



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

Suggestions for Over The Counter (OTC) Medicines

BACKGROUND/JUSTIFICATION:

- 1) It is well known that it has been a very long time since the Drugs & Cosmetics Rules have been framed/amended with respect to the medicine categories. Since then a lot of changes have taken place with reference to advances in medicine and pharmacy, both nationally and internationally.
- 2) India is one of the countries where implementation of the law has been very poor. It is a well-known fact that prescription medicines are easily available without a prescription. Of these, some are actually more suitable to be OTC medicines.
- 3) In most countries of the world, medicines are well classified, including the category of OTC medicine. Such a specific category does not exist in India. Besides, the categorization of medicines in India is also not very transparent.
- 4) India does not have an OTC list. It is crucial to prepare one immediately as there is considerable ambiguity about OTC medicines in the minds of stakeholders such as drug regulators, pharmacists, public and doctors.
- 5) Most countries in the world have clear cut guidelines for OTC medicines while there are none in India. Different stakeholders exhibit varying understanding and opinions about which medicines can be sold without a prescription and which can be recommended by a pharmacist, apart from those which have to be sold only on a doctor's prescription.

Ambiguities include, for the same drug, some company labels state that a prescription is needed for sale, while some other company labels do not state that.

- 6) In most countries, there are clear cut guidelines laid down for prescription to OTC and OTC to prescription switches. India has no such guidelines. It is very essential to have such guidelines in place.
- 7) Pharmacists often face the criticism that they dispense prescription medicines without a prescription. Whilst it is essential that many medicines need to be dispensed against a prescription, there are many other medicines which may be dispensed under the



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

supervision and wisdom of a pharmacist without a prescription. However, in India, many such medicines fall under the prescription category.

- 8) Therefore, it is essential to re-examine the whole issue, and recategorize medicines in a manner based on scientific principles, patient safety, but at the same time considering the prevailing circumstances in India.

This concept paper is an attempt to create a specific category for OTC medicines. The entire list of OTCs with detailed information (rather than medicines of all categories) should be displayed on the website of CDSCO and on websites of State Drugs Controllers, MoHFW and Consumer Affairs ministry.

SUGGESTIONS-

- The word OTC (Over the Counter) Medicines needs to be defined under the Act, giving it legal status.
- We need a clear cut list of OTC medicines. A separate list for :
 - a) Single ingredient OTCs
 - b) Fixed Dose Combination (FDC) OTCs

In addition, we need to have 2 sub-categories of OTC medications:

	Suggested category	Brief description	Justification	For example
A	OTC Medicine – (Pharmacy) – (Non-prescription medicine)	OTC Medicines - to be sold only through pharmacies	Presence/supervision of a pharmacist is important. Besides, it is easier to track the medicines when sold to licensed pharmacies, which are regulated by the drug regulatory authorities.	Paracetamol, Aspirin, Antacids, Topical preparations of certain NSAIDs (Ibuprofen, Diclofenac), Cetirizine, Albendazole, Mebendazole, Povidone-Iodine preparations, Ranitidine, Ibuprofen (200mg), Normal saline nasal drops, Xymetazoline nasal drops, etc. In addition, all Drugs which are currently under Schedule K
C	OTC – General Sales	OTC - which could be sold through outlets other than pharmacies also.		Dettol, Savlon, Band aids, etc.



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

Note: There should be restrictions and guidelines on advertisement for OTC medicines. DTCA (Direct to consumer advertisement) should be permitted only for those which are specifically listed out by the Govt. The others cannot be advertised to the public.

In order to prevent misinterpretations/ambiguity, it is necessary to lay down clear cut rules/guidelines for handling of such medications. For example:

A. Non-Prescription or OTC Medicines :

These are OTC Medicines - to be sold only through pharmacies -

1. Non- Prescription medicines (OTC medicines) – These medicines can be sold only at a pharmacy (and not in any other shop). They can be displayed/visible to the public but out of reach (no choose and pick)
2. Such medicines can be stocked for sale to the patient only by a duly licensed pharmacy (retail/hospital pharmacy)
3. Medicines in this category can be dispensed either against a proper, valid, prescription of a Registered Medical Practitioner, who is registered with the State Medical Council in which he practices, or they can be recommended on his own by a Registered Pharmacist in the Pharmacy, to a patient, or they can be asked for by a client across the counter at the Pharmacy. If the pharmacist feels that such a medicine should not be dispensed to the patient, he shall not dispense it.
4. Role of pharmacist in dispensing of OTCs can be defined, algorithm can be developed. While dispensing such medicines, the Pharmacist should preferably provide guidance and help to the patient in selecting the right medicine and the dose and should preferably counsel the patient about the correct use of the drug, precautions to take, any contra-indications, what adverse effects to expect and which to ignore and which to report, when to refer to a doctor, etc.
5. The maximum quantity of medicines which can be prescribed in one prescription and/or dispensed/sold at one time to a patient should be specified separately in the D & C Rules for each drug in this category.
6. Prescription validity and its time limit should be well defined.
7. The sale to the patient can be done only by a retail pharmacy and not a wholesaler. The sale has to be done under the direct supervision of a Registered Pharmacist.
8. Besides the prescriber (RMP), decision to refill such medicines can be taken by the Pharmacist. These medicines thus can be dispensed “again” on the same prescription if the pharmacist in his/her judgment feels so.



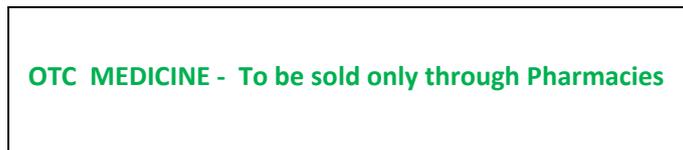
The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

9. The prescriptions for such medicines need not be retained by the pharmacy. However, detailed record of the purchase and sales of such medicines need to be produced if asked by the Regulatory authorities.
10. A proper bill of sale bearing the details of medicine sold, and signed by the Registered Pharmacist should be issued to the patient. Carbon copy, bearing the same details to be retained by the pharmacy for a period of 3 years, and open for inspection by the Regulatory authorities.
11. Hospitals/R.M.P.s can procure such medicines from the authorized wholesaler only against a stamped and signed order, from a R.M.P. (containing all the details of the R.M.P) on the letterhead. They must keep a record of the purchase and use of such medicines, including the name and address of the patient and the quantity administered/given to the patient. These medicines can be used for their patients, but cannot be sold to them.

LABELLING:

12. The medicine label should clearly specify that it is an OTC Category Medicine , a green vertical line of 1 mm thickness, and have the written box as below (and a symbol):



In addition to the above messages, the package should include one of the following:

- a. The medicine package should compulsorily contain a **PPI (Patient Product Information/Patient Package Insert/s) or a PIL (Patient Information Leaflet)** (in a readable font) -in English and at least 2 local languages prevailing in the locality/state in which the medicine is sold. This PPI or PIL must be approved by Drugs Control authority, and has to be inserted by the manufacturer.
- b. The medicine carton/label should bear the “Drug Facts”. The below stated example is from the USA:



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

Drug Facts

Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mgAntihistamine

Purpose

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

The information provided in these should cover:

- Any warnings/contra-indications for use.
- Indications, dosage, frequency of dose, maximum daily dose.
- Potential adverse effects (those which can be ignored, and those if seen by the patient, he should stop taking the medicine.
- “ DO NOT use for more than a 3 days/week without consulting your doctor or pharmacist”.
- Please read the enclosed PPI (Patient Package Insert) carefully before using the medicine.



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

B. OTC - GENERAL SALES MEDICINES :

1. Besides pharmacies, these medicines can be sold at shops/general stores. The medicine label should clearly specify that it is a OTC - General Sales medicine, have a specific symbol designating so, a green vertical line of 2 mm thickness, and have the written box as below.



2. These medicines can be advertised to the public, but without making tall claims, or misleading the public. All advertisements should also contain the Warning messages in bold and easy to locate and read, in English and at least 2 local languages
3. Examples of drugs in this category would for example include: Dettol, Savlon, Band aids, etc.

Note:

- A. **AYUSH Medicines:** The thought process should be started to categorize AYUSH medicines too and some of these should be placed under Prescription category, and sale through licensed pharmacies.

Other Categories:

- A. **Pharmacist Only Medicines:** It is important to create this additional category of medicines. These medicines need not require a doctor's prescription but can be recommended/dispensed only by the registered pharmacist after assessing the situation and where self-medication will not be possible.

This particular category becomes more relevant and important in the background of the current national discussion which talks about giving prescribing rights to AYUSH doctors after a bridge course.



The Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai 400 098

There are no sufficient number of doctors in the country. More so in rural areas. Pharmacists often operate in rural areas, in locations where there are no doctors. For such reasons, if pharmacists are given authorization to recommend Pharmacist Only Medicines (besides OTC medicines) to patients, it will be of great benefit to society.

Examples: Ibuprofen 400mg, Diclofenac 50mg, SR 75, 100mg, Loratidine, Omeprazole 10mg, etc.

B. Prescription Medicines: To be dispensed only against a valid prescription