

E-Mail

RG-15

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN
TILAK MARG, JAIPUR

No. DC/D-1/DCG/2015/394

Dated:- 29/06/2015

All Asst. Drugs Controller, Rajasthan State,
All Drug Control Officer, Rajasthan State.

Subj.:- Dangers of easy availability of prescription medicines without a prescription – regarding.

Ref.:- DCG (I), New Delhi letter No. 7-5/2015/PMO/004 Dt. 28.05.2015

Reference to subject cited above, Photocopies of letter with enclosures received from Drug Control General (I), New Delhi are hereby enclosed. You are all directed to convey your suggestions in matter of implementation in subject matter to this office.

Encl. As above.

28/6/15

(K Jayawant)
Drugs Controller
Rajasthan, Jaipur

No. DC/D-1/DCG/2015/

Dated:-

Copy to :- Drug Control General (I), FDA Bhawan, Kotla Road, New Delhi in ref. of letter No. 7-5/2015/PMO/004 Dt. 28.05.2015

✓ Incharge, Surver room. Pl. e-mail this letter with enclosure to all ADC's + DCS's.

Encl. - As above

(K Jayawant)
Drugs Controller
Rajasthan, Jaipur

कार्यालय
औषधि नियंत्रक (सज.) जयपुर
12 JUN 2015
6168
क्रमांक

7-5/2015/PMO/004

Directorate General of Health Services
Office of Drug Controller General (India)

FDA Bhawan, Kotla Road,
New Delhi – 110002.

Dated 28 MAY 2015

To,

All State Drug Control Authorities

Subject: Dangers of easy availability of prescription medicines without a prescription-
regarding.

Sir,


D.C.
11.6.15

Shri Kaushik Desai, Hon. Gen. Secretary, Indian Pharmaceutical Association, has written to Hon'ble Prime Minister of India raising concerns over dangers of availability of prescription medicines without a prescription. He has also enclosed a note on "The serious problem of availability of prescription medicines without a prescription in India and possible solutions" (Copy of the letter enclosed).

It has been suggested to create awareness about the legal aspects and dangers involved in sale of drugs without prescription through advertisements, pamphlets and other sources of creating awareness in public as well as chemists may be adopted. Above all sustained campaign is required to be launched in the States to ensure that drugs are dispensed as per the provisions of the Drugs and Cosmetics Rules.

In view of the seriousness of the issue raised and to address the problem of the availability of prescription medicines without a prescription you are hereby, requested to ensure, compliance and uniform implementation of the provisions under the Drugs and Cosmetics Act 1940 and Rules made thereunder.

Yours faithfully


(Dr. G. N. Singh)
Drugs Controller General (I)

Copy To:

1. PPS to JS(R)

FTS- 24994 | D(41D) | 12/5/15

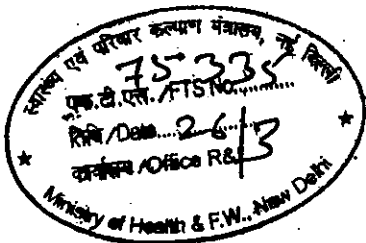


प्रधान मंत्री कार्यालय
Prime Minister's Office

नई दिल्ली- 110011
New Delhi- 110011

Sub:Petition of SHRI KAUSHIK DESAI
INDIAN PHARMACEUTICAL ASSOCIATION
KALINA
SANTACRUZ(EAST)
MUMBAI
MAHARASHTRA-400098

A letter dated 07/01/2015 received in this office from SHRI KAUSHIK DESAI is forwarded herewith for action as appropriate.



Handwritten notes:
21.12.2015
Alok Suman

Signature:
[Alok Suman]
Section Officer

SECRETARY, DEPARTMENT OF HEALTH & FAMILY WELFARE

PMO ID No.: PMOPG/D/2015/13503 Dated: 11/03/2015

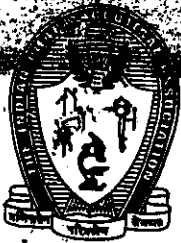
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Pl call a meeting
of IPA for their
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30/3 2015

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30/3 2015
JDC (ER)
12-05-15



The Indian Pharmaceutical Association (IPA)

Platinum Jubilee Year

Society Regn No. Bom. 10 of 1960 GBBSD • Public Trust Regn. No. F- 746 (Bom) dt. 4.4.1960
Kalina, Santacruz (East), Mumbai - 400 098. India • Tel.: +91 22 2667 1072 • Telefax : +91 22 2667 0744
E-mail : ipacentre@ipapharma.org • Website : http://www.ipapharma.org



MISSION

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, to improve the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support research in pharmacy and sciences in all aspects.

PHARMACEUTICAL OFFICE

13 JAN 2015 January 07, 2014
DAK SECTION

2014-2016

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IPA/110/219

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Shri Narendra Modi,
Prime Minister of India
New Delhi

Vice Presidents
Divisional Heads

Sub : Dangers of easy availability of prescription medicines without a prescription.

Community Pharmacy
Manjiri Gharat

Respected Sir,

Education
T. V. Narayana

Greetings from the Indian Pharmaceutical Association, which is a premier professional organization of pharmacist professionals in India, with an objective to promote the science and art of pharmacy in all aspects and impart suitable education and training to professionals working in the pharmacy profession.

Hospital Pharmacy
Ramesh Adepu

Industrial Pharmacy
Subhash Rijhwani

We are thankful to you Sir that you have raised the very crucial problem of "availability of certain addictive cough syrups at medical stores without a prescription, and their misuse", during your MaankiBaat programme on 14th December 2014.

Regulatory Affairs
Subhash Mandal

Hon. Gen. Secretary
Kaushik Desai

We must accept the fact that it is not only Codeine, but a host of many other habit-forming, drugs with abuse potential are available many times without a prescription of a qualified doctor.

Hon. Treasurer
Surendra Manek

This has serious repercussions on the health of the people of India. Worldwide, Adverse Drug Reactions, medication errors, are a grave problem even in well regulated countries where the law enforcement is very strict.. Adverse Drug Reactions have been the 4th leading cause of the deaths in the USA.

Editor - Pharma Times
Alka Mukne

Editor - IJPS
Divakar Goli

In India, the problem is likely to be manifold and we don't have the nation wide data for the number of ADRS, misuse of medicines drugs, and resulting morbidity, mortality, and development of resistance to antimicrobials/antibiotics..

Secretary General
S. D. Joag

Sir, it quite apparent that one of the reasons for this problem in India is the poor implementation of the Drug Laws, which makes it easy for the public to get almost all prescription medicines without a prescription in most pharmacies/medical stores in the country. This results in rampant misuse, abuse, or improper use of medicines.

Ignorance in the society about responsible use of medicines is a serious problem too. Thus self- medication practices are very common.

Signature
M/o Health



= 2 =

Unfortunately, in our country, the drug regulatory system has not been able to curb this problem of sale of prescription medicines without a prescription. India is also called by foreigners as a place for drug tourism since prescription drugs are easily available over the counter.

In view of the SERIOUS nature of the problem, we sincerely request your Government to take up the matter with urgency and seriousness, and draw out short, medium and long term strategies to curb this problem in the best interest of the health and SAFETY of the citizens in our country. Please find attached, a strategic plan worked out by the Indian Pharmaceutical Association to address the problem of availability of prescription medicines without a prescription, in a phase-wise manner, with involvement of all stakeholders. We would appreciate Sir if the Government would seriously take up the suggestion and urgently move into action mode so that we all can collectively set about implementation of the plan.

The IPA, which is in its Platinum Jubilee year has also already launched Campaign for Awareness for Responsible Use of Medicines (CARUM) [please find attached some of the material developed in Hindi for the campaign, material in English and some regional languages is available on www.ipapharma.org], and we are eager to partner with the Govt. to reduce the improper use of medicines.

The Indian Pharmaceutical Association is keen to work with the Government in addressing this serious problem and we look forward to hear from you to collectively work towards a much safer India with respect to medicines usage!

Thanking you,

Kaushik Desai
Hon. Gen. Secretary
Indian Pharmaceutical Association

Encl : Note on "The Serious Problem of Availability of Prescription Medicines without a Prescription in India & possible solutions"

Detail Note

on

The Serious Problem of Availability Prescription Medicines without a Prescription in India & Possible Solutions

As per the Drugs & Cosmetics Act and Rules, applicable in India, the retail sale of certain medicines through pharmacies/medical stores/chemists & druggists (termed as pharmacies throughout this paper) can be done only against a valid prescription. Such medicines are commonly called as "prescription medicines", and have been categorized into various Schedules (Schedule H, Schedule X, Schedule H1), depending on certain factors like potential for side effects, habit forming or misuse potential, new drugs, etc.

The labels of such medicines carry on them a warning to the effect "Not to be sold by retail without the prescription of a Registered Medical Practitioner". Many times it is not easy to read it on the label, many times it is ignored.

Certain medicines, by law, can be sold without a prescription. They are commonly called as "non-prescription" or "OTC" medicines.

In this paper, we will try and point out the extent of the problem of "sale of prescription medicines without a valid prescription" in India, the possible reasons for the same, the possible consequences, and the possible solutions.

1. Extent of the problem:

- A. There are no statistics/records, but it is a well known, common fact that :
 - i) Many/most of the times "prescription medicines" are available/sold in many/most pharmacies, without a valid prescription.
 - ii) The extent of the problem could vary from pharmacy to pharmacy :
 - a) Some pharmacies will strictly refuse to sell medicines of abuse or habit forming ones without a prescription, while they may sell the other "prescription medicines" without a prescription. After introduction of the Schedule H1 category of medicines from 01-03-2014, many pharmacies sell them only against a valid prescription.
 - b) Some pharmacies will strictly refuse to sell medicines of abuse or misuse, Schedule H1 medicines, other psychiatric medicines, antibiotics, and certain other medicines without a valid prescription, but may sell other "prescription medicines"
 - c) Many pharmacies may be strict in not selling certain medicines of misuse to certain patients without a valid prescription, but may sell it without a prescription to their regular patients, or to those whom they 'know' have been prescribed by the doctor.

- d) Many pharmacies may not bother much, and sell almost any medicine to anyone, without a valid prescription.
- e) Some pharmacies are notorious in selling medicines of misuse or abuse, often to be taken aboard by clients.

B. Other common facts which take place in India are :

- i) Most of the times no prescription is presented by the patient/client at the pharmacy. They ask for the prescription medicines:
 - a. Verbally (by name, or at times asking by colour, or price)
 - b. By producing old strips or bottles or covers
 - c. By showing sms messages on the mobile
 - d. By writing/scribbling on a piece of paper
 - e. Over the telephone, sms or email
- ii) Many times old, or even very old prescriptions are presented for repeat use
- iii) Allopathic "Prescriptions" written by Quacks, doctors of non-allopathic systems of medicines are also presented at the pharmacy, and are dispensed most of the times by most pharmacies even though not permitted by law.
- iv) Large quantities of prescription medicines purchased without a valid prescription are taken abroad
- v) Prescription medicines are available online through the internet, and sent to the address specified by the client. No prescription is asked for.
- vi) The sale of prescription medicines quite often happens in the absence of a Registered Pharmacist (which is again a breach of the law)

Thus, the law is broken to varying degrees, by different pharmacies, under different circumstances. This has become a chronic problem across the country. So much so that it seems to have become a "part of life" and very few complain about it or consider it important to raise the issue, or even think of doing something about it.

In reality, the problem in India is widespread and dangerous.

Pharmacies are aware that it is not legal to sell without a valid prescription, but it has become a part of the system to sell without a prescription. It has reached to such a point that:

- if a patient is asked for a prescription, it is seen as strange, and a fact not liked by the patient
- if a pharmacy decides to "strictly" follow the law and not sell a single prescription medicine without a valid prescription, there is a high possibility that the pharmacy soon may have to be closed down.

2. Reasons for the problem:

The problem has become chronic over the years, and could now be attributed to several different reasons, responsible to varying extents as the cause for the problem:

- a. Regulations not implemented/enforced properly and possible reasons being:
 - I. Insufficient regulatory officers to carry out routine inspections

- II. Corrupt practices. Pharmacies are either forced to bribe, or many are happy to bribe to be allowed to carry on wrong practices. It has become an accepted part of the system.
- III. Political interference/influence, not to act against law breakers

b. Lack of awareness amongst public about:

- 1) Types of medicines and the purpose behind such categories or how to identify the difference between two categories
- 2) The fact that a prescription is mandatory to buy certain medicines. Public don't see the necessity of a prescription each time.
- 3) The fact that buying certain medicines without a prescription could be harmful to them

Because of this, patients/clients insist that they be dispensed prescription medicines without a proper/valid prescription. If a pharmacy, which would like to follow the law, insists on a prescription, then the pharmacy is offered with a whole variety of excuses from the clients/patients:

- "I forgot to bring the prescription"
 - "The doctor has prescribed over the telephone/by SMS"
 - "The doctor is my relative and has told me verbally what to take"
 - "First time anyone has asked me for a prescription"
 - "I know my medicine. I am taking them for years"
 - "Why does one need a prescription for an antibiotic/"
 - "You want me to go all the way home and bring the prescription?"
 - "The prescription is at home. My wife told me over the telephone/SMS"
 - "All pharmacies give – why can't you?"
 - "Here, speak to my doctor...he will confirm..."
 - "Don't worry, I won't hold you responsible"
 - "My friend recommended the medicine for me since he found it effective for the same condition"
 - "We cannot afford to go to a doctor again to get a prescription"
 - "Are you and the doctors hand-in-glove?"
 - "I have paid fees to the doctor and you say that this doctor is not qualified and not authorized to prescribe allopathic medicines?"
- 4) Unawareness of the law and related issues among key opinion leaders, media and other stakeholders. It has never been a much talked about matter so far in the country. Also, even if known, there is a tendency to either ignore or take it casually. Not seen as a serious problem. Because there are no complaints from people! (People will complain if they are asked for prescriptions. Since most of times they are not asked, people do not complain"
 - 5) Going to a doctor does take time, and involves paying fees and sometimes doctors may not be available.

- 6) The pharmacy is nearby and easily accessible. The person at the pharmacy is also seen by many clients as competent to recommend medicines.
- 7) Improper labeling – the warning labels on the medicines that they are “prescription medicines” and cannot be sold without a prescription are not easy to read. Besides, illiteracy continues to be a problem in our country.

3. Ranges in the seriousness of the problems:

While by law those medicines bearing the warning “To be sold by retail on the prescription of a RMP” have to be sold only against a valid prescription, since it is a risk to the patients because medicines have to be used carefully, within these medicines, different countries divide these medicines into several categories depending on the severity of the risk or abuse/misuse potential. India too has such categories. Since March 2014, some drugs having misuse potential have been categorized in Schedule H1 with little more stringent requirements. The Schedule H category of drugs (to be sold by retail only against the prescription of a RMP) has a large number of drugs over a wide range of risks of misuse or abuse or improper use. Therefore, the following categorization of the dangers/risks is made, keeping in mind that it is going to be very difficult to implement the law right away. Therefore, the law could be implemented in a step-wise manner, going category-wise, from those drugs which could cause serious problems to those causes less serious problems.

| | Category | Problem | Comment |
|---|---|---|--|
| 1 | Drugs under the NDPS Act - Drugs used in terminal patients, those in severe pain – (e.g. fentanyl, morphine, pethidine) | Very useful drugs, but have high habit forming potential. | Very few retailers stock these products, the procedures are quite strict, so generally misuse does not happen |
| 2 | Drugs under Schedule H category – used for severe pain, post-surgical, or for de-addiction (e.g. pentazocineinj, buprenorphine tab/inj), ethymorphine | Useful if properly used, but are widely misused by addicts. Often sold clandestinely, and in some pharmacies it is sold freely, often at higher rates. | Pentazocine is stocked by many pharmacies/hospitals for regular prescription dispensing. |
| 3 | Drugs under Schedule H1 category - codeine containing cough syrup – for severe dry cough) | Prescribed by doctors, but more sales are without a prescription, to addicts who often drink a bottle at a time. Many brands are available, and 2 brands are in the top 10 selling brands in the country. Large shipments are often smuggled across | Regularly stocked by almost all pharmacies since it is prescribed by doctors commonly. People also ask for it and use it as a common cough syrup. |

| | | | |
|---|--|---|--|
| | | the country's borders. More than 70 court cases pending in West Bengal. | |
| 4 | Drugs in Schedule H1 category – having habit forming potential (e.g. antianxiety, sleeping pills) | Are also abused by addicts. Are also purchased in bulk for taking abroad. Are also used regularly by large number of patients since they have become habituated to them. | Before being in Schedule H1 they were quite easily available without a prescription. Present status needs to be evaluated. In some/many pharmacies things have become stricter. |
| 5 | Drugs for mental health disorders (In Schedule H category) –E.g.- antidepressant, antimanic drugs for schizophrenia, antiepileptics, antianxiety, sleep disorders) | When prescribed some patients keep buying from time to time, without producing a prescription, and many times without visiting the doctor regularly. Some of these could be misused, or abused by some patients. Also purchased to take abroad. | Unfortunately, in many places, they are dispensed without a valid prescription. |
| 6 | Drugs in Schedule H category –used for abortion (mifepristone, high dose estrogen + progesterone) | Need to be used prescribed and used under gynaecologist supervision. Can cause severe bleeding/death in some patients. | Often sold without a prescription, some pharmacies also recommend. Non-gynaecologists also stock and recommend/prescribe. Companies offer high schemes to pharmacies and doctors (e.g. Buy 1, get 3 free). |
| 7 | Drugs in Schedule H category – used for erectile dysfunction (sildenafil, tadalafil), performance enhancement (anabolic steroids) | By law, can be sold only against prescription of certain specialists. More often misused by patients, even young patients without the disorder/s or body building, etc. Huge quantities taken abroad by visitors or through post/courier. | More often sold without a prescription, or against prescription of doctors not authorized to prescribe these drugs. Companies offer high schemes to pharmacies and doctors (e.g. Buy 1, get 3 or 4 free). |

| | | | |
|----|---|--|---|
| 8 | Antibiotics – 24 of these now have been put in Schedule H1 category, rest are in Schedule H category. | One of the most misused category of drugs. Often sold without a prescription, patients self-medicate, some pharmacies recommend to their patients | Wrong/misuse/overuse use causes resistant bacterial strains. India has been blamed as a country having the worst problem because of misuse. |
| 9 | Drugs in Schedule H category – used for chronic conditions (diabetes, hypertension, hyperlipidemia, etc.) | Large range of drugs, very large consumption. Need to be taken daily, long term. People get used to buying without a prescription | Very often patients do not go to their doctor regularly, and keep on taking their medicines, at times punctually, at time irregularly. Improper usage causes harm |
| 10 | Drugs in Schedule H category – many other drugs other than listed above – e.g. NSAIDs, PPIs, hormones, ENT preparations, corticosteroid containing dermal preparations, etc. etc. | Often sold without a prescription, patients repeat usage on their own, use on suggestions from others, etc. | Patients avoid going to doctor. Easy availability at the pharmacy without a prescription. Improper usage causes harm to varying extents. |
| 11 | Drugs in Schedule H category in India, but could be in OTC or pharmacy only category in other countries – e.g. loperamide, low potency ibuprofen, anticold and cough preparations, low potency H1 blockers, some drugs or FDCs newly introduced in the our country. | All medicines can be harmful if not used carefully, but these medicines are relatively less harmful. Worldwide, by law they can be sold without a prescription | In India, since even these drugs legally require a prescription, it increases the guilt of the pharmacy when sold without a prescription, though morally it could be all right do so. People need not always go to the doctor for minor ailments. |

4. Consequences: The consequences of the availability of prescription medicines without a prescription are many-fold:

- Improper/irrational use of medicines in India
- Increased medication errors
- Increased ADRs (adverse drug reactions or side effects)
- Increase in morbidity and mortality
- Delays in diagnosis
- Antimicrobial resistance and emergence of super bugs

5. Possible Solutions:

Since the problem has become chronic and often is not seen as a problem by most, or at least no much attempt is made to reduce/do something about the problem all this while – so tackling it is going to be a huge challenge.

There is no single solution and it is not going to be easy. It needs a multi – pronged approach, and it could take many years to reduce/control the problem.

Two aspects need to be considered:

- A. Step-wise implementation – the law needs to be implemented in a step-wise manner, perhaps by starting with Category 1 - 4 listed above first, and slowly extending to additional categories one by one
- B. Involvement of all stakeholders, as listed below:

| Stakeholders | What could be done |
|--|---|
| Prime minister, Home minister, Ministers, Parliamentarians | Give a nationwide call, talk in speeches, launch nationwide public education campaign Allocate fund for the campaign |
| State CMs, Ministers, MLAs | Same as above, at state level |
| Secretaries of Health, Consumer Affairs, Pharmaceuticals | Plan and implement massive national/state campaign. Involve all stakeholders |
| Doctors – Allopathic (including dentists, veterinarians), nurses, doctors of other systems of medicine | Create massive awareness about legal aspects and dangers. Involve their respective Councils and Associations. Encourage to educate, create awareness amongst their patients Involve in campaign Include students during their study years in the awareness drive |
| Pharmacists, pharmacy owners, staff | Massive awareness, reminders of punishments, involve pharmacy and trade associations. |
| Regulators – central, state | Stringent punishments against corruption to be implemented for regulatory officers not discharging their duties Implementations of punishments for breach of Rules, sale without a prescription Due modifications in the drug laws need to be done to recategorize all the drugs Due labeling changes to be done to educate public about compulsion for prescription Need for regulations to curb the wrong use of online availability of drugs, |

| | |
|-------------------------------------|---|
| Public, school/high school students | Awareness campaigns in students Include as a compulsion in the curriculum – simple basics of prescription medicines and need for prescription. |
| Media (print, electronic) | Involve in the awareness campaigns |
| NGOs, Consumer organizations | Be a part of the awareness campaigns |
| PMO | Take up the issue in programme such as <i>Mann Ki Baat</i> , call for suggestions from public on this issue |

Details can be worked out.

6. Matter/Material to be prepared for the campaigns :

- Advertisements
- Posters
- Pamphlets
- Short videos
- Use of social media
- Articles
- Feeder material for Ministers, MPs, MLAs, etc.

How IPA would like to contribute and work with the Government to improve this situation?

- IPA educates pharmacists and the pharmacy staff, on various aspects related to medicines, and in partnership with the Government, it can be taken to a higher level.
- IPA has launched a campaign CARUM (Campaign for Awareness on Responsible Use of Medicines) for public awareness. It can be taken to a higher level and can make it massive campaign with the involvement of the Govt. and other stakeholders.
- IPA will contribute to development of any IEC material for public awareness, for school curriculum, etc
- IPA will also like to contribute expertise and experience to develop policies for recategorisation of medicines and related issues
- And, pleased and honored to do any other job assigned by the Government for improving health of citizens of India.