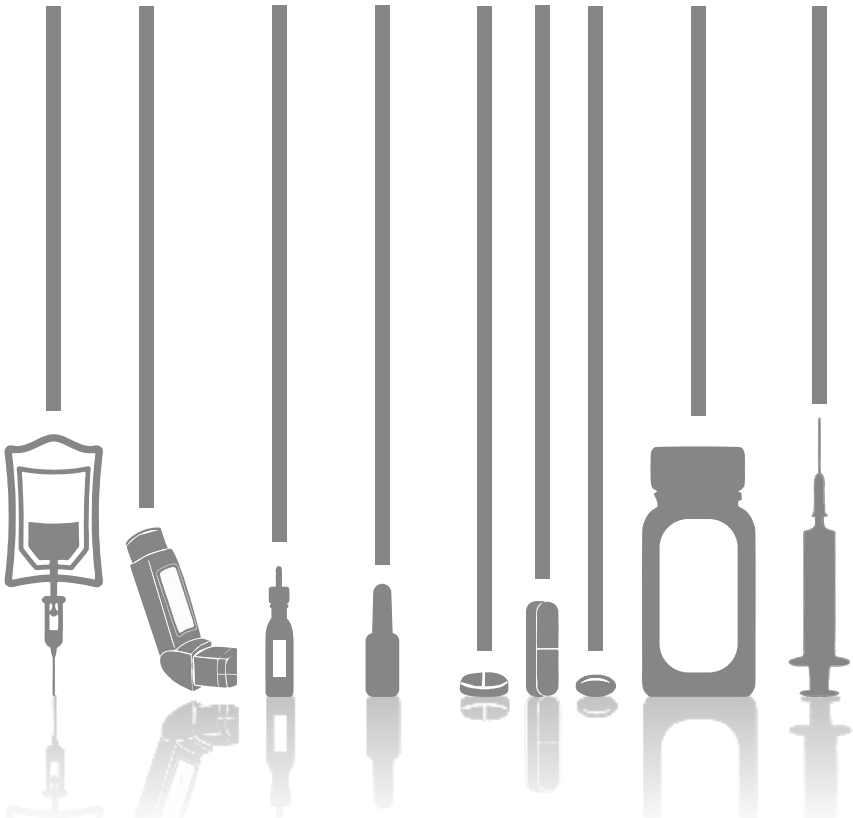
All you need to know about

SPURIOUS MEDICINES



A Practical Handbook
for Healthcare Professionals in India

World Health Professions Alliance

WHPA Indian Partners

INDIAN MEDICAL ASSOCIATION

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Abbreviations

AIOCD	All India Organization of Chemists & Druggists
API	Active Pharmaceutical Ingredient
C&F	Carrying & Forwarding
CDC	Center for Disease Control and Prevention
CDL	Central Drugs Laboratory
CDSCO	Central Drugs Standard Control Organization
CDTL	Central Drugs Testing Laboratory
CVDs	Cardiovascular Drugs
DPCO	Drugs Price Control Order
EU	European Union
FDI	World Dental Federation
FIP	International Pharmaceutical Federation
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
HCP	Healthcare Professional
ICN	International Council of Nurses
IMA	Indian Medical Association
INC	Indian Nursing Council
INR	Indian Rupee
IPA	Indian Pharmaceutical Association
IV	Intravenous
MoHFW	Ministry of Health and Family Welfare
NABL	National Accreditation Board for Testing and Calibration Laboratories
NGO	Non-governmental Organisation
NMCH	Nalanda Medical College and Hospital
NNAs	National Nurses Associations
NPW	National Pharmacy Week
NSAIDs	Non-steroidal Anti-inflammatory Drugs
NSQ	Not of Standard Quality
OSD	Oral Solid Dosage
PMCH	Patna Medical College Hospital
RDTL	Regional Drugs Testing Laboratory
SFFC	Spurious/falsely-labelled/falsified/counterfeit
SMS	Short Message Service
SSP	Senior Superintendent of Police
TB	Tuberculosis
UK	United Kingdom
USA	United States of America
USD	United States Dollar
WCPT	World Confederation for Physical Therapy
WHO	World Health Organization
WHO-SEARO	World Health Organization - South East Asian Regional Office
WHPA	World Health Professions Alliance
WMA	World Medical Association

Foreword

Foreword

Dear Colleagues,

In recent years the World Health Professions Alliance has been particularly concerned by the issue of spurious or counterfeit medicines. They are unsafe and ineffective and threaten patient health. They also result in wasted resources spent on purchasing, inventory, transport and dispensing, as well as additional healthcare costs associated with poorly controlled disease.

The World Health Professions Alliance represents more than 26 million healthcare professionals in over 130 countries. We bring together the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the World Confederation for Physical Therapy (WCPT), the World Dental Federation (FDI) and the World Medical Association (WMA).

Spurious medicinal products threaten patient safety by, at best, causing no improvement or, worse, causing added burden of disease and even death; endangering public health by increasing the risk of antimicrobial resistance; and eroding patients' trust in health professionals and health systems, who are seen not to be able to provide an adequate treatment. Public health and patient safety are being put at risk and now is the time to act.

We believe that healthcare professionals are central to the fight against counterfeit medicines. We share a common goal: safeguarding the well-being of patients across the world, including protecting them from poor quality, substandard and counterfeit medical products.

The Alliance is proud to see this collaboration of its local partners in India to tackle the issue. It supports and congratulates the Indian Medical Association, the Indian Pharmaceutical Association and the Indian Nursing Council in their work, and acknowledges the collaboration from Pfizer Inc. This Handbook supports the active engagement of all healthcare professionals in India. Patients count on each of you and we invite all of you to read this document.

Best regards

Luc Besançon	David Benton	Otmar Kloiber	Jean-Luc Eiselé	Brenda Myers
CEO, FIP	CEO, ICN	CEO, WMA	CEO, FDI	CEO, WCPT

Foreword

Foreword

Dear Healthcare Professionals,

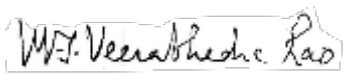
It's a pleasure to write the preface for this Handbook released under WHPA Campaign against Spurious Medicines in India. This Handbook is the first of its kind in the area of Spurious Medicines. It is the most welcomed and much-needed initiative. It gives comprehensive information with statistical data, case studies and tools, useful to tackle the menace of spurious medicines. Doctors, Pharmacists and Nurses all have important roles to play to prevent spurious medicines from reaching patients. In countries like India, where health and medicine literacy in the society is not yet fully developed, healthcare professionals have an even a bigger role to play compared to their counterparts in the developed world. This handbook will help enrich their knowledge and confidence to fight against the spurious medicines.

This campaign has brought together for the first time in India three premier healthcare professional associations, the Indian Pharmaceutical Association (IPA), the Indian Medical Association (IMA) and the Indian Nursing Council (INC). We are certain that this partnership will continue beyond the Spurious Medicines campaign and will work together for the safety of the Indian citizens.

Best regards

Dr. K. K. Aggarwal
Hony. Secretary General 2014-16
Indian Medical Association (IMA)

T. Dileep Kumar
President
Indian Nursing Council (INC)



Rao Vadlamudi
President
Indian Pharmaceutical Association (IPA)

Introduction

Introduction

This booklet aims to provide healthcare professionals with a ready-reckoner and a “go to” guide against spurious medicines in India.

Spurious drugs (sometimes referred to as *fake*, *adulterated* or *counterfeit* by the general public) are a challenge to healthcare systems all across the globe. Poverty, deficiency of drug regulation and legislation and their enforcement, alongside diminutive penalties makes this a boom in developing countries. If we want to attain the goal of health for all and looking for universal health coverage, the threat of spurious medicines needs to be managed, with proper systems in place. Spurious medicines in the healthcare domain leads to therapeutic failures, emergence of drug resistance and huge loss to public health.
This Handbook has been developed by the World Health Professions Alliance (WHPA) together with inputs from the Indian Medical Association (IMA), Indian Nursing Council (INC) and Indian Pharmaceutical Association (IPA).

It aims to provide healthcare professionals with a ready-reckoner and a “go to” guide against spurious medicines in India. This Handbook includes interventions (e.g. tips, advice) on prevention, detection, and advocacy on how to fight and minimize this threat with the interest to increase knowledge as well as change behaviors.

The Handbook is a part of the “WHPA campaign against spurious medicines in India“, a campaign that benefits from a collaboration with Pfizer Inc. This campaign was guided by an advisory board comprising representatives from Government officials of Ministry of Health and Family Welfare (MoHFW), Regulators from Central Drugs Standard Control Organization (CDSCO), Experts from leading Healthcare facilities, Security and Market research.

SSFFC medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.

Definition of a Spurious Medicine

At international level

At an international level, the most common used term is counterfeit medicines, and there are several definitions available worldwide.

Spurious/Substandard/falsely-labelled/falsified/counterfeit (SSFFC) medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SSFFC medicine is unknown and its content unreliable. SSFFC medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.[1]

In India

The term, 'counterfeit' that is commonly used worldwide does not appear in Drugs and Cosmetic Act of India as the term 'spurious' is preferred:

Box 1: Definition of Spurious Drugs:

The term "spurious" is loosely equivalent to the term "counterfeit". However, in this handbook the term spurious is being used to comply with the relevant portion of the definition of Spurious drugs as provided in Section 17-B of the *Drugs and Cosmetics Act, 1940 of Government of India.*

For the purpose of the booklet, a medicine (drug) has been deemed to be spurious if:

(a) it is manufactured under a name which belongs to another drug; or

(b) it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

(c) the label or container bears the name of an individual or company purporting to be the manufacturer of the drug , which individual or company is fictitious or does not exist; or

(d) it has been substituted wholly or in part by another drug or substance; or

(e) it purports to be the product of a manufacturer of whom it is not truly a product.

Spurious Drugs as in Drug and Cosmetic Act 1940 (D&C) (Amended 2005, 2008), D&C Act accessible at http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf

In the document, the terms spurious medicines and counterfeit medicines are considered as interchangeable.

Extent of the issue

Spurious medicines have been reported to occur worldwide. The problem of spurious medicines is not limited to developing countries only. They are also found in developed countries. But the problem is more pronounced in countries where medicine regulation is ineffective, smuggling of medicines is rampant, clandestine manufacturing exists, sanctions are absent or very weak, and there is high corruption. No country is immune to the problem.

An international overview

According to the WHO estimates[2]:

- Most industrialized countries with effective regulatory systems and market control (e.g. USA, EU, Australia, Canada, Japan, New Zealand) currently have a very low proportion, i.e. less than 1% of market value. However, we must keep in mind that indications point to an increase in the prevalence of spurious medicines even in such countries;
- Many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more than 30% of the medicines on sale can be spurious. Other countries, however, have less than 10%; overall, a reasonable estimate is between 10% and 30%;
- Many of the former Soviet republics have a proportion of spurious medicines which is above 20% of market value - this falls into the developing country range;
- Medicines purchased over the Internet from sites that conceal their actual physical address are spurious in over 50% of cases.

The problem is more pronounced in countries where medicine regulation is ineffective, smuggling of medicines is rampant, clandestine manufacturing exists, sanctions are absent or very weak, and there is high corruption.

Stories, News and Facts

Counterfeit medicines have a long history. In the first Century in Greece, Dioscorides (40-90 A.D., physician, pharmacologist and botanist, author of DeMateria Medica) first classified drugs by their therapeutic use, warned of the dangers of adulterated drugs, and advised on their detection. The phenomenon is not new and globalization has led to its increase. In the 17th Century, the demand for Peruvian Cinchona bark by Europeans increased. This was due to it being the first effective treatment of malaria. The incentive to adulterate also increased, because this “medicine” was not regulated. This increased adulteration led to the loss of confidence in the health system by patients.[3]

Within the South East Asia region, the country with the highest number of media reports is India (39), followed by Bangladesh (16), Indonesia (06) and Thailand (02).

Regional situation

South East Asia Region

The print and electronic media in South East Asia has been widely reporting the problem of spurious medicines. The open source media reports continue to provide coverage on the various permutations of pharmaceutical counterfeiting and substandard drugs. This includes identical copies, look-alikes, rejected medicines and re-labeled medicines.

However, a shortcoming of open source media reporting is that the same data may at times be published by multiple agencies. The duplicate information can falsely inflate the extent of the problem. Nevertheless, in the absence of large-scale research based data, it is natural for us to depend upon news items published in credible leading newspapers and journals. These reports have mainly dealt with the situation in India, Indonesia, Bangladesh, Thailand and Sri Lanka.

SEARPharm Forum has compiled data on the number of reports related to counterfeit medicines found in open source media for the year 2012-13[4] (Table: 1). The country with the highest number of reports is India (39), followed by Bangladesh (16), Indonesia (06) and Thailand (02). While in Sri Lanka, Maldives and Myanmar there is one report, countries like Nepal, Bhutan, DPR Korea and Timore-Leste have no reported incidents of SSFFC medicines. This list neither claims to include every media report published nor does it contain any confidential information.

Table 1: News reports on spurious medicines in Newspapers and Journals

Country	Number of Reports in the media* (2012-13)
India	39
Bangladesh	16
Indonesia	06
Thailand	02
Sri Lanka	01
Nepal	No Reported incidences
Bhutan	No Reported incidences
DPR Korea	No Reported incidences
Maldives	01
Myanmar/Burma	01
Timor-Leste	No Reported incidences

**Reports on drug product counterfeiting*

The state-wise data revealed prevalence of counterfeit suspects was highest in Bihar, followed by Gujarat, West Bengal, Rajasthan and Maharashtra with over 4 percent suspects.

The national situation

In India, there is limited scientific data available on spurious drugs. Most of the information available in the public domain is in the form of news and media reports, but there have been two major widely quoted studies one by SEARPharm Forum in 2007 and a second study in 2009, conducted by Indian regulators {Central Drugs Standard Control Organisation (CDSCO)}. In a SEARPharm Forum study, the samples were purchased against prescriptions from retail pharmacies by "Professional Associates" posing as "mystery customers"; while in a CDSCO study, it was NGOs and consumer associations who collected the samples from retail pharmacies. The extent of spurious medicines found in these studies was less than 1% to 3%.

SEARPharm Forum study[5] reveals that based on the domestic sales of INR 31,500 crore (7 billion USD) in 2006, the extent of suspected spurious medicines would be extrapolated to be approximately INR 1000 crore (USD 250 million).

A total of 10,743 samples were collected including 56 medicines from 15 states covering 38 Locations of Interest (LoIs) in 5 regions throughout the country. These samples were inspected and were identified as either passing or failing (based on chemical analysis as per pharmacopoeial standards). The study addressed the extent of spurious drug prevalence in India; relative prevalence of spurious drugs in various states and regions; estimation of approximate volume and percentage of spurious drugs available through retail drug stores; prevalence of spurious drugs in various identified therapeutic segments and estimation of the extent of spurious drugs in the identified segments.(See Tables 2-3).

The state-wise data revealed prevalence of counterfeit suspects was highest in Bihar, followed by Gujarat, West Bengal, Rajasthan and Maharashtra with over 4 percent suspects.

Table 2: Distribution of failing samples under different Cost range

Cost range (INR)	Result of NABL report	
	Fail	Pass
Less than 20	225 (5.2%)	4078 (94.8%)
20 - 50	75 (2.2%)	3359 (97.8%)
51 -100	31 (1.4%)	2167 (98.6%)
101 - 500	0 (0%)	569 (100%)
More than 500	4 (1.7%)	235 (98.3%)
Total	335 (3.1%)	10408 (96.9%)

Source: Extent of Spurious (counterfeit) Medicines in India, 2007.[5]

Almost all therapeutic categories are subject to spurious medicines.

In terms of cost ranges, medicines in the cost range of less than INR 20 had the most failed samples at 5.2%. The second highest cost range in this sample was INR 20-50 at 2.2% followed by INR 51-100 at 1.4%, INR more than 500 at 1.7% and INR 101-500 at 0%. The findings in the specific study show that medicines in price range of less than INR 20 per sample has the highest rate of counterfeits. This is contrary to the common belief that the high cost medicines are more prone to counterfeiting. (See table 2).

In terms of therapeutic categories studied, the extent of relative prevalence of counterfeit suspects were: Anti-infectives 3.5%; Steroids 6.5%; Anti-histamines 11.7%; CVDs 0.6%; Anti-diabetics 0.9%; NSAIDs 4.1%; Anti-malarials 4.6%; Anti-TB Nil; Anti-ulcerants 1%; Anti-cancer 9.9%; and Miscellaneous 1.5%. While within this study the medicines in the anti-histamine category were found to be more prone to counterfeiting, at the same time, it is noteworthy to mention that among anti-TB and anticonvulsant drugs no samples of counterfeit suspects were detected. These results demonstrate that most therapeutic categories are subject to spurious medicines. (See table 3).

Table 3: Distribution of failing samples under different Therapeutic categories

Therapeutic Category	Result of NABL report	
	Fail	Pass
Anti-infective	80 (3.5%)	2224 (96.5%)
Steroids	41 (6.5%)	590 (93.5%)
Anti-histamine	55 (11.7%)	417 (88.3%)
CVDs	6 (0.6%)	947 (99.4%)
Anti-diabetic	8 (0.9%)	892 (99.1%)
NSAIDs	79 (4.1%)	1833 (95.9%)
Anti-malarials	22 (4.6%)	459 (95.4%)
Anti TB	0 (0%)	533 (100%)
Miscellaneous	12 (1.5%)	796 (98.5%)
Anti-ulcerants	14 (1%)	1396 (99%)
Anti-cancer	18 (9.9%)	163 (90.1%)
Anti-convulsant	0 (0%)	158 (100%)
Total	335 (3.1%)	10408 (96.9%)

Source: Extent of Spurious (counterfeit) Medicines in India, 2007.[5]

The CDSCO Study[6] (2009) reveals that: The extent of circulation of spurious drug is about 0.3%. Samples of 61 popular brands of oral solid dosage (OSD) formulations, belonging to 9 therapeutic categories (anti-infective, anti-malarial, anti TB Drugs, steroids, "antihistamine", cardiovascular drugs, anti-diabetics, NSAIDs, and multi-vitamin preparations), were collected from retail pharmacy outlets (25 each from metros, big cities, district headquarters, towns and villages) in each zone of CDSCO (East, West, North and South). This was done with the help of NGOs and consumer associations, who in turn, collected drugs without prescription from retail shops by acting as surrogate patients.

A total of 24,780 samples were collected by visiting around 40,000 pharmacy outlets. The results show that 644 samples were of SALA (Sound Alike and Look Alike). Only 11 samples from the remaining 24,136 samples were not accepted by manufacturers as being their genuine product by physical examination. These unaccepted samples were mainly from Bihar, West Bengal, UP and Gujarat states accounting for five, three, two and one sample, respectively. However, none of these samples failed in identification testing. 305 samples out of the 24,780 collected were subjected to chemical analysis, 3 were found to be substandard with respect to the amount of the active ingredient for the product. The results showed the amount of active ingredient was 86.0%, 89.3% and 84.8% of the intended amount. An additional 2,671 samples were subjected to testing on the direction of the Ministry of Health & Family Welfare (MoHFW), these showed 100% conformity with respect to identification and assay as reported by the government analyst at various central government testing laboratories.

Based on the analysis of 2,976 samples in this study, the extent of spurious drug in retail pharmacy was found to be 0.046 % (11 samples out of 24,136 samples).

CDSCO has an ongoing surveillance program,[7] in which the state drug control offices pick samples (Suspects), which are tested in Government laboratories in the region. The data from the last 3 years reveals that, out of 43,383 samples collected, 1563 samples (3.60%) were found to not be of standard quality (NSQ) while 15 samples (0.03%) were spurious (See Table 4).

Table 4: Details of Samples Tested (2010-13) by All the Seven Drug Testing Government Laboratories in India

Year	No. of samples tested	No. of samples declared as not of standard quality	No. of samples found to be spurious
1. Central Drugs Laboratory (CDL), Kolkata			
2011-12	3525	308	9
2012-13	3343	316	1
2013-14	3316	382	1
2. Central Drugs Laboratory (CDL), Kasauli			
2011-12	3467	02	--
2012-13	4046	11	--
2013-14	3564	06	--
3. Central Drugs Testing Laboratory (CDTL), Mumbai			
2011-12	2782	105	Nil
2012-13	2774	59	1
2013-14	2774	64	1
4. Central Drugs Testing Laboratory (CDTL), Chennai			
2011-12	875	36	--
2012-13	1224	27	--
2013-14	1633	11	--
5. Central Drugs Testing Laboratory (CDTL), Hyderabad			
2011-12	161	Nil	--
2012-13	483	Nil	--
2013-14	579	Nil	--
6. Regional Drugs Testing Laboratory (RDTL), Guwahati			
2011-12	1152	33	Nil
2012-13	1040	72	Nil
2013-14	1680	87	2
7. Regional Drugs Testing Laboratory (RDTL), Chandigarh			
2011-12	1361	11	Nil
2012-13	1401	06	Nil
2013-14	2207	27	Nil

What products are likely to be spurious?

At global level, high volume (high consumption) and expensive medicines are the main targets of counterfeiters. The largest number of reports relate to antibiotics, antiprotozoals, hormones and steroids. In developing counties, antibiotics and antiprotozoals such as anti-malarial medicines are commonly counterfeited. In developed countries, hormones and steroids account for the majority of the cases reported.

In some countries, like in USA, the National Association of Boards of Pharmacy has created the "National Specified List of Susceptible Products," available at http://www.nabp.net/ftpfiles/NABP01/List.pdf, which identifies 32 drugs that are most susceptible to adulteration, counterfeiting or diversion and that pose the greatest risk to public health.

In a study[8] focusing on 8 drug types on the WHO-approved medicine list, the authors constructed an original dataset of 899 drug samples from 17 low- and median-income countries (including India) and tested them for visual appearance, disintegration, and analyzed their ingredients by chromatography and spectrometry. Fifteen percent of the samples failed at least one test and by virtue of this can be considered substandard.

After controlling for local factors, this study found that drugs that failed testing were priced 13-18% lower than non-failing drugs. The researchers concluded that consumers are likely to suspect lower quality when they pay less.

They went on to pose that poverty may be a reason for the selection of lower price drugs. The study showed that the price differential between failing and non-failing drugs (controlling for other factors) was about $0.59-0.80, which could be substantial for a country like India where more than 40 percent of the population lives on less than $1 a day. Severe poverty, plus ignorance on the harm of poor quality drugs, could foster demand for counterfeit and substandard drugs.

In India, based on the data available from SEARPharm Forum study,[5] the following types of medicines are more likely to be spurious:

- Medicines in price range of less than INR 20 per sample are maximum targets for spurious medicines. However, all medicines can be subject to counterfeiting.
- Anti-histamine category was found to be more prone to spurious, however most therapeutic categories are subject to spurious medicines.

Based on this list, it is therefore rather hard to determine a specific profile of medicines which are more likely to be spurious. It is therefore important for every Healthcare Professional to pay attention to every product they dispense/prescribe/use in their practice. Additional information will be provided in this document under -When to suspect/how to detect a spurious product? (See Page 17).

It is rather hard to determine a specific profile of medicines which are more likely to be spurious. It is therefore important for every Healthcare professional to pay attention to every product they dispense/prescribe/use in their practice.

What are the consequences for personal and public health?

At patient level

Based on the WHO definition and the different reports provided by major international organizations, spurious medicines can include:

- No active principle ingredients: As a consequence, patients are deprived of essential medicines for their therapy and may have a worsening of their medical condition.
- An insufficient amount of active pharmaceutical ingredients (API): As a consequence, the medicine may not be effective in treating the patient. Moreover, with sub-therapeutic dosage forms leading to treatment failure or resistance, prescribers may consider increasing the dose for the non-respondent patients. In some cases, this may result in increased side effects, injuries or death to patients due to non-intentional over-dosing caused by spurious medical products.

  In addition, given the lack of therapeutic results, this may lead to a shift to a second-line treatment (which may be more expensive or associated with a higher frequency of severe side effects).
- An excessive amount of active pharmaceutical ingredients: In this case, the patient will be more likely to face adverse drug reactions.
- Toxic ingredients: These toxic ingredients can induce unusual symptoms that could deter diagnosis and effective management of medical conditions and in some cases, lead to death.

It is important to know that the difference in the amount of active principle ingredients can either be due to an incorrect amount of API used in the manufacturing phase or a drug delivery formulation which doesn't mimic the release profile of the original drug. The pharmacological effects of absorption, distribution, metabolism and excretion of drugs are especially critical for drugs with a narrow therapeutic index, for example: warfarin.

Stories, News and Facts

Fake drugs worth Rs 25 lakh seized, 4 held[9] The Times of India(7/6/14)

PATNA, 7 JUNE 2014: Patna police on Friday seized suspected fake medicines worth Rs 25 lakh and arrested four persons in this connection with this incident. A large number of medicines cartons were found stored at the godowns. The medicines were dumped in different cartons while their labels were stored in separate boxes. A police official said, "The labels were probably locally printed, and we are looking for the manufacturing companies of such medicines. The capsule and tablet strips were printed and manufactured in different states like Uttarakhand, Maharashtra, Andhra Pradesh and other states." The arrested persons revealed to police that they used to bring the medicines from Delhi via trains and couriers." The types of medicines seized included calcium, vitamins and hormones. Most of them were for infants and pregnant women. "Earlier, we had arrested some persons near Patna Medical College Hospital (PMCH) and Nalanda Medical College and Hospital (NMCH) who used to sell duplicate medicines to the poor," said the SSP. "There are several medicine godowns in the Boring Road and Boring Canal Road area which could be full of duplicate medicines," said an official.

At society level

Not only are spurious medicines a danger for individual health, but they can also be a threat for public health and the community. If an antibiotic does not contain the correct amount of APIs, patients receiving them as treatment may have a lower concentration than the therapeutic dose, enabling the emergence of anti-microbial resistance. This could lead to the inefficacy of both original and spurious medicines. Moreover, a pharmacotherapy may be considered as ineffective and a second-line treatment may be chosen based on the poor outcomes of the initial treatment, whereas the clinical decision is biased by the use of a spurious product. This change in treatment could lead to increased expenditures in the healthcare system through additional medical visits and second line treatments (which are often more expensive than the first line ones). The inefficiency of the first line medicines can increase healthcare costs resulting in an overall cost to the entire society.

In addition to this direct threat to public health, spurious medicines when found in the legal distribution chains can also erode public trust and confidence in health systems.

When to suspect / how to detect a spurious product?

Visual inspection

First of all, it should be noted that in many cases, spurious products are rather similar in appearance to the original products. Therefore, their identification may require chemical analysis.

Nevertheless, for some spurious medicines, they can be detected by a visual inspection. To facilitate this inspection, the International Pharmaceutical Federation (FIP) together with the US Pharmacopeia and the International Council of Nurses (ICN) developed a checklist for a visual inspection of medicines in order to help identifying suspicious products for further examination. These signs include elements such as improper packaging, labeling and description of dosage. All suspicious drugs with incorrect labels, missing information about the strength, dosage, or expiration date should be reported to the appropriate authority. It has been adapted for use in India by enforcement officers in other similar contexts. See Appendix 1 - Visual inspection tool.

Selection of suppliers

In many cases, the infiltration of spurious medicines within the legitimate pharmaceutical distribution chain is made possible through an operator of this chain buying from an unauthorized seller/unofficial seller *(in Indian context it can be a sub-distributor, who is not an officially appointed distributor by the company, but works under an authorized distributor for a commission).*

In India, through Drug Price Control Order (DPCO) prices of Essential Medicines are regulated by the government. When medicines prices are highly regulated, being offered a medicine at an unusually low price (especially from a new source) should raise suspicion.

Feedback on the administration of medicines

While administering a product (e.g. vaccines and IV Drugs) or splitting a tablet or dispersing a tablet in a glass of water, HCPs can see differences in the product's characteristics and that could raise suspicion in certain cases. The HCPs could investigate the origin of the product, conduct a visual inspection (of the dosage forms and the packaging) for the detection of spurious drugs and should always report such cases to their colleagues and relevant authorities.

While administering a product (e.g. vaccines and IV Drugs) or splitting a tablet or dispersing a tablet in a glass of water, HCPs can see differences in the products and that could raise suspicion in certain cases.

When treatment fails, healthcare professionals should consider spurious medicines as a potential reason for non-response or for an unexpected response in pharmacotherapy.

Patient reported information

In 2004, in the UK, a patient complained to his pharmacist that some of his purchased tablets of an erectile dysfunction pill completely crumbled when he tried to cut them in half. The manufacturer was notified. An analysis of the suspect tablets revealed the presence of two active substances instead of just one. Based on this example, it is clear that patients can be effective partners in detecting spurious medicines.

Through their everyday interaction with patients, healthcare professionals often come across such "complaints" by patients on their use of the medicines, including abnormalities such as difference in taste, color or medical response. In all cases, healthcare professionals should report to the relevant authority, including the CDSCO where appropriate.

Moreover, when treatment fails, healthcare professionals should consider spurious medicines as a potential reason for non-response or for an unexpected response in pharmacotherapy. The HCP should inquire about where the medication was purchased. Caution is especially important if the patient bought their medicine from an illegal or risky source (i.e. Internet, a foreign country with little regulation and enforcement).

Technology for authentication

In India for some products, the manufacturers may adopt anti-counterfeiting technologies such the use of a hologram or other overt and covert measures on the packaging of their products. These serve to validate the authenticity of the product. Another system that can be employed to validate authenticity includes a tracking methodology. A specific code is placed on the pack of medicine which can be checked using mobile SMS. The code is sent to a pre-designated number which validates that the medicinal product is genuine. In India, there is no regulatory guideline for mandatory use of anti-counterfeiting technology; however some manufacturers have employed these types of technology for some of their products.

In case of any doubt, please refer to section "What should healthcare professionals do when they encounter a suspected spurious medical product?" (Page20).

What can healthcare professionals do to reduce the risks of buying counterfeit medical products?

Pharmacists who are responsible for purchasing medicines should refer to the national Good Distribution Practices (GDP) to evaluate and select their source of medicines.

As part of the distribution chain, pharmacists and other healthcare professionals have a shared responsibility to avoid any infiltration of spurious medicines within the legitimate pharmaceutical supply chain. Therefore, before buying products from a new supplier or distributor, purchasing healthcare professionals should check at the State regulatory approved list of distributors or buy from company C&F agents. In case of Schedule X drugs (Narcotics) CDSCO has an approved list of retail Pharmacies.[10] For veterinary drugs there is an approved list[11] and for medical devices list of licensed indigenous manufacturers approved by CDSCO.[12]

Pharmacists who are responsible for purchasing medicines should refer to the national Good Distribution Practices (GDP) to evaluate and select their source of medicines. GDP guidelines are available by CDSCO for biological products.[13] Healthcare professionals should keep in mind that the fewer hand-offs there are between the producer and the hospital / pharmacy, the traceability of the product will be stronger.

Box 2: Information specific to the distribution practices

Pharmacists can verify the authenticity of an authorized wholesaler from trade channels (AIOCD) or through medical representatives of the Pharmaceutical company.

Good Distribution Practices (GDP) Guidelines by CDSCO state:

1. The activities of persons or entities involved in the distribution of products shall be regulated by applicable National legislation.
2. The distributor or the organization to which the distributor belongs shall be an entity that is appropriately authorized by applicable legislation to perform the function(s) that it intends to perform and the distributor or the organization to which it belongs shall be held accountable for the activities that it performs related to the distribution of products.
3. Only authorized persons or entities who hold the appropriate license shall be entitled to import or export pharmaceutical products.
4. Distributors or their agents shall obtain their supplies of pharmaceutical products from persons or entities authorized to sell or supply such products to a distributor and shall supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient or to his or her agent.
5. If the activity of a distributor or his or her agent is subcontracted to another entity, the person or entity to which the activity is subcontracted shall be appropriately authorized to perform the subcontracted activity and shall uphold the same standards as the distributor.

For specific medicines required for clinical trials Form 11 & 12 test license is issued by State Regulatory Agencies.

When necessary emergency recall procedures shall be implemented as per the guideline on Recall and Rapid Alert System for Drugs this includes biologicals and vaccines. This can be found on the CDSCO website (Accessible at http://www.cdsco.nic.in/writereaddata/Guidlines%20on%20Recall.pdf)

Box 3: Information specific to the return policy practices

Return of medicines in India is allowed through the trade channels. A retail/hospital Pharmacy can return expired/damaged, suspected medicines or soon to expire (6 months prior to the expiry date) to the wholesaler/stockiest who in turn returns these medicines to C&F Agents of the manufacturers.

However, it is advised not to allow any products to go back to the distribution chain (for instance from a patient through a community pharmacy and then through a wholesaler), as it could be a way of entrance of spurious medicines. Moreover, the product return could impact the traceability of the medicines, any returned product should be destroyed and not be re-introduced in the pharmaceutical distribution chain. However, in India, this is a common practice by manufacturers and there is no return policy recommended by CDSCO.

What should healthcare professionals do when they encounter a suspected spurious medical product?

The procedure to follow as per Good Distribution Practices (GDP)[13] Guidelines of CDSCO, if spurious medicines are found in the supply chain:

1. Spurious pharmaceutical products if found [or suspected] in the distribution chain shall be completely segregated from other pharmaceutical products, clearly labeled as not for sale and national regulatory authorities and manufacturer of the original product shall be informed immediately.
2. The sale and distribution of a suspected spurious pharmaceutical product shall be suspended and the national regulatory authority shall be notified without delay.
3. A formal decision shall be taken on its disposal, ensuring that it does not re-enter the market upon confirmation of the pharmaceutical product being spurious and the decision shall be recorded.

For reporting of spurious medicines, CDSCO has come out with a Whistle blower scheme in 2009 (recently updated version available)[14]: the CDSCO has a reward scheme applicable for whistle blowers in the area of drugs, cosmetics and medical devices. A maximum reward of up to 20% of the total cost of consignments seized will be payable to the informer / officials which should not in any case exceed Rs 25 Lakh.

The CDSCO has a reward scheme applicable for whistleblowers in the area of drugs, cosmetics and medical devices.

Box 4: Information specific to the reporting procedures of spurious medical products

The details of the nodal authority and the zonal / sub-zonal officers of the CDSCO for the purposes of this reward scheme, to whom the concerned information may be given by the whistle blower / informer, are as follows[14]:

Name and Designation	Addresses and phone number, fax number and e-mail address
Dr. G.N. Singh Drugs Controller General (India),	Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002; Phone: +91-11-23236965 / 23236975; Fax: +91-11-23236973 E-mail address: dci@nic.in
Mr. A. K. Pradhan Deputy Drugs Controller (India) (For the states Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttaranchal, Uttar Pradesh, N.C.T. of Delhi & Union Territory of Chandigarh)	Central Drugs Standard Control Organization (North Zone), CGO Building – I, Kamla Nehru Nagar, HapurChungi, Ghaziabad-201002 (U.P.) Phone: +91-120-2719483 / 2750013 Fax: 0120-2701927 E-mail address:cdsconz@gmail.com
Dr. K. Bangarurajan, Deputy Drugs Controller (India) (For the states Chattisgarh, Goa, Daman & Diu, Madhya Pradesh, Maharashtra, Dadar & Nagar Haveli and Lakshadweep)	Central Drugs Standard Control Organization (West Zone), 4th Floor, Zonal, FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai-400008, (Maharashtra) Phone: +91-22-23002279 / 23002215; Fax: 91-22-23002271 E-mail address:cdscowz@gmail.com
Dr. S.E. Reddy Deputy Drugs Controller (India) (For the state Gujarat)	Central Drugs Standard Control Organization (Sub-Zonal Office), Air Cargo Complex, Old Terminal Building, Airport, Ahmedabad-380016 (Gujarat) Phone: +91-79-22865244; Fax:079-22865244 E-mail address:cdscosbz@gmail.com
Sh. P.B.N. Prasad Deputy Drugs Controller (India) (For the state Andhra Pradesh)	Central Drugs Standard Control Organization, Beside AP T.B Demonstration and Training Centre, S.R. Nagar, Hyderabad, (Andhra Pradesh) Phone: +91-40-23811481 Fax:040-23811483 E-mail address:ddchyderabad@gmail.com
Dr. S. Manivannan Deputy Drugs Controller (India) (For the states Karnataka, Kerala, Pondicherry and Tamilnadu)	Central Drugs Standard Control Organization (South Zone), 2nd Floor, Shastri Bhavan, Annexe 26, Haddows Road, Chennai – 600006, (Tamil Nadu) Phone No. +91-44- 28278186 / 25610402 / 25610906; Fax: 044-28213079 E-mail:-ddcsz@tn.nic.in
Sh. S. P. Shani Deputy Drugs Controller (India)(For the states Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura & West Bengal)	Central Drugs Standard Control Organization (East Zone), CGO Buildings, Nizam Palace West, 2nd Floor, 234/4, Lower Circular Road, Kolkata-700020 (West Bengal) Phone: +91-33-22470513; Fax:033-22813806, E-mail address:cdscoez@gmail.com

Any clarification / information may be directed to:

Sh. Sudipta Dey
Deputy Drugs Controller (India),
Central Drugs Standard Control Organization, Directorate General of Health Services,
Ministry of Health and Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi -110002;
Phone: +91-11-232 36975 / 23236971; Fax: +91-11-23236973

Important issues to be considered by a healthcare professional

Recall

When spurious medicines are discovered in the legal pharmaceutical chain, most of the time the Central Drugs Standards Control Organization (CDSCO) will proceed to a batch recall based on a risk analysis.

Batch number and expiry dates are important elements for any recall, as this is a first step to identify products suspected of being spurious.

In addition to these data, the CDSCO may inform healthcare professionals how to detect spurious medicines (i.e. visual inspection, hologram).

In the stock of the community or hospital pharmacies as well as in any other healthcare settings, these data enable healthcare professionals to separate (potential) spurious medicines from original ones. It is therefore important to store these recalled products in a separate room and with proper information on them to avoid dispensing / administrating them, before destroying them or sending them back, based on the CDSCO instructions.

It is advised to check all incoming orders, during the next days after the batch recall, in order to detect possible spurious products which were not withdrawn from the market and/or which were already in their journey to the healthcare settings.

Pharmacists and other healthcare professionals should comply with the requirements of the CDSCO which could require contacting individual patients to proceed to a batch recall down to patient level.

Recording the batch number and expiry dates in the pharmacy / hospital records on a patient level will facilitate executing the recall down to the patient.

If these data are not recorded, the healthcare professional will have to go back to the product's dispensing / administering data and contact all patients who received the products for the last month (or 3 months) depending on the amount of doses dispensed.

Communication to the public

Whether it is a pro-active communication (healthcare professionals calling the patients to inform them) or a reactive communication (patients asking healthcare professionals for more details), in the case of a recall a clear message should be given to the patient.

This message needs to be based on reliable information, mainly from the CDSCO and the original pharmaceutical manufacturer. Healthcare professionals should give precise information based on verified facts, and have a balanced message.

If patients have questions about generics, make the distinction between generics and spurious products. Generics are approved and their quality is assessed by the CDSCO. Spurious medicines are not controlled and their ingredients and manufacturing process can be very different from what is expected from licensed medicines. Healthcare professionals can refer to the definition of page 9 to highlight these differences.

Consider disruption of treatment in regard to the risk of spurious medicines

In the case of detecting a suspicious medicine that may be spurious, the healthcare professional will have to evaluate the risks posed by the spurious medicines versus the risks of treatment disruption. There may be another manufacturer for the suspected spurious product and it can be replaced. Withdrawal or recall of a medication can be based on a category or class of drugs and can be voluntary or statutory. This is according to the Guideline on Recall and Rapid Alert System for Drugs (Including biological and vaccines) (accessible at: http://www.cdsco.nic.in/writereaddata/Guidlines%20on%20Recall.pdf)

Special focus on the Internet

Internet pharmacy in India

Internet pharmacy is not allowed in India. The provision of medicines over the Internet in India is therefore illegal and patients should know that such products are more likely to be spurious than those in the authorized supply chain.

Box 5: Tips specific to the Internet pharmacy

Here are some key messages and tips that HCPs can provide to their patients and customers related to an "e-pharmacy":

- *It is difficult to determine whether a website is legitimate*
- *There is a higher chance of obtaining spurious medicine from a website; especially, if the true source of the site is not known*
- *Be suspicious if:*
  - *You can obtain a prescription-only medicine without providing a prescription*
  - *Fast or sensational results are presented, supported by personal testimonials.*
  - *You can obtain a medicine which is not authorized in India (there could be a good reason for it).*
  - *You are presented with new astounding theories regarding diseases or a secret recipes that should be passed on.*
  - *The treatment is noted to be riskless or no side-effects are reported on the website.*
  - *Everyone can use the medicine or take it on a lifelong basis*
  - *If the "e-pharmacy" full address is missing (or only accessible through an e-mail address)*

Special focus on Raw materials for compounding medicines

Compounding is permissible in India, but hardly practiced.

Some rules should be followed to ensure that the ingredients used for this activity are not spurious, such as:

- Only buy ingredients from reliable sources
- Only buy ingredients with an authorized analytical certificate (analytical certificate released by a qualified person)
- Check the identity of the ingredients while receiving them.

Schedule N of Drugs & Cosmetics Act deals with compounding of medicines.[15]

Anti-spurious medicines initiatives and other useful resources for healthcare professionals

International level

WHPA Counterfeit Medical Products Campaign

The World Health Professions Alliance (WHPA) is extremely concerned about the infiltration and sale of counterfeit medical products in the legitimate supply chain in causing life threatening, adverse effects patients. With WHPA "Be Aware, Take Action" we provide dentists, nurses, pharmacists, physicians and physical therapists with tools and strategies to advocate for appropriate investments in the education and capacity building of health professionals to detect counterfeits and to safely inform colleagues and patients.

Education of health professionals is crucial for detection and prevention of counterfeit medical products and is required in order for them to educate patients and populations about the risks of buying counterfeit medical products from unknown and unreliable sources.

Furthermore, international workshops for health professionals in several regions were organised which lead to a joint call for action.This is accessible at: http://www.whpa.org/counterfeit_campaign.htm

- WHPA Statement on Counterfeit Medical Products
- WHPA Call for Action- Asia region, Central America, Africa and Eastern Europe

FIP

The International Pharmaceutical Federation (FIP) mission is to "*improve global health by advancing pharmacy practice and science to enable better discovery, development, access of and safe use of appropriate, cost-effective, quality medicines worldwide*". Therefore, the FIP has been involved for many years in the fight against spurious medicines to protect patients' health.

In 1999, the FIP council adopted a statement on counterfeit medicines and updated its statement in 2003. This statement provides policy directions to combat spurious medical products and can be downloaded on the FIP website: http://www.fip.org

FIP has shared its expertise with the Council of Europe Committee of Experts on spurious medicines since 2003.

FIP has established an online resource center on combating spurious medicines: highlighting key information for patients, publications and international guidelines/tools that can be useful in policy development and advocacy against spurious medicines. This is accessible at: http://www.fip.org/counterfeit-

medicines

WMA

WMA joined the " Fight the Fakes campaign", which gives a voice to those who have been personally impacted and shares their stories. It seeks to build a global movement of organizations and individuals who will shine light on the negative impact that fake medicines have on people and by this increase awareness and reduce the negative consequences on individuals worldwide. This is accessible at: http://www.wma.net/en/20activities/30publichealth/50counterfeits/

ICN

International Council of Nursing is very concerned with the growing problem of counterfeit medicines and the negative consequences on the prevention and treatment of disease, which can include poor treatment outcomes or failure of treatment, loss of confidence in health care, resistance to antibiotics and poisoning due to harmful ingredients. ICN supports international initiatives to combat counterfeiting and urges nurses and national nurses associations (NNAs) to collaborate with pharmacists, physicians and others to disseminate accurate information on detection and elimination of counterfeit medicines.

ICN has joined with colleagues in medicine, pharmacy, dentistry and physical therapy to advocate for appropriate investments in the education and capacity building of health professionals to detect counterfeits and to safely inform colleagues and patients. This is accessible at: http://www.icn.ch/projects/counterfeit-medecines/

By regional organizations

Box 6: Activities at regional level

FIP/WHO pharmaceutical forum for South East Asia i.e. SEARPharm Forum activities:

- Yearly report on compilation of news and media reports on counterfeit/spurious medications since 2007. (available at http://www.searpharm.org/#!publications/cyg)
- SEARPharm Forum study along with Apothecaries Foundation (provided the technical assistance) and WHO-SEARO conducted probably the first scientific study on prevalence of spurious medicines in India. 2007(Accessible at media.wix.com/ugd/1a16f6_052d6082 983e4228bd248eebe2b07f08.pdf)
- SEARPharm Forum does advocacy against spurious medicines at various trade and industry platforms.

By national stakeholders

Box 7: Examples of Activities at National level

IPA: Indian Pharmaceutical Association is involved in activities both at national and state level to spread awareness and educate pharmacists and consumers about the menace of spurious drugs.

- Booklet on Responsible Use of Medicines: It is a booklet for consumers with a 2 page chapter on Spurious Medicines describing what it is, its harm, precautions to take, as well it covers Internet pharmacies and their dangers
- National Pharmacy Week (NPW): Over the years IPA during the NPW comes out with leaflets and posters for consumers: they focus on promoting know your medicines. Themes have included, "Take the bill", "Buy only from licensed pharmacies under supervision of the registered pharmacist" and "Do not fall prey to the misleading advertisements"
- Medicine Literacy Campaign (since year 2010): it has Posters and Leaflets for use through Pharmacies and Doctor's Clinics. The emphasis is on "Take the bill" and "Buy only from licensed pharmacies under supervision of the registered pharmacist".
- Lectures by IPA team members on "Correct Use of Medicines" at public forums
- Articles in newspapers by IPA team members in national and local language newspapers.

Central Drugs Standard Control Organization (CDSCO)
Initiatives in Enforcement of the Drugs and Cosmetics Rules:

- More than 100 import licenses of drugs were cancelled in 2009 following cancellation of registration certificates due to submission of non-authentic GMP certificates.
- Surveillance by the CDSCO officers at the ports in 2008 resulted in detection of certain cases of import of drugs from unregistered sources of doubtful quality. The cases were handed over to the CBI for investigation and taking further action.
- Implementation of "whistle blower scheme" to motivate the public and provide information to the regulators on movement of spurious drugs.
- The surprise investigation/ Inspection of Whole Sale/Retail/Hospital premises for the availability of prohibited drugs (Gatifloxacin, Tegaserod and Rosiglitazone) was carried out on dated 15th June 2011 at National Capital Region New Delhi and Bhiwadi (Rajasthan).

The office of CDSCO has started inspection of Pharmaceutical firms for import registration of drugs. In May 2011, six bulk drugs manufacturing in China were inspected out of which registration certificate and import license of one unit was cancelled. Further, in February 2012, 4 drug manufacturing in China were inspected as per the provisions.[16]

Responsibility on spurious medicines issue

Moral responsibility

In accordance to their Code of Ethics, healthcare professionals should think of their moral responsibility to protect their patients from spurious medicines. Such a moral responsibility is of course to be considered in addition to the legal requirements.

Indeed, healthcare professionals are trusted people by the community. The provision of medicines by the healthcare professionals is expected to improve or at least maintain health conditions.

When a spurious medicine is distributed through the legal distribution chain to the patient, it could be seen from a patient's perspective, like an attempt to harm their health and his trust in his healthcare professionals could be weakened.

Therefore, the image of the healthcare professionals could be altered in such a case.

It is therefore in the interest of the patients for healthcare professionals to take part in the fight against spurious medicines.

Code of Ethics of HCPs

1. Code of Pharmaceutical Ethics (Accessible at http://www.ipapharma.org/HTML/communitypharmadivision.html)

Chapter II, Handling of Drugs: .....Further, a Pharmacist should always use drugs and medicinal preparations of standard quality available. He should never fill his prescriptions with spurious, sub-standard and unethical preparations.

Chapter III, Purchase of Drugs: Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub-standard drugs.

2. Code of Medical Ethics (Accessible at http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthics Regulations 2002.aspx.)

Evasion of Legal Restrictions: The physician shall observe the laws of the country in regulating the practice of medicine and shall also not assist others to evade such laws. He should be cooperative in observance and enforcement of sanitary laws and regulations in the interest of public health. A physician should observe the provisions of the State Acts like Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic substances Act, 1985; .....and such other Acts, Rules, Regulations made by the Central/State Governments or local Administrative Bodies or any other relevant Act relating to the protection and promotion of public health.

3. INC code of ethics for nurses in India (Accessible at: http://www.indiannursingcouncil.org/)

   2.2 Nurse protects public from misinformation and misinterpretations.

Key national legislations and/or relevant regulations

Box 8: Information specific to penalties relating to counterfeiting

Penalties Under The Drugs And Cosmetics (Amendment) Act, 2008:[17]
The penalty for manufacture of spurious or adulterated drugs has been enhanced to an imprisonment for a term which shall not be less than 10 years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drug confiscated, whichever is more. In certain cases offences have been made cognizable and non-bailable.

Where to find further information

Find more information on spurious/counterfeit medicines on:

- Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare, Govt. of India, website

  http://www.cdsco.nic.in/

- FIP website dedicated on counterfeit medicines

  http://www.fip.org/counterfeit-medicines

- World Health Professional Alliance. BE AWARE - campaign on counterfeit medicines

  http://www.whpa.org/counterfeit-campaign.htm

- Institute of Medicine of the National Academies Campaign on fake drugs

  http://www.iom.edu/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx#

- Center for Disease Control and Prevention (CDC) website's links on counterfeit medicines

  http://www.cdc.gov/Features/CounterfeitDrugs/index.html

- US FDA webpages on counterfeit medicines

  http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/counterfeitmedicine/

- Medicines and Healthcare Products Regulatory Agency, webpages on counterfeit medicines

  http://www.mhra.gov.uk/

- European Medicines Agency webpages on Fighting Pharmaceutical Crime and Counterfeit Medicines

  http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500010359.pdf

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11. Approved lists of veterinary drugs approved by CDSCO available at http://www.cdsco.nic.in/writereaddata/Final%20List%20of%20Veterinary%20approved%20drugs.pdf (Latest access: 09th October 2014)
12. List of Licensed indigenous Manufacturers of Medical Devices available at http://www.cdsco.nic.in/Forms/list.aspx?lid=1759
13. http://www.cdsco.nic.in/writereaddata/GUIDELINES%20GDP.pdf (Latest access: 09th October 2014)
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15. http://comtax.up.nic.in/Miscellaneous%20Act/the-drugs-and-cosmetics-act-1940.pdf (Latest access: 09th October 2014)
16. Initiatives, Achievements and Targets Central Drugs Standard Control Organization (2001 - 2020) available at http://www.cdsco.nic.in/writereaddata/CDSCO%20Initiatives%20&%20Targets%20for%20website%2013-7-2012_17-07-2012.pdf (Latest access: 09th October 2014)
17. Drug and Cosmetic Act available at http://www.cdsco.nic.in/forms/contentpage1.aspx?lid=1888 (Latest access: 09th October 2014)

Appendix 1 - Visual inspection tool

Packaging

Any drug should be packaged in a container, which can be anything from a glass bottle to a blister pack, to a tube of glass, plastic or metal. A folding carton bearing the label very often protects the container. Check the type of packaging and compare it to known containers for the same drug from the same manufacturer. The packaging and the labeling of pharmaceutical products is a very complex and expensive business. Thus, the process and the quality of packaging material are difficult to counterfeit. This is why a thorough visual inspection could be an important screening step for drug quality control. However, producers of counterfeit drugs are quick to copy special labeling and holograms.

1.1 Container and Closure

	Yes	No	Other Observations
Do the container and closure protect the drug from the outside environment e.g. properly sealed?			
Do they assure that the drug will meet the proper specifications throughout its shelf life?			
Are the container and the closure appropriate for the drug inside?			
Is the container safely sealed?			

1.2 Label

The information written on the label is very important. The information can be printed on a label adhered to the container, or printed directly onto the container itself, but all information must be legible and indelible.

If there is a carton protecting the container, does the label on the carton match the label on the container?			
Is all information on the label legible and indelible?			

1.2.1 The trade name:

Is the trade name spelled correctly?			
Is the drug (trade name) registered in the country by the CDSCO?			
Is the drug legally sold in the country?			
Does the symbol ® follow the trade name?			

1.2.2 The active ingredient name (scientific name):

Is the active ingredient name spelled correctly?			
Do the trade name and the active ingredient name correspond to the registered drug?			

1.2.3 The manufacturer's name and logo:

Are the manufacturer's name and logo legible and correct?			
Does the logo or hologram (if applicable) look authentic?			
Does it change color when viewed from different angles?			

1.2.4 The manufacturer's full address:

All manufacturers are required by international law to print their complete address on the label. Many companies making substandard or counterfeit drugs do not have a traceable address on the label.

	Yes	No	Other Observations
Is the manufacturer's full address legible and correct?			
Has the company or its agent registered the drug in the country?			

1.2.5 The drug strength (mg/unit):

Is the strength - the amount of active ingredient per unit - clearly stated on the label?			

1.2.6 The dosage form (e.g., tablet/capsule):

Is the dosage clearly indicated?			
Is the indicated drug under this dosage form is registered and authorized for sale in the country?			

1.2.7 The number of units per container:

Does the number of tablets listed on the label match the number of tablets stated on the container?			

1.2.8 The batch (or lot) number:

Drugs under the same batch number are expected to be equivalent. In a continuous process, a batch corresponds to a defined portion of the production, based on time or quantity. Drugs from the same batch number should have the same history of manufacturing, processing, packing, and coding. All drug quality control testing should be based on batch numbers.

Does the numbering system on the package correspond to that of the producing company?			

1.2.9 The date of manufacture and the expiry date:

An expired drug should not be sold under any circumstances.

Are the manufacture and expiry dates clearly indicated on the label?			

1.2.10 Storage information:

Are the storage conditions indicated on the label?			
Has the drug been properly stored?			

1.3 Leaflet or package insert:

All drug packages should contain a leaflet explaining dosage, the drug content, the adverse affects, the drug actions, and how the drug should be taken. The only exceptions are where the packaging includes all the information that would otherwise be in the leaflet.

	Yes	No	Other Observations
Is the package insert printed on the same colored or same quality paper as the original?			
Is the ink on the package insert or packaging smudge-proof?			

Physical Characteristics of Tablets/Capsules

All types of medicines can be and have been counterfeited from cough syrups to injections. As mentioned above, it is important to check the packaging of these drugs. Additionally, medicines in the form of tablets or capsules can be checked for signs of moisture, dirty marks, abrasion erosion, cracks, or any other adulteration.

2.1 Uniformity of Shape:

Are the tablets/capsules uniform in shape?			

2.2 Uniformity of Size:

Are the tablets/capsules uniform in size?			

2.3 Uniformity of Color:

Are the tablets/capsules uniform in color?			

2.4 Uniformity of Texture:

Tablets can be film-coated, sugar-coated or enteric-coated.

Do the tablets have a uniform coating?			
Is the base of the tablets fully covered?			
Are the tablets uniformly polished, free of powder, and non-sticking?			

2.5 Markings (scoring, letters, etc):

Are markings uniform and identical?			

2.6 Breaks, Cracks and Splits:

Are the tablets/capsules free of breaks, cracks, splits or pinholes?			

2.7 Embedded surface spots or contamination:

Are the tablets/capsules free of embedded surface spots and foreign particle contamination?			

2.8 Presence of empty capsules in the case of a sample of capsules:

Is the sample examined free of empty capsules?			

2.9 Smell

Does the medicine smell the same as the original?			

Design:

PMS
Arts & Communications

www.pmsarts.com

Working together against Spurious Medicines

WHPA has launched an education and awareness raising campaign supported by its Indian partners (IMA, IPA & INC). This partnership serves the needs of health professionals, patients, the public and governments. WHPA and its Indian partners have developed this practical handbook for healthcare professionals to develop their knowledge on prevention, detection and reporting on Spurious Medicines.

The World Health Professions Alliance WHPA brings together the global organizations representing the world's dentists, nurses, pharmacists, physical therapists and physicians and speaks for more than 26 million healthcare professionals in more than 130 countries. WHPA works to improve global health and the quality of patient care.

For more information, please visit http://www.whpa.org

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