

Drug Quality Report Matrix of USAID-assisted Countries By the U. S. Pharmacopeia Drug Quality and Information (USP DQI) Program

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USP DQI SUBSTANDARD/COUNTERFEIT DRUG QUALITY REPORT IN USAID-ASSISTED COUNTRIES

REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
AFRICA			
Benin		At the National Hospital and University Centre in Cotonou on average 10 people arrive each day with kidney problems and at least one person dies each day from taking medicines bought on the parallel market. There is an increased number of hospital admissions and deaths occurring throughout the country because of drug poisoning. The National Office of Health Protection estimates that 85% of the population buy their drugs on the parallel market; antibiotics, antimalarials, and anthelmintics are the most requested medicines. Counterfeit drugs are said to have originated from Gabon, Nigeria, and certain Asian, European, and North American countries. The parallel market is controlled by traveling salespeople who have no training to dispense drugs. A study carried out in 10 localities counted 6,000 drug sellers, mostly women.	Crackdown on illegal sale of medicines in Benin. WHO Essential Drugs Monitor 1999; 27: 5.
Botswana	Anti-tuberculosis drugs	13 convenience samples of fixed-dose combination TB drugs from “The Fixed Dose Combination Project” were analyzed by the University of Botswana and U.S. FDA using thin-layer chromatography (TLC), ultraviolet (UV) spectrophotometry, and liquid chromatography (LC). 4 (31%) were substandard, including 2 (15%) with low rifampin content, 1 (8%) with excessive rifampin content, and 1 (8%) with excessive pyrazinamide.	Kenyon TA, Kenyon AS, Kgarebe BV, et al. Detection of substandard fixed-dose combination tuberculosis drugs using thin-layer chromatography. Int J Tuberc Lung Dis 1999; 3(11): S347-S350.

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AFRICA			
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	Chloroquine phosphate tablets and syrups	<p>Percentage of drugs that failed quality testing: 6% public sector, 6% NGOs, 0% private sector.</p> <p>Results of an eight-year study (1992-1999) conducted by the Ghana Standards Board showed that 4 of the 38 chloroquine tablet samples tested at their laboratory contained levels of the active ingredient below the minimum requirement (BP 92.5% and 107%) and 1 sample contained only 38.9%; 10 out of 57 samples of syrup tested were below the minimum required.</p>	<p>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.</p> <p>Ohene-Manu C, Martey J. Substandard chloroquine in Ghana. Essential Drugs Monitor (Letter to the Editor) 2000; Issue 28 & 29: 19.</p>
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

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AFRICA			
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; 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.	Issack MI. Substandard drugs. Lancet 2001; 358: 1463.
Nigeria	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 Syrups of Chemiron, Ranferon, Couflin, and Nivaquine as well as Tixylix, Gestid, Flagyl suspensions, and Ferric Ammonium Chloride solution	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. 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).	e-drug@usa.healthnet.org: the menace of fake drugs in Nigeria, 3/26/2002 Vanguard 2/26/ 2002

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REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
AFRICA			
Nigeria (continued)	Antimalarials (chloroquine, proguanil, quinine, pyrimethamine/sulfadoxine), antibacterials (□moxicillin, ampicillin, benzylpenicillin, cloxacillin, dapsone, doxycycline, metronidazole, ampicillin/cloxacillin trimethoprim/sulfamethoxazole), antituberculosis (isoniazid, pyrazinamide, rifampicin, streptomycin), anthelmintic (mebendazole), and antifungal (ketoconazole)	<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).</p> <p>Results: 279 (48%) samples were found to contain amounts of the active ingredient outside the appropriate limits.</p> <p>More than 50% of the group of drugs (antimalarials, antibacterials, and antituberculosis) failed to comply with BP specifications, although some individual drug preparations were found to be within limits.</p> <p>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.</p> <p>Some capsule preparations contained capsule-shell fragments suggesting some kind of recycling of product.</p>	Taylor RB, Shakoor O, Behrens RH, et al. Pharmacopeial quality of drugs supplied by Nigerian pharmacies. Lancet 2001; 357: 1933-6.

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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 than the claimed amount.</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 Program. Rockville, MD: United States Pharmacopeia.</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. <i>SCRIP World Pharmaceutical News</i> June 21, 2002. Issue: 2757; West Sussex, UK. PJB Publications Ltd. 18.

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AFRICA			
Tanzania (continued)	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, Masele AY. Comparative bioavailability of oral sugar-coated and plain formulation of chloroquine phosphate marketed in Tanzania. Trop Doctor 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. 15 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.	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.
ASIA and NEAR EAST			
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.	Hossain A, Rafiqzaman, 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.

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ASIA and NEAR EAST			
Cambodia (continued)	Antimalarials	<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>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>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> <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>
China	Sildenafil (Viagra)	<p>According to the State Drug Administration, a nationwide survey on the quality of medicine carried out in 1998 found that 13.1% of the 20,000 batches tested were either counterfeit or fell below minimal pharmaceutical standards.</p> <p>Chinese authorities seized about 100,000 fake anti-impotence pills from an underground factory in Jiangkou.</p>	<p>Tomlinson R. China cracks down on counterfeit medicines. Brit Med J 1999; 318: 624.</p> <p>Drug fakes, Asia's 'murderous' trade. CNN.com new June 2001. Available from: wysiwyg://74/http://www.cnn.com/2001/06/16/asia.drugs/...RLD/asiapcf/east/06/16/asia.drugs/</p>

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ASIA and NEAR EAST			
Indonesia		Estimated average of counterfeit drugs is 8%.	European Federation of Pharmaceutical Industries Association Available from: www.efpia.org/2_indust/counterfeitdrugs.pdf
Laos	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 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%. The Ministry of Health estimates 40% of all drugs are fake.	Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. Lancet 2001; 357: 1948-9. Blum N, Smine A. USP Drug quality and information program Mekong Malaria Initiative seminar. Presented at USAID July 16, 2002.

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ASIA and NEAR EAST			
Laos	Ampicillin, tetracycline, chloroquine, acetylsalicylic acid (ASA)	In 1997, 366 samples and in 1999, 300 samples obtained from licensed pharmacies were analyzed according to identity, content, and weight variation, and compared to the standards set by USP and BP. Results showed the percentage of substandard drugs decreased significantly from 46% to 22% between 1997 and 1999 (p < 0.001). Substandard ampicillin and tetracycline were reduced significantly from 67% to 9% and from 38% to 12%, respectively. In total, 3% vs 1% contained no active ingredient, 12% vs 4% had too little or too much active ingredient, and 35% vs 14% had weight variation outside the pharmacopeial limits. Authors concluded that the improvement in drug quality may have been due to the implementation of the National Drug Policy Programme through improved manufacturing practices and import procedures.	Syhakhang L, Lundborg CS, Lindgren B, et al. The quality of drugs in private pharmacies in Lao PDR: A repeated study in 1997 and 1999. Submitted to Division of International Health (IHCAR), Karolinska Institutet, SE-171 76 Stockholm, Sweden.
Myanmar	Artesunate tablet Amoxicillin, ampicillin, chloramphenicol, chloroquine, cotrimoxazole metronidazole, paracetamol, ranitidine, rifampicin, tetracycline	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%. 215 samples were collected and 212 were sent to a WHO lab for testing. Results showed 34 (16%) failed to pass quality test with active ingredients below BP and USP limits. One sample contained the wrong ingredient. The content of active ingredient in 6 samples was in the range of 2 to 60% of the labeled amount. Chloramphenicol preparations showed a high failure rate (35%) followed by ranitidine (20%), cotrimoxazole (19%), and amoxicillin (16%).	Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. Lancet 2001; 357: 1948-9. World Health Organization. Counterfeit and substandard drugs in Myanmar and Vietnam. Available from: http://www.who.int/medicines/library/qsm/who-edm-qsm-99-3/who-edm-qsm-99-3.htm

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ASIA and NEAR EAST			
Pakistan	Engerix-B	<p>Estimates about the private sector suggest about 50% of drugs in the market are counterfeit.</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>European Federation of Pharmaceutical Industries Association. Available from: www.efpia.org/2_indust/counterfeitdrugs.pdf</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>

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ASIA and NEAR EAST			
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	<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 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>Results of an intensive investigation of samples of medicines taken from pharmacies around the country showed that over 10% of the medicines were counterfeit.</p> <p>The Bureau of Food and Drugs 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>Scrip World Pharmaceutical News February 27, 2002. Issue 2724; West Sussex, UK. PJB Publications Ltd.</p> <p>European Federation of Pharmaceutical Industries Association Available from: www.efpia.org/2_indust/counterfeitdrugs.pdf</p> <p>Republic of the Philippines Department of Health-Bureau of Food and Drugs Health Advisory No. 01-06. November 7, 2001.</p>

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ASIA and NEAR EAST			
Thailand	Artesunate tablet	<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.</p> <p>Overall, 30 (29%) of these blisterpacks did not contain artesunate. Of the samples bought from pharmacies and shops, 39 (38%) were counterfeit.</p> <p>Proportion of fake artesunate in Thailand is 11%.</p>	<p>Newton P, Proux S, Green M, et al. Fake artesunate in southeast Asia. Lancet 2001; 357: 1948-9.</p>

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ASIA and NEAR EAST			
Vietnam (continued)	Amoxicillin, ampicillin, chloramphenicol, chloroquine, diazepam, metronidazole, paracetamol, rifampicin, salbutamol, tetracycline Fortum injection	288 samples were collected and sent to a WHO lab for testing. Results showed 21 (7%) products contained active ingredients below the labeled amount (60-89%), one contained active ingredients above the pharmacopeial limit, and the remaining 266 (92) samples contained active ingredients within BP and USP limits. 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.	WHO. Counterfeit and substandard drugs in Myanmar and Vietnam. Available from: http://www.who.int/medicines/library/qsm/who-edm-qsm-99-3/who-edm-qsm-99-3.htm Power G. Counterfeit pharmaceuticals (GSK). Proceedings of the Global Forum on Pharmaceutical Anticounterfeiting; 2002 Sept. 22-25; Geneva, Switzerland. Greenwood Village: Reconnaissance Intl; 2002.

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EUROPE and EURASIA			
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.
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.
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.

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EUROPE and EURASIA			
Russia (continued)	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 active substances and higher than permissible levels of the toxic substance, methanol.	Association of International Pharmaceutical Manufacturers. AIPM position paper. Counterfeit drugs in Russia 2001. AIPM, Moscow. 1-10.
		Russian health authorities estimate that counterfeit medicines make up 5 to 10% of the total amount of medicines in the market.	European Federation of Pharmaceutical Industries Association. Available from: www.efpia.org/2_indust/counterfeitdrugs.pdf

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EUROPE and EURASIA			
Ukraine (continued)	<p>Pentalgin B</p> <p>Cephasoline-KMP</p> <p>Beres Plus drops</p> <p>Essel Forte</p> <p>Trihopol</p>	<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> <p>Counterfeit Cephasoline with false labels contained streptomycin and penicillin instead of the active ingredient mentioned in the labels.</p> <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> <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> <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>	

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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.

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REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
LATIN AMERICA and the CARIBBEAN			
Brazil	<p>Oral contraceptive (OC) pills</p> <p>Anticancer drug for prostate CA</p> <p>Amoxicillin, captopril, cotrimoxazole, hydrochlorothiazide, mebendazole, metronidazole, paracetamol, rifampicin/isoniazid</p>	<p>An estimated 10% of the annual Brazilian pharmaceutical production is either stolen or falsified.</p> <p>Dummy pills stolen from a local pharmaceutical company and sold as OC in 1998; use resulted in 200 suspected unwanted pregnancies; pill turned out to be wheat flour, produced by the company when it was testing a new packaging machine.</p> <p>Dummy drug hastened death of several patients.</p> <p>Percentage of samples that failed quality testing: 14% public sector, 10% NGOs, 9% private sector.</p>	<p>Csillag C. Epidemic of counterfeit drugs causes concern in Brazil. Lancet 1998; 352 (9127): 553.</p> <p>Csillag C. Epidemic of counterfeit drugs causes concern in Brazil. Lancet 1998; 352 (9127): 553.</p> <p>Csillag C. Epidemic of counterfeit drugs causes concern in Brazil. Lancet 1998; 352 (9127): 553.</p> <p>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.</p>

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REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
LATIN AMERICA and the CARIBBEAN			
Colombia	<p>Chlorpheniramine, phenylephrine, and acetaminophen combination (Dristan), generic aspirin (Dolex), mefenamic acid (Ponstan)</p> <p>Diclofenac (Voltaren)</p> <p>Isoniazid (INH) and rifampin (RMP) as single and fixed dose combinations (FDC)</p>	<p>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%.</p> <p>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>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.businessweek.com/content/01_25/b3737153.htm</p> <p>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.businessweek.com/content/01_25/b3737153.htm</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>

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REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
LATIN AMERICA and the CARIBBEAN			
Colombia (continued)		<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.</p> <p>Between Oct 1999 and March 2002, INVIMA identified counterfeit medications with a value over \$US 1,196,808.</p> <p>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.</p> <p>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>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>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>
El Salvador	Amoxicillin, cotrimoxazole, folic acid, hydrochlorothiazide, mebendazole, metronidazole, paracetamol, captopril, furosemide	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; 2001.

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REGIONS	DRUG/S	REPORTS (1998-2003)	REFERENCES
LATIN AMERICA and the CARIBBEAN			
Haiti	Acetaminophen	There were 109 cases identified with acute renal failure caused by intake of locally manufactured acetaminophen syrup contaminated with diethylene glycol (DEG). Of those available to follow-up, 85 (98%) of 87 children in Haiti and 3 (27%) of 11 patients transported to the U.S. died. The raw material, glycerin, which was imported to Haiti and used in the acetaminophen formulation, was found to be contaminated with 24% DEG.	O'Brien K, Selanikio J, Hecdivert C, et al. Epidemic of pediatric deaths from acute renal failure caused by diethylene glycol poisoning. JAMA 1998; 279(15): 1175-80.
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.