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DR. M. M. Jumle

AGENDA

- Discussion about statutory provisions provided under various related statutes.
- Discussion about ideal format of prescription & prescription guidelines.
- Enforcement of these guidelines.
- Any other issues with the permission of the Chairman.

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Prof

DR. A. Kulkarni

(a) the date of purchase,

(b) the name, address and the number of relevant licence held by the person from whom purchased,

(c) the name of the drug, the quantity and the batch number, and

(d) the name of the manufacturer of the drug.

(ii) Purchase bills including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.]

(6) The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these Rules, and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(7) Except, where otherwise provided in these Rules, all registers and records maintained under these Rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8) Notwithstanding anything contained in this Rule it shall not be necessary to record any particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.

[43][(9) (a) Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years.

(b) The supply of drugs specified in Schedule H or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years.]

(10) For the purposes of clause (9) a prescription shall -

(a) be in writing and be signed by the person giving it with his usual signature and be dated by him ;

[44][(b) specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use ;]

(c) indicate the total amount of the medicine to be supplied and the dose to be taken.

(11) The person dispensing a prescription containing a drug specified in Schedule H [45][and Schedule X] shall comply with the following requirements in addition to other requirements of these Rules-

(a) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;

(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions;

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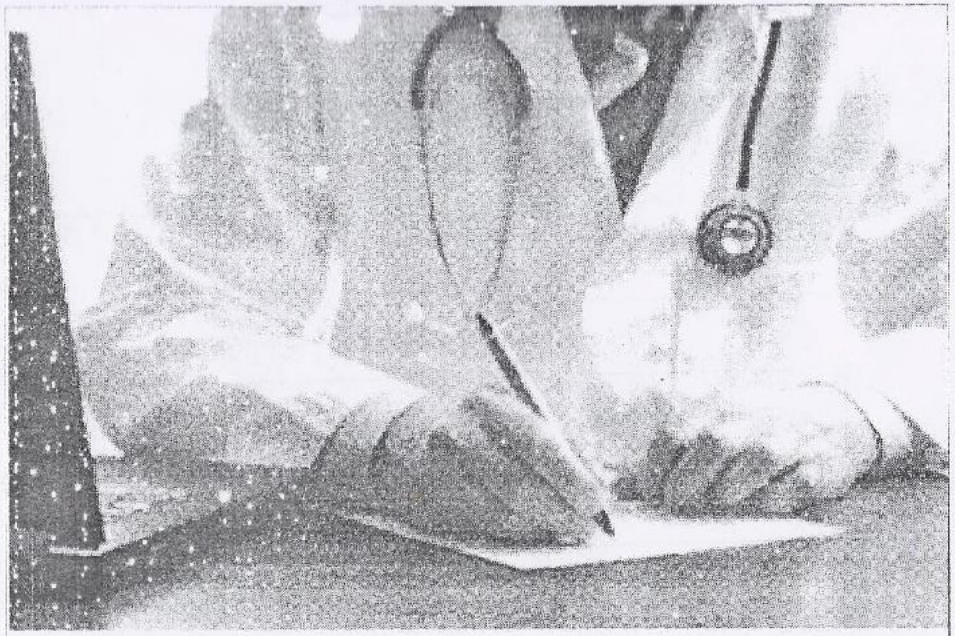
43. Subs. by G.S.R. 462(E), dt. 22-6-1982 (w.e.f. 22-6-1982).
44. Ins. by G.S.R. 926(E), dt. 24-6-1977 (w.e.f. 15-7-1977).
45. Subs. by G.S.R. 462(E), dt. 22-6-1982 (w.e.f. 22-6-1982).



Rx 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

Dr. Gladstone D'Costa

Mr. Raj Vaidya

THE VOLUNTARY HEALTH ASSOCIATION OF GOA

With inputs from the following stakeholders:-

1. 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

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 inte pretations 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

1. 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 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.
6. The Voluntary Health Association of Goa

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 3rd 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.

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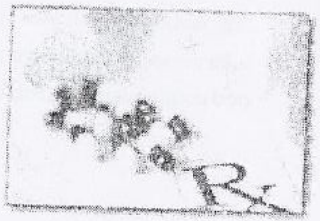
CROSS PRESCRIBING IS ILLEGAL AND PUNISHABLE BY LAW ! PLEASE STICK TO THE SYSTEM OF MEDICINE YOU ARE AUTHORIZED TO !



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 requirement?	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 ments	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 ments	What happens if missing	Other comments
Doctor's registration number and the registering authority printed on the letterhead.	For further authentication of the doctor. e.g. GMC Reg. No. xxxxx, (or MMC Reg. No. xxxx)	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.