

Counterfeits kill[®]

Nurses target counterfeit medicines



Counterfeits make up more than 10% of the global medicines available in the market and are available in both developed and developing countries.

International Nurses Day
12 MAY 2005



INTERNATIONAL NURSES DAY 2005

NURSES FOR PATIENT SAFETY:

**TARGETING COUNTERFEIT
AND
SUBSTANDARD MEDICINES**

Information and Action Tool Kit



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TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES

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Nurses for Patient Safety: Targeting Counterfeit and Substandard Medicines

Dear Colleagues,

As nurses, we are all concerned with patient safety and counterfeit medicines are increasingly becoming a serious threat to patient safety. ICN has chosen this topic as the focus of this year's IND in order to inform nurses and to provide you with the tools to tackle this growing problem. Counterfeit medicines make up more than 10% of the global medicines available in the market and are found in both developed and developing countries. The World Health Organization estimates that up to 25% of the medicines used in developing countries are counterfeit or substandard.

In a 2004 Gallup survey on the honesty and ethical standards of various professions, nurses topped the list for the fifth year out of six. But public confidence in health care professionals and health systems is being eroded by counterfeit medicines. Patient health is being put at risk and we strongly believe that the time to act is now. Counterfeit medicines are unsafe and ineffective. They result in wasted resources spent on purchasing, inventory, transport and dispensing with little or no effect or even with disastrous patient outcomes such as poisoning, disability and death.

This year's IND theme of Nurses for Patient Safety: Targeting Counterfeit and Substandard Medicines is the launch and centrepiece of an ICN led multi-sector campaign including other health professions, patient groups, industry and regulators. The campaign aims to:

- Increase awareness of the existence and consequences of counterfeit medicines.
- Provide tools to identify counterfeit drugs and to report any suspicious medicines.
- Encourage nurses and other health professionals to lobby governments and regulatory authorities for attention to the existence and dangers of counterfeit and substandard medicines.

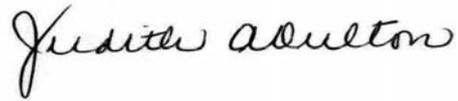
Nurses are on the frontlines of health, administering and often prescribing medicines, particularly in primary health care settings. We are well positioned to monitor drug effects and side effects and must be vigilant for signs of counterfeiting such as improper packaging and labelling. Nurses also have a key role in educating the public about the dangers of buying medicines through the Internet or on the streets from unauthorized sources.

Our patients have trust and confidence in us; it is our duty to uphold that trust. By targeting counterfeit medicines, nurses can help ensure the safety of patients and restore the public's trust in health care systems.

Sincerely,

Handwritten signature of Christine Hancock in black ink.

Christine Hancock
President

Handwritten signature of Judith A Oulton in black ink.

Judith A Oulton
Chief Executive Officer

TERMINOLOGY

Active ingredient	An ingredient in a medicine that is capable of action under defined conditions and is responsible for the effect on the patient's health.
Antibiotics	Antibiotics are substances produced by micro-organisms that kill or inhibit other micro-organisms.
Antimicrobial resistance	The ability of a micro-organism to withstand an antimicrobial agent such as antibiotics. Bacteria may be inherently resistant to, i.e. unaffected by, an antibiotic or may develop resistance and the drug becomes useless. Also known as drug resistance.
Branded product	An innovative pharmaceutical product with patent protection. A branded medicine is one that is marketed under its trademark or brand name rather than the chemical name. When a medicine is prescribed by brand name, only the product from the original manufacturer of the brand can be dispensed.
Counterfeit medicine	A medicine that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredient or with fake packaging.
Excipient	A pharmacologically inactive substance that is combined with a drug to confer a suitable physical form to the mixture and facilitate the administration of a medicine.
Expired product	Expired medicines are those that have reached the date limit set for shelf life. There is always a date limit set on medicines, as the active ingredient does not always have as much effect or becomes inactive after the expiry date.
First line drugs	First line drugs are those prescribed alone as the first type of medication given to the patient at the beginning of their treatment. Second line drugs are prescribed in addition to the first line drug when the patient's condition does not improve.
Generic product	A generic medicine is the therapeutic equivalent of an originator pharmaceutical product whose patent has expired. It contains the same active substance as, is essentially similar to, and is interchangeable with the originator product. Two products (branded and generic) are considered pharmaceutically equivalent

if they contain the same active ingredient(s) and are identical in strength, dosage form and route of administration.

Pharmacological

The drug-like properties or effects of a substance.

Substandard medicine

The term substandard is used to describe the quality status of genuine drugs produced by legitimate manufacturers. Normally, there are quality standards or specifications for each drug product that a manufacturer produces. Such specifications are also published in official pharmacopoeias such as the United States Pharmacopoeia, the European Pharmacopoeia, and the WHO International Pharmacopoeia. If a drug, upon laboratory testing in accordance with the specifications with which it claims to comply, fails to meet the specifications, then it is classified as a substandard drug.

Tracking information

Medicine manufacturers put systems into place so that a drug can be tracked throughout the distribution chain, from the moment it leaves the factory to the time it reaches the patient. Systems include electronic tracking devices, radio frequency identification and other techniques.

Tampering

To deliberately alter or falsify a medicine or its packaging, usually secretly or dishonestly. Some criminals obtain expired, reject or stolen medicines and change the expiration or tracking information to resell products into the distribution system. Others empty the actual medicine and refill the packages with fakes.

Sources:

Churchill's Medical Dictionary (1898). Churchill Livingstone, Inc. London.

WHO (2004). The World Medicines Situation.

http://www.who.int/medicines/organization/gsm/activities/qualityassurance/cft/counterfeit_faq.htm; <http://www.egagenerics.com/FAQ-generics.htm>
<http://www.briefings.com/pdf/955/Creinin.pdf>

What is a Counterfeit or Substandard Medicine?

Inherently defective and substandard products such as counterfeit medicines pose a serious threat to patient and public safety and quality of care. According to the United States Food and Drug Administration (FDA), counterfeit medicines make up more than 10% of the global medicines available in the market and are available in both developed and developing countries. It is estimated that up to 25% of the medicines used in developing countries are counterfeit or substandard.¹ It is clear that globalization and wide use of the Internet to penetrate markets have led to the spread of counterfeit products.

Patients and consumers are the primary victims of counterfeit medicines. In order to protect them from the harmful effects of counterfeit medicines it is necessary to provide them with appropriate information and education on the consequences of counterfeit medicines. As frontline health care providers, nurses are key players in increased vigilance for counterfeit medicines and increased reporting of possible counterfeit drugs.

According to the World Health Organization (WHO), a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source and may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.² Similarly the International Pharmaceutical Federation (FIP) defines counterfeit medicines as the deliberate and fraudulent mislabelling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product.³

A substandard drug, according to the World Health Organization⁴, is a genuine medicine produced by legitimate manufacturers that fails to meet quality specifications and standards. Such medicines are due to poor manufacturing practice or improper storage conditions. Substandard products may occur as a result of negligence, human error, insufficient human and financial resources or counterfeiting. Sometimes substandard drugs occur if a legitimate manufacturer gets involved in criminal activity. When substandard drugs are produced to make unlawful profit, they become counterfeit.

Counterfeiting can apply to both branded and generic products, prescription medicines and self-medication, as well as to traditional remedies. They may contain different ingredients, both harmless and toxic, or different quantities of ingredients.⁵

In addition to fake or altered *active* ingredients (i.e. with a pharmacological activity or other direct effect on the disease), there are also fake or diluted *inactive* ingredients (excipients), which can also be harmful to patients. Excipients are used in the composition of medicines, sometimes as the medium of administration of medicines, and are generally substances that are inert or only slightly pharmacologically active. In some countries, criminals obtain expired, rejected or stolen medicines and change the expiration or tracking information to resell products into the distribution system. Product tampering, such as emptying out the medicine and filling the packaging with fake product, also exists. Counterfeit medicines thrive in countries where there is a

breakdown in health care infrastructures, for example in war-torn countries, and where regulatory structures and enforcement are lax or insufficient. They are also more likely to occur where essential medicines are highly priced and therefore not affordable for most who need them, leading consumers to look for cheaper products from alternative sources.

Counterfeit medicines are unsafe and ineffective, fail to treat or prevent the intended disease and can even cause harm to the patient. Counterfeit medicines result in wasted resources spent on purchasing, inventory, transport and dispensing with little or no effect or with disastrous patient outcomes such as poisoning, disability and death. Counterfeit medicines are among the main cause of antimicrobial resistance in infectious diseases such as tuberculosis (TB). For example, counterfeit antimicrobials can turn a TB case that could be cured in three months at a cost of US\$11 into a multidrug resistant TB that takes two years to treat and is over 100 times more expensive than the first-line drugs used to treat non-resistant forms.⁶

The World Health Organization (WHO) figures suggest that developing countries account for around 60% of all reported cases of counterfeit and substandard drugs.⁷ In developing countries, medicines that are commonly found to be counterfeit are generally life saving, not lifestyle – such as those used to treat life-threatening conditions such as malaria, TB and HIV/AIDS.

A recent WHO survey of the equality of antimalarial preparations in seven African countries revealed that up to 38% of chloroquine tablets and up to 90% of sulphadoxine/pyrimethamine tablets were substandard. Further, a study in *The Lancet* concluded that up to 40% of artesunate products (the best medicine to combat resistant malaria today) contain no active ingredients and therefore have no therapeutic benefits against malaria. The World Health Organization estimates that around 200,000 annual malaria deaths could be avoided if medicines were of high enough quality to actually treat the illness.

A WHO survey of counterfeit medicines in 20 countries between January 1999 and October 2000 found that in 60% of the 325 cases an active ingredient was missing from the product.⁸ In 2003, WHO reported that fake drugs reported between 1999 and 2002 include pain killers and fever control medicines, antimalarials, anti-asthma and anti-allergy, antibiotics, hormones and steroids.⁹

In a WHO survey between 1992 and 1994, as many as 51% of counterfeiting cases uncovered revealed that these drugs carried no active ingredient whatsoever. Among the counterfeits, yet another 17% contained the wrong ingredient, while an additional 11% contained weaker than recommended concentrations of active medication. Indeed, some of these, so-called "medications" contained poisons capable of causing severe disability or death. Overall, only 4% of counterfeits contained the same quantity and quality of medication as their authentic counterparts.¹⁰

Trade in counterfeit medicines is more prevalent in countries with weak drug regulation control and enforcement, scarcity or unreliable supply of basic medicines, unregulated markets and high cost of medicines.

Harming HIV Patients

In 2002, GlaxoSmithKline in the United States discovered suspect bottles containing 60 tablets of Combivir (lamivudine plus zidovudine) that actually contained another medicine, Ziagen (abacavir sulfate). The company determined that counterfeit labels for Combivir tablets were placed on two bottles of Ziagen and labels on another two bottles were suspect. Both medicines are used in combination to treat HIV infection and can cause potentially life-threatening hypersensitivity reactions in patients taking other medicines in the combination.

As the following figures show, counterfeit medicines are widely prevalent and of global concern.

- One in 10 medicines sold worldwide is fake, with no medical effect but generating US\$32 billion a year in sales for counterfeit drug dealers.
- In poor countries, up to 25 percent of drugs are counterfeit, and particularly rampant among those sold on the street.

- Pharmaceutical companies typically name China, Nigeria and the former Soviet Republics as epicentres of counterfeit drug production. Other sources that have been suggested include Egypt, Pakistan, India and Indonesia.¹¹
- In 1992, at least 233 Bangladeshi children died after taking a paracetamol-based syrup that was tainted with antifreeze.
- In 1990, 109 Nigerian children died under similar circumstances.
- In 2001, an estimated 192,000 people died in China because of fake drugs.¹² Some die from toxins in counterfeit medicines and others from infection as a result of taking fake pills instead of antibiotics.
- In 2003, the United States Food and Drug Administration issued an alert that nearly 200,000 counterfeit bottles of Lipitor, widely used to control cholesterol, had made their way onto the market, representing "a potentially significant risk to consumers."¹³
- In Southeast Asia, the situation seems to have reached a very serious level. In Bangladesh, sampling of 5,000 medicines by the Public Health and Drug Testing Laboratory found that 300 medicines were either counterfeit or of very poor quality.
- In wealthier countries, expensive lifestyle medicines such as drugs to combat erectile dysfunction, hormones and steroids, and antihistamines appear to be the most likely to be counterfeited.¹⁴
- In India, in addition to drugs for tuberculosis and malaria, cough syrups are commonly counterfeited. Cough syrups containing double the permitted codeine levels are sold as counterfeits of well-known brands. Investigations in India have also revealed counterfeit drugs containing chalk powder.¹⁵

Internet Purchasing

The advent of Internet has boosted the commerce of fake medicines by facilitating the creation of Internet pharmacies i.e. websites from which medicines are sold. Some Internet pharmacies are branches of community pharmacies. Others exist only on the Internet and ship medicines directly from a warehouse. Some Internet pharmacies conduct illegal and unsafe prescribing, do not require prescriptions to sell medicines, and can endanger the patient's life.

The Internet has extended the reach of those seeking to sell counterfeit drugs so that now anyone anywhere in the world is a potential victim. Internet pharmacies encourage self-diagnosis and self-treatment, in the sense that medicines can be freely purchased without health professional and competent control. For example, a licensed pharmacist may never be involved in reviewing the prescription and warning of potential side effects and drug interactions.

In some industrialised countries where medicines are expensive, patients are looking elsewhere to purchase cheaper pharmaceuticals. For example, in the past two years the number of parcels containing prescription drugs entering the US from other countries has risen by 1,000 per cent. The US Food and Drug Administration (FDA) has investigated 71 incidents of fake drugs in the past seven years but says that many illegal drugs are still getting through.¹⁶ Viagra, a drug used to correct erectile dysfunction, is reportedly the most counterfeited drug for sale on the Internet.

In 1999, in an attempt to combat illegal Internet pharmacies, the American National Association of Boards of Pharmacy (NABP) established the voluntary Verified Internet Pharmacy Practice Sites (VIPPS) programme. It is designed to assist the

public in identifying properly licensed Internet pharmacies that have agreed to comply with federal and state laws. Other countries are examining ways to establish similar safeguards.

Nurses can advise patients not to purchase medicines off the Internet where there is no guarantee that the product is authentic.

Case History: Dangers of International Internet Purchasing

An overseas Internet site was identified in 2004 by the FDA and Johnson & Johnson as selling counterfeit contraceptive patches that contained no active ingredients. The counterfeit contraceptive patches were promoted as Ortho Evra transdermal patches, which are FDA approved, and made by Johnson & Johnson's Ortho-McNeil Pharmaceutical, Inc. subsidiary.

Customers received packages of patches without the active ingredient necessary to make the patches effective. Moreover, the counterfeits were dispatched to customers in simple plastic zip-lock bags without identifying materials, lot numbers, expiration dating or any other labelling information. The counterfeit patches provided no protection against pregnancy.

The domain name, www.rxpharmacy.ws, was apparently owned by American Style Products of New Delhi, India. The site also sold other products that purported to be versions of FDA-approved drugs. FDA obtained the cooperation of the US-based Internet service provider in shutting down service to this site.

The FDA-approved Ortho Evra contraceptive patch is an adhesive patch that contains a combination of an estrogen and a progestin for contraception. The patch is applied to the skin of a woman's abdomen, upper outer arm, upper torso or buttock for seven days. A new patch is applied each week for three weeks (21 total days), followed by one patch-free week.

The counterfeit product is 1½ inches square, brown in color, made of woven material, and has 5 holes that appear as red dots on the middle of the top side of the patch. This product also has a ¾ inch orange square resembling gauze under the plastic liner on the back of the patch. The product does not come packaged in a sealed pouch and does not contain lot number or expiration date information.

[Source: FDA press release]

International Travel

Another way for counterfeit drugs to come into contact with a wider audience is through holidaymakers and students who travel extensively. Sometimes, travellers visit countries where counterfeiting is rife and, because they are not informed of the dangers of purchasing medicines on open markets or off the Internet, buy medicines from unlicensed sources. Open-air markets all over the world sell pills by unit; there is no guarantee that the pills are real medicines.

Consequences of Counterfeit and Substandard Medicines

Counterfeit medicines can have serious effects. Some of the main consequences include treatment failures, erosion of public confidence in health care, prolonged illness, unexpected side effects, antimicrobial resistance, and even death.

The regular use of substandard or counterfeit medicines leads to therapeutic failure, and in many cases it can lead to death. During the meningitis epidemic in Niger in 1995, over 50 000 people were inoculated with fake vaccines, received as a gift from a country which thought they were safe. The immunisation with substandard vaccine resulted in 2,500 deaths.

The consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze) led to 89 deaths in Haiti in 1995 and 30 infant deaths in India in 1998.

In 1999, at least 30 people died in Cambodia after taking counterfeit antimalarials prepared with sulphadoxine-pyrimethamine (an older, less effective antimalarial), which were sold as Artusenate.

Counterfeit medicines erode the public confidence in health care professionals and health systems, which can lead to reluctance to use health care facilities. On the other hand, it can also lead to patients consuming more health care services by consulting different health care professionals and centres if the medicines dispensed do not have an effect.

Nurses play a key part in administering medicines and often have prescribing and dispensing roles as well, particularly in primary health care settings.

They are well positioned to monitor drug effects and side effects and must be vigilant for signs of counterfeiting such as improper packaging, labelling, description of dosage, etc. (see tool). Nurses also have a key role in educating the public about the dangers of buying medicines through the Internet or on the streets from unauthorized sources. It is unethical to knowingly administer counterfeit medicines that will cause harm to the patient. Nurses must report all suspect counterfeit medicines to the appropriate authority.

Counterfeit drugs are a major problem that directly contribute to antimicrobial resistance. It is estimated that 5% of all antibiotics sold globally are fake drugs that claim the lives of victims worldwide.¹⁷ Resistance to antibiotics flourishes wherever they are abused, misused or dispensed at levels lower than recommended treatment guidelines.

Antimicrobial medicines have saved the lives and eased the suffering of millions of people and led to major gains in life expectancy. These gains are now seriously jeopardized by the emergence and spread of microbes that are resistant to cheap and effective first-choice, or "first-line" drugs. The bacterial infections, which contribute most to human disease, are also those in which emerging and microbial resistance is most evident: diarrhoeal diseases, respiratory tract infections, meningitis, sexually transmitted infections and hospital-acquired infections. The development of resistance to drugs commonly used to treat malaria is of particular concern, as is the emerging resistance to anti-HIV drugs.¹⁸

The emergence and spread of antimicrobial resistance is a complex problem that is driven by a variety of factors, including human practices. Some critical factors in the emergence of drug resistance include, under use through lack of access, inadequate dosing, poor adherence and counterfeit or substandard antimicrobials. Knowledge of health professionals and patients and drug regulatory mechanisms are also important contributory factors. Self-medication with antimicrobials is another major factor contributing to resistance. Self-medicated antimicrobials may be unnecessary, are often inadequately dosed, or may not contain adequate amounts of active drug, especially if they are counterfeit drugs. In many developing countries, antimicrobials are purchased freely and there is no way of assuring quality. As well as causing deaths, counterfeit antimicrobial drugs with deliberately reduced amounts of the active ingredient contribute to the problem of drug resistance through failed treatments.

The consequences of antimicrobial resistance are serious. Infections caused by resistant microbes fail to respond to treatment, resulting in prolonged illness and greater risk of death. Treatment failures also lead to longer periods of infectivity, which increase the number of infected people in the community and thus expose the general population to the risk of contracting a resistant strain of infection.

When infections become resistant to first-line antimicrobials because of counterfeit products or other factors, treatment has to be switched to second- or third-line drugs, which are almost always much more expensive and sometimes more toxic as well. In many countries, the cost of such replacement drugs is very high and further encourages fraudulent manufacturing of counterfeit medicines, which are sold at cheaper prices.

What Nurses and National Nurses Associations Can Do to Combat Counterfeit Medicines

Nurses as frontline health care providers can become key players in increased vigilance for and increased reporting of possible counterfeit drugs. Noticeable differences from the original in the appearance of a drug or its packaging, ineffective action, or very low price are top indicators of fake drugs. Tools for identifying possible counterfeit medicines have been included in this kit as Annexes 1 and 2.

In Daily Practice

Nurses can assist in the identification of counterfeit products by direct observation of people and products. If patients report that:

- the medicine prescribed has no effect;
- the medicine prescribed has an effect that is different to the expected outcome;
- the medicine package was not intact e.g., not sealed properly, blurred expiry date etc;
- the medicine has a different taste, consistency or appearance than usual.

then nurses should look into the possibility that the medicine is fake.

The “look and feel” of a product can be an indication that something might be wrong with the product. When nurses are dispensing medicines, they should look out for products that are not intact, that have been altered, damaged or that have unsealed packaging.

Nurse identifies fake through labelling

According to the chairman of Ebonyi State Task Force on Counterfeit and Fake Drugs, Emmanuel Inya-Agha, 48% of goods and drugs imported to Nigeria are sub-standard and counterfeit.

Alice Ajibade, a retired nurse in the Lagos State Ministry of Health experienced this first hand, when she found that a syrup bought in a chemist's shop was fake. The syrup was destined for her one-week-old grandchild. Ms Ajibade identified the fake after taking a close look at the label, which differed from the label of the real medicine. When she took the medicine back to the chemist, the latter did not have the original.

Source: *This Day* (2004), Lagos, November 2, 2004, <http://allafrica.com/stories/200411020488.html>.

At the Front Line

Activities undertaken to curb counterfeiting include information campaigns to sensitise the public against the dangers of substandard products, monitoring of products and networking with pharmacy, medical and other professional groups to exchange information and education. Nurses and their national associations can also:

- Be involved in national efforts to raise awareness and combat counterfeiting.
- Disseminate information on counterfeit pharmaceutical products, including education of nurses and other health professionals.
- Collaborate with pharmacists, health care facility managers and others to establish reporting mechanisms, collect and verify more accurate data on counterfeiting.
- Be part of the national monitoring and reporting of counterfeit drugs. This can include initiatives to introduce toll free telephone lines for anonymous reporting of counterfeit drug trafficking.
- Lobby for fair prices of medicines as the high cost of medicines in developing countries makes them unaffordable to large sectors of the population and increases the risk of counterfeiting.
- Lobby for appropriate legislation, drug regulation and law enforcement against counterfeit drugs.

The ICN Position Statement on Counterfeit Medicines ¹⁹ highlights that it is essential to educate health professionals about counterfeit medicines so that they in turn can:

- Support national regulatory authorities in their fight against counterfeit medicines;
- Effectively lobby local, regional and national governments to establish regulatory mechanisms where there are none; and
- Educate patients to:
 - **Speak up** if they have any queries about the medicine, the packaging, the expected health outcomes etc.;
 - **Ask questions** about the medicine and its effects and possible side effects;
 - **Find the facts** about what the medicine should do (expected health outcome);
 - **Evaluate choices** and understand the effect of the medicine and monitor effectiveness;
 - **Report any lack of improvement** in their health status, unexpected or adverse event related to the medicine.

Nurses are key to patient education and creating public awareness about counterfeit medicines.

Case History: Informed Patients Alert Others to Fakes

In 2002, the Bulletin of Experimental Treatments for Aids, a publication run by AIDS treatment activists, warned its readership: “Counterfeiting of hgh (human growth hormone – used to fight wasting syndrome) is a growing problem. Like sidewalk vendors selling \$20 Rolex watches, Internet sites offering cut-rate growth hormone prices are too good to be believed - and should not be. But counterfeit drugs can also enter the regular distribution chain, complete with knock-off packaging and bogus manufacturing lot numbers.” The article goes on to specify that the only noticeable variation is in lot number and in package design. The website www.aids.about.com further warned that the “counterfeit drug carries the lot number MNK612A with an expiration date of 08/02. The fake drug appears powdery instead of the typical caked appearance of the genuine drug.”

Reporting Fake Medicines

If there is any suspicion that a medicine may be a fake, the first thing to do is to contact the company that makes the medicine. Within the health care facility (e.g. community clinic, hospital, private practice) other staff should be informed that there is a possibility of a counterfeit product having entered the site. Law enforcement (e.g. police, customs) and regulatory authorities should also be informed (see flow chart). It is important to keep samples of the suspected product, as proof will be required if the medicine is really counterfeit.

Creating Public Awareness

Patients and consumers are the primary victims of counterfeit medicines. In order to protect them from the harmful effects of counterfeit medicines it is necessary to provide them with appropriate information and education on the consequences of counterfeit medicines.

The ICN Position Statement on Counterfeit Medicines calls on nurses and NNA to:

- Look out for counterfeit and sub-standard medications;
- Enquire about any doubtful medications; and
- Denounce counterfeit and sub-standard medications to the appropriate authorities.

Similarly in its Position Statement on Antimicrobial Resistance,²⁰ the ICN calls for responsible prescribing and affirms its commitment to work with national nurses associations and others to:

- Provide patient and public education about the determinants of antimicrobial resistance and preventive measures, and
- Support infection control policies and practices in health care settings that aim to prevent nosocomial infections.

Patients and consumers expect to get advice from national authorities, health care providers, health professionals and others on where they should buy or obtain their medicines; and what measures they should take in case they come across counterfeit medicines or are affected by the use of such medicines.

Recently WHO and others have launched World Alliance for Patient Safety²¹ in order to encourage Patient Involvement in Patient Safety. The Alliance acknowledges the important role patients and patient organisations could play in improving the quality and safety of their healthcare.

Among the priorities for patient involvement in safety are for nurses to identify and engage with consumer and patients' groups, allow for reporting and feedback of patient safety issues and make patient representatives available to healthcare systems.

Nurses and NNAs must work closely with national medicines regulators, other health professional associations, nongovernmental organisations and other stakeholders in campaign activities targeting patients and the public to promote awareness of the problem of counterfeit medicines. Posters, brochures, radio and television programmes are useful means for disseminating messages and advice.

Annex 4 contains a model prepared by a WHO Working Group, which can help nurses and national nurses associations develop national campaign materials. ICN is keen to receive copies of national campaign materials and outcomes of such campaigns.

TOOL KIT

TARGETING COUNTERFEIT

AND

SUBSTANDARD MEDICINES

Tool for Visual Inspection of Medicines

A checklist for visual inspection of medicines in order to identify suspicious products for further examination.

This document has been produced in partnership with the United States Pharmacopeia Corporation (USP). It is designed to help nurses carry out a visual inspection of medicines for signs of counterfeiting such as improper packaging, labelling, description of dosage, etc. All suspicious drugs with incorrect labels, missing information about the strength, dosage, or expiration date should be reported to the appropriate authority.

1. Packaging

Any drug should be packaged in a container, which can be anything from a glass bottle to a blister pack, to a tube of glass, plastic or metal. A folding carton bearing the label very often protects the container. Check the type of packaging and compare it to known containers for the same drug from the same manufacturer. The packaging and the labelling of pharmaceutical products is a very complex and expensive business. Thus, the process and the quality of packaging material are very difficult to counterfeit. This is why a thorough visual inspection could be an important screening step for drug quality control. However, producers of counterfeit drugs are quick to copy special labelling and holograms.

	Yes	No	Other Observations
1.1 Container and Closure			
Do the container and closure protect the drug from the outside environment?			
Do they assure that the drug will meet the proper specifications throughout its shelf life?			
Are the container and the closure appropriate for the drug inside?			
Is the container sealed?			
1.2 Label			
The information written on the label is very important. The information can be printed on a label adhered to the container, or printed directly onto the container itself, but all information must be legible and indelible.			
If there is a carton protecting the container, does the label on the carton match the label on the container?			
Is all information on the label legible and indelible?			

1.2.1 The trade name:			
Is the trade name spelled correctly?			
Is the trade name registered and can the drug be legally sold in the country?			
Does the symbol ® follow the trade name?			
1.2.2 The active ingredient name (scientific name):			
Is the active ingredient name is correct?			
Do the trade name and the active ingredient name correspond to the registered drug?			
1.2.3 The manufacturer's name and logo:			
Are the manufacturer's name and logo legible and correct?			
Does the logo change colour when viewed from different angles?			
1.2.4 The manufacturer's full address:			
All manufacturers are required by international law to print their complete address on the label. Many companies making substandard or counterfeit drugs do not have a traceable address on the label.			
Is the manufacturer's full address legible and correct?			
Has the company registered the drug in the country?			
1.2.5 The drug strength (mg/unit):			
Is the strength - the amount of active ingredient per unit - clearly stated on the label?			
1.2.6 The dosage form (e.g., tablet/capsule):			
Is the dosage clearly indicated?			
Is the indicated drug under this dosage form is registered and authorized for sale in the country?			
1.2.7 The number of units per container:			
Does the number of tablets listed on the label match the number of tablets stated on the container?			
1.2.8 The batch (or lot) number:			
Drugs under the same batch/lot number are expected to be equivalent. In a continuous process, a batch corresponds to a defined portion of the production, based on time or quantity. Drugs from the same batch number should have the same history of manufacturing, processing, packing, and coding. All drug quality control testing should be based on batch/lot numbers.			
Does the numbering system on the package correspond to that of the producing company?			
1.2.9 The date of manufacture and the expiry date:			
An expired drug should not be sold under any circumstances.			
Are the manufacture and expiry dates clearly indicated on the label?			

1.2.10 Storage information:			
Are the storage conditions indicated on the label?			
Has the drug been properly stored?			
1.3 Leaflet or package insert:			
All drug packages should contain a leaflet explaining dosage, the drug content, the adverse affects, the drug actions, and how the drug should be taken. The only exceptions are where the packaging includes all the information that would otherwise be in the leaflet.			
Is the package insert printed on the same coloured or same quality paper as the original?			
Is the ink on the package insert or packaging smudge-proof?			
2. Physical Characteristics of Tablets/Capsules			
All types of medicines can be and have been counterfeited from cough syrups to injections. As mentioned above, it is important to check the packaging of these drugs. Additionally, medicines in the form of tablets or capsules can be checked for signs of moisture, dirty marks, abrasion erosion, cracks, or any other adulteration.			
2.1 Uniformity of Shape:			
Are the tablets/capsules uniform in shape?			
2.2 Uniformity of Size:			
Are the tablets/capsules uniform in size?			
2.3 Uniformity of Colour:			
Are the tablets/capsules uniform in colour?			
2.4 Uniformity of Texture:			
Tablets can be film-coated, sugar-coated or enteric-coated.			
Do the tablets have a uniform coating?			
Is the base of the tablets fully covered?			
Are the tablets uniformly polished, free of powder, and non-sticking?			
2.5 Markings (scoring, letters, etc):			
Are markings uniform and identical?			
2.6 Breaks, Cracks and Splits:			
Are the tablets/capsules free of breaks, cracks, splits or pinholes?			
2.7 Embedded surface spots or contamination:			
Are the tablets/capsules free of embedded surface spots and foreign particle contamination?			
2.8 Presence of empty capsules in the case of a sample of capsules:			
Is the sample examined free of empty capsules?			

2.9 Smell			
Does the medicine smell the same as the original?			

Reporting Counterfeit Medicines

If, after carrying out the above visual inspection, you suspect you have discovered a counterfeit medicine, you should report this immediately to your local health authority. Alternatively, you can contact WHO's Department of Quality Assurance and Safety of Medicines (QSM):

- Quality Assurance and Safety of Medicines (QSM)
Department of Essential Medicines and Policy (EDM)
World Health Organization CH-1211 Geneva 27
Switzerland
Tel: +41 22 791 37 43
Fax: +41 22 791 47 30
<http://www.who.int/medicines/organization/gsm/activities/qualityassurance/cft/CounterfeitReporting.htm>

How to Recognize Counterfeit Medicines Five Steps for Consumers

- 1. Know your medicine:** The best way for consumers to identify potential counterfeits is to be as familiar as possible with the drugs they regularly take. It's difficult to tell just by looking at them, but the more familiar you are with both the packaging and the drugs themselves, the better the chances that you'll detect a fake drug before taking it. If you know the size, shape, colour and taste of the medications you take, you will more easily identify possible counterfeits. When something doesn't look or taste quite right, be suspicious. Talk to your pharmacist or health care provider.
- 2. Buy drugs from safe sources:** Only buy drugs from licensed pharmacies and drug outlets. Do not buy from peddlers or market places. Insist on getting a receipt when buying drugs and be suspicious of heavily discounted drugs. You can reduce the risk of getting counterfeit drugs by buying from reputable pharmacies, but even they sometimes offer counterfeit drugs for sale without realizing it. Do not buy prescription drugs without seeing a doctor first. If you buy medicine online, beware! Purchasing a medication from an illegal website puts you at risk. You may receive a contaminated or counterfeit product, the wrong product, an incorrect dose, or no product at all. Talk to your health-care professional before using any medications for the first time.
- 3. Examine the packaging:** Closely examine the appearance of your medicine and its packaging. Check that the packaging is properly sealed. Can you clearly read the label? The information written on the label is very important. It should include the batch number, manufacturing date, expiry date and the manufacturer's name. If you are renewing medicine, compare the new package carefully with the original. Are there any changes in the packaging or label?
- 4. Examine the tablets/capsules:** In some cases, patients have noticed a different taste, consistency or appearance of products that are later identified as being counterfeit. Tablets/capsules should be uniform in shape, size and texture.
- 5. Note how your body responds:** You might be able to tell if a drug doesn't have the effect that it promises, has different side effects than described, or doesn't work in the same way as it did when you took it previously. Talk to your pharmacist or health worker if you notice anything unusual, or if you have a different reaction to your medicine.

Targeting Counterfeit Medicines: What Nurses Can Do

- Look out for counterfeit and sub-standard medications (see enclosed fact sheet on visual inspection). Enquire about any doubtful medications. Denounce counterfeit and sub-standard medications to the appropriate authorities.
- Lobby for fair prices of medicines as the high cost of medicines in developing countries makes them unaffordable to large sectors of the population and increases the risk of counterfeiting.
- Call on your government and local industries to help develop materials on identifying counterfeit medicines and organise workshops for health professionals to make them aware of the problem.
- Develop a position statement on counterfeit and substandard medicines.
- Form partnerships with other health professionals, the pharmaceutical industry, importers, government and consumers to work together to fight the importation of substandard and counterfeit drugs.
- Inform community-based organisations and consumer associations about the problem of counterfeiting and provide them with information on how to identify counterfeit drugs and what procedures to follow when reporting any suspected counterfeits.
- Organise patient and public safety events and provide public education on counterfeit medicines. Disseminate brochures and posters, organise media events and publish a press release on medication safety (see sample).
- Improve patients' knowledge about their treatment. Discuss medicine use and contra-indications. Encourage patients to talk to you about any adverse effects.
- Be constantly alert to changes in the overall condition of patients, their response to treatment and any signs of toxicity or overdose, and take appropriate and timely action including referrals.
- Lobby local, regional and national governments to establish regulatory mechanisms where there are none and to actively prohibit the manufacture, import and sale of counterfeit drugs.

counterfeit medicines kill

Medicines must be safe, effective, and of good quality, and used appropriately. Quality medicines are lifesaving. Unfortunately, nowadays, many counterfeit medicines are reported to circulate in national and international market. Criminals who make money unlawfully produce these.

Counterfeit medicines:

- ❑ usually don't contain the active ingredients mentioned on their labels and/or have false manufacturer's names and/or country of manufacture on their labels.
- ❑ sometimes contain less quantities of the active ingredients stated on their labels or contain active ingredients that are different from those stated on their labels.

BE CAREFUL!!!!

If you take a counterfeit medicine you will not be relieved from your sickness quickly or you may not be cured at all. If the medicine you are taking is a counterfeit antibiotic or antimalarial resistance may develop and the disease may spread to affect more people. In extreme cases counterfeit medicines kill. Buying counterfeit medicines is a waste of money.

BE AWARE.....HOW CAN YOU AVOID COUNTERFEIT MEDICINES?

- Buy/Get your medicines from licensed pharmacies, medicines outlets, health centres and clinics.

**Get your medicines
from authorized sources**

SAMPLE PRESS RELEASE
Nurses Raise the Alarm: Counterfeit Medicines Kill!

Geneva, 12 May 2005 - Nurses worldwide are using the occasion of International Nurses Day to draw the public's attention to the dramatic increase of counterfeit drugs in today's global market. WHO estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever. In developing countries, up to 25% of the medicines used are counterfeit or substandard. Some estimates place the annual earnings from counterfeit medicines at over US \$32 billion globally.¹

Counterfeiting is not only costly to consumers, it is a particularly serious area of crime because it puts the lives and well-being of patients at risk, leads to loss of confidence of the medical profession and in the quality, safety and efficacy of the medicines they prescribe.

Counterfeit medicines can kill. In 1992, 233 Bangladeshi children died after taking a paracetamol-based syrup that was tainted with antifreeze. In 1995, 2,500 children in Niger died after taking a fake meningitis vaccination. Of the one million deaths that occur from malaria annually, as many as 200,000 would be avoidable if the medicines available were effective, of good quality and used correctly.

"Patients and consumers are the primary victims of counterfeit medicines. In order to protect them from the harmful effects of counterfeit medicines it is necessary to provide them with appropriate information and education on the consequences of counterfeit medicines," says Christine Hancock, President of the International Council of Nurses. "As frontline health care providers, nurses are key players in increased vigilance for counterfeit medicines and increased reporting of possible counterfeit drugs."

In their campaign to improve patient safety, nurses worldwide are hoping to raise awareness of the increasing availability of counterfeit and substandard drugs and to lobby for fair prices of medicines as the high cost of medicines in developing countries makes them unaffordable to large sectors of the population and increases the risk of counterfeiting, as well as compelling people who cannot afford legal medicines to seek out alternative sources. ICN is working with governments, industry and regulatory authorities in this initiative and encourages National Nursing Associations to do the same at the national level.

¹ World Health Organization (WHO) (2003). *Substandard and Counterfeit Medicines*, Fact Sheet no. 275. Retrieved December 2004 from <http://www.who.int/mediacentre/factsheets/fs275/en/>

Editor's note

The International Council of Nurses (ICN) is a federation of 125 national nurses' associations representing the millions of nurses worldwide. Operated by nurses for nurses since 1899, ICN is the international voice of nursing and works to ensure quality care for all and sound health policies globally.

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Facts and Figures - Counterfeit Medicines

51%	In a WHO survey between 1992 and 1994, as many as 51% of counterfeiting cases uncovered revealed that forged drugs carried no active ingredient whatsoever.
25%	The percentage of medicines, used in developing countries, which are counterfeit or substandard.
1 in 10	One in 10 medicines sold worldwide is fake, with no medical effect whatsoever (USFDA)
\$32 billion	Counterfeit medicines generate \$32 billion a year in sales for drug dealers.
233	In 1992, 233 Bangladeshi children died after taking a paracetamol-based syrup that was tainted with antifreeze.
2,500	In 1995, 2,500 children in Niger died after taking a fake meningitis vaccination.
200,000	The number of deaths per year from malaria that could be avoided if medicines were of high enough quality to actually treat the illness (WHO).
38%	The percentage of malaria medications in Southeast Asia which have no active ingredient.
2,500	The number of deaths from fake vaccines during the 1995 meningitis epidemic in Niger.
200,000	The number of counterfeit bottles of Lipitor, widely used to control cholesterol, which had made their way onto the market in 2003 (USFDA).
30	The number of people who died in Cambodia in 1999 after taking counterfeit antimalarials.
5%	The percentage of all antibiotics sold worldwide which are counterfeit.

Counterfeit Medicines

ICN Position:

The International Council of Nurses (ICN) is very concerned with the growing problem of counterfeit medicines and the negative consequences on the prevention and treatment of disease, which can include poor treatment outcomes, or failure of treatment, loss of confidence in health care, resistance to antibiotics and poisoning due to harmful ingredients.

ICN supports international initiatives to combat counterfeiting and urges nurses and NNAs to collaborate with pharmacy associations, pharmacists, physicians and others to disseminate accurate information on detection and elimination of counterfeit medicines. More specifically ICN supports actions that aim to:

- Strengthen quality assurance and medicines regulatory authorities.
- Detect and expose sources of counterfeit medicines.
- Improve supply of medicines to health facilities.
- Educate nurses in detection and prevention of counterfeit medicines.
- Monitor for any failure of treatment that could be a sign of counterfeit medicine.
- Educate and create awareness among the public of counterfeit medicines.

Background

According to the United States Food and Drug Administration (FDA), counterfeit medicines make up more than 10% of the global medicines available in the market and are available in both developed and developing countries. Though there is no accurate data, the World Health Organization has announced that up to 25% of medicines consumed in developing nations, often to treat life-threatening conditions, are believed to be counterfeit or substandard.¹ All medicines and even vaccines can be counterfeited with serious consequences to patients and the health care system.

Patients and consumers are the primary victims of counterfeit medicines. In order to protect them from the harmful effects of counterfeit medicines it is necessary to provide them with appropriate information and education on the consequences of counterfeit medicines. As frontline health care providers, nurses are key players in increased vigilance for counterfeit medicines and increased reporting of possible counterfeit drugs.

¹ World Health Organization (2003). Fact Sheet no. 275, Substandard and counterfeit medicines, November 2003, www.who.int.

Counterfeit medicines, as deliberate and fraudulent products with questionable efficacy, represent a serious challenge to the treatment or prevention of disease. According to the World Health Organization's definition² a counterfeit medicine is one, which is deliberately and fraudulently mislabelled with respect to identity and/or source.

Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

Counterfeit products may contain too much, too little or no active ingredient, the wrong ingredients or high levels of impurities, contaminants and even toxic substances. They could be reject or out-of-date formulations withdrawn from the market which are obtained by counterfeiters, relabelled as *bona fide* product and introduced back into circulation. Counterfeit medicines have killed and injured thousands of people around the world.

Adopted in 2004

Related ICN Positions:

- Antimicrobial resistance
- Participation of nurses in health services decision-making and policy development
- Patient safety
- Health information: protecting patient rights
- Informed patients

Related ICN Publications:

- Fact Sheet: Antimicrobial Resistance: World Health Professions Alliance

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² WHO Ibid.

Antimicrobial Resistance

ICN Position:

The International Council of Nurses (ICN) is very concerned with the widespread use of antimicrobial agents and the increasing global resistance, which is now a major public health problem. ICN calls for responsible prescribing and regulation and together with its member national nurses associations will:

- Work in partnership with consumers, physicians, pharmacists, veterinarians and others to prevent antimicrobial resistance, including establishing Codes of Practice for the use of antimicrobials.
- Lobby governments for policies regulating the licensing, distribution, and sale of antimicrobial agents.
- Collaborate with nursing education systems to address antimicrobial resistance at basic and continuing education levels.
- Provide patient and public education about the determinants of antimicrobial resistance and preventive measures such as adherence to treatment, inadequate dosing and counterfeit medicines.
- Support infection control policies and practices in health care settings that aim to prevent nosocomial infections.
- Ensure nurses and nursing organisations are part of national strategies for preventing antimicrobial resistance.
- Lobby to prohibit use as animal food additives of any antimicrobial agents used by humans.

Background

Nurses can play a key role in reducing antimicrobial resistance. Antimicrobial resistance is a result of poor practices such as poor adherence by patients, inadequate dosing, a substandard medicines or use of antimicrobials in animals and poultry for growth promotion or prophylaxis.

Antimicrobials were effective in control of many infectious diseases in the past. However, today many microbes are becoming resistant to antimicrobials and our ability to fight disease is under threat.¹ As a result there is re-emergence of old diseases, such as malaria and tuberculosis, and resistance in “new” diseases, such as HIV/AIDS. Nurses are key health professionals in administering antimicrobials and monitoring their effect.

¹ Microbes denoted the collective term for bacteria, fungi, parasites, and viruses.

The consequences of microbial resistance include prolonged illness, spread of resistant microbes, high health care cost and preventable deaths. The spread of resistant microbes is facilitated by factors such as urbanization with overcrowding and poor sanitation, environmental degradation, demographic changes with an ageing population, new diseases such as HIV/AIDS and growth in global trade and travel.

Adopted in 2004

Related ICN Positions:

- Counterfeit medicines
- Management of nursing and health care services
- Participation of nurses in health services decision-making and policy development
- Patient safety
- Health information: protecting patient rights
- Informed patients

Related ICN Publications:

- Fact Sheet: Antimicrobial Resistance: World Health Professions Alliance.
- TB Guidelines for Nurses in the Care and Control of Tuberculosis and Multidrug Resistant Tuberculosis (2004)

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