

Matrix of Drug Quality Reports in USAID-assisted Countries

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

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

REGIONS	DRUG/S	REPORTS	REFERENCES (2001-2006)
AFRICA			
Cameroon	Antimalarials (chloroquine, quinine, and antifolates)	* 284 samples of three antimalarial drugs from 132 different sources in 16 villages and cities throughout the country were collected. Drug quality was assessed by a simple color reaction test and semi-quantitative thin-layer chromatography. Fifty (38%) of 133 chloroquine, 52 (74%) of 70 quinine, and 10 (12%) of 81 antifolates had either no active ingredient, an insufficient active ingredient, the wrong ingredient, or unknown ingredient(s).	Basco, L. Molecular epidemiology of malaria in Cameroon: quality of antimalarial drugs used for self-medication. <i>Am. J. Trop. Med. Hyg.</i> , 70(3), 2004: 245-250
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. <i>E-DRUG</i> . 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. <i>The Lancet</i> 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
Gabon	Chloroquine tablets	* 5 (29%) of 17 samples of chloroquine tablets had content	Maponga, C and Ondari, C. The quality of

		failure; 1 (5.8%) of 7 samples failed dissolution tests	antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.
Ghana	Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	<p>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, 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.</p> <p>* 1 (5%) of 20 samples of CQS had content failure; 12 (66.7%) of 18 samples of CQT had content failure; 3 (20%) of 15 samples of CQT failed dissolution tests; 3 (37.5%) of 8 samples of SPT had content failure; 3 (75%) of 4 samples of SPT failed dissolution tests</p>	<p>Counterfeit medicines becoming harder to spot. SCRIP World Pharmaceutical News August 13, 2004. Issue: 2976; London UK. PJB Publications Ltd. 15.</p> <p>Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.</p>
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	Siringi S. AIDS drugs being sold illegally on market stalls in Kenya. <i>Lancet</i> 2004; 363: 377.

	Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	<p>the normal price. The drugs can be bought without doctors' prescription.</p> <p>* 2 (25%) of 8 samples of CQS had content failure; 3 (42.8%) of 7 samples of CQT had content failure; 2 (28.6%) of 7 samples of CQT failed dissolution tests; 11 (91.7%) of 12 samples of SPT failed dissolution tests.</p>	Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.
Mali	Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	<p>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.</p> <p>* 4 (66.7%) of 6 samples of CQS had content failure; 9 (47.3%) of 19 samples of CQT had content failure; 1 (5.2%) of 19 samples of CQT failed dissolution tests; 7 (100%) of 7 samples of SPT failed dissolution tests.</p>	<p>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</p> <p>Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.</p>
Mozambique	Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	* 3 (25%) of 12 samples of CQS had content failure; 3 (20%) of 15 samples of CQT had content failure; 1 (6.7%) of 15 samples of CQT failed dissolution tests; 1 (5.5%) of 18 samples of SPT had content failure; 18 (100%) of 18 samples of SPT failed dissolution tests.	Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.
Nigeria	Common analgesics, antibiotics such as ciprofloxacin (Peflacin) advertised as 500	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.	e-drug@usa.healthnet.org: the menace of fake drugs in Nigeria, 3/26/2002

	<p>mg but actually 250 mg, antidiabetics (Diabenese), 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>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>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</p>	<p>Vanguard 2/26/2002</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</p>
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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</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. Intl J Infect Dis 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)</p>

		<p>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>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.
Sudan	Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	* 4 (26.6%) of 15 samples of CQS failed content tests; 1 (5.2%) of 19 samples of CQT failed content tests; 2 (12.5%) of 16 samples of CQT failed dissolution tests; 12 (80%) of 15 samples of SPT failed dissolution tests.	Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003
Tanzania	Sulfadoxine-pyrimethamine Chloroquine	<p>Percentage of drug samples that failed quality testing: 6.5% public sector, 0% non-government organizations (NGOs), 8.7% private sector.</p> <p>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.</p> <p>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</p>	<p>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.</p> <p>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 51st annual meeting, Denver, Nov 10-14, 2002.</p> <p>Rimoy GH, Moshi MJ, Masele AY. Comparative bioavailability of oral sugar-coated and plain formulation of chloroquine phosphate marketed in</p>

	Amodiaquine (AQ), sulfadoxine-pyrimethamine (SP)	<p>± 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.</p> <p>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 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.</p>	<p>Tanzania. Trop Doctor 2002; 32: 15-7.</p> <p>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. J Clin Pharm Ther 2003; 28(2): 117-22.</p>
Uganda	Antiretrovirals Cloxacillin	<p>Fake antiretrovirals were found in the market.</p> <p>A batch of the antibiotic Cloxacillin was declared fake by both the National Medical Stores (NMS) and the National Drug Authority (NDA).</p>	<p>E-drug: Fake ARVs on Uganda market. Kibumba G. 5 Aug 2004. Available from http://www.essentialdrugs.org/edrug</p> <p>Nyakairu Frank, and Nakabugo Zurah. Fake drugs smuggled from DR Congo. The Monitor (Kampala), October 1, 2005. Available from: www.allAfrica.com September 30, 2005.</p>
Zimbabwe	Zidovudine tablets Chloroquine tablets (CQT), chloroquine syrup (CQS), and sulphadoxine/Pyrimethamine tablets (SPT)	<p>An HIV-infected man was reported to purchase zidovudine that turned out to contain no active ingredient upon analysis.</p> <p>* 2 (13.3% of 15 samples of CQS had content failure; 8 (57.1%) of 14 samples of CQT had content failure; 1 (7.1%) of 14 samples failed dissolution tests; 1 (10%) of 10 samples of SPT had content failure; 10 (100%) of 10 samples of SPT failed dissolution tests.</p>	<p>Apoola A, Sriskandabalan PS, Wade AAH. Self-medication with zidovudine that was not. Lancet 2001; 357: 1370.</p> <p>Maponga, C and Ondari, C. The quality of antimalarials: a study in selected African countries. EDM Research Series No 30 Geneva: World Health Organization, May 2003.</p>

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. Hamdard Medicus; 2004; XLVII(2): 58-62.
Burma (see Myanmar)			
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. Lancet 2001; 357: 1948-9.

Artesunate, mefloquine	<p>Fake artesunate was sold by 71% and fake mefloquine by 60% of drug vendors and pharmacies surveyed in 1999.</p> <p>17% of drugs are counterfeit according to a recent Phnom Penh study; Ministry of Health (MOH) estimates 30% of drugs nationwide are counterfeit.</p> <p>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.</p>	<p>Rozendaal J. Fake antimalarial drugs in Cambodia. <i>Lancet</i> 2001; 357: 890.</p> <p>Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.</p> <p>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.</p>
Antimalarials	<p>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.</p>	<p>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</p>
Artesunate	<p>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.</p>	<p>Newton P. Counterfeit artesunate antimalarial tablets. <i>WHO Pharmaceuticals Newsletter</i> No. 3, 2003: 9.</p>
Antimalarials	<p>In May 2003, a Cambodian government research project purchased antimalarial drugs from rural pharmacies; more than 27% of the drugs bought were counterfeit.</p>	<p>Crampton T. Fake malaria pills haunt Asians. <i>International Herald Tribune</i>, August 25, 2003. Available at : www.iht.com</p>
Artesunate	<p>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.</p>	<p>Crampton T. Fake malaria pills haunt Asians. <i>International Herald Tribune</i>, August 25, 2003. Available at : www.iht.com</p>
Artesunate	<p>The Ministry of Health reports that nearly two-thirds of the artesunate tested by its laboratory were counterfeit.</p>	<p>Crampton T. Fake malaria pills haunt Asians. <i>International Herald Tribune</i>, August 25, 2003.</p>

	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.	Available at: www.ihf.com
	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 professionals to discuss the issues of counterfeit drugs in Cambodia.	Antimalarial drug quality monitoring project in the Mekong region 2004. U.S. Pharmacopeia Drug Quality and Information (USP DQI) Program. Available from: www.uspdqi.org
	Antimalarials	A study conducted by USP DQI in 2003 found that 27% of 451 samples tested were counterfeit. * WHO estimates that Cambodia has about 2800 illegal medicines sellers and about 1000 unregistered medicines on the market.	Poor quality of antimalarial drugs in Cambodia addressed. USP Press. 2006 Jan; vol 3, issue 3. WHO launches campaign against counterfeit medicines. Bulletin of the World Health Organization 2003; 81 (12): pp. 921-22
	Antimalarials	* 34% of all 498 known facilities and drug outlets in 4 provinces were surveyed, and 451 drug samples were collected. 79% of these were not registered at the Cambodia Department of Drugs and Food (DDF), 27% failed thin layer chromatography and disintegration tests – all of these samples were unregistered.	Lon CT, Tsuyuoka R, et al. Counterfeit and substandard antimalarial drugs in Cambodia. Trans R. Soc. Trop. Med. Hyg.; June 8, 2006: In press.
China	Imuran tablets	The counterfeit tablets contained the correct amount of the	Power G. Counterfeit pharmaceuticals (GSK).

		<p>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.</p>	<p>Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p>
	Zinacef tablets	<p>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.</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>
	Albumin	<p>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.</p>	<p>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</p>
	Diet pills	<p>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.</p> <p>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.</p> <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</p>	<p>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</p> <p>Goodman P. Not what the doctor ordered: China is awash in fake drugs. International Herald Tribune. Aug. 31, 2002-Sept. 1, 2002: p. 4.</p> <p>Fighting fake pharmaceuticals: small steps. Shanghai enforcement. Authentication News, 2003. Available from: http://www.AuthenticationNews.info</p>

	Antimalarials	<p>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 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</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>
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	<p>Zantac, Reductil, Stinox, Viagra, Cialis, flu drugs, unknown others</p> <p>Armillarisni A</p> <p>Viagra and Cialis</p>	<p>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>According to UK sources, some 100,000 people in China died from illicit medicines in 2003.</p> <p>* China ranked second in the number of counterfeit drugs seized/destroyed in 2005—a total of 87 seizures.</p> <p>* Nine people died in a hospital in Guangdong province after being injected with fake Armillarisi A, a drug used in the treatment of gall bladder, liver, and gastric disorders. China’s Premier ordered an investigation into the incident as well as a safety review of the country’s pharmaceutical factories. The State Food and Drug Association (SFDA) announced a ban on all products of Qiqihar No. 2 Pharmaceutical Company, Ltd. during the investigation.</p> <p>* A total of 381,000 fake Viagra pills and 1.4 million counterfeit Cialis tablets, worth a combined total of approximately US\$29 million on the market, were seized from workshops at Kangdeli Health Care, according to a release from the court.</p>	<p>Counterfeit medicine ring busted. The China Post. 2005 Dec 9. http://www.chinapost.comtw/i_latestdetail.asp?id=33348</p> <p>Nigeria criticizes China over counterfeit threat. Daily International Pharma Alert. Feb 14, 2006; vol 3, no 31. www.fdanews.com</p> <p>WHO global taskforce to tackle counterfeit drugs. www.scripsnews.com, February 24, 2006, no. 3134, p. 16.</p> <p>Nine killed by fake Chinese Drug. May 22, 2005. http://news.bbc.co.uk/go/pr/fr/-/2/hi/asia-pacific/5003548.stm; and Harsh Penalties needed to discourage counterfeit production, says expert. May 18, 2006. http://www.interfax.cn/showfeature.asp?aid=12952&slug=health</p> <p>Xiaoyi S, Fake Viagra maker given 10-year prison term. China Daily; May 10, 2006.</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</p>	<p>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.</p> <p>Singh J, Dutta AK, Khare S, et al. Diethylene glycol poisoning in Gurgaon, India, 1998. Bull</p>

		<p>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>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>WHO 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>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.</p> <p>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. <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>
	Artesunate	<p>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.</p>	<p>Newton P. Counterfeit artesunate antimalarial tablets. <i>WHO Pharmaceuticals Newsletter</i> No. 3, 2003: 9.</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 countries have taken appropriate action to address the problem. The Food and Drug Department of Laos has issued recall notice for four lots of artesunate tablets to all 17 provincial Health and Drug Authority after receiving a verification test report of these fake artesunate from Food and Drug Quality Control Centre. The provincial authorities, in turn, have conducted investigative inspections of the distribution chain and confiscated all fake artesunate tablets found in pharmacies and drug retailers. Legal action is under way against all those who sell these fake drugs.</p> <p>At the 2nd global forum on pharmaceutical anticounterfeiting, a drug quality study on artesunate was reported that involved a large stratified random samples (about 2300 samples); the objective of the study was to obtain a reliable and unbiased estimate of the prevalence of counterfeit and substandard drugs</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> <p>Newton P. Fake antimalarials in SE Asia. . <i>Proceedings of the 2nd Global Forum on Pharmaceutical Anticounterfeiting</i>; 2005 Mar. 15-17; Paris, France. Denver CO: Reconnaissance Intl; 2005.</p>

		in the country, and study was funded by the govt, Wellcome Trust, CDC, British Embassy in Bangkok. Samples were randomly obtained from the districts, pharmacies, shops that were selected by persons not involved in the collection of samples in the field. Provisional results have shown that 28 of the 29 (96%) artesunate tablets collected did not contain the active ingredient, suggesting that the previous high estimates on the prevalence of fake artesunate using non-random sampling reflected the real situation. The results for the other 15 drugs samples are not yet available.	
Myanmar (Burma)	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.
	Oral Artesunate	* In February 2005, a 23-year old Burmese man died after being treated with oral artesunate for malaria. After analysis, it was found that the main active ingredient in the substance he was given was paracetamol (acetaminophen). Though artesunate was	Newton PN, McGready R, et al. (2006) Manslaughter by Fake Artesunate in Asia – will Africa be next? <i>PLoS Med</i> 3(6): e197.

		<p>found to be present in the tablets, the content was only 10 mg per tablet, instead of the 50mg present in the genuine product.</p> <p>* 16% of randomly collected samples of medicines failed laboratory testing for quality assessment.</p>	<p>WHO launches campaign against counterfeit medicines. Bulletin of the World Health Organization 2003; 81(12): pp.921-22.</p>
Nepal		<p>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.</p> <p>The DDA also found druggists in Narayanghat, Butwal, and Krishnaagar with 11 brands of unlicensed medicines and collected 18 dubious samples of substandard drugs; tests by the Royal Drugs Laboratory on the samples collected found 3% to be substandard.</p> <p>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.</p>	<p>Rai D. Which is real, and which is fake? Ever wondered why the medicine you take for that cough never seems to work? Nepali Times March 19-25, 2004. Available from: http://www.nepalitimes.com/issue/188/nation.htm</p>
Pakistan	<p>Engerix B</p> <p>Alternative medicines and Viagra</p>	<p>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.</p> <p>The WHO estimates that in 2004, 40-50% of drugs consumed in Pakistan were counterfeit.</p> <p>* Provincial authorities seized 495 samples of substandard, fake or illegal medicines in 2005, out of which 64 (13%) were fake.</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> <p>Multinationals urge Pakistan to raise drug prices. Daily International Pharma Alert. Jan 27, 2006; vol 3, no 19. www.fdanews.com</p> <p>Waqar A. Sale of homeopathic and herbal 'Viagra' rampant. Daily Times; April 6, 2006.</p>
Philippines		<p>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</p>	<p>Scrip World Pharmaceutical News February 27, 2002. Issue 2724; West Sussex, UK. PJB Publications Ltd.</p>

	<p>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</p> <p>Maintenance drugs for cancer, diabetes, and cardiovascular diseases; OTC products such as analgesics (paracetamol); antibiotics; cough syrups, tablets, and capsules</p> <p>Vitamins (Calpol and Ceelin)</p> <p>Amira Whitening Cream</p>	<p>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.</p> <p>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.</p> <p>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. 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>* National Bureau of Investigation (NBI) agents arrested a businesswoman for selling fake whitening cream worth P.5 million (approximately US\$94,340) in Pampanga. During the operation, NBI agents seized 700 bottles of fake Amira Whitening Cream.</p>	<p>Republic of the Philippines Department of Health-Bureau of Food and Drugs Health Advisory No. 01-06. November 7, 2001.</p> <p>Martin S. P7-B fake drugs for sale. From maintenance to paracetamol. <i>The Manila Times</i>. October 07, 2004.</p> <p>Gevera Mai. Fake drugs alarm DOH. Philippine Information Agency press release, October 13, 2005.</p> <p>Vendor of fake whitening cream nabbed. Tempo; May 19, 2006 http://www.tempo.com/ph/news.php?aid=24106</p>
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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 investigation on substandard quinine, artesunate, and chloroquine with local manufacturers and distributors to find the root cause of the problem.</p> <p>* Substandard medicines are believed to account for 8.5% of medicines on the market.</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> <p>WHO launches campaign against counterfeit medicines. <i>Bulletin of the World Health Organization</i> 2003; 81(12): pp.921-22.</p>
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</p>	<p>Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. <i>Lancet</i> 2001; 357: 1948-9.</p>

	<p>Isoniazid (INH) and rifampin (RMP) as single or fixed dose combinations (FDC)</p> <p>Fortum injection</p> <p>Antimalarials</p>	<p>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>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>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>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 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.</p> <p>* 8% of randomly collected samples of medicines failed</p>	<p>Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.</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>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> <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> <p>WHO launches campaign against counterfeit</p>
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	Acetaphen Levitra	laboratory testing for quality assessment. * Drug inspectors in Bac Ninh province found fake 30mg/2ml ampoules of Acetaphen, used as a painkiller and antipyretic. * The health ministry's Drug Administration Department said bogus Levitra 20mg was found on sale at many drugstores.	medicines. Bulletin of the World Health Organization 2003, 81 (12) Chau L. Vietnam on the lookout for fake drug. Thanh Nien News; May 12, 2006. Son N. Fake erectile dysfunction medicines on sale in Vietnam; April 24, 2006.
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

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		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.
Azerbaijan		* The health ministry inspected more than 230 pharmacies in Baku alone, revealing pharmaceuticals of low quality, 33 brands in total. These were withdrawn from pharmacies and 12 pharmacies were closed.	Measles/rubella vaccination funded in Azerbaijan...pharmacy inspections. www.scripsnews.com , March 29, 2006, no. 3143, p. 17.
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	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

		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.	
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	In 1998, physicians reported Sumamed capsules as ineffective.	Association of International Pharmaceutical

	<p>No-spa (drotaverine) tablet Nizoral (ketoconazole) tablet</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>Russia's federal service for surveillance in healthcare and social development, Roszdravnadzor, pulled 162 batches of counterfeit drugs under 47 names from the market in 2005, compared with 60 names in 2004. Amendments to the criminal code have been drafted, including fines and prison sentences.</p> <p>5-10% of pharmaceuticals consumed in Russia are counterfeits. A recent UN survey states that Russia is the fifth-largest producer of fake medicines in the world.</p> <p>* Russia ranked first in the number of counterfeit drugs seized/destroyed in 2005—a total of 93.</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> <p>Russia to introduce criminal penalties for counterfeit drugs. www.scripsnews.com, January 25, 2006, no. 3125, p. 6.</p> <p>CIS states in joint anti-counterfeiting action plan. Daily International Pharma Alert. Jan 20, 2006; vol 30, no 14. www.fdanews.com</p> <p>WHO global taskforce to tackle counterfeit drugs. www.scripsnews.com, February 24, 2006, no. 3134, p. 16.</p>
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	Antibiotics, cardiovascular and gastrointestinal medicines	* Russia's health ministry estimates that counterfeit pharmaceuticals worth US\$250-300 million are being sold in the country every year; almost 70% of them—including antibiotics, cardiovasculars, and gastrointestinals— are being made in Russia. In 2005, state control organizations seized from pharmacies 182 batches of medicines under 48 names, of which more than 70% imitated imported products.	Counterfeits worth \$250 million sold in Russia. www.scripsnews.com , February 24, 2006, no. 3134, p. 2.
Ukraine	Sumamed Cerebrolysin Nistatine	Counterfeit/substandard pharmaceuticals accounts for up to 40% or, in the case of certain pharmaceuticals, even up to 80% in this country. The State Department for Quality Control carried out raids and revealed the following counterfeiting cases: 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 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. 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. Substances other than therapeutic agents are passed off as pharmaceuticals. The Customs at Illichevsk suspended a	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.

	Pentalgin B	consignment that contained magnesium and calcium silicates, instead of pharmaceutical substances. 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.	
	Cephasoline-KMP	Counterfeit Cephasoline with false labels contained streptomycin and penicillin instead of the active ingredient mentioned in the labels.	
	Beres Plus drops	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.	
	Essel Forte	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.	
	Trihopol	Inspection of counterfeit Trihopol revealed that these medications had false quality certificates. Laboratory analysis showed these medications did not meet technical standards for Trihopol.	

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Argentina		The agency ANMAT estimates that up to 70% of medicines sold outside pharmacies are counterfeit or have some irregularities.	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.
Bolivia	Ampicillin capsules	A German relief organization detected counterfeit ampicillin through visual inspection. Later assays revealed these products to	Kusters G. Partnerships for public awareness and patient protection. The GPHF-Minilab project.

		be 80% low in content.	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 (Ponstan) Diclofenac (Voltaren) Isoniazid (INH) and rifampin (RMP) as single and fixed dose combinations (FDC)	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 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. 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. INVIMA reported in 1999 a 400 million dollar market for counterfeit medicines that exists in Colombia.	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 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. 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.

	Sildenafil (Viagra)	<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>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>Aldana JC. Politica de lucha contra la corrupcion de medicamentos en Colombia. Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.</p> <p>Ex-FBI man warns of counterfeit threat. SCRIP World Pharmaceutical News July 2, 2004. Issue no. 2966; PJB Publications Ltd London, UK. p. 6.</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	Amoxicillin, cotrimoxazole, folic acid, hydrochlorothiazide, mebendazole,	Percentage of samples that failed quality testing: 45.5% public sector, 27.8% NGOs, 34.6% private sector	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;

	metronidazole, paracetamol, captopril, furosemide		2001.
Mexico	Zocor, Carisoprodol	<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>The illegal drug trade stands at US\$650 million per year, equal to around 10% of total drug sales.</p> <p>Mexico has pledged to reform its Health Law to strengthen regulators' powers to crack down on the country's US\$70 million illegal drug counterfeiting sector. Under the reforms, counterfeiting would become a crime punishable by imprisonment.</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> <p>Latin America battles counterfeit drug threat. Daily International Pharma Alert. Feb 27, 2006; vol 3, no. 40. www.fdanews.com</p> <p>Multinationals urge firm action on Mexican counterfeiting. Daily International Pharma Alert. Feb 14, 2006; vol 3, no. 31. www.fdanews.com</p>
Peru		<p>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.</p> <p>Local regulator DIGEMID impounded 28 tons of fake drugs in 2004, and another 460,000 illegal products were intercepted in 2005. 43% of intercepted products were found to be lacking the active ingredient claimed on the packaging.</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> <p>Latin America battles counterfeit drug threat. Daily International Pharma Alert. Feb 27, 2006; vol 3, no. 40. www.fdanews.com</p>

		* Peru's Ministry of Health estimates that illegal sales of medicines account for 15 to 20% of the local market.	World Health Organization Fact Sheet no. 275, revised Feb 2006; http://www.who.int/mediacentre/factsheets/fs275/en/print/html
Venezuela		It is estimated that one in four pharmaceuticals is a counterfeit or fails to meet regulatory standards.	Latin America battles counterfeit drug threat. Daily International Pharma Alert. Feb 27, 2006; vol 3, no. 40. www.fdanews.com

MULTI-COUNTRY/GLOBAL

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. Tropical Medicine and International Health, Dec 2004; vol. 9 no 12: p 1241-1246.
		* In 2005, there were 781 counterfeiting incidents, representing a 40% increase over 2004, according to the Pharmaceutical Security Institute. Eighty-nine countries were connected to the trade in 2005, a rise of 32% from 2004.	WHO global taskforce to tackle counterfeit drugs. www.scripsnews.com , February 24, 2006, no. 3134, p. 16.