AN UPDATE

A Database of the incidences of Counterfeit Medicines in the SEA Region

For the Period of
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An Update
DATABASE ON THE INCIDENTS OF COUNTERFEIT MEDICINES IN THE WHO-SEA REGION

Background

**Definition of counterfeit medicines:**

In its 2003, FIP Statement on Counterfeit Medicines, FIP adopted the 1992 WHO definition of a counterfeit medicine, that is to say: “the deliberate and fraudulent mislabeling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product. Counterfeiting can apply to both branded and generic products and to traditional remedies. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with false or misleading packing; they may also contain different, or different quantities of, impurities both harmless and toxic.”

This WHO definition was officially endorsed in a meeting, convened in Geneva, 1-3 April 1992, which gathered experts from governmental institutions of WHO member states, INTERPOL, World Customs Organization (at the time known as Customs Cooperation Council), International Narcotics Control Board, IFPMA, International Organization of Consumer Unions, and the International Pharmaceutical Federation (FIP).

One of the SEARPharm Forum's objectives is to encourage and support a dialogue and collaboration among national and regional pharmaceutical associations in the South-East Asia Region of WHO by supporting WHO-policies and goals and combating the production and distribution of counterfeit medicine and sale of medicine by people who are not qualified. The print and electronic media has been widely reporting the problem. The open source media reports continue to provide coverage on the various permutations that encompass the act of pharmaceutical counterfeiting and substandard drugs like identical copies, look-alikes, rejected and relabeled.

**Identical copies:** These are made with the same ingredients, formulation and packaging as the originals. As high priced prescription medications, they are irresistible to counterfeiters.

**Look-alike:** the packaging and appearance are high quality, but there may be little or no active ingredient. Some look-alikes may even contain harmful substances such as chalk, boric acid, glass or fungus etc.

**Rejects and relabeled:** Drugs that have been rejected by the manufacturer for quality reasons are illegally obtained by counterfeiters or authentic drugs that have expired are relabeled with the longer shelflife and sold.
However, the shortcoming of the open source media reporting is that the same data at times get published by different agencies compound the information and show the problem in a much larger magnitude.

Nevertheless, in the absence of any authentic data, we depend upon news items being published in credible leading newspapers and journals. These reports mainly deal with situation in India, Nepal, Bangladesh, Thailand, Sri Lanka and Indonesia.

The Secretariat has been regularly updating such data since 2001. It is now submitting the updates on the incidents of counterfeit medicines for the year 2012-2013. This list does not reference every media report published, nor does it contain any confidential information.

Pradeep Mishra
Professional Secretary
SEARPharm Forum Secretariat

11th November 2013
New Delhi
Spurious drugs on sale in Kushtia
The Independent, January 02, 2013

Sale of contraband Indian drugs like phensidyl, hemp, heroin, Yaba tablets is going on unabated in the district. Various drugs were smuggled into the country from India on the occasion of the celebration of thirty-first December. Officials of Department of Narcotics Control and other sources told that smuggling of phensidyl into the country from India increased alarmingly in the last month allegedly due to lax border vigilance. More than 30-32 types of narcotics and contraband items were pouring in through 15-16 points along the 135-kilometer long frontier with India. Of it 65 kilometer is waterway. The smugglers stepped up operations across the India-Bangladesh frontier and smuggled contraband items are carried by push and buffalo carts, vans and rickshaws or by boats from boarding points to the houses of ‘Mahajans’ or ring leaders of smugglers. Those are then carried to markets by women and adolescents packed in gunny bags, according to sources. Smuggled contraband items are transported by local passenger buses and trucks and are unloaded at different bus terminals. According to sources, scores of phensidyl factories have been set up across the frontiers inside Indian territory to push phensidly into Bangladesh territory. The officials of Narcotics Control Department said that they cannot cope with the growing number of narcotics-related criminal activities and smuggling on border due to absence of adequate staff and lack of coordination with other law-enforcement agencies and acute shortage of logistic support. On the other hand, people of Daulatpur upazila alleged that some of the police sold out seized contraband items to the smugglers for their personal benefits. The conscious people of the district urged the authority concerned to take immediate measures to stop the menace.

Fake, sub-standard medicine sale unabated in N districts
The Independent, February 10, 2013

Sale of sub-standard ‘life saving’ medicines is going unabated in different pharmacies in northern parts of the country including Pabna district recently causing risks to lives of hundreds of people. This was disclosed by a noted medicine trader, Ansar Ali,
owner of Taraque Surgical, at Hamid Road in Pabna district town while talking with The Independent correspondent here recently. It is alleged that fungus, flies, sediment etc are often found in many drug containers including IV saline, injection and liquid bottled medicines. The intake of those contaminated drugs has been endangering the lives of patients at any moment. Many drug companies are allegedly manufacturing the substandard drugs including antibiotic capsule and syrup without obtaining certificates from concerned authorities and they market their products with attractive publicity and 50% to 60% percent commission to the local pharmacy businessmen at different markets in northern districts. A section of physicians is also prescribing these sub standard medicines, patients complained that the agents or medical representatives of drug companies in different ways to prescribe their sub standard medicines, patients complained that the agents or medical representatives of drug companies in different ways to prescribe their products manage to physicians. But lastly the medicine is no impact to cure the diseases causing patients are some times death threat and to losing money. Later on it has been proved that the medicine was fake or sub-standard. The quacks and village doctors prescribe these medicines as they are available at cheaper rates. The patients complained that they are not getting any results after using these medicines. It this regard while taking with president of Pabna district Palli Doctor Samity Mohammad Abdus Sattar and its general secretary Abdus Salam both are said that they are unwary about medicines is sub-standard or quality. It was fully responsible to see and supervision of the Drug Administration and health officials under drug act and the drug policy, they added. In this position due to lack of proper administrative action against the dishonest medicine traders and many others reason a section of dishonest pharmaceutical company owners and medicine businessmen have been marketing huge quantity of sub-standard medicines and looting crores of taka from the innocent and common people very nose of law enforcement agencies and concerned authority. As a result everyday hundreds of treatment seekers have been fell prey victims to consume sub-standard medicines and cheating various way. In Pabna district alone in the last two years- police of Pabna has unearthed about 13 fake medicine companies. The concern sources said this fake company are engaged in manufacturing fake diazit, Laktonit, varmikom, jolin, ceprocian and others verities of life saving medicines. Although fake and sub-standard medicine business is going unabated in Pabna district since long. But the matter is not brought under knowledge in common people. So the kingpin of the fake medicine businessmen syndicate could not arrest by the law enforcement agencies. Most of the northern districts mainly in boarding areas are suitable position for fake and sub-standard medicines business. Side by side Indian fake and sub-stranded medicines have been rampantly selling Rajshahi, chapinawabagang, Natore and Pabna districts. Forgein made and costly medicines are mainly in countries noted pharmaceuticals companies are widely manufacturing and marketing in fake level and names, it is widely alleged.

- Tk 3 crore spurious medicines seized in Mitford
  Natunbarta.com, April 21, 2013
Members of Rapid Action Battalion (RAB) conducted a drive at Dhaka’s Mitford area Saturday night and seized spurious drugs worth three crore taka.

The law enforcers also detained 56 people on charges of selling counterfeit medicines and selling medicines without required licenses.

The detained traders were fined 41,10,000 taka and two of them were sentenced to prison.

Four regular cases against the detainees were also ordered to file.

RAB sources say 56 traders were detained from Taj, Mohammadia and Sarder markets during a drive at around 09:00 pm.

 Fake medicine-making factory unearthed

UNBconnect, June 08, 2013

A mobile court here on Saturday unearthed a fake medicine-making factory and held a fake doctor at Patuatuli in the city.

The arrested was identified as MA Barek, 45, son of late Tamij Uddin of Manikganj Sadar upazila.

Aided by a team of Rab-10, the court, led by executive magistrate of Rab headquarters AHM Anwar Pasha, raided a house on Wize Ghat Road under the kotwali thana at noon and unearthed the factory and recovered huge fake SMC Saline, different medicines, medicine-making instruments and other goods.

Barek was also arrested during the drive, according to a press release of Rab.

On interrogation, Barek, who used to run the factory at a rented house, confessed to the crime.

He told that he was a fake physician and he has another illegal clinic in Keraniganj on the outskirts of the capital.

Later, the mobile court sentenced him to two years’ imprisonment on charge of making the fake medicines.

 Fake drug business rampant

Dhaka Tribune, June 26, 2013

It continues despite attempts by the drug administration and law enforcers to reign the trade through mobile court drives.

Despite mobile court drives, the illegal business of making and selling adulterated
and fake drugs has been going on unabated around the country.

Over the last eight months, more than 700 cases have been filed against various individuals and organisations by mobile courts under the Directorate General of Drug Administration (DGDA).

These cases had been filed on charges of preserving, storing and selling of fake, adulterated, expired, low quality and unapproved drugs.

Some 357 companies and drug sellers have been fined over Tk 27.7m. A total of 92 individuals has been handed down various jail terms from 10 days to 2 years by the mobile courts.

Fake and adulterated drugs are being made in the capital, under the very nose of the drug administration.

A mobile court drive on April 20, conducted in three markets in the capital’s Mitford area, seized huge amounts of fake, adulterated and low quality drugs.

42 cases were filed against various individuals and companies. They were also fined Tk 4.2m on various charges.

During the drives, the DGDA mobile courts also recovered huge amounts of drugs marked green and red and were actually supplied to various government hospitals for being distributed free of cost to the patients.

Drug traders told the magistrates of the mobile courts that a section of unscrupulous government employees and officials smuggle these free drugs out of the government hospitals.

Sharif Md Farhat Hossain, executive magistrate of a mobile court that works with the Rapid Action Battalion (Rab), told the Dhaka Tribune many of these traders continue doing illegal business despite serving jail terms and paying fines.

He said for manufacturing and selling drugs of any kind, a company must secure a license from the DGDA, have the required mechanism for ensuring quality of the products and the required manpower and expertise.

He regretted that most companies had not been following that stipulation.

Sharif, however, claimed that the manufacturing and selling of low quality drugs had been curbed by certain extents over the last few years.

Health sector experts also said the activities of the drug administration had gained a lot of visible momentum in recent times.

They said this was the kind of role that the DGDA should have always played in ensuring that people did not get cheated with sub-standard drugs.

DGDA sources said various mobile courts have fined a total of Tk 29.7967m in 494 cases and jailed 91 people to various terms from 10 days to two years in drives conducted from September 2012 to May 2013 on various charges relating to illegal drug sale.

Studies have revealed that many drugs available in the market did not have the main ingredient that they were supposed to, said Pro Vice-Chancellor of East West University Muniruddin Ahmed.
The former Dhaka University Clinical Pharmacy professor also said some of these drugs only contained flour, arrowroot and lactose.

Studies have also revealed that the antacid syrups manufactured by some of the local companies contained only 30-40% of the main substance, while a 250mg antibiotic capsule was often found to contain only 100mg or less of the main component.

DGDA drug supervisor Saikat Kumar Dhar said a man named Russel had been recently arrested at Keraniganj near Dhaka who had, for many years, been manufacturing a Tk 2 painkiller pill and selling it in the market by wrapping it in the package of Tk 10 pill of a reputed company.

According to the Special Powers Act 1974, the highest punishments for manufacturing and selling fake and adulterated drugs are death and lifetime imprisonment.

But people concerned said these stipulations could not be implemented to the fullest extent due to weaknesses in the legal fabric and lack of initiatives by the authorities.

28 pharmacies sealed

A mobile court has sealed 28 pharmacies and realised Tk 12.5 million in fine in Old Dhaka for selling expired, spurious and illegal drugs.

It also sentenced 20 men to jail for one year each during Saturday's drive, Major Abdullah Al Mamun of Rapid Action Battalion (RAB)-10 told bdnews24.com. During the seven-hour raid, starting at 11am, a total of 103 persons were detained for possessing counterfeit drugs, banned medicines and having no drug licences. The RAB mobile court’s Magistrate Sharif Md Farhad Hossain fined the rest Tk 12.25 million. A truckload of counterfeit, expired and illegally imported medicines, with an estimated market value of around Tk 50 million, was seized from these shops. A total of 80 cases have been filed over the incident. The RAB mobile court raided nine markets at Mitford and Babubazar. The markets are: the Samiti Market, Yousuf Market, Ali Market, Nayna Market, Khan Market, Nurpur Market, Dhaka Market, Sureshwar Market and Nupur Market. A shop owner alleged RAB did not raid the pharmacies which sold low quality and illegal medicines. Maj Mamun said there are over 40 pharmacies at Mitford and Babubazar, and they raided only nine markets.

11 fake herbal businessmen jailed in city
New Age, September 11, 2013

A mobile court by Rapid Action Battalion sentenced 11 businessmen to one year
imprisonment each and sealed two herbal shops and a warehouse in the capital’s Farmgate area on Tuesday. RAB executive magistrate Sharif M Farhad Hossain sentenced 11 ‘dishonest’ herbal businessmen to one year imprisonment each. The accused used to produce and sell illegal, fake and substandard herbal medicine, magistrate Farhad Hossain said. He said mainly two herbal shops titled The Khan Kabiraj Ghar and Bombay Herbal were selling fake medicines with half nude photo for attracting young people. A team of RAB-2, along with an executive magistrate, raided the area at around 5:00pm and arrested them. Later, they were jailed.

12 held for selling fake medicine
New Age, September 24, 2013

Twelve alleged spurious medicine businessmen were fined and given different terms of imprisonment by a mobile court of the Rapid Action Battalion in the capital on Monday. A RAB-3 mobile court, led by executive magistrate Sharif Md Forhad Hossain, conducted a drive against fake herbal medicine shops at Gulistan and arrested 10 fake herbal businessmen. The court fined them Tk 1 lakh each and sentenced six of them to 10 days of imprisonment. Later, the court conducted another drive at Nawabganj in Dhaka and arrested two people on allegation of selling spurious herbal medicine. The court fined and sentenced them to different terms. Executive magistrate Sharif Md Forhad Hossain said the accused used to produce and sell illegal, fake and substandard herbal medicines. Banned and substandard medicines are available in the areas at low prices and the sellers woo the buyers by giving false assurance, said Forhad Hossain. He said mainly they were targeting the youth and allured them with half nude photos.

Fake drugs worth Tk 10 lakh seized, 10 fined
The Daily Star, September 24, 2013

A mobile court of Rapid Action Battalion (Rab)-3 yesterday recovered a huge amount of fake medicines and fined a total of Tk 10 lakh to 10 persons who used to sell those on footpath in the capital’s Gulistan. The medicines are worth around Tk 10 lakh, said Rab sources. Six of those who were fined were each sentenced to a 10-day jail term. However, the elite force is yet to find the storage of the drugs, most of those being herbal, he further said. The medicines, which had been produced without any permission from the drug authorities, are detrimental to kidney, said Muhit Islam, superintendent of drugs, Drug Administration.

Fake medicines worth Tk 5 crore seized at Mitford
The Rapid Action Battalion seizes a huge amount of spurious medicine at Mitford and nine other markets in Old Town of Dhaka on Saturday. — New Age photo

The Rapid Action Battalion, Drug Administration and Bangladesh Standards and Testing Institution in a joint drive on Saturday seized a huge amount of fake and substandard medicines at Mitford in Old Town of Dhaka. A mobile court sentenced 20 medicine wholesalers to one year imprisonment and fined them Tk 1.25 crore and sealed off 28 wholesale shops. Fake and substandard medicines worth of at least Tk 5 crore were seized from nine wholesale medicine markets and 77 cases filed against 103 medicine traders during the drive, said executive magistrate Sharif Md Forhad Hossain who led the court. RAB-3 deputy director Major Md Tawfiq said they conducted the drive on allegation of selling counterfeit medicines by a section of greedy traders. The mobile court came to know that a good number of medicine shops in these markets were selling their substandard drugs, posing serious threat to public health, he said. As Mitford is the country’s largest wholesale medicine market and the nationwide marketing chain of medicines is controlled from here, some druggists and traders utilise the opportunity to make extra profit and manufacture counterfeit medicines, Abul Khair, director of Drug Administration, told New Age. It was also found during the drive that some of the shop owners were selling drugs which were stolen from different public hospitals. Some shop owners alleged that the officials and law enforcers were harassing them despite having licences and proper documents of medicines. On April 20 this year, the Drug Administration and RAB seized substandard and banned medicines worth about Tk 3 crore from three markets at Mitford.

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**Mitford Market Raided: Fake, foreign medicine seized**

*The Daily Star, September 29, 2013*

A mobile court accompanied by the Rapid Action Battalion seizes fake and unauthorised drugs from Mitford medicine market in Old Dhaka yesterday. Photo: Banglar Chokh

As many as 103 people were detained, 28 shops sealed and over Tk 1.25 crore fined yesterday in a joint drive against fake and unauthorised medicine at Mitford in Old Dhaka, the country’s largest hub of wholesale medicine. The eight-hour-long drive that started at 10:00am was conducted by a mobile court, the Rapid Action Battalion, the Directorate General of Drug Administration and Bangladesh Standard and Testing Institution (BSTI).

Habibur Rahman, director of Rab’s media wing told The Daily Star that 20 of the detainees were sentenced to one year’s imprisonment while 80 cases were filed. The rest of the detainees faced a fine or a three-month prison sentence. “About Tk 5 crore worth of medicine was seized,” Habibur mentioned. Sharif Md Forhad Hossain,
magistrate of Rab-10, said, “About 500 shops and godowns in nine markets were checked.” Some medicine traders scuffled with the Rab members during the drive. Rab-10 Commanding Officer Lt Col Md Imran Ibne Abdur Rouf said, “Our members in plain clothes were standing near the exits of the market as part of our operations strategy.” But when the traders heard about the mobile court’s arrival, those who sell fake medicine tried hurriedly to escape through one of the exits, he added. “Jostled by a crowd of traders, a Rab member standing there fell and hurt himself on the collapsible gate of the market.” Medicine traders told The Daily Star that import-banned medicine had been available at Mitford for a long time and that they sold those by bribing law enforcers. Therefore, some traders became angry that their shops were being raided even after they had paid bribes. The traders claimed that it was because of the scuffle that such a large number of traders were detained. “Some of these medicines are very effective and many doctors prescribe them so we bring them illegally,” said one of them.

Drive against spurious and banned drugs
The Financial Express, October 01, 2013

In perhaps the biggest and most coordinated ever raid lasting eight hours at the country's largest wholesale medicine market at Mitford in old Dhaka, 103 people were detained, 28 shops, sealed off, spurious and unauthorised drugs worth Tk 50 million, held and a fine of Tk 12.50 million, imposed, last Saturday. A mobile court, the Rapid Action Battalion, the Director General of Drug Administration and Bangladesh Standard and Testing Institution (BSTI) were involved with the massive hunt for fake and banned medicines in as many as 500 shops and godowns in nine markets. The shares of spurious medicines, illegally imported and time-barred drugs in the haul are not known. But the price of those medicines gives an indication of the extent of clandestine business within business. Spurious medicines have long remained a headache for the drug administration, physicians and patients. The look-alike drug intended to cure illness may end up causing irreparable damage or even death. As for the banned imported drugs, opinions may split because physicians prescribe those either because there is no local substitute or if any, it is not as effective as the imported counterpart.

Evidently, illegal business in drugs can be a consequence of conflicting concerns. Some take recourse to it knowing full well that the locally produced spurious varieties are marketed from a profit motive and others just respond to genuine demand by importing illegally banned medicines of foreign origin. In the latter case, the authorities are in favour of protecting the interests of local companies. But then the issue has to be settled after careful analysis of physicians' and patients' complaints. Why make the drug sellers the scapegoat? If the trade is demand-driven, there should be some truth in the complaints. However, this should not be reason enough for drug wholesalers to violate the legal restrictions. Better it would be to take up the issue with the authorities concerned and highly respected physicians may be consulted to see if a few foreign medicines must be subjected to exception
to the law.

Finally, medicines are meant for relieving physical discomfort or saving lives. When the production or supply-line somehow becomes suspect because, at some point, standard or precision has been compromised, the whole edifice of trust which is the driving principle of all trades, crumbles. In case of drugs, this is only truer. In Bangladesh, there have been occasions when people felt mortified to find impostor drug companies produced and marketed syrups that caused death to children. Here is a proof that some people holding authoritative positions do not perform their duties well enough. Swindlers either bribe people in positions or clandestinely market their products in an effort to make ill-gotten money. Common people are not expected be on guard, particularly when it comes to fake or genuine medicines. It is the duty of the authorities concerned to ensure that the consumers get their money's worth. This raid seems to have been comprehensive but will its deterrent effects last long? Regular market surveillance and, if necessary, such raids can do away with spurious and banned medicines.


- Gang of medicine smugglers busted

_The Daily Star, October 04, 2013_

A criminal gang, under the guise of garment accessories exporters, smuggled local medicinal drugs abroad for the last four years to produce narcotics. A team of Rapid Action Battalion-1 busted the smugglers’ den at the capital’s Uttara early yesterday and detained 10 people, including seven Chinese. “During primary interrogation, the detainees admitted that they have been smuggling tablets for the last four years in the name of exporting garment accessories such as buttons and zippers,” ATM Habibur Rahman, director of the Rab’s legal and media wing, told newsmen at a press briefing at its Uttara headquarters. The gang was sending 12 cartons of tablets to Hong Kong through Expo Freight Limited, an air freight company. The consignment weighed 300 kg. Out of suspicion, the company with permission from Bangladesh Customs checked the cartons and found tablets in those instead of buttons as declared by its sender Mizanur Rahman. When Mizanur was contacted, Chinese national Lieu Xing Hui answered the phone, raising the freight company’s suspicion. The firm then informed the Rab about the matter. The elite force tested the tablets at its laboratory. They contained ephedrine, a chemical similar to methylamphetamine, the main ingredient of Yaba, said Habibur. The Rab-1 team then tracked down the alleged smugglers and raided their den on Road-11 of Sector-3 in Uttara. The detainees are Lieu Xing Hui 46, Rau Rui Aung,46, Kui Haung Tu, 36, Jang Chau Liang, 40, Lin Lian Fu, 35, Lieu Xi Jin, 27, Yang Hi Cheng, 40, Mushfiqur Rahman Khan Sohel, 35, Raqibul Hassan, 34, and Muniruzzaman, 38. The law enforcers also recovered a huge amount of tablets of different renowned Bangladeshi companies, an apparatus for producing fake medicine, liquor, six foreign passports, Tk 24,40,300 and some US currency notes from their possession. The Chinese nationals have been here on work permits. Two of them are overstaying their visas. They collected the tablets with the help of the three Bangladeshis, two of
who are medical representatives of drug companies. “Though the tablets are prescription drugs, the Bangladeshis bought those from pharmacies in bulk at prices higher than the maximum retail price,” said the Rab official. According the Narcotics Control Act, 1990, ephedrine is a controlled drug and special government permission is required for its export, import and storage. A controlled drug also in other countries, ephedrine is not available for purchase in large quantities. The quality of Bangladeshi medicines is high and can be purchased easily from drug stores, which often sell medicines without prescription, mentioned Habibur. Responding to a query by a reporter, he said till now they have no knowledge of illegal laboratories in the country where ephedrine is separated from tablets to produce meth and yaba. The seized tablets, including those in 12 cartons, have an estimated worth of Tk 2.5 crore. The Rab-1 last night handed over the detainees to police and filed a case with Uttara Police Station under the special powers act against them for smuggling of medicinal drugs.

**Expired, fake medicines flood Ctg markets**

*The Independent, October 07, 2013*

Illegal and expired medicines have flooded the markets of Chittagong as several syndicates are active behind it. The customs and drug department authorities, police and Rapid Action Battalion (RAB) are yet to take any measures against the smugglers and traders responsible for the marketing of the illegal and expired medicines. According to sources, in the past several years, the authorities have taken special measures against all illegal drug traders and peddlers. Now the measures of law enforcing agencies are limited only against Yaba peddlers. As a result, many expired and contraband drugs have flooded the medicine markets in the port city. The situation has left the renowned medicine manufacturing companies counting heavy losses and public health is at risk. Earlier, law enforcing agencies took special measures against illegal and expired medicine smugglers and traders. Besides, law enforcing agencies also unearthed illegal medicine companies several years before. At that time, following the raids of the law enforcing agencies, the owners of the pharmacies at wholesale markets at Hajari Lane in Chittagong observed a three-day strike. The leaders of Bangladesh Chemists and Druggists Association demanded an end to harassment of the owners of pharmacies. After the strike of the owners of pharmacies in the port city and pressure of the leaders of Bangladesh Chemists and Druggists Association, the law enforcing agencies could not take any action against them or even conduct raids till now. Consequently, expired drugs and medicines have flooded the market of Chittagong. According to sources in law enforcing agencies, there are several syndicates in the port city to smuggle drugs, wine and medicine etc. They are active in Cox’s Bazar, Chittagong and Bandarban, Rangamati and Khagrachari hill district. The drugs, including wine and sex stimulating tablets etc are smuggled from Myanmar, India and Thailand. The sea is the main route of smuggling. Moreover, several fake medicine factories are involved in producing illegal medicines in the port city. Vested quarters are the expiry dates from the
packets of medicines and paste new labels on the packets of the expired drugs. As a result, many recognised drug companies are suffering loss of reputation and business. The representatives of some recognised drug companies told the Independent that there are many expired drugs and medicine from their companies in the market which might hamper health. They said, “if the customers check the date of expiry they can recognise the fake drugs and medicine. The syndicates are using the fame of the recognised companies,” they added. It is reported that several fake medicine companies produced seven types of medicines including Bitrax, Bicozin, Bicoliv, Menos, Carmina, Bicoglobin, Inflavic and Arozin without permission of the legal authority. On the other hand, the drug Department, police and RAB already recovered huge quantities of wine, contraband drugs and narcotics during the intensified the operation last month. They also arrested some smugglers at that time.

Sealed stores reopened, owners still in jail
* Dhaka Tribune, October 13, 2013*

Concerns raised about the possibility of seized drugs returning to the market. The Directorate General of Drug Administration (DGDA) reopened 24 drugstores of the Mitford medicine market on Thursday, which were sealed during a mobile court drive on September 28, on charges of selling “fake and expired” drugs.

Out of the 28 drugstores that were sealed that day, all except four were later able to produce legal documents to the mobile court magistrate.

Earlier, drug traders withdrew a nationwide day-long strike after Director General of DGDA Major General Jahangir Hossain Mollik assured leaders of Bangladesh Chemist and Druggist Samity (BCDS) of reopening the sealed stores and assisting in the release of the 21 detained drugstore owners.

However, Abu Bokor Khan Milon, general secretary of the Dhaka district unit of BCDS, told the Dhaka Tribune on Saturday that the release of all the drugstore owners would not be possible before Eid, as all legal documents for submitting bail petitions had not yet been collected from the deputy commissioner’s office.

He informed that out of the 21 arrested drugstore owners, only the ones who had been given 10 days’ jail time, had been released. Bail prayers for three more owners would be presented before the court on Sunday.

A mobile court on September 28 seized three truckloads of drugs worth more than Tk50m from the market near the Mitford Hospital in Dhaka, arrested 103 people, filed 74 cases, fined over Tk10.25m and sealed 28 stores.

Meanwhile, there are claims that the seized drugs were likely to return to the market, as a section of brokers who are close to few DGDA officials have allegedly been contacting drugstore owners at the Mitford medicine market to sell the seized drugs.
Seeking anonymity, several DGDA officials told the Dhaka Tribune that there were prior instances of reselling seized drugs. They alleged that drugs seized during a mobile court drive – that fined Dhanmondi drugstores Tk1.1m a few months ago – were later sold at the Mitford market.

Selim Barami, a director of DGDA, however denied allegations that seized drugs were being sold in the market again, saying no one could show a single instance of seized drugs being sold in the market by any DGDA officials.

Claiming that the DGDA had no connection to the seized drugs, Barami said the mobile court magistrate had sent the confiscated medicines to Rab offices.

He also informed that the sealed drugstores had been opened after sending documents regarding the drive to the court.

On the other hand, Monir Hossain, deputy secretary of BCDS, said the organisation was yet to receive the drug seizure list from the mobile court drive. Talking about the unregistered and banned drugs found during the drive, he said, “Renowned doctors had been prescribing these items. Nobody takes action against them. If there are so many agencies in the country; then how are these banned drugs coming?”

Regarding the seized drugs, Monir said the BCDS wants to donate the banned, but lifesaving drugs, to public hospitals or have them destroyed in the presence of their traders.

Sadekur Rahman, president of BCDS, also recently said, “The traders [who were arrested] cannot be held responsible for the fake, adulterated and sub-standard drugs that the mobile court had seized. They do not have any laboratory. How would they know which drug is fake and which is not? The drug companies are the main culprits.”

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**JS panel for closing down 29 drug producers**

*New Age, October 23, 2013*

A parliamentary standing committee on Tuesday asked the health ministry to close down 29 pharmaceutical factories for producing substandard medicine. The standing committee also asked the ministry to allow more time to 23 companies to reach required standard. The committee on the ministry of health and family welfare at a meeting discussed the report of a subcommittee on the drug producers. The subcommittee had earlier recommended closing down 62 of the 151 drug manufacturing companies. The committee, after a further scrutiny, asked the ministry to close down 29 errant companies and allow some time to 23 companies to meet the required standard, said the committee chairman Sheikh Fazlul Karim Selim. The committee also allowed three companies to produce all other drugs but high-end antibiotics and steroids. The committee was informed that the remaining seven companies had already closed down the factories on their own. The committee observed that despite repeated warning and imposing restrictions, the 29 companies...
did not develop their quality-control and maintain standard. It asked the ministry to vigil against those companies so that they could not produce or market any drug and to take legal action against them. The committee also asked the ministry not to compromise with the errant drug producers. ‘We cannot allow any company to produce medicines that might kill patients,’ Sheikh Fazlul Karim Selim told reporters after the meeting at the Jatiya Sangsad Bhaban. Selim said the companies must follow international standards of production as a large chunk of drugs were being exported. The subcommittee during its inspection found the errant companies allowing dogs to give birth to puppies inside the factory, people to sleep at night where drugs are produced, water kept in buckets and pharmacists not wearing aprons. The subcommittee headed by Nazmul Hasan was appointed by the standing committee on July 29, 2009 and it had submitted the report on July 3, 2011 identifying 62 errant pharmaceutical companies and asked the government to take action against them. The drug administration later certified that some of those companies were up to the mark. State minister for health Majibur Rahman Fakir, committee members M Amanullah, Nazmul Hasan and M Murad Hasan also attended the meeting.

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**BHUTAN**

- No Reported Incidences.

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**DPR KOREA**

- No Reported Incidences.
INDIA

- Fake drug racket flourishing in state
  *Hindustan Times, November 07, 2012*

The recent crackdown by a joint team of Special Task Force (STF) and Economic Offences Unit (EoU) on the wholesale market of medicines in Govind Mitra Road, SP Ghosh lane, Jahaji Kothi and Jain Gali in the state capital has blown the lid off a massive racket in Bihar. “The racket has been thriving in connivance with insiders as well as the local police and drug officials. The seized medicines appear not only sub-standard but also fake. We also recovered a number of seals of ‘Physician’s sample, not to be sold’, which found their way into the market,” said a police officer.

The recent crackdown by a joint team of police, the seized drugs are valued at more than Rs. 10 lakh, though surprisingly, 60% of them carried the label of ‘Physician’s sample, not for sale’.

The recent crackdown by a joint team of Police said the roads were so congested that only two-wheelers could move in there, but still huge consignments managed to reach there on a regular basis.

The recent crackdown by a joint team of On Monday, a joint team of STF and EoU raided four locations, two medical shops and godowns and seized huge quantities of fake medicines being sold and stored there. The team arrested eight persons -Kumar Gaurav, Mukesh Prasad, Pankaj Kumar, Uday Shankar, Randhir Kumar, Abhay Kumar, Sushil Kumar Sah, and Ashraf Ali. Later, they were handed over to EoU police station after lodging an FIR against 10 named accused and an unidentified person on the basis of the statement of drug inspector Yashwant Kumar Jha.

The recent crackdown by a joint team of An EoU official said, “We would investigate every aspect of the case, including involvement of government officials, if any. We can’t imagine such a huge supply of physician’s samples in the market without the involvement of drug Mafiosi.” Even medical representatives of several pharmaceuticals companies used to sell off physician’s samples to the racketeers, he added.

The recent crackdown by a joint team of Additional director general (ADG), headquarters, Ravindra Kumar said the raid was carried out in the presence of drug inspectors and samples of the seized drugs would be sent to forensic sciences laboratory to check their authenticity.

The recent crackdown by a joint team of During investigation, stockists revealed that they were having a tough time due to the growing demand for fake medicines from retailers coming from rural areas of the state. “Poor people always seek a major discount on costly drugs. They are easily trapped by unscrupulous retailers who oblige them by giving fake medicines,” said a stockist of a reputed drug company.
The recent crackdown by a joint team of The dealers maintained that the sale of high-quality medicines of reputed companies has been badly affected by the huge supply of ‘fake and substandard drugs’ in the market.

The recent crackdown by a joint team of This is the fifth time in the recent past when police team conducted raids on medicine shops and recovered ‘fake medicines’ on such a large scale. Earlier on May 2010, the sleuths of the drug control department recovered medicine worth Rs. 1 crore and lodged nine separate FIRs against 175 persons including five government officials on the basis of the statement of the then drug inspector AK Yadav.

FDA warning on some ‘defective’ vaccines

The Times of India, November 19, 2012

The death of a two-and-a-half-month-old child after he was administered some vaccines at the government-run Indira Gandhi Government Medical College and Hospital (IGMCH) has led to a warning against the use of medicines from the same batch. The Food and Drugs Administration (FDA) has warned all hospitals that medicines from the same batch by the manufacturers should not be used.

On Wednesday, Ashutosh Gujar had been taken to hospital for routine vaccination. After returning home, the child’s health deteriorated and he was rushed back to hospital. The hospital maintained that the child was weak and suffered from meningitis, which may have caused a fatal seizure. They also said that the cause of death can be found only in the post mortem.

Meanwhile, the FDA has taken samples of the allegedly faulty medicines and sent them to the central government’s drug testing laboratory at Kasoli, Uttarakhand.

“We have shared the batch numbers and manufacturers of these medicines with all hospitals. They are advised not to use these until reports from Kasoli determine whether or not the medicines are at fault,” said assistant commissioner of FDA (drugs) Amrut Nikhade. He added that further directions will be given by the FDA after the report arrives.

UNDER THE SCANNER

Poliomyelitis vaccine (oral) IP: Batch number P-200 manufactured by Bharat Immunologicals and Biologicals Corporation Limited, Bulandshahar, UP

Abhay-TAG (DPT vaccine) IP: Batch number TAG12B/11 manufactured by Human Biologicals Institute, Gachibowli, Hyderabad

Revac-B (Hepatitis B) vaccine IP: Batch number 51AD11114 manufactured by Bharat Biotech Genome Valley, Shameerpet, Hyderabad
Spurious drugs seized at Kukatpally
The Hindu, December 12, 2012

THE SEIZED DRUGS

- **Anti-Allergic**: Cezet (Brand Name)
- **Anti-Pyretic**: PC Kids Plus DS (Brand Name)
- **Cough Drops**: Resprl Drops (Brand Name)
- **Cough Syrup**: Resprl-D (Brand Name)
- **Paracetamol**: Gepar-250 (Brand Name)
- **Cough**: Resprl Expectorant (Brand Name)

G.S. Life Sciences manufacturing syrups under brand names of other companies

The Drug Control Administration (DCA) authorities have seized spurious drugs allegedly being manufactured on the premises of a company G.S. Life Sciences at Prasanthnagar, Kukatpally on Monday. According to authorities, the establishment did not have a license to manufacture drugs but only permitted to deal in sale of medicines.

Authorities said the two Directors of the G.S. Life Sciences, U. Gowri Shankar and J. Srinivasulu were found to be manufacturing spurious syrups on the premises. “We have seized 101 cartons of syrups, packaging material, batch printing machines and filling syringes worth Rs. 3 lakh from the company premises. They did not have any licence to manufacture,” said DCA Director General, B.L. Meena.

Officials said that G.S. Life Sciences had a third party agreement with Esteem Laboratories, Aleap Industrial Area, Kukatpally and Bridge Pharmaceuticals, Prasanthnagar. “According to the agreement, the two companies were supposed to manufacture the syrups in their facility and then sell them to G.S. Life Sciences,” Deputy Director, DCA, G. Dharma Data, who led the investigating team, said.

However, DCA authorities said that G. S. Life Sciences was manufacturing spurious drugs on their premises and claiming that they were manufactured by Esteem Laboratories and Bridge Pharmaceuticals in Kukatpally. “Such offences attract jail term extending from seven years to even life imprisonment,” Mr. Meena said.

The authorities said that all the spurious drugs were syrups and were anti-pyretic, anti-spasmodic, anti-allergic and antibiotic syrups. “The spurious syrups were being manufactured under brand names of other companies. For the inexperienced eye, these would look like any other normal syrup. In our raids, we also found spurious syrups meant for children with high grade fever,” Mr. Dharma Data said.

Cases were registered on the Directors of G. S. Life Sciences under the various provisions of Drugs and Cosmetics Act, 1940, officials said.
**Bangalore couple, two Nigerians arrested for selling fake drugs**  
*The Deccan Herald, Feb 24, 2013/ NDTV, Press Trust of India, Feb 24, 2013*

An Indian couple and two Nigerian nationals have been arrested for selling a senior citizen fake drugs for nearly Rs. 12 lakh claiming it could cure cancer.

The four approached the senior citizen through e-mail and lured him into believing that he can earn big money by selling the “drug” which was “pieces of wood mixed with hair-dye”.

They collected Rs. 11,95,000 from him, police said here.

The Central Crime Branch (Women and Narcotics) squad arrested Revathi (20), her husband Muralidharan (22), both residents of Bangalore, along with Arebamen Abibu Obadan (35) and Joseph Nnamdi Emeanuwa (32), they said.

The squad seized three laptops, as many mobile phones, a car and other valuables that the accused bought with the money.

During investigation it came to light that the two Nigerians were overstaying in the country, as their visa had expired and had not been renewed. A local court has remanded the four in judicial custody.

A search is on for the fifth accused and foreign national Mark Hebert who is absconding, police said.

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**Jammu and Kashmir govt hospitals give away fake medicines to patients**  
*Headlines Today, April 4, 2013*

The Jammu and Kashmir government has been providing sub-standard medicines to poor patients undergoing treatment in its hospitals. Headlines Today has obtained documents that reveal that the Omar Abdullah government has made available thousands of fake amoxicillin tablets to its hospitals.

The documents available with Headlines Today suggest that the drug controller had seized around 8,000 tablets that were found to be sub-standard after being tested in a state laboratory. However, the government still continued to supply the medicine to patients in its various hospitals in November 2012.

The revelations raise question mark on the supply-chain mechanism adopted by the government. The reports of drug controller and the laboratory suggest that the drug named "Maximizin 625", which was supplied to patients, had "zero quantity of the real salt”. It was, therefore, declared of sub-standard quality.

Deputy Drug Controller Nazir Ahmed Wani said, "We have tested the sample and the report suggests that it is substandard medicine which was supplied to government hospitals. We are seizing the medicine."
Database on the Incidents of Counterfeit Medicines in the WHO-SEA Region [2011-2012]

- **Sub Standard Drugs Supplied To Govt. Hospitals Seized**
  
  *Authint Mail, April 04, 2013*

In what could turn out to be a major scandal of deliberately risking the lives of the patients, Drug Control department of Kashmir on Thursday seized hauls of sub standard medical supply in various govt. hospitals which were being distributed among patients free of cost. Deputy Drug Controller Kashmir Nazir Ahmad while cautioning patients against the use of Himachal based company’s product Maximizen tablets told KNS that the drug was found sub standard and has been seized from various hospitals. “ We had been receiving complaints about the supply of sub standard drugs in govt. hospitals, so we constituted a team headed by Dr. Sameer Sajad.” Ahmad told KNS. He added, “ we have seized at least 8,500 sub standard tablets from various hospitals during last three days.”

According to Dy. Drug Controller, the antibiotic tablets maximizen has been manufactured by a Himachal based Company and marketed by a Bombay Based company. However, the Medical department has received the consignment from the dealers Life Line Pharma Co. after the drug was passed for use in hospitals by the department’s Purchasing committee of Jammu Province. According to deputy drug controller, as per the norms the maximizen tablet should have 500 mg. of amoxicillin ad 125 mg. of calvulanate substances, however shockingly as per the officers it does not contain even a single percent of amoxicillin.

Meanwhile Minster for Medical Education Taj Mohi ud din told KNS that he has asked concerned officers to stop the supply of sub standard medicine to the hospitals. He also revealed that the same sub standard drugs were being supplied to the state assembly dispensary also. “ They have not spared the law makers also. These drugs have been supplied to the assembly dispensary also for last two years.” Taj, who recently took charge of the department told KNS on Thursday.

The Minister further said, samples of various drugs from all government hospitals and health centers would be taken and examined. “Within three days the report will be submitted”. He said that these sub standard drugs have been approved by Jammu purchasing committee. (KNS)

- **Spurious tablets scam busted in J&K by drug dept**
  
  *Hindustan Times, April 11, 2013*

The drug control department of Jammu & Kashmir has busted a scam involving the supply of around two lakh spurious antibiotics to hospitals in the Valley.

President of the doctors association of Kashmir, Dr Nisar-ul-Hussain told HT that the fake antibiotics could have led to hundreds of deaths. The association blamed former health minister Sham Lal Sharma as the drugs were purchased during his tenure and demanded a judicial probe into the case. “If even 10% of the patients who took the drug suffer acute infection due to the fake drug, the number would be
"huge," said Hussain.

Investigations have revealed that the Jammu-based distributor supplied Maximizen-625, a compound of amoxicillin trihydrate and potassium clavulate, purportedly manufactured by Himachal-based Affy Parenterals.

Not only was the drug "not of standard quality", it did not contain any amoxicillin at all, revealed a report from the state drug and food control department. Amoxicillin is used to treat bacterial infections.

Meanwhile, Affy Parenterals has denied its involvement in the scam. "These are not our drugs. The packaging is different from ours. Somebody has been misusing our name," said general manager, marketing, Geeta Jain.

The JK authorities, however, are not taking Affy's denial at face value. The assistant drug controller, Kashmir, Nighat Jabeen said, "The investigating team has been sent to Himachal to check all relevant records. We are waiting for their report."

The authorities had apparently placed the order with Jammu-based distributors Lifeline Pharmaco Surgical.

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**Jammu and Kashmir drugs case: Two held**

*Zee News, April 22, 2013*

Two brothers were held by Crime Branch of the Jammu and Kashmir Police in connection with purchase of spurious drugs by the state government, which had triggered protests in Kashmir Valley.

Amardeep Raina, one of the accused in the supply and purchase of spurious drugs, was arrested from New Delhi late last night and his brother Ashok was nabbed from here, a senior Crime Branch official said.

Amardeep, who is reportedly one of the proprietors of the company which supplied the fake drugs, and Ashok have been held here for questioning, the officer said.
Search is on to nab another accused Akhil Gadoo, who is reportedly the second proprietor of the company, he said.

Crime Branch had registered a case in this regard, he said.

The CB team has seized vital documents and other material in connection with the case during raids at various places in Jammu and outside.

A report submitted on Saturday by a committee constituted by government to enquire into lapses leading to purchase of these drugs, had given clean chit to former health minister Sham Lal Sharma, who is the present PHE, Irrigation and Flood Control Minister in supply of Rs 11.32 lakh spurious 'Amoxicillin Trihydrate' to the state government.

The committee had ordered probe by Crime Branch and Vigilance Organisation against the Proprietors of Life Line Pharmaco Surgicals and officers of purchase committee-II of Medical Education department.

The report showed that the owners of Life Line Pharmaco Surgicals flouted government norms while participating in the tendering process, Crime Branch officials had said.

The accused proprietors reportedly produced a fake authorization certificate by Medley Pharmaceuticals Ltd, they said.

The rate quoted by Life Line Pharmaco Surgicals was found to be the lowest by the Purchase Committee-II and supply orders were placed for 2,65,000 tablets, they said.

The company supplied spurious drugs in connivance with officials of the Purchase Committee-II, the officers said.

On April 05, the state government had blacklisted Life Line Pharmaco Surgical Ltd and cancelled its drug licence for supplying sub-standard antibiotic medicines meant for government hospitals.

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**J&K drug control organisation moves court against 17 firms**

_The Hindu, April 26, 2013_

The Drug and Food Control Organisation on Wednesday filed challan in Srinagar’s Terrorist and Disruptive Activities (Prevention) against 17 companies allegedly involved in the supply of spurious drugs and other violations, sources told _The Hindu_.

The TADA court is the designated court for filing cases under the Drug and Cosmetics Act.

The Inspector General of Crime Javed Mujtaba Gillani maintained that the DFCO’s challan was a separate process that would not have any bearing on the Crime Branch’s probe into the infamous spurious drug scam. There was a possibility that some of the trials could be clubbed at a later stage, he said.

Sources said an advocate and a Drug Inspector filed the challan in the TADA Court before its presiding officer Muzaffar Iqbal Qureshi, adding the seventeen companies,
among them the Jammu-based Lifeline, the Dehradun-based Sanative and the Mumbai-based Medley, whose labels and stationery have been found to have been used by the proprietors of Lifeline.

❑ Valley Falls Prey To Deadly Spurious Drugs

_Tehelka Magazine, Volume 10, Issue 17, April 27, 2013_

Thousands of fatalities in two J&K hospitals are linked to fake drugs supplied by the state’s health department

In the past five years, 7,875 patients have died within 48 hours of being admitted at the Sher-i- Kashmir Institute of Medical Sciences (SKIMS), the only super-specialty hospital in Jammu & Kashmir. If a recent exposé is to be believed, most of them could be victims of spurious drugs supplied by the state government’s health department.

The scam came to light when the state’s Drug and Food Control Department discovered that Maximizin- 625, an antibiotic that is administered within hours of surgery, was fake. The antibiotic, which was supplied to hospitals in the Valley last year by Jammu-based distributor Life Line Pharmaco, contained zero milligrams of Amoxicillin instead of 500 milligrams as claimed by the company.

Incidentally, the test was done last July, but the results were made public only last week, which means the antibiotic continued to be in circulation until then. Following random laboratory tests, around 43 drugs sold in the Valley were found to be either spurious or substandard.

The antibiotic Maximizin- 625 is manufactured by Himachal Pradesh-based Affy Parenterals and marketed by Mumbai-based Medley Pharmaceuticals Ltd.

Around two lakh tablets of the medicine, which doctors say is prescribed for post-operative care, were delivered to J&K government hospitals last year, including GB Pant Hospital in Srinagar and SKIMS. Almost half of the two lakh tablets have already been administered to patients in the Valley.

Incidentally, both GB Pant Hospital and SKIMS have experienced high mortality rates in recent years. Last year, GB Pant Hospital reported deaths of more than 636 children, while around 4,000 patients died at SKIMS.

“These statistics are worrying enough to raise a strong suspicion that patients are being treated with spurious drugs, considering the number of deaths occurring within 48 hours of admission,” says Dr Geer Mohammad Ishaq, a senior faculty at the Department of Pharmaceutical Sciences, University of Kashmir. “There are also genuine apprehensions that last year’s extraordinary number of deaths at the children hospital are attributable to spurious drugs in circulation.”

Medicines worth 50 crore are supplied annually to government hospitals in the Kashmir Valley, which is a tiny percentage of the Rs 1,000 crore drug market in J&K.

“If the government supplies substandard medicine to its own hospitals, who will stop the proliferation of these drugs in the market?” asks Dr Nisar-ul-Hassan, president of
the Doctors Association of Kashmir (DAK).

DAK has filed a PIL with the J&K High Court to seek an independent probe into the scandal. The association has, meanwhile, asked the doctors in the Valley not to prescribe hospital medicines to patients unless tested for quality. DAK has also sought a probe into former health minister Sham Lal Sharma’s involvement in the scam.

“We will treat all hospital medicines as spurious unless proven otherwise,” says Dr Hassan. “As it is the antibiotic cannot treat infections, which will progress to septicaemia and prove fatal for a patient. There is no telling how many patients must have expired in hospitals because of this drug.”

At a press conference in Srinagar on 15 April, Dr Hassan also displayed another fake drug, Curecef 1000 (Ceftriaxone Sodium), whose laboratory analysis showed the presence of particulate matter. “This is very dangerous to human life,” he said.

Dr Hassan also said that doctors will hit the streets to protest the scam. “We want heads to roll. We want the former health minister Sham Lal Sharma, who is now the public health engineering minister, and the purchase committee members, who gave the nod for the purchase of these medicines, to resign.”

Maximizin-625 was randomly picked up for testing from hospital supplies. Now, this has raised suspicions about the stock of medicines in government hospitals. “I have submitted a report to my seniors at the department about all the 43 drugs found to be substandard,” says Dr Reema Khatib, who works at a drug analysis laboratory in Srinagar.

This is not the first time that the Valley has made news for spurious drugs. Last year, noted cardiologist Dr Naresh Trehan termed Kashmir a hub of spurious medicines. “A single spurious drug can cost a life. The government should immediately intervene to stop it,” Dr Trehan had said while addressing a conference in the Valley.

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❖ ‘Bansal’s kin makes spurious medicines’

*Hindustan Times, May 07, 2013*

Former parliamentarian and BJP leader Satya Pal Jain alleged that the pharmaceutical company run by railway minister Pawan Bansal’s family had been manufacturing sub-standard medicines and no action had been taken against it.

A parliamentary standing committee gave a report on Theon Pharmaceuticals, run by Bansal’s son Amit Kumar and wife, Madhu, and it was placed in the both Houses of Parliament on May 8, 2012, he said, adding that the government looked the other way.

He said according to the report some drugs were not safe for patients. Jain said it was clear the wrongdoing took place “under the patronage of Bansal only”.

“We demand the CBI interrogate him immediately as he is an important link in the case.”
Database on the Incidents of Counterfeit Medicines in the WHO-SEA Region [2012-2013]

- **Fake cosmetics, medicines flood Patna market**
  *The Times of India, May 20, 2013*

The state capital has become a favorite market for fake cosmetics and spurious medicines. The recovery of consignments and unearthing the manufacturing units of counterfeit products recently have also proved that the ‘business’ has been running across the state with Patna being the easy route.

On Sunday, a team of drug inspectors seized a huge amount of medicines from Mithapur bus stand on Sunday. A drug inspector said, “The medicines were being loaded in a bus to Supaul. The dealers could not show any transaction bill to the police. We have sent the samples of the medicines for quality check. The medicines were first stocked at some godown at Govind Mitra Road under Pirbahore police station.”

Most of the medicines, ranging from calcium, vitamins, hormonal and pain killers, had ‘physicians sample, not for sale’ printed on their covers.

The cops, along with the officials of drug controller’s office, frequently conduct raids at the Govind Mitra Road and Makhania Kuan lane where a large number of fake medicines are stored. An official of the special task force said, “Whenever we conduct raids in these areas, huge amount of medicines are seized and sent to the laboratories to check their authenticity. But due to some unknown reasons, no major crackdown has ever taken place. The dealers store the medicines at their residences which have secretly turned into godowns.”

The same problem occurs when raids are conducted in Patna City area in search of factories making fake cosmetics. According to police sources, the congested lanes and old buildings of the areas help the dealers of fake medicines and cosmetics. The cops said they cannot conduct raid randomly at anyone’s residence without any specific tip-off.

- **Guj FDCA busts racket in Ahmedabad selling spurious drugs of top brands**
  *www.phramabiz.com, May 23, 2013*

The Gujarat Food and Drug Control Administration (FDCA) recently busted a racket of illegal manufacturing and sale of spurious drugs in Ahmedabad. In a raid carried out by the the FDCA officials, the authorities seized drugs worth Rs. 2 lakhs from the main accused Jayesh Mehta’s residence, which he had stocked without any valid license.

The test results from the samples that were collected during the raid showed 0 per cent active drug ingredients in it. During the course of the investigation, the FDCA officials found that the accused where involved in counterfeiting three leading brands categorized and recognised as fast moving products belonging to reputed
companies.

The drugs that were counterfeited and sold to the unsuspecting patients were Duphastone-10 mg (dydrogesterone tablets BP) of Abbott, a leading synthetic hormone used for prevention of miscarriage among pregnant women sold at Rs.354 per strip. Udiliv 300, ursodiol tablets USP, again a leading brand of Abbott sold at Rs.200 for liver disorder and bladder stones; Zifi 200 cefixine tablets IP 200 mg manufactured by FDC limited and sold at Rs.100 per strip.

The state FDCA has already filed an FIR against the main accused Jayesh Mehta for the same as he has been found to be violating Section 18(c) of Drugs & Cosmetics Act, 1940, (D&C Act) by manufacturing, selling and distributing drugs without license, stocking drugs without license and selling counterfeit drugs of leading drug brands in the market.

The investigation revealed that the modus operandi adopted for this racket headed by Mehta, an ex-medical representative (MR), functioned by selling three major drugs that were manufactured outside the state without any license. Dr H G Koshia, commissioner, Gujarat FDCA, informed that the accused used to procure the finished products from Agra through a source called Pappu. Later, the consignment was marketed by Mehta through sub stockist, using his previous MR references, to select seven to eight chemists shops in Ahmedabad.

“We will be taking all the possible steps to see to it that all the accused in this case are severely punished, especially since their actions have put the health and life of the patients at high risks. Further investigations are underway to find out the level of involvement of the chemists and sub-stockists in this case, and we assure that strict action will be taken against those who have been found guilty. We do not take public grievances lightly especially, when the actions can have a life threatening effect on patients, we would simultaneously like to warn everyone that we will be strengthening our monitoring system further to ensure that such incidents do not go occur again,” warned Dr Koshia.

Interestingly, it is understood that Gujarat FDCA chanced upon this racket during an ongoing investigation against Mehta who had been alleged to be stocking and selling physicians samples. During the raid, the investigators uncovered a considerable amount of physicians samples as well in his custody along with the other drugs proved counterfeit.

* India rejects allegations of exporting counterfeit drugs  
* Business Standard, June 03, 2013

India Monday rejected allegations of exporting counterfeit drugs, saying those are desperate attempts by some countries to malign its flourishing pharmaceutical industry, which enjoys a unique position of low-cost manufacturing and highest quality medicine.

It said there were reasons to believe that “vested interests” were raking up isolated
issues about technical deficiencies in good manufacturing practices (GMP). There have been extensive media reporting about on the quality of drugs (pharmaceutical products like Active Pharmaceutical Ingredients and formulations) manufactured in India for exports.

Some isolated reports have also been received about export of spurious /counterfeit drugs attributed to some source in India.

“Government has strong reason to believe that some of the spurious drugs detected in the international markets, alleged to be exported from India, are desperate attempts by other countries getting affected by the strength of Indian pharma industry,” the ministry of commerce and industry said in a statement to clarify on reports of malpractices of pharma manufacturing in India.

The statement came after New Delhi-based Ranbaxy Laboratories, India’s largest drug company by sales, pleaded guilty in the United States to criminal charges of making adulterated medicines and agreed to a 500 million dollar (around Rs.2,833 crore) settlement.

The ministry said the pharmaceutical sector in the country is a highly regulated one and the exports are heavily guided by various regulatory regimes of the importing countries. And there is also a requirement for continuous monitoring of quality related aspects, including complaints of sub-standard / falsified drugs from various countries.

The Drugs Controller General of India (DCGI) is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India. The State Drug administration offices regulate issue the manufacturing licenses and quality control monitoring etc.

The DCGI regularly holds meetings with the State authorities and also interacts with drug regulators across the globe to ensure that the international practices of manufacture and supply of drugs are followed in India. India’s compliance with TRIPS and consequent implementation of Patents Act is appreciated all over the world.

“All the concerned organisations in the government are constantly interacting to ensure that India’s image as a safe exporter is protected from all angles. Government and the industry is already working on a ‘trace and track’ mechanism which would enable monitoring of the supply chain possible at all the three levels — tertiary, secondary and primary.”

The pharma industry is a highly knowledge based industry which is growing steadily and playing a major role in the Indian economy. India has a large vendor base for supplying quality generics/API/ contract manufacturing with state of the art facilities.

The ministry said there are more than 350 manufacturing sites endorsed by EU for their GMP standards in India as on April 30, 2013. As on December 30, 2012, over 3,000 drug master filings (DMFs) with the US, amounting for an almost 40 percent of the total DMFs filed With the USFDA, are filed by over 233 different companies from India.

“Companies/importers from all over the globe are encouraged to visit the manufacturing facility in India to satisfy themselves of the quality of production of
“Drugs,” the government said.

❖ Parliament committee holds parleys on spurious drugs in markets
   *The Times of India, June 05, 2013*

A parliamentary committee on petitions was in the city on Monday to hold consultations with stakeholders on the extent of spurious drugs available in market and seek suggestions from them to ensure patients get safe and cheap drugs.

The committee, headed by Bhagat Singh Koshyari, an MP and former chief minister of Uttrakhand, with A V Swamy, Rajya Sabha member from Odisha, P Rajeev, Paul Manoj Pandiya, PG Reddy and Husain Dalwai, held discussions with representatives of doctors from Indian Medical Association (IMA), Nagpur District Chemists and Druggists Association (NCDA), the Akhil Bhartiya Grahak Panchayat (Vidarbha region) and representatives from the pharmaceutical industry and people’s representatives.

The IMA representatives are learnt to have raised concern over replacing branded drugs by generic ones. City IMA president Dr Warsha Dhawale told TOI that the association had requested the committee to reconsider the issue in the wake of possibilities of compromise on quality of drugs, if every drug is brought under the generic category.

The Grahak Panchayat’s regional president Gajanan Pande held a contrarian view. “The majority of drugs should be brought under generic category. Branding increases the cost manifold unnecessarily leaving the patient to bear the brunt. We also raised the issue of adulterated drugs and demanded a testing laboratory in city,” he said.

The panchayat also expressed suspicion over actual use of all the drugs which the doctors prescribe for hospitalized patients and force the relatives to buy from shop in hospital premises. “These medicines are much expensive. And who knows if all of them are used,” asked Pande.

❖ Inferior drugs disturb doctors
   *The Telegraph, June 06, 2013*

The medical fraternity is worried over the seizure of sub-standard and fake drugs, at times lethal for patients.

Police on Wednesday seized 30 boxes of suspected spurious drugs from a cart in the Gandhi Maidan area. Station House Officer of Gandhi Maidan police station Rajbinder Prasad said nobody could produce transaction bills for the consignment.

The drugs seized were ofloxacin (for respiratory tract infections), oflozen (for typhoid), ossopan (calcium tablets prescribed to pregnant ladies and those with fractured leg) and azithromycin (for respiratory tract infections). The seized drugs
belong to popular brands.

That fake and sub-standard drugs were in circulation in the state was obvious after 12 out of 954 samples tested by the drug controller’s office last year were found to be substandard. In 2011, eight out of 879 samples were found to be below par.

Cases of fake and substandard drugs have surfaced this year too.

The drug controller administration last month seized 200 boxes of fake N-Flox TZ drug, used to treat diarrhoea, from a shop on Govind Mitra Road in Patna. Last Sunday, fake drugs worth Rs 3 lakh were seized from a factory in the Khemnichak area under the jurisdiction of Ramakrishna police station.

Though the number of substandard and fake drug cases is not huge, experts believe they should not be taken lightly.

Dr Diwakar Tejaswi warned that popping substandard pills can dangerous affect one’s health, even cause death. “Every drug has a calculated chemical composition that helps kill the bacteria, virus or protozoa causing a disease. But if a person takes a substandard drug, which has sub-therapeutic concentration (lower percentage of effective chemical), the bacteria, virus or protozoa would not die. Rather, the virus, bacteria or protozoa would get time to undergo changes and develop resistance to the drug.

“If a person continues taking substandard drugs, his/her condition can only worsen. Say, if a typhoid patient is on substandard levofloxacin drug, the bacteria will not die. It will proliferate and the patient might die,” Tejaswi said.

“According to the Drugs and Cosmetics Act, any drug manufactured by compromising on quality or stored in a way that it has lost its actual properties or has been tampered with or misbranded, is a fake or spurious drug. According to Drug Controller General of India guidelines, drugs that have 70 per cent therapeutic concentration should be considered substandard. Those with therapeutic concentration below 70 per cent are fake drugs. In Bihar, we mostly encounter cases of substandard drugs,” state drug controller Hemant Kumar Sinha said.

Packaging of fake and substandard drugs is so like the original that only tests can expose them. “How can a common man spot the difference?” Sinha asked.

State drug controller office sources said many small drug factories in the state are clandestinely manufacturing fake drugs while others are pouring in from other states. The drug controller administration does not have a clear idea of the total number of units in the business of fake and substandard medicines.

Even drug testing faces obstacles. While only 954 of 2,996 drug samples collected were tested in 2012, just 879 of 2,420 samples collected in 2011 could be tested.

Asked about the low drug testing figures, Sinha said the state does not have proper infrastructure in place for the same.

“Bihar has only one drug testing laboratory, which is in Agamkuan. The laboratory has only three technicians against the seven sanctioned posts. So, even if we collect a huge sample, we are not able to carry out testing efficiently. However, there is a ray of hope. We are soon going to develop infrastructure at the Agamkuan-based
laboratory as we have received Rs 1.49 crore funds for it. After the infrastructure development, we can expect to test 5,000 samples,” Sinha said.

2 drugs found spurious in Jammu and Kashmir

*Kashmir Times, July 01, 2013*

The Drug Controller General of India (DCGI) today confirmed that two drug samples taken from Jammu and Kashmir hospitals for testing efficacy have been found spurious.

“The Union of India (UoI) filed a status report on behalf of DCGI saying that we have received efficacy report of 25 out of 156 drug samples taken from different places in Jammu and Kashmir. Out of the 25 samples two have been found spurious,” Showkat Ahmad Makroo, the Assistant Solicitor General of India told this reporter.

He said the efficacy report has been received from Regional Laboratory Chandigarh. “We have been given four weeks by the High Court to update our status report vis-à-vis the efficacy confirmation of the left out drug samples,” Makroo informed.

Meanwhile, the state government also filed the status report through Advocate General Mohammad Ishaq Qadri. In its report the government said it has presented the charge sheet before a designated court against accused persons involved in spurious drug scam. The state government sought time to seek sanction for prosecution against the accused government employees.

On April 24, TADA court, the designated special court had issued non bailable arrest warrants against 15 accused persons who belong to different states in the country in spurious drug scam.

The warrants were issued after a complaint was moved before TADA court saying that samples of Maximizin-625 tested sub standard and the accused who manufactured, supplied and distributed these drugs be dealt under law.

The arrest warrants were issued after advocate Musavi Rafiq Joo, standing counsel drugs department filed an 18-page complaint against 15 accused allegedly involved in the spurious drugs scam. The accused include Akhil Gadoo (Jammu), Amardeep Raina (Jammu), Ashok Raina (Jammu), Prem Prakash (UP), Manjula Barnwalm (Utrakhand) Ashok Kumar (Dehradun Utrakhand), Manoj Kumar Agarwal (Bihar), Rahul Kumar Singh (Dehradun), Managing Director Medley Pharmaceuticals (Mumbai), Arvind Billa (HP), Vilas Bhimarao (HP), Sumit Bhardwaj (HP), Sanjay Mishra (HP), Bipin Kumar (HP) and Suraj Enterprises (Haryana).

In the complaint the drugs department had said that samples were lifted from provincial drugs store Barzulla and the analysis of lifted samples declared that drug Maximizin—625 supplied to government run hospitals across the valley were found of sub standard quality. During the investigations it was found that the accused persons manufactured and distributed these drugs just to mint money, the complaint said further praying that the accused persons be dealt under law for commission of offence.
The issue evoked widespread condemnation and calls for shutdown from separatist leadership in Kashmir. Protest demonstrations were held in various parts of the valley particularly in Srinagar where doctors’ associations, members of civil society, people associated with pharmaceutical companies, chemists and traders registered their protest in strongest terms.

Spurious drug scam: CB seeks details of purchases, payments 'urgently'

*Early Times Plus, July 06, 2013*

Crime Branch of Jammu and Kashmir Police, which is investigating the infamous spurious drug scam, has sought details of purchases and payments made by various procurement agencies in the Health Department.

In its latest communication to the Directors of Health Services Kashmir and Jammu, the Deputy Superintendent of Police, Crime Branch Jammu has asked the officers to submit details of drugs and other items approved by the Purchase Committee-II headed by the DHS Jammu.

While referring to case No. 10/2013 under sections 274, 420, 465, 467, 468, 471, 120-B/RPC r/w section 5(2) P.C. Act Svt. 2006 and section 27 of Drugs and Consumables Act 1940 registered in the scam at Police Station Crime Branch Jammu, the DySP writes, "In connection with the investigation of above cited case, please intimate the details of purchases made by different units under your command in the province of all the medicines/items approved by Purchase Committee-Il vide NIT-4 of 2012 for supply of Allopathic drugs and IV fluids for the year 2012-13", adding "The details of all the payments made against the purchases on medicine in this regard may be furnished to this office at an earliest. Matter most urgent".

Earlier the Crime Branch had sought details from the Health Department regarding use of the antibiotic drug, Maximizin 625, which was earlier found to be spurious. The CB Jammu had shot a letter to DHS Kashmir asking for the original copy of agreement signed between the supplier and the purchasing officer 'as required as per the tender notice'.

The CB has also asked for details about distribution and use of the drug under scanner by the CB and the State Vigilance Commission.

However, according to sources, the Health Department has so far failed to provide the information to the Crime Branch as asked for by it through its letter No CBJ/2013/201-02 dated 10.05.2013.

"Detailed information as sought by the CB is being collected and consolidated before it could be forwarded to them. The information needs to be collected from every hospital and as such needs some time. However, a circular has been issued and the information will be forwarded soon," official sources told Early Time Plus.

Pertinently, following an outcry on the issue of supply of spurious drugs to hospitals in the State, the Jammu and Kashmir Government had ordered separate probes by
the Crime Branch and the Vigilance Department into the purchase and supply of spurious drugs in the State. Later, Chief Minister Omar Abdullah had said that the newly constituted State Vigilance Commission (SVC) would probe the spurious drug scam in Kashmir and 'whosoever is found involved in it would be brought to justice'.


Woman, son die after quack administers post expiry date drip in UP

_Deccan Herald, July 23, 2013_

It seems that patients in Uttar Pradesh are faced with a double whammy. While sweepers, ward boys and rickshaw-pullers treat them at government hospitals, quacks prey on them outside.

A woman and her son died in Bhadohi district, about 300 kilometres from here, allegedly after being administered a saline drip by a quack on Sunday night, according to reports. Reports said Phoolmani Devi had been ill for the past few months.

On Friday, her husband took her to a quack Vijay Shanker Bind, who administered drips to her saying that it would give her strength, as she was weak.

However, he withdrew the drip after the women complained of uneasiness a little later.

Bind then told Phoolmani’s son Virendra, who was also physically weak, that he would feel stronger if he were administered with the saline. However, Virendra’s condition began to worsen soon after being given the intravenous and before his family could take him elsewhere he died.

Phoolmani too died on Sunday night. It is alleged that the liquid given to the two was past its expiry date.

A case was registered against the quack that was absconding. Chief medical officer Dr Zubair Ahmed said the person who administered medication did not have any medical degree.

However, he expressed his inability to crack down on the quacks as they enjoyed political patronage. An irate mob later laid a siege to local police station demanding action against the quack and also blocked traffic on the busy Grand Trunk Road near Aurain in the district.

The death of the two comes close on the heels of two other deaths at government hospitals in Ballia and Ambedkar Nagar where a sweeper and rickshaw-puller gave the victims injections.

There are reports of deliveries being done on the rooftops of the hospitals in some districts.
A few months ago, auxiliary nurse midwives were found engaged in delivery of babies under candlelight as there was no power and the generator was out of order at a community health center in Barabanki district.

24 more drugs found fake: DAK

Greater Kashmir, August 04, 2013

Accusing several officials and politicians of being behind the supply of spurious drugs in Kashmir, Doctors Association Kashmir (DAK) Saturday revealed that 24 more drugs supplied to J&K have been found substandard by two premier drug testing laboratories of the country. Asking government to suspend and arrest those involved in the fake drug scam or be ready to face State-wide agitation after Eid-ul-Fitr, the DAK said that it is in the process of sensitizing the people about the serious issue. Addressing a press conference here, DAK President Dr Nisar ul Hassan revealed that out of 50 new drugs tested in laboratories, 24 have been found substandard. “Out of 156 samples taken from different parts of Jammu and Kashmir, 24 drugs were declared as ‘not of standard quality’ by the Government Analyst of Central Drugs Laboratory Kolkata and Regional Drug Testing Lab Chandigarh,” said Hassan. These drugs include life saving medicines. “It is shame for both State and Central Governments. I want nation to react,” Hassan appealed. He said that he was convinced that various (Government) agencies were involved in the scam. He said that he was shocked to see the drug tests report. “I don’t know how to react to it. I’m speechless. But as a doctor it is painful for me. It should not be acceptable to any human being. People have to wake up now,” said Hassan. He said that death of 500 children in GB Pant Hospital didn’t occur because of negligence of doctors, but due to spurious drugs. He said that not only drugs supplied to government hospitals are spurious but also samples collected from private chemist shops have been found substandard. Giving details about the new drugs found spurious, he said: “The drugs include Dicloflam injection, Inj Amoxicillin and Potassium Clavulenate, Zexpoxin, Traxol, Boitocin, Dexamethasone, P-Min10%, Metonorm (Metclopramide Injection IP), Pheiramine Maleate Injectin IP, Diclofenac Sodium Injection, Metonorm (Metoclopramide Injection IP), Bolecef 250 Injection, Metonorm (metoclopramide Injection IP), Cefotaxime Sodium Injection IP 500 gm, Pheiramine Laleate Injection IP, Curfcef 1000 Injection, Cureclox (Amoxycillin Dicloxacillin Capsules), Levecetirizine Dihydrochloride Tablets IP 5mg (Levitrax), Cefpodoxime Proxetil Tablets IP (Cefdom-p), Calcium Carbonate tablets (Marycal 500), Ofloxacin Tablets IP (ONOFBACT-200), Nirofuratone Tab IP and Clonazepam 1mg IP.” “Two drugs collected from SKIMS have also been found substandard,” he informed. The doctor said that the report was prepared by Central Drugs Controller Organization and sent to State vide its letter number JSZ/SDC/Sample Report/2013/700, adding, “The samples were taken randomly from various hospitals in Pulwama, Pampore, Baramulla, Doda, Bhaiderwah and Srinagar.” “The fake drug scam is government sponsored, making police helpless to arrest those who have been charge sheeted in the crime,” he said, reiterating the demand to set up an independent commission to ascertain facts, suspend and arrest
those involved in the scam. Hassan asked the Government to ‘adopt any other way of corruption to earn crores than supplying spurious drugs at the risk of human lives.’ The DAK president said: “Those involved in the scam include high-ups and politicians. But they are not being suspended and arrested because they have the cover of politicians who know that once accused are arrested, they (politicians) would be exposed.” He said that he had written a letter to UPA Chairperson Sonia Gandhi asking federal government’s intervention in fake drug scam to punish the guilty as the matter involves human lives. “But I didn’t receive any response till date.” Hassan said that he had also sent a documented proof to Chief Minister Omar Abdullah against the involved persons. “But the CM gave clean chit to (former Health Minister) Sham Lal Sharma claiming that no evidence is available against him.” Reiterating DAK’s commitment to carry on its fight against spurious drugs, he said: “Government had plans to put me behind bars for a long time but I’m thankful to media who pressurized government for my release. Our fight against fake drugs will continue to unveil the culprits. And truth shall prevail.” The fake drug scam surfaced several months ago as many medicines supplied to Kashmir were found sub-standard, raising public outcry. The DAK president was arrested as he had announced plans to protest on the visit of prime minister to Srinagar on June 25.

❖ Manufacturer of fake oxytocin held
*The Times of India, August 14, 2013*

The Babupurwa police seized a sack full of oxytocin injections from Naubasta area and arrested a man, Brijesh Pal, for illegally manufacturing and supplying oxytocin, on Tuesday. Around 700 injections of 100 ml and 60 ml were recovered from his possession. Brijesh used to illegally manufacture the drug in a room in Naubasta area.

Oxytocin is a schedule H-drug which means that it cannot be bought or sold without prescription. It is specifically banned under the Prevention of Cruelty to Animals Act, 1960 and Section 12 of and the Foods and Drug Adulteration Prevention Act, 1960. Many dairies use it illegally.

During routine checking, the police traced Brijesh, who was carrying a sack full of injections on his bike. On being interrogated, the accused initially said that he was going to supply the drug to medical stores but later accepted that he was supplying oxytocin to dairy owners in Babupurwa.

The police also raided the location of manufacturing the drug revealed by the accused and recovered another sack of oxytocin injections along with chemicals used for making oxytocin and packing material from the room.

"Brijesh was in the illegal business of oxytocin since several years. He belongs to Juhi area of the city and has an illegal factory of oxytocin injections in Naubasta. We also traced several primary packing material and empty bottles from his factory. Around 700 injections were traced from the spot as well," said Kamal Yadav, SO,
Babupurwa. The police also called the officials of Food and Drug Department (FDA) to take the samples of the injections and chemicals. "The dairy owners use oxytocin injection twice a day to extract milk from buffaloes," said AK Jain, FDA inspector. The officials said oxytocin leads to abandonment of calves and selling them to abattoir for money minting. For the crime, the offenders can be booked under the Prevention of Cow Slaughter Acts, besides getting punishment under the Prevention of Cruelty to Animals Act.

Fake drug trafficking case: CID to reveal more details

The Times of India, August 23, 2013

After the fake encounter cases, this is one case that may cause embarrassment to the Gujarat police. Seven years after Vadodara cops and two businessmen tried to implicate Prakash Pillai in a fake drug trafficking case, more skeletons may tumble out of the cupboard. The CID (crime) has begun fresh investigations in the case and has named two more retired cops in its remand application to a local court.

The accused had planned to put Pillai behind the bars for 20 years by accusing him of being a drug trafficker. But Pillai fought back and turned the case on its head. He not just proved that the case made against him was false, but also ensured that the cops and businessmen who tried to implicate him were put behind the bars. Two police inspectors K V Vahoniya and R M Rathod and businessmen Krishna and Govind Somani were arrested in the case.

What has surprised the CID (crime) officials currently investigating the case is that Govind and Krishna registered a fake drug trafficking case against Pillai in Madhya Pradesh (MP) as well.

"It is a rare crime wherein the cops have been involved in planting drugs in someone's residence. Some of the accused even tried to implicate Pillai again by dragging his name in another fake drug trafficking case in Madhya Pradesh in 2007. The idea was to prove that Pillai was a drug peddler," DIG, CID (crime), R J Savani said.

"The Vadodara cops had flouted all rules while raiding Pillai's house in 2006. One of the police inspectors reached Pillai's residence, which was not under his jurisdiction. Further investigations may show involvement of more cops," Savani added.

After being arrested in April 2006, Pillai had to spend some months in jail. He then filed a complaint on CM online and approached senior police officials. The case was then transferred to CID (crime) that arrested Krishna Somani and the two cops. Later it surfaced that Pillai was framed and he was also made complainant in the case.

According to Pillai, Krishna was to pay few crores rupees to a steel company and the former was playing the role of mediator. When Pillai pressurized Krishna to pay up the money, Krishna decided to frame him in a false narcotics case with the help of Rathod and Vahoniya, who died in Vadodara Central Jail in 2011.
Cracking down on spurious medicines

*DNA India, August 24, 2013*

In a global sting operation targeting the spurious medicine trade, the Interpol has seized 98 lakh doses of spurious medicines so far this year. The operation led to the shutdown of more than 9,600 fake online pharmacies and dozens of arrests across the globe. Information such as this was among the case developments disclosed at the national training workshop on ‘Secured Medicines and Robust Pharmacovigilance’, organised by the Partnership for Safe Medicines (PSM) India Initiative on Friday in the city. “Spurious medicines pose a global and borderless threat and can impact any consumer regardless of age, income or geographic location. We must protect patients by educating them on the importance of choosing safe medicines,” said Scott LaGanga, executive director of PSM. Bejon Misra, trustee of the Consumer Online Foundation and founder of PSM India Initiative, said that though there are a lot of mechanisms to ensure safe medicines for consumers in India, a lot of work remains to be done. “India now serves as a model for other countries working to ensure safe medicines for consumers. However, work remains to be done and we must continue to share ideas that will only help us achieve our shared goals,” he said.

Tamil Nadu blacklists 24 substandard drugs, devices

*The Times of India, August 29, 2013*

The Tamil Nadu Medical Services Corporation has blacklisted 24 brands of drugs and medical devices in the last eight months after tests found them to be substandard.

The blacklisted products include contaminated needles, and syringes poor medicines such as aspirin, antibiotics and vitamins. The government will not buy from these blacklisted manufacturers for two years. Doctors said many of these medicines could cause severe side effects including drug resistance or death.

The state-run TNMSC buys and distributes drugs to all government hospitals. Most companies that supply drugs to the corporation make generic drugs at cheaper prices. It is mandatory for TNMSC to check every batch supplied. "Samples are drawn from different warehouses and sent for tests. It is released for distribution only if the lab approves the drug. We also do periodic checks later to ensure the drug holds its strength till the date of expiry," said a senior health official.

Yet on many occasions, substandard and spurious drugs have found their way to the government pharmacies. In 2010, samples from at least six batches of povidone-iodine solution - a disinfectant used in emergency rooms and operation theatres - were found to be 'not of standard quality' by the government analyst attached to the state directorate of drugs control. Two samples showed no trace of the active ingredients of the solution. "It increased infection risks inside the operation theatre and among patients in the recovery room," said a senior ophthalmologist at the
Government Institute of Ophthalmology.

Since 2009, the TNMSC has blacklisted 64 products for various reasons including "not of standard quality", "poor performance" and "non-execution of purchase order". This year, the process was intensified. One-third of products were blacklisted in the last six months. "We can't say there is an increase in quantity of substandard drugs. It is probably because we have intensified our testing. In fact, these are not dangerous or spurious drugs, they just didn't meet standards," said a senior official at the TNMSC.

Experts in the field of pharmacology said substandard drug is as bad as spurious medicine. Former director of drugs control Dr M Bhaskaran said, "A substandard drug is the result of shoddy manufacturing. Drug inspectors have the power to close down units that don't have good manufacturing practices. But it is rarely done," he said.NGOs like Pharmacare Foundation have urged the government to speed up cases filed against individuals and companies who have been booked for cases under the Drugs Act. "Three years ago, the drug department booked cases against several people for relabeling expired drugs and reintroducing them into the supply chain. Some of those who were booked are back in business," said Srinivasan R, who heads Pharmacare.

FDA sting traps makers of ‘bogus’ drug

*Mumbai Mirror, September 02, 2013*

After trying in vain for days to locate the distributors of a bogus ‘de-addiction powder’ advertised on TV, Food and Drug Administration (FDA) commissioner Mahesh Zagade decided there was only one way to nab them – order a batch of the product himself. Zadage carried out his ‘sting’ last week, following which FDA officials seized a consignment of the “spurious” product worth Rs 12 lakh.

According to an FDA official, the product, called ‘No Addiction’, is marketed as an effective ayurvedic medicine for alcoholics. Each packet of No Addiction contains three bottles and is priced at Rs 2,999.

Manufactured by Sanjivani Drugs in Haryana, it claims to contain over 20 ayurvedic ingredients that help alcoholics quit the habit gradually. Officials clarified, however, that the powder merely triggers a vomiting sensation to deter alcoholics from reaching for a drink. The advertisement says that the powder can be added to the addict’s food or water twice a day.

Actor Anuj Soni is the products brand ambassador, and features in infomercials in which viewers are encouraged to call a number to order the product. “As the telephone number flashed on the screen was the only way to reach them, our commissioner decided to call and order the product under a fake name,” said drug inspector V Singhvi.

FDA officials are now issuing notices to the manufacturer, distributors and actors who promoted the product. For his sting, Zagade asked that the packet be delivered
near the MHADA officer in Bandra-Kurla Complex, a few metres away from the FDA’s head office. On August 28, when the delivery boy reached the spot, Singhvi and two other drug inspectors – Parvin Pawar and Pramod Yasatwar – collected the package and revealed their identity.

The delivery boy led the officials to the distributor in Goregaon West, where they seized powder worth Rs 12 lakh under the sections of Drug and Magic Remedies (Objectionable Advertisements) Act, 1955. “None of the seized packets have a drug licence number printed on them. If the manufactures do not have a drug license, it simply means that the drug is being manufactured without permission and without following any standards,” explained Singhvi. He said that while the Drug and Magic Remedies Act attracts a maximum punishment of six months’ imprisonment, or a fine, or both, manufacturing a drug without a licence can lead to a year’s imprisonment under the Drug and Cosmetics Act.

While the samples of the powder have been sent for testing, FDA officials fear that it could contain a dangerous pesticide called disulfiram. “We had seized a similar powder from a doctor based in Chembur and tests revealed that it contained disulfiram,” said Singhvi, adding that the No Addiction powder looks and feels similar.

Mirror contacted Sanjivani Drugs for comment, but the firm’s spokesperson refused to speak about the issue.

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- **Four Indian drug companies blacklisted**

  *Daily News, September 16, 2013*

Four Indian generic pharmaceutical firms have been banned and blacklisted in Sri Lanka for selling substandard drugs on the direction of Health Minister Maithripala Sirisena. The minister decided to ban drug imports from four Indian companies after health authorities discovered substandard medicines in their shipments.

Indian drug companies, Laborate Pharma, Vivek Pharma, Bafna Pharmaceuticals and Elysium Pharmaceuticals have been banned from supplying poor quality and unsafe medicine to Sri Lanka continuously, Health Ministry sources said.

Minister Sirisena also instructed health authorities to stop purchasing drugs from these companies with immediate effect and to take action to claim the money the Health Ministry had paid them to purchase their drugs, and to lobby for compensation from the drug companies and file legal action against their dealers in Sri Lanka, the sources said.

According to National Medicinal Drug Regulatory Authority sources, these companies have supplied substandard pharmaceutical products to the country over the last four years.

Cosmetics, Devices & Drugs Regulatory Authority Deputy Director General Dr. Hemantha Benaragama said poor manufacturing, distribution and business practices
followed by these pharmaceutical companies have led to a situation of people being exposed to some 122 ineffective, defective, fake and substandard drug items this year alone.

Dr. Benaragama said of the substandard drug items supplied by them, Laborate Pharma had supplied 18 drug types, Bafna Pharmaceuticals 84, Vivek Pharma five and Elysium Pharmaceuticals five types.

Meanwhile, the Ministry of Health, as an alternative program to meet the demand of medicine after the ban on medicines supplied by the four companies, will purchase medicine from Bangladesh under the Sri Lanka-Bangladesh Government to Government Drug Purchasing program, CDDRA sources said.

India-made anti-malaria drug banned in Ghana

_Zee News, September 29, 2013_

The distribution of Gsunate Plus, an anti-malaria drug for children, said to be imported into Ghana from India where it is manufactured by Bliss GVS, has been banned by the Food and Drugs Authority (FDA).

Investigations by the FDA has revealed that "no clinical trial study had been conducted on the product which is made up of the combination of Artesunate 25 mg and Amodiaquine 75 mg and manufactured by Bliss GVS Pharma Limited, located at 10 Dewan Udyog, Nagar, Aliyali Palghar, Maharashtra - 400404, India."

The Pharmaceutical Export Promotion Council of India has been approached by IANS to ascertain the authenticity of the manufacturer's address and whether it is registered in India, but no response has been received even after a week.

The FDA claimed the product has not been approved, neither registered nor approved by the pharmaceutical regulatory authority in India for sale or use.

"The efficacy of the combination of Artesunate and Amodiaquine through the rectal route has not been established, and therefore treatment of malaria in children with this drug could lead to therapeutic failures and complications," FDA chief executive Stephen Opuni said.

The FDA has, accordingly, ordered "hospitals, clinics, pharmacies, licensed chemical sellers and other health facilities with stocks of Gsunate Plus Suppository to immediately stop dispensing them and hand over stocks to the FDA offices countrywide for safe disposal."

This ban comes in the wake of allegations of manufacture and exports of fake as well as counterfeit drugs against India's pharmaceutical companies. In March, India's Commerce Minister Anand Sharma expressed support for the industry and said the allegations were part of calculated attempts to destroy the country's march to produce affordable medicines.

Sharma said "Indian generics have changed the face of health" around the globe
because of their affordability. Unfortunately, since Indian companies introduced generic medicines to fight drug resistant malaria on the market at cheaper costs, they have been inundated with several allegations of wrongdoing.

"This is all due to the fact that these companies have broken the back of the cartels that control global medicines," Sharma added.

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**Illegally operating drug factory sealed**

*The Times of India, October 01, 2013*

The drug controlling authority of Himachal Pradesh raided a pharmaceutical unit in Sirmaur district and found out that illegally manufactured drugs were being supplied to government hospitals of Chhattisgarh, Tripura and Uttar Pradesh. Following the raid, the authority sounded national alert to alert other state governments. A couple from Ambala in Haryana who were running the unit were booked by police on Sunday night.

The raid carried out at Vardhman Pharmaceutical in Kala Amb area started on Saturday morning and continued till late Sunday. 700 boxes of spurious drugs were seized and the illegally running factory was also sealed. According to sources, Vardhman Pharmaceuticals had started operation from the industrial area of Kala Amb on December 24, 2004 after obtaining a license to manufacture drugs. The license was never renewed after 2009 but production continued without informing the authorities concerned.

Based on a complaint lodged by the Drug Controlling Authority, a case was registered by police against M C Jain and his wife Meenakshi Jain. The company was in the name of Meenakshi Jain while M C Jain was having its power of attorney, officials added.

Himachal Pradesh Drug Controller Navneet Marwaha said that 700 boxes of injections, tablets, capsules and syrups were seized from the unit that was closed on record since 2009. Marwaha said few days back they got information about some clandestine activity taking place in this unit after which the unit was kept under surveillance with the help of police. He said the main gate of the unit used to remain closed and was being opened only for few hours during the day while production work was being done during night.

"We raided the premises on Saturday morning and found the unit functioning. Drugs, mostly antibiotics which comes under lifesaving drugs category, were being manufactured by around 30-32 people," he said.

The Ambala couple was also running a dairy and raids conducted by Haryana Drug Controller also resulted in recovery of some more drugs.

Himachal Pradesh caters to around 40 to 50% drug demand of the country. Last year, the drug controlling authority had suspended the license of seven manufacturing units after drugs manufactured by them failed quality test.
Tobinco Admits To Fake Drugs Imported To Ghana

*Ghana News, Oct 01, 2013*

The Executive Chairman of Tobinco Pharmaceuticals Ltd and the Director of Bliss GVS Pharma, distributors of anti-malaria suppository, Gsunate Plus, have been invited by the Bureau of National Investigations to assist the Food and Drugs Authority (FDA) in investigations over alleged importation of fake drugs.

A statement issued by the FDA said the Chairman of Tobinco Pharmaceuticals Ltd, Mr Samuel Tobbin and the Director of Bliss GVS Pharmam, Mr S. N Kamath have admitted to importing and distributing fake anti-malaria drugs and apologised to the FDA for engaging in the act.

It said, the two were made to sign an undertaking dated September 26, 2013, not to import or distribute unregistered or fake medicines onto the Ghanaian market.

The statement said Mr Kamath in a letter to the FDA confessed to that the Gsunate Plus suppository was fake and that no clinical trial study had been conducted on it, and admitted that the drug was not used to treat Malaria in children in India although malaria was prevalent in that country.

The FDA over the past two weeks have seized over 100 medicines imported and distributed by Tobinco Pharmaceuticals Ltd.

Out of the number, only seven (7) have duly been given approval by the FDA. The approved medicines are; Nifin 20-R Tablets, Slipizem 2.5mg Suppository, Slipizem 5mg Suppository, Lonart tablets, Lonart Forte Tablets, Lonart Oral Suspension and Ciprotab Tablets.

Apart from the approved list of medicines, the FDA is cautioning the general public not to patronise any other medicines from Tobinco Pharmaceuticals Ltd and Bliss GVS Pharma-India, since their efficacy, safety and quality cannot be guaranteed.

FDA cautions public against purchasing drugs from Tobinco

*www.Ghanaweb.com, October 02, 2013*

The Food and Drugs Authority (FDA) has cautioned the public against buying medicines from Tobinco Pharmaceuticals Limited and their supplier, Bliss GVS Pharmaceuticals, an Indian company, since there are doubts about the efficacy, safety and quality of some of the drugs from the two companies. The warning follows a revelation that out of over 100 medicines imported and distributed by Tobinco, only seven had been approved by the FDA. Tobinco and Bliss GVS have both written to apologize for the incident. They have also pledged, in two separate letters, against a recurrence of the unfortunate incident. The letters, both dated September 26, 2013, was addressed to Dr. Stephen Opuni, Chief Executive of the FDA shortly after the Bureau of National Investigation (BNI) picked up the heads of the two companies for questioning over circumstances surrounding the importation
of the drugs. A press statement signed by the FDA boss, Dr. Opuni, admitted the receipt of the two separate letters from the chairman of Tobinco, Mr. Samuel Tobbin and the Managing Director of Bliss GVS Pharmaceuticals of India, Mr. Shibroar Kamath, adding that the two companies would be assisting with investigations. One of the fake drugs, Gsunate Plus, was imported into Ghana by Tobinco Pharmaceuticals Ltd, and it is purported to be for the treatment of malaria in children by administration through the anus. However, samples of the drug were found to be fake after tests were conducted on them by the FDA. The FDA have, however, revealed that drugs from Tobinco such as Nifin 20-R Tablets, Slipizem 2.5mg Suppository, Slipizem 5mg Suppository, Lonart tablets, Lonart Forte Tablets Lonart Oral Suspension and Ciprotab Tablets, have been approved and hence could be purchased.

- **Ghana Food and Drugs agency pulls alarm over counterfeit baby drugs**
  *The African Report, October 03, 2013*

Ghana’s Food and Drugs Authority has warned consumers that counterfeit anti-malarial drugs for children are being sold in the country.

Tobinco Pharmaceuticals and Indian pharmaceutical medicine exporter Bliss GVS Pharma are being investigated by the country’s Bureau of National Investigations following the importation and distribution of unregistered drugs.

The anti-malarial drug that triggered the investigation, GSUNATE Plus Suppository, had not been clinically tested in India before being exported and sold in hospitals and medical stores across Ghana.

In a statement, FDA said the combination of two of the drug’s ingredients, artesunate and amodiaquine, had not been tested together and their effectiveness is unproven such that “treatment of malaria in children with this drug could lead to therapeutic failures with complications."

The FDA made the discovery in the middle of September and recalled the drug.

It has since seized over 100 types of drugs from Tobinco Pharmaceuticals, of which only seven had been approved by the FDA.

Managing director of Bliss GVS Pharma, Shibroor N. Kamath, has since arrived in Ghana, joining Samuel Amo Tobin, chairman of Tobinco to assist the BNI in its investigations.

"The problem is that the FDA believe they shouldn't have to find out how the medicines are procured and manufactured," says Franklin Cudjoe, head of the policy think tank, IMANI.

"The only way to sort this is to have co-regulation with manufacturers and regulators of drugs from their countries of origin."

Cudjoe said the authority should employ the necessary technologies to avoid
counterfeit medicines coming onto the market. Such technologies have been developed by the m-Pedigree network. The platform allows consumers to check the authenticity of medicines by sending a text message to m-Pedigree with the product's code. The network will then send a response advising whether or not the drug is fake. Tobinco says it has paid a fine to the FDA for "issues surrounding medicine registration." The company has since been banned from importing drugs. Bliss GVS Pharma have yet to be reprimanded for the untested GSUNATE Plus Suppository drug. Although the drugs were found last month, it is not yet known for how long they were in the system.

DAK continues to gun for Sharma's head

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**Indian pharma company in dock over fake medicines in Ghana**

_The Economic Times, October 03, 2013_

Indian drugmakers continue to find themselves on the wrong side of global regulators, with the latest being Maharashtra-based Bliss GVS Pharma which has been alleged by African nation Ghana's health watchdog to be supplying "fake" medicines in the country.

Food and Drug Authority Ghana said in a statement that officials of Bliss GVS Pharma of India and Ghanaian drug maker Tobinco Pharmaceuticals have apologised to it for importing 'fake malaria medicine' to Ghana to treat malaria in children.

In recent months, some Indian drugmakers have received warning letters from global regulators, including from the US, for issues related to manufacturing norm violations.

"Tobinco Pharmaceuticals had imported into Ghana a fake antimalarial medicine for children called GSUNATE Plus, a suppository which is manufactured in India by Bliss GVS Pharma," FDA Ghana said.

"The director of Bliss GVS Pharma confessed to the FDA that GSUNATE Plus suppository is fake and that no clinical trial study has been conducted on it and also admitted that it is not used to treat Malaria in children in India although malaria is prevalent in India," the regulator said.

FDA has seized the face medicine for destruction, it said, while cautioning the general public not to use any medicines, other than seven approved by FDA, from Tobinco and Bliss GVS Pharma-India, "since their efficacy, safety and quality cannot be guaranteed".

The regulator further said that Tobinco and Bliss GVS Pharma have given an
undertaking "not to import or distribute unregistered or fake medicines into the Ghanaian market".

The FDA said it has seized and destroyed large consignments of unregistered medicines from various regional medical stores and hospitals in the country.

Bliss Gvs Pharma was incorporated in 1984 as a public limited company and its shares are listed on the BSE and NSE in India.

**Calls For Protests On Sunday; Says 20 More Drugs Found Sub-Standard**

*Greater Kashmir, October 04, 2013*

Demanding sacking of former Minister for Health, Sham Lal Sharma, for his alleged involvement in fake drug scam, Doctors Association Kashmir (DAK) President Dr Nisar ul Hassan Thursday said the Association would hold protest demonstrations on Sunday in support of their demand. He said that 20 more drugs have been found of sub-standard quality. Addressing media persons here, he said: “Supply of fake drugs to government hospitals in the Valley is the conspiracy of government of India to kill people here. First it used bullets and now it is supplying fake drugs for genocide here.” Terming the attitude of government unfortunate in handling the fake drug scam, he said: “Chief Minister Omar Abdullah gave a clean chit to Sharma in fake drug scam. Police exonerated him. We talked to Sharma’s party chief and next day he shared dice with him.” He said that Union and State governments are intentionally shielding the culprits involved in the scam. He said: “Minister for Home Mr Kichloo can be sacked on the demand of BJP within seconds but lives of Kashmiris are so cheap for India that it provides shield to culprits of the scam.” He said that government is adopting double standards in punishing criminals. “When it comes to genocide in Kashmir, Ministers and officials are covered by government. But when it happens in any other State, Union Ministers are not spared and are sacked on minor allegations of corruption.” He said the time has come when people here have to evolve as a nation. He said: “We are slaves and slaves have no rights. The time has come when people have to come on streets to struggle for freedom. Development and progress should be our second priority. Let us get together first to attain freedom.” He said that demands of JCC are genuine and justifiable, adding, “But I urge its leadership to come on streets for national cause first and then for personal welfare. Let them join their voices with us for freedom.” Threatening to hold massive protest demonstrations at Lal Chowk on Sunday evening, he said: “We demand immediate sacking of Sham Lal Sharma for his involvement in fake drug scam by Sunday and arrest of other culprits involved in it. We demand their arrest and punishment. If he is not sacked by Sunday, we’ll hold protest demonstrations at Lal Chowk and appeal other organizations to join us in the interest of society at large.” He said the only remedy to stop fake drug supply is to punish the guilty. He said that more 20 drugs have been found of sub-standard quality. The drugs include: Ceftriaxone injection batch number 6421, Ceftriaxone injection batch number CFIJ13003, Ceftriaxone injection batch number CFIJ13002, Amoxycillin and Potassium Clavulanate injection, Hydrocort 100, Dynacil 500, Pantoprazole Sodium,
Vidan (Povidone-Iodine ointment USP), Vidin (Povidone Iodine), Vidin ointment.

- Ghana drug regulator blacklists Indian firm
  *The Economic Times, October 06, 2013*

Under fire for supplying fake medicines, Indian pharmaceutical firm Bliss GVS Pharma has been banned by Ghana's health watchdog from importing and distributing medicinal products to the African nation.

The Maharashtra-based company was found to be selling fake and unregistered malaria drugs in Ghana, along with a local company named Tobinco Pharmaceuticals.

"The Food and Drugs Authority (FDA)... has with immediate effect banned the importation and distribution of all medicinal products manufactured by Bliss GVS Pharma Limited," FDA Ghana Chief Executive Stephen K Opuni said in a statement.

The African nation watchdog, which regulates the over USD 300 million country's drug market, said the step has been taken as a result of the manufacture and distribution of medicinal products by Bliss GVS Pharma into the country without adherence to the registration requirements.

Top officials of Bliss GVS Pharma of India and Ghanaian drug maker Tobinco have apologised to it for importing 'fake malaria medicine' to Ghana to treat malaria in children, according to Ghana's Food and Drug Administration (FDA).

"The company manufactured a fake antimalarial medicine (Gsunate Plus Suppositories) which was imported into the Ghanaian market. The efficacy and safety of this antimalarial medicine has not been ascertained since there has not been any clinical trial study to justify the use of this medicinal product for the treatment of Malaria," Opuni said.

Bliss GVS Pharma has not registered this drug in the country of origin (India) even though malaria is prevalent in India and the manufacturer is therefore without the requisite regulatory authorization using Ghanaian children as "clinical trial subjects," he added.

In recent months, some Indian drug makers have received warning letters from global regulators, including from the US, for issues related to manufacturing norm violations.

The Rs 400-crore Bliss GVS Pharma was incorporated in 1984 as a public limited company and its shares are listed on the BSE and NSE in India.
STATE security organs and the International Police (INTERPOL) have conducted a massive operation to seize substandard and counterfeit drugs in the country as recent statistics show that 80 per cent of malaria patients die after consuming substandard and fake anti-malarial medication.

The Director of Criminal Investigations (DCI), Mr Robert Manumba, said that the campaign christened 'Operation Giboia' which was conducted in nine regions between October 1 and 3, have seized 273 different types of drugs traded illegally in the local market.

Apart from Tanzania, similar operations were also conducted in South Africa, Angola, Malawi, Mozambique, Swaziland and Zambia as part of a campaign launched five years ago to apprehend and intercept the movement of substandard drugs in the region.

But according to DCI Manumba, the recent operation was a huge one showing rampant movement of illegal medicines in Dar es Salaam, Mwanza, Shinyanga, Mara, Geita, Mbeya, Arusha and Dodoma.

"During the operation we discovered two types of counterfeit medicines called Asdoxin manufactured by Astra Lifecare(India) Pvt Ltd of India and Penizin-V with particulars showing it was manufactured by Zenufa Laboratories of Tanzania," he said.

He said that an operation which involved the Police Force, the Intelligence Unit and the INTERPOL, Tanzania Food and Drug Authority (TFDA) in collaboration with other local authorities seized 76 types of expired drugs, 28 types of government drugs and 86 types of unregistered drugs.

Also in the list were 40 types of substandard drugs including anti-malarials and antibiotics while 41 types of drugs were already de-registered in the TFDA inventory list.

All the drugs were worth 49.6m/-.. Nineteen other types feared counterfeit according to the DCI are still undergoing lab tests and their status will be communicated to the public as soon as lab results are out.

Following the outcome of the operation, the DCI said already 42 charges have been filed at the Police stations and investigations launched is seeking to bring suspects behind bars.

"If convicted apart from being jailed and fined, the culprits might have their business licenses revoked, professional licenses cancelled and all seized inferior drugs disposed of," he insisted.

Such operations, he said, have awakened the Police Force and intelligence organs on how they have to effectively investigate criminals behind the drug scams as evidence shows they are using advanced technologies and techniques.

He called on the public to continue extending maximum cooperation with security
organs and relevant authorities, otherwise it will be extremely difficult to realise any meaningful impact in the battle against the crime.

On his part, the TFDA Director General, Mr Hiitl Sillo, said that drugs increasingly traded illegally include ARVs, Anti-biotics, Viagra, anti-malarias and anti-pains. He called on people to be careful when buying them.

Ambala couple wanted in spurious drug making case still at large

*Hindustan Times, October 12, 2013*

The kingpin in the spurious and substandard drug manufacturing case are still at large. The Kala Amb police had lodged a case under the Drug and Cosmetics Act on September 29, but the police have failed to trace them since then.

During the interim bail of the two accused, which was rejected on October 9, one of the main accused, Meenakshi Jain, had joined the investigations, but after October 9, the whereabouts of Meenakshi was not known to the police.

However, Meenakshi's husband MC Jain did not even join the investigation.

Based on the complaint lodged by the drug controlling authority, a case was registered against the Jain couple. The pharma company - Vardhman Pharmaceutical - was in the name of Meenakshi Jain, while MC Jain had the power of attorney.

The police are yet to confirm that the illegal factory was supplying drugs to some other states or not. The unit was raided on September 28, which continued till September 29 night. During the raid, 700 boxes of spurious drugs were seized and the illegally operational factory was sealed.

The Ambala-based Jain couple was also running a dairy at Ambala. Raids conducted by the Haryana drug controller resulted in recovery of some more drugs.

Assistant superintendent of police (ASP) Swapana, who is looking after the affairs of the Kala Amb police station, said it seemed that the couple had went underground. She added that efforts were on to nab the accused in the case.

650 bottles of fake cough syrup seized, four held

*The Times of India, October 14, 2013*

In a major breakthrough, sleuths of Railway Protection Force (RPF) on Sunday confiscated around 650 bottles of fake cough syrup from Allahabad railway junction.

The consignment was to be delivered to West Bengal. The police also arrested four key operators of the racket from Allahabad railway junction premises.

The arrested persons were identified as Rakesh Sharma, a resident of Kareli, Allahabad, and Malda residents Salim, Obaid-ul-Haque and Inam-ul-Haque. Four
general class railway tickets were recovered from their possession.

During routine checking on platform number 6 of Allahabad railway junction, RPF personnel found six large bags kept on the platform. On probing, they found around 650 bottles of counterfeit cough syrup in the bags.

They subsequently seized the consignment and the four persons who were carrying it.

On interrogation, the arrested persons revealed that they used to supply the cough syrup bottles to rural areas in Malda.

Talking to TOI, RPF inspector Anand Kumar said a sample of the cough syrup has been send to the drug inspector for testing. A case has been lodged against the accused.

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**Major pharmaceutical firm under scrutiny for producing spurious drugs**

*CNN-IBN, October 17, 2013*

Fake drugs are one of India's worst kept secrets. Almost 45 per cent of drugs distributed in the country are manufactured in Himachal Pradesh and a major company based in the state, Vardhaman Pharmaceuticals, is under scrutiny for producing and distributing spurious drugs across the country. Filthy machines prepare spurious drugs at the medical factory which then go on to supply them to the central government, Tripura, Chhattisgarh and UP governments. After the Tripura government sounded an alert, Vardhaman Pharmaceuticals in Nahan, Himachal Pradesh, was put under surveillance by the state's drug control authorities. Close to 700 cartons containing 40 different types of 'medicines' were recovered from the factory during raids, including injections for meant for children and animals. Nineteen samples have now been sent for testing. "These are all fake medicines being made in dirty conditions without license. We have issued a warning to all states through Drug Controller General of India," said Navneet Marwah, drug controller, Himachal Pradesh. Vardhaman Pharmaceuticals' licence lapsed in 2009, but the factory continued manufacturing fake drugs and labeling them with government supply stickers. Employing 30 to 32 workers, the factory functioned only during the night to avoid detection. Its operations stretched to Haryana, where raw materials used to manufacture the drugs were found lying beside animal fodder at an unused dairy in Ambala. Various cases have been registered but the well connected owners of the factory and MC Jain and his wife are now absconding. For a state that relies on medicine manufacturing units for substantial revenue, the stakes are high to curb the fake drug industry. However, without co-operation and support from other states it is going to be an uphill task even as the police wait to question the owner couple of the factory supplying fake drugs to several state governments.
Spurious drugs case: Hue and cry notice issued to Ambala couple
Hindustan Times, October 24, 2013

The Kala Amb Police have issued a hue and cry notice to Ambala-based Jain couple, owner of Vardhman Pharmaceutical Private Limited.

The duo is wanted in the case of production of spurious drugs and production without licence. Sources said the police were also trying to get their passport numbers so that a look-out notice could also be issued against them.

The main accused, Meenkashi Jain, had joined the police investigation on October 9, but since then her whereabouts could not be ascertained, whereas MC Jain has been absconding since September 29. The police had lodged a case against the couple on September 29 under different sections of the Drugs and Cosmetics Act. The couple was also running a dairy at Ambala.

According to information, the police have also written to UP and Tripura as it was suspected that the fake drug firm was supplying medicines to the government, but the states are yet to file their reply.

In the notice, an alert has been sent to neighboring states about the suspected hideouts of the couple.

In common law, a hue and cry is a process by which bystanders are summoned to assist in the apprehension of a criminal who has been witnessed in the act of committing a crime.

Sources added that the couple got ample time to flee. Such notice is issued in a rare case.

Assistant superintendent of police Swapna, who is looking after the affairs of the Kala Amb police station, confirmed that the hue and cry notice has been issued against the Jain couple. Regarding the lookout notice, she said some information such as passport numbers of the accused were needed for it. “We are collecting more information about the absconding couple,” she added.
Despite a crackdown by the Food and Drug Monitoring Agency (BPOM) on online pharmacies selling illegal and counterfeit drugs, consumers say it will not stop them from buying the products over the Internet. Most online shoppers looking for supplements, cosmetics and sexual enhancement pills said that buying the items over the Internet provided them with convenience and anonymity. A 25-year-old female private company employee said she would continue buying slimming pills from klinikion.com. She said a friend had recommended the pills to her and she was satisfied with the product. “I’m a young female and I want to look good. I don’t know whether the product is original, but I am quite sure it is,” she said, requesting anonymity. The website also provides other services, such as consultations with a health expert via Yahoo Messenger or BlackBerry Messenger. Dwi Ariyansah, 21, said he would unlikely heed the BPOM warning against buying drugs from online pharmacies. He said he would continue buying protein supplements from an online seller that advertised on a Facebook page as SuplemenFitnessIndonesia. “I don’t know whether the supplement I use is counterfeit or not, but I don’t feel any bad effects. Besides, I really want to work on my body,” he said. Dwi said buying supplements online was the only way for him to source products as decent pharmacies were not common in his area, Lubuklinggau regency, South Sumatra. “If it was available here and the price was about the same or even less, I would definitely buy it at a local pharmacy,” he said. Another online shopper, Desy Kencanawati, 25, who likes Japanese and Korean beauty products, said she would continue shopping online at her favorite shopping destination www.qoo10.co.id as it was not included on the list of 129 websites shut down by the BPOM for selling counterfeit drugs or beauty products. “I’m pretty sure that the beauty products I use, such as Etude, Shara-Shara and Wakilala, are safe and original. I actively engage in discussions on several blogs that review products and I never see bad comments about these products,” she said. Desy, who is a graduate student living in Yogyakarta, added that most products she bought were not widely available in the country, particularly in Yogyakarta. She said that buying online enabled her to thoroughly review products and move from one store to another. “I don’t like being asked a lot of questions by shopkeepers, like ‘what do you want to buy?’, ‘which one do you like?’, ‘what about this one?’, because in many cases, I just want to window shop. On the Internet, I can do that freely,” she said. In the recent Operation Pangea VI, in six major provinces across the country, BPOM identified 129 websites and 20 stores selling or producing 721 types of counterfeit drugs, supplements or beauty products in a market worth Rp 5.59 billion (US$485,184). In collaboration with the Communication and Technology Ministry (Menkominfo), the agency decided to shut down the websites.
In a joint operation, law enforcers recently tracked down 83 websites that were used to distribute illegal and counterfeit medicines, most of which were sexual performance boosters. In the fifth Pangea Operation from Sept. 25 to Oct. 2, the National Drug and Food Monitoring Agency (BPOM) confiscated unlicensed drugs worth Rp 150 million (US$15,642). BPOM chairwoman Lucky S. Slamet said on Monday that the agency had requested the Information and Communication Ministry to close down the websites. “We have found 83 websites that distribute illegal and counterfeit medicines and we have requested the ministry to block them,” she told a press conference in Jakarta. In the crackdown, BPOM seized 66 types of unlicensed and counterfeit drugs, most of which were used for erectile dysfunction, body slimming and to boost female libido. The agency conducted the operation in Jakarta and Yogyakarta in cooperation with the National Police, the Attorney General’s Office (AGO) and the Customs and Excise Office. Officials posing as potential buyers were able to trace the route of the illicit online trade and found four distributors, three in Jakarta and one in Yogyakarta. They arrested two suspects and are in the process of bringing four cases to court. “We hope the sentences can have a deterrent effect on the person being punished and other perpetrators,” said Lucky. Indonesia was one of 100 countries taking part in the fifth Pangea Operation, which was coordinated by the International Criminal Police Organization (ICPO)–Interpol to root out the illicit internet trade in unlicensed and counterfeit drugs. When the ICPO–Interpol held the first Pangea Operation in 2008, only eight countries participated. By 2011, a total of 81 countries, including Indonesia, took part in the effort. In last year’s operation, BPOM seized 57 counterfeit drugs, primarily sexual performance enhancers and diet pills, worth Rp 82 million. Two suspects were arrested and two cases were brought to court. “The dossiers of the two suspects have been handed over to the prosecutors,” said Hendri Siswadi, the BPOM’s chief of drug and food investigations. The Information and Communication Ministry’s chief of investigations and law enforcement, Aidil Chendramata, said his ministry had yet to receive official requests for the closure of the 83 websites found in this year’s operation. He said that in 2011, his ministry closed down 30 websites that distributed unlicensed and counterfeit medicines. “We blocked and closed down the websites based on recommendations we received from BPOM. We cannot close down any single website just as we like. We can block and close down the website only if we have a recommendation from the agency,” he said. According Law No. 36/2009 on Health, all products distributed and sold by retailers must have a BPOM product distribution permit. In previous market surveillance, BPOM revealed that traditional medicines containing illegal substances were widely found in local markets. As of the first semester of 2012, BPOM had recalled 25 traditional medicines, down from 64 in 2010 and 98 in 2009.

83 websites found selling illegal drugs
The Jakarta Post, October 10, 2012/ Tech in Asia, October 09, 2012/ Yahoo News, October 09, 2012
BPOM destroys 1,698 types of illegal food and drugs
The Jakarta Post, April 26, 2013

Batam-chapter Food and Drugs Monitoring Agency (BPOM) destroyed 48,151 items of food and drug products, which comprised 1,698 types, in the Industrial Waste Management Area (KPLI) in Kabil, Batam, on Friday.

The destroyed illegal food and drugs, worth Rp 379.8 million (US$39,070) were confiscated by the agency during a string of monitoring operations it conducted from 2011 to April this year.

A number of processed food and canned drinks from various brands were destroyed using a press machine while the illegal drugs were destroyed in an incinerator.

BPOM chairwoman Lucky S.Slamet said the food and drugs were mostly imported from other countries and had no distribution permits from the agency.

The confiscation and monitoring activities carried out by the BPOM aimed to protect consumers from any unstandardized food and drug products, she went on.

“These products have no distribution permits; so, we destroy them to prevent consumers from consuming such products,” said Lucky.

During 2013, BPOM has destroyed more than Rp 6 billion worth of illegal food and drugs taken from six cities: Bandar Lampung, Jakarta, Medan, Palangkaraya, Palembang and Pekanbaru.

On Thursday, the BPOM chairwoman and the Trade Ministry’s director general for product standardization and consumer protection, Nus Nuzulia Ishak, led a raid confiscating a number of illegal cosmetics and drugs from several stores and distributors in Batam, including Belezza, a major cosmetics store in the Harbour Bay Mall.

The BPOM and Trade Ministry officials confiscated 10,753 items of cosmetics and drugs, which comprised 1,003 types, worth Rp 900 million. The products were imported from China and Korea.

BPOM destroys Rp 2.7 b worth illegal drugs and food
The Jakarta Post, May 23, 2013

Not fit for human consumption. Trade Minister Gita Wirjawan (second from right), accompanied by Food and Drugs Monitoring Agency (BPOM) chairwoman Lucky S.Slamet (right) and Banten Governor Ratu Atut Chosiyah (center), destroy illegal food and drugs confiscated during this year’s post-market surveillances in Serang, Banten, on Thursday. (Courtesy of BPOM)

Serang-chapter Food and Drugs Monitoring Agency (BPOM) today destroyed a large stock of illegal drugs, cosmetics and food worth Rp 2.7 billion (US$276.299) taken
The illegal products destroyed included 218,896 pieces of illegally-distributed cosmetics consisting 607 different items worth Rp 1.97 billion and 21,461 pieces of unregistered drugs worth Rp 20.9 million.

Other products destroyed included 3,081 pieces of traditional herbal medicines without distribution permits worth Rp 13.5 million and 720,107 pieces of damaged and expired food products worth Rp 720.2 million.

A statement released by BPOM said it was the 9th crushing of illegally-distributed drugs and food the agency had conducted during 2013.

Previously, BPOM destroyed illegal food and drugs amounting to Rp 10 billion in Bandar Lampung, Batam, Jakarta, Medan, Palangkaraya, Palembang, Pekanbaru and Semarang.

During the period, BPOM Serang has brought 14 cases to justice.

“Supply reduction policies will be less effective to curb the spread of illegal food and drugs unless people are more aware of the danger of taking these products,” it said.

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**War against counterfeit drugs moves online**

*The Jakarta Post, August 28, 2013*

With the Internet now a hotbed for illegal and counterfeit drug sales, the Food and Drugs Monitoring Agency (BPOM) is moving its campaign online. Antonia Retno Tyas Utami, deputy of the narcotic and therapeutic drug monitoring division at BPOM, said on Tuesday that the agency had formed a special task force to handle the problem. The agency had also joined the global Operation Pangea coordinated by the International Criminal Police Organization (Interpol) to combat counterfeit drugs, particularly those marketed online. “We combat illegal and fake drugs because they threaten the health of our people. We will continue to crack down on their sale,” she told reporters. Retno said that the Internet had become a major marketplace for illegal and counterfeit drug sellers as more and more people in the country went online. She also said that monitoring the activity of Internet users was very complicated. “People can easily create web pages on the Internet. When we shut pages down, they can make another one with just one click of a button,” she said. Retno said that BPOM had been working with the National Police and the Communication and Information Technology Ministry (Kemenkominfo) since its participation in the 2011 Operation Pangea IV. In the recent Operation Pangea VI in six major provinces, the agency found 129 websites and 20 stores selling or producing 721 types of counterfeit drugs worth Rp 5.59 billion (US$485,184). Data from the agency shows that the number of counterfeit drugs marketed in the country has steadily been increasing. In its operation last year in two provinces, the agency found 83 websites and four stores selling or producing 66 types of fake drugs worth Rp 150 million. The agency found 30 websites and four stores selling 57 types of counterfeit drugs worth Rp 82 million in 2011. Kemenkominfo spokesman Gatot
Dewa Broto said that the ministry had worked with BPOM to shut down websites marketing counterfeit drugs. “I have not checked whether all the 129 websites have been blocked, but I can assure the public that we are responding to BPOM’s requests.” Retno said that besides joining Interpol’s Operation Pangea, BPOM would also bring the issue to the upcoming Asia-Pacific Economic Cooperation (APEC) Summit in Bali in October. Online sales of counterfeit medicine has been a global concern since the first Operation Pangea in 2008 pioneered by several developed countries, including the US, UK, Australia and Canada. The annual operation has steadily attracted more participation, including from developing countries. In Operation Pangea VI, 99 countries successfully shut down more than 13,000 websites and confiscated 10.1 million illicit and fake pills worth $36 million. Retno said that most counterfeit drugs found in Indonesia were in the form of lifestyle drugs, such as erectile dysfunction drugs, slimming pills, and vitamin C serum. She cited some of the counterfeited brands as Viagra, Cialis, and Laroscorbine. (koi)

Websites selling illegal and counterfeit drugs

- http://www.solusiejakulasidini.com/
- http://www.sediaobat.com/
- http://www.adaobatkuat.com/
- http://www.obatkuat-kecantikan.com/
- http://www.rumahobatkuat.com/
- http://www.ragamkosmetik.com/
- http://www.tokosuntik.net/
- http://www.blessing-house.net/
- http://www.suntikputihdanpelangsing.com/
- http://www.lacantik.com/

BPOM seizes Rp 150 m worth of fake drugs distributed online

*The Jakarta Post, October 08, 2012*

The National Drug and Food Monitoring Agency (BPOM), in conducting its fifth Pangea Operation, has seized thousands of illegal and fake drugs marketed online.

BPOM chairwoman Lucky S. Slamet said Monday that during the operation, her agency had identified 83 websites that allegedly distributed illegal and fake drugs, up from the 30 sites it uncovered during the previous Pangea Operation in 2011.

“We have asked the Communications and Information Ministry to immediately block and close down those websites,” she told a press conference at BPOM headquarters on Jl.Percetakan Negara in Central Jakarta.

During this year’s Pangea Operation, the BPOM seized 66 types of counterfeit drug, mostly erectile-dysfunction drugs, followed by slimming pills and female libido drugs, worth Rp 150 million (US$ 15,642), which were being distributed online.

Lucky said that during the operation, officials arrested two alleged perpetrators and were in the process of bringing four cases to court.
“We will conduct further investigations to find the people behind these websites,” she said.

The BPOM held the operation, which was carried out in two cities -- Jakarta and Yogyakarta, from Sept.25 to Oct.2 in close cooperation with law enforcement institutions including the National Police, the General Attorney's Office (AGO) and the Customs and Excise Office at the Finance Ministry.

About 100 countries including Indonesia took part in the fifth Pangea Operation, which was facilitated by the National Central Bureau (NCB)-Interpol, with the aim of uncovering illegal products including counterfeit drugs distributed online.

NCB-Interpol held the first Pangea Operation in 2008 with only eight participating countries, followed in 2009 with 25 countries. The operation in 2010 included 44 countries and the last one, in 2011, had a total of 81 countries.

Indonesia first joined with the Pangea Operation in 2011. During that operation, the BPOM seized 57 counterfeit drugs, which were dominated by online marketed sexual-performance boosters and slimming pills worth Rp 82 million.
MALDIVES

Dangerous fake ‘LSD’ in the Maldives, warns Police Commissioner
Minivan News, February 06, 2013

Police Commissioner Abdulla Riyaz has warned that a very dangerous fake LSD drug is being distributed in the Maldives by local drug lords, which could “stop your heart.”

“LSD is a very dangerous drug. It could stop your heart. Reports received that fake LSD is supplied and that some drug users are on it,” Riyaz tweeted yesterday.

Today police released a statement informing the public that early this morning at 3:30 am the body of a man was discovered lying inside Antennae Park.

According to the statement, Nazeef’s body was taken to ADK hospital immediately where doctors determined he was dead.

Yesterday, police reported the discovery of dead body lying on a street in Hulhumale’ at 4:45am early on Tuesday morning.

According to police, two men were standing next to the body when it was discovered. Police said the two men were intoxicated and were arrested.

Sources familiar with the case told Minivan News that the two persons arrested tested positive for LSD and were in possession of the drug when police arrested them.

In a statement, police said doctors at the hospital had informed them the victim was dead when he reached hospital.

Two further deaths

Meanwhile, two residents of Villingili in Gaafu Alifu Atoll died after having difficulties breathing.

According to Villingili hospital, the men were dead when they were brought to the hospital.

According to the police, one of the men died while he was on the island of Kooddoo in Gaafu Alifu Atoll and the other died while he was on Villingili, also in Gaafu Alifu Atoll.

Police said they men were aged 33 and 58 and both died after having difficulties breathing.

Police have not said the deaths are linked.
MYANMAR/BURMA

Mobile team targets illegal border trade
Myanmar Times, January 28, 2013

A mobile investigation team on the Mandalay-Muse highway has seized contraband valued at more than K60 million since January 1, an official said last week.

The team was established last year to increase legal trade volumes and improve consumer protection. From November 1 to December 31, 2012, it conducted “educative” activities, issuing warnings rather than confiscating goods.

But since January 1, it has uncovered 19 cases of contraband goods worth more than K60 million. Food items are usually destroyed, while other confiscated goods are auctioned or returned after paying a fine, said U Aung Win, director of the Mandalay-Muse Mobile Team. Those who tip off the team to illegal trade are rewarded with a percentage of the value of confiscated items, he said.

“We burn imported foods, such as frozen chicken, duck, chicken sausage and some other meats that are imported without the approval of the Food and Drug Administration,” he said. “Other illegal goods that we seized can be returned, after paying a fine that is equivalent to double their value, within one month. If the fine is not paid we will auction them.”

The 31-member team comprises officials from the Customs Department, Myanmar Police Force, region-level general administration department, a border trade association and even journalists.

Minister for Commerce U Win Myint urged cooperation with the mobile team and said it would help the country reach its trade volume target of US$19 billion.

“Fertilisers, insecticides, foods that are dangerous for children and fake drugs are entering the country. The government needs to take action against [illegal imports] and we are now investigating. This can also encourage trade volume growth if traders pay tax for a licence to import goods legally,” he told journalists in Shan State on January 18.

“[Traders] should not respond to our action with anger because we are guiding them towards doing business the right way.”

But the main opposition to the team appears to be coming from motorists, who have complained that the stringent checks are creating long queues at the 105-mile checkpoint on the Mandalay-Muse highway.

“There’s normally a queue of vehicles about 4 miles long (6.4 kilometres) waiting at the 105-mile checkpoint. The investigation team was needed to increase its workforce and it takes too long to scan goods using its X-ray machine,” said Ko Maung Htoo, who drives regularly on the highway.
Officials also concede that there are other routes that can be used to bypass the investigation team, and say they plan to expand the investigation team. “We will expand the investigation team members to be more effective and we will install another X-ray machine at the gate,” U Win Myint said. Department of Border Trade deputy director U Myo Aung said more mobile teams will be formed to combat illegal trade between Yangon and Myawaddy on the border with Thailand and at railway stations and ports.
NEPAL

- No Reported Incidences

SRILANKA

- Sri Lankan health authority warns of dangerous counterfeit cosmetics
  
  *Cosmetic Design Asia, October 18, 2012*

The Cosmetics Devices & Drugs Authority in Sri Lanka has issued a statement warning that more than half of the cosmetics used by the public are illegal and could contain harmful ingredients.

The issue relates to illegal imports and products that are smuggled into the country from overseas that contain harmful ingredients that would normally be banned in their country of origin.

A Public Health official of the CDDA told *The Nation Newspaper* in Sri Lanka of the warning and reiterated that all cosmetics must be registered by the health authority.

Out-dated rules

“Before registering a cosmetic we look into the country of origin to see if they are freely available without restrictions in those countries. After checking we have found that some are banned even in the countries from where they have originated,” the official said. The problem arises because the rules and regulations regarding cosmetics products have not been changed in a long time, compromising their strength and relevance.

“The last time there was any amendment to the Cosmetics Devices & Drugs Act No. 27 with regard to cosmetics was in 1983. We are now trying to amend these regulations due to the surge of illegal cosmetics in the country. New regulations are being drafted by our legal draftsman. But it will take time,” the spokesperson told local news.
Undetected and unsanctioned

As it stands, fines in place for offending products range anywhere between 5000 rupees to 50000 ($95 - $945), although are not a deterrent.

“Our concern is that most of these cosmetics are never detected, as they are smuggled in baggage or in handbags,” the health official continued.

“Since they can have adverse reactions on those using them, we warn the public only to buy cosmetics of a known brand, as several counterfeit products are now circulating in the country.”

In 2012 there has only been six cases of illegal cosmetics detected to date.
THAILAND

- Illegal sex drugs confiscated
  *The Pattaya Today, January 07, 2013*

Police busted a number of pharmacies suspected of selling unlicensed or fake sex stimulants such as oral jelly and super Viagra.

Large quantities of the illegal substances were confiscated. Some drug store owners claimed they did not know the items were bogus, saying it was the fault of distributors. Others justified their actions by pointing out that many Thai and foreign tourists demanded the products. Several arrests followed.

- Bali Monitoring Agency cracks down on illegal cosmetics
  *Cosmetic Design Asia, December 06, 2012*

The Bali National Drug and Food Monitoring Agency (BPOM) is warning consumers to be more cautious when buying cosmetics after finding in a recent operation, a large number of illegal traditional beauty products.

Targeting distributors and stores in Denpasar, Tabanan and Gianyar, enforcement officials are said to have seized

39,000 packages of 238 kinds of traditional cosmetics and medicines over a two-day operation.

According to the Agency’s Corry Panjaitan, officials confiscated products that were either unregistered, had fake distribution licenses, or contained dangerous chemical substances.

“We also arrested three suspects during the operation,” she added. Whilst samples of the seized products have been sent to labs to establish whether they contained dangerous chemical substances, the team’s representative says that they have yet to determine the parties responsible for producing the illegal products.

“We currently have no knowledge as to whether the illegal beauty products were produced in Indonesia or abroad,” she explains.

**Not the first of their kind!**

According to the monitoring body, illegal cosmetics are widely distributed and still easily available in Bali and their inexpensive prices and availability make them desirable to some consumers.

In the last year alone, Corry says the Agency has prosecuted eight people for
allegedly selling illegal products to the public.

“Unfortunately, the court only punished them with light sentences, including probationary sentences ranging from two to three months,” added the agency’s investigation head, Gusti Ayu Adhy Aryapatni.

Gusti Ayu goes on to explain that, in Indonesia, the defendant does not have to serve any prison time when receiving a probationary sentence.

"All that is necessary is to refrain from repeating the crime that resulted in the sentencing for the length of the probationary period, and the light sentence would be no deterrent on these people."

**Global crack down on illegal cosmetics**

Meanwhile across the water, UK based cosmetics retailer ‘Sabina Hair and Cosmetics’ was recently fined £24,000 (129,000) after being caught selling illegal skin whitening creams containing a banned substance, hydroquinone, which is linked to cancer.

Found during a raid by the Trading Standards, all the products were being sold from below the counter, an indication that the company was aware of the illegal implications of the sales.

Targeting the large ethnic population in the UK, the shopkeeper was said to be selling over 200 banned products which contained ingredients that have been known to irreversibly damage health when used in excessive quantities.

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**TIMOR-LESTE**

- No Reported Incidences
Government is mooting a proposal to set up more drug testing laboratories in various states in a bid to rid the country’s growing market from spurious medicines.

This was stated by Minister of State for Health Sudip Bandopadhyay on the sideline of a workshop which was organized by PSM India in collaboration with the Ministry of Health and Family Welfare, Government of India and World Health Organisation (WHO) India Country Office to demonstrate its commitment towards Patient Safety globally. More than 50 eminent experts from overseas on the subject, participated representing countries from Europe, USA, China, Argentina, Nigeria, Thailand, Singapore and others.

The Minister said manufacturing of spurious drugs was “more criminal than murder”.

“So, regulation has to be followed strictly. Anyone found manufacturing spurious drugs, his entire factory should be shut...,” Bandopadhyay said.

As manufacturing licenses to most drug producers are issued by states, the Health Ministry plans to strengthen state departments first.

“Our plan is to strengthen states’ health department with more manpower. Secondly, we want to open drug testing labs in different locations including in Himachal Pradesh, Gujarat and other states where majority of drugs are produced,” he said.

A recent sample collection found that 4.7 per cent of the 50,000 drugs were spurious or extension of sub-standard drugs.

“Though it looks small, the magnitude is not so small. We would like to bring it to zero level. Send more drug samples for tests in drug-testing laboratories.

IF things go as planned, people involved in drug counterfeiting or importation of fake drugs into the country will soon begin to get life imprisonment, without an option of fine. Dr. Paul Orhii, director-general of the National Agency for Food and Drug Administration and Control (NAFDAC), who dropped the hint said the government was also considering confiscation of the property of people involved in the illicit and killer business to compensate the victims.

Orhii, who spoke during a meeting of the West African Health Organisation to
harmonize the process of medicine registration in West Africa said that experts working on the country’s anti-counterfeiting law have made significant progress on the document and that they would send it to the National Assembly after concluding work on it.

This is good news. In India and China, the wages of the crime is death. And, one may be tempted to want to recommend that Nigeria totes this path in view of the fatal consequences of the actions of the criminals involved in the illegal business. Perhaps the realisation by those putting the proposed legislation together, that headache cannot be cured simply by beheading those suffering from it should also be welcome.

Fake drugs are often manufactured in dirty, unhygienic warehouses and sometimes can contain little or none of the genuine active ingredient, or remarkably harmful industrial compounds. The least harm one could suffer from buying of such drugs is for them to be ineffective, i.e. when the active ingredients are below what is claimed on their containers. In many cases, people have died after taking such drugs; many others suffered permanent deformities.

We understand the basis of the proposal to deny bail to suspects held for the crime; that is to prevent them from continuing their trade, thereby stopping them from further jeopardizing the lives of innocent members of the public. But we wonder if that can stand in our legal milieu where an accused is deemed innocent until proven otherwise by a competent court of law.

However, we urge those putting the law together to expedite action and forward it to the National Assembly. While we urge the law makers to scrutinize the document, with a view to making it water-tight; they should also expedite action on it when it gets to them so as to save their compatriots from untimely deaths or deformities arising from consumption of counterfeited drugs.

But we also want to quickly remind the authorities that the problem is not about legislation per se. Right now, there are laws prescribed for people involved in drug counterfeiting; but enforcement is the problem. Even if death penalty is prescribed for the offence and the law is not enforced, there won’t be appreciable result. Again, it does not seem NAFDAC is well funded and equipped to do the job thoroughly. For the proposed law to be meaningful when it becomes operational, the agency must be provided the wherewithal to adequately cover the whole country.

Fake drug business is big business and those involved in it have become too sophisticated to be trailed or monitored by an under-funded and ill-equipped agency. For the law to be effective, NAFDAC officials must always be a step ahead of the criminals. This implies that the whistle blowers should start to benefit from the incentives that Dr Orhii said were in the offing for them to further encourage them to put in their best.

It is also important that the Federal Government expedite action on the Memorandum of Understanding between it and China to check the influx of fake and substandard drugs from that country. China is not just a major exporter of drugs to Nigeria; it is also one of the world’s biggest exporters of counterfeit drugs.
Drug resistance looms large in Myanmar

Myanmar Times, October 29, 2012

Mg San Win from Win Kan village in Mon State’s Kyaikto township caught malaria in July while working in a lemon orchard.

“It was the worst illness I’ve ever had,” he said following his recovery earlier this year. “The headaches and muscle pain were terrible.”

His father said that Mg San Win has a habit of sleeping without a bed net coated in insecticide, which is an important form of protection against malaria-carrying mosquitoes.

“I hate bed nets – I can’t breathe properly,” Mg San Win said.

Mg San Win lives in an area where re-infection looms large due to growing resistance to artemisinin, a drug used to treat Plasmodium falciparum, the most dangerous of the five parasites that cause malaria.

According to a 2008 World Health Organization (WHO) report, malaria is the most significant public health challenge in Myanmar. There are an estimated 4.2 million cases every year, accounting for about 20 percent of the total figure in Southeast Asia.

About 69pc of Myanmar’s population lives in areas where malaria is endemic or prevalent, the WHO says, while 75pc of malarial deaths in the Greater Mekong sub-region occur in Myanmar.

Three-quarters of cases are caused by the most dangerous strain, said the 2011-15 Strategic Framework for Artemisinin Resistance Containment in Myanmar (MARC).

MARC is endorsed by the Ministry of Health and was launched by a large number of national and international partners in July 2011.

But Myanmar is also more affected by artemisinin resistance than any other country, ahead of Cambodia, Thailand and Vietnam, a study published in the Lancet journal earlier this year found. MARC is an initiative to tackle this growing public health issue.

“The joint effort is a response to a growing concern regarding the emergence of malaria parasite resistant to artemisinin derivatives,” the WHO says.

Artemisinin-resistant malaria was first detected in Cambodia in late 2006. Growth since then – drug resistance along Thailand’s northwestern border near Myanmar shot up from 0.6pc in 2001 to 20pc in 2010, the Lancet says – prompted WHO regional director Shin Young-soo to warn on October 1 that countries in the region must “intensify and expand” efforts to contain it.

Resistance to the anti-malarial drug could “eventually render [artemisinin] obsolete, putting millions of lives at risk”, the UK-based Wellcome Trust says.

“If drug resistance isn’t successfully halted in Myanmar, it could strike Bangladesh, India and possibly Africa,” agrees Mr James Howlett, communication officers for the Three Diseases Fund.
With the exact cause of resistance unknown, further research is being undertaken to determine whether it is a result of treating the falciparum malaria strain using only artemisinin-based medication, known as monotherapies.

Monotherapy medication continues to be widely manufactured despite a 2007 United Nations resolution highlighting the associated dangers.

Monotherapies are cheaper to produce than combination therapies but the World Health Organization says resistance develops more quickly.

“WHO recommends the combination therapy because it is more effective, not only to contain drug resistance but also to combat the disease,” said Dr Phyo Min Swe, public health analyst from the Three Diseases Fund.

Scientists believe self-prescribing anti-malarial drugs might also be a factor contributing to resistance. A spokesperson from the Myanmar Medical Association’s malaria project told The Myanmar Times this was a problem in Myanmar, despite some modest behavioural changes.

Mr Howlett said education was needed to combat the practice of self-prescribing malaria medication.

“Rather than going to see a trained physician, malaria patients sometimes buy medicine from the nearest shop. And they don’t complete the dose once they start feeling better,” he said, adding that he was also concerned about the prevalence of counterfeit drugs, another possible contributor to artemisinin resistance.

“Some of the fake drugs are manufactured in neighbouring countries. It’s hard to pinpoint where exactly, but the border is porous and there is no way to guarantee the efficacy of these drugs,” he said.

While the monitoring of medication and its use is important in the fight against drug-resistant malaria, prevention is also a priority. In Myanmar, Tanintharyi and Bago regions and Mon and Kayin states are among the nation’s priority areas for these programs.

World Concern Myanmar is implementing community-based malaria prevention and control programs in Bilin, Thaton and Kyaikto townships in Mon State with funding from the Three Diseases Fund. The programs have seen health volunteers trained and health education programs carried out in 46 villages in the three townships.

“In the past, the public wasn’t afraid of malaria. However, now that people are better educated about the disease, they visit the doctor for a diagnosis as soon as they catch a fever,” Daw Than Nwet, a village health worker in Win Kan village told The Myanmar Times on 28 August.

“There have been fewer cases of malaria this monsoon season. Far more people used to die of it 10 years ago than is the case now.”
WHO shows interest in Guj’s SMS model to check fake medicines

The Indian Express, November 06, 2012

The World Health Organisation has shown interest in Gujarat’s SMS alert system of keeping a check on spurious medicines, a top health official said.

As part of its e-governance initiative, the Gujarat Food and Drug Control Administration (FDCA) had developed an SMS alert system through which all the stakeholders in the state could be notified of the recalled fake drugs.

This cost-effective model was launched in the state earlier this year to protect the patients from spurious drugs.

“WHO has evinced interest in Gujarat’s SMS recall model for the spurious drugs. It plans to implement this cost-effective model for patient safety in the developing countries,” Gujarat FDCA Commissioner H G Koshia said.

“We have submitted a concept note of this model to them, after the recent visit of Dr Veer Surya from WHO headquarters to Gujarat’s FDCA,” he said.

Commenting on the model, Dr Surya had said that it was a viable tool to protect the patients’ health and could be implemented in the developing countries, Koshia said.

This model has also been appreciated and praised by top executives of global pharma giants like US-based Abott Laboratories and Israel-based Teva Pharmaceutical.

WHO is the directing and coordinating authority for health within the United Nation system, with over 150 countries as its members.

Several Indian states are also in the process of replicating this model.

The system has issued around 60 alerts so far on sub-standards drugs detected during random sampling done by the FDCA, asking chemists to stop the sale of such spurious medicine.

Row flares over global fight against fake medicine

Reuters, November 13, 2012/ The Deccan Herald, November 14, 2012

A group of experts calling for a global treaty to stop the lethal trade in fake medicines has been barred from attending a World Health Organisation meeting, highlighting deep divisions that are blocking progress on the subject.

Leading academics and health professionals hoped to provoke debate on the need for a new international law to prevent falsified and substandard drugs reaching the market with a paper published in the British Medical Journal on Wednesday.

Their article, which sets out a clear case for a fake drugs treaty similar to existing ones on money laundering and human trafficking, comes a week before 100 states hold the first meeting of its kind to discuss the problem in Buenos Aires.
But lead author Amir Attaran of the University of Ottawa said he was told on Monday by the World Health Organisation (WHO) that he and other non-governmental representatives could not attend, following an objection by India.

A WHO spokeswoman declined to comment on the details of particular invitations but said it was up to member states to determine who was permitted to attend. Indian officials, whose government is wary of multinational drug firms using the issue to curb competition, were not immediately available for comment.

Attaran called it a "scandal" that only government officials would be at the meeting in Argentina to discuss strategy.

The clash exposes distrust among governments, the pharmaceutical industry and healthcare campaigners about how to tackle fake and dangerous medicines, which are a growing problem in both poor countries and rich. Risks include ineffective material packaged as medication and real drugs made in poor conditions.

In developing countries, the WHO estimates that more than 10 percent of medicine may be fake or substandard, with bogus malaria drugs a particular threat in parts of Asia and Africa.

But the danger is real in the rich world, too.

Earlier this year, fake vials of Roche's cancer drug Avastin were found in the United States, while a recent U.S. meningitis outbreak, due to contaminated steroid injections, shows the country is not immune to quality problems.

In the European Union, medicines are now the top illicit product seized at the border and authorities have found fake versions of drugs purporting to come from companies including Sanofi, Eli Lilly and AstraZeneca.

**LAW TOUGHER ON TOBACCO THAN FAKE DRUGS**

The need for action seems clear enough - but advancing the debate involves navigating some big divides.

India, whose large drugs industry produces cheap generic versions, is concerned that Western governments backed by Big Pharma are using the fight against fakes as a cover to restrict trade in unpatented medicines much needed by the world's poor.

Some health activists support New Delhi's charge that worries about counterfeit drugs are being hijacked by "Big Pharma" global pharmaceutical companies to protect their profits and patented products against legitimate generic competitors.

In east Africa, for example, international drug companies have taken advantage of anti-counterfeiting laws that are sometimes poorly drafted to curb sales of otherwise legitimate generics, threatening the availability of essential drugs.

India is particularly resistant to any role for pharmaceutical firms in setting the agenda, and Brazil has expressed similar concerns in the past.

Given the distrust, the authors of the paper in the BMJ - who include leaders of nursing, pharmacy and public health bodies - argue there is a need to find neutral ground to address what appears to be a gaping hole in international law.

They point out that thanks to a new convention on tobacco control, international
law is now tougher on counterfeit cigarettes than it is on fake medicines.

"We hope that this will form the basis for getting some consensus on a definition of counterfeit drugs, which would then be transferable into a legal instrument," said another of the paper's authors, Martin McKee of the London School of Hygiene and Tropical Medicine.

The lack of a treaty means there is no agreement on which medicines are illegal and criminals can do business in countries where laws or enforcement are lax. There is also no requirement for police and prosecutors to cooperate across borders.

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Check your prescription meds
Ceylon Today, December 16, 2012

Huge quantities of unregistered prescription drugs are being smuggled into the country to meet the demands of the medical fraternity in the country, senior Pharmacists who do not want to be named, reveal.

They claim drugs which are registered in the country of manufacture are not available nor registered with the Cosmetics, Devices & Drugs Regulatory Authority of Sri Lanka, for use here.

"Doctors prescribe drugs recognized by the drug indices. They are not aware whether they are registered or not," one of the pharmacists said.

The Cosmetics, Devices and Drugs Act allows a certain quantity of drugs that are not locally available to be imported at the request of a doctor on a special license issued by the Cosmetics, Devices & Drugs Regulatory Authority of Sri Lanka, for the personal use of a patient. The licenses is issued to the patient, who has to get down the medicine.

More often than not, patients are clueless as to how to get down the drugs, and invariably the licenses are handed over to pharmacies, some of them are agents for the company manufacturing the drugs, which then get down the particular drugs for them.

A side bar to this transaction is that the drugs also end up on the pharmacy shelves, available for other prospective customers as well.

When officials of the Drugs Regulatory Authority raid these pharmacies looking for counterfeit drugs, they come across the unregistered drugs, which are by no means counterfeit, but nevertheless illegal in Sri Lanka. The pharmacists are fined as per the laws. But such detections are only a minute fraction of the larger quantities of unregistered and counterfeit drugs that enter country and make their way to pharmacies across the country on a regular basis.

According to several senior pharmacists, there are large stocks of unregistered drugs in the country at any given moment and some of them are used by State hospitals and renowned consultants. These unregistered drugs include: Multisol Spray
Ministry is hopeful of implementing this policy soon.

Commenting of National Medicinal Drugs Policy of Professor Seneka Bibile, the renowned pharmacologist and the founder Chairman of the State Pharmaceuticals Corporation (SPC) nearly forty years ago.

According to the President of the Pharmaceutical Traders' Association, Ananda Samarasinghe, both unregistered and counterfeit drugs are brought into the country on a regular basis. Given the fact that 30% of medicinal drugs in India are counterfeit, they manage to find easy passage to Sri Lanka, he said, both the World Health Organization (WHO) and the Indian Government have accepted and acknowledged the counterfeit drug reality.

Samarasinghe also said that although Sri Lankan authorities try to stop counterfeit and unregistered medicinal drugs being smuggled into the country, they still manage to find their way to the local market. He said the Indian counterfeits can be easily identified as they have brand names close to the original names.

He also said that there are many ways in which those involved in the trafficking of unregistered and counterfeit drugs can entice pharmacies to sell the drugs, the main lure being the drugs can be offered at any price.

“Though most pharmacies abide by the rules and do not stock these drugs, some of course do not mind and purchase the drugs and sell them at the price of registered drugs,” he claimed, adding that the media needs to expose these issues.

**Check before buying**

Samarasinghe advised the public to check whether the prescription or even over-the-counter drugs have been registered under the Cosmetics, Devices & Drugs Regulatory Authority, before they make the purchase.

When it comes to identifying these things, he said people have to be careful with the brand names. Prices of the counterfeit drugs are very cheap when compared to the authentic drugs, as researching, developing and the manufacturing process is a costly matter. Giving an example he said if a pharmacy says a certain drug is Rs 100 but is willing to sell it at Rs 25, the buyer should be cautious because there can’t be that big a disparity, if the drug is genuine.

According to the WHO standard, manufacturers have to meet the Good Manufacture Practice (GMP) standard, a very expensive standard. Drugs manufactured all over the world have to maintain these standards.

Samarasinghe explained that for a drug to be deemed genuine it has been manufactured under the GMP standard, which is expensive.

Commenting of National Medicinal Drugs Policy of Professor Seneka Bibile, he said it was important for every country to have a drug policy and added that the Health Ministry is hopeful of implementing this policy soon. However, he said, as the
Seneca Bibile Policy was drafted some 40 years ago, it should be improved upon to suit modern society. “It has to adapt to new society” he said, adding that having a drug policy in place would help regulate what drugs should come in and what should not.”

**Poor quality drugs**

The importance of a national drug policy was underscored by the Government Medical Officers’ Association (GMOA), whose spokesperson; Dr. Navin de Soyza, said the outcome of the effect of counterfeit or poor quality drugs is on the patients as they are the ones who suffer when such drugs are used. If the National Medicinal Drug Policy is implemented, unregistered drugs being brought into the country can be eliminated, as all the drugs that are required and permitted entry to the country will be listed out, he said.

“If we prescribe a drug such as Amoxicillin to a patient, there are almost a 1,000 brands of that same drug; therefore, this kind of thing should be controlled. They pay more for a particular drug, but don’t get the exact one. If there is a policy it will be very helpful,” he said, adding if the policy is implemented properly then unwanted drugs will be done away with.

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**Guardian report on fake medicine totally incorrect: India**

*www.twocircles.net, December 29, 2012*

The government Saturday termed as "totally incorrect" a report in Britain's Guardian newspaper alleging that fake medicines from India were being sent to Africa, adding India "interacts extensively" with African countries "to provide quality medicines at affordable prices".

The external affairs ministry was responding to a Dec 24 report in The Guardian which alleged that counterfeit medicines from Asia - mainly China and India - were playing havoc with the treatment of diseases like malaria in Africa.

The report titled, "Counterfeit medicine from Asia threatens lives in Africa", said in one part: "But several recent studies warn that as many as one-third of malaria drugs in Uganda and Tanzania are fake or substandard, with most believed to originate in China or India."

In a statement, the external affairs ministry said: "The Government of India would like to state categorically that the report is totally incorrect. No fake medicines have been sent from India to the continent of Africa."

It said that such allegations have earlier been investigated both in Africa and in India "and have been found to be baseless with the origin of such drugs not being from India. As the Guardian report itself acknowledges, India has stepped up oversight on this subject".

The statement said that India "continues to interact extensively with countries in Africa to provide quality medicines at affordable prices. The Government of India is
committed to continue this cooperation in the strong belief that this is an ideal means of enhancing South-South cooperation and engagement."

The Guardian report quoted Patrick Lukulay, vice president of the US Pharmacopoeial Convention's global health impact programmes, as saying that "it was no secret that the majority of dangerous medications came from China and India, as those countries had the world's largest production bases for both active ingredients and finished drugs".

While India has stepped up oversight, "China is only now just catching on", Lukulay added.

- **India rejects claims it exported fake medicine to Africa**
  
  *www.theguardian.com, January 02, 2013*

India has denied claims that it has exported large quantities of counterfeit medication to Africa, after the Guardian published a front-page exposé on the phenomenon.

“No fake medicines have been sent from India to the continent of Africa,” a spokesman for the ministry of external affairs in Delhi said.

The article cited experts and NGO reports as saying that up to a third of anti-malarial drugs in Uganda and Tanzania might be fake or substandard, and the majority of them were manufactured in China and India. The drugs look identical to real ones, and can only be distinguished with lab testing.

Aside from malaria drugs, analysis of antibiotics and contraceptives has also identified fakes. “Some pills contain no active ingredients, some are partial strength and some the wrong formulation entirely,” said the article.

The fake medications have led to deaths, prolonged illness and increased drug resistance in parts of east Africa, the article said.

The Indian official said allegations of the nature of those mentioned in the Guardian had “surfaced previously” and “had been thoroughly investigated both in Africa and in India and found to be baseless”.

“As the Guardian report acknowledges, India has stepped up oversight on this subject [and] ... continues to interact extensively with countries in Africa to provide quality medicines at affordable prices,” the spokesman said.

“The Government of India is committed to continue this co-operation in the strong belief that this is an ideal means of enhancing south-south co-operation and engagement.”

Chinese officials also denied the charges made in the report.

Counterfeit drugs are a long-running issue in China. According to official statements, Chinese police seized £113m of fake pharmaceuticals in July alone and £19m worth
in November. Many ingredients were found to be harmful or toxic.

The Indian Health ministry launched a huge campaign last month to check the quality of medication manufactured across the country. India is home to more than 10,000 drug manufacturers.

High Court upholds packaging norms for curbing export of fake drugs
The Hindu, January 13, 2013

The Madras High Court has upheld packaging norms introduced by the government in 2011 for curbing the export of counterfeit pharmaceutical products and medical devices.

The court agreed with the Centre’s stand that these were necessary to protect the country’s trade reputation.

The Directorate-General of Foreign Trade issued notifications in January and June 2011 with regard to primary, secondary and tertiary levels of packaging of pharmaceutical products meant for export to foreign countries.

In his order dismissing two petitions, which challenged a notification of June 30 modifying the notification dated January 1, 2011 and sought their quashing, Justice K. Venkataraman agreed with Additional Solicitor-General of India, P. Wilson, that the Centre thought it fit to impose certain conditions on the export of drugs and medicines in furtherance of the country’s trade reputation.

Industry contention

The Confederation of Indian Pharmaceutical Industry (SSI) and the Indian Drugs Manufacturers’ Association filed the writ petitions. The confederation, among other things, said that the notification would increase the cost of production. This would have to be thrust upon the foreign buyers, who may, due to higher price, opt out of purchasing Indian products and switch to countries such as China. The confederation members, who were registered small scale industries, would incur heavy loss because of the plant and machinery for the new packing line as per the GSI standard.

Mr. Justice Venkataraman said that in the minutes of the meeting of the Commerce Secretary of June 2010 regarding the strategy to contain the campaign against fake drugs, it was notified that a concerted campaign against Indian pharma industry had been launched by MNCs whose interests were getting adversely impacted due to the increasing global presence of Indian pharma companies, especially in the generic segment.

It was also been notified that news was appearing in the international press to malign the growing Indian generic drugs by labeling them as fake.

It was felt that there could not be any laxity in enforcement as that also harmed the domestic industry’s interest and domestic consumers. The Judge noted that in the counter, it was stated that to protect Indian medicines in the international market
and to fulfill the manufacturers’ obligations, the Centre had issued public notice imposing certain conditions. When such was the government’s motto, the court could not sit over the government’s decision.

The petitioners had not established that the government’s decision and the public notice were arbitrary or a colorable exercise of power, Mr. Justice Venkataraman said.

🔗 **Counterfeit pharmaceutical products in South East Asia**

*IP KOMODO, January 16, 2013*

A report on counterfeit pharmaceuticals published by the American Enterprise Institute here [http://www.aei.org/files/2012/02/27/-appendix-a-master-2_170026856632.pdf](http://www.aei.org/files/2012/02/27/-appendix-a-master-2_170026856632.pdf) called the Deadly World of Fake Drugs provides a highly comprehensive global report on this issue compiled from news reports over the last 10 years or so. IP Komodo summarizes some key South East Asia comments below.

In the Philippines estimates vary from 8-30% of pharma products being fake. Fake drugs seen included cardiovascular, rheumatoid arthritis, osteoarthritis, asthma, anti-infective, and anti-inflammatory medications. Many are smuggled too. Counterfeits are imported from India, China, Taiwan, and Pakistan mainly but also Saudi Arabia, Thailand, Malaysia, Singapore, Colombia, Indonesia, Nepal and Myanmar. But the vast majority is from China and numerous examples of Chinese arrests during police and NBI raids are provided. Local production of fakes has also been reported too; from 2002–2005, there were 20 cases reported of fake manufacturing. A rise in raids through the early 2000s is alleged although more recently the Department of Health suggests there has been a decline.

In Thailand the figures for fakes vary, but numerous seizures suggest it is a multi million dollar annual industry. Viagra features heavily in the data, but other fakes are prevalent. The porous border areas of Myanmar, Malaysia and Cambodia are cited as a major gateway. Significant increases in fines have been implemented recently and 2005, police and customs now use GPHF’s Minilab, a mobile, compact laboratory, to quickly detect counterfeit and substandard drugs.

In Indonesia the International Pharmaceutical Manufacturers Group (IPMG) estimates that 25 -40% of the pharmaceutical market is fake, increasing in the last 6 years. Common fake medicines include antimalarials, antibiotics, and analgesics. Examples of fake drug seizures provided by the Indonesian Drug and Food Control Agency (BPOM) include substandard amoxicillin and refilled syringes full of with water. The BPOM complains of weak law enforcement and corruption in the judicial system and lenient sentences for counterfeiters as part of the problem.

In Vietnam there is a very large fakes market due to the border with China. These include antibiotics, erectile dysfunction treatments, traditional medications, fake liver disorder drugs, anti sinusitis products and relabeled generics. Vietnam appears to be a transit route from China to destination markets like Thailand. Smuggling is
rife and in the local market there is a problem of unregulated pharma sellers. Weak government capacity to take action appears to be improving over time.

\textbf{India Will Need To Resolve ‘Fake’ Drug Conundrum – OpEd}

\textit{Euro Asia Review, February 28, 2013}

That spurious drugs have been doing the rounds isn’t news but what’s shocking is the way the scourge has spread to OTC drugs too sparking widespread worries. Earlier, the ‘faking’ was restricted to costly and exclusive drugs like Viagra. But now, copies of over-the-counter pills like vitamin supplements, cough syrups and pain killers are being manufactured and circulated freely in India. India is left with little option but to stand up and face the conundrum…firmly!

A Right to Information (RTI) application filed this year revealed that that the problem of fake drugs in the country is much larger than we ever could believe. According to the reply provided by the Ministry of Health, a total of 345 cases of spurious drugs have been reported by Central Drugs Standard Control Organisation (CDSCO) between 2009 and 2012. Of these, 117 were reported in between 2009-10, 95 in between 2010-11 and 133 in 2011-12.

The data provided by the Health Ministry revealed, out of 1.37 lakh drug samples tested by CDSCO in the last three years, a total of 6,500 samples were found to be of sub-standard quality and 345 samples were reported fake.

Contrary to the ministry’s notion that rewarding whistle-blowers will affect the production of fake drugs, reality is quite the adverse and the number of fakes only seems to be increasing by each year. It was in 2009 that the Ministry had launched a scheme to reward those who give information regarding fake drugs.

Details provided through the RTI query revealed, in all, 37 complaints were received and investigated by the State Drug Controlling Authorities and CDSCO. However, none of the 37 complaints were found to be true and so far no one has been rewarded under the scheme.

\textbf{Concern For The Issue Goes Global}

An international newspaper had just recently carried a front page ‘exposé’ about how India has been exporting fake drugs to Africa and endangering the lives of thousands in the process. In reply, India denied claims that it has exported counterfeit medication to Africa.

A spokesperson for ministry of external affairs was reported saying “No fake medicines have been sent from India to the continent of Africa.” The article published in an English newspaper had reportedly cited concerns of experts and quoted NGO reports stating that almost one-third of the Malaria medicines imported to Uganda and Tanzania from India and China were counterfeit or of sub-standard quality. The drugs which looked identical to real ones could only be testified by laboratory tests. It was not just malaria drugs, the newspaper had also claimed that
antibiotics and contraceptives imported from India were fake. “Some pills contain no active ingredients; some are of partial strength and some have the wrong formulation entirely,” it reported.

The fake medications have reportedly led to deaths, prolonged illness and increased drug resistance in parts of east Africa, the article said. Indian officials denied the allegations adding this is not the first time that India has been accused of exporting counterfeit medicines.

A few years back, in 2009 too, there were reports of India supplying fake medicines to Africa. But investigations in the matter revealed that it was, in fact, China that had been supplying counterfeit drugs to Africa with a ‘Made in India’ tag to mar India’s image.

Although India had not named any country, probes conducted by drug controlling authorities in Nigeria and other African countries proved that the counterfeit medicines were in fact produced in China.

India’s pharmaceutical export to Kenya had almost doubled from Rs 292.94 crore in 2006-07 to Rs 543.86 crore in 2008-09. The drug export to Uganda and Tanzania alone rose during this period from Rs 152.75 crore to Rs 290.76 crore and from Rs 152.24 crore to Rs 274.94 crore respectively. This time around, China too has denied charges of importing fake medicines to Africa. It has been reported that, last year, Chinese police seized £113m of fake pharmaceuticals in July alone and £19m worth in November. Many ingredients in the medicines were found to be harmful or toxic.

Earlier this year, China, after denying claims of exporting counterfeit drugs, appealed to India to deal with the menace of fake drugs, which had been marred images of both the nation, together. The Chinese newspaper had, last month, carried out an article about how smugglers from inside and outside Africa are responsible for the problem of fake drugs.

**Dealing With The Issue At Home**

India has more than 10,000 drugs manufacturer and is the third-largest medicine producer all over the world. It has an estimated 5,000 production lines.

To tackle the problem of counterfeit drugs, the Indian health ministry launched a huge campaign last month to check the quality of medicines manufactured across the country.

Several pharmaceutical companies are planning on using barcode technology to help distinguish the genuine from the fake. These companies are also urging the users to use mobile phones to verify the authenticity of medicines by sending SMS or checking on the internet. Although India is a major player in pharmaceutical sector, its image is at risk and also globally with the growing fake-drugs market.

A recent report showed how grave the situation really is when it comes to fake drugs in the Indian market. But of all the state in India, Maharashtra came out to as the worst affected with 23 per cent of the medicines in the state found to be ‘not of standard quality’. In Tamil Nadu, the figures were a lot lower than Maharashtra at 13 per cent, Kerala was at 9.2 per cent, Gujarat at 8.5 per cent, Karnataka came to 7.2 per cent, Uttar Pradesh at 6.9 per cent, Jammu & Kashmir at 6.08 per cent and
Rajasthan 5.8 per cent.

It’s not just the ‘inaction’ of these fake drugs that is the matter of concern, many of these counterfeit drugs are also found to be dangerous and sometimes even fatal. A large portion of counterfeit drugs seized by the government were found to contain toxic chemicals like mercury and other heavy metals.

These chemicals, when consumed, can be extremely dangerous. When taken in place of genuine medicines, spurious drugs can be fatal. The government, thus, seeing this dangerous trend, has started a campaign to implement bar codes on drugs, so as to distinguish the real ones from the fakes.

The global anti-counterfeit packaging market is expected to be worth $79.3 billion by 2014. This opens up a significant market potential for bar-coding product authentication solutions for the pharmaceuticals industry. Hopefully, this would herald the end of counterfeit drugs that besides affecting India’s image globally are fatal too.

**Govt tightens rules to curb spurious drugs production**

*BioSpectrum, March 14, 2013*

The Department of Pharmaceuticals had constituted a High Powered Inter-ministerial Coordination Committee (HPIMCC) to implement the government’s commitment to provide quality medicines at affordable prices to the public

To minimize the manufacture of substandard drugs in the country and making the regulatory control more effective, the 12th Five Year Plan contains substantial provision for further strengthening the drug regulatory system both at central and state level.

Sharing information on this Mr Ghulam Nabi Azad, Minister for Health and Family Welfare, Government of India said, "The licensing and regulatory control of manufacture of drugs are the subject matter of the State Licensing Authorities and State Drugs Control Departments. The information about the details of the manufacturers are, therefore, not maintained centrally. Further, the Central Drugs Standard Control Organization (CDSCO) does not regulate the quantum of production of drugs by the drug companies."

The minister further said, "The Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers had constituted a High Powered Inter-ministerial Coordination Committee (HPIMCC) under the chairmanship of the secretary of that department to implement the government’s commitment to provide quality medicines at affordable prices to the public. As per the available information, the first meeting of the Committee was held on March 29, 2010. Based on the decision taken in that meeting, two Working Groups, viz., Working Group for Quality of Medicines and Working Group for Pricing of Medicines were formed. In its second meeting held on June 26, 2012, the HPIMCC considered the suggestions made in the reports of the two Working Groups. Thereafter, the minutes of that meeting and the
Indonesia remains an easy target for the distribution of counterfeit medicine sold not only through the Internet but also in pharmacies. Indonesian Pharmacists Association (IAI) secretary-general Nurul Falah said. Apart from Jakarta, there are also fake drug distribution hubs in Surabaya, East Java, and Medan, North Sumatra. Nurul said the distribution of fake drugs continued despite raids by the authorities. “We have tried our best to curb the distribution of fake drugs but those sold in pharmacies are hard to detect because they resemble the real thing,” Nurul told The Jakarta Post on Monday. “It is believed that these counterfeit drugs enter the pharmacies through freelance drugs salespeople.” The Victory Project research, conducted by the University of Indonesia’s urology department in 2011, showed that drugs related with erectile dysfunction therapy (phosphodiesterase type 5 inhibitor, or PDE5I) were the mostly counterfeited drugs. The research, sponsored by drug manufacturer PT Pfizer Indonesia, in the Greater Jakarta area; Bandung, West Java; Surabaya, Malang, East Java; and Medan showed that the drug sildenafil (an erectile dysfunction drug sold as Viagra, Revatio and various other trade names) was sold in drugstores, pharmacies, sidewalk stalls and via the Internet. Of the 518 tablets bought from the 157 outlets in the areas, 45 percent of the samples collected were counterfeit. Based on research in the respective areas, the distribution of fake drugs in both Greater Jakarta and East Java reached 50 percent, while Medan and Bandung recorded 20 percent and 18 percent respectively. Nurul predicted that the amount of fake medicine in circulation would rise further because a number of pharmacies lacked the sufficient equipped to detect counterfeit drugs. “In the near future, we will provide training to pharmacists to monitor the distribution of fake drugs. We will also use special devices to detect fake drugs to prevent counterfeit drugs from being sold in pharmacies next year,” he said. He added that his association would also request that the relevant agencies monitored drug sales at Pramuka Market in East Jakarta. Another worrying observations was that some pharmacists worked for up to four pharmacies. “If they work in four pharmacies simultaneously, they will face problems in monitoring the drugs sold there,” he said. Meanwhile, a researcher from the University of Indonesia’s pharmacology department Melva Louisa said that in addition to erectile dysfunction drugs, other drugs often counterfeited were those to treat headaches and pain. “Fake medicine are not made in accordance with regulatory standards. The issue is not only occurring in Indonesia, but also other developing countries,” Nurul said. The Indonesia Anti-Counterfeiting Community chairwoman Widyaretna Buenastuti proposed that the relevant agencies should raise the issue of transnational medicine trade at the upcoming Asia-Pacific Economic Community Forum in Bali. “The international trade in counterfeit medicine must be addressed together to prevent a developing country, such as Indonesia,
from becoming a conduit for the illegal medicine trade,” said Widyaretna.

- Source code: PharmaSecure goes mobile in battle against fake drugs
  www.theguardian.com, May 09, 2013

Counterfeit drugs affected people in 124 countries in 2011. Among them was India, where 20% of the drugs on the market are fake, according to the World Health Organisation.

It's a global war, hitting the developing world hard, says the Pharmaceutical Security Institute, a not-for-profit network of the security divisions of 25 big pharma companies. Counterfeit drugs, which are also referred to as substitute or falsified drugs, are a $75bn-200bn market according to estimates by Deloitte.

Roger Bate, an economist at the American Enterprise Institute in Washington DC, calculates that at least 100,000 people, mainly in poor countries, die annually from fake drugs. Asia has the most confiscations, but data – the bulk of which is withheld by pharma companies and governments – is lacking and statistics are estimated.

However, a 29-year-old from New Hampshire has decided to take on this battle from his office in a clocktower building in Gurgaon, in the Indian state of Haryana. Nathan Sigworth and a fellow Dartmouth College graduate, N Taylor Thompson, who has since left, founded PharmaSecure in 2007. Sigworth is now chief executive of the company, which is based in Gurgaon and Lebanon, New Hampshire, and prints unique codes on medicines to enable consumers to verify their validity and potency using their phones.

PharmaSecure is not the only company providing medical authentications. Sproxil and mPedigree are also using mobile technology to authenticate drugs, but do not operate on the same scale as PharmaSecure, which will soon be operating beyond India and has produced more than 500m coded packages. Up to 2m packages are coded every day, says Sigworth.

"Even though we're churning out so many meds, we are still only saturating 5% of the Indian market. We are now working hard to make this scale," he says.

That means integrating with pharmaceuticals. It's merely a matter of time, says Sigworth; pharma companies that previously printed codes on only three of their 17 medicines are now authenticating all of them.

Sigworth began digging into healthcare as a college student, volunteering in hospitals in rural India. "That's where I saw how cheap human labour is. In some cases, patients would not be given injections because they could just be monitored instead by staff to make sure their condition did not worsen."

Sigworth wanted to create a village-level healthcare solution. "That's where my roots are," he says. Even though Pharma Secure has developed an app that is user-friendly for middle class Indians with smart phones, its primary aim was to ensure that the bottom-of-the-pyramid consumer would be able to authenticate medicines with a
basic mobile. There is therefore no charge to consumers for the service; PharmaSecure’s revenues come from pharmaceutical companies that subscribe to the printing services.

Last year, Sigworth’s team collaborated with the Indian government to ensure all drug exports are coded. It’s now a mandate. Tom Woods, a Washington-based consultant and former diplomat who argues for stronger regulation of the drug trade, says India is an ideal place for this venture because the country is practically a "medicine cabinet to the developing world". India’s pharmaceutical industry is worth $12bn, according to Business Week.

The drugs that are hardest hit are the cheapest ones, says Sigworth. Criminals go for volume, which is much more profitable. The Institute of Medicine, which advises the US federal government, called the illegal drug trade the "perfect crime" in a February study called Countering the problem of falsified and substandard drugs. It said the "cost of making a fake drug is minimal and often leaves no paper trail, making it difficult to investigate and prosecute". Identifying a fake isn’t a job for the naked eye.

Mark Davison, PharmaSecure’s chief business officer and author of Pharmaceutical Anti-Counterfeiting: Combating the Real Danger from Fake Drugs, says the highly regulated nature of the pharmaceutical industry "engenders an overcautious approach", which has slowed innovation in the supply chain.

As supply chains in pharmaceuticals become more global and complicated, a tracking system becomes more critical. "[It’s a very] conservative industry," says Sigworth. "In the early days, it was a lot of banging your head against the wall and knocking on doors."

Now, though, the industry has an incentive to use these platforms, he says – and it’s all connected to the mine of data that companies like PharmaSecure are amassing.

PharmaSecure works with Interpol, which can detain illicit medicines. If the same code is verified in two locations using the PharmaSecure platform, an alert goes out, suggesting that fraudulent activity may be taking place.

Live, interactive information can be captured, compiled and analysed. A host of factors can be determined – where drugs are being used, when patients are dropping out, and what follow-up services should be offered to ensure that the drugs are properly taken. PharmaSecure 2.0 will go beyond medical authentication.

Telemedicine is starting that process. PharmaSecure users get a second SMS asking if they’d like a free consultation with a doctor via the online appointment service DocSuggest. These calls illuminate trends and data about drug consumption in India, Sigworth says.

PharmaSecure is "banking on the emerging markets", says Sigworth. "The way mobile leapfrogged in India and Africa, bypassing landlines, the same is going to happen in healthcare, with mHealth."

- This article was produced with the Pulitzer Center on Crisis Reporting
- This article was corrected on 9 May 2013. The original said PharmaSecure has produced more than 500bn coded packages. The correct figure is 500m. It was
Unlike India, China not helping Nigeria stop fake drugs'
One India News, May 15, 2013

Unlike India, China is not assisting in the fight against counterfeit medicines even though the influx has been mainly from that country, Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) says. "Comparative analysis has shown that China is not doing anything to help the Nigerian government in its attempt to control the import of counterfeit medicines, even though much of these medicines have been traced to China," NAFDAC spokesman Abubakar Jimoh told IANS on the phone from Nigerian capital Abuja. On the other hand, the Indian government "has joined hands with the Nigerian authorities to fight the influx and has thus reduced the flow of such medicines from India," Jimoh added. Nigeria has been faced with the influx of counterfeit medicines over the years and has tried several methods to overcome the scourge. Last year the government proposed a bill providing stiffer punishment for organisations and individuals who may be arrested for dealing in the manufacture and sale of counterfeit medicine. The government at the time wanted to use the bill to protect local manufacturers against inferior imports that were selling cheap on the market. It was proposed to provide support to three agencies - Standards Organisation of Nigeria (SON), National Agency for Food and Drug Administration and Control (NAFDAC) and the Consumer Protection Council (CPC) - to link their activities and work in concert. The government at the time promised to support to the organisations in the enforcement of regulations in the control of fake products. It has been revealed that NAFDAC has been able to bring the prevalence rate of fake drugs down to six percent from the 16.7 percent over the past five years. The proposed bill, however, turned out to be much ado about nothing as there was no movement forward. Jimoh's comments come to confirm an earlier statement by NAFDAC director general Paul Orhii that most fake, substandard and counterfeit drugs imported and openly sold on the Nigerian market were from China through smuggling with the connivance of some unscrupulous persons whose only interest is to make money. Orhii said even though Nigeria had been doing everything possible to fight the scourge of counterfeit drugs, China had remained a problem. This is because the authorities in China have refused to show any interest to assist in the elimination of the chain that had been traced to their country. "India has tried to collaborate with Nigeria maximally on strategies to reduce the importation of counterfeit medicines to the country," Orhii said, adding, "But, concerning China, we are still trying to work out how to collaborate with each other. For now, without fear of contradiction, I will say that China remains the highest exporter of these fake products and China is a problem for Nigeria." He said the Agency was working closely with the Chinese embassy in Nigeria to track down the company in China that connived in the shipping of counterfeit medicine into this country. Orhii said the recent discovery of a huge consignment of counterfeit drugs

Further amended to clarify that PharmaSecure offers doctor appointment services via DocSuggest. It does not have a partnership with mDhil.
had also revealed that these drugs were being sold in the market by those who also dealt in other products to escape the attention of the security agencies. Expressing his determination to fight the influx, Orhii said, "There will be no sacred cow in the fight against counterfeit medicines. Any counterfeiter arrested will be prosecuted according to the law of the land." This is an indication that foreigners who hide behind the cordial relationship between their country and Nigeria to engage in negative activities will not be spared the rod. It is however not clear how the Nigerian authorities intend to deal with the Chinese diplomatic mission that doesn’t seem to be interested in helping to fight the influx of counterfeit medicine. To achieve its aim to beat the influx, NAFDAC has also appealed to the general public, market unions and transporters to report any suspicious activities that would help it ensure that those who may try to avoid arrest were not spared but were prosecuted according to the law.

- The counterfeit medicines landscape in Indonesia

*IP KOMODO, May 15, 2013*

The Jakarta Post reported recently that Indonesia remains a counterfeit medicines hotspot. Distribution is though both the Internet and also in pharmacies. “It is believed that these counterfeit drugs enter the pharmacies through freelance drugs salespeople.” said Indonesian Pharmacists Association (IAI) secretary-general Nurul Falah.

Research sponsored by Pfizer in the capital and surrounding cities as well as East Java and North Sumatra showed the wide availability of counterfeits. It focused on Pfizer's drug sildenafil (an erectile dysfunction drug usually sold as Viagra,) They analysed sales at drugstores, pharmacies, sidewalk stalls and via the Internet. Of 518 tablets found in 157 outlets some 45 % turned out to be counterfeit. They also identified Jakarta's Pramuka Market a well known source of fake drugs.

This is consistent with IP Komodo's understanding. Counterfeit pharmaceuticals are either made locally or sometimes imported; distribution is via wholesale markets like Pasar Pramuka, then through roving salesmen, on motorbikes, who sell their wares to pharmacies and medicine shops throughout cities. Despite being a regulated industry pharmacies themselves do not always observe rules, such as having a pharmacist present. They find no problem sourcing from roving salesmen. The Department of Health officers that regulate pharmacies have made some efforts to investigate them, but few sanctions are ever given.

But the real problem is the scale of supply end in the wholesale markets where criminal elements rule the fake drugs industry. For this only police investigations will have any effect and unfortunately police IPR raids have all but ceased in Indonesia.
Amend law governing spurious drugs, say chemists
The Hindu, May 20, 2013

‘Consider medical shop owners as witnesses, but do not book cases against them’

Medical shop owners should only be seen as witnesses in spurious drug cases and not booked as accused. The legislation governing spurious drugs should be amended to this effect, demanded the Krishna District Chemists and Druggists Association here on Sunday.

Participating in the 68 anniversary of the association, the office-bearers said that medical shop owners would be forced to intensify their agitation if the law was not amended. They said that they should be only witnesses because they were purchasing the drugs from registered wholesale distributors.

The members also protested against the efforts of the Central government to curtail their profit margin.

They appealed to MLAs Malladi Vishnu and Vellampalli Srinivas, and MLC Ilapuram Venkaiah to plead their case with the Central government. The MLAs said these issues were not in the purview of the State government, but they would prevail on it to take up the issue with the Centre.

Drug Controllers’ Association state president M. Amrutha Rao said cases had to be booked against the medical shop owners and staff as per the law. The amendment of the law was in the purview of the government.

Until that happened, medical shop owners should double check the goods they were purchasing.

Association general secretary P.S. Patnaik, Federation of Drug Traders of A.P. general secretary J. Sateesh Rao, and president B. Venkata Raju spoke.

They sought the cooperation of the elected representatives in conveying their demands to the government.

Biological, mobile drug testing labs planned to plug substandard drugs
The Hindu, June 02, 2013

The Karnataka State Drugs Control Department is gearing up to establish mobile and biological testing laboratories in the State. A proposal seeking funds from the Centre has already been submitted to the Union government, said State Drugs Controller B.R. Jagashetty on Saturday.

Speaking at a programme organised to mark the golden jubilee celebrations of the Government Pharmacy College in the city, Dr. Jagashetty said the proposal to set up these labs had been pending for long.

He later told The Hindu that vaccines, blood products and biological drugs had
become indispensable therapy options in the healthcare sector. “There is a need to ensure that there is an advanced testing facility in Karnataka. Many of these drugs face issues pertaining to quality (substandard) mainly because of poor cold storage facilities,” he said.

While the biological lab would facilitate testing of vaccines, blood products and biological drugs, the mobile labs would help in testing drugs in rural areas. “The plan is to start with five mobile labs in the districts of Bangalore, Mysore, Hubli, Bellary and Gulbarga. Each mobile van will be customized with advanced testing equipment and manned by qualified analysts and technicians. These vans will visit chemists’ shops and pharmacies randomly in rural areas and also based on complaints,” he said.

He said this would not only instill a sense of responsibility among the chemists and discourage them from selling spurious drugs but also ensure proper storage of medicines.

“It has been our dream to set up these laboratories. Although it had been decided to set up the labs with funds from both the State and Central governments, we have sent a proposal to the Centre seeking grant of Rs. 149 crore for the labs,” said Dr. Jagashetty.

**Pharmacy college**

Earlier, Minister of State for Medical Education Sharanaprakash Rudrappa Patil, who released a souvenir brought out to mark the occasion, said the government would expedite the process of setting up a second government pharmacy college in north Karnataka.

“The demand for a second college has been pending. We have also realized that there is a need for another college and we will meet the demand,” he said.

**As a profession**

Minister for Health and Family Welfare U.T. Khader spoke on the importance of pharmacy as a profession. “All our plans to upgrade hospitals and provide quality healthcare can be implemented only if we have the required number of qualified pharmacists. I assure all assistance from the Health Department to the Drugs Control Department,” he said. Principal Secretary (Health and Family Welfare) M. Madan Gopal released a documentary on the completion of 50 years of the Government College of Pharmacy.

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**India rejects allegations of exporting counterfeit drugs**

*DNA India, June 03, 2013*

Some isolated reports have also been received about export of spurious /counterfeit drugs attributed to some source in India.

India on Monday rejected allegations of exporting counterfeit drugs, saying those
are desperate attempts by some countries to malign its flourishing pharmaceutical industry, which enjoys a unique position of low-cost manufacturing and highest quality medicine.

It said there were reasons to believe that "vested interests" were raking up isolated issues about technical deficiencies in good manufacturing practices (GMP). There have been extensive media reporting about the quality of drugs (pharmaceutical products like Active Pharmaceutical Ingredients and formulations) manufactured in India for exports.

Some isolated reports have also been received about export of spurious /counterfeit drugs attributed to some source in India.

"Government has strong reason to believe that some of the spurious drugs detected in the international markets, alleged to be exported from India, are desperate attempts by other countries getting affected by the strength of Indian pharma industry," the ministry of commerce and industry said in a statement to clarify on reports of malpractices of pharma manufacturing in India.

The statement came after New Delhi-based Ranbaxy Laboratories, India's largest drug company by sales, pleaded guilty in the United States to criminal charges of making adulterated medicines and agreed to a 500 million dollar (around Rs.2,833 crore) settlement.

The ministry said the pharmaceutical sector in the country is a highly regulated one and the exports are heavily guided by various regulatory regimes of the importing countries. And there is also a requirement for continuous monitoring of quality related aspects, including complaints of sub-standard / falsified drugs from various countries.

The Drugs Controller General of India (DCGI) is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India. The State Drug administration offices regulate issue the manufacturing licenses and quality control monitoring etc.

The DCGI regularly holds meetings with the State authorities and also interacts with drug regulators across the globe to ensure that the international practices of manufacture and supply of drugs are followed in India. India's compliance with TRIPS and consequent implementation of Patents Act is appreciated all over the world.

"All the concerned organisations in the government are constantly interacting to ensure that India's image as a safe exporter is protected from all angles. Government and the industry is already working on a 'trace and track' mechanism which would enable monitoring of the supply chain possible at all the three levels — tertiary, secondary and primary."

The pharma industry is a highly knowledge based industry which is growing steadily and playing a major role in the Indian economy. India has a large vendor base for supplying quality generics/API/ contract manufacturing with state of the art facilities.

The ministry said there are more than 350 manufacturing sites endorsed by EU for their GMP standards in India as on April 30, 2013. As on December 30, 2012, over 3,000 drug master filings (DMFs) with the US, amounting for an almost 40 percent of
the total DMFs filed with the USFDA, are filed by over 233 different companies from India.

"Companies/importers from all over the globe are encouraged to visit the manufacturing facility in India to satisfy themselves of the quality of production of drugs," the government said.

India’s pharma industry is 4th in the world in terms of production volumes and over 55% exports are to highly regulated markets.

India’s drug exports totaled $14.6 billion (around Rs.82,730 crore) in the financial year up to March 31, marking growth of nearly 11 percent from the previous financial year.

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**India Says Its Drugs Are Safe, Despite Generics Fraud**

*The Jakarta Globe, June 03, 2013.*

India, known as the “pharmacy to the world,” on Monday defended its lucrative generic drug industry as safe and strongly regulated after the nation’s biggest drug firm pleaded guilty to US charges of making adulterated medicines.

In a bid to defend its generic export sector, the government also charged that “isolated reports” of spurious drugs found in global markets and alleged to be from India were “desperate attempts” by other countries hurt by “the strength of the Indian pharma industry.”

India’s “pharmaceutical sector is a highly regulated one and the exports are heavily guided by various regulatory regimes of the importing countries,” the government said in a statement.

The statement came after New Delhi-based Ranbaxy Laboratories, India’s largest drug company by sales, pleaded guilty in the United States to criminal charges of making adulterated medicines and agreed to a $500 million settlement.

The fraud, investigated over eight years by US authorities, was brought to light by a whistle-blowing ex-employee, who said Ranbaxy created “a complicated trail of falsified records and dangerous manufacturing practices.”

India built a reputation as the “pharmacy to the world” for its production of life-saving generic versions of medicines for poor nations that cost a fraction of brand-name versions.

But analysts have warned that Indian drug makers may find it tough to win new contracts in their main US market, with the case involving New Delhi-based Ranbaxy raising questions about the safety and quality of Indian-made drugs.

Generic drug firms in India have been a major supplier of copycat medicines to treat diseases such as cancer, TB and AIDS for those who cannot afford expensive branded versions.
The country “has proven international quality standard capabilities,” the government said.

It said India enjoys “a unique position of low-cost manufacturing and the highest quality medicine, the best of both the worlds.”

India’s drug exports totaled $14.6 billion in the financial year to March 31, marking growth of nearly 11 percent from the previous year.

Japanese drug company Daiichi Sankyo which bought Ranbaxy in 2008, has since alleged that the Indian firm’s former owners hid vital information about US regulatory inquiries at the time of the $4.6-billion purchase.

The charges have been strongly denied by the billionaire Singh family which used to control the company.

India has long alleged that some complaints about the quality of its generic medicines originate with rival brand-name manufacturers unhappy about the growing use of cheaper knock-off drugs as developed nations tackle soaring health care costs.

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**Special courts to try spurious drugs cases**

*The Hindu, June 12, 2013*

The State government has designated five District and Sessions Judge Courts as special courts for trial of offences pertaining to adulterated or spurious drugs.

The District and Sessions Judge Courts of Koraput, Ganjam, Sambalpur, Balasore, and Cuttack would deal with cases pertaining to adulterated drug cases. The special court in Cuttack would have jurisdiction over eight districts.

The courts have been designated as per one of the provisions of the Drugs and Cosmetics (Amendment) Act, 2008, that relates to constitution of special designated courts for trial of offences relating to adulterated or spurious drugs.

The provision says the Central or the State government, in consultation with the Chief Justice of the High Court, would designate one or more courts of session as special courts for trial of offences relating to adulterated drugs by notification.

The Drugs and Cosmetics Act, 1940, was amended by the Drugs and Cosmetics (Amendment) Act, 2008, enhancing penalties for various offences. It was passed by Parliament on December 5, 2008.

The Act came into force on August 10, 2009. It provides deterrent penalties for offences relating to manufacture of spurious or adulterated drugs, which have serious implications on public health.

After the amendment, the penalty for manufacture of spurious or adulterated drugs was enhanced to imprisonment for a term that shall not be less than 10 years, but which may extend to imprisonment for life, and shall also be liable to fine that shall
not be less than Rs.10 lakh or three times the value of the drug confiscated, whichever is more.

In Odisha, by the end of 2010, drug-related cases numbering 381 were pending with different courts of law. The expeditious trial of such type of cases necessitated constitution of special courts.

**Fake & sub-standard drugs: India, China may be worst offenders**

*Economic Times, June 16, 2013.*

The World Health Organisation (WHO) has a humble disclosure to make: there is still no accurate estimate of the global scale of counterfeit medicines. Perhaps as compensation, the multilateral body has hung a new name on such products: substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medicines.

Various reports by others suggest that the size of the global fake drugs industry could run into hundreds of billions of dollars. Deloitte’s vice-president Terry Hisey says it could be in the range of $50 billion to $200 billion annually. Health economist Roger Bate, who is also the author of the book Phake, which is an outcome of years of research into counterfeit drugs, says countries such as India and China are at the forefront of such a menace, selling fake drugs locally and globally.

**Asia Ranks No. 1 in Pharma Crimes...**

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<th>Region</th>
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<tr>
<td>Africa</td>
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<td>Latin America</td>
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*Note: The numbers are incidents of pharma crime*

But he doesn't blame Indian companies entirely, and hastens to add that one must differentiate the substandard from the fake. That makes sense, says the father of an eight-year old child in Bangalore who became "semi-blind" after using fake eye drops. The 40-year-old father didn't wish to be named. He also didn't name the company that sold the product. "A substandard drug wouldn't have harmed his vision, but a counterfeit or fake drug in which the components are chalk or dust or
some other cheap powder has," says a Karnataka health ministry official who asked not to be named because he is not authorised to speak to the media.

Another health official, based in Delhi, is worried: will health regulations help? Can the private sector chip in to check the menace? He doesn't have an answer yet. He spoke on condition of anonymity.

**Death By a Pill**

Kolkata-based Shanth, 25, who doesn't want to disclose his surname, believes that his 65-year-old father died last year of a heart attack after using "a famous antitriglyceride drug" made by a foreign company for two years; he was told by doctors that the drug appeared ineffective. "We paid for the drugs and were sold fake drugs," he claims. Doctors that ET Magazine spoke to say a person with high triglycerides can die of multiple reasons, but don't rule out the possibility of "the villain": the fake drug. While several reports quoting the WHO say that up to 20% of the drugs sold in India are fake, the health body told ET Magazine that "we will not comment on individual countries. This is a worldwide problem".

It is a global menace indeed: according to a report by International Protection Network, fake tuberculosis and malaria drugs are estimated to kill 700,000 people a year; it adds that most fake drugs originate from India and China. A recent Lancet study says 7% of anti-malarial drugs in India — where 70% of the population faces the risk of contracting the killer disease — are counterfeit.

**Victim of Perception?**

Dr Jeffrey L Sturchio, senior partner at US-based health consultancy Rabin Martin and former president and CEO of the Global Health Council, says almost all the recent studies on counterfeit drugs indicate that India and China are two countries from which a large fraction of the global flow of SSFFC medicines come. But he feels that it not so much the big Indian companies which are responsible for counterfeits.

"After all, many of them have substantial export businesses to markets in North America and Western Europe and would not want to jeopardize their investments in products for those markets," notes Sturchio, adding that "although from time to time you might find an example like the Ranbaxy products for which test data were falsified, for the most part Indian pharma firms have a clear economic interest in producing medicines of international quality standards".

Ranbaxy, India's No. 1 drug maker by sales, was recently fined $500 million in the US after it was found guilty of misrepresenting clinical generic drug data and selling adulterated drugs to the US. A Ranbaxy spokesperson insisted that it sold "only adulterated drugs, not fake drugs". Both Sturchio and Bate feel that the problem in both India and China — and in several African markets like Nigeria — is that there are thousands of pharmaceutical producers, many of which are small businesses beyond the reach of overworked regulators. "Without adequate surveillance and appropriate penalties for not playing by the rules, regulators don't have the tools to enforce quality standards and take SSFFC off the market," says Sturchio.
SSFFC What?

Sturchio has his reservations about the nomenclature. "Rather than speak only of counterfeit medicines [it would seem the definition of these is straightforward — medicines that are not what they purport to be], we have the complex locution of SSFFC. The challenges to global public health from unscrupulous producers are as clear as the solutions are elusive," he argues.

Prafull D Sheth, a former president of the Indian Pharmaceutical Association who has done a survey for the WHO on India's counterfeit medicines, says: "Unfortunately, media reports have a multiplier effect and the situation in India is clearly blown out of proportion." His logic is similar to Bate's and unlike Jeff's: differentiate between fake and substandard drugs. The former is far more dangerous than the latter, argues the health ministry official.

The study led by Sheth in 2007 arrived at the conclusion that the extent of counterfeit suspects was to the tune of 3.1% of total drugs sold in the country. He said the country faced a graver problem from substandard drugs that did not have all the ingredients that should be there in a drug. "Based on domestic sales of Rs 31,500 crore in 2006, the extent of suspected counterfeit medicines would be extrapolated to Rs 100 crore. The figure is considerably lower than Rs 4,000 crore in earlier reports," the report said. Sheth was executive vice-president of Ranbaxy.

Conspiracy Theory

For her part, Dr Mira Shiva, renowned public activist, sees a conspiracy against the flourishing Indian pharmaceutical sector which sells "cost-effective as well as high quality drugs". But the health ministry official begs to disagree: "Since we got freedom we have been fed on this foreign hand political diet. I think it is baseless to blame foreign companies for malpractices by our companies."

He concedes that various panels set up to look into manufacture and sales of counterfeit drugs following a rap by the Allahabad High Court three years ago have
not yet produced much results. The court had noted that fly-by-night operators had set up base in several areas of Uttar Pradesh and Haryana, and that more than 60% of the drugs go to rural markets or to Africa.

Early this year, India denied exporting large quantities of counterfeit drugs to Africa following an expose by the Guardian. "No fake medicines have been sent from India to the continent of Africa," a spokesman for the ministry of external affairs had said.

However, much to the anguish of all those who refer to "a foreign hand", the parliamentary standing committee on health and family welfare had last year issued a damming report accusing drug regulatory agency — Central Drugs Standard Control Organisation (CDSCO) — of "colluding" with pharmaceutical companies and medical experts.

The 78-page report pointed out a series of procedural failures and sought explanations on how some drugs banned for sale in the US were allowed to be sold in India. The local pharmaceutical market is the fourth largest in the world in terms
of volume and generates $12 billion in sales.

Bate, who has studied the issue closely, says that following this "extensive corruption and misrepresentation of pharmaceutical drug data, the health ministry set up a committee to investigate the findings, but nothing has come of it".

The 13 drugs studied by the panel can't be sold in Canada, Britain, European Union and Australia as well. Shiva, who is a member of the Indian government's sub-group on "spurious and adulterated drugs" constituted by a "task force" headed by Dr VM Katoch, has not heard anything about its 2011 recommendations to "strengthen the drug sector" in the country.
The Chinese Hand

A foreign ministry official ET Magazine spoke to alleges that several Chinese companies are zealously manufacturing "Made in India" drugs for sale in Africa, especially in Nigeria where many "Indian counterfeit" drugs have been confiscated over the past few years.

ET Magazine couldn't independently verify this claim. Sheth also backed the official version, adding that the Indian government has very often taken up the matter with the Chinese government. According to official estimates, of the Rs 1,00,000 crore worth drugs made by the Indian manufacturing industry, medicines worth Rs 42,000 crore are exported.

Whatever the claims and counter-claims are, says Sturchio, the impact of counterfeit medicines and substandard medicines around the world is appalling. Explains he: "When life-saving medicines are counterfeited and don't contain the active ingredient, they can kill the patients. Other counterfeit medicines might have deleterious products in them that cause harm. The global trade in these SSFFC medicines is now measured in tens of billions of dollars, and governments, industry and civil society are beginning to take up seriously the need to develop the necessary partnerships to curb these practices."

Problem at Hand

Ranjit Shahani, managing director of Novartis India, is highly pessimistic about implementation of local rules. "The regulations against counterfeiters exist. The serious gap is in their implementation. Most major pharmaceutical companies together with the regulatory authorities carry out raids against counterfeit medicines but it seems to be an uphill task notwithstanding the stringent penalties for counterfeiters.

A whistle-blower policy was announced by the health minister with a reward of Rs 25 lakh two years ago. No one has received it so far — that speaks for itself," he points out, emphasising that the situation is very grave at home. In a country that is home to more than 6,000-8,000 small units manufacturing medicines, he says, the government must first ensure that they adhere to basic good manufacturing practices. He can't hide his scorn for the talk of lack of resources when it comes to health care.

"What can be more important than health and yet you always hear 'lack of resources' — we have heard this long before, we hear it today and I can assure you we will hear it tomorrow as well," he declares. Shahani shares the views of several other health experts that lack of "proper data" is a big curse. "India, of course, is not a data rich country and there is no reliable data available [on fake drugs]. Estimates available vary widely," he says, adding, "It is important, however to note that the quality of medicines available in the country is highly variable. At one end, you have plants with global standards and at the other end you have plants that are literally hole-in-the wall operations."

Bate feels that the most important thing for the Indian government is to acknowledge the problem of fake and substandard drugs. The government must stop pretending that anyone raising concerns is just trying to destroy Indian exports.
or is working for a competitor. He, however, adds: "There are folks out there who want to run down Indian generics, and the government is right to oppose them."

He also says that India should take the lead at international SSFFC fora and push for better global law against fakes and sub-standards. "As I explain in my book (Phake), this [move] would directly help patients and the Indian industry.

Right now the government of India is seen as obstructionist. As to taking Indian medicines...the last time I was in Chennai I was very sick, and knowing what I knew then about Ranbaxy I still took Ranbaxy drugs (ciprofloxacin in that case).... In other words Indian drugs are generally good, but Indian companies need to do more to ensure they improve," he adds.

Rays of Hope

A Lupin spokesperson says: "If there is no barcode [or a unique number] and a phone number to SMS that number [on our medicines], they are not our drugs." He is referring to the serial number generated by global firm PharmaSecure, which is now actively present in India. There are many companies that provide "solutions" to check the threat of counterfeit drugs (see The Cure).

Kishore Kar, who heads PharmaSecure's business in India and South Asia as its senior vice-president, says the company offers compliance solutions to six of the top 10 pharma firms in India. Its solutions are simple: a serial number and a phone number on the drug package. If you type the number and text it to the phone number — which is not yet toll-free — you get a reply similar to this one: "Lupin Limited authenticates genuine pack of lovax 150, Batch No PP20004. Thanks for your patronage."

In a country where people have more access to mobile telephony than toilets, this solution connects directly with the end user. Kar, a former IAF officer who later sold satellite-based technology solutions across Asia, says the response is huge. PharmaSecure has also launched value-added services such as drug refill reminders and calls to alert a patient to take his or her medications. Kar explains that the new launches have shown to increase patient retention for companies by up to 5%.

That is good news indeed in a market where everything from relatively less hazardous Viagra knockoffs to fake HIV/AIDS and cancer drugs are aplenty.

Vigil up on spurious drugs

_The Hindu, June 14, 2013_

The Regional Pharmacovigilance Centre (RPC) set up at the Government General Hospital (GGH) here is going to be of immense benefit to the patients as they can complain of adverse reactions of drugs, thereby facilitating appropriate action against the pharmaceutical companies found supplying substandard drugs. It is the first Pharmacovigilance Centre sanctioned in government hospitals in the State.

Complaints lodged in the RPC will be sent to the Department of Health & Family
Welfare and State Pharmacovigilance authorities, whose responsibility is to report the same to the Central Drugs Standards Control Organisation (CDSCO), which is the apex body that regulates the manufacture, sale, and distribution of drugs in the country and also of imported drugs.

Both the government and private hospitals in Krishna, Guntur, Prakasam, and Nellore districts can refer complaints to the RPC, where a team of experts in pharmacology, toxicology, and epidemiology will check the genuineness of the drugs suspected to be spurious or of substandard quality and report to the higher officials for facilitating action against the companies which supplied the drugs.

Every teaching hospital is supposed to have a Pharmacovigilance Centre as per the guidelines of the Medical Council of India (MCI) and the GGH has got the first one in the State being a major hospital catering to the health care of more than 2,000 outpatients daily.

Complaint boxes are being set up in all wards of the GGH and the aggrieved patients can also lodge complaints personally. Head of Department of Pharmacology Zaheeda Bano will look into the complaints and get necessary analysis done.

Case studies

Students of pharmacy are allowed to make case studies in the RPC for keeping themselves informed of the patterns of usage of drugs and their reactions on patients.

GGH Superintendent Ch. Mohan Rao and Guntur Medical College Principal K.S. Vara Prasad will be monitoring the functioning of the RPC and ensure interdepartmental coordination.

Fake Drugs Menace: India among Worst Offenders

Silicon India News, June 19, 2013

The World Health Organisation (WHO) has come up with a new name for counterfeit medicines, namely, the substandard, spurious, falsely labeled, falsified and
counterfeit (SSFFC) medicines. As per different reports the size of the global fake drugs industry could be worth billions of dollars, reported Ullekh NP for ET Bureau. Health economist Roger Bate, who is also the author of the book Phake is of the opinion that countries like India and China are at the vanguard of selling fake drugs locally and globally. Further, numerous reports quoting the WHO say that up to 20 percent of the drugs sold in India are fake. As per a report by International Protection Network, fake tuberculosis and malaria drugs are estimated to kill 700,000 people annually. The report adds that most fake drugs come from India and China. Prafull D Sheth, a former president of the Indian Pharmaceutical Association has done a survey for the WHO on India's counterfeit medicines in 2007 and was quoted by the ET, saying, "Unfortunately, media reports have a multiplier effect and the situation in India is clearly blown out of proportion." Talking of the difference between fake and substandard drugs, he says, the former is far more dangerous than the latter.

Sheth concluded that the extent of counterfeit drugs was 3.1 percent of total drugs sold in India. He said that the country faced a glitch from substandard drugs that lacked the ingredients that should be there in a drug. His report said "Based on domestic sales of Rs 31,500 crore in 2006, the extent of suspected counterfeit medicines would be extrapolated to Rs 100 crore. The figure is considerably lower than Rs 4,000 crore in earlier reports," reported by the ET. Further, it is seen that a whistle-blower policy was announced by the health minister with a reward of Rs 25 lakh two years ago, but no one has received it so far, revealed Ranjit Shahani, managing director of Novartis India. This only highlights the poor regulation and law in India. While India faces the menace of substandard drugs and the healthcare industry lacks transparency, the country should push for better global laws against fake and substandard drugs.

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**It's all fake**

*Ceylon Today, June 25, 2013*

Of late, the health sector has come under public scrutiny. The most recent raids on pharmacies and hospitals have brought to the forefront duplicity in the medical fraternity by unmasking many health officials who are exploiting the naivety of the nation.

A survey done by the Government Medical Officers Association (GMOA) has revealed that there more than 40,000 unregistered doctors in the country, practicing as 'quacks.' This figure comprises doctors who have been interdicted, medical college dropouts, paramedical officers, retired pharmacists and even relatives of doctors.

GMOA President, Nalin de Soyza, asserted that quacks are providing treatment and dispensing medication, putting patients' lives at risk. He further stated that banned and unregistered drugs are being distributed to patients by these so-called 'doctors' who operate with impunity.
Meanwhile, customs officials recently detected 30,000 vials of abortion pills worth over Rs 30 million hidden in a consignment of potatoes from Pakistan.

Around the first week of May, this year, too, the Consumer Devices & Drug Regulatory Authority, detected a lorry load of unregistered cosmetics and drugs in Gampola. It was discovered that the racket had been going on for a long time, prior to it being exposed.

Additionally, according to the People's Movement for the Rights of Patients (PMRP), unregistered and unapproved drugs are on sale in pharmacies around the country. There are some 15,000 drugs flooding into the market and it has been found that the resources available to test the quality of these drugs are limited. With no quality assurance and post-marketing surveillance, these drugs are being distributed to patients haphazardly. Also, it has been found that the same drug is imported under different brand names and distributed at high prices. Pharmacists say that a certain variety of the antibiotic, Amoxicillin, can go up to Rs 80 per capsule. What's more, there are around 50 varieties of the analgesic paracetamol and over 100 varieties of the Amoxicillin sold in pharmacies across Sri Lanka.

**Thirty per cent drugs are fake**

Most of the pharmaceutical drugs imported into the country are from India. However, it must be noted that in India, 30% of medicinal drugs are fake, some of which are being channeled towards unsuspecting neighbors by unscrupulous businessmen, who smuggle them across the border. Thereafter, they are introduced into the mainstream health arena by fraudulent doctors who dispense them to innocent patients. Pharmacists in turn are enticed into selling these bogus drugs alongside registered medications, presenting patients with the attractive possibility of buying the 'same' drug at lower price.

Secretary, All Island Pharmaceutical Traders Association, P. Sundersan, said patients are fooled by pharmacists into purchasing fake drugs. He points out that the Sri Lankan public has always been ignorant of its right to information even on mundane matters. This is apparent even during the consultation of a doctor, when patients who are generally in awe of their authority, do not question them on the type of treatment given to them, particularly on the abundance of medication sometimes prescribed for a simple cough or flu.

According to him, the lack of foresight extends to the transaction that occurs over the drug counter as well. "Patients who demand for air conditioning inside pharmacies often do not care to find out whether the person dispensing the medication is a qualified pharmacist or not. They take it for granted that he or she is one." he said.

A survey by the health authorities has revealed that there are more than 6,000 pharmacies operating in the island, with 50 % having no in-house registered pharmacists. Most of them have bought licences from qualified pharmacists who are never physically present at the site. The medications are distributed by a salesperson, which increases the risk for error, and in turn poses a hazard to a patient's life.
Imports far surpass need

PMPR Joint Secretary, Christine Perera, confirmed that drugs with the same or similar name as the original are offered to patients at half the normal price of the medication. The patient who is blissfully unaware of the difference is happy to procure the required medication at a reduced cost.

The glaring fact, which Perera too emphasized, remains that the counterfeit medications which are manufactured at cottage level industries in various parts of rural India and come in convincingly neat packs of cards, are ineffective and do not even come close to the original medication prescribed. An antibiotic dispensed thus by a pharmacy was found to have wheat flour as its main component.

Pharmacist Sundersan went on to say that the country’s import of pharmaceutical drugs surpasses the need for them. He also highlighted the fact that, "The antibiotic, Amoxicillin, comes into the Sri Lankan market in 100 different forms under various brand names and is dispensed very generously."

Most of the antibiotics are to be taken as a course. and more often doctors do not inform or caution the patient that it is necessary to take the entire course in order for the drug to be effective. It has been found that many patients abandon the course when they start to feel better and this may lead to further complications in the patient’s health at a future date. For instance, the patient could become resistant to antibiotics and may not respond to treatment involving these if the need arises for such drugs to be prescribed to the patient.

CAA takes action

Compounding the issue, recent media reports revealed that many unqualified and ayurvedic doctors are misleading naïve patients by providing the drug paracetamol in different colours and forms. The patients who mistakenly believe that the doctor has given them a different medication and proceed to take additional doses of the generic form, end up with an overdose of the same medicine. Overdoses of any medicine, even one as seemingly harmless as paracetamol, may easily become fatal.

To counter this practice, the Cosmetic Devices and Dug Regulatory Authority (CDDRA) ruled last month that all paracetamol tablets manufactured locally or imported into the country should be white in colour. "This would allow patients to recognize the drug and also minimize the doctors’ ability to confuse them," CDDRA Chairman, Dr H. Beneragama, said.

Last month, patients in private hospitals in Navinna, Kerawelapitiya, and Kurunegala were administered with outdated saline. Following a complaint made by the parent of a patient to the Consumer Affairs Authority, the hospital was raided and was found to have stocks of expired saline and pharmaceuticals drugs that were being given to unwitting patients.

The Consumer Affairs Authority (CAA), under the direction of Trade and Co-operatives Minister, Johnston Fernando, is now on a rampage checking all pharmacies and hospitals for the possession of drugs that have expired. CAA Chairman, Rumy Marzook, said they have already raided over 40 pharmacies and hospitals out of which 10 pharmacies have been charged for selling expired drugs.
Sundersan further observed that doctors have no compassion on the patients who consult them. Very often they do not hesitate to prescribe branded drugs that are expensive, even to a patient who clearly cannot afford it. The patient is not informed that there are cheaper drugs of the same generic name and ends up with unnecessarily large bills for his medication. "The poor patient in addition to paying an exorbitant fee to the doctor, ends up paying more for the same drug he could have bought cheaper, if only the doctor had prescribed it under its generic name," he noted.

"The alternative course of action for a patient is to buy the prescribed drugs from the government pharmaceutical drug outlets, Osu Sala. The problem with this, however, is that there are only a few of these outlets in the city and its suburbs. The financial constraints within the Health Ministry do not allow for island wide branches," Christine Perera said.

**Unscrupulous elements can be eliminated**

"This brings us again to the implementation of the National Drug Regulatory Policy (NDRP). It is eight years since the NDRP was taken up by the Cabinet under the Mahinda Chinthana with a promise extended to the public, to implement the policy soon. Since then, two Health Ministers have held office in succession but the NDRP is still to see the light of the day," she pointed out.

The NDRP states that only about 1,000 varieties of drugs under five brand names can be imported into the country. This would allow the regulation of drugs that enter the Sri Lankan market. Along with regulation, the quality of the drugs too may be tested. Further, through the imposition of this policy, unscrupulous elements within the pharmaceutical industry can be eliminated and only the necessary quantity of drugs within the general patient's budget can be brought in. Thus, Sundersan's concern that a person spends over Rs 8,000 or more of his allowance on branded medication, will also be addressed.

Perera described the operation of quacks in the country as a 'huge' problem, and placed the sole responsibility of weeding these illegitimate practitioners out of the health sector on the Sri Lanka Medical Council (SLMC). The patients on the other hand are helpless as they are not able to identify the quacks. "Most of these unregistered doctors operate in the suburbs and rural areas, so innocent villagers are duped," she said.

Commissioner of the Sri Lanka Human Rights Commission (SLHRC), Dr. Prathiba Mahanama, said the health system in the country is deteriorating due to the lack of a proper monitoring system. He declared that Sri Lanka is being used as a lab for experimenting with new drugs, and that most of the untested drugs are dumped here, making convenient guinea pigs out of the Sri Lankan masses. "The Health Ministry has no proper control over the distribution of drugs," he noted.

He also blamed the doctors for the present state of affairs, and said a patient's rights are compromised when the doctor who dispenses the medication does not spend enough time to talk about the side, or after or long-term effects of the medication that had been prescribed to him or her. "Modern day doctors do not spend any time with the patients. They do a cursory examination on the patient and send them off."
Their main concern is with numbers – the number of patients they can consult within a specific time span. It is all about the money. The patient’s right to ask questions is being infringed,” he said.

❖ Counterfeit drugs issue forwarded to parliamentary committee
   *CNM, July 13, 2013*

Maafannu South member of Parliament (MP) Ibrahim Rasheed has asked the parliamentary Committee on Executive Oversight to investigate the widespread import and sale of counterfeit pharmaceutical drugs in Maldives.

In a letter to the committee chair, Thoddoo MP Ali Waheed on Thursday, Rasheed alleged that the government's State Trading Organization (STO) was also complicit in the scam.

Rasheed said that the counterfeit business has reached "extreme" levels.

While the Maldives Food and Drug Authority (MFDA) recently issued a warning against the use of India's Baxter intravenous (IV) solutions - after suspect particles were found in them - and called on authorities and healthcare centers to return them to MFDA, Baxter products are still widely in use, Rasheed said. Though they should be immediately destroyed, they are still being used widely in the atolls, Rasheed said, adding that this puts many people's lives at risk.

Rasheed went on to say that counterfeit drugs are being consumed by many without their awareness and that this can be stopped only by holding the government and state institutions accountable. He called on the committee to investigate the matter at the earliest.

❖ India, Africa to check fake drug menace
   *Deccan Herald, September 27, 2013*

Medicines from China being off-loaded as Indian products in Ghana, South Africa and Ivory Coast

With Chinese counterfeit medicines being pushed into Africa with fake "Made-in-India" labels, New Delhi is in favour of close interaction between Indian drug regulators and their African counterparts to jointly fight against the menace.

Keen to make it sure that mischief by some pharmaceutical companies based in China does not have any adverse impact on India’s growing business interests in Africa, New Delhi took up the issue with Beijing and requested it to take action against the fake drug makers. “The health of our brothers and sisters in Africa are as important for the Indian government as that of our own citizens,” said Gurjit Singh,
Joint Secretary in the East and Southern Africa Division of the Ministry of External Affairs. “It is now clear that the fake drugs being sold in Africa with ‘Made in India’ tag are not produced in India, but elsewhere,” he said. Singh did not specify in which country the fake medicines were actually being produced. But probes by drug controlling authorities in Nigeria and other African countries over the past few years proved that the counterfeit medicines were in fact produced in China. The National Agency for Food and Drug Administration and Control of Nigeria in 2009 seized a large consignment of counterfeit anti-malarial generic medicines with “Made in India” labels and later found that the fake drugs had in fact been produced in China. New Delhi suspects that Chinese companies were marketing fake drugs with “Made in India” tags in order to malign the image of the Indian pharmaceutical companies in the African continent.

Market share Sources said the Centre had been receiving information about fake drugs from China being off-loaded as Indian drugs in countries like Ghana, South Africa and Ivory Coast in general, where India had a substantial market share. But the report from Nigeria’s National Agency for Food and Drug Administration and Control was the first confirmation, which New Delhi followed up by lodging a strong protest with Beijing. To counter the efforts to malign the image of Indian drug companies in Africa, New Delhi is embarking on a Brand India promotion campaign in the continent and sending a high-level delegation to the African countries like Uganda, Tanzania and Kenya on March 28 next. The delegation, according to the sources, will comprise drug regulators and key officials from the Ministry of Commerce and Ministry of Health, in addition to the representatives from pharmaceutical industries and it will tour the African countries till April 10. The Ministry of Commerce in association with the Indian Missions in those countries would also hold exhibitions, conferences and buyer-seller meets to dispel doubts about Indian pharmaceuticals. The African nations are all potentially growing market for the pharmaceutical industry of India, with export of generic drugs to these countries witnessing steady growth over the last few years. India’s pharmaceutical export to Kenya almost doubled from Rs 292.94 crore in 2006-07 to Rs 543.86 crore in 2008-09. The drug export to Uganda and Tanzania alone rose during this period from Rs 152.75 crore to Rs 290.76 crore and from Rs 152.24 crore to Rs 274.94 crore respectively.

Ex MS writes to CM to stop manufacturing medicines at govt ayurvedic pharmacy

_Hindustan Times, September 27, 2013_

With high level inquiry regarding purchase of substandard raw materials for ayurvedic medicines delayed for past two years, the former medical superintendent of Government Ayurvedic Pharmacy and Stores in Patiala has written a letter to Punjab chief minister Prakash Singh Badal to stop manufacturing medicines in the pharmacy immediately.
Former MS Dr Shivraj Singh was in charge when the scam was unearthed in 2011, cited reasons for serious threats to lives of people in the state after consuming medicines manufactured with substandard herbs found then.

"The drug store, which was sealed then, was opened after health department claimed that in 23 drugs substandard were found out of collected 124 samples of drugs after Pharmacopoeial Laboratory for Indian Medicine, (PLIM) Ghaziabad submitted its report to the department", Dr Singh said.

"There was no good storage practices (GSP), which is mandatory for a good manufacturing practice (GMP) unit or any ayurvedic pharmacy in India. The quality of these raw drugs has been reduced to their lowest level due to their prolong and unscientific storage,"he said.

Dr Singh added said earlier, even though 'sitopladi churun' was found substandard at government drug testing laboratory, 2700 kg of it was supplied to state-run ayurvedic dispensaries and hospital.

"The issue was brought to the notice of higher authorities of the department but no action has been initiated yet," he said.

He also alleged that health department had presented concocted facts of the reports based on identity, purity and strength of the drugs.

"Analysis report procured under RTI Act by activist Jeet Singh revealed that only 26 samples of these raw drugs are found of standard quality while the other were not up to standard limits," he said.

**Case history**

The scam got highlighted after Kulwant Singh, former sarpanch of Ballan village in Sanour block complained directly to the CM about selling low quality herbs and readymade medicines by ayurveda department.

The spurious medicines were purchased from the funds provided under National Rural Health Mission of `81.5-lakh and `98.7-lakh.

It was also found that agmark honey, which was bought for `278 per kg then, was available in the market for `130 per kg, while 500 kg of atees meetha was purchased by the department for `3,000 per kg against actual price of `1,000 per kg.

Questions were also raised about quality of sesame oil, which was purchased at much lower rate than actual price.

Following this, former health minister Satpal Gosain constituted four-member committee to investigate into the matter but the committee yet to submit its report.

- **Drive against spurious medicines**

  *The Daily Star, October 01, 2013*

  EDITORIAL: Adhocism won't do
MITFORD, the hub of wholesale medicine marketing in the capital, shuttering down in reaction to a comprehensive mobile court drive on Saturday, unavailability of medicines is having a telling effect on treatment of patients. After allowing a free hand to the drug markets—thanks to lack of regular monitoring and enforcement of standards by the agencies concerned—it is only natural that a big raid would dredge up sizable malcontent. Thus we see a seizure of counterfeit, contraband or date-expired drugs worth Tk 5 crore, 94 people arrested of whom 72 have been released and realisation of fines to the tune of Tk 1.20 crore. Furthermore, it brings to light doing business without licenses from authorised bodies. What a sudden wakeup disaster has it been from a Rip Van Winkle sleep on the part of the Directorate General of Drug Administration (DGDA) and Bangladesh Standards and Testing Institution (BSTI)! This seasonal and ad-hoc operation at long intervals can at best have a cosmetic effect. Regular monitoring is of the essence in keeping a tab on criminality in the drug trade. This is not to make light of the offences playing around with the lives of human beings by providing from the shelves medicines of substandard, even injurious kinds. The reaction is culpable too in that they have blocked traffic and caused a ruckus bringing public disorder in tow. This is reprehensible.

**Mitford: A hub of illegal drug ingredients**

*Dhaka Tribune, October 01, 2013*

The less educated people in the country’s rural areas are the end buyers of these dangerous drugs.

The greedy profiteering motives of some pharmaceutical companies and wholesaler of drug-making materials have put the lives of a huge section of the country’s population at stake.

There are allegations that some renowned pharmaceutical companies have been importing more raw materials than is needed for their production and selling them in the open market, mainly concentrated in Mitford area.

Most of the sellers of this “buffer stock” do not have proper storage facilities. These drug-making substances must be stored in certain temperature and humidity for them to stay usable for longer stretches of time.

Unless stored properly, some of these substances may even transfigure into deadly poisons.

Some smaller pharma units with questionable integrity have been reportedly buying these ingredients and manufacturing drugs – often lifesaving ones.

The less educated people in the country’s rural areas are the end buyers of these dangerous drugs.

Asked why they had been illegally storing and selling the raw materials, some of the sellers said the question should be directed to those who distribute them in the
open market.

On Saturday, a team of the Directorate General of Drug Administration (DGDA), conducted a raid in the Mitford area. Sensing their presence, most of the sellers of illegal raw materials locked their outlets and fled the scene.

A member of the team said they could have recovered huge amounts of illegally hoarded raw materials had these sellers not fled the scene.

According to the DGDA, more than 250 allopathic pharmaceutical companies in the country import drug-making raw materials worth Tk30bn every year.

Existing regulations bind these companies to mention the exact volume of drugs they will manufacture using the raw materials.

Seeking anonymity, a DGDA official said it was the National Board of Revenue’s duty to make sure through VAT registration that the pharma companies did not import extra raw materials.

He alleged that some companies made their way through with the buffer stock by bribing NRB officials.

He also said the irregularities could be easily dug out if the intelligence agencies inspected the documents that the NBR officials issued to these companies.

The Dhaka Tribune has learnt that some unscrupulous businessmen import drug-making substances from India in the guise of food materials and sell them to the traders in the capital’s Mitford, Babubazar and Chakbazar areas.

Monir Hossain, deputy secretary general of Bangladesh Chemist and Druggist Samity, said it was true that a bulk of the supply of substances for adulterated drugs in the country came from these markets.

He suggested that the production of all kinds of low-quality drugs could be stopped if these markets were shut down.

Professor Dr ABM Faruque from the Pharmacy department of Dhaka University told the Dhaka Tribune that selling drug-making substances in the open market was a serious crime.

DGDA Director Selim Barami told the Dhaka Tribune that selling drug-making substances in the open market was illegal. Mainly the food and perfume manufacturers import these substances illegally.

He said stronger monitoring was needed to check the illegal practice.

(rules drafted to check sale of fake drugs)

*The Financial Express, October 06, 2013*

The government is going to take a number of measures to regulate sale, distribution and marketing of counterfeit drugs and also ensure rational and safe use of other licensed medicines. As stated in the draft Drug Rules 2013, the government will
introduce hospital pharmacies and community pharmacies across the country. Graduate pharmacists will be posted there. They will officially be responsible for unsafe use of any counterfeit, fake or low quality drugs. Apart from that, the government will also form separate committees on 'pharmacy and therapeutics' at hospitals to ensure safe use of drugs. A quasi-judicial bench under the Directorate of Health will also be there to take speedy action against those who will be found guilty of selling, distributing and marketing counterfeit drugs. A high official of the health ministry said the draft rules had been finalised by the committee concerned and the rules were already posted on the ministry website soliciting opinions from stakeholders and the general people. "On review of the suggestions and recommendations, the drug rules will be finalised and sent to the cabinet for its nod," he said. In the draft drug rules it has been proposed that sale of any kind of drugs other than the over-the-counter (OTC) medicines without prescription must be stopped. A list of OTC drugs has already been finalised in this connection. "Under the draft drug rules, introduction of special colour for OTC drug packets has also been proposed so that everyone can easily identify them," a member of the drug rules committee said. According to the draft drug rules, companies will be requested to give the generic names of their drugs so that doctors and pharmacists can easily prescribe them. When the country's pharmaceutical industry exports drugs to as many as 87 countries across the world, investigation has revealed that spurious drugs worth US $ 450 million are posing a serious health risk. The Public Health and Drug Testing Laboratory (PHDTL) tested over 2,500 drug samples last year. It found that 300 drugs were either counterfeit or of very poor quality. They included many popular antibiotics and lifesaving drugs. According to sources, Bangladesh has over 100,000 non-registered drug stores selling counterfeit drugs without any restriction. The draft rules proposed cancellation of approval of several hundred drugs.

- No authentic data on spurious drugs: Ranjit Sinha, CBI Chief
  *The Economic Times, October 08, 2013*

Not even one per cent of the accused have been arrested in cases of spurious medicine trafficking in 2001-12 in the country which lacks authentic data on the extent of the problem, CBI Director Ranjit Sinha said today.

Expressing concern over poor detection of spurious drug network in the country, Sinha said, "According to the statistics of the year 2011-12 (upto March 2012) of Ministry of Health and Family Welfare, out of 48,082 drugs tested across the country, 133 turned out to be fake, which translates to roughly 0.27 per cent."

He said prosecution was launched only in 0.43 per cent of these 133 cases and only 0.23 per cent of accused who were found involved in the manufacture of these fake drugs were arrested.

Speaking at the three-day training on 'Investigation of Trafficking of Spurious Medical Products' in collaboration with Interpol, Sinha said failure to prosecute an accused could be due to several factors including lack of expertise on the part the
investigating officers to gather evidence to implicate the accused.

"...counterfeiting cases that are detected and investigated are not prosecuted, perhaps due to certain weaknesses in investigation. Needless to say that the investigating capability of officers is required to be beefed up," Sinha said.

The CBI Chief said low detection rate could be due to lack of an efficient intelligence collection apparatus or awareness among the stake holders.

"It has been difficult to assess the extent of the problem of counterfeit medicines in many settings because of the lack of resources or skills to detect counterfeit medicines, the absence or weak medicines regulatory systems, the different definitions of counterfeit medicines in different countries worldwide, as well as the variations in the distribution systems," he said.

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**Indian illicit drugs find growing haven in Bangladesh**

*Hindustan Times, October 12, 2012*

Special jackets, inside the body, in coffins and even inside pumpkins...smugglers are seeking out ingenious ways to sneak out drugs from India to Bangladesh making the neighbouring country a haven for Indian drugs.

“It is a huge concern for the entire region. The supply of illegal drugs in Bangladesh has increased and so has the demand,” said Mohammad Iqbal, director-general, Department of Narcotics Control, Bangladesh.

For Bangladesh, India is the main source for illegal narcotic drugs like phensedyl, amphetamines, ganja (cannabis) and other precursor substances for psychotropic drugs and also the transit to huge consignments of synthetic drugs from countries like Myanmar and China.

In the last five years, about one crore phensedyl bottles with Bangladesh as the destination has been seized along both sides of the border. “A crore of phensedyl bottles have been seized from both sides of the border in the last five years. And that is just the tip of the iceberg,” said Ajay Chadha, DG, Narcotics Control Bureau.

A bottle of India-made phensedyl sells for about 10-15 times more on the Bangladeshi side costing about 300 takas.

In July, a regional level meeting in Shillong of officials from the tax department, narcotics, customs, police and intelligence agencies, had underscored how phensedyl smuggling and ganja cultivation by illegal immigrants from Bangladesh along both sides of the Brahmaputra in western Assam was getting “too serious”.

The route to Bangladesh is usually along riverine tracts from the Indian states like Bengal, Assam and Tripura which is infamous because of its porous nature and breaches. It is also known for allowing unhindered passage for men seeking to enter Indian territories.

The two countries share a 4,165 km long border.
The ganja is grown for smuggling into Bangladesh and is cultivated mainly in the river’s sandbars locally called ‘chars’ or ‘saporis’ with tillers, tractors and fertilizers being used in the illegal farming effort.

“The cultivation is so extensively-spread and in such remote areas that even speculating on the numbers is difficult. After destruction by our teams, in no time another crop comes up,” a narcotics official had said admitting that one reason hampering stricter control is the acute lack of resources both in terms of men and material.

DCGI to check on quality of India made medicines

*The Times of India, October 26, 2013*

At a time when the country is generating 26 billion US dollars from pharmaceutical industry alone, to keep a check on quality and enhance revenue, Drugs Controller General of India (DCGI) will be starting a worldwide check of Indian drugs, which are exported and produced for domestic consumption. Such a check/sampling is based on complaints from the west about spurious drugs made in India.

DCGI Dr G N Singh, who had visited Institute of Microbial Technology (IMTECH) in Chandigarh on Friday, said that there has been no database or evidence collected so far on spurious drugs in the country. "We have been accused of counterfeit drugs, which are exported abroad. By involving CBI, Interpol and civil society, we will obtain samples picked up by NGOs and check their quality," he said.

The massive drug checking campaign will kick off in three-four months and will continue for two years. "This is the first such exercise in the world. We want to give a message to the world, with the help of scientific evidence, about the quality of drugs in India. Entire exercise will incur an expense of Rs 4-5 crore," said the DCGI.

On Friday, DCGI signed an MOU with IMTECH to provide standard and certified reference microbial cultures required for quality check of drugs in the industry. "This has made India fourth such nation to have its own certified microbial culture after US, UK and Japan. We will be able to serve as a market for other countries who depend on Europe and US for this,” said Dr Girish Sahni, director IMTECH. According to the DCGI, India has 10,000 pharma companies and 5,000 require microbial cultures.

'Confusion about clinical trials will be overcome'

Recent ban imposed by the Supreme Court on drug trials after thousands of tribals died in Andhra Pradesh following cervix vaccination, has halted the discovery of newer molecules. Labeling this as a state of confusion, the DCGI said, "A stringent regulation has been framed by the government for clinical trials. There is a lot of confusion on this as of now." When asked about consequent withdrawal of Western companies, which invest in clinical trials in the country, the DCGI said, "Our priority is safety of patients. Clinical research may or may not take place."
Congress leader for probe into spurious drugs
*The Times of India, November 03, 2013*

Senior Congress legislator of Tripura, Ratan Lal Nath has demanded a probe into the administrative irregularities in procurement and supply of spurious drugs to hospitals by a sitting high court judge. He demanded a CBI investigation into the incident.

The matter relates to the procurement of spurious medicines from a banned company of Himachal Pradesh for the last four years by the Tripura government. The drugs were used in government hospitals and dispensaries of the state.

The state government has already denied the allegation that it procured the medicine even after knowing those are spurious. Health minister Tapan Chakraborty said immediately after the report, the government stopped using the drugs. He also denied the allegation of corruption in the procurement of the medicines. Nath, however, alleged that the medicines had been approved by the higher purchase committee headed by the director.

According to Drug and Cosmetics Act, 1940, before administering any drug to a patient, it is necessary to test its quality. But in this case, the department did not do it, alleged Nath.

Nath said the government did not file any FIR against the company and the officials concerned for supply, procurement and distribution of spurious drugs, which was mandatory as per law.

Bangladesh’s battle with fake and low-standard medicine
*IRIN News, November 04, 2013*

Despite a backlash to its recent crackdown on the sale of counterfeit medicines in Bangladesh’s capital, Dhaka, the government has vowed to continue fighting the growing industry of illicit, substandard, counterfeit and life-endangering medicines.

On 3 October, vendors in the country’s main medicine sales hub (Mitford Medicine Market in Dhaka), and most pharmacies nationwide, staged a one-day strike protesting against the recent government crackdown at Mitford market.

Law enforcement officers seized some US$640,000 worth of fake, substandard and unauthorized medicine from Mitford market on 28 September. About 100 people were detained and nearly 30 shops shuttered following the swoop. The shops later reopened after vendors protested.

Sadekur Rahman, president of the Bangladesh Chemist and Druggist Samity, an association of pharmacies across the country, said vendors should not be held responsible for the quality control of their products.

“We buy medicine from drug companies and the companies or drug administration
is responsible for that,” he said. “The national drug administration should strictly monitor the market if counterfeit or sub-standard medicines are being sold,” he added.

Golam Kibria, a director of the Directorate General of Drug Administration, told IRIN the government continues its investigations, despite the backlash. “Vigilance has not stopped and it will continue,” he said.

“People are taking poison without knowing it,” said Abdur Rahman, a professor in the pharmacology department at the University of Dhaka, who noted sales of counterfeit or sub-standard medication are most common in rural areas due to the lower levels of health awareness and formal education there.

**Counterfeit sales up**

Kibria said Mitford market is a “hub” for counterfeit medicines.

The administration has increased raids based on reports that more counterfeits are being traded, he added.

In 2010 after testing 5,000 medicine samples from across the country the Public Health and Drug Testing Laboratory (the country’s testing authority) found that 300 (6 percent) were either counterfeit or of substandard quality, according to one trade report.

Just two years later local media reported the same laboratory finding that the percentage of counterfeit or “very poor quality” drugs had doubled, according to results from a 2,500 drug sample test. Drugs failing the test included popular antibiotics and lifesaving drugs.

In 2009 a government team visited 193 pharmaceutical companies, examined their levels of performance, and divided them into A, B, C, D, E and F categories.

According to their report, companies ranked A-C produced drugs in compliance with the Good Manufacturing Practice (GMP), an international standard of medicine quality control; those falling into D-F did not.

The probe found 62 companies to be in non-compliance with GMP.

In 2009, 24 children died of acute renal failure after taking adulterated Paracetamol syrups made by a local medicine company, Rid Pharmaceuticals Ltd. A government probe detected diethylene glycol, a chemical used in the dyeing and leathery tannery industries.

The situation has only grown worse since then, say experts, even though recent systematic studies are lacking.

“The great danger of counterfeit and sub-standard medicine is they are silent killers [slowly] damaging important organs, but people who are taking the medicine do not understand it,” said Rahman, who noted most suspicious cases are not reported or investigated.

**Affordability**

Traders told IRIN they earn large profits by selling outlawed medication supplied by rogue companies at low cost.
“It is possible to make double the profit by selling counterfeit and sub-standard medicine than the original [product],” said Belal Hossain, a trader at Mitford market, who emphasized that he did not knowingly sell fake medicines.

According to market research firm Business Monitor International, sales of pharmaceuticals in Bangladesh in 2013 are expected to reach $1.8 billion. In 2010 the company estimated that due in part to the country’s unlicensed pharmacies, about 9 percent of sales then were linked to “spurious drugs”.

Traders told IRIN adulterated or fake versions of medication were more popular in rural areas where cost is a larger factor in what people buy.

“It is easy to sell substandard and counterfeit medicine in the rural area as people prefer low-cost medicine,” said Hossain.

Health Minister Ruhul Haque said in parliament in mid-October that 20 of the 62 companies found to be below standard in 2009 have had their business licenses suspended, while cases are pending against the remaining companies.

Haque said that when the national drug administration verified medication was substandard, they file cases in court per the 1982 Drug Control Ordinance and its 2006 amendment.

According to the Health Ministry, from January 2012 to June 2013, 13 such cases were filed.

The country’s only drug testing laboratory (in Dhaka) tests about 3,000 drug samples a year, only 6.5 percent of the 23,000 brands of allopathic (usual as opposed to homeopathic) drugs manufactured in the country, according to Drug Administration officials.

The government is drafting “2013 drug rules” (still not before parliament) to fight fake and sub-standard pharmaceuticals.
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