AN UPDATE

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

For the Period of 2011- 2012

Compiled by:

Ms. Pooja Khaitan
Dr. Sohail Hasan

SEARPharm Forum Secretariat
E-256, Greater Kailash-I, New Delhi-110048, India.
Telefax: +91-11-41632089/45566411
Email: searpharmforum@hotmail.com
Website: www.searpharmforum.org
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 mislabelling 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 shelf life 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 2011-2012. This list does not reference every media report published, nor does it contain any confidential information.

**Prafull D. Sheth**
SEARPharm Forum Secretariat

16th September 2012
New Delhi
Vigilance raids unearth sale of spurious drugs

The Hindu, August 11, 2012 / The Times of India, August 11, 2012

Thiruvananthapuram: A large section of the public could be naively consuming spurious medication for a whole slew of ailments ranging from hypertension and diabetes to epilepsy, according to Vigilance and Anti-Corruption Bureau (VACB) officials who conducted State-wide surprise checks at medical stores, public health centers, warehouses of distributors of pharmaceutical products, and stockiest of prescription drugs on Friday. Director General, VACB, Venugopal. K. Nair and Additional Director N. Sankar Reddy ordered the operation code-named ‘tablet.’

Anti-corruption enforcers also inspected district offices of the State Drugs Control Department, the agency tasked to tackle the menace of spurious and adulterated drugs by regulating the manufacturing, sales, and distribution of pharmaceutical and cosmetic products.

The VACB found that at least two pharmaceutical distributors in the State stocked large quantities of lethal methanol, alcohol made deliberately unfit for human consumption, without license and in violation of the State’s poison rules.

The VACB also found that corrupt doctors at scores of rural public health centers had a stake in local medical stores and that they helped their business partners by not availing themselves of a whole range of medicines available at subsidized rates from State-run pharmacies. They forced the public to buy prescription drugs of dubious quality at higher rates from private stores.

The agency also found that renewal and issuance of licenses for operating medical stores was a major avenue of corruption. Investigators found hundreds of pending applications in various drug controllers’ offices. Investigators also found several drug enforcers had more money on their person than what they had declared when they entered office.
FDA Haryana seizes 600 Amps of Oxytocin Injections

Rewari: A Team of FDA Haryana led by Lalit K Goel, Senior Drugs Control officer along with K K Garg, DCO and members of animal cruelty act Haryana raided grocers shop of Tilak Raj situated at subzi mandi, Rewari (Haryana). The team recovered 600 ampoules of Oxytocin Injection.

The team seized all the stock and taken custody orders from CJM court. “These injections are stocked without bill, license and not found in blister pack” said Goel, SDCO.

“Action is taken under section 18 A, 18 C and Rule 105 of Drugs Act. FIR has also been lodged against Tilak Raj under Drugs Act at Police Station, city Rewari. Many complaints are received regarding illegal sale of Oxytocin Inj”, said Goel.

APDCA seizes substandard Cofcin syrup worth Rs.6.5 lakhs from Gaba Pharma in Hyderabad

Hyderabad: In another case of seizer of substandard drugs in Andhra Pradesh, the state drug control authorities (APDCA) have recently seized Cofcin (Chlorpheniramine Oral Solution BP) Syrup worth Rs.6.5 lakhs from Gaba Pharmaceuticals Private Limited in Hyderabad. Over the past few days, the APDCA has been actively working in pinning down the defaulting pharmaceutical units in the state. As part of its series of investigations the state DCA has been successful in digging out the fraudulent activities of the defaulting drug manufactures in the state. “Upon inspecting the premises of Gaba Pharmaceuticals private Limited, we have found not-of-standard drugs worth Rs.6.5 lakhs. We have stopped the consignment consisting of 14,384 bottles containing (450 milliliters in each bottle) Cofcin syrup (chlorpheniramine Oral Solution BP) with batch numbers 549, 567 to 576. If not booked, these drugs were supposed to be distributed to Andhra Pradesh Medical Services and Infrastructure Corporation (APMSIDC). And part of the consignment was also meant for marketing to other clients,” said RP Thakur, DG, APDCA, who has been playing an active role in bringing to book the defaulting drug manufacturers in the state.

Earlier the DCA office had cancelled the company’s license for Gaplex B-Complex syrup in June 2012 for manufacturing not of standard quality drugs in the state. Government analysts from Maharashtra and Central Drugs Laboratory from Kolkata have also confirmed the same and declared the drugs, Gaplex B-Complex Syrup, with batch number-08, Salbutamol Syrup (For Asthma) with batch number-158 and Grovit (Multivitamin Drops) with batch number-75, as not of standard drugs manufactured by the company.

It was believed that the company was flouting the norms frequently and manufacturing substandard drugs. In view of this, the DCA officials had kept a
serious vigil on the company’s activities and conducted thorough inspection and found that the company was resorting to grave non-compliance of provisions and manufacturing rules while producing the medicines. The DCA authorities are further investigating the issue and very soon the authorities are expected to take appropriate action against the defaulters.

APDCA seizes Rs.9 lakhs worth cough syrups produced without license from S K Healthcare

Hyderabad: In a big haul of cache, the Andhra Pradesh Drug Controller Authority (APDCA) has seized illegally manufactured drugs worth Rs.9 lakh and froze 50 kgs of ‘codeine phosphate’ (an addictive ingredient used in Cofcare syrup) from S K Healthcare Formulations Pvt. Ltd. here in Hyderabad.

Moving forward with the intention to crack down all those firms violating the laws and regulatory norms, R P Thakur, IPS, director general of APDCA, has initiated a special drive to investigate all those firms which have been illegally manufacturing, distributing and selling the drugs without a valid license and also without following the various provisions of drugs acts, as they may have far reaching consequences in the public health.

According to official sources from APDCA, S K Healthcare has been manufacturing Cofcare and Bro-cofdex syrups along with New Okaril expectorant without having any license from the drug control authorities in the state. The Cofcare syrup is meant for treating patients suffering from cough while Bro-cofdex and New Okaril expectorant are anti-cold decongestants. Incidentally, all the above three brands belong to Cipla Limited and are manufactured by S K Healthare and marketed by Cipla itself. Upon conducting inspections, the officials found that the company S K Healthcare, which is located at Bachupally in Quthubullapur Mandal of Rangareddy district, is acting as a third party manufacturer for Cipla and the firm does not have any licenses for manufacturing these formulations.

Taking serious note of the issue, the APDCA had already issued notices to Cipla and S K Healthcare and had ordered a recall of entire stocks of drugs sold by them under their mutual marketing agreement.

Cipla, being an internationally reputed drug maker in the country, should have had minimum diligence to cross check or verify the manufacturing license of the S K Healthcare formulations. They have done a grave mistake by not verifying the firm’s license. They should take corrective steps at the earliest, otherwise law will take its own course, opined the DG.

Cofcare syrup contains an addictive substance called codeine phosphate and that falls under narcotic drug psychotropic substance list. Use of this substance in disproportionate ratio will have unsafe health repercussions in the patients and may become addictive to the drug. “Since the company had
also violated the Narcotic Drug Regulations (NDPS) Act, we have informed Narcotic Control Bureau about this issue. Once we get a detailed report we will prosecute and charge sheet all those involved in this illegal business,” informed the DG.

**Fake medicine factory busted in Ghaziabad; five arrested**
*NDTV, May 17, 2012*

Ghaziabad: Five men were on Wednesday arrested from a factory in Modinagar where a fake variant of Unani medicine ‘Safi’ was allegedly manufactured.

Harish Goyal, Amit, Shivam, Tiloo and Sanju were taken into custody and 400 bottles of the fake medicine recovered, SSP Preshant Kumar said. Several machines used for sealing and cleaning the bottles were also seized, he said. The company of the original brand, Hamdard, has been informed of the fake product. The five men have been sent to 14 days judicial custody after being presented before a judicial magistrate.

**Fake Malaria medicines found in India**
*The Times of India, May 22, 2012*

A third of malaria drugs, used around the world to keep the spread of the disease at bay, are counterfeit, a recent data has suggested. According to a study published in the reputed journal The Lancet, around 7 per cent of the drugs tested in India was found to be of poor quality with many being fake.

Researchers who looked at 1,500 samples of seven malaria drugs from seven countries in Southeast Asia said poor-quality and fake tablets are causing drug resistance and treatment failure. Data from 21 countries in sub-Saharan Africa, including over 2,500 drug samples, showed similar results. From 1999 to 2010, seven multi-country surveys with data from seven countries in Southeast Asia included chemical assays or packaging analysis for 1,437 samples of seven anti-malarial drugs. Of the total 437 samples of drugs, 497 (35 per cent) failed chemical analysis, 423 (46 per cent) of 919 failed packaging analysis, and 450 (36 per cent) of 1,260 were classified as falsified.

“6,55,000 and 1.2 million people die every year from Plasmodium falciparum infection. Children in sub-Saharan Africa and Southeast Asia have the highest risk of contracting and dying from malaria,” it added.

Researchers add caution, as they believe that poor-quality anti-malarial drugs are very likely to jeopardize the unprecedented progress and investments in control and elimination of malaria made in the past decade. Anti-malarial drugs comprise 25 per cent of the drugs consumed in malaria-infected countries, and when these drugs are of poor quality, they afflict the most vulnerable populations.
**Drugs seized, Counterfeit racket busted**
*The Sangai Express, May 08, 2012*

Imphal: A large quantity of pharmaceutical drug Acti-Feel, which is abused by a section of youngsters as intoxicating substance, has been seized by Imphal West District Police from Imphal Airport.

Speaking to media persons at district police headquarters today, Imphal West SP K Jayenta said that the 21 cartons containing 700 strips of Acti-Feel were seized from the airport this afternoon. The seized drugs were sent from IGI Airport, New Delhi. It was not known who sent the drugs and to whom as the consignments did not specify its recipient, said the SP adding that investigation has been launched to ascertain the facts. Authorities of the three airlines, Air India, Kingfisher and Indigo would be asked to cooperate in the police investigation and also to take up necessary action if there was any lapse on the part of their staff.

Acti-Feel tablets have been already banned in Manipur in view of its large scale abuse by some sections of youngsters.

**Cure-all drugs seized in raids**
*IBN Live, May 12, 2012*

Kochi: The Drugs Control Department continued its search operations for the second day in Ernakulam and Idukki districts. The search was conducted at the ayurveda medicine wholesale shops, which have been allegedly misleading the public through false claims and advertisements of the ‘cure-all’ drugs.

Drugs worth Rs 2.75 lakh were seized from the stockists during the search operations conducted at Aluva. Drugs worth Rs 1.15 crore were seized from Thodupuzha.

The Drugs Control Department had initiated the move against some ayurveda companies, which had been allegedly misleading the public through false claims and advertisements. Drugs worth Rs 51 lakh were seized on Thursday in different parts of the state by the department.

Drugs Controller Sathish Kumar said that prosecution steps were initiated against the ayurveda companies for flouting the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. According to the act, no product should be sold with false and misleading claims.

**DCA Chhattisgarh seizes cough syrup Phensedyl**
*The Pharma Biz, April 18, 2012*

Chennai: In a recent raid conducted in various parts of the state, the Chhattisgarh drugs control administration has seized 8,79,981 bottles of restricted drug, Phensedyl cough syrup manufactured by Nicholas Piramal,
from various shops in Raipur and nearby areas. The seized items would worth about Rs.6.15 crore.

The inspectors could not find the sale detail records of the drugs during the inspections in any of the raided shops, said S Babu, director FDA, Chhattisgarh. The drug was brought from Mumbai by agents and was planning to export to Bangladesh through Meghalaya, said the director.

According to the director, during raids the officials could not find any sale detail records of these bottles. Records showing from where these abundant quantities of drugs were brought to the stores and to whom those were sold, were not found in the shops during raids. Cases have been filed against the company and the traders, whose sale licenses were also cancelled.

Speaking to this reporter, S Babu said with the marketing of this cough syrup, the volume of sale of Nicholas has increased and the company stopped manufacture of other products for a short period taking advantage of the situation. He added that in the boom period Nicholas sold one of its divisions to Abbot Lab promising them a huge turn over. Following the deal, the sale of the drug was stopped due to seizure by various enforcement agencies in several parts of the country.

- **Rs 17-lakh worth illegal cough syrup seized**
  *The Times of India, April 20, 2012*

Kozhikode: The drug control department has seized 20,000 bottles of illegally made cough syrup worth Rs 17 lakh after it was found being sold here among students as a sedative.

A seven-member squad seized the medicine ‘Cofcare’ from a local distributor at Puthiyara on Thursday. Officials say an unlicensed firm in Hyderabad made the medicine. The manufacturing company did not have any valid licence for commercial production and sale of the syrup from the Andhra Pradesh government.

According to assistant drug controller P K Sreekumar the drug contains huge quantity of Codeine Phosphate, which blurs vision and creates breathing discomfort apart from loss of consciousness among regular users.

- **APDCA unearth expired medicines worth Rs.65,000 from corporate hospital pharmacies**
  *The Pharma Biz, March 31, 2012*

Hyderabad: The drug control administration in Andhra Pradesh has raided four premises of a corporate hospital in Hyderabad and found expired, sub-standard drugs worth Rs.65000, stored illegally in unauthorized premises.
Based on a tip off, the Drug Control Authority of Andhra Pradesh raided corporate pharmacies attached to the hospitals and found huge quantities of substandard, expired medicines stocked in the premises.

Earlier, the DCA had raided retail pharmacies and found that many of them did not adhere to prescribed rules and norms. It was also found that more than 70 per cent of the pharmacies are operating without registered pharmacists and do not issue regular bills to consumers. The DCA is also working on an action plan to raid all the corporate hospitals in the state and their attached pharmacies.

**10 Lakh violated bottles Coughed up in Gujarat**

*The Economic Times, March 18, 2012*

Ahmedabad: Stocks of over 10 lakh cough and cold syrup bottles worth about Rupees four crore made by some of the well-known companies have been sealed by drug officials in Gujarat at the level of stockists after being found to contain codine, a derivative of opium, a top GFDCA official said today.

“The manufacturers were selling these drugs without mentioning the generic name of the medicine – codine,” he said adding that ten lakh bottles of cough and cold syrups valued at over Rs 4 crore have been restricted from sale here pending further investigations. Around 22 different brands sell cough and cold syrups in Gujarat, of which 20 leading brands were found violating the rules during a week-long drive launched here, Koshia said.

The GFDCA also got 15 chemist shops closed here that were found selling these H-scheduled drugs without prescription or were operating without a pharmacist.

**2 held for selling fake drugs**

*The Times of India, February 23, 2012*

Patna: The Pirbahore police arrested two persons on Wednesday from Govind Mitra Road on charges of selling fake medicine. The police said the arrested persons are Awadhesh Singh and Sunil Singh, owners of Shiv Shakti Enterprises and R S Pharma, respectively. They were arrested from Beni Madhav Lane, the police said.

**Gujarat FDCA busts racket making IV sets without license near Ahmedabad**

*The Pharma Biz, March 06, 2012*

Mumbai: The Gujarat Food and Drug Control Administration (FDCA) recently busted a racket involved in the business of manufacturing Intravenous (IV) stents without having a valid license from Vutva near Ahmedabad. During the raid, the officials from the drug licensing authority successfully seized IV
stents and some of its components worth Rs.12 lakh from their manufacturing unit at Vatva. The raid was carried out in a company called Tridhara Surgicals after receiving a tip off on its questionable activities through the state FDCA’s toll free number 100 233 5500. The FDCA officials found that the company was involved in illegal activity of manufacturing IV stents and its components without license and selling it within the state to various sources under fake identity. Some of the seized product samples have been sent to Baroda food and drugs testing laboratory for checking its safety and efficacy. Once the drug regulators get confirmation on the whether the manufacturers have compromised with the quality of the products, they will further probe into the activities of the company.

Since IV stent is one of the few notified medical devices in the country and is considered as a drug under the Drugs and Cosmetics (D&C) Act, all the provisions of the Act is thus applicable to it as well. According to Dr H G Koshia, commissioner, Gujarat FDCA, law of the country states that for any person to manufacture IV stent in the country it is essential for him to procure a valid licence with due diligence failing to which his actions will be deemed punished under the law. Moreover, due to the low cost involved in manufacturing the products it has a huge market both within the country and internationally, acting as a potential attraction for wrongdoers as well. To avoid any discrepancies that may arise out of illegal activities that may affect quality of the products coming out of the state, we keep a close watch on all the activities of the medical device industry within the state,” Dr Koshia added.

❖ Spurious drugs claim four, seven taken ill

Express Buzz, February 07, 2012 / IBN Live, February 08, 2012

Cuttack: At least four persons died and seven others were taken seriously ill allegedly due to overdose of medicinal formulations with high alcohol content at several villages under Cuttack Sadar police limits late on Monday.

While the Excise Department and police have arrested two persons, including a woman, in this connection, the nature of the brew has come as a shocker. The bottles, recovered from the house of the main accused and supplier, Baidhar Bhoi of Tukulpada, who also lost his life, were found to have contained Orange Tincture and Epeecarm.

Orange Tincture BP is a solution with an ethanol content as high as between 62 and 69 per cent. It is used mainly as a flavouring agent during manufacture of pharmaceutical drugs. Epeecarm also has high concentration of alcohol but more dangerously has high beladona content, which can cause poisoning. It is also used a flavouring and colouring agent in drug making.

How the raw materials were procured or supplied for consumption as a substitute of liquor has raised several questions on the efficacy of drug control and monitoring mechanisms in the State. According to reports, the victims were all daily labourers working at different brick kilns in the Sadar area while Baidhar was a known bootlegger.
On Monday night, they had reportedly boozed together at Baidhar’s house. About 20 bottles, including three of Orange Tincture BP, and the rest Epeecarm had been consumed as the empty bottles reflect. The people soon complained of chest pain and nausea and were rushed to the Mahidharpada PHC and then referred to the SCB Medical. Three died at the hospital while Baidhar died at his house.

As Excise officials led by SP Pradipta Patnaik and Sadar police raided the house they found the empty bottles as well as two unconsumed ones that were hidden inside a clay pot. Baidhar’s wife Chhabi and son Benudhar, who had been assisting him in the illicit liquor business, were immediately arrested.

81-year-old doctor let off after over 28 yrs of trial

_Daily Bhaskar, February 19, 2012_

A Delhi court has let off an 81-year-old doctor, caught manufacturing and selling spurious drugs and cosmetics over 28 years ago and sentenced to three years in jail for his crime, on probation.

Additional Sessions Judge (ASJ) Savita Rao let off Dr H R Kanwal on a year’s probation after modifying the three-year jail-term, imposed by the magisterial court upon him, to a year. The court enlarged the convict on probation saying though the offences committed by him have grave social and economic implications, sending him to jail will not serve any purpose in the given circumstances. The sessions court also took note of the convict’s pleading for leniency on the ground that he faced the trial for 28 years, during which his only son was murdered.

“Though the trial court has rightly observed that the offence committed by the appellant have grave social repercussions upon the consumers who were using it believing it to be a genuine product and there is also heavy revenue loss to the company having license to manufacture the same, thereby affecting the economy of the country, but considering the reasons as stated above, no purpose would be served by sending him behind the bars,” the ASJ said. The ASJ ordered Kanwal’s release on one year probation on furnishing a bond of Rs 50,000 with one surety of like amount. Dr Kanwal was caught nearly three decades ago by a Drug Inspector and the trial court in September last year had sentenced him to three years in jail, while also imposing a a total of Rs 35,000 as fine for offences punishable under various provisions of Drugs and Cosmetics Act dealing with manufacture and sale of misbranded, adulterated and spurious drugs.

Spurious drug makers arrested

_www.webindia123.com, December 28, 2011_

Two individuals charged with making and supplying spurious ayurvedic medicines have been arrested, one from Badayun district, Uttar Pradesh, and
the other from Red Fort, Delhi. The duo, from whose possession spurious ayurvedic medicines have been recovered, had a drug factory in Bareilly. A third person believed to be involved in the racket – a factory owner, is on the run.

Fake cosmetics nabbed in Nagpur
The Times of India, December 01, 2011

The city’s Crime Branch has busted a racket involving the sale of counterfeit cosmetics in Nagpur. Acting on a tip off, the social service department of Nagpur city’s Crime Branch has seized misbranded cosmetics worth Rs. 1.80 lakhs. The products carried the names of leading brands and were meant for sale to unwary rural consumers. One Rajesh Sachdeo, believed to be the kingpin in the racket, was arrested from a godown. His aide managed to flee the police net.

Blacklisted 9 firms’ drugs
Deccan Chronicles, December 15, 2011

Hyderabad: Drugs of 9 pharmaceutical companies were found to be substandard and have been blacklisted by the Andhra Pradesh Medical Services and Infrastructure Development Corporation (APMSIDC). The following drugs meant for common ailments have failed the quality test. They are:
- Karnataka Antibiotics and Pharmaceuticals Ltd Injection Verclov 1.2gm (Amoxycillin+Clavulanic Acid), Batch no. 3401410
- * Cipco Pharmaceuticals Tablet Dicyclomine HCL 10mg, Batch No. CT-91201
- * Hindustan Pharmaceuticals Etophylline and Theophylline injection, Batch No. 426
- * Vital Health Care (P) Ltd. Prednisolone Acetate Opthalmic Suspension USP Batch No. V9094
- * Jackson Laboratories (P) Ltd. Pentasol Injection, Batch No. I.P.B NO.1-3236
- * Bengal Chemicals Ciprofloxacin Tablet 250mg, Batch No. 0578002
- * The Swastik Pharmaceuticals Povidone Iodine Solution, Batch No. 2667
- * Eurokem Laboratories (P) Ltd. Nifidifine Tablet I.P 10mg Batch No. F62
- * Agron Remedies (P) Ltd. Diclofenac Sodium Tablet, Batch No. DDF-35

Busted in Baddi
Consumer Conexion, November 13, 2011

In a raid on the premises of a drug manufacturing unit operating from Bagvania village near Baddi, sleuths from Delhi Zone of the Directorate of Revenue Intelligence, along with police officials, unearthed a massive hoard of veterinary and allopathic medicine, which the drug manufacturing unit, Ten Star, had not been licensed to manufacture. According to Drug Controller Navneet Marwaha, who received a tip off from a Joint Director in the Directorate of Revenue Intelligence and participated in the bust, the
pharmaceutical formulations seized in the raid were found to be fraudulently labeled with the names of companies like Torranto Welcare Pharmaceuticals, Tranesia Bioceuticals, MPPL Rudrapur and Excel Biolife Private Limited. On completion of investigations, a case will be registered against Ten Star under Sections 18(a)(i) of the Drugs and Cosmetics Act, Mr. Marwah said.

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**Pharma unit found making spurious medicines**
_The Times of India, May 28, 2011_

CHANDIGARH: The state drug control department in Haryana on Friday unearthed a racket involving manufacturing of spurious medicines of a Goa-based pharma unit from the premises of Jorker Pharmaceutical Ltd in HSIIDC complex at Rai in Sonipat.

The department has lodged a criminal case against company director Ranjan Kumar, manufacturing chemist Umesh Gupta and annalist chemist B K Pandeyat at Rai police station. At the same time, the department has initiated criminal prosecution against Jorker Pharmaceutical, Rai, the errant pharma unit, under various provisions of Drugs and Cosmetics Act. The department has also cancelled the licence of the manufacturing unit.

On Tuesday the drug control department seized 2.5 lakh tablets of Coscold, a cough tablet sold by Cosmo Pharma Ltd from the premises of Jorker Pharma. After the Goa-based company confirmed the counterfeits, a complaint was lodged with the police.

The counterfeit drugs are learnt to have been largely supplied to defense as well government supplies. This is in addition to supplies in local markets of Goa and Maharasthra, an official said, adding that further details were awaited. "Samples tested at Chandigarh laboratory confirmed zero trace of Pseudo Aphedrine (a salt used to heal cough problem) as mentioned on the cover. So was the case with four other medicines, which were manufactured by Jorker under their own brand names. Tests suggested only 50 to 60 per cent of traces of salts mentioned on pickings,“ said P K Das, secretary health, Haryana.

Elaborating more, additional drug controller G L Singhal informed that preliminary investigations suggested some other serious lapses were also found during investigation carried out by them. Other four medicines manufactured by Jorker Pharma, which failed the test included Rimole tablets 500mg (an alternate of paracetamol), Roxyin 150 MG (antibiotic containing Roxythromycin) and Jorcycline 500 (tetracyclin) and Cipbid (ciprofloxacin with einidazole).
Fake Maroperam injections likely cause of several deaths: Report
The Times of India, September 06, 2012

Jaipur: The fake antibiotic injection of Maroperam provided to patients through the life line stores of the Mahatma Gandhi Hospital and Mathura Das Mathur Hospital in Jodhpur has caused death of patients.

The shocking suggestion has been made in a report prepared by the principal of SN Medical College in Jodhpur in response to the police queries regarding a fake medicine racket. The report has given the police ground to book the 10 accused arrested so far in the case under Section 27 of the Drug and Cosmetic Act, apart from other sections of the IPC.

The police had seized nearly 1,000 Maroperam injections from a drug store on May 26. The police have since then arrested nine people including the kingpin, Rajesh Purohit, who was running a bogus pharmaceutical firm, a life line store owner and a nursing tutor. Police are gathering evidence against at least 12 doctors suspected to be involved in prescribing fake medicines manufactured by this bogus pharmaceutical company to earn hefty commissions.

Vigilance raid unearths sale of fake drugs
The Times of India, August 11, 2012

Kochi: The surprise raids conducted by the state vigilance and anti-corruption bureau at the offices of drug controllers and drug testing laboratories in the state on Friday unearthed large scale irregularities and sale of spurious drugs. The raids, code-named 'Operation Tablet', were conducted as per the direction of vigilance director Venugopal K Nair and were coordinated by vigilance ADGP N Shanker Reddy.

According to officials, spurious drugs were being sold in the state under different brand names. "We found test results of sample drugs were not submitted at the offices of the drug controllers in the state. We will get a clearer picture only after studying the final report from the officers. Preliminary probe points towards irregularities in collecting drug samples for tests and renewal of licenses of various drug stores," said Reddy.

He said it would take minimum two months for the department to prepare the report.

New Delhi: Spurious drug racket busted
Criminal Record India, June 15, 2011

The police busted an organized gang selling spurious drugs and those meant for CGHS, MCD, ESI and even the Director-General of Armed Forces Medical Services (DGAFMS) for the past 10 years. This is the first time that such a racket has involved the DGAFMS. A special investigation team said raids
were carried out at central Delhi’s medical wholesale market, Bhagirath Place, and subsequently also in Agra. Raids in the city were conducted on June 3 and drugs worth Rs. 8 lakh were seized. The Agra raids were conducted on June 6 and yielded drugs worth Rs. 34 lakh.

**Gang selling spurious, ‘free’ medicines busted**  
*The Times of India, February 15, 2011*

New Delhi: The police on Tuesday busted an organized gang selling spurious drugs and those meant for CGHS, MCD, ESI and even the Director-General of Armed Forces Medical Services (DGAFMS) for the past 10 years. This is the first time that such a racket has involved the DGAFMS.

A special investigation team said raids were carried out at central Delhi’s medical wholesale market, Bhagirath Place, and subsequently also in Agra. Raids in the city were conducted on June 3 and drugs worth Rs 8 lakh were seized. The Agra raids were conducted on June 6 and yielded drugs worth Rs 34 lakh.

Racketeers may have stamped the spurious medicines with the names of different government agencies to authenticate them so that people will assume that these medicines are genuine and purchase them,” said DCP (crime) Ashok Chand said.

Additional DCP Joy Tirkey said medicines recovered from Agra were past the expiry date. “They were pushed into north Indian markets after recycling. Worse, a senior official of a pharmaceutical company, who accompanied the raiding party, told the police that 45 ampoules of seized ‘Susten 100’ injections, used by pregnant women, and were also spurious. Other medicines include those meant to cure heart ailment and diabetes.

While the raids in Delhi were conducted on June 3, the Agra raids were conducted on June 6. “We have recovered Rs 8 lakh worth of spurious drugs in Delhi and another Rs 34 lakh worth of drugs in Agra. We have now written to the concerned government agencies to ascertain whether the medicines, which are stamped, have been siphoned off from their stocks. For this, the manufacturing date and batch numbers have been preserved.”

**Cops bust fake drug racket**  
*The Indian Express, August 21, 2012*

The arrest of three persons in the Temple City on Sunday night for their alleged involvement in spurious drug trade has revealed that a gang with well-entrenched networks has been involved in supply of counterfeit drugs in Southern districts and the Textile City of Coimbatore for almost a year now. Preliminary investigations reveal that the gang has been operating from Chennai.
The main accused - Malieek of Villupuram - had been despatching fake ‘Vicks Action 500’ tablets from Chennai for packing to one Thamaraiselvan of Madurai.

Thamaraiselvan (43) of Anupanadi, who is alleged to have been involved in preparing fake carton boxes for various items such as asafoetida, had designed them for the drug also from printing units in Sivakasai.
Based on a complaint from senior employees of IPR Vigilance Service, (which was engaged by the Procter and Gamble to prevent the supply of fake products of their brands), it was found that fake Vicks Action 500 was in circulation in Madurai.

Following this, a special police team arrested Thamaraiselvan and two others - Anand (23) of Anupanadi and Mariselvam (42) of Solaiyalagupuram and seized 20 boxes (each box containing 9,600 counterfeit tablets). The packed spurious drugs would be sent back to Chennai in private buses and from there, the gang would circulate them across the State. A senior police official who was investigating the 2010 expired drugs case in Chennai said that most of the spurious drugs were manufactured in Puducherry, where many pharmaceutical companies were functioning.

Meenakshi Sundaram, the main accused in the expired drug case, also owned pharmaceutical establishments in Puducherry, he said. The official also pointed out that gangs involved in spurious drugs trade were mostly involved in producing either cheaper drugs or costlier ones, which have more demand in the market.

Fake medicines racket busted in Faridabad, Three detained
_Pardaphash, July 16, 2011_

New Delhi: Three people have been arrested for making fake drugs of leading pharmaceutical firms and spurious medicines worth lakhs of rupees have been seized, said the official on Friday. The racket has been broke out in Faridabad, Haryana.

Ramesh Gupta, Food and Drugs Administration Commissioner was informed that fake drugs of well known companies like Glaxo and Alcum were being manufactured in Faridabad city, neighboring Delhi, said a department spokesman in Chandigarh.

The spokesperson added, "A special team of the department, along with crime branch officials, raided the premises in Faridabad's Sector 6 and recovered huge cache of fake drugs worth lakhs of rupees." Daya Shankar Misra, owner of the factory was arrested in Delhi earlier also and a large amount of spurious medicines seized from him.

According to Delhi Police's Deputy Commissioner Ashok Chand, "Misra (55) and Dinesh Sahu (52) were arrested from Old Delhi Railway Station on
Monday following a tip-off that spurious medicine racket was operating in Delhi and Faridabad."

According to police’s rough estimate, they supplied fake medicines worth more than Rs.8 crore in Delhi and other states in the last five years.

**Drugs seized**

_The Sangai Express, September 28, 2012_

Imphal: Together with impounding a briefcase containing Actisun tablets having banned Pseudo-ephedrine Hydrochloride content from Imphal airport, Imphal East District Police have arrested three persons.

Displaying the seized drugs at Porompat police station today, a senior police officer said that the drugs were seized by a special unit together with a team of Porompat police station at about 1 pm today.

The tablets were being brought to Imphal on an Air India flight from Delhi by Md Riyaj Ahmad (38) s/o Md Siraj Ahmad of Sangaiyumpham Nung-phou Bazar who works in the CISF at Delhi. He has been apprehended.

Along with Riyaj Ahmad, Md Ajim Khan (25) s/o Abdur Salam and Md Imraz Hussain (22) s/o Md Iboyaima of Keirao Makting Mayai Leikai who came to receive the consignment have also been arrested, said the officer. It is estimated that the seized tablets would cost around Rs eight lakhs at the rate of Rs 8 per strip. Each uncoated Actisun tablet contains 2.5 mg of Tripolidine Hydrochloride and 60 mg of Pseudoephedrine Hydrochloride. The case would be handed over to Singjamei police station for further investigation, added the officer.

**5 nabbed for selling fake cosmetics**

_The Times of India, July 12, 2012_

Patna: Patna police on Wednesday raided three shops on Nala Road under Kadamkuan police station area and recovered fake cosmetics of a reputed company worth about Rs 2 lakh.

City SP Kim, along with officials of the cosmetic company, raided the three shops and arrested five persons in this connection. The mastermind behind the fake cosmetics racket, Mukesh Kumar, is absconding, Kim said.

She said police had information regarding the fake cosmetics being sold at some reputed stores. "Police collected a few samples and sent it to the company for quality check. When the company confirmed that the fake cosmetics were being sold in its brand name, we decided to raid the shops," she said.
Mustafa Hussain, a legal department official of the cosmetic company, said, "There are many shops in the city which openly sell fake products of the top brands. The mastermind behind the racket, however, escaped." He said the company was searching the factory where such fabricated cosmetics were being manufactured. The arrested persons are Kamal Dubey, Md. Alam, Shashi Kumar, Sunil Tiwari and Dilip Thakur. However, they could not give much information to the police about the factory and the supply chain.
THAILAND

Dirty Laundry Deals in Drugs
The Pattaya People, November 04, 2011

On Wednesday night, the police from the Special Suppression Department, led by its Chief Pol. Lt. Col. Kwanpichai Mano-jarern-sahb entered the laundry of Mr. Soheep Farudee aged 25 and Mr. Faisal Nadeem aged 40, both from Pakistan, after being informed that these 2 men were selling many types of sexually enhancing illegal drugs. The officers discovered a large shipment of Viagra and other drugs, plus sleeping pills worth 1,900,200 Baht in the premises. The impounded drugs were mostly manufactured in India, and some were fake drugs from China. The so-called erectile dysfunction drugs were mostly for foreign tourists, and the sleeping pills were mostly for bar girls and prostitutes. The men were remanded for legal proceedings and further investigation.

Five nabbed in Thai fake sex drugs swoop: Police
The Sunday Times, August 02, 2011

Bangkok: Bangkok authorities arrested five men in a crackdown on sex drugs sold illegally to tourists in streets around the city’s red light districts, Thai police said Tuesday. Raids on July 25 and 28 netted several fake or unlicensed drugs such as Viagra, which is normally prescribed for men suffering from erectile dysfunction. In total five men, two Myanmar nationals and three Thais, were arrested in the two raids, carried out in the China Town and Nana areas of the city. They were charged over offences including the illegal sale of drugs and selling fake and unlicensed drugs. If convicted they could face up to 20 years in prison. Police released a list of items seized in the operation, which were estimated to be worth a total of 500,000 baht ($16,800). These included various types of Viagra, “Waman penis enlarging tablet”, Kamagra oral jelly -- in banana, apple and blackcurrant flavours -- and an item intriguingly listed as “Night fire heartily burnable lady's intense emotion”. “This has tarnished Thailand's tourism image,” said an official from the Thai Food and Drug Administration, which also took part in the raids.
BANGLADESH

- One arrested while making fake drugs
  The Daily Star / Metropolitan, June 04, 2012

A man was held in the port city yesterday allegedly for producing and selling fake medicines. The arrestee was Masud Rana, 32, of the city's Char Patharghata.

Detective Branch (DB) of police caught Masud along with fake drug items, worth Tk 50,000 while he was making fake medicines in a room beside a pharmacy around 3:00pm at a pharmacy in Char Patharghata, said Deputy Commissioner of DB Mohammad Maniruzzaman at a press briefing in CMP Headquarters yesterday.

Masud confessed before the press that he did the acts under the company name ‘SAMA Marketing Company,’ which has no existence. He used to collect Calcium tablets from different medicine companies, adulterate and pack those into fake packets of medicine company Beximco Pharmaceuticals and then sell those to the retailers in the name of ‘Vitamin tablets,’ he said. A case was filed with Karnaphuli Police Station under the Special Power Act in this regard.

- Youth held with fake medicine
  The Daily Star, June 02, 2012

Rapid Action Battalion members detained a youth on charge of selling fake medicines in Chittagong on Thursday. The detainee was identified as Alam, 27, son of Md Shamsul Alam of Nolanda village under Patiya upazila in Chittagong.

Following a tip-off, a team of Rab-7 men conducted a special drive at Hasina Medico, a pharmacy located at the city's GEC intersection, around 9:15 pm, said a press release.

The law enforcers led by Lt Zakir Hossain caught Alam red handed while he was selling fake medicines at the shop. They also seized fake drugs worth around Tk 5 thousand from his possession. During primary interrogation, Alam confessed that he had been selling fake medicines to different pharmacies in the city under the brand name Novogen Bangladesh, the release added. Filing of a case in this regard was under process, said Rab-7 officer SM Nurul Huda.
Database on the Incidents of Counterfeit Medicines in the WHO-SEA Region [2011-2012]

❖ **Fake phensidyl factory**  
*The Daily Star, September 21, 2011*

Rapid Action Battalion (Rab-12) on Monday unearthed a fake phensidyl factory at Atua near the district town. The elite force raided the residence of Riazul Haque Shimul of the area where he set up the spurious phensidyl factory. Mehedi Hassan Shourav, 25, son of Riazul was repacking the drug made of water and other chemicals when Rab raided the place. Shourav fled the scene but the elite force arrested his wife Ritu from the spot.

❖ **Two men arrested with fake medicine**  
*The Daily Star/ Metropolitan, October 4, 2011*

Detective Branch (DB) of Police arrested two men with fake medicine from the city's Uttara on Sunday. However, the medicine factories are yet to be busted. The arrestees Mizanur Rahman alias Rubel, 30, and Yusuf Zaman, 35, at a press conference at DB headquarters yesterday, admitted their crimes. DB officials said the arrestees are involved with a gang producing, packing and selling fake medicine at pharmacies in Uttara and adjacent areas.

The medicine bottles labelled “One To Nine”, “Nervicon” and “Soya Protein” claimed to be dietary supplements and were marked as products from the US. At the press conference, Additional Deputy Commissioner (DB-South) Molla Nazrul Islam said Rubel distributed the medicine and was caught while packing them at his Sector 9 house in Uttara around 4:30pm.

For the past six months, a man named Kamal used to provide the coloured tablets which Rubel packed in plastic bottles, bought from Old Dhaka, and stuck the labels, which came from printing presses in Nilkhet, said Rubel.

❖ **Fake medicine factory**  
*The Daily Star, November 16, 2011*

Dinajpur: A mobile court on Monday sealed an illegal drug factory and jailed five people in Rajbari area of the district town. Police said the court led by executive magistrate Tasnin Jebin Binte Sheikh raided Bengal Ayurvedic Laboratories in the area and found syrups being produced in an unhygienic condition and without any chemist. Officer in-charge of Dinajpur police station Hasan Shamim Iqbal said the owner of the factory could not able to show certificates of Directorate General of Drug Administration and Bangladesh Standard Testing Institute (BSTI) for producing the drugs.
NEPAL

Fake vaccinators apprehended in capital
*My Republica, April 03, 2011*

Kathmandu: Police apprehended four people for administering fake hepatitis B vaccine to the public in Boudha following the tip-off from the District Public Health Office (DPHO), Kathmandu.

DPHO Chief Bisho Ram Shrestha said the police have handed over the quack vaccinators to Kathmandu District Administration Office for punishment. Claiming such vaccines can have disastrous impact on human health, Shrestha said, "Preventing fake vaccinators from selling unapproved vaccines has become a major challenge for us."

According to DPHO, all vaccines must have quality approval from World Health Organization (WHO) before being administered. Likewise, vaccines must also get approval from the Department of the Drug Administration (DDA). The vaccines administered by the arrested vaccinators had approval from neither of the agencies.

"We have not given consent to any organization in the country to administer hepatitis B vaccines," Shrestha said. The government does not have a policy to give consent for administrating hepatitis B vaccine. The vaccines for hepatitis B, the most common serious liver infection, are administered in Nepal only through those authorized by the government.

The arrested vaccinators were found to possess identity cards of a fake non-governmental organization.

"We confiscated bills and identity cards of ‘Heal Nepal’ and ‘Janasewa Nepal’ from them," Dhurba Adhikari, a public health officer at DPHO, Kathmandu, revealed. Adhikari said the vaccinators smuggled unapproved vaccines from India. "We do not know about the quality of the vaccines they were using. It could be distilled water or something else," Adhikari said.

The vaccinators were found charging Rs 50 for administering vaccine to children aged 10 years, and Rs 100 to those above the age. DPHO chief Shrestha revealed that such fake vaccinators influence school principals to sell vaccine to students. Due to open border, the DDA faces difficulty in curbing the flow of unapproved medicines into the Nepali market. Though DDA has prohibited pharmacies from selling unregistered drugs, the agency’s latest report indicate their existence in the market.
Fake anesthetic in market
My Republica, May 27, 2011

Biratnagar: Fake vials of Vacuron, an anesthetic injection used for major surgeries, have been found in the market. The fake vials that look exactly like the genuine ones, work for barely five minutes in patients.

The sale of fake vials of the anesthetic came to light after a patient who underwent gall stone surgery at a private hospital in Biratnagar regained consciousness just five minutes after being administered with 4 mg of the anesthetic.

The genuine Vacuron that is manufactured by Sun Pharmaceuticals of Gujarat, India, is capable of keeping a patient sedated for 20 minutes. A vial of the genuine medicine costs Rs 127, while the fake one is being sold for Rs 45 per vial in Biratnagar. According to sources, the fake vials are brought to Nepal by traders entering Nepal from Bihar, India.
INDONESIA

Fake Viagra pills confiscated
The Jakarta Post, June 23, 2011

Jakarta: A joint team set up by the Jakarta administration raided on Wednesday illegal drug vendors in a number of spots in the city, confiscating 700 fake Viagra pills. Officials from the East Jakarta Health Agency, Public Order Office and the Food and Drug Monitoring Agency (BPOM) raided 20 illegal drug stores in a number of spots Wednesday including on Jl. Pemuda, Jl. Dewi Sartika, Jl. I Gusti Ngurah Rai and Jl. Raya Bekasi. The raids were conducted from information given by locals who became suspicious after learning that the “blue pills” were offered at a discount price. East Jakarta Health Agency head Yenuarti said as quoted by tempointeraktif.com that the fake Viagra pills could have side effects. Yenuarti said the pill had also been abused by locals to engage in promiscuous activities. “We will conduct a raid every month,” she said.
SRILANKA

- Sri Lanka bans import of Pakistani medicines
  
  *The Express Tribune, February 02, 2012*

Following the PIC medicine debacle, Sri Lanka has banned the import of medicines from Pakistan — a move that would badly hurt the export of locally manufactured medicines, which had surged to over $400 million over the last two years.

The health ministry of Sri Lanka has taken the decision after over 100 people died due to alleged spurious medicines in Lahore. It was further revealed that more countries — including Vietnam, Burma, Philippines, and Yemen as well as countries from Africa and South America — are also considering reviewing their policies to import medicines from Pakistan.

Sri Lanka suspended the sale and use of Pakistani-manufactured Isosorbide Mononitrate 20 mg drug, used for chest pains, said a senior doctor of the National Cancer Institute of Sri Lanka.

On the other hand, officials dealing with the issue revealed that the government was deliberating putting around 12 drugs on the import ban list. However, the final decision will be taken after taking into account the investigation reports received from abroad, added an official of the Punjab Health Ministry.

Islamabad is issuing 32 licenses to pharmaceutical companies on a daily basis, the senator revealed. “So, this is the main reason which led to the use and distribution of substandard medicines.”
Maharashtra, TN account for 36% of sub-standard drugs

The Times of India, August 22, 2012

New Delhi: Almost one in three drugs (36%) found “not of standard quality” from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone. Around 9.2% of the rest of the sub-standard quality drugs were from Kerala, Gujarat (8.5%), Karnataka (7.2%), Uttar Pradesh (6.9%), Jammu & Kashmir (6.08%) and Rajasthan (5.8%).

Union health minister Ghulam Nabi Azad said on Tuesday that of the 48,082 drug samples tested by state drug controllers between 2011 and 2012 (till October); 2,186 samples, or around 4.5% failed the quality test. In comparison, 4.9% of the samples tested in 2009-10 and 4.7% in 2011-11 were sub-standard. Of these, around 133 samples — almost 6% — were found to be spurious or adulterated, the minister said. The maximum number of samples tested were from Maharashtra (6,928), followed by Karnataka (5268), Andhra Pradesh (4,758), Tamil Nadu (4,110), Kerala (3,904), Punjab (3,031) and Gujarat (2,874). A very few samples were tested in Delhi (283) of which only 13 samples — around 4.5% — were found to be sub-standard. As far as spurious or adulterated drugs are concerned, which has no active ingredient or is an expired drug that has been re-labeled and sold, Gujarat recorded the highest number of such samples at 64, followed by Maharashtra (19), UP (11) and Delhi (9).

Union health ministry officials say there are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs. Experts say acute shortage of drug inspectors (DI) is hampering the nation’s fight against spurious and fake drugs. The Central Drug Standard Control Organization (CDSCO), which lays down standards of drugs, estimates that the nation requires 3,200 DIs for its six lakh chemists, but only about 1,000 DIs are available. The size of India’s pharmaceutical industry is pegged at Rs 90,000 crore of which 40% is exported. CDSCO estimates that in the next five years, drug exports may rise from Rs 42,000 crore to Rs 2 lakh crore. Azad said “spurious drugs not only affect the citizens’ health but also the prestige of the country’s pharmaceutical trade interests”. The Union health ministry had earlier formulated a whistleblower policy — to handsomely reward both public and officers who help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices. The policy stipulated a reward of maximum of 20% of the total cost of consignments seized as payable to the informer that won’t exceed Rs 25 lakh for a case. However, the policy fell flat. The working group on health for the 12th five year plan has recommended setting up of eight new Central Drugs Testing laboratories for Rs 320 crore, besides upgrading the six existing ones for Rs 15 crore each. Although many labs have facilities for testing of drugs (quality), they aren’t equipped to test contaminated substance in drugs, it said.
Real or fake? Just dial an Interpol registry to find out

The Hindu Business Line, July 19, 2012

Mumbai: No matter where you are in the world, you may soon be able to check, if the medicine you just bought is a fake or genuine. An Interpol Global Register (IGR) has been created to allow consumers check the authenticity of certain medicines using their unique security features. First off the block on the initiative is PharmaSecure, a drug authentication technology company that has security coded more than one million packets of medicines produced every day in India. It has provided drug-makers what is known locally as the SMS-check on medicines. Medicine strips have a mobile number and an SMS code printed on them. A consumer in doubt about the authenticity of the drug, can SMS the code to the number and get a confirmation. Drug companies such as Lupin and Unichem, for instance, have adopted the technology to empower consumers to check the authenticity of medicines, said Mr Kishore Kar of PharmaSecure in India. Google Ideas developed a ‘proof of concept’ model for the IGR, unveiled at the Google INFO summit in Los Angeles, where its functionality was first demonstrated. Searches can be conducted by entering details manually or scanning a code via mobile applications available on the Android, Apple, Microsoft and BlackBerry platforms which will then deliver fast, accurate and location-based information.

Pharma units in Himachal under scanner for spurious drugs production

The Times of India, June 21, 2012

Shimla: Seeing around 25000 crore pharmaceutical industry of Himachal Pradesh facing credibility crisis, due to the production of sub standard drugs, state government has finally started acting against the drug manufacturing units by suspending their licenses. Recently, the licenses of seven companies were suspended after drugs manufactured by them failed the test. Considering the fact that 600 pharmaceutical industries located in Himachal Pradesh caters to around 50% demand of country, over the years Himachal Pradesh has become the largest suppliers of drugs and almost all the states in India are getting supplies from Himachal. But in recent past, quality of drugs manufactured in the hill state have come under the scanner after states like Maharashtra, Karnataka and others returned the supplies for their being sub standard. While, the state government has allowed hundreds of pharmaceutical units in the state, but it has not been able to ensure required manpower in the state drug controlling authority to check the quality which is resulting into frequent complaints from other states regarding the poor quality of drugs supplied to them, sources said. In Baddi-Barotiwala-Nalagarh (BBN) area, seven licenses were suspended, while one has been cancelled permanently for violations. Similarly one license has been cancelled in Paonta Sahib too, as during check 30 types of medicines were found to be of sub standard quality, which includes those, manufactured in other states too.
Government cracks down on fake drugs

Mail Today, June 18, 2012

The government is taking major steps to crack down on the fake drugs menace in India. The health and family welfare ministry has hired about 100 inspectors to check spurious medicines, while the department of pharmaceuticals has issued notifications asking pharma companies to use nanotechnology for identifying such drugs. According to a World Health Organization report, almost 20 per cent medicines sold in India are fake. Dr Jagdish Prasad, director general of health services in the health ministry, said: “There are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs. We are in the process of increasing the man force to check counterfeit drugs.” National Pharmaceutical Pricing Authority (NPPA) director and central public information officer K.K. Jain confirmed a notification had recently been issued for a nonclonable ID nanotag for pharmaceutical companies. “They can affix it on a strip or blister provided that the manufacturing or marketing company concerned has no objection in providing and sharing the data contained in the tag with the NPPA and government,” Jain said. He added that the cost per tag on the packaging of tablets and capsules will come to Rs.1.02. “Not many companies are using it currently because of the costs involved. They prefer holograms to check drug piracy as they are cost-effective,” Jain said.

National Consultation on Safe and Quality Healthcare organized by PSM India

Safe Medicines India, February 11, 2012

Hyderabad: The country’s pharma industry might be the third largest in the world in terms of volume and 14 in terms of value but Indian medicines carry the “sub-standard” tag in the international market. “The perception has gained ground due to poor manufacturing practices but it is not true”, asserted Mr. Bejon Misra, founder, Partnership for Safe Medicines (PSM) India. Similarly, the percentage of spurious drugs or substandard drugs in the state is only two per cent contrary to some reports of their widespread penetration, pointed out K Subbi Reddy, regional director, Pharmaceuticals Export Promotion Council.

They were speaking at a National Consultation on Consumers’ Right to Safe and Quality Healthcare organised by Partnership for Safe Medicines (PSM) India, here on Thursday. The event also marked the silver jubilee celebrations of the Consumer Protection Law in India and it also saw the launch of a national campaign against spurious medicines in the supply chain. Minister for Consumer Affairs, Govt. of A.P., Shri. D. Sridhar Babu, who inaugurated the program, stressed on the need for ensuring easy accessibility of good quality medicines to the poor at affordable prices. Most of the speakers, however, focused on the brighter side and suggested measures to effectively end the supply of spurious drugs. “The percentage of substandard drugs is only 2 per cent in the state when compared to 11 per cent in the country over the last 5 years…and the percentage of spurious drugs in the market amounts to only 0.2 per cent in the state compared to the national average of 0.4 per cent over
the last 5 years,” explained Subbi Reddy, pointing out that the state was a leader in the export of ‘bulk drugs’ in South East Asia. Dr Praful Naik, chief scientific officer, Bilcare technologies Ltd, called for the usage of ‘track and trace technology’ to counter supply of spurious drugs. The Pune-based company claims to have invented a solution for prevention of duplication using a unique ID which even the inventor cannot duplicate. According to Dr Naik, the technology is being used in defence and other high-security sectors and can be made available for pharmaceutical sector as well without any added cost. According to B Vaidyanathan, chief mentor, Consumer Protection Council, Rourkela, “Indian health infrastructure matched only the sub-Saharan countries. Only 11 per cent of Indians are covered under Health Insurance and 25 per cent have access to quality healthcare.” Concluding the consultation program, Bejon Misra said the government should mandate the use of technologies to overcome the problem of spurious drugs. He further added, “The government needs to come up with a portal which identifies low-cost generic replacements for the costly branded medicines.” He also urged consumers to make use of The PSM India toll free helpline 1800-11-4424, to bring cases of spurious drugs or overcharging of drugs to the notice of the authorities.

5% drugs in Indian market sub-standard, says Union health ministry

The Times of India, November 05, 2011

New Delhi: The Union health ministry says around 5% of drugs in India's one lakh crore pharmaceutical industry is sub-standard drugs. At a conservative estimate, drugs worth about Rs 5, 000 crore could be sub-standard - popping of which would not result in optimum effect.

Alarmed, the drug controller general's office has decided to put in place proper guidelines on what needs to be done when the quality of drug is found to be sub-standard through lab tests, and by when they need to be taken off the shelves at retail outlets.

A meeting of all state drug controllers has been called on November 14 on "how to combat India’s growing problem of sub-standard drugs and to put in place a three-member committee that will finalize the guidelines". A ministry official said, "Now, once a lab in Maharashtra confirms that a batch of drugs found in Delhi is of sub-standard quality, nobody knows who should take action and what it should be. In reality, such drugs need to be taken off the shelf as soon as they are found sub-standard before they reach the consumers who won't benefit from them. The guidelines will specify the action for all state drug controllers and also for the first time quantify within how much time the sub-standard drug needs to be taken off the shelves of all retail outlets."

Drugs of poor quality - both irrational and sub-standard drugs - flooding Indian market have been a serious concern even among the Planning Commission. The report said of the top 10 products, which accounted for 10% of the
medicines sold in the market in the last few years, two belong to the category of irrational vitamin combinations and cough syrup, while the other is a liver drug of unproven efficacy.

Drug Controller General of India (DCGI) estimates that about 46 banned fixed dose combination drugs (FDCs) continues to be marketed, irrespective of the ban. About 1,067 FDCs are freely marketed with the state drug controllers' approval, but without the DCGI's concurrence.

It added, "A recent government survey of drugs reveals that 0.3% of all sample drugs were found to spurious, while 6%-7% of drugs in the country are found to be sub-standard in quality," it adds. In India, less than 1% of the drugs manufactured are tested. Each of the 26 government labs test a small amount of drug samples annually and have backlogs of about six-nine months.

**National Rural Health Mission under CBI scanner**

*Hindustan Times, December 29, 2011*

A probe into drug purchases of the National Rural Health Mission by the Central Bureau of Investigation has uncovered massive irregularities. Though a tender for medicines-supply floated by the Director-General (Medical Health) of the National Rural Health Mission was meant to procure branded drugs, unbranded products from Lucknow based companies were allegedly slipped in by the pharmaceutical wholesaler, Jain Medical, which had been contracted to supply Rs. 3 crore worth of drugs to government hospitals in 24 districts of U.P. This was uncovered by the Central Bureau of Investigation (CBI), whose sleuths found also that as much as four-fifths of the drugs stocked by the Central Medical Store Department (CMSD) were unbranded. The investigative agency had been probing the National Rural Health Mission in Lucknow and 72 districts on the directions of the Lucknow Bench of the Allahabad High Court. District Magistrates and Chief Medical Officers, who hold top-level positions in district health societies, as well officials of the health and family welfare department, are under the CBI scanner. The firms involved in the racket made profits to the tune of 500%, and the probe into these firms is ongoing.

**Alarm & optimism in Kashmir**

*ConsumerConexion, November 28, 2011*

Alarmed by reports of a flourishing spurious drugs market in Kashmir, world-renowned cardio-thoracic surgeon Dr Naresh Trehan urged governmental action while addressing a school function in Srinagar. Echoing Dr. Trehan’s alarm, Dr. Surinder Bazaz, a cardiologist who also participated in the function, said on the occasion that Kashmir had become a den of spurious and substandard drugs”. The importance of a healthy lifestyle was another issue that was underscored, with Dr. Trehan counseling proper diet and exercise as a way of keeping heart ailments at bay. Dr. Trehan went on to add that
Medanta, a Delhi based multi-specialty hospital, was preparing to set up a facility in Kashmir in the coming months.

**Worrisome Statistics**

*Consumer Conexion, November 13, 2011*

Government of India sources revealed shocking statistics on the incidence of spurious and sub-standard drugs in India. On a positive note, there are indications of fresh initiatives by means of which the government is gearing up to meet the challenge. Sub-standard and irrational drugs in the Indian market are a matter of serious concern, according to government sources. One such source - the Union Ministry of Health, estimates that out of the one lakh crores worth of drugs produced in India, as many as 5000 crores worth are sub-standard. In a study commissioned by another government body – the Planning Commission, it was found that of the top 25 products sold in the country in 1999, ten - comprising blood tonics, cough expectorants, non-drug formulations, analgesics, nutrients and a liver drug - were hazardous, non-essential, or irrational. Practically all the major drug manufacturers were bringing out irrational formulations, the study also reports (Sinha 2011a). In another damning indictment, the DCGI – the Drug Controller General of India, estimates that 46 FDCs (Fixed Drug Combinations) continue to be available in the market despite being banned, while another 1,067 of them are marketed with the approval of state drug controllers, but without the DCGI's consent (Sinha, 2011a). Two important factors are responsible for the proliferation of spurious and sub standard drugs in the country, according to the Planning Commission study cited above. The first relates to the regulatory instrument – the Drug and Cosmetics Act, which is either not effectively enforced, or is subject to multiple interpretations, making it ineffectual. In an effort to strengthen the regulatory mechanism, guidelines are now being formulated to specify the time frame within which pharmaceutical formulations will have to be taken off the shelves, once they are identified as sub standard. At this time, it is not even clear as to which officials are responsible for taking action (Sinha, 2011a).

**U.S. Embassy in Sri Lanka hosted workshop on combating counterfeit drugs**

*The Sri Lanka Time, Colombo Page, May 26, 2011*

*US Embassy website May 25, 2011*

Colombo: The United States Embassy in Colombo, Sri Lanka recently hosted a workshop in Jaffna on combating counterfeit drugs for the pharmacists and law enforcement officials.

The workshop titled "Protecting Sri Lankan Families from Counterfeit Drugs" was organized by the American Chamber of Commerce, the National Intellectual Property Office, and the Sri Lanka Chamber of Pharmaceutical Industry (SLCPI) along with the U.S. Embassy in Colombo.
This was the fourth and the final seminar the Embassy has hosted to educate pharmacists, doctors, the police and other government officials to work together to protect Sri Lankan families from the dangers of counterfeit drugs. The Embassy has hosted previous workshops in Colombo, Galle and Kandy. The U.S. State Department was the principal sponsor of the campaign, the Embassy said.

Speaking at the seminar Mr. Edward Heartney, Economic Counselor of the U.S. Embassy has said that every country has to deal with the problem of fake, counterfeit, and unregistered drugs and he was pleased to see the active participation of Sri Lanka's pharmacists, chemists, pharmacy students, and pharmacy owners at the workshop as they play a critical role in countering the fraud.

GSK pharmaceuticals, a leading drug manufacturer has conducted a session on identification of counterfeit drugs.

- **Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa**

  *The Lancet Infectious Diseases, Vol. 12, Issue 6, Pages 488-496, June 2012*

Poor-quality antimalarial drugs lead to drug resistance and inadequate treatment, which pose an urgent threat to vulnerable populations and jeopardise progress and investments in combating malaria. Emergence of artemisinin resistance or tolerance in Plasmodium falciparum on the Thailand—Cambodia border makes protection of the effectiveness of the drug supply imperative. We reviewed published and unpublished studies reporting chemical analyses and assessments of packaging of antimalarial drugs. Of 1437 samples of drugs in five classes from seven countries in southeast Asia, 497 (35%) failed chemical analysis, 423 (46%) of 919 failed packaging analysis, and 450 (36%) of 1260 were classified as falsified. In 21 surveys of drugs from six classes from 21 countries in sub-Saharan Africa, 796 (35%) of 2297 failed chemical analysis, 28 (36%) of 77 failed packaging analysis, and 79 (20%) of 389 were classified as falsified. Data were insufficient to identify the frequency of substandard (products resulting from poor manufacturing) antimalarial drugs, and packaging analysis data were scarce. Concurrent interventions and a multifaceted approach are needed to define and eliminate criminal production, distribution, and poor manufacturing of antimalarial drugs. Empowering of national medicine regulatory authorities to protect the global drug supply is more important than ever.

- **Fake Drug Traders Getting Off Easy in Indonesia: US Official**

  *Jakarta Globe, April 12, 2012*

Weak law enforcement has made Indonesia a safe haven for people distributing fake drugs, a US official says. Peter Fowler of the US Patent and Trademark Office said Indonesia, along with several other countries in
Southeast Asia, has meted out very light punishments to those producing and trading counterfeit medicines. “Some countries like Indonesia and Singapore apply the death penalty for people selling narcotics, while drug counterfeitters get light sentences,” he told a discussion in Jakarta on Tuesday. Fowler said counterfeitters get light punishments because Indonesian authorities typically only apply trademark law when prosecuting them. According to him, despite the relatively lighter sentences, drug counterfeitters reap much more in profits than narcotics traffickers. Widyaretana Buenastuti, chairwoman of the Indonesian Anti-Counterfeiting Society (MIAP), said Indonesia actually has several laws that could provide heavy punishments to counterfeiters.

**Concerns Fake Cancer Medicine on Indonesian Market**

*Jakarta Globe, April 21, 2012*

Drug regulators are warning of the possibility that knockoffs of a key cancer medicine may have found their way into the Indonesian market. Endang Woro Tedjawati, director of medicine evaluation and biological products at the Food and Drug Monitoring Agency (BPOM), said on Friday that her office was looking into reports that fake versions of Avastin were now available in Indonesia after cropping up in the United States. “We’re still in the process of tracking down the reports, so we can’t say for certain yet whether this fake cancer drug is already in Indonesia,” she said. Avastin, the trade name for the drug Bevacizumab, is produced by Roche and commonly used to treat breast, lung, kidney and colorectal cancers that have reached the metastatic phase and are spreading to other organs. Endang said that although the BPOM has not yet found fake cancer drugs being distributed in the country, counterfeit versions of drugs to treat illnesses such as malaria were already available. She said the most common knockoffs were those for the popular erectile dysfunction drugs, as well as for the painkiller Ponstan (mefenamic acid) and various medicines to lower cholesterol. Most are openly sold in markets or by mobile vendors. Last year, the BPOM found only eight types of knockoff drugs in the Indonesian market, down from 28 in 2008. Endang denied that the BPOM was not serious about cracking down on counterfeit drugs, saying that officials routinely carried out stings against dealers in addition to raids on drugstores. She added that while the BPOM could censure legitimate pharmaceutical companies for producing fake drugs, it was powerless to take legal action against any perpetrators that it found. “That’s the responsibility of the police and courts,” she said. She attributed the continued presence of fake drugs in the country to the lack of strong sentences against the perpetrators, which would act as a deterrent.

**Drug Distribution Better Regulated to Fight Fakes**

*Jakarta Globe, November 22, 2010*

Jakarta. The national drug administration has announced a new campaign to control the distribution of medicine and stem the circulation of counterfeit drugs. Lucky S. Slamet, deputy director of the Food and Drug Monitoring Agency (BPOM), said on Monday that of the approximately 7,500 medicines
in current circulation in the Indonesian market, counterfeiters were producing copies of up to 20 of the more popular ones. He said these included “lifestyle medicines” such as Viagra, as well as life-saving drugs such as the antimalarial Fansidar. To deal with the issue, he said, the BPOM had set up the National Single Point of Contact, a post within the agency that would be responsible for the national circulation of medicine. “Besides establishing the SPOC, we’re also campaigning through the media for greater public awareness about counterfeit medicines,” he said. “We lack the manpower to campaign directly to the public, so we need help from NGOs and the media to run campaigns on how to identify counterfeit medicine. He added in this case, people should only purchase medicine at authorized places, such as pharmacies or hospitals. The Indonesian Consumer Protection Foundation (YLKI) says the lost revenue from counterfeit drugs amounts to Rp 2.5 trillion ($280 million) annually. Meanwhile, Slamet Budiarto, secretary general of the Indonesian Doctors Association (IDI), accused the government of putting the interests of the legitimate producers above those of consumers in this issue.

He said this was apparent in the Health Ministry’s definition of counterfeit drugs, which makes no mention of harmful ingredients. “It’s fine as long as there aren’t any harmful ingredients in the drugs, but what if there are such ingredients, which can delay the healing process or even cause death?” he said. He added there was also no official data on deaths caused by the use of counterfeit medicine in the country. Puspo Sumadi, country manager for US pharmaceutical company Eli Lilly, called for harsher punishment for drug counterfeiters. According to World Health Organization statistics, 10 percent of medicines sold worldwide are fake; while in Indonesia, that figure is closer to 25 percent, as stated in a US Trade Representative report. The WHO also estimates some 200,000 people die worldwide every year because of the problem.

Third of Malaria Drugs in Southeast Asia Are Fake
Jakarta Globe, May 22, 2012

Paris. More than a third of malaria drugs examined by scientists in Southeast Asia were fake, and a similar proportion analyzed in Africa were below standard, doctors warned on Tuesday. “These findings are a wake-up call demanding a series of interventions to better define and eliminate both criminal production and poor manufacturing of antimalarial drugs,” said Joel Breman of the Fogarty International Center at the US National Institutes of Health (NIH). Trawling through surveys and published literature, the researchers found that in seven Southeast Asian countries, 36 percent of 1,437 samples, from five categories of drugs were counterfeit. Thirty-percent of the samples failed a test of their pharmaceutical ingredients. In 21 sub-Saharan countries, 20 percent of more than 2,500 samples tested in six drug classes turned out to be falsified, and 35 percent were below pharmaceutical norms. Sub-standard medications are a major problem in the fight against malaria, a disease which killed 655,000 people in 2010, according to the UN’s World Health Organisation (WHO). Many of the drugs that are being faked or poorly manufactured are artemisin derivatives, the study said. This is a special worry, for artemisinins are the frontline treatment for malaria, replacing...
drugs to which the malaria parasite has become resistant. The study says there are many causes for the problem, ranging from widespread self-prescription of drugs to shoddy controls to monitor drug quality and prosecute counterfeiters. “Poor-quality antimalarial drugs are very likely to jeopardise the unprecedented progress and investments in control and elimination of malaria made in the past decade,” said Breman. Last month, the Institute of Health Metrics and Evaluation at the University of Washington in Seattle reported that artemisin-resistant malaria which was first spotted in Cambodia in 2006 has since surged 800 kilometers westward to the Thailand-Burma border.

\[\text{Database on the Incidents of Counterfeit Medicines in the WHO-SEA Region [2011-2012]}\]

\[\text{Counterfeit drugs ‘a serious threat’}\]

*The Jakarta Post, April 12, 2012*

An expert has warned that rampant drug counterfeiting may not only lead to financial losses to producers, but also give rise to drug-resistant diseases. Widyaretna Buenastuti, chairwoman of the Indonesian Anti-Counterfeiting Society (MIAP), said on Tuesday that consumer education remains the best way to combat drug counterfeiting, to ensure safe drugs were being distributed. “We won’t be able to distinguish whether a product is counterfeit or not. Counterfeiters are really good at coming up with convincing looks for their products,” Widyaretna said in a seminar organized by the US Embassy in Jakarta. She suggested that people only buy medicine from reputable pharmacies or licensed drugstores. Counterfeit drugs have caused serious losses to the government, Widyaretna said, with the amount of potential tax revenue lost reaching Rp 43.2 trillion (US$4.76 billion) between 2005 and 2010. Widyaretna also said counterfeit drugs could be harmful to patients. “If you compare it with other sectors, the economic losses from drug counterfeiting makes up only 3.5 percent of the total figure in the past five years, which is not too high. The problem is that counterfeit drugs can be dangerous and can even kill you, no matter how small the percentage is,” she said. Meanwhile. US Ambassador to Indonesia Scot Marciel said that more than $75 billion worth of fake drugs were sold globally in 2010. He said the latest estimates suggested over 30 percent of medicine sold in Southeast Asia was counterfeit, resulting in serious problems. “The US and Indonesian companies that are making real medicines lose out to people who are making fake or counterfeit medicines,” Marciel said. He said counterfeit drugs could also have severe health impacts. For certain diseases, taking improper medication can contribute to the development of strains of the diseases resistant to regular drugs. In the US, the problem has also affected companies producing drugs for serious illness. Recently, authorities found fake Avastin, a cancer drug produced by Roche, in the market, as well as fake antibiotics, HIV and tuberculosis drugs. But combating counterfeit drugs is not an easy undertaking. Peter N. Fowler, the US regional intellectual property attaché, said most countries, including Indonesia, had regulations against counterfeiting that impose a range of penalties. But in reality, he said, many law-enforcement agencies did not take counterfeiting seriously. Fowler said that the judiciary has also been lax against counterfeiters. “They may get three to six months in jail, they may get fine that they can easily pay because
again, the profit from the activity as a criminal business enterprise is huge,” said Fowler. He said some criminals would not be bothered by a six-month jail sentence and would return to counterfeiting upon release. Fowler said counterfeiting drugs is a profitable business, with the profit margin for Viagra could be 2,800 percent of costs, compared to counterfeit tobacco (800 percent), heroin (1,200 percent) and cocaine (1,400 percent). “In Asia, the risk of smuggling narcotics is the death penalty. If you’re just involved in counterfeit medicine, it’s sometimes seen only as trademark violation — although this is a very significant public-health threat,” Fowler said.

Illegal drug threat still looms over public
The Jakarta Post, February 08, 2012

Unlicensed cure-alls: An official from the Food and Drug Supervision Agency (BPOM) displays a number of unregistered drugs widely sold around the country. Despite the government’s efforts to contain illegal drugs, the public still faces looming threats due to the rampant distribution of the substances. Many people have fallen victim to illegal drugs. This indicates the inability of the Drug and Food Supervisory Agency (BPOM) to deal with the problem. Founded in 2001, the agency may have been able to bring perpetrators to court but, unfortunately, they have only faced light sentences that have not provided a strong enough deterrent. Data from the BPOM shows as many as 209 drug counterfeiters were sent to 1.5 months in jail in 2010. Meanwhile, in 2009, 174 drug counterfeiters were sent to five months in jails and had to pay Rp 5 million (US$560) fine as the heaviest sanction. Obviously, such light sentences have little deterrent effect. The 2009 Health Law stipulates that people who commit the crimes of producing and selling illegal drugs and foods face a maximum of 15 years in jail and Rp 1.5 billion fine. The recent succession in the BPOM chairmanship should now be used as momentum to show the public the agency’s power. Speaking after the inauguration of Lucky Oemar Said, the new BPOM chairperson, Health Minister Endang Rahayu Sedyaningsih said the agency should confront food and drug counterfeiting by launching effective and consistent law enforcement. Separately, public health professor Hasbullah Thabrany said the government must take bold measures to protect people from the dangers of illegal drugs. “The government should not only find and seize counterfeit drugs on the market. It must also combat and put an end to counterfeiting,” said Hasbullah. During the fourth Pangea Operation in September 2011, the agency seized counterfeit drugs distributed online worth Rp 82 million. The drugs turned out to be medicines for erectile dysfunction and libido boosters. While praising ongoing efforts, Hasbullah said, the BPOM did not show its power when it came to business-oriented medication. It was quite surprising to know that neither the Health Ministry nor the BPOM investigated alternative therapies, including herbal remedies or body massage with specific techniques, that were massively promoted via the media, whereas no scientific-based research could support their claims. Responding to this condition, Lucky said her office kept on doing its job of supervising food and drugs in the market. “We already have power, but still it is not strong enough.
We need a specific law that regulates drug and food control,” she said, adding that the House of Representatives planned to deliberate the long-awaited draft law on drug and food control this year. “With the umbrella law, I’m sure we can conduct firmer action to combat drug counterfeits,” Lucky said, adding that the draft law was already in this year’s national legislation program. Citing an example, she said the 2009 Health Law still considered drug counterfeiting as not a serious crime. As a result, courts charged most perpetrators with light criminal violations. “They received only four months in jail or a Rp 1 million fine with little deterrent effect. With the new law we’ll have significant changes,” she said.

**Bogus Drugs And Counterfeit Viagra In Thailand**  
*Bangkok Times, Sep 01, 2011*

A viagra-like drug will be launched by the Government Pharmaceutical Organisation next month in a bid to battle counterfeit products and the brand-name pill's steep price.

The GPO's managing director Witit Artavatkun said yesterday the organisation had been given permission by the Food and Drug Administration (FDA) to produce Sidagra, a generic drug with a similar composition to Viagra, to help men with erectile dysfunction.

Sales of Sidagra will begin on Oct 15 in two sizes — a 50mg tablet at 25 baht and a 100mg pill at 45 baht. The prices of the pills are a lot cheaper than Viagra's retail price of 200 baht per tablet, Dr Witit said. Sidagra will be rolled out to give consumers a safe alternative to counterfeit products and to help elderly men who cannot afford Viagra, he added. Manufacturing processes have been boosted to meet standards in other Asean countries, he said, adding that the factory's capacity now stands at 5 billion tablets a year. Drugs for the treatment of diabetes, high blood pressure and Aids will be produced at the GPO factory and distributed to Myanmar, Laos, Cambodia, Vietnam and Malaysia, he said.

**Constant demand keeps fake drugs in the market**  
*The Jakarta Post, September 25, 2010*

The risks of counterfeit drugs have apparently failed to drive people away from buying them. With consistent demand the circulation of fake drugs remains unchecked, an official recently said.

Erita Harun from the United States Department of Justices’ International Criminal Investigative Training Assistance Program (ICITAP) Indonesia, said that raids have proven that Indonesia was a haven for counterfeit drugs. “There are gaps [in the pharmacy industry] that can be used by those producing fake drugs, such as gathering used packets to be refilled [by bogus products],” she said in Jakarta during a lecture on intellectual property rights.
Erita said that high demand is part of the reason why illegal drugs are still very common in Indonesia.

Panji Pragiwaksono from the Community for Children with Cancer (C3) said that parents of children with cancer often resorted to drugs that were cheaper but “shady”.

Lucky S. Slamet from the Food and Drugs Monitoring Agency (BPOM) said that bogus drugs make up around 2 to 3 percent of the illegal drugs confiscated during regular raids conducted by 32 of its offices across the country. “There were about 20 bogus brands,” she said. In 2009, BPOM confiscated around 1,000 samples from locations notorious for selling illegal drugs. About 2 percent of these drugs were discovered to be fake. Lucky said that taking fake drugs carried various risks. From a public health perspective, if a producer tries to copy an anti-diabetic drug but only uses flour as the main ingredient, this may result in ineffective treatment, and even death. During a raid, the agency discovered a counterfeit vaccine in the form of liquid containing mere electrolytes stored inside a used syringe sold as a new one. “There were blood specks on the needle,” she said. Lucky said that typical drugs to be copied were painkillers and sexual performance enhancers. Lucky pointed out that places that officially sell medical products, such as licensed pharmacists, were usually free from counterfeit drugs.

- **Indonesia's pharma IP problems**
  *Komodo Dragon Blog, June 22, 2011*

There are constant complaints about the prevalence of counterfeit medicines in Indonesia. Given the lack of effective overall enforcement in Indonesia, alternatives are being tried. The bureau of food and drugs, BPOM took part on a joint raid this week with the East Jakarta local government health office to raid 20 outlets and seized some 700 fake Viagra pills. The news reports say there was a tip off, but this usually means the IP holder's investigations identified the fakes.

The interesting point is that these agencies don't really have a proper enforcement role, but the difficulty of working with the police makes finding such alternatives necessary. For example BPOM has powers of supervision over medicine sales but not arrest. While it can work on retail targets, finding the suppliers typically is much harder since they are found in the wholesaler markets and distribute to pharmacies more covertly to avoid detection.

In late 2010, BPO announced a campaign to fight the circulation of counterfeit drugs. The deputy director indicated then that counterfeiters were selling copies of 20 of the more popular ones. The Indonesian Consumer Protection Foundation (YLKI) has estimated that lost revenue from counterfeit drugs amounts to Rp 2.5 trillion ($280 million) annually.

Meanwhile, the International Pharmaceutical Manufacturers' Group chairman complained at a press conference this week at the restriction on foreign
ownership in distribution. Indonesia requires that medicines be made locally, in order to be distributed locally by international pharma companies. At present ownership restrictions mean that unless a medicine is made locally, the distribution must be turned over to a local Indonesian distributor. This means turning over all the regulatory data for marketing approvals, which research based companies are reluctant to do.

Expired, Fake Medicines Flood Pharmacies in Nepal

Global Press Institute, September 12, 2012

As Nepalis rely on local pharmacies for everything from prescriptions to abortions, many get sick and even die from the fake and expired medicine that is flooding the market here. The government acknowledges that pharmaceutical monitoring has been weak and is striving to strengthen industry regulation as well as consumer awareness.

Although Nepalis frequent pharmacies to obtain medicine to ease a variety of symptoms and ailments, they often end up feeling worse thanks to expired and fake products that have flooded the market. Expired and fake drugs have been linked to countless deaths, injuries and ailments here. Authorities attribute victims’ susceptibility to illiteracy and lack of awareness. Although the government has various regulatory measures and bodies in place to monitor the industry, officials admit that implementation is weak. As many accuse pharmacists of caring more about profits than customers’ health, pharmacists say it’s difficult to meet government standards. Meanwhile, the government is striving to strengthen monitoring and to increase consumer awareness.

Statistics on the number of people affected by expired or fake medicine in Nepal are unavailable. But lawyer Jyoti Baniya, chairman of the Forum of Protection of Consumer Rights, a nongovernmental organization that advocates for consumer rights, estimates that more than half of Nepal’s population may be using and affected by expired and/or fake medicine.

Sanjib Acharya, office assistant at the Nepal Pharmacy Council, the autonomous professional and regulatory body for pharmacists created by Parliament in 2001, attributes the victims’ susceptibility to fake and expired medicine to illiteracy and lack of awareness. Elaborating on the trend in Nepal, Acharya says that people don’t visit hospitals here unless it’s serious because of long lines at public hospitals and high bills at private ones. Instead, they usually go to their closest pharmacy when they think they require any medication.

Bodily damage from medicine can lead to fines and up to 10 years in prison for the seller, Baniya says. Selling potentially life-threatening expired medicines could result in life in prison. The Department of Drug Administration also has policies regarding marketing and guidelines for standards of quality. But Baniya says pharmacies are still cheating people and making them suffer because of the government’s weak implementation of laws and policies and the strong position of manufacturers, distributors and sellers.
The court process is also long and tedious to charge pharmacists for selling fake or expired medicine, says Shyam Adhikari, one of the drugs inspectors at the Department of Drug Administration. Therefore, he says the department has appealed to the ministry to enable the inspectors to issue penalties on the spot.

Nepal Health Council, a body under Nepal government, recently partnered with WHO to monitor pharmacies in 22 of Nepal’s 75 districts. It found that most of the pharmacies didn’t have skilled professionals, says Dhana Prasad Poudel, registrar at the council.

Another problem is a lack of qualified staff available to prescribe medicine. In order to run a pharmacy, a person must pass a three-year course to obtain a diploma in pharmacy, as well as receive a license from the Department of Drug Administration.

❖ Now send SMS to find if pill is genuine

The Times of India, September 23, 2012

Mumbai: Now before popping a pain-killer or having cough syrup, you can be sure that it's not fake or spurious, thanks to an innovation designed to curb the menace of spurious medicines. Strips of popular and commonly-used medicines like Combiflam, Dispirin, Crocin, Voveran and multi-vitamin Becosules will soon carry a unique code, which sent out through a SMS by a mobile phone of a consumer can help him verify the genuineness of the medicine.

While certain companies like Roche, Lupin and Unichem have started rolling out medicine packs with a new packaging including the unique code printed on it, many like Sanofi, Pfizer, GlaxoSmithKline are planning to follow suit. The tech innovation is being seen as a new weapon by pharma companies to combat the menace of spurious and fake drugs.

This is how it will work. Consumers will need to send the random alphaneumric code printed on the medicine strip through their mobile phone. Once they get a response that it is a genuine medicine, and not spurious or fake, it can be used. Not only that, the consumer will also get health tips and drug-refill reminders.

There is no uniform figure to determine the penetration of spurious, fake or misbranded medicines in the country, with the industry and government, offering varying estimates. Recently, the health ministry announced that of the over 48,000 drug samples tested by state drug controllers between 2011 and 2012, nearly 5% failed the quality test, while, almost one in three drugs (36%) were found to be "not of standard quality" from across the country. States like Maharashtra and Kerala have a huge issue of sub-standard drugs, with the incidence more in semi-urban and rural areas.
Mostly, the drug’s quality suffers and so does its efficacy, while in certain cases, it may cause serious side-effects and even be fatal. There may also be instances when these “fake” medicines offer no therapeutic benefits. It is virtually impossible to tell the difference between real and fake medicines unless a laboratory analysis is carried out. Since that’s may not be a practical solution, drug companies along with regulators have been trying to counter the menace through measures like bar-coding, embedded holograms, RFID, but have met with little success. Industry sources say most frequently fake or spurious medicines are those which are of a high value (turnover) basically brands with Rs 100 crore plus, and those which are fast-moving from the retail counter.

Pfizer India has faced the issue of fake and substandard in its heritage and high-selling brands multivitamin Becosules, cough syrup Corex and Dolonex and Viagra, a company official said.

In the case of widely-used medicine Crocin, the company GlaxoSmithKline Consumer Healthcare rolls it out with a holographic strip, with a company and Crocin logo, while each tablet is embossed with the ‘CROCN’ lettering, as an anti-counterfeit measure.

MNCs like Roche have also made a small beginning in all their cancer drugs, and have engaged supply chain security experts Kezzler to provide encryption software that enables consumers to verify that their medicine is genuine.

Another company, PharmaSecure is working with over 10 leading pharmaceutical manufacturers and has coded over 300 million drug packages to fight the problem of counterfeit drugs. Certain companies are not rolling out the new packaging because of cost issues, and since many of these medicines are under price-control.

Chemists to become new drug busters

The Times of India, September 09, 2012

New Delhi: India's most ambitious "whistleblower policy" to handsomely reward those who help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices has failed miserably. Not a single reward has been given out till now even though Union health minister Ghulam Nabi Azad had announced the policy in Parliament in July, 2009.

Drug Controller General of India (DCGI) Dr G N Singh told TOI in an exclusive interview that "no credible information pin-pointing a place where manufacturing or supply of fake drugs was supplied by the public to the government." Now, Dr Singh has decided to rope in India's seven lakh chemist outlets to help government check the commercial sale of fake or spurious drugs. He is travelling to Chandigarh on Sunday to make an open plea to chemists during his address at the executive meeting of the All India Organization of Chemists and Druggists — an apex body of nearly 7.5 lakh members involved in wholesale and retail trade of pharmaceutical products.
According to Dr Singh, a vigilance cell is being set up in every state to monitor fake or spurious drugs. The ministry had earlier received tip-offs from states like Himachal Pradesh, Haryana and Rajasthan in the northern region and one from a southern state, but none produced concrete results. The policy stipulates that the reward of a maximum of 20% of the total cost of consignments seized would be paid to the informer, which will not in any way exceed Rs 25 lakh in each case.

In respect to an officer in the government or the Central Drugs Standard Control Organization (CDSCO), the reward would not exceed Rs 5 lakh for one case and a maximum of Rs 30 lakh in h/his entire service. The reward would be given only when there would be confirmation of the seizure of spurious drugs, cosmetics and medical devices by the designated officers of CDSCO.

The policy said that once the fake drugs are seized, the government would engage senior advocates who have sufficient experience of cases relating to drugs to help punish the guilty. To ensure speedy trials, these cases will be filed before the designated/special courts set up for the purpose of drug-related issues, as per provisions of the Drugs and Cosmetics Act. The health ministry estimates that 5% of drugs in India are counterfeit, while 0.3% are spurious.

A vision paper prepared by the CDSCO, quantifying how much funds are needed under the 12th Five Year Plan (2012-17), says that India would require Rs 3,256 crore to strengthen its drug regulatory system. This includes cost of upgrading state laboratories, improving manpower by 2,500, creation of additional labs, mobile drug testing labs and the CDSCO's pharmacovigilance programme.

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War on bad medicine

_The Times of India, July 05, 2012_

Gandhinagar: When you buy a drug over the counter, there is no way to determine if it is substandard or spurious. From September 2009 till now, the Gujarat Food and Drugs control administration (FDCA) recalled 615 batches of tablets, injections, and capsules that did not meet pharmacological standards. Considering this problem, and following an Allahabad High Court ruling in October 2010, a special task force headed by Gujarat was formed for implementing the unique 'track-and-trace' system for every strip or bottle of medicine you buy off the counter anywhere in the country.

This system has been planned to give every medicine a unique identity number and a possible bar code. Customers can simply SMS this identity number to a toll-free number to learn whether the drug is from an authentic manufacturer. If the drug happens to be low on efficacy, the licensed company can be hauled up for pumping in substandard products. The task force also proposed the use of non-clonable ID stickers, in place of barcodes, to carry the unique ID (UID) for medicines. The task force report was
submitted to the Union ministry of health recently. However, this proposed system has drawn fierce opposition from drug manufacturing companies.

"Few months back we had caught a licensed manufacturer, Hardik Drugs from Santej, printing duplicate labels of cough syrups made by Cipla. The labels were the exact copy of the original," says food and drugs commissioner H G Koshia, who is heading the task force. The department caught another manufacturer, Radhe Biotech, manufacturing fake syrups of a dubious Himachal-based company in Maninagar.

Drug manufacturers' organizations like the Confederation of Indian Pharmaceutical Industry (CIPI), Federation of Pharma Entrepreneurs (FOPE), Indian Drugs Manufacturers Associations (IDMA), and Organization of Pharmaceutical Producers in India (OPPI) had opposed the tracking system. They claimed that it will be a huge burden to small and medium enterprises. The associations in the report said that an SME with exports of around Rs 15-20 crore would need to invest Rs 2 crore on barcode machines (one for each blister machine and one each for syrups and injections).

The system is so designed that if a duplicate UID drug number or a number printed on spurious medicine is SMSed, the system immediately alerts the local drug inspector.

Highlights of the track and trace model
1. Drug manufacturers will have to label every medicine with a barcode which will have the details of a product including its batch number and date of manufacturing
2. Details, including the bar code used, will be uploaded in the manufacturer's portal
3. An SMS based authentication of drugs can be implemented for customers in this system.
4. Each time the product is invoiced or transferred to a subsequent wholeseller or retailer, the data will be updated in the manufacturer's portal.
5. More than 700 pharmaceutical companies, with approximately 8,000 export bar-coded products; resist introducing the system in India

 횟 China-made fake drugs flooding Asian countries

ELEVEN Myanmar, August 15, 2012

Fake medicines made in China, including life-threatening anti-malaria drugs, are flooding Asian countries, especially Myanmar, Laos and Cambodia, according to experts.

IMS Health, a pharmaceutical company based in the US, has described China as the world’s biggest counterfeit medicine producer. The company has its branches in Canada, Japan, China, Latin America, the Pacific, Europe, Africa and the Middle East.
Reports said that in China, an anti-fraud squad comprising more than 18,000 police had cracked down on at least 2,000 drug fraudsters. The confiscated counterfeit medicines are valued at 1.16 billion yuan (US$182 million).

Websites worldwide have stated that there are two kinds of fake drugs from the mainland – fake drugs and imitations of renowned brands. They said these drugs claim at least 700,000 lives every year. A study by IMS Health shows there has been an increase in production from 19 to 22 per cent since 2008. About 50 per cent of illicit drugs are mainly exported to Angola, Burundi and Congo, whereas two-thirds of the rest make inroads in Myanmar, Laos and Cambodia, according to the website policynetwork.net. Reports said a haul of painkillers, cold drugs, and drugs for abdominal pain as well as counterfeit anti-malaria drugs have found their way into Myanmar through Chinese businessmen.

Dr. Win Si Thu, chairman of the Myanmar Drug Dealers Association, said the only way to raise public awareness about fake drugs was to launch organizational campaigns, adding that they report to the authorities like the Food and Drug Administration (FDA), calling on them to seize counterfeit drugs from the market. The FDA, in return, informs the association of the unsafe drugs and the association asks the dealers concerned to get the drugs out of the market, he said.

Myanmar is cooperating with related international organizations to address the issue of fake medicines. Some cases were found to have been linked mainly to Chinese businessmen. An FDA official said: “The problem does not concern China alone. We conduct regular inspections in the market. In some cases, fake medicines are found to have been produced domestically. But we are solving the problem of fake medicines from other countries in collaboration with Interpol, WHO [World Health Organisation] and WCO [World Customs Organisation].” “Among China-made fake medicines is an anti-malaria drug, whose ingredients are life-threatening. This is why we are carrying out inspections across the country. Officials from international malaria-related organisations visited us last week for inspection,” he said. Myanmar needs to take more systematic steps to clamp down on illegal imports of fake medicines. It also should release a statement on the possible spread of China-made fake medicine brands by seeking bilateral cooperation between the two governments, officials from Myanmar Medical Association said.

❖ One-third of malaria drugs in SE Asia are fake

*The Myanmar Times, Volume 32, No. 628, May 28 - June 3, 2012*

Paris: More than a third of malaria drugs examined by scientists in Southeast Asia were fake, and a similar proportion analysed in Africa were below standard, doctors warned last week.

“These findings are a wake-up call demanding a series of interventions to better define and eliminate both criminal production and poor manufacturing
of antimalarial drugs,” Joel Breman of the Fogarty International Center at the US National Institutes of Health (NIH) said on May 22. Trawling through surveys and published literature, the researchers found that in seven Southeast Asian countries, 36 percent of 1437 samples from five categories of drugs were counterfeit. Additionally, 30pc of the samples failed a test of their pharmaceutical ingredients.

Sub-standard medications are a major problem in the fight against malaria, a disease which killed 655,000 people in 2010, according to the UN’s World Health Organisation (WHO). Many of the drugs that are being faked or poorly manufactured are artemisin derivatives, the study said. This is especially worrying as artemisinins are the frontline treatment for malaria, replacing drugs to which the malaria parasite has become resistant. Last month, studies published in The Lancet and Science journals reported that artemisin-resistant malaria, which was first spotted in Cambodia in 2006, has since been detected 800 kilometres (500 miles) westward on the Thailand-Myanmar border.

Dangerous Malaria Drug
Bangkok Post, December 07, 2011

In South-East Asia, the malaria parasite is acquiring new resistance to once-effective drugs used against it. Indian, Chinese and Vietnamese pharmaceutical companies are believed to be contributing to the phenomenon in a big way.

The malaria parasite's resistance to artemisinin, a once effective drug used against it, is spreading along the Cambodia-Thai border, where it was first detected in 2009, and possibly is making inroads into Myanmar as well, according to the World Health Organisation. Resistance to artemisinin now threatens the most effective treatment around for malaria, namely, artemisinin-based combination therapy.

Part of the problem of the malaria parasite acquiring resistance to drugs can be attributed to the use monotherapies, that is, pharmaceuticals that contain just one active agent. Combination therapies, in which more than one agent works in tandem, are believed to hold out longer. Monotherapies, still being manufactured in India, China and Vietnam, not only contribute to antimicrobial resistance in a big way, they also hampers new drug formulations.

Anti-microbial resistance (resistance by microbes to drug formulations) is caused also by the use of sub-standard pharmaceuticals. Notably, of the anti-malaria drugs that were found to be sub-standard, as much as half contained artemisinin, which was a contributory factor in the malaria parasite's resistance to the drug, Bate told the panel. Not only is the use of poor quality medicines in the affected region (the Thai-Cambodia-Burmese border) by no means negligible, the poor grade pharmaceuticals in question are not illegal there either, he went on to add.
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