

Matrix of Drug Quality Reports on USAID-assisted Countries

By the U. S. Pharmacopeia Drug Quality and Information Program

Joyce Primo-Carpenter, M.D., BSc. Pharm.
Associate Director

Milissa McGinnis, M.A.
Program Associate

USP DQI, Global Assistance Initiatives
U.S. Pharmacopeia
12601 Twinbrook Parkway, Rockville MD 20852

January 4, 2006
* new information

This publication was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement number HRN-A-00-00-00017-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

For more information, contact:

<p>U.S. Agency for International Development G/PHN/HN/HPSR 1300 Pennsylvania Avenue, NW Washington, DC 20523-3700 USA Phone: (202)-712-4789 Fax: 202-216-3702 Email: aboni@usaid.gov</p> 	 <p>United States Pharmacopeia 12601 Twinbrook Parkway Rockville, MD 20852 USA Phone: (301)-816-8162 Fax: (301)-816-8374 Email: uspdqi@usp.org</p>
---	--

USP DQI SUBSTANDARD/COUNTERFEIT DRUG QUALITY REPORTS ON USAID-ASSISTED COUNTRIES

REGIONS	DRUG/S	REPORTS	REFERENCES (2001-2006)
AFRICA			
Democratic Republic of the Congo (DRC)	Antiretrovirals	Fake antiretrovirals were found in Lubumbashi in December 2003. The bottles and blisters which were not in carton boxes were labeled “Triomune” (stavudine, lamivudine, and nevirapine) and “Duovir” (lamivudine and zidovudine), both of which are Cipla’s brand products. Preliminary investigations showed that fake labels were put on bottles containing non-ARV pharmaceutical products. Some tablets have been identified to contain fluvoxamine (antidepressant) or cyclobenzaprine (muscle relaxant). Counterfeiters have targeted health prescribers and patients to buy these cheap ARVs.	Ravinetto R. Counterfeit ARVs in DRC. E-DRUG. 2/11/2004. Available from: http://www.essentialdrugs.org/edrug
	Antiretrovirals (“Triomune” and “Duovir”)	* Medecins Sans Frontieres (MSF), which is running an HIV/AIDS program in the DRC, reported that fluvoxamine (an antidepressant) and cyclobenzaprine HCl (a muscle relaxant) had been labeled as either “Triomune” or “Duovir”, the two commonly prescribed antiretroviral brands that are manufactured by Indian pharmaceutical company Cipla.	Antidepressants are sold as antiretrovirals in DR Congo. The Lancet 2004; 363: 713.
Ethiopia	Antiretrovirals	Smugglers are illegally importing drugs and passing them off as antiretroviral drugs. Ethiopian health officials have warned the public not to buy these drugs. According to Ethiopia’s Drug Administration and Control Authority, these illegally imported drugs are of unauthorized quality and with unpredictable effects.	Kaisernetwork.org. Daily HIV/AIDS Report. Drug Access/Ethiopian Health Officials Warn Public Against Counterfeit Antiretroviral Drugs. (Oct. 9, 2003). Available from: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=20261
Ghana		Percentage of drugs that failed quality testing: 6% public sector, 6% NGOs, 0% private sector. Professor Johnson Kwakye of Kwame Nkrumah University of Science and Technology has analyzed the fake drugs in the market. He discovered the root crop cassava masquerading as ampicillin. Cassava when pulverized turns into a white powder,	Aoagyne-Nyame F, Arhinful DK. Ghana case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001. Counterfeit medicines becoming harder to spot. SCRIP World Pharmaceutical News August 13, 2004. Issue: 2976; London UK. PJB Publications Ltd. 15.

		similar in appearance to the antibiotic. The country's regulatory agency, the Food and Drugs Board (FDB), is taking concerted efforts to combat counterfeit drugs. Such actions appear to be paying off. Professor Kwakye reports that the decrease in the number of fake drugs on the market can be attributed to FDB's efforts.	
Ivory Coast	Ginovir 3D capsule (antiretroviral combination product consisting of zidovudine 200 mg, lamivudine 150 mg, and indinavir 40 mg)	The WHO received information about the availability of a counterfeit version of this antiretroviral triple combination product. Analysis of the fake drug was done by the Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS) upon request from the Association of AIDS Patients (AIDES). Results showed the samples did not contain lamivudine or indinavir; they contained zidovudine 201 mg, stavudine 40 mg, and an unidentified substance. The manufacturer on the label was Selchi Pharmaceuticals, Namibia.	Counterfeit triple antiretroviral combination product (Ginovir 3D) detected in Cote d'Ivoire. WHO QSM/MC/IEA.110, November 28, 2003. Bulletin d'Analyse N° 2003/U/NX/20391/M/ NC, Direction des Laboratoires et des Contrôles, (date de notification 11 juillet 2003) AFSSAPS.
Kenya	Antiretrovirals	The <i>Daily Nation</i> newspaper reported that antiretrovirals for distribution as part of Kenya's AIDS medicine program were being sold on the black market in Nairobi. The drugs are being sold at less than US\$65 for a monthly cocktail, nearly quarter the normal price. The drugs can be bought without doctors' prescription.	Siringi S. AIDS drugs being sold illegally on market stalls in Kenya. <i>Lancet</i> 2004; 363: 377.
Mali		Pharmacists are spearheading a campaign against unlicensed drugs. "Street drugs kill," is the slogan used to increase public awareness of the health risk posed by these drugs.	Mali. IRIN focus on efforts to curb the vending of medicines. IRIN news.org June 2002. Available from: http://www.irinnews.org/report.asp?ReportID=28550&SelectRegion=West_Africa&SelectCountry=MALI
Mauritius	Gentamicin eyedrops	Occurrence of outbreak of postoperative eye infections at a national eye hospital in July 1999; 4 patients presented with hypopyon about a week after cataract surgery; samples taken from the eyes of 3 patients grew gentamicin-resistant <i>Pseudomonas aeruginosa</i> ; investigation showed contamination of gentamicin eyedrops, which were imported by the hospital from an obscure company that manufactured these medicines under suboptimum conditions resulting in contamination;	Issack MI. Substandard drugs. <i>Lancet</i> 2001; 358: 1463.

		organism found was identical to culture isolates taken from the patients; other bacteria also were found in some vials; after removal of gentamicin eyedrops from the hospital, no further cases of <i>P. aeruginosa</i> post-op infection occurred.	
Nigeria	<p>Common analgesics, antibiotics such as ciprofloxacin (Peflacin) advertised as 500 mg but actually 250 mg, antidiabetics (Diabinese), antihypertensives, Betnesol-N eye ear and nose drops</p> <p>Syrups of Chemiron, Ranferon, Couflin, and Nivaquine as well as Tixylix, Gestid, Flagyl suspensions, and Ferric Ammonium Chloride solution</p> <p>Antimalarials (chloroquine, proguanil, quinine, pyrimethamine/sulfadoxine), antibacterials (amoxicillin, ampicillin, benzylpenicillin, cloxacillin, dapsone,</p>	<p>Sources in Nigeria's pharmaceutical industry estimate 40% of the drugs in circulation are either fake or adulterated; the majority of fake drugs identified were imported from India; fake drugs either contain ordinary powder or starch, or poison, while others have expired or are well below the dose mentioned in the packaging.</p> <p>500 cartons of these syrups were seized from the illegal manufacturing syndicate in a village in Ihialla by the National Agency for Food and Drug Administration and Control (NAFDAC).</p> <p>581 samples of these drugs were taken from 35 pharmacy outlets identified from the Nigerian register of pharmacies, bought without prescription; samples were analyzed using high performance liquid chromatography (HPLC) and the amount of active ingredient compared with the limits set by the British Pharmacopeia (BP). Results: 279 (48%) samples were found to contain amounts of the active ingredient outside the appropriate limits. More than 50% of the group of drugs (antimalarials, antibacterials, and antituberculosis) failed to comply with BP</p>	<p>e-drug@usa.healthnet.org: the menace of fake drugs in Nigeria, 3/26/2002</p> <p>Vanguard 2/26/2002</p> <p>Taylor RB, Shakoor O, Behrens RH, et al. Pharmacopeial quality of drugs supplied by Nigerian pharmacies. Lancet 2001; 357: 1933-6.</p>

	<p>doxycycline, metronidazole, ampicillin/cloxacillin in trimethoprim/sulfa methoxazole), antituberculosis (isoniazid, pyrazinamide, rifampicin, streptomycin), anthelminthic (mebendazole), and antifungal (ketoconazole)</p>	<p>specifications, although some individual drug preparations were found to be within limits. Pyrazinamide and metronidazole did not meet specifications. One sample of pyrazinamide was devoid of active ingredient. Ampicillin and amoxycillin had low quantities of active ingredient (24 to 40%); of the 13 syrup samples analyzed, the mean active drug content was 63% of the stated dose. Five metronidazole suspensions had no active ingredient. Medicines originated from 12 countries per labeled information; 38 samples were not labeled as to country of manufacture. Some capsule preparations contained capsule-shell fragments suggesting some kind of recycling of product.</p> <p>A recent survey conducted by the Nigerian National Institute of Pharmaceutical Research reported that 80% of drugs in all major pharmacies in Lagos were fake and 7% of these fake drugs contained dangerous ingredients.</p> <p>Progress is being made by NAFDAC in clearing the Nigerian market of fake drugs. In 2001, a study by NAFDAC found that almost 70% of pharmaceuticals on the market were not authorized. By June 2004, the figure was down to 20%. This was made possible through an enlightenment campaign. The next step undertaken by NAFDAC was to tackle the problem at its source. NAFDAC identified India and China as the main sources of counterfeit drugs in the Nigerian market. The agency established independent contacts in both countries to regulate the exports. Measures included awarding a certificate for export to Nigeria from India, random checks on shipments, sending samples to laboratories throughout India for sampling, pre-shipment information requirement.</p> <p>NAFDAC's improved surveillance activities resulted in increased seizures at the port and within the country. This led to the public burning of fake and substandard regulated products between 2001 and 2004 worth over 8 billion naira (US\$60 m) out of which drugs amount to N4,933,916,013 (US\$35, 753,014)</p>	<p>Fighting fake pharmaceuticals: small steps. Nigeria attacks fakes. Authentication News, 2003. Available from: http://www.AuthenticationNews.info</p> <p>Nigeria fights corruption. SCRIP World Pharmaceutical News July 7, 2004. Issue no. 2967; PJB Publications Ltd. London, UK.</p> <p>Akunyili D. Pharmaceutical counterfeiting: Nigeria's efforts in fighting drug counterfeiting. Proceedings of the 2nd Global Forum on Pharmaceutical Anticounterfeiting; 2005 Mar. 15-17; Paris, France. Denver CO: Reconnaissance Intl; 2005.</p>
--	--	--	--

		<p>Early results from a draft report by the Nigerian drug regulator, NAFDAC, say the number of counterfeit medicines circulating in the community has declined from nearly 70% in 2002 to less than 10% in 2005.</p> <p>As many as 80% of all drugs distributed are fake, according to Council of Europe and WHO statistics.</p>	<p>Nigeria says counterfeit medicines are falling. www.scripsnews.com, September 21, 2005, no. 3091, pg 19.</p> <p>Sliva Jan. Counterfeit drugs deemed threat in Europe. September 22, 2005 ABC News Internet Ventures.</p>
Senegal	<p>Ampicillin 250 mg capsule, oxytetracycline 250 mg capsule</p> <p>Chloroquine and sulfadoxine-pyrimethamine (SP)</p>	<p>26% of patients use the illegal market (64% because drugs are cheaper, 27% because prescription is not needed, 17% because of location).</p> <p>21 of the 22 samples of ampicillin analyzed at the Parke Davis control laboratory in Dakar in 1997 did not contain the active ingredient but contained flour instead. Physical analysis of these 21 samples of ampicillin and 6 of 12 samples of oxytetracycline showed unusual appearance.</p> <p>40 samples of chloroquine obtained from 19 locations in Senegal were tested at USP laboratories; 35% of the samples analyzed contained more than the claimed amount. Twenty-seven samples of sulfadoxine-pyrimethamine taken from 15 locations were also tested at USP; 55% of the tested SP contained less than the claimed amount.</p> <p>Abdoulaye Wade, the president of Senegal, has allocated CFA 25 million (\$48,000) for the 2006 budget to tackle the country's estimated \$11.4-15.2 million black market in medicines. The money will be used "to promote generic medicines and strengthen inspections to control the illegal market, reports IRIN, the UN news service.</p>	<p>Teulieres L. Senegal case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001.</p> <p>Sow PS, Gueye TSN, Sy E, et al. Drugs in the parallel market for the treatment of urethral discharge in Dakar: epidemiologic investigation and physicochemical tests. <i>Intl J Infect Dis</i> 2002; 6(2): 108-12.</p> <p>Smine A, Diouf K, Blum NL. USPDQI Antimalarial drug quality in Senegal 2002. Submitted to the U.S. Agency for International Development by the United States Pharmacopeia Drug Quality and Information (USP DQI) Program. Rockville, MD: United States Pharmacopeia.</p> <p>Senegal tackling counterfeits. www.scripsnews.com, September 21, 2005, no. 3091, pg 19.</p>

Sub-Saharan Africa (countries not identified by authors)	Antimalarials	Minilab tests showed that 60% of antimalarials were substandard as to concentration and release of the active ingredient.	Minilab detects substandard drugs. SCRIP World Pharmaceutical News June 21, 2002. Issue: 2757; West Sussex, UK. PJB Publications Ltd. 18.
Tanzania	Dihydroartemisinin (Cotecxin)	Percentage of drug samples that failed quality testing: 6.5% public sector, 0% non-government organizations (NGOs), 8.7% private sector. The Tanzania Pharmacy Board has warned health workers, private pharmacists, and the public of fake Cotecxin tablets, packaged similarly to the genuine tablet but lacking the active ingredient dihydroartemisinin.	Upunda G. Tanzania case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001. United Nations Foundation UNWIRE March 2, 2001. Fake malaria drugs reported in Tanzania (<i>Marketletter</i> , 24 Feb 2001). Available from: http://www.unfoundation.org/unwire/archives/UNWIRE010302.asp
	Sulfadoxine-pyrimethamine	145 samples obtained from 92 outlets underwent disintegration testing and were analyzed for content by colorimetric method (compared with the limits set by USP); 50% of the samples failed content analysis and disintegration testing showed a wide variability.	Smith EE, Goodman CA, Green M, et al. A simplified assessment for quality of sulfadoxine-pyrimethamine products from rural Tanzania. Presented at the American Society of Tropical Medicine and Hygiene 51 st annual meeting, Denver, Nov 10-14, 2002.
	Chloroquine	Result of an open randomized study showed that chloroquine was less bioavailable in a sugar-coated compared to a plain formulation. The mean area under the curve (AUC) was 4396.3 ± 833.0 for plain chloroquine and 2060.0 ± 339.0 for sugar-coated ($P = < 0.001$). The maximum blood concentration ($C_{p_{max}}$) for plain chloroquine was 161.2 ± 14 ng/mL compared with 56.6 ± 5.2 ng/mL for sugar-coated chloroquine ($P = < 0.001$). Investigators attribute the problem to poor quality control procedures of some drug manufacturers.	Rimoy GH, Moshi MJ, Massele AY. Comparative bioavailability of oral sugar-coated and plain formulation of chloroquine phosphate marketed in Tanzania. <i>Trop Doctor</i> 2002; 32: 15-7.
	Amodiaquine (AQ), sulfadoxine-pyrimethamine (SP)	To assess the quality of AQ and SP, samples of these drugs were obtained from eight wholesale pharmacies authorized to import medicines in Dar Es Salaam. Fifteen AQ and 18 SP samples were collected and tested for identity, content of active ingredients and dissolution assay as described by USP. Results	Minzi OM, Moshi MJ, Hipolite D, et al. Evaluation of the quality of amodiaquine and sulphadoxine/pyrimethamine tablets sold by private wholesale pharmacies in Dar Es Salaam Tanzania. <i>J Clin Pharm Ther</i> 2003; 28(2): 117-22.

		showed all samples passed the identity test; 2 out of 15 (13%) AQ samples failed the dissolution test but passed all the assay for content, whereas 2 out of the 18 (11%) and 8 out of the 18 (44%) SP samples failed the assay for content and dissolution tests, respectively.	
Uganda	Antiretrovirals	Fake antiretrovirals were found in the market.	E-drug: Fake ARVs on Uganda market. Kibumba G. 5 Aug 2004. Available from http://www.essentialdrugs.org/edrug
	Cloxacillin	A batch of the antibiotic Cloxacillin was declared fake by both the National Medical Stores (NMS) and the National Drug Authority (NDA).	Nyakairu Frank, and Nakabugo Zurah. Fake drugs smuggled from DR Congo. The Monitor (Kampala), October 1, 2005. Posted to www.allAfrica.com September 30, 2005.
Zimbabwe	Zidovudine tablets	An HIV-infected man was reported to purchase zidovudine that turned out to contain no active ingredient upon analysis.	Apoola A, Sriskandabalan PS, Wade AAH. Self-medication with zidovudine that was not. Lancet 2001; 357: 1370.

ASIA AND NEAR EAST

	Artesunate	At least 5 new counterfeit versions of artesunate have been found in Southeast Asia since the beginning of the year. 53% of artesunate bought in shops in mainland Southeast Asia in 2004 was estimated to be counterfeit.	Counterfeits continue to emerge in Asia. www.scripsnews.com , September 21, 2005, no 3091, pg 22
Bangladesh	Ciprofloxacin	A sample of 15 brands of the drug was collected for chemical (HPLC) assay and bioassay. Chemical assay showed 7 brands contained less active ingredient than USP specification. The Drug Administration (DA) put all drug imports under pre-customs inspection at all entry points (seaports and airports) to crack down on substandard drugs and fake packaging. Special police force will support inspectors in this action. In early 2003, the Public Health and Drugs Testing Laboratory in its annual testing of 5000 local samples found 300 either counterfeit or substandard. The country is reported to have about 30,000 illegal drugstores in addition to a similar number of licensed drugstores.	Hossain A, Rafiquzzaman, Haque M. Studies on quality of marketed drugs-“ciprofloxacin” a case study. Proceedings of the International Conference on Pharmaceutical Affairs; 2001 Dec 17-20; Kathmandu, Nepal. Kathmandu: Graduate Pharmacists' Association, 2002. 172. War against fake drugs waged. Pre-customs inspection at all entry points, special police force in action. The Daily Star Web Edition, vol. 4 no. 170, Nov. 14, 2003. Available from: http://www.thedailystar.net/2003/11/14/d3111401011.htm

	Cotrimoxazole pediatric suspensions	Ten brands obtained from various drug shops in the country were analyzed for potency and other important pharmaceutical parameters (appearance, weight, pH, etc) using BP specifications. Seven out of 10 were found substandard; pH of 6 brands were out of BP range and less viscosity was found on 2 brands.	Choudhury MMH, Rana MS, Amin MN, et al. Quality assessment of some paediatric cotrimoxazole suspensions marketed in Bangladesh. <i>Hamdard Medicus</i> ; 2004; XLVII(2): 58-62.
Cambodia	Artesunate tablet	Tablets were obtained from shops, pharmacies, NGOs, and hospitals in 1999-2000 from 5 Asian countries. 104 blisterpack samples were obtained (of which 26 came from Cambodia) and tested for authenticity using the Fast Red TR dye method. Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit. Proportion of fake artesunate in Cambodia is 25%.	Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. <i>Lancet</i> 2001; 357: 1948-9.
	Artesunate, mefloquine	Fake artesunate was sold by 71% and fake mefloquine by 60% of drug vendors and pharmacies surveyed in 1999. 17% of drugs are counterfeit according to a recent Phnom Penh study; Ministry of Health (MOH) estimates 30% of drugs nationwide are counterfeit. A Ministry of Health drug market study reported an overall failure rate of 13.5% with 5.2% failure rate in registered products and 22.3% failure rate in unregistered products. Percentage of drugs that failed quality testing: 13% public sector, 7.7% NGOs, 9.6% private sector.	Rozendaal J. Fake antimalarial drugs in Cambodia. <i>Lancet</i> 2001; 357: 890. Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.
	Antimalarials	After an information campaign about fake antimalarials, a follow-up survey conducted in August 2000 found only 25% prevalence of the fake drugs available in the market, down from 70% in 1999.	Phirun U, Sokhan C. Cambodia case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health: 2001. Seyha R. Government anticounterfeits intervention: the social marketing of EDAT. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002

	Artesunate	Sophisticated second and third generations of counterfeit artesunate labeled as produced by Guilin Pharma have been found in this country. The fake products have new, convincing, and very well crafted but fake holograms attached to the blisterpacks. The results of the Fast Red Dye test and HPLC analysis showed that these products did not contain artesunate.	Newton P. Counterfeit artesunate antimalarial tablets. WHO Pharmaceuticals Newsletter No. 3, 2003: 9.
	Antimalarials	In May 2003, a Cambodian government research project purchased antimalarial drugs from rural pharmacies; more than 27% of the drugs bought were counterfeit.	Crampton T. Fake malaria pills haunt Asians. International Herald Tribune, August 25, 2003. Available at : www.ihf.com
	Artesunate	In Phnom Penh, fake artesunates described as Category 2 were being sold in a pharmacy for 50 cents for 12 pills instead of a dollar; they proved not to be artesunate when tested by Ministry of Health scientists.	Crampton T. Fake malaria pills haunt Asians. International Herald Tribune, August 25, 2003. Available at : www.ihf.com
	Artesunate	The Ministry of Health reports that nearly two-thirds of the artesunate tested by its laboratory were counterfeit.	Crampton T. Fake malaria pills haunt Asians. International Herald Tribune, August 25, 2003. Available at: www.ihf.com
	Quinine sulfate tablet	TLC testing using GPHF mini-lab on 39 samples collected showed the following results: 7 passed the basic tests for quality, 30 have the wrong active ingredient, and one sample was subpotent. This represents an average failure rate of 77% of all quinine samples collected in the four provinces.	Smine A, Phanouvong L, Chanthap L, et al. Antimalarial drug quality in Mekong countries 2004. Available from: http://www.uspdqi.org
	Antimalarials	Data obtained from the USP DQI antimalarial drug quality monitoring project started in 2002 in the Mekong region showed the presence of fake and substandard antimalarial drugs. Results obtained from this project have been reported to authorities and communicated to relevant parties. The DRAs of the various countries have taken appropriate action to address the problem. The Food and Drug Department (FDD) of Cambodia produced information, education and communication materials (TV spots, calendar, T-shirt, and posters) to raise awareness among health care professionals and the general public on the danger of using fake drugs (including artesunate, quinine, and tetracycline) in collaboration with other law enforcement agencies, e.g., police and customs. The FDD also organized a workshop and invited manufacturers, wholesalers, retailers, and health care	Antimalarial drug quality monitoring project in the Mekong region 2004. U.S. Pharmacopeia Drug Quality and Information (USP DQI) Program. Available from: www.usp.dqi.org

		professionals to discuss the issues of counterfeit drugs in Cambodia.	
China	Sildenafil (Viagra)	Chinese authorities seized about 100,000 fake anti-impotence pills from an underground factory in Jiangkou.	Drug fakes, Asia's 'murderous' trade. CNN.com new June 2001. Available from: wysiwyg://74/ http://www.cnn.com/20...RLD/asia.pcf/east/06/16/asia.drugs/
	Imuran tablets	The counterfeit tablets contained the correct amount of the active ingredient azathioprine but were incorrectly labeled Azathiopring. Upon testing, these tablets failed the quality specification for disintegration time. After 4 hours in water, the tablets remained intact, whereas the genuine tablets dissolve within 45 minutes.	Power G. Counterfeit pharmaceuticals (GSK). Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.
	Zinacef tablets	The genuine tablets contain the oral dosage form cefuroxime axetil. Analysis of the counterfeits revealed the injectable dose form, cefuroxime sodium, which when taken orally results in minimal absorption by the digestive system and therefore has no therapeutic benefit.	Power G. Counterfeit pharmaceuticals (GSK). Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.
	Albumin	In September 2002, a patient died after albumin was administered intravenously by the physician. Police found the albumin bottle counterfeit. It was falsely labeled to look like a local Chinese pharmaceutical brand and contained an unknown liquid that proved fatal in the human bloodstream.	Fackler M. China's fake drugs kill thousands. San Francisco Examiner 07/29/02. Available from: http://www.examiner.com/sfx/templates/printer.jsp?story=n.bogus.0729w
	Diet pills	Drug quality problems in China's pharmaceutical industry gained international attention when five women in Japan and Singapore died and 60 more became sick after taking Chinese-made diet pills in 2002. Shenzhen Evening News reported 192,000 deaths in China with the use of bogus or poor quality drugs in 2001. The Chinese government has started to crack down on counterfeit drug manufacturing by increasing penalties, creating an effective state drug administration, and investigating more cases. In 2001, Chinese authorities shut down 1300 factories and investigated 480,000 cases representing counterfeit drugs valued at \$57 million.	Fackler M. China's fake drugs kill thousands. San Francisco Examiner 07/29/02. Available from: http://www.examiner.com/sfx/templates/printer.jsp?story=n.bogus.0729w Goodman P. Not what the doctor ordered: China is awash in fake drugs. International Herald Tribune. Aug. 31, 2002-Sept. 1, 2002: 4.

	Antimalarials	<p>The PBI Asian Medical eNewsletter reported on March 4, 2003 that the Shanghai Drug Administration Bureau plans to strengthen its anti-counterfeiting efforts through increased monitoring of the drug market and by following the whole process from manufacturing to selling and tracking adverse reactions. In 2002, the Bureau inspected 14,980 drugs and found 1833 to be below quality standards. Some contained talcum powder or flour while others contained toxic materials. The Chinese government reported that during the first half of 2002, it found 70,000 cases of counterfeit drug production, exceeding the total number of cases uncovered throughout 2001.</p> <p>The head of the litigation department of Rouse and Co, a legal firm in China, reported progress in curbing illegal pharmaceutical manufacturers through criminal action against large scale networks; 11 people have recently been arrested and are facing prosecution. China tackles counterfeiting through an administrative raid by China's State FDA, civil action in court, or the pursuit of a criminal case.</p> <p>The Shanghai Municipal FDA signed a memorandum of understanding with Pfizer which will train staff in detection and dealing with counterfeit pharmaceutical activities. The training is part of the preparation for planned SMFDA raids to shut down fake pharmaceutical production operations.</p> <p>In 2002, USP DQI under the cooperative agreement with USAID began monitoring the quality of antimalarials in the Mekong region. Early 2004, the sentinel sites staff of Yunnan Province completed round 1 testing of antimalarials (artesunate, quinine, chloroquine, SP) using basic tests (visual inspection, dissolution, and TLC). A total of 39 samples were tested. Basic test results indicated that 35 of the 39 samples were authentic, while two samples failed and two were considered doubtful. Overall, about five percent of all samples (based on unique lot/batch number) failed, but more than half (53%) of samples did not identify the manufacturing or expiration date, important quality indicators. Based on established criteria, five samples (including all failed samples) were taken for verification testing</p>	<p>Fighting fake pharmaceuticals: small steps. Shanghai enforcement. Authentication News, 2003. Available from: http://www.AuthenticationNews.info</p> <p>Scrip World Pharmaceutical News June 11, 2004. Issue 2960; London, UK. PJB Publications Ltd: P. 17.</p> <p>Scrip World Pharmaceutical News June 11, 2004. Issue 2960; London, UK. PJB Publications Ltd: P. 17.</p> <p><i>Fake antimalarials found in Yunnan Province, China.</i> USP Drug Quality and Information program, 2004. Available from: www.uspdqi.org</p>
--	---------------	---	--

	Zantac, Reductil, Stinox, Viagra, Cialis, flu drugs, unknown others	<p>at the National Institute of Drug Quality Control of Vietnam [NIDQC] using TLC and HPLC). Testing results indicate that two artesunate lots (030101 and 030801) contained no active ingredient. USP DQI notified relevant parties (regional WHO, the Yunnan Quality Control Laboratory, colleagues in China at the Yunnan Institute of Parasitic Diseases who informed the Yunnan Health Bureau and subsequently, the regulatory body, and State Drug Administration) so that the fake products can be removed from the drug outlets. Yunnan DRA is trying to investigate the main source(s) of these fake drugs.</p> <p>* Due to lax regulations in mainland China, ingredients for these drugs were imported to Taiwan for manufacture, packaging and sale. Up to 550,000 pills were seized by the Criminal Investigation Bureau (CIB).</p>	<p>Counterfeit medicine ring busted. The China Post. 2005 Dec 9. http://www.chinapost.comtw/i_latestdetail.asp?id=33348</p>
India	<p>Isoniazid (INH) and rifampicin (RMP) as single or fixed dose combinations (FDC)</p> <p>Cough syrup</p>	<p>A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including India = 22) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs 21% (5/24), than single drug samples 13% (2/16), were substandard.</p> <p>Between April and June 1998, 36 children under 6 years of age had unexplained acute renal failure of which 33 died despite peritoneal dialysis and supportive treatment. Subsequent investigation showed locally manufactured “cough syrup” contaminated with diethylene glycol was administered to the children.</p> <p>Percentage of drug samples that failed quality testing: 6% public sector, 12.7% private sector, 0% NGOs.</p>	<p>Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. <i>Int J Tuberc Lung Dis</i> 2001; 5(5): 448-54.</p> <p>Singh J, Dutta AK, Khare S, et al. Diethylene glycol poisoning in Gurgaon, India, 1998. <i>Bull WHO</i> 2001; 79(2): 88-95.</p> <p>Garg RK, Gupta SD. India case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001.</p>

		<p>An interim report from an expert committee to India's health minister revealed that 9% of drug samples tested by state government inspectors last year were of poor quality. The committee recommended stiffer penalties such as death for selling or producing fake medicines.</p> <p>The drug control department of the Delhi government carried out 618 inspections of chemists and manufacturing units in January. As a result, licenses of 112 chemists and three manufacturing units were suspended for violations of the Drugs and Cosmetics law (sale of schedule 'H' drugs without prescription). According to Delhi health minister Yoganand Shastri, the testing laboratory of the government took 132 samples of drugs and cosmetics, of which eight were found to be substandard. Prosecutions followed for the chemists and manufacturers found in violation. The government has decided to coordinate better with the Delhi police in curbing the manufacturing and sale of spurious drugs as well as the sale of drugs without prescription.</p>	<p>Mudur G. India to introduce death penalty for peddling fake drugs. Br Med J 2003; 327: 414.</p> <p>New Delhi: The weather change may have sent people rushing to their chemists, but they were not the only ones visiting. Times News Network (Wed, March 03, 2004 10:30:24 pm)</p>
Indonesia		<p>The Indonesian Drug and Food Control Agency (BPOM) reported that the most commonly counterfeited drugs are the antibiotics, analgesics, and drugs for diabetes. In May 2003, BPOM discovered 55 counterfeit medicines being sold in the market. Among them were amoxicillin 500 mg capsule that contained only 45.84% and penicillin that contained 45.34% of the active ingredient.</p>	<p>BPOM finds 55 items of counterfeit medicines in circulation. Issue 368 June 23, 2003. Extracts from: http://www.cic.co.id/majalah/368_02chem.htm</p>
Laos	Artesunate tablet	<p>Tablets were obtained from shops, pharmacies, NGOs, and hospitals in 1999-2000 from 5 Asian countries. 104 blisterpack samples were obtained (of which 8 came from Laos) and tested for authenticity using the Fast Red TR dye method. Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit. Proportion of fake artesunate in Laos is 38%.</p> <p>The Ministry of Health estimates 40% of all drugs are fake.</p>	<p>Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. Lancet 2001; 357: 1948-9.</p> <p>Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.</p>

Myanmar	Artesunate tablet	Tablets were obtained from shops, pharmacies, NGOs, and hospitals in 1999-2000. 104 blisterpack samples were obtained from 5 Asian countries (of which 51 came from Myanmar) and tested for authenticity using the Fast Red TR dye method. Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit. Proportion of fake artesunate in Myanmar is 40%.	Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. <i>Lancet</i> 2001; 357: 1948-9.
	Artemether	There are reports of fake intramuscular artemether labeled as produced by Kunming Pharmaceuticals.	Newton P. Counterfeit artesunate antimalarial tablets. <i>WHO Pharmaceuticals Newsletter</i> No. 3, 2003: 9.
	Antibiotics	Among the 21 different specialty products tested, only three displayed the official “registered” label. Three drugs were expired and the expiration date was not available for six others. One product did not contain the active drug declared (chlortetracycline; Lombisin, unicorn, China) and did not show any in vitro activity against bacteria. Seven of 21 products (33%) did not contain the stated dosage. The highest deficit observed was 48% in two products (co-trimoxazole, Yong Fong, Myanmar; benzylpenicillin, China [city and manufacturer unknown]). The dosage was not available for 5 drugs. 8 of 21 products (38%) did not contain the stated dosage of active drug.	Prazuck Thierry, Falconi Isabelle, et al. Quality control of antibiotics before the implementation of an STD program in Northern Myanmar. <i>Sexually Transmitted Diseases</i> , 2002; vol. 29, no 11.
Myanmar, Laos, Vietnam, Cambodia and Thailand	Antimalarial (Artemisinin derivatives or Mefloquine)	Of the 188 tablet packs purchased which were labeled as ‘artesunate’, 53% did not contain any artesunate. Of the 44 mefloquine samples, 9% contained less than 10% of the expected amount of active ingredient.	Dondorp, A.M., et al. Fake antimalarials in Southeast Asia are a major impediment to malaria control: multinational cross-sectional survey on the prevalence of fake antimalarials. <i>Tropical Medicine and International Health</i> , Dec 2004; vol. 9 no 12: pg 1241-1246.
Nepal		In February 2004, the Department of Drug Administration (DDA) seized 1200 capsules of amoxicillin 250 mg from three pharmacies in Rupendehi district. The manufacturer listed was Adip Labs of Kalol in India; investigation revealed that no such company exists. Test revealed the capsules contained a white odorless powder that was not the active ingredient. The DDA also found druggists in Narayanghat, Butwal, and Krishnaagar with 11 brands of unlicensed medicines and	Rai D. Which is real, and which is fake? Ever wondered why the medicine you take for that cough never seems to work? <i>Nepali Times</i> March 19-25, 2004. Available from: http://www.nepalitimes.com/issue/188/nation.htm

		collected 18 dubious samples of substandard drugs; tests by the Royal Drugs Laboratory on the samples collected found 3% to be substandard. One DDA inspector estimates that up to 20% of the drugs in the market are substandard. In a batch of spot tests conducted last year, 96 out of the 359 samples of medicines (expired Thiabric, Antozol, Omiproazol and Norifloxacin) were found to be substandard.	
Pakistan	Engerix B	On examination of the Engerix-B products, the labels and components were clearly counterfeit, the vials contained no trace of vaccine, and the contents were not sterile.	Power G. Counterfeit pharmaceuticals (GSK). Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.
Philippines	Appetens tablet, Ponstan capsule, Mosegor Vita tablet, Augmentin injection, Decilone-Forte tablet, Fortum injection, Propan with Iron capsule, Voltaren SR tablet, Inoflox capsule, Verorab Injection Maintenance drugs for cancer, diabetes, and cardiovascular	The Dept of Health noted that up to 300 million pesos (US\$6 million) worth of fake medicines are confiscated every year in the country (less than 1% of the country's 50 billion pesos drug market and probably only a fraction of the total counterfeit market); 80% of confiscated drugs are not officially registered while the rest do not meet state quality standards and most drugs were imported illegally from other Asian market. The Bureau of Food and Drugs (BFAD) found several drug outlets selling counterfeit drug products, including drug products that are not registered with the bureau. The most commonly found counterfeit drugs are listed in the previous column. A local newspaper reported that a Senate inquiry was told that more than 7 billion pesos worth of fake medicines is being sold in the country, most of them coming from India, China, Taiwan, and Pakistan. Among the fake drugs are those listed in the	Scrip World Pharmaceutical News February 27, 2002. Issue 2724; West Sussex, UK. PJB Publications Ltd. Republic of the Philippines Department of Health-Bureau of Food and Drugs Health Advisory No. 01-06. November 7, 2001. Martin S. P7-B fake drugs for sale. From maintenance to paracetamol. <i>The Manila Times</i> . October 07, 2004.

	<p>diseases; OTC products such as analgesics (paracetamol); antibiotics; cough syrups, tablets, and capsules</p> <p>Vitamins (Calpol and Ceelin)</p>	<p>previous column. It was also reported that the director of the BFAD admitted to the committee that her office failed to conduct random sampling of drugs in the past due to limited resources (budget and adequate staff).</p> <p>The Department of Health (DoH) warned the public on the proliferation of counterfeit drugs sold in some drugstores in Davao City. Most of the fake drugs are vitamins, according to Gil Cawad of the DOH.</p>	<p>Gevera Mai. Fake drugs alarm DOH. Philippine Information Agency press release, October 13, 2005.</p>
Thailand	<p>Artesunate tablet</p> <p>Furosemide (Lasix), levonorgestrel (Postinor), norethisterone (Primolut), finasteride (Proscar), sildenafil (Viagra)</p> <p>Antimalarials</p>	<p>Tablets were obtained from shops, pharmacies, NGOs, and hospitals in 1999-2000 from 5 Asian countries. 104 samples were obtained (of which 8 came from Thailand) and tested for authenticity using the Fast Red TR dye method. Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit. Proportion of fake artesunate in Thailand is 11%.</p> <p>Counterfeit versions of the products mentioned in the previous column were found in drugstores in 2003, according to a senior pharmaceutical inspector of FDA at the pre-International Conference of Drug Regulatory Authorities; the agency has undertaken measures to combat counterfeit medicines: monitoring and surveillance activities; sampling of products; strong measures for law enforcement; increased cooperation with nongovernment bodies, the police, and customs; and provides training for law enforcement officers.</p> <p>Data obtained from the USP DQI antimalarial drug quality monitoring project started in 2002 in the Mekong region showed the presence of fake and substandard antimalarial drugs. Results obtained from this project have been reported to authorities and communicated to relevant parties. The DRAs of the various countries have taken appropriate action to address the problem. The Food and Drug Administration of Thailand is undertaking</p>	<p>Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. <i>Lancet</i> 2001; 357: 1948-9.</p> <p>Asian countries on the road to tackle counterfeits. <i>SCRIP World Pharmaceutical News</i> Feb 20, 2004. Issue 2928; west Sussex, UK. PJB Publications Ltd: 18.</p> <p>Antimalarial drug quality monitoring project in the Mekong region 2004. U.S. Pharmacopeia Drug Quality and Information Program. Available from: www.usp.dqi.org</p>

		investigation on substandard quinine, artesunate, and chloroquine with local manufacturers and distributors to find the root cause of the problem.	
Vietnam	Artesunate tablet	<p>Tablets were obtained from shops, pharmacies, NGOs, and hospitals in 1999-2000 from 5 Asian countries. 104 blisterpack samples were obtained (of which 11 came from Vietnam) and tested for authenticity using Fast Red TR dye method. Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit. Proportion of fake artesunate in Vietnam is 64%.</p> <p>The Ministry of Health estimates 1% of all drugs are fake.</p>	<p>Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. <i>Lancet</i> 2001; 357: 1948-9.</p> <p>Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.</p>
	Isoniazid (INH) and rifampin (RMP) as single or fixed dose combinations (FDC)	<p>A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including Vietnam = 1) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were substandard.</p>	<p>Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. <i>Int J Tuberc Lung Dis</i> 2001; 5(5): 448-54.</p>
	Fortum injection	<p>Hospital staff discovered adulterated product with the carton and labels showing staining, which indicated that they may have been salvaged from the waste stream. Upon removal of the plastic flip-off, puncture marks in the rubber plugs and yellow staining were noted, which meant they had been used previously and degrade residues were not cleaned off. Analysis showed the content to be streptomycin, which is a cheap and ineffective substitute for ceftazidime, the active ingredient of Fortum.</p>	<p>Power G. Counterfeit pharmaceuticals (GSK). Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p>
	Antimalarials	<p>Data obtained from the USP DQI antimalarial drug quality monitoring project started in 2002 in the Mekong region showed the presence of fake and substandard antimalarial drugs. Results obtained from this project have been reported to authorities and communicated to relevant parties. The DRAs of the various</p>	<p>Antimalarial drug quality monitoring project in the Mekong region 2004. U.S. Pharmacopeia Drug Quality and Information Program. Available from: www.usp.dqi.org</p>

		countries have taken appropriate action to address the problem. The Drug Administration of Vietnam has issued an investigation notice to all 64 provincial health and drug authorities to inspect targeted pharmacies for the specific lot number of fake artesunate tablets as reported by the monitoring project. The Provincial authorities have ordered a recall of this product from the market.	
Yemen	Antimalarials (Chloroquine & Sulfadoxine/Pyrimethamine)	Percentage failure of samples based on ingredient content is 6.7% for chloroquine base syrup (CQS) and 20% for chloroquine phosphate (CQT). In dissolution, failure rate was 8% for CQT and 70% for sulfadoxine/pyrimethamine (SPT).	Abdo-Rabbo Ahmed, Bassili Amal, and Atta Hoda. The quality of antimalarials available in Yemen. Malaria Journal 2005; vol. 4 no. 28

EUROPE AND EURASIA

		Counterfeit medicines make up approximately 10% of the European pharmaceutical market, up from nearly zero 10 years ago, per the World Health Organization (WHO).	Sliva Jan. Counterfeit drugs deemed threat in Europe. September 22, 2005 ABC News Internet Ventures.
Estonia	Isoniazid (INH) and rifampin (RMP) single and fixed dose combinations (FDC)	A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including Estonia = 25) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were substandard.	Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. Int J Tuberc Lung Dis 2001; 5(5): 448-54.
Kyrgyzstan		The Ministry of Health reported that up to 70% of pharmaceuticals being bought in Bishkek, the country's capital, could be counterfeit. Further, the proportion of counterfeit and low-quality products identified in pharmaceutical deliveries that pass through customs was 5%. The high price of officially imported medicines drives the patients to street markets where they can buy cheaper drugs but are more likely to be fake and of poor quality. The ministry has proposed an amendment to the country's Criminal Code through introduction of criminal charges for those producing counterfeit drugs.	Counterfeit drugs spreading in Kyrgyzstan. Scrip World Pharmaceutical News. April 9, 2004. Issue 2942. London, UK. PJB Publications Ltd: p.20. Also available at: www.scrippharma.com

Latvia	Isoniazid (INH) and rifampin (RMP) single and fixed dose combinations (FDC)	A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including Latvia = 8) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were substandard.	Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. Int J Tuberc Lung Dis 2001; 5(5): 448-54.
Moldova		Local companies produce about 10% of the country's 3749 registered pharmaceuticals with the remainder being imported. According to the National Institute of Pharmaceuticals, up to 10% of pharmaceuticals being sold could be counterfeit or date expired. It also reported that only 2% of pharmaceuticals that might have been smuggled last year were actually identified. The government plans to open special quality control laboratories at customs terminals in order to reduce the circulation of counterfeit drugs in the country.	Moldova concerned about counterfeits or date-expired products. Scrip World Pharmaceutical news March 12, 2004. Issue 2934; London, UK. PJB Publications Ltd. p.4. Also available at www.scrippharma.com
Russia	Isoniazid (INH) and rifampin (RMP) single and fixed dose combinations (FDC)	A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including Russia = 4) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were substandard.	Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. Int J Tuberc Lung Dis 2001; 5(5): 448-54.
	Insulin	A Danish manufacturer reported that more than 1,000 patients were hospitalized in Volgograd as a result of complications linked to counterfeit insulin.	Association of International Pharmaceutical Manufacturers. AIPM position paper. Counterfeit drugs in Russia 2001. AIPM, Moscow. 1-10.
	Antibiotic (Sumamed)	In 1998, physicians reported Sumamed capsules as ineffective. The manufacturer found fake packaging in the market. Analysis in Zagreb showed fake drug contained no active substances.	Association of International Pharmaceutical Manufacturers. AIPM position paper. Counterfeit drugs in Russia 2001. AIPM, Moscow. 1-10.
	Antibiotic (Claforan)	In August 2000, the manufacturer identified fake Claforan in pharmacies. Lab analysis conducted by the company and the Ministry of Health revealed that the fake product contained	Association of International Pharmaceutical Manufacturers. AIPM position paper. Counterfeit drugs in Russia 2001. AIPM, Moscow. 1-10.

	<p>Ampicilline (ampicilline) tablet Claritin (loratadine) tablet Mezim-forte (proteolytic enzyme) tablet Lorinden (flumetasone) ointment Omez (omeprazole) Cerebrolysin injection Biseptol (cotrimoxazole) tablet No-spa (drotaverine) tablet Nizoral (ketoconazole) tablet</p>	<p>active substances and higher than permissible levels of the toxic substance, methanol.</p> <p>Among the findings of a survey by a Russian think tank and PhRMA headed by the Coalition for Intellectual Property Rights (CIPR), 93% of Moscow residents have encountered counterfeit items at retailers during 2002; 6% of counterfeits are sold in pharmacies.</p> <p>The Status Report of a recent AIPM/Coalition for Intellectual Property Rights (CIPR) survey of pharmaceutical manufacturers found that counterfeit medicines account for 12% of pharmaceutical products sold in the market, costing the producers \$250,000,000 annually.</p> <p>At a roundtable discussion organized by AIPM, CIPR and the American Chamber of Commerce in Russia on 16 April 2002, Alexander Toporkov, Deputy Head of the Ministry of Health Department for State Quality Control, reported that, in 2001, there were 101 documented cases of counterfeited lots and 49 cases of counterfeited medicines, with antibiotics being the most frequently counterfeited (47%) followed by hormone-containing drugs (11%). At the 8th Adams Smith Institute International Conference “The Pharmaceutical and Healthcare Sector in Russia,” held in St. Petersburg 22-23 May 2002, Mr. Toporkov presented statistics for the first four months of 2002: 23 cases of counterfeit medicines contained within 43 different lots.</p> <p>The drugs listed in the previous column were counterfeited during the first 3 months of 2004, according to data provided by the Department of the Control of Drug Quality.</p>	<p>Russian survey reveals rampant fakes and consumer psyche. Authentication News, April 2003; vol 9 no.3: 3.</p> <p>Counterfeit medicines rise to 12% of total Russian market; cost to pharmaceutical manufacturers totals \$250 million annually. The Coalition for Intellectual Property Rights. For immediate release April 25, 2002. http://www.cipr.org/activities/20020619/release.htm</p> <p>2004 Report from Elena Ushkalova, M.D., USP DQI Russia coordinator. eushk@mars.rags.ru</p>
--	---	--	--

		<p>At the 2nd global forum on pharmaceutical anticounterfeiting, it was reported that fake medicines are on the rise in the country, about 15% now; an estimated 70% of these fake medicines are produced domestically while some are imported from China and other Asian markets.</p> <p>Counterfeit drugs make up some 20% of all drugs distributed, Council of Europe and WHO statistics show.</p> <p>* Russian authorities have seized over 1000 tonnes of illicitly manufactured pharmaceuticals in the previous three years, according to the Federal Control Service. Counterfeit drugs account for approximately 5-10% of all drugs consumed in Russia. A recent UN survey ranked Russia as the fifth-largest producer of counterfeit pharmaceuticals in the world, with around 70% of these products produced domestically. Officials have been trying to tighten border controls, but these efforts have been undermined by the recent abolition of the Department of Pharmaceutical Inspection.</p>	<p>Thomson T. Strengthening pharmaceutical controls in Eastern Europe. Proceedings of the 2nd Global Forum on Pharmaceutical Anticounterfeiting; 2005 Mar. 15-17; Paris, France. Denver CO: Reconnaissance Intl; 2005.</p> <p>Sliva Jan. Counterfeit drugs deemed threat in Europe. September 22, 2005 ABC News Internet Ventures.</p> <p>Russia in new crackdown on counterfeits. Daily International Pharma Alert. Dec 27, 2005; vol 2, no. 250. www.fdanews.com</p>
Ukraine	<p>Sumamed</p> <p>Cerebrolysin</p>	<p>Counterfeit/substandard pharmaceuticals accounts for up to 40% or, in the case of certain pharmaceuticals, even up to 80% in this country.</p> <p>The State Department for Quality Control carried out raids and revealed the following counterfeiting cases:</p> <ol style="list-style-type: none"> 1. About 15 series of counterfeit Sumamed were found in several pharmacies (the genuine product is produced by Pliva of Croatia). The capsules and package did not differ from the genuine product in appearance; however, the capsules did not contain the active ingredient azithromycin, but instead contained streptocide. 2. Cerebrolysin solution produced under a nonexistent series was confiscated from pharmacies in Kiev. All medications as a whole met the requirements set forth in the specifications, but their markings differed from those of the genuine product. The package of counterfeit drugs did not bear the corresponding trademark. The manufacturer (Ebeve, Austria) said this series was not produced by the company and was not exported to Ukraine. Investigation by 	<p>Pakharenko-Anderson A. Building legislation and regulatory implementation environments: the Ukraine experience. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p>

		<p>the State Department for Quality Control revealed that the certificate accompanying the medication was issued for another medication produced by a pharmaceutical company from India. Counterfeit cerebrolysin was also found in Volhynia wherein the ampoules had labels different from the authentic product.</p>	
	Nistatine	<p>3. Counterfeit tablets of nistatine bearing trademarks of the pharmaceutical company “Biosynthesis” (Penza, the Russian Federation) were found in Sevastopol; these tablets did not contain nistatine but an unknown substance.</p>	
	Pentalgin B	<p>Substances other than therapeutic agents are passed off as pharmaceuticals. The Customs at Illichevsk suspended a consignment that contained magnesium and calcium silicates, instead of pharmaceutical substances.</p> <p>Counterfeit Pentalgin B tablets were found marked as being produced by the pharmaceutical company Biostimulator in Odessa and did not contain codeine and other ingredients. Biostimulator, which produces narcotics and psychotropic preparations, claimed that these tablets have never been produced by the company.</p>	
	Cephasoline-KMP	<p>Counterfeit Cephasoline with false labels contained streptomycin and penicillin instead of the active ingredient mentioned in the labels.</p>	
	Beres Plus drops	<p>Counterfeit Beres Plus drops were found in the Zaporzhzhia region with a 1999 manufacturing date on the package. The manufacturer, Lubnypharm, revealed that these products had not been packaged by the company since 1996.</p>	
	Essel Forte	<p>Essel Forte capsules manufactured by Nabros Pharma Pvt. Ltd (India) had packages that imitated the design of a well known medication (Essentiale Forte) by Rhone-Poulenc Rorer (France). The names of both medications were similar. Some of the packages of the Essel Forte had the logo of a Ukrainian pharmaceutical company, Darnitsa, which later issued an official statement that it was not involved with this series of medications.</p>	
	Trihopol	<p>Inspection of counterfeit Trihopol revealed that these medications had false quality certificates. Laboratory analysis showed these medications did not meet technical standards for Trihopol.</p>	

LATIN AMERICA AND THE CARIBBEAN

Argentina		<p>In May 2000, 200 truckloads of pharmaceuticals were hijacked and 50 production plants were raided in various parts of the country. Investigations by the Argentine drug regulatory authority (ANMAT) reported that 6% of the drugs were smuggled from neighboring countries with less stringent controls, 4% had altered packaging, 2% were free samples intended for health professionals, and 17% were bogus drugs.</p> <p>The agency ANMAT estimates that up to 70% of medicines sold outside pharmacies are counterfeit or have some irregularities.</p>	<p>WHO. Argentina takes action against black market pharmaceuticals. WHO Drug Information 2001; 15 (2): 69.</p> <p>Lacerca F. The manufacturer's perspective on counterfeit drugs in Latin America. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p>
Bolivia	Ampicillin capsules	A German relief organization detected counterfeit ampicillin through visual inspection. Later assays revealed these products to be 80% low in content.	Kusters G. Partnerships for public awareness and patient protection. The GPHF-Minilab project. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.
Brazil	Amoxicillin, captopril, cotrimoxazole, hydrochlorothiazide, mebendazole, metronidazole, paracetamol, rifampicin/isoniazid	Percentage of samples that failed quality testing: 14% public sector, 10% NGOs, 9% private sector.	Acurcio F, Chaves JG. Brazil case study: State of Minas Gerais. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001.
Colombia	Chlorpheniramine, phenylephrine, and acetaminophen combination (Dristan), generic aspirin (Dolex), mefenamic acid	In May 2001, the National Institute for the Supervision of Medications and Foods (INVIMA) discovered in Bosa counterfeit drugs being produced containing boric acid, cement, floor wax, talcum powder, yellow paint with lead. Within 18 months, INVIMA confiscated more than 18 tons of adulterated, relabeled, stolen, contraband, and counterfeit drugs. INVIMA General Director estimated that 10% of the \$1.2 billion worth of drugs sold	What's in that pill? In Latin America, fake drugs are as lucrative as cocaine. <i>Business Week Online</i> . June 2001. Available from: http://www.businesswe...agazine/content/01_25/b3737153.htm

	<p>(Ponstan) Diclofenac (Voltaren)</p> <p>Isoniazid (INH) and rifampin (RMP) as single and fixed dose combinations (FDC)</p> <p>Sildenafil (Viagra)</p>	<p>in the country each year are counterfeit. Global drugmakers' estimate is about 30%. In 2000, INVIMA confiscated 6 million doses of diclofenac from fraudulent labs. Vials contained colored water.</p> <p>A total of 71 anti-TB drug samples obtained from National TB programs and hospital and local pharmacies from 6 countries (including Colombia = 11) were analyzed using TLC, UV, and confirmatory techniques by U.S. CDC and FDA. Overall, 10% (4/40) of all samples, including 13% (4/30) RMP, were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples 13% (2/16), were substandard.</p> <p>INVIMA reported in 1999 a 400 million dollar market for counterfeit medicines that exists in Colombia.</p> <p>Amount of pharmaceutical losses due to diverted medications as calculated by FASECOLDAS (Oct 1999 to March 2002) is US\$ 3,183,635, equivalent to about 70 kilos diverted medications. Between Oct 1999 and March 2002, INVIMA identified counterfeit medications with a value over \$US 1,196,808. An estimated 40% of pharmaceuticals on the black market are counterfeit. Bulk materials used for counterfeiting medicines are: cement, talc, boric acid, and other industrial components. About 30% of medicines on the black market are altered on the following: expiry date, lot numbers, bar codes, labeling, content. Between 2000 and 2002, INVIMA confiscated 15 tons of different brands of tablets and capsules, 10 million ampoules of different brands, and 18,000 vials of different medicines.</p> <p>A global security representative of Pfizer reported about a raid on a manufacturing facility for fake Viagra. The authorities found bags of boric acid (a low-grade insecticide) used to make pills masquerading as Pfizer's Viagra. The finished product lay in piles on the floor.</p>	<p>Laserson KF, Kenyon AS, Kenyon TA, et al. Substandard tuberculosis drugs on the global market and their simple detection. <i>Int J Tuberc Lung Dis</i> 2001; 5(5): 448-54.</p> <p>Lacerca F. The manufacturer's perspective on counterfeit drugs in Latin America. <i>Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting</i>; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p> <p>Aldana JC. Politica de lucha contra la corrupcion de medicamentos en Colombia. <i>Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting</i>; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p> <p>Ex-FBI man warns of counterfeit threat. <i>SCRIP World Pharmaceutical News</i> July 2, 2004. Issue no. 2966; PJB Publications Ltd London, UK. p. 6.</p>
--	---	---	--

		<p>Invima reported that in 2003, more than 1000 tons of fake medicines that were locally produced were seized, including analgesics and a brand of antiretroviral produced by a multinational company in Colombia. The fake medicine market is estimated to be worth more than 14M pesos (\$5.5M). In 2004, 38 illegal laboratories producing fake drugs were dismantled and Invima found fake medicines made of flour, sugar, boric acid and cement lime. Invima is on the look out for drugs that are bought in neighboring countries like Peru, Ecuador, and Venezuela that are nearing or past their sell-by-date, and are then repackaged in Colombia with a different expiry date and sold to illegal dealers. Invima works in collaboration with pharmacy owners, police, public prosecutors, and regional health authorities to try to identify the fake drugs on a local level.</p>	<p>Colombian regulatory agency seizes 1,000 of fake medicines. SCRIP World Pharmaceutical News Oct 29, 2004. Issue no. 3000; PJB Publications Ltd. London, UK. p. 22.</p>
El Salvador	<p>Amoxicillin, cotrimoxazole, folic acid, hydrochlorothiazide, mebendazole, metronidazole, paracetamol, captopril, furosemide</p>	<p>Percentage of samples that failed quality testing: 45.5% public sector, 27.8% NGOs, 34.6% private sector</p>	<p>Beltran JFL. El Salvador case study. Strategies for Enhancing Access to Medicines (SEAM) Conference on Targeting Improved Access, Washington, DC, 27-29 November 2001. Arlington, VA: Management Sciences for Health; 2001.</p>
Mexico	<p>Zocor, Carisoprodol</p>	<p>Mexican authorities are investigating the sale of counterfeit medicines in a border town that is popular among American tourists looking for cheap medicines. U.S. officials reported one pharmacy sold useless tablets labeled Zocor (cholesterol-lowering drug) to an American citizen in this border town. This incident led to an alert issued by the U.S. FDA on July 30, 2004 about the fake Zocor which had no active ingredient and also about substandard Carisoprodol (anti-muscle spasm) which was found to have a very low level of active ingredient.</p> <p>As many as 40% of all drugs distributed are fake, according to Council of Europe and WHO statistics.</p>	<p>Stevenson M. Mexico eyes fake drugs on border. CBSNews.com Available at: http://www.cbsnews.com/stories/2004/08/10/world/main635220.shtml Accessed 3/22/2005.</p> <p>Sliva Jan. Counterfeit drugs deemed threat in Europe. September 22, 2005 ABC News Internet Ventures.</p>

Peru		Results of an investigation by the agency DIGEMID concluded that 80% of the medicines distributed in Lima through ambulatory commerce were counterfeit, lacked a sanitary registration, or were in a bad state.	Lacerca F. The manufacturer's perspective on counterfeit drugs in Latin America. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.
------	--	---	---

VARIOUS COUNTRIES

Thirteen schistosomiasis-endemic countries (not identified by authors)	Praziquantel	A total of 34 samples from 19 different manufacturers were collected and subjected to chemical analysis at the Laboratory of the Government Chemist, UK. Fifteen of the 19 brands met satisfactory quality standards; 3 brands failed to meet BP or USP standards. One brand collected from two sources in Sudan was counterfeit and contained no active substance. The declared content of active substance was 600 mg, but the gross mean weight of each tablet was 480 mg.	Sulaiman SM, Traore M, Engels D, et al. Counterfeit praziquantel. Lancet 2001; 358 (9282): 666-7.
--	--------------	---	---