and for his/her patients only;
- It is also understood that a Veterinary Doctor should prescribe only those medicines which are related to and needed, for his/her profession, and for his/her veterinary patients only;
- ♦ An Ayurvedic doctor, a Homeopathic doctor, a Unani doctor, a Naturopath, etc. are NOT authorized to prescribe/recommend allopathic medicines.
- ♦ A Nurse or Pharmacist is not authorized to prescribe allopathic "prescription" medicines to their patients.
- Unqualified persons or persons with dubious and unauthorized degrees not recognized by the Govt. of India are also not authorized to prescribe allopathic medicines. Those who do prescribe/recommend allopathic medicines without proper authorization are termed Quacks.

NOTE: Certain medicines can be supplied on the prescription of doctors of a particular specialty only. For example, Sildenafil Citrate can be prescribed only by an Urologist, Psychiatrist, Endocrinologist, Dermatologist or Venerologist. Letrozole can be prescribed by a cancer specialist only.



CROSS PRESCRIBING IS ILLEGAL,
AND PUNISHABLE BY LAW!
PLEASE STICK TO THE SYSTEM OF
MEDICINE YOU ARE
AUTHORIZED TO!



# 3. JUSTIFICATION FOR VARIOUS PARTS OF A PRESCRIPTION

A prescription has various parts; some of them "mandatory" (as per the Drugs & Cosmetics Act and Rules, or the Medical Council of India), and some of them though not mandatory, important for better understanding of the prescription by the pharmacist and the patient also.

The justification may arise from rationality, legality, practicality or situational realities. These various aspects are discussed below.

In the process of listing the justifications, we have tried to take into account various aspects of the problem. These may relate to the patient (or their relatives), the pharmacy personnel, or the prescribing discipline of the doctor. At every stage, the safety and well-being of the patient, particularly in terms of appropriate usage of medication remains the primary concern.

### A. Details pertaining to the DOCTOR:

Part of prescription	Why needed	Legal require ment?	What happens if missing	Other comments
Doctor's full name (printed on the letterhead)	To authenticate the prescription before dispensing. The prescription is a legal document. It can be used in the court of law.	YES	The pharmacy personnel are in a dilemma as to whether the prescription is genuine or from a quack or homoeopathic/ayurvedic doctor. If the prescription is from a hospital, it is not known which of the faculty doctors has prescribed it.	Allopathic Govt. doctors doing private practice most often prescribe without their name, qualification, etc. These prescriptions are illegal, and pharmacies are not authorized to dispense them and can be penalized for doing so

Part of prescription	Why needed	Legal require ment?	What happens if missing	Other comments
Doctor's details such as address, consultation timings, telephone/ contact numbers. printed on the letterhead	Helps the patient as well as the pharmacist to contact the doctor in case of discrepancies and doubts over prescription (including misuse of blank prescription by patients), or in case a substitution is necessary.	YES	The prescription cannot be dispensed unless the query is resolved, or a substitute given for the unavailable product. Without clarification, delay in initiation of treatment may ensure with all its attendant risks.	As above
Doctor's Qualification printed on the letterhead. This means ALL the degrees, especially the primary degree, namely, M.B.B.S./B.D. S./B.V.Sc	For verifying the authenticity of the doctor. Writing the basic degree e.g. M.B.B.S. gives a direct indication that the doctor is allopathic, because there are doctors of other systems of medicine & quacks who write M.D. in front of their name.	YES	The patient may end up taking medicines prescribed by unauthorized personnel	Helps the pharmacy confirm that it indeed is an allopathic doctor.

Part of prescription	Why needed	Legal require ment?	What happens if missing	Other comments
Doctor's registration number and the registering authority printed on the letterhead.	For further authenticatio n of the doctor. e.g. GMC Reg. No. xxxxx, (or MMC Reg. No. xxxxx)	YES	As above	Confirmatory evidence that doctor is an allopath and not a quack.
Doctor's full signature and date, both in blue indelible ink.	To confirm authenticity of prescription; to avoid misuse of blank prescription pads, especially by addicts.	YES	If the prescription has been typed or printed, the pharmacy personnel cannot confirm that it is the doctor who has actually prescribed the medicine. Misuse of blank prescription cannot be detected in such cases.	A hurried signature, or scribble, or no signature is not advisable. It should be a legible signature, which most pharmacies can easily recognize. A signature in blue indelible ink automatically rules out the possibility of a misused photocopied signature
Date of prescribing	To know the validity of prescription and to avoid unnecessary refilling of the prescription.	YES	Pharmacy personnel cannot identify an old prescription brought for refill; and in many cases not advisable.	The risks of self-medication by repeated, unwarranted usage increases.

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Part of prescription	Why needed	Legal require ment?	What happens if missing	Other comments
Rx superscription	This is a matter of practice.	NO		It comes from the Latin "Take Thou"
Doctor's rubber stamp containing his full name, qualifications, and Reg. No. below his signature.	The rubber stamp gives additional confirmatory evidence, and helps prevent misuse of prescription	NO	Potential for problems in computer generated prescriptions	As an added authentication of the prescription; mandatory for computer generated prescriptions

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Other suggestions pertaining to DOCTORS	Justification
A doctor should NOT recommend prescription medicines over the telephone or SMS messages to his patients. If at all one has to do so in an emergency situation, one must ensure that he talks to the pharmacist on the telephone, and reinforces the order. This must be followed by a hard copy of the prescription to be delivered to the pharmacy as soon as possible. A doctor must instruct the pharmacies in his neighbourhood not to dispense verbal prescriptions quoting his name as the prescriber, and to call him up in case such incidents occur.	The pharmacy personnel are in a dilemma whether or not to believe the client.
Even if the medicine is for a family member of the doctor, or relative staying in the doctor's house or otherwise, the doctor must make it a point to issue a prescription, and discourage them from asking for medicines without a prescription.	The doctor's relatives could be harming themselves by purchasing medicines using the doctor's name as the prescriber. On the other hand, the pharmacy personnel may find it difficult to refuse the medicine even though a prescription is not produced because they know that the client is a doctor's relative!

Other suggestions pertaining to DOCTORS	Justification
If the doctor types or generates his prescription on a computer, he must ensure that he places his full, recognizable signature on the prescription in blue indelible ink, and date it. He must sign as close as possible to the last drug listed in the prescription.	To avoid miscreant/addicts printing out the doctor's prescription pad and typing out a prescription, and scribbling a signature.
In hospitals, nurses should be barred from writing on a prescription pad and giving the same, unsigned to the client to procure the medicines. The concerned doctor's signature should compulsorily be on the prescription, verifying the prescription, and making it a valid one. Doctors, for their own safety, should not get into the habit of leaving behind blank pre-signed prescriptions.	Hospital prescription pads are often left lying around in the ward/nursing station, and can be misused/stolen by miscreants/addicts. Pharmacies are not authorized to dispense prescriptions without a doctor's signature.
Prescription blanks/pads should not be left unattended at reception desks; they should not be left in the car where they could be easily visible and tempt addicts to steal them; when not in use, prescription pads/blanks should always be kept under lock & key, (in the clinic/surgery or home), and should not be entrusted with anyone, or left lying around on the doctor's table, even if one has to go out for a short while. The doctor should draw a diagonal line across the blank part of the prescription.	Anyone could be tempted to misuse the doctor's prescription pad.  This includes unauthorized additions to authentic prescriptions.

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Other suggestions pertaining to DOCTORS	Justification
Doctors should always encourage pharmacies to call them up on telephone in case of any problems/ discrepancies/doubts/queries in their prescription. However busy one may be, one must always take the call as soon as one can, be polite, and sound encouraging so that the pharmacist does not hesitate to call up in in future. Doctors must thank the pharmacy for calling up for whatever query, however insignificant it may be. The pharmacist has called because of a doubt. After all, pharmacists are health professionals, and members of the health care team.  Pharmacies, which have to dispense the medication prescribed by doctors, are quick to recognize a deficiency in a prescription. They will also be aware of the availability or change in a medicine.  Hence the calls ensure that prescriptions are kept updated in all respects; thereby reducing the need for calls.	Pharmacies often hesitate to call doctors because they do not always have pleasant exchanges with them when they do call. This may even apply to the patients themselves. Ultimately it is the patient who suffers.
One should avoid having names of two or more doctors on the same prescription pad (even if it is a husband and wife team). More so if they belong to different specialties or systems of medicine.	The pharmacy is in a dilemma as to which of the two or more doctors have prescribed the medicine/s, and whom to contact in case of a doubt. The dilemma may extend to dispensing allopathic medicines against a prescription bearing the name of an ayurvedic/homeopathic doctor.

Other suggestions pertaining to DOCTORS	Justification
It is unethical for a doctor to prescribe medicines for his own use other than the simplest OTC medicines.	Self medication as a concept is to be discouraged.
Doctors must make it a point to visit their neighbourhood pharmacies once in a while, to learn how they work, what practical difficulties they face, or find out whether they have any problems with their prescriptions, & their legibility, and should ask for suggestions to doctor's prescribing.	
A doctor should not use another doctor's prescription pad, even with his consent. Conversely a doctor should not allow another other doctor to use his/her prescription pad.	A prescription is a document from a particular doctor to a specific patient. This individuality is lost when prescription pads are "borrowed". Further the law requires that the doctor should use his own pad/letterhead.
Doctors should not use prescription pads, with pre-printed messages at the bottom, like "Available at XYX Medical Stores".	It reflects very badly on the doctor and suggests that there is some nexus between the doctor and the pharmacy. It also creates animosity amongst other pharmacies that may be presented with these prescriptions. Further, it may arouse suspicion amongst the public and patients.
Doctors should be extra careful in prescribing habit forming medicines or drugs with potential for misuse like sedatives, hypnotics, codeine containing cough syrups, Pentazocine, Buprenorphine, etc. Prescribers should inform the patient about their potential for habit forming, as well as the dangers of long term and excessive use.	A single prescription for habit forming medicines can make a lifetime addict of the patient. Therefore doctors must ensure that they take precautions, so that the chances of the prescription being dispensed again are minimized.

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Other suggestions pertaining to DOCTORS	Justification
Doctors should doubly careful in writing the potency & quantity of the drug/s. It is advisable to write the quantity in words also so that patients/clients do not manipulate the numbers.	Writing "DO NOT DISPENSE MORE THAN ONCE" re-emphasizes to the patient & the pharmacist that it should not be repeated.
Write in bold "DO NOT DISPENSE MORE THAN ONCE", in the in the middle or bottom of the prescription (bearing in mind that sometimes what is written at the bottom is cut off by the patient).	
The doctor should not write s.o.s. against any medicine. It is not an accepted abbreviation. The doctor should use the correct abbreviation - p.r.n. (pro re nata) or the English equivalent – 'as and when required'. In such cases, the minimum dose interval, the maximum daily dose and maximum duration and the maximum quantities to be dispensed, should be specified.	If this is not specified, it may result in the patient taking doses more frequently and for a longer duration than is pharmacologically safe/permitted.
Avoid unnecessary use of units	E.g. c.c. should not be used. Similarly, abbreviations like mcg should be avoided in favor of the full word "micrograms".

### B. Details pertaining to MEDICINES :

Part of prescription	Why needed	Legal req- uirement ?	What happens if missing	Other comments
Name of the medicine-preferably write the GENERIC NAME IN CAPITAL, with the brand name/comp any name in	Illegible handwriting, and too many confusing, similar generic & brand names cause difficulties in the pharmacy. Pharmacists have problems deciphering the drug name, as	YES	Chances of errors during dispensing can increase. Pharmacies sometimes dispense by guesswork, about the prescribed drug.	Govt. hospitals write the abbreviation CPZ – does that mean Chlorpromazine or Carbamazepine? The pharmacy personnel cannot decide that!

Part of prescription	Why needed	Legal requirement?	What happens if missing	Other comments
brackets. Strictly avoid abbreviation s or scribbling the name of the medicine/s.	there are more than 100 brand /trade names in the market today.			
Strength or potency of the medicine	Many medicines are available in varying potencies, and unless potency is correctly written the pharmacist cannot dispense the correct medicine. Many pharmacies follow the principle of "dispense the lowest potency if nothing is mentioned", which is a totally erroneous practice.	YES	It becomes difficult for the pharmacy to decide which particular strength the doctor intended to prescribe. Often, the doctor is not traceable at that particular time. This could delay treatment even by a few days. Patients have also got into the habit of saying "don't give a strong dose" or "give the lightest dose".	
Dosage Form	Unless correct dosage form is written, the pharmacist often		Pharmacy has to do guesswork. Often the	A dosage form suitable for one patient may not be suitable for

Part of prescription	Why needed	Legal requirement ?	What happens if missing	Other comments
	is in a dilemma which particular one to give, because at times, medicines are available in different forms. E.g. DT or tablet, or syrup etc.		pharmacist is not available for making a decision.	another. For example a child may require a syrup form rather than a tablet.
Dosage & dosing instructions	Patient needs to know the quantity of tablets/cap/ liquid & number of times the medicine needs to be taken. Oral instructions to patients are most of the times forgotten. The pharmacist can also counsel the patient.	YES	Patient is confused what dose to take and how often. What the pharmacy may suggest may not always coincide with what the doctor had in mind. Also, the pharmacist cannot predict the dose in all cases, since it is based on diagnosis or extent of disease/ailment.	This needs to be clearly written, in simple language and a format that is easily understood by the patient or the relative, even if there is no time. If Latin names/short forms are to be written, at least the pharmacy should understand what it is, so that it could be explained to the patient.
Total Quantity	So that both patient and the pharmacist are left with no ambiguity as to the quantity to be	YES	Particularly important for pediatric antibiotic liquid preparations, where 2 or 3	Also important in case of medicines of misuse where some patients may demand more quantities.

Part of prescription	Why needed	Legal requirement?	What happens if missing	Other comments
	consumed/ dispensed. It can also deter patients from using more/less of the medicine.  For long term prescriptions (for chronic illnesses) it is not advisable to write "Continue", or "Patient on long term therapy - Continue".		bottles need to be given to complete a dose. If not specified, parents tend to use only one bottle. This leaves the prescription open for repeat purchase with no controls.  The doctor should instead write on the prescription for how long the medication is to be continued before the next visit/next review for example 3 months, 6 months, etc. and preferably write the quantity of medicine to be dispensed over	
Refill information	If the doctor wants the prescription to be filled/dispensed	NO. But if no refilling instructions	As is happening today, the patient buys	

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Part of prescription	Why needed	Legal requirement ?	What happens if missing	Other comments
	only once, he should clearly write that it "SHOULD NOT BE REFILLED" or "DO NOT DISPENSE MORE THAN ONCE" at the bottom of the prescription (or get it pre-printed on the prescription blank). If the doctor wants the prescription to be refilled, he should clearly write the number of times the prescription should be refilled. This is very important to deter patients from refilling (repurchasing) the same prescription again & again unless so directed by the doctor.	are written on the prescription, it means that it should be dispensed ONCE ONLY!	the medicine on the same prescription for days, months, & even years together.  By writing this it also assists the pharmacy in convincing the patients that the medication should not be repeated unless instructed by the doctor.	

Other suggestions pertaining to MEDICINES	Justification
Always write the potency for single ingredient drugs even if no other potency is marketed. You never know, when a new potency (higher or lower) would be introduced in the market.	E.g. Mosafe was first launched as 5 mg tab. Doctors used to write only "Mosafe". Then, the 2.5 mg was launched after few months. Thus, if the doctors continued to write "Mosafe", the pharmacy is in a dilemma which potency to dispense. Similar problem exists for many other products also.

Other suggestions pertaining to MEDICINES	Justification
In case of combination products, it is always advisable to write the potencies of all the individual components in order to eliminate any	e.g. Ampicillin + Cloxacillin 250 + 250 instead of AmpiClox 250 e.g. Glimiprex MF 1/500
misinterpretation at the pharmacy.	Some doctors write AmpiClox 250 to mean 250 + 250, while others write AmpiClox 250 to mean 125 + 125. This is very confusing, and bound to cause errors as it is dependent on the individuals interpretation at the pharmacy.
Alterations/overwriting in the prescription are best avoided, but if any are made, they should be clear and unambiguous. Doctors should make sure to add their initials against the altered items.	Especially important for drugs liable for misuse/abuse.
Brands - Doctors should prescribe only those brands/products of those companies that are easily available in most of the pharmacies.	If the brand is uncommon, or the company's' products are not commonly stocked by pharmacies, patients often hunt around at various pharmacies, for hours, often for days, hoping to find that specific prescribed medicine. If a prescribed Brand is not available, the Pharmacist should inform the doctor about non-availability and suggest an alternate Brand.
Doctors should refrain from prescribing medicines of other systems of medicine.	Just as allopaths do not like homeopaths and ayurvedic doctors to prescribe allopathic medicines, allopathic doctors also should not prescribe medicines of other systems of medicine. This amounts to cross practice and is prohibited by the supreme court.

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### 3. Details pertaining to PATIENT

Part of prescription	Why needed	Legal requirement?	What happens if absent	Other comments
Patient's Full Name	For proper identification of a patient. A prescription is meant for an individual, and there may be two clients at the pharmacy with the same first/last names whose prescriptions may get exchanged.	YES	If the name is absent, it cannot be linked to a particular patient with certainty. There is room for error when two patients go to a doctor together. Similarly prescriptions can get mixed up between family members when the consult the doctor, as is very common. In case of family members, writing only the surname can cause errors.	
For Veterinary patients, besides writing the given name of the animal,		YES	Difficult to trace the owner in case of any dispensing problem/error.	Makes the identity of the intended beneficiary clear to the pharmacy.

Part of prescription	Why needed	Legal requirement?	What happens if absent	Other comments
it is mandatory to write the name and address of the owner of the animal. For example, Timmy (A Dog), owned by Mr. A M Mathews, Flat A/6, Mia Mansion, Panaji.	recipient of the medicines			
Patient's age, weight	Useful information especially for children for whom dosage is based on body weight. It acts as a safety measure against dosage errors.	NO	May make it difficult for the pharmacy to confirm the medication.	Helps the pharmacy personnel assess the prescription and be confident of dispensing the right drug and dosage form.
Patient's address and telephone number (including Mobile No.)	Essential for follow-up of patient, or to get in touch with the patient, especially in case of prescribing or dispensing errors.	YES	Difficult to trace the patient in case of a dispensing problem/error.	Writing the address on the cash memo is a legal requirement.

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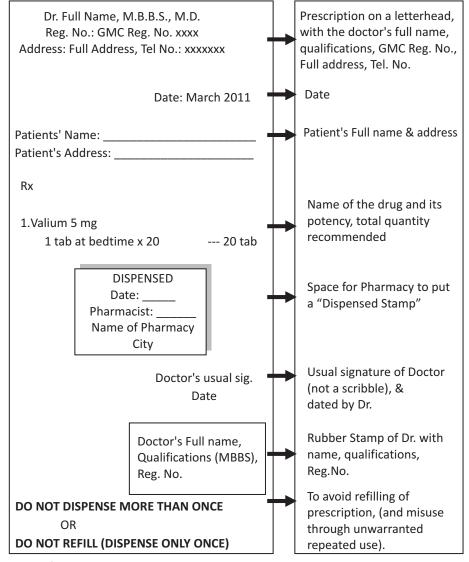
Part of prescription	Why needed	Legal requirement?	What happens if absent	Other comments
Patient's Sex	Important for pharmacist to know/ assess appropriateness for patient, particularly in view of illegible handwriting or confusingly similar brand names. Special precautions are required in pregnancy and breastfeeding.	NO	Sometimes, some names are associated with both males and females, and the pharmacy staff may not be able to assess whether the name is that of a male or female.	Medicines for gynecological problems are obviously unsuitable for male patients



Always issue a proper prescription to your patients.... Help pharmacies follow the law!

# 4. FORMAT FOR AN IDEAL AND COMPLETE PRESCRIPTION FROM A PRIVATE DOCTOR

(It is important to follow the format to ensure proper use of drug, avoid and detect any forgeries)



Ideal/ Minimum Size Of The Prescription Blank: 14 X 21cm (A5 size)

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### Note:

- 1. Letterheads/prescription blanks should be kept secure to avoid misuse.
- 2. Overwriting on a prescription should be avoided. In case of overwriting, doctor must initial each correction.
- 3. Prescription may be typed/computer generated, but it has to be signed and dated by Doctor in blue indelible ink.
- 4. It is illegal to allow nurses/assistants to write prescriptions/medication orders.
- 5. Only allopathic doctors (including Dentists, Veterinarians) can prescribe allopathic medicines.
- 6. Pharmacies are authorized to refuse to dispense prescriptions which do not conform to the above format.
- 7. If Pharmacies dispense prescriptions which do not conform to the above format, they are liable to be prosecuted under the Drugs & Cosmetics Act & Rules there under.

### 5. PRESCRIPTIONS WRITTEN ON LETTERHEAD OF A PRIVATE HOSPITAL

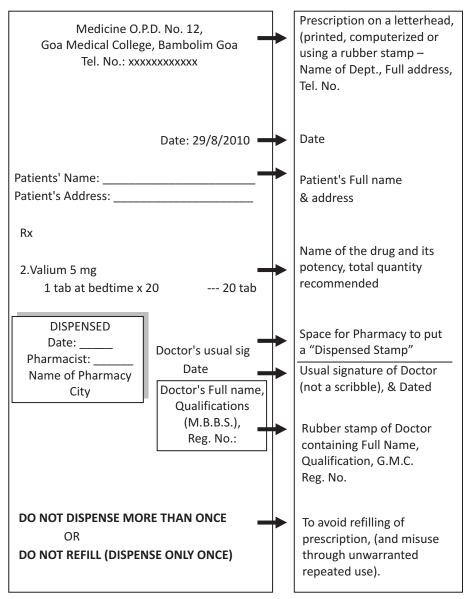
Doctors should generally prescribe medicines on their own letterhead. In case a doctor does not have his own prescription pad at a hospital or a clinic other than his own, the following points need attention, in addition to the guidelines for prescription writing for private doctors:

- 1) The prescribing doctor should put his rubber stamp bearing his full name, qualification, & Reg. No. at the bottom of the prescription.
- 2) The prescribing doctor should sign his usual signature and date it in blue indelible ink.

If, the rubber stamp is not carried/not available, the doctor should write his full name, qualification, Reg. No., and sign and date the prescription, along with the rubber stamp of the hospital.

(A doctor should avoid writing a prescription on the letterhead of another doctor).

### 6. FORMAT FOR A COMPLETE IDEAL PRESCRIPTION FROM A PUBLIC HOSPITAL



Ideal/ Minimum Size Of The Prescription Blank: 14 X 21cm (A5 size)

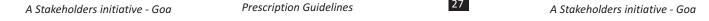
### Note:

- 1. Letterheads/prescription blanks should be kept secure to avoid misuse.
- 2. Overwriting on a prescription should be avoided. In case of overwriting, the doctor must initial each correction.
- 3. Prescription may be typed/computer generated, but has to be signed and dated by Doctor in indelible ink.
- It is illegal to allow nurses/assistants to write prescriptions/medication orders.
- 5. Only allopathic doctors (including Dentists, Veterinarians) can prescribe allopathic medicines.
- 6. Pharmacies are authorized to refuse to dispense prescriptions which do not conform to the above format.
- 7. If Pharmacies dispense prescriptions which do not conform to the above format are liable to be prosecuted under the Drugs & Cosmetics Act & Rules there under.

HELP THE PHARMACY TO SERVE YOUR PATIENTS BETTER.
HELP THE FDA TO IMPLEMENT THE DRUG LAWS.

# 7. GUIDELINES FOR DOCTORS AND HOSPITALS PURCHASING MEDICINES:

- 1. As per Schedule K of the Drugs & Cosmetics Act, a qualified doctor can purchase medicines for use for his patients. However, he must keep a record of the details of the purchase and the dispensing of the drugs
- While ordering, the doctor must issue a written order on a letterhead to the wholesaler/pharmacy, containing all the details as in an "ideal/complete prescription". The doctor must further justify/state for what purpose he wishes to procure the medicines (e.g. for use in his patients, for use in his clinic/hospital, or for personal use)
- 3. It is compulsory for the wholesaler/pharmacy to retain such written orders from the doctor for a period of 2 years. A wholesaler/pharmacy is authorized to dispense medications to the doctor only on the strength of a proper complete written order.
- 4. It is mandatory for the doctor to maintain a detailed record of the medicines purchased against such orders this includes maintaining the batch number and quantity purchased along with the invoice. A record of the medicines dispensed to his/her patients name and address of the patient, name of medicines, quantity, and batch number is also required. These records are open to inspection by the inspectors/authorities of the FDA.
- 5. If a hospital wants to procure medicines for stocking and supply to its patients, it is advisable that the hospital takes a license for a pharmacy in the premises, as per the Drugs & Cosmetics Act, and maintain all the records as per laws of the procurement and sale/dispensing of medicines for its patients. The pharmacy must function under the supervision of a registered pharmacist.
- 6. It is an unacceptable practice to write "self" on a prescription and ask the patient to buy directly from the wholesaler or pharmacy. A doctor is expected to maintain records of such medicines purchased, and dispensed.
- 7. If a doctor visits a pharmacy and asks for a drug, the pharmacy is authorized to refuse to dispense the drug unless he is presented with a proper written order for the drugs by the doctor, which indicates his qualifications and registration number. In any event the pharmacy is within its rights to refuse to honor a self prescription for scheduled drugs. The written order needs to be kept by the pharmacy for a minimum of 2 years.



**Prescription Guidelines** 

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### 8. GUIDELINES FOR PHARMACIES/ CHEMISTS & DRUGGISTS

### **SALE/DISPENSING:**

- A) Prescription medicines should be sold STRICTLY AND ONLY against a fresh prescription of a qualified/authorized doctor.
- B) A prescription which has been dispensed once should be stamped with a "Dispensed" stamp below the prescribed medicines, and dated and signed by the Pharmacist under whose supervision the medicines have been dispensed

DISPENSED					
Date:	Pharmacist Sig.: _				
Name of Pharmacy,					
	Address:				

- C) Such a prescription should not be dispensed again unless the doctor indicates on the prescription that the prescription may be refilled. In such cases the doctor must indicate the number of times the prescription may be refilled and on each occasion the pharmacist should put the "Dispensed" stamp.
- D) The pharmacist should check the prescription carefully for various aspects, as listed in the Guidelines for prescription writing for doctors, and ensure that it is complete in all respects.
- E) A Pharmacy has the right to refuse to dispense a prescription if:
  - 1) Any one or more of the listed items, mandated by law to be on a prescription, are missing, incomplete or improper.
  - 2) The Pharmacy has any doubt about the prescription e.g. suspicion of forgery, overwriting, prescription written by an unqualified person.
  - 3) The medicines prescribed are of unduly large quantities, and suspected to be for misuse.
- F) The Pharmacist should double check the medicine being dispensed, by tallying against the prescription. He/she should double check the quantity on the prescription, actual quantity dispensed, and actually quantity billed. He/she must ensure that the batch and expiry date on the medicine dispensed tallies with that on the bill. In case the patient wishes to purchase a quantity less than that

- prescribed, this could be indicated at the "dispensed on" stamp and an entry made as to the quantity purchased. The same prescription can then be used later to dispense the balance quantity if required.
- G) The cash memo/bill should be complete in all respects It should contain the full name and address of the patient, name of the drug/s, Schedule, batch number, date of expiry, name of manufacturer, quantity dispensed, price, and signature of the Pharmacist.
- H) It must be ensured that the Pharmacist on duty signs every such bill, and his signature appears on the carbon/duplicate copy as well.
- I) A bill/cash memo should be made for all such medicines sold and a record should be available whenever asked for, particularly with reference to batch and quantity. (as per rule 65/11 of the Drug & Cosmetic Act & Rules)
- J) The owner of the Pharmacy must ensure that these medicines are sold ONLY when the pharmacist is present and under his/her personal supervision.
- K) A pharmacy need not keep a copy of the prescriptions dispensed.

Additional points to be considered while dispensing medicines:

Item	Suggestions	Why this is important?	Other comments
1. Dispensing prescriptions brought in by children	It is inappropriate to accept and dispense prescriptions brought in by children below age of 18.	To prevent abuse/ misuse of medicines.	Misuse of medicines/ prescriptions (lying around the house) can be more hazardous in case of children.
2. Doubts about prescription	When in ANY doubt, contact the doctor. If in serious doubt about a prescription, or a particular prescribed medicine, and if the doctor cannot be contacted, DO NOT DISPENSE.	To make sure the medicines are dispensed exactly as that prescribed by the doctor.	for success of the treatment. Pharmacy personnel should not dispense unless they
3. Dispensed Stamp	<ul><li>a) Put a 'Dispensed Stamp' when a prescription is dispensed.</li><li>b) Write in the space provided in the left hand</li></ul>	It is mandatory by law	To ensure that the medicines are not purchased repeatedly against the same prescription.

Item	Suggestions	Why this is important?	Other comments
	side of the prescription, the number of each of the items dispensed.		
4. If prescriptions are purchased in part, i.e. in lesser quantity or fewer items. a) If it is a fresh prescription,	a) Enquire whether the patient has bought the remaining amount at some other pharmacy, and if the full amount has been bought, put a dispensed stamp. If not, then write the amount bought against the medicine (in the column provided in the prescription)	that excess quantities are not it is prescrib financial real.  There is no locuntry as to many days a prescription from the day prescribing.	Some patients may not come to buy the medicine as soon as it is prescribed, for financial reasons.  There is no law in our country as to how many days a prescription is valid from the date of prescribing. The
b) If a prescription is a few days old,	b) The patient might have taken a few tablets and come back for the balance. Ask, verify and then put a dispensed stamp.		pharmacist has to use his experience to decide if a prescription dated a few days earlier can still be dispensed. This will vary with the medical conditions and the medicines prescribed
5. Prescriber Contacted	When the prescriber is contacted regarding the prescription and any changes are made in consultation with the prescriber, a stamp be put against the change – P.C. (Prescriber Contacted) along with the pharmacist's signature and date	To document the fact that the change was authentic, by whom it was done, and in what manner.	It becomes too inconvenient and sometimes impossible for the patient to take the prescription back to the doctor for modification/rectification.

Item	Suggestions	Why this is important?	Other comments
5. Incomplete prescriptions	*The pharmacist has to check the prescription for completeness with respect to the doctor's details, patient's details and medicine details.	is important:	Comments
i) Incomplete doctor's details (full name, qualifications, reg.no., address)	If these are missing, the pharmacist may identify the handwriting. But if in doubt, the pharmacist should ask the patient the doctor's name and if necessary contact the doctor by phone (*use the telephone number on the directory rather then asking from the patient)	Ideally all prescriptions should be written on a letterhead where the prescription blank contains all details of the doctor, or at least a rubber stamp with the doctor's details.	Reduces the possibility of misuse
ii) Incomplete patient's details (full name, age, sex, address)	If these details are missing, they could be obtained from the client/patient and noted on the prescription.	Ideally, the patient's details should be written on the prescription.	Reduces errors and misuse
iii) Incomplete medicine details (name, strength, dosage form, dosage, dosing instructions).	If the medicine details are missing, or illegible the pharmacist should contact the doctor. In any case where the doctor is not available on the phone, do not dispense. Ask the patient to go to the doctor and confirm the details.	Dispensing a prescription with incomplete medicine, by details, by guess work runs the risk of serious error.	DO NOT DISPENSE BY GUESSWORK

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Item	Suggestions	Why this is important?	Other comments
6. Analyze the prescription	The prescription should be checked for the prescriber's specialization, and the age and sex of the patient to confirm the appropriateness of the prescription.	Some drugs are age or sex specific	This will reduce the possibility of error
7. Dosing/ Prescribing error	If a prescribing error is detected, the pharmacist should contact the prescriber and then make appropriate corrections in consultation with the prescriber (stamp – P.C.), and only then dispense.	Increases margin of safety	Detection and correction of errors must be done in a professional and ethical manner
8. Brand substitution	Brand substitution is illegal and should not be done. If the brand is not available, the doctor should be contacted and the Brand changed.		Brand substitution is not always done with the patients' best interests in mind.
9. Potency/ strength of medicine not mentioned on the prescription	If no potency/ strength is mentioned by the doctor, it is wrong to dispense the lowest potency.	The doctor needs to be contacted to make the decision.	Guess work or misplaced "initiative" is to be eliminated.
10. Labeling medicines	It is advisable for the pharmacist to write a label for each medicine in simple language and paste it on each medicine.	The label should indicate at what times and how much quantity of the medicine is to be take and for how many days	The instructions on the label should be written by the pharmacist as a direct interpretation of the instructions on the prescription by the doctor (and not his own directions)

Item	Suggestions	Why this is important?	Other comments
11. Change in potency mentioned on prescription	A pharmacist is NOT authorized to change the potency of the drug, even if the patient so demands e.g. higher potency cannot be given.		A pharmacist has to execute the doctors instructions on the prescription and NOT superimpose his own ideas.
12. Unauthorized prescriptions; prescriptions from quacks, or cross-prescribing (allopathic doctors prescribing ayurvedic medicines or vice versa)	Pharmacist should politely tell the patient that he/she cannot dispense the prescription, and why. DO NOT DISPENSE.	Prescriptions by quacks/ unauthorized doctors should not be honored. It is illegal to do so, and subject to penalty	The issue has been settled by Supreme Court judgments
13. Misuse of prescription blank	If the pharmacist feels that the doctor's prescription blank is being misused, he/she should bring it to the notice of the doctor and the Goa Medical Council if necessary.	Such misuse is most common in substance abuse and addicts.	Awareness about this is a professional commitment to society.
14. Issuing a bill	The sale of all medicines should be against a bill as per the law. The bill should have the patient's name, doctor's name, date, and the medicine particulars (quantity, name, manufacturer, batch number, expiry date, individual cost) and the total cost. The bill should be signed by a pharmacist.	This is a legal requirement	

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Item	Suggestions	Why this is important?	Other comments
15. Sale of medicines without a prescription	Prescription medicines should not be sold without a prescription, or in the absence of a pharmacist. Only OTC medicines can be sold without a prescription.	This is a legal requirement	
16. Expressing an opinion or commenting on a prescription	1.Do not comment on the content of the prescription even by body language or facial expression. Neither should the prescription be discussed with a colleague in front of the patient. The behavior/ attitude to the prescription in no way should produce ANY doubt in the mind of the patient about the doctor.		If a mistake is suspected, they should discreetly enquire with doctor or politely suggest the patient that the medicines are shown to the doctor.
17. Prescribed quantity	Do not dispense more than the prescribed quantity.	At best this leads to wastage and financial burden. At worst it may lead to over medication	

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### 9. GUIDELINES FOR WHOLESALERS/DISTRIBUTORS

The Proprietor of the wholesale depot should ensure that all the staff members handling medicines are provided with adequate information and training on proper handling of medicines.

- Purchase and records: A wholesaler must purchase all medicines from authorized dealers/suppliers only, and keep a proper record of all purchases done.
- A wholesaler is authorized to sell allopathic medicines only to the following:
- Licensed pharmacies/chemists & druggists
- R.M.P.s (qualified allopathic doctors, including dentists, veterinary doctors) against a proper written order
- Hospitals against a proper written order from a R.M.P.
- A wholesaler cannot sell/supply allopathic medicines to doctors other than duly qualified doctors.
- Sale/supply to R.M.P.s or hospitals should be done only against a written order on the letterhead of the doctor or hospital, with justification/statement from the doctor stating for what purpose he wishes to procure the medicines (e.g. for use for his patients, in his clinic/hospital, or for personal use).
- 5. It is compulsory for the wholesaler to retain such written orders from the doctor for a period of 2 years. It is not permissible to supply/sell medicines on a "self" prescription written by a doctor and then asking the patient to buy the medicines directly from the wholesaler. A doctor is expected to maintain records of such medicines purchased, and dispensed.
- 6. A qualified person should double check the medicine being dispensed, by tallying it against the prescription order. He/she should double check the quantity on the prescription, actual quantity dispensed, and the quantity billed. He/she must ensure that the batch number and expiry date on the medicine dispensed tally with that on the bill.
- The invoice/bill should be complete in all respects It should contain the full name and address of the retail pharmacy/doctor, name of the drug/s, batch number, and date of expiry, name of manufacturer, quantity dispensed, price, and signature of the Qualified Person.
- It must be ensured that the Qualified Person on duty signs every such invoice/bill, and his signature appears on the carbon/duplicate copy as well.
- An invoice/bill should be made for every such medicine sold and a record of such medicines purchased and sold should be available whenever asked for, batch wise, quantity wise.
  - The owner of the wholesale depot must ensure that these medicines are sold ONLY when the Qualified Person is present and under his/her personal supervision.

# 10. GUIDELINES FOR MEDICINES/DRUGS HAVING MISUSE/ABUSE POTENTIAL:

Extra special care needs to be taken for prescribing, handling, storage, and dispensing such drugs. Examples of such drugs are:

BENZODIAZEPINES i) Diazepam containing products ii) Alprazolam containing products iii) Lorazepam iv) Nitrazepam v) Flurazepam vi) Midazolam vii) Clonazepam viii) Clobazam ix) Chlordiazepoxide containing products	NON BENZODIAZEPINES i) Zopiclone ii) Zolpidem iii) Eszopiclone iv) Etizolam v) Phenobarbitone vi) Pentobarbitone	
OTHERS i) Morphine* ii) Pethidine* iii) Pentazocine iv) Buprenorphine v) Propoxyphene (Dextropropoxyphene)	OTHER DRUGS WHICH HAVE HABIT FORMING/ABUSE/ADICTION POTENTIAL or could be MISUSED OR HARMFUL:  1. Codeine containing products 2. Tramadol containing products 3. Modafinil 4. Misoprostol 5. Mifepristone 6. Sildenafil citrate 7. Ketamine	

<sup>\*</sup> **Pethidine** can be purchased, stocked and dispensed/sold only by a Retailer having a valid drug license under the Narcotics Drugs & Psychotropic Substances (NDPS) Act.

It is mandatory under law that the prescription should be complete, written by an authorized R.M.P. and be retained by the Pharmacy. A written record of the prescription, along with batch no., expiry date, and quantity purchased and sold, name of R.M.P., and name of patient needs to be maintained.

A quarterly report in the specified format needs to be submitted to the FDA (stating quantities of sale and purchase).

\*. **Morphine** can be stocked only by a stockist who is having a valid drug license under the NDPS Act, and sold directly to the patient. Moreover, it can be sold only against a valid permit issued by the State FDA containing the quantity of Morphine to be dispensed.

The Permit can be obtained by the patient from the FDA against submission of a proper, complete prescription for Morphine, written by a R.M.P.

### A. Guidelines for doctors:

Besides all the instructions/guidelines for prescription medicines, additional care needs to be taken in prescribing the above listed medicines:

- 1. For safety, and to avoid misuse, use a separate prescription for such drugs; and it is preferable NOT to give a computerized or typed prescriptions.
- Ensure that the exact quantity to be dispensed is written, along with the dosing, and the number of days – this in order to deter/prevent the patient from manipulating the quantity by writing additional numbers before or after the quantity prescribed.
- 3. Do not write such words as "Continue.....", or "for long term use", etc. for such medicines as this gives no finite quantity, and can be misused by some patients to go on accumulating large quantities of the medicines.
- 4. Strictly avoid overwriting. If at all there is a need for any, strike out the wrong word/quantity, write it afresh and countersign it.
- 5. The medicines listed above should not be prescribed/recommended/advised to patients or pharmacy over the telephone, though text messages (SMS), or through Email/internet. Pharmacies are not authorized to dispense these drugs against such orders and have the right to refuse to dispense.
- 6. Quantities prescribed for such types of drugs should be reasonable. It is advisable to give due justification for large quantities of a particular drug prescribed. If any doctor misuses his powers to indiscriminately prescribe large quantities other than for justifiable medical use, the Medical Council has the powers to take action against the doctor. Pharmacies are authorized to refuse to dispense such prescriptions if they suspect any misuse.

### B. Guidelines for the Pharmacy:

### **PURCHASE & STORAGE:**

The Pharmacy owner and Pharmacist should ensure that all the staff members are provided information and given training in handling of such medicines, and the need

for such careful handling.

- a) Only minimum quantities should be ordered, as required, from authorized distributors/wholesaler/supplier, having a proper wholesale drug license. Avoid over stocking. Pharmacies should opt to stock reputed brands only.
- b) These drugs should be checked as soon as they are received from the wholesaler. One must tally the quantity, batch and expiry date on the medicine received with that on the invoice of the supplier. If any of these do not tally, please bring it to the notice of the supplier, and get it rectified from them immediately – either as a new corrected invoice, or corrections done in pen and countersigned by the Qualified Person and rubber stamped. Please do not make the changes/corrections on the invoice yourself.
- c) Once checked, these drugs should be immediately transferred to a specially designated cupboard, meant to stock only such drugs, and always kept under lock & key. The key should be with a responsible person.
- d) As a matter of caution it is advisable to check and tally these drugs from time to time to ensure that there is no pilferage, or errors in handling.

### **DISPENSING:**

- a) At the pharmacy, such prescriptions should be carefully scrutinized by Pharmacists who should read it with extra care and caution. One needs to ensure that the prescription is genuine, prescribed by an authorized doctor, and complete in all aspects, and that there is no manipulation/overwriting in the prescription, etc.
- b) To ensure that there is no misuse/repeat buying by the patient, the pharmacy must put a "Dispensed" stamp without fail on the prescription.
- c) The quantity sold against such orders must not be more than that ordered.
- d) Do not allow these medicines to lie around promptly put them back in the separate shelf reserved for them, under lock and key.
- e) Strictly, no verbal orders from a doctor/hospital should be entertained for such drugs.
- f) Sale of such drugs to doctors/hospitals must be strictly against a written order on a letterhead with all the doctor's details, signature and date. If from a hospital, the order must be from the hospital pharmacist countersigned by the administrator or by a qualified doctor, on a letterhead of the doctor or the hospital, bearing all the details as per Guidelines. The doctor must be an authorized, qualified allopathic doctor (R.M.P. - Registered Medical Practitioner). Dispensing/sale of such medicines strictly cannot be done to or against the prescription of doctors of other

- systems of medicines or unqualified persons/quacks. Pharmacists or nurses strictly cannot recommend/prescribe such medicines.
- g) The invoice/cash memo should be complete with respect to name and address of the doctor/hospital or the pharmacy to whom the drug is sold, drug license number, name of the drug, quantity, batch number, expiry date, Schedule, price, and the signature of the Pharmacist.
- h) The Pharmacist must ensure that the quantity, batch and expiry of the drug dispensed actually tallies with that on the invoice.
- i) Such drugs must be dispensed only under the personal supervision of the Pharmacist
- j) Owners must strictly ensure that such drugs are not sold in absence of a Pharmacist.
- k) The Pharmacy must be able to produce the records of purchase and sale of all such

### C. Guidelines for Wholesaler/Stockist:

The owner should ensure that all the staff members are provided with information and given training in handling of such drugs, and the need for very careful handling.

- a) Only minimum quantities required should be ordered, as required, from authorized distributors/suppliers/C&F agents or manufacturers, having a proper wholesale drug license. One should preferably stock reputed brands only, and avoid over stocking.
- b) These medicines should be checked as soon as they are received from the Superstockist/C&F/Company/Suppliers - One must tally the quantity, batch and expiry date on the medicine received with that on the invoice of the supplier. If it does not tally, bring it to the notice of the supplier/manufacturer, and get it rectified from them immediately - either as a new corrected invoice, or corrections done in pen and countersigned by the Qualified Person and rubber stamped. Please do not do the changes/corrections on the invoice yourself.
- c) Once checked, these should be immediately transferred to a specially designated shelf/cupboard, meant to stock only such drugs, and under lock & key. The key should be with a responsible person.

### Sale by Wholesalers

i. Wholesalers must "sell" only to those retailers who have a valid retail drug license under Drugs & Cosmetics Act to stock such medicines.

- ii. Wholesalers should be doubly careful if any retailer asks for what looks like excess/unreasonable quantities of such medicines. One should deal with such matters on a case to case basis.
- iii. Orders for such medicines from Retailers must be on the letterhead of the retailer, rubber stamped and signed by the Pharmacist.
- iv. It is advisable to make separate bills/invoice for any such drugs; and to receive payments for such invoices by crossed cheque of the pharmacy/retailer only, and not by cash.
- v. Sale of such medicines to doctors/hospitals must be strictly against a written order on a letterhead with all the doctors' details, signature and date. If from a hospital, the order must be from the hospital pharmacist countersigned by the administrator or by a qualified doctor; on a letterhead of the doctor or the hospital, bearing all the details as per Guidelines. The doctor must be an authorized, qualified R.M.P. Such sale cannot be executed against the prescription of doctors of other systems of medicines or unqualified persons/quacks.
- vi. The record of receipt and sale of such medicines must be conveyed to the FDA before the 5<sup>th</sup> of every month.
- vii. The wholesaler must keep a hard copy of all the orders received from doctors/hospitals and retailers, and retain the same for at least 2 years.
- viii. The quantity sold against such orders must not be more than that ordered.
- ix. The invoice should be complete with respect to name and address of the doctor/hospital or the pharmacy to whom sold, drug license number, name of the drug, quantity, batch number, expiry date, Schedule, price, and the signature of the competent person.
- x. The Competent Person must ensure that the quantity, batch and expiry of the medicine dispensed actually tallies with that on the invoice
- xi. Such drugs must be dispensed only under the personal supervision of the Competent Person. Owners must ensure that such drugs are not sold in absence of Competent Person.
- xii. The wholesaler must be able to produce the records of purchase and sale of all such medicines.

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