

# WATCH

o n m e d i c i n e s

VOLUME 15

| NUMBER 01

| MAR-APR 2010



**The growing  
menace of  
spurious drugs**

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# Editorial

This issue of 'Watch on Medicine' comes to you when health issues have acquired importance denied to them over decades in Pakistan. One indicator of this being growing international donors' interest in health as essentially issue of human security. The range of health issues keeps growing because of long governmental neglect and institutional apathy. The only loser in this is the poor consumers who, despite paying expenses out of pocket, ends up consuming expensive, substandard, and often not-required medicines, contracting water borne diseases and failing to access health facility. This list is by no means a definitive catalogue of all health-related problems confronting consumers in Pakistan. More crucially, with ever declining health budget and growing population, there is no end to these escalating miseries in sight. This issue seeks to highlight some of these flagship issues.

The growing menace of substandard and spurious drugs, highlighted in the media recently, poses a major challenge to health managers. There may be disagreement over the size of the problem depending upon where you come from, but growing menace of this problem has never been in question. Only recently Supreme Court closed a reputable drugs company for supplying substandard medicine to government health centres over a period of many years. And this may not be an isolated event, as rightly feared by many health rights advocates. Against this backdrop of rising crescendo over the menace of spurious medicine, it would be fatal to pretend that the problem either does not exist, or exists in pockets. Instead debate should focus on what to do about this problem to relieve the plight of patients. The

specter of spurious drugs haunting us also reinforces the need for essential drugs list which, apart from beefing up public health system, can also resolve related issues of drug pricing. This hydra-headed problem calls for joined up regulatory and enforcement action to protect patient from unsafe drugs and ensure their accessibility to safe and affordable medicine. Time to act and revisit old assumptions and failed strategies has never been more appropriate.

The issue also touches upon mushrooming growth in medical stores, in a substantial number of cases unlicensed, which has contributed to irrational use of medicine on an epidemic scale. This problem is compounded by the fact that a substantial number of medical stores are owned by doctors who prescribe medicines pushed by pharmaceutical companies engaged in splashing out gifts and inducement to stores-owning doctors.

There are also other issues like upsurge in ill effects sourcing from human use of pesticides and the importance of community pharmacy for a good health care system. Therefore this issue offers just a few tips of a large iceberg of a poorly-funded and inefficient Pakistani health system where right to health is under constant threat. This is just the beginning of a larger conversation on these issues. We would welcome your feedback on the issues raised, and on how to improve the contents and quality of the magazine in future.

**Dr Arif Azad**  
Editor-in-chief



# The growing menace of spurious drugs and poor consumers

**By Dr Arif Azad**

The spectre of spurious or counterfeit drugs has been looming on health horizons for the last two decades. This is evident in global trade in counterfeit medicine spreading like contagion during the last two decades despite siren calls from World Health Organisation (WHO) to control this trade. WHO has estimated that trade in counterfeit medicine constitutes 10 percent of medicine market worldwide. The Centre for Medicine in the Public Interest, US based non-profit organization, estimate put the volume of counterfeit drugs trade growing to 75 billion US dollars by end of 2010. There have been world wide instances of public health emergency caused by spurious drugs. In 1995, fake drug killed 2500 people which were infected by meningitis. However, despite WHO's initiatives the International Medical Products Anti-Counterfeiting task force (IMPACT), scourge of spurious drugs has not only endured but growing. Worryingly, most of the global trade in spurious trade occurs in the developing world. Like other developing country, Pakistan suffers from the scourge of spurious medicine in big way. After having downplayed the extent of the problem for years, the real extent of the problem came to light when the Interior Minister, Rehman Malik, put the size of the problem between 45-50 percent. This should serve as a wake up call as what is going to hit the health sector in future if immediate corrective steps were not put in place.

Counterfeit or spurious medicine is the one made in imitation of a genuine medical product. Apart from passing spurious drug off as genuine by artful packaging, counterfeit medicine lack either active ingredients or contain substandard ingredients which wreak havoc on consumer's health. Spurious drugs particularly hit the poor consumers who, despite paying out of pocket, end up worse off after administration of spurious drugs. Spurious drugs can



result in a number of harmful outcomes when ingested or administered: 1) they often fail to cure the patient or achieve desired result from the drugs (when they fail to cure consumer switch to other medicine without exposing the counterfeit nature of the drug); 2) they can cause unexpected adverse drugs reaction which can be fatal; 3) they can kill consumers which is often put down to medical negligence. Spurious drug trade also causes loss of revenue as it operates outside of normal tax channels.

In Pakistan, use of counterfeit medicine is growing due to lax regulatory and enforcement mechanism, deepening poverty, lack of punitive deterrents, absence of consumer education and inadequate laboratory testing facilities.

The growth in spurious drug trade showcases regulatory failures which have resulted in curbing consumer right to highest attainable level of health through safety from harmful drugs. There are many legislative and policy instruments in place, yet without any appreciable effects on the growing problem. The Drugs Act 1976, with a limited ground force of drugs inspectors, has failed to make any dent on the

volume of trade in spurious drugs. In recent years addition of a fistful of drugs inspectors has hardly matches the extent of this proliferating problem. The Drugs act also does not cover other nutritional and herbal products which have flooded the market, without any regulatory mechanism. The problem is further compounded by lack of coordination between a plethora of bodies like Central Licensing Board, Drug Appellate Board, Drug Registration Board and Quality Control Board. This lack of coordination and separation of policy making and regulatory regime has also contributed. Furthermore, much-anticipated Drugs Regulatory Authority has yet to see light of the day after being years in the pipeline.

scheme where whistle blowers are monetarily rewarded.

- Government of Pakistan needs to launch a public campaign to educate consumers and health professionals about the circulation of spurious drugs, their harmful effects and on how to tell spurious drugs from genuine ones.
- Registration and regulation of drugs stores particularly in rural areas where counterfeit medicine flourish due to mixture of low awareness, poverty and lax controls.
- Greater collaboration between industry, trade associations and regulatory body is badly needed to address the problem in coordinated fashion.
- A closer and organics interaction between poli-



The growing menace of spurious drugs can be controlled if a number of direly needed policy measures are instituted:

- A country wide research study project to determine the size and operation of spurious drugs industry to design appropriate strategy.
- The Drugs Act 1976 needs to be upgraded, including tougher sentences for those involved in practice.
- Setting up more drugs testing laboratories and using modern equipment like Spatially Offset Raman Spectrometry (SORS) at all levels in particularly rural areas where thinly spread drugs inspectors and poverty contribute to this problem.
- Putting in place proper reporting centre where spurious drugs can be reported to regulatory authority. India has introduced whistle blowing

cy making and regulatory parts of spurious drugs control regime is also required as part of joined up action.

- Collaboration with foreign stakeholders to develop strategy to curb the global source of spurious trade.

Cumulatively, these steps are going to contribute to the government of Pakistan's obligation to ensure the right of every citizen to highest attainable standards by ensuring safety of patients from unsafe drugs. The UN guidelines on consumer protection also require its signatories to protect consumer from unsafe products. Only by taking this problem seriously can we begin to address it seriously. So far the government's record on this issue has been far from encouraging. [www.pharm](http://www.pharm)



# Upsurge of pesticide industry affects human health in Pakistan

**Dr. Aftab Turabi**

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Pakistan has basically an agrarian background and agriculture is mainstay of its economy. About 70% of its population depends directly or indirectly on agriculture and approximately 68% of its industries are agro-based. Pakistan possesses high potentialities to grow almost all types of tropical and sub-tropical field and garden crops in abundance. Cotton, wheat, paddy and sugarcane are the major crops of the country other than the fruit & vegetables. 45 multinational companies in association with local agent by way of import and other 13 local pesticide manufacturing plant are fulfilling pesticide requirement of the country. As the use of pesticide to avoid crops losses is increasing, numbers of pesticide toxicity cases are also increasing so there is immense need to develop other methods for adequate plant protection.

In course of struggle between mankind on one side and insects, pathogenic organisms and weeds on the other side, the newly developed chemical pesticide gave hope that the ultimate weapon had been found but these being poisonous substances were found to be quite dangerous if not handled carefully and cautiously.

Pesticides, however, can be categorized in groups in view of their chemicals properties, which dictate relevant sets of precautionary measures for safety and curative treatments against their injurious effects of different types and intensities.

Presently, the basic manufacturing facilities for pesticides do not exist in the country. However there were two manufacturing units for the production of Dichloro Diphenyl Trichloro Ethane (DDT) and Benzene Hexa Chloride (BHC) in



Pakistan, located at Kala Shah Kaku (Punjab) and Nowshera (NWFP). The total installed capacity of these two units for DDT and BHC were 2,020 and 2,310 MTPY respectively. These units were closed many years ago because both pesticides have been banned in Pakistan. The problem needs to be intervened by the state, as the officially banned pesticides are still available in the local market.

Pesticides used at present are either organic or inorganic in nature. Organic group contains natural plant oils, nicotine and pakerthsun as natural pesticides. About twenty four pesticides have been banned in Pakistan that includes synthetic pesticides as compound of chlorine like DDT, BHC and endrin, aldrin, dieldrin, heptachlor etc.

Some of the pesticides were subsidized, 75% share was passed to private sector while the government retained remaining 25%. However, since February 1985, all subsidies were withdrawn and private sector was fully made responsible for imports, distribution and sales of pesticides



throughout Pakistan except Baluchistan. Pesticides were imported under generic names from 1991. By the year 2000 the local formulation exceeded the imported pesticides several times.

Presently, the installed capacity for the formulation of various types of pesticides is more than the local requirement. There are about 40 companies involved in the formulation of pesticides. The local formulation product includes liquid pesticides, powder and granules that contribute 67% in the local market. Most of the raw materials including active ingredients as well pesticides in finish form are being imported. The sector growth rate is 3%. Insecticides account for 88%, herbicides 11% and fungicides 1% of the total pesticides used for plant protection. Additional quantities of pesticides are used for public health and household.

During the past decade, the public has grown concern about agricultural pesticides use. Exposure to pesticides, even at low doses, is associated with a wide variety of health effects, and these compounds are now commonly found throughout our environment. Despite some important advances, federal pesticides regulatory programs have failed to prevent an overall increase in pesticides use, risks, and reliance. This not only threatens public

health and the environment, but it puts farmer's livelihood in jeopardy. Farmers using the pesticides that are legal and safe and also effective for crop production, later come to know that they were hazardous.

In the long run, both farmers and public will be best protected by a fundamental restructuring of pesticide policies and agricultural and education programs to minimize pesticide use and rely instead on non-chemical, biologically based methods that prevent pest problem. A wide variety of alternative agricultural tools are available to reduce pesticide use and reliance, including those used in Integrated Pest Management (IPM) and sustainable organic farming system.

Various alternative pest management techniques are:

- Scouting and monitoring for pest and natural enemy population levels
- Precision pesticides application equipment
- Rotating crops and planting cover crops
- Switching to biologically based pest control products
- Conservation tillage, irrigation management, and soil-building





# Rational Drug Use

## Adherence issue: can we make a difference?

Health economists state that compliance [adherence] is a major problem and the alarming current trends regarding medication tend to confirm this:

- 75% of patients do not take their medications as prescribed.
- 49% of patients forget to take their medications.
- 31% of patients do not follow their prescriptions.
- 29% of patients stop taking their medications before their supply runs out.
- 24% of patients take less medication than the recommended dose.

A November 23, 2009 Business Week article discussed 10 ways to cut [health] care costs, and mentioned that "getting patients to take their medicine was one strategy to reduce health care costs right away because even in USA 3 of 4 Americans do not take their medicine as directed."

It seems as though nothing has changed in last 30 -40 years, except that we now have the studies to prove that patients who take their medications correctly have lower total health care costs. Furthermore, we also know that pharmacists can and do play an important role in coaching patients to be compliant. In the same Business Week article, John O'Brien, assistant professor at the College of Notre Dame School of Pharmacy in Maryland, said it is "one of the best ways to improve care...and get more out of each health care (budget)."

So, which health profession should take ownership of this adherence problem to help patients use their medications correctly? Although our current pharmacy practice model makes it difficult for the dispensing pharmacist to assume this role, and the prescription drug reimbursement system fragments the drug distribution between several different pharmacy providers (i.e., local pharmacy, mail-order pharmacy, specialty pharmacy), the profession of pharmacy is the most logical health profession to take ownership of this critical role. A definite need exists to improve

the 2-way communication between the patient and their health care provider. What can the pharmacist do? The pharmacist can contribute by helping patients better understand exactly why it is important for them to take their medications as prescribed.

In suggesting that pharmacists take ownership of the adherence problem, I do not mean to oversimplify the solution. Medication adherence is a complex issue, and no one solution will work in every situation. The Boehringer Ingelheim Pharmacy Satisfaction 2009 Medication Adherence Report ([www.pharmacysatisfaction.com](http://www.pharmacysatisfaction.com)) outlines 11 dimensions of non adherence, and it proposes strategies aimed at increasing individual patient medication adherence and compliance at the pharmacy level. The National Council on Patient Information and Education's "National Action Plan" ([www.talkaboutrx.org](http://www.talkaboutrx.org)) includes barriers to compliance, action steps, and recommendations. Based on studies that show that patients, who understand health instructions make fewer mistakes, may get well sooner, or be able to better manage a chronic health condition, the National Patient Safety Foundation has initiated the Ask Me 3 program ([www.npsf.org/askme3](http://www.npsf.org/askme3)): (1) What is my main problem? (2) What do I need to do? (3) Why is it important I do this?

### The pharmacist as coach

Clearly, many resources are available to help the pharmacist who wants to help patients use their medications appropriately. Yes, the problem can be complex, but the advantage the pharmacist has is the opportunity to work with the patient over a long period of time through regular interactions-acting as the patient's coach. Such focused interactions lead to positive results. Identify 5 or 10 patients who could benefit from your help, and personally commit yourself to being those patients' coach, helping them to make the best of their medications. You can make a difference.

Source: [www.pharmacysatisfaction.com](http://www.pharmacysatisfaction.com)



## Media Scan



**By Qudrat Ullah**

In Pakistan, the unchecked population explosion has heightened the need to ensure uninterrupted access to improved drinking-water supply, especially in mega cities like Karachi and Lahore, where traces of multiple deadly rudiments, including human feces are reported by laboratory reports. This shows the height of criminal neglect exhibited by the civic bodies towards the public's right to safe drinking water.

The provision of pure water, to all, by the government is not only a basic need and precondition for a healthy life, but it is also a vital human right of all people, which mustn't be ignored at any cost, as the whole edifice of human life revolves round it. Various improved water supply technologies have been developed by the modern nations, which include household connections, public standpipes, boreholes,

protected dug-wells, protected springs and rainwater collections.

It is reported in the media, many times, that the global water shortage of affordable and safe drinking water is conspicuously visible in Pakistan, with an estimated 44 percent of the total population without any access to safe drinking water. This paucity of clean drinking water can be more visibly seen in the rural areas where up to 90 percent of the inhabitants may lack such access.

On the other side, only three percent of Pakistan's sweet water resources are used for household purposes and drinking. As a warning of the large-scale drinking water problem prevalent in our society and public ignorance about it, it is anticipated that more than 2.5 lacs infant children die of diarrhoeal diseases every year. The results of five years National Water Quality Monitoring Programme, which covers 23 major cities, eight rivers, nine lakes and many reservoirs show widespread bacteriological contaminants in the drinking water.

Chemical contaminants in drinking water such as arsenic, fluoride and nitrate are discovered at various locations. Arsenic contamination is found in southern Punjab and central Sindh. Contamination in drinking water is a major cause of many serious water-borne diseases.

Water is accepted in Islamic teachings as an essential source of life and everybody has the right to have a fair share. According to a hadith, Prophet Muhammad (PBUH) said, "Muslims have a common share in three (things): grass, water and fire".

Moreover, the Holy Quran has also warned human beings against the unfair distribution of national goods and Islamic scholars concur that Islam forbids unfair consumption, exploitation and uneven earnings of common commodities like water.

It is pity that even in the 21st century, majority of the population is destined to use or drink polluted water and due to that, various problems have arisen, increas-



ing the number of terminal diseases like Hepatitis. For those who can afford to avoid this unclean drinking water, bottled water is the only solution.

Therefore, many in Pakistan have turned to bottled water as an apt substitute to drinking unfiltered faucet water or contaminated water of other sources, where there is no public drinking water service. The average person consumes just two liters of bottled water per annum in Pakistan, compared to four in India and 10 in China.

While bottled water is an awfully classy alternative to drinking water; it has been reported many times in the media that it is not all the time fit for human health, because intermittent testing of contaminants and sporadic inspection of processing plants shows that not all bottled water plants are being run according to health and hygiene standards set by the UN.

Bottled water, it may be noted, should not be taken as an appropriate replacement for sufficient tap water. But during the past thirty years, use of bottled water is increasingly in demand the world over, as it has become a global phenomenon.

The bottled water sector, despite its excessively high price compared to tap water, is measured as one of the powerful sectors of the food and beverage trade as its consumption increases by an average of 12% every

year. The government has termed the bottled water market, with 33 million liters of consumption per annum in 1999, as small but positively on the rise.

It is envisaged that a bottle of 1.5 liters has a production cost of Rs 12.51 only. In the United States, bottled water costs between 0.25 dollar to 2 dollar per bottle, while tap water costs less than US \$0.01.

This shows the high rate of return in this field. In our country, there are approximately twenty to thirty companies engaged in this business.

Official figures show an estimated number of 26 corporations, while in summer

time, this number increases up to 70. But from the perspective of quality control, Pakistan Council of Renewal Water Resources is witnessing a fluctuation in the market of 50 percent, e.g. half of the brands disappear and are replaced by new brands every year.

Recently, it was told to the Lahore High Court that out of a total of 64 bottled and mineral water companies in Punjab, only 10 are working under valid licenses. For the interest of the common readers, it may be added here that MNCs engaged in the bottled water business are very powerful in Pakistan, and can violate the quality standards.

One case is particular to note, when on December 31, 2004, the Supreme Court approved the decision of the Lahore High Court, which dismissed Rs 6.35 million Pakistan Railways contract that granted exclusive rights to Classic Needs Pakistan (Pvt) Ltd to sell bottled water to Railway passengers during 2004-05.

Furthermore, the Court directed the railway administration to revoke the contract, invite fresh bids and award the contract of bottled water supply to a firm after examination of water by a credible laboratory. Classic Needs Pakistan (Pvt) Ltd is the exclusive distributor of Nestlé's 'Pure Life' which is its own brand. The Supreme Court declared the bottled water being supplied to passengers unfit for consumption.

The bottled water sector has great scope to expand but it also needs to develop a composite regulatory authority to keep a constant check on quality and price. We are facing a serious water challenge as Pakistan's water quality ranks 80th out of 122 nations. As a consequence, the government has to spend about Rs 20 billion annually on medication for water-borne diseases.

This situation shows that criminal neglect has been shown by the public sector in providing clean drinking water to the people and on the other hand, the government is also neglecting its obligations towards implementing laws for a healthy society. If we want to emerge as a healthy, vibrant and developed nation in the 21st century, then we will have to implement laws in their true spirit as no democracy can flourish without the rule of law.

**Source:** Business Recorder (February 21, 2010)





### Asthma watch

#### Kids with asthma may have harder time with H1N1

Children with asthma may be more prone to pick up more severe cases of H1N1 flu, compared with seasonal flu, according to a study published online November 19 in the Canadian Medical Association Journal. For the study, Canadian researchers studied the medical records of 58 children with pandemic H1N1 influenza admitted to the Hospital for Sick Children in Toronto between May 8 and July 22, 2009. Upton Allen, MBBS, MSc, and fellow colleagues compared risk factors, severity indicators, and outcomes of those children with H1N1 with those of 200 children admitted with seasonal influenza A between 2004 and 2009.

After reviewing the charts of all children, the researchers found that children with H1N1 influenza were significantly more likely to have asthma than those children with seasonal flu (22% vs 6%). Of those children with H1N1, 21% required admission to the intensive care unit (ICU); 14% of those with seasonal influenza had to be admitted to the ICU. The results demonstrated that asthma appears to cause a more severe disease in children with H1N1 compared with seasonal flu.

"Because the risk of severe disease appears to have to clear relation to the severity of asthma," concluded the authors, "even children with mild asthma should receive vaccination and be considered for preemptive antiviral therapy."

#### Control good for patients with COPD

When patients with Chronic Obstructive Pulmonary Disease (COPD) or those who care for patients with COPD were recently surveyed, the findings indicated that patients feel better about themselves and their situation when their disease is managed properly. Findings of the survey of 400 patients and 400 caregivers, conducted via telephone by the COPD Foundation and Dey Pharma LP, included:



- Well-informed patients with self-reported moderate breathing conditions are most likely to have high levels of satisfaction with their current therapy.
- 9 in 10 patients who use nebulizers reported satisfaction with their current treatments.
- Caregivers were more likely than patients to wish that those they cared for had been placed on nebulization therapy sooner.

#### Pollution may pose breathing problems for inner-city children

A recent study from the Columbia Center for Children's Environmental Health (CCCEH) at Columbia University's Mailman School of Public Health found that young inner-city children who were exposed shortly after birth to ambient metals from fuel oil combustion and particles from diesel

emissions had associated respiratory problems.

In the December 1, 2009, issue of the American Journal of Respiratory and Critical Care Medicine, senior investigator Rachel L. Miller, MD, associate professor of medicine and environmental health sciences at New York-Presbyterian Hospital/ Columbia University Medical Center and co-deputy director of CCCEH, said, "The effects of exposure to airborne metals had not been studied previously in children so young, and these findings could have more important public health implications for members of inner-city communities in New York City and elsewhere."

### **Asthma may be helped by "the pill"**

A new study suggests that women with asthma who also take oral contraceptives may benefit from reduced asthma symptoms. Typically, women may notice that their asthma symptoms fluctuate during the month—due in part to fluctuating female hormone levels that affect airway inflammation.

A recent study included 17 women—8 were taking birth control pills that contained estrogen and progesterone (average age: 25.5 years); 9 were not taking birth control pills (average age: 37.5 years). In the latter group, researchers from the University of Alberta in Canada found that increased levels of estrogen were associated with decreased levels of exhaled nitric oxide, signaling decreased airway inflammation, and increased levels of progesterone were associated with increased levels of exhaled nitric oxide, signaling increased airway inflammation. Thus, asthma symptoms are likely to be worse when progesterone levels are elevated (before menstruation). In the group taking the oral contraceptives, however, the birth control pills lessened the

### **Over 10m suffer from asthma in Pakistan'**

According to Pakistan Chest Society about 10 million people in the country suffer from asthma and visit hospitals every year while 15,000 households have asthma patients. In Pakistan, prevalence of asthma symptoms in children is estimated between 10 and 20 per cent by experts.

### **Fast fact: in USA**

- Every day in America, 30,000 individuals have an asthma attack.
- Number of non-institutionalized adults who currently have asthma: 16.4 million
- Percent of non-institutionalized adults who currently have asthma: 7.3%
- Number of children who currently have asthma: 7.0 million
- Percent of children who currently have asthma: 9.4%
- Number of deaths: 3,613
- Deaths per 100,000 population: 1.2

dramatic hormone fluctuations, and no difference in asthma symptoms was noted throughout the month.

In the November issue of Chest, lead author Piush Mandhane, MD, PhD, assistant professor of pediatric pulmonology, University of Alberta, said that this study represents "a first step in looking at the relationship between hormones and asthma." Further studies are necessary, because of the small size of this study. ?





# Concept and scope of community pharmacy

**Muhammad Tanweer Alam**

Community pharmacists are the health professionals most accessible to the public. They supply medicines in accordance with a prescription or, when legally permitted, dispense them without a prescription. In addition to ensuring an accurate supply of appropriate products, their professional activities also cover counselling of patients at the time of dispensing of prescription and non-prescription drugs, drug information to health professionals, patients and the general public, and participation in health promotion programmes. They maintain links with other health professionals in primary health care.

Today, an increasingly wide range of new analogous products are used as medicinal, including high technology biological products and radiopharmaceuticals. There is also the heterogeneous group of medical devices, which includes some products analogous to medicines, some of which demand special knowledge with regard to their uses and risk of contra indication and adverse reactions. (e.g., dressings, wound management products, narcotics, psychotropics, hormones, vaccines, antibiotics and anticancer etc.).

Pharmacists have progressively undertaken the additional task of ensuring the quality of the products they supply.

The main activities of community pharmacists are described below:

### **Processing of prescriptions**

The pharmacist verifies the legality, safety and appropriateness of the prescription order, checks the patient medication record before dispensing the prescription (when such records are kept in the pharmacy). The community pharmacist also ensures that the quantities of medication are dispensed



accurately, and decides whether the medication should be handed to the patient, with appropriate counselling. In many countries, the community pharmacist is in a unique position to be fully aware of the patient's past and current drug history administration and, consequently, can provide essential advice to the prescriber.

### **Clinical pharmacy/care of patients:**

The pharmacist seeks to collect and integrate information about the patient's drug history, clarify the patient's understanding of the intended dosage regimen and method of administration, and advises the patient of drug-related precautions, and in some countries, monitors and evaluates the therapeutic response. Pharmacist has always played a vital role in a therapeutic committee established for the proper health care system.

### **Monitoring of drug utilization:**

The pharmacist can participate in arrangements for monitoring the utilization of drugs, such as practice research projects, and schemes to analyze prescriptions for the monitoring of adverse drug reactions.

### **Extemporaneous preparation and small-scale manufacturing of medicines:**

Pharmacists everywhere continue to prepare medi-



cines in the pharmacy. This enables them to adapt the formulation of a medicines to the needs of an individual patient. New developments in drugs delivery systems may well extended the need for individually adapted medicines and thus increase the pharmacist's need to continue with pharmacy formulation. In some countries, developed and developing Pharmacists engage in the small scale manufacture of medicines which must accord with good manufacturing and distribution practice guideline.

#### **Traditional and alternative medicines:**

In some countries, pharmacists supply traditional medicines and dispense homeopathic prescriptions. WHO promotes the safe and effective use of traditional medicines. WHO's role is to assist those countries where traditional medicine is widely practiced to incorporate it into their national health systems and encourages their potential in health care system. It aims to enhance national programme development, operational research, clinical and scientific investigations, education and training.

#### **Responding to symptoms of minor ailments:**

The pharmacist receives requests from members of the public for advice on a variety of symptoms and, when indicated, refers the inquiries to a medical

practitioner. If the symptoms are related to a self-limiting minor ailment, the pharmacist can supply a nonprescription medicine, with advice to consult a medical practitioner, if the symptoms persist for more than a few days. Alternatively, the pharmacist may give advice to a patient without supplying medicine.

#### **Informing health care professional and the public:**

The pharmacist can compile and maintain information on all medicines, and particularly on newly introduced medicines, provide this information's necessary to other health care professional and to patients, and use it in promoting the rational use of drugs by providing advice and explanations to physicians and to members of the public.

#### **Health promotion:**

The pharmacist can take part in health promotion campaigns, locally and nationally on a wide range of health-related topics, and particularly on drug-related topics (e.g., rational use of drugs, alcohol abuse, tobacco use, discouragement of drug use during pregnancy, organic solvent abuse, poison prevention) or topics concerned with other health problems (diarrhoea diseases, tuberculosis, leprosy, HIV-infection/AIDS) and family planning. They may also take part in the education of local community groups in health promotion, and in campaigns on disease prevention, such as the Expanded Programme on Immunization, and malaria and blindness programmes.

#### **Agricultural and veterinary practice:**

Pharmacists supply animal medicines and medicated animal feeds. They also supply information regarding safety, efficacy to veterinary doctor or public engaged with live stock or agriculture.

#### **Counselling:**

In a number of countries, the pharmacist provides advisory services as well as supply information to residential homes for the elderly, and other long-term patients. In some countries, policies are being developed under which pharmacists will visit certain categories of house-bound patients to provide the counseling service that the patients would have received, had they been able to visit the pharmacy.





## Growing need of pharmacovigilance?

**By Imran Hayder**

Pharmacovigilance (PV) is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.

Generally, it is considered as the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to:

- Identifying new information about hazards associated with medicines
- Preventing harm to patients.

The etymological roots are: pharmakon (Greek), "drug;" and vigilare (Latin), "to keep awake or alert, to keep watch."

Pharmacovigilance is particularly concerned with adverse drug reactions, or ADRs, which are officially described as: "A response to a drug which is noxious and unintended, and which occurs at doses normally used... for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function."

Pharmacovigilance is gaining importance for doctors and scientists as the number of stories in the mass media of drug recalls increases.

Because clinical trials involve several thousand patients at most; less common side effects and ADRs are often unknown at the time a drug enters the market. Even very severe ADRs such as liver damage are often undetected because study populations are small. Post-marketing pharmacovigilance uses tools such as data mining and investigation of case reports to identify the relationships between drugs and ADRs.

### Risks of medical treatment

- While medicines have led to major improve-



ment in the treatment and control of diseases, they also produce adverse effects on the human body from time to time.

- While many drugs are precisely targeted to the causes and mechanisms of disease, they may also have minor or distressing effects on other parts of the body, or interact negatively with the systems of the particular individual or with other drugs or substances they are taking, or not work well or at all for some, many or all of those who take them for illness.
- There are risks in any intrusion into the human body, whether chemical or surgical. Nothing in this field is entirely predictable as the interaction between chemicals and the human body may produce surprises.

### Finding the risks of drugs

Pharmaceutical companies are required by law in all countries to perform clinical trials, testing new drugs on people before they are made generally available. The manufacturers or their agents usually select a representative sample of patients for whom the drug is designed - at most a few thousand - along with a comparable control group. The control group may receive a placebo and/or another drug that is already market-

## Terms commonly used in drug safety

**Benefits** are commonly expressed as the proven therapeutic good of a product, but should also include the patient's subjective assessment of its effects.

**Risk** is the probability of harm being caused, usually expressed as a percent or ratio of the treated population; the probability of an occurrence.

**Harm** is the nature and extent of the actual damage that could be caused. It should not be confused with risk.

**Effectiveness** is used to express the extent to which a drug works under real world circumstances, i.e., clinical practice (not clinical trials).

**Efficacy** is used to express the extent to which a drug works under ideal circumstances (i.e., in clinical trials).



Clinical trials do, in general, tell us a good deal about how well a drug works and what potential harm it may cause. They provide information which should be reliable for larger populations with the same characteristics as the trial group - age, gender, state of health, ethnic origin, and so on.

The principle of international collaboration in the field of pharmacovigilance is the principal basis for the WHO International Drug Monitoring Programme, through which over 90 member nations have systems in place which encourage healthcare personnel to record and report adverse effects of drugs in their patients. These reports are assessed locally and may lead to action within the country

For example Pharmacovigilance in the U.S. include the FDA, the pharmaceutical manufacturers, and the academic/non-profit organizations (such as RADAR and Public Citizen).

ed for the disease.

The purpose of clinical trials is to discover:

- if a drug works and how well
- if it has any harmful effects, and
- its benefit-harm-risk profile - does it do more good than harm, and how much more? If it has a potential for harm, how probable and how serious is the harm?



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TheNetwork's **WATCH on Medicines**, formerly **Drug Bulletin**, is a member of the International Society of Drug Bulletins (ISDB), a network of independent drug bulletins which aims to promote international exchange of quality information on drugs and therapeutics.

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Printed by Maria Printers, Rawalpindi  
Address: 67 Stadium Road, Rawalpindi - Pakistan

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