

# BE AWARE

Helping to fight counterfeit medicines,  
keeping patients safer

BACKGROUND FOR HEALTH PROFESSIONALS

INFORMATION FOR PATIENTS

SAMPLE REPORTING FORM

VISUAL INSPECTION FORM

INFORMATION FOR HEALTH PROFESSIONALS

POSTER



## Dear colleagues

The growing menace of counterfeit medicines presents a serious and increasing threat to patient safety and public health. As health professionals you all have ongoing responsibilities and some new ones, in ensuring that your patients receive safe and appropriate medications. The World Health Professions Alliance (WHPA)\* aims to support you in this essential work and has taken on the fight against counterfeits as a priority action area. We are committed to combating counterfeits through raising awareness among health professionals and providing some tools and strategies for detecting counterfeit medicines and for safely informing colleagues and patients. We want to raise the 'suspect' index for counterfeit medicines where patients on treatment do not report getting better or appear with new unexpected symptoms. At the same time WHPA is keen to manage the risk communication aspect of this effort, ensuring patient adherence to medicines.

The World Health Organisation (WHO) has established an International Medical Products Anti Counterfeiting Task Force (IMPACT) in order to bring together all stakeholders on the global level to fight counterfeit medical products. IMPACT requested WHPA to develop a toolkit for health professionals and patients.

Accordingly we have developed this toolkit to assist dentists, nurses, pharmacists and physicians to tackle counterfeit medicines in your daily practice.

### **The kit includes:**

1. An overview of the situation and suggestions as to what health professionals can do to help fight counterfeit medicines
2. A reporting form that can be copied and used to report any suspected counterfeit (This form serves as a model and does not replace any existing ones in-country)
3. A visual inspection check list that can be used if a counterfeit medicine is suspected
4. An information leaflet that you can share with colleagues
5. A patient information leaflet for distribution to patients or in community areas
6. A poster that can be put in waiting rooms

We encourage health professionals to use any or all documents as they judge appropriate and to share these with colleagues in the effort to raise awareness. Thank you for joining the World Health Professions Alliance in the fight against counterfeit medicines.

Sincerely,

**International Council of Nurses**  
**International Pharmaceutical Federation**  
**World Dental Federation**  
**World Medical Association**

\* The World Health Professions Alliance brings together the International Council of Nurses, the International Pharmaceutical Federation, the World Dental Federation and the World Medical Association and speaks on behalf of more than 25 million health care professionals worldwide.

# Some Background

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.

Counterfeiting can apply to both brand-name and generic products, prescription medicines and over the counter medication, as well as traditional remedies. Counterfeits may contain different ingredients, both harmless and toxic, or different quantities of ingredients.

## Threat to patient safety

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 cause harm to the patient. Counterfeit medicinal products threaten patient safety by, at best, causing no improvement or, worse, causing added burden of disease and even death. They endanger public health by increasing resistance to some medicines (for example antimicrobials, anti-malarials) and patients' trust in health professionals and health systems, who are seen not to be able to provide adequate treatment. Public health and patient safety are being put at risk and now is the time to act.

## The scope of counterfeits in health systems

It is reasonable to estimate that the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries, to between 10-30 percent in developing countries, depending on the geographical area<sup>1</sup>.

Counterfeiting tends to be greater where regulatory and legal oversight is weak, and differs from rural to urban settings even within a country. This is why each health professional has a role to play in helping to stop these medicines reaching patients and endangering their health.

## What can health professionals do?

There are some key steps that health professionals can take to identify and report counterfeit medicines, to help fight such criminal practices and make treatments safer.

### BE AWARE<sup>2</sup>

**B**e observant. Become familiar with the WHPA visual inspection tool so you can identify counterfeit medicines. If anything about medicines is unusual or different, consider counterfeit medicines.

**E**valuate your patient's response to the medicine use. If treatment fails, or has an unexpected effect, consider counterfeit medicines as possible suspects.

**A**cquire as much information as possible about the product, its packaging, pharmaceutical properties and usage.

**W**here was the product procured? Find out whether it was purchased from a known and reliable source.

**A**ctively inform your health professional colleagues if medicines have been confirmed as counterfeit, as well as other patients who might also have received the medicines.

**R**emove any suspect medicines from the pharmacy, clinic, hospital or consulting room. Report the suspected counterfeit to the relevant health authorities.

**E**ducate your colleagues, patients and the public to identify and avoid counterfeit medicines by purchasing their medicines from known and reliable sources.

<sup>1</sup> International Medical Products Anti-Counterfeiting Taskforce (IMPACT), set up by the World Health Organization, to fight counterfeit medicines.

<sup>2</sup> This acronym has been developed by the WHPA for the purpose of this toolkit.

## Communication with patients

Many counterfeit medicines are first detected by patients. Health professionals should share any concerns about counterfeit medicines with their patients in a safe and non-threatening manner, ever mindful of unnecessarily undermining adherence to treatment.

A patient information leaflet can be available in waiting rooms, on counters, and in common areas, for patients to read. A poster can be placed on the walls of medical and nursing practices, pharmacies, clinics, hospitals and community centres. Patients may then ask about the subject or wish to discuss it spontaneously.

There are several points of contact where the subject of counterfeit medicines can be discussed, for example at consultation, during diagnostic tests, when the treatment is being prescribed, at the medicine purchase point, when monitoring treatment. A patient may feel vulnerable because of being unwell; discussion might be experienced as threatening or invasive.

**It is important to query gently, by asking about:**

**1. Where** patients will or did buy the medicine. Emphasis can be placed on the importance of buying medicine from a pharmacy or other known and reliable sources.

*For example: "Did you purchase the medicine from a known and reliable source?"*

**2. What** patients should look out for when they buy medicines. It can be suggested that patients check the packaging, the product and the patient leaflet when they purchase medicine.

*For example: "Was the packaging of the product intact, properly sealed, clearly labeled with dosing, manufacturer, batch number, and expiry date?"*

**3. How** the medicine is expected to take effect. By explaining what should happen when patients take medicine, health professionals can help patients identify anything unusual.

*For example: "Did the medicine cause any unexpected side effects?"*

**4. When** the first improvements in condition should be experienced. If a medicine is supposed to start relieving symptoms within 24 hours for example, then patients should know, so that if the medicine does not take effect, they can notify their health professional.

*For example: "Has the medicine taken longer than anticipated to have an effect?"*

## In daily practice

When prescribing, dispensing or administering medicines, health professionals should explain to patients in what way the medicine should improve their health and what benefits and/or side effects patients may experience. It can be suggested that medicines should only be obtained from known and reliable sources.

### **Health professionals can encourage patients to:**

- Buy their medicines from known and reliable sources.
- Purchase their medicines from properly trained personnel, such as properly qualified pharmacists.
- Tell their health professional about any problem, lack of reaction, overreaction or adverse event subsequent to using the medicine.
- Discuss the possibility that a medicine may be counterfeit only where there is no response or an unexpected response to the medicine.
- Remain vigilant about the possibility of counterfeit medicines.

### **If counterfeit medicines are suspected, health professionals should:**

- Ask patients to bring in their medicine. Compare the medicine with other samples.
- Use the WHPA visual inspection tool to assess the suspected counterfeit medicine.
- Act quickly to change the medicine if it is substandard or counterfeit.
- Report the suspected counterfeit to the appropriate authorities.
- Reassure the patient on the way forward and reassess therapy accordingly.
- Assist in ensuring replacement of any suspect medicines so the patient is not left without treatment.

### **Taking precautionary measures**

It is important that once a counterfeit medicine has been identified, precautions are taken to prevent others from being exposed.

- Warn colleagues and management that counterfeit medicines have been identified in the workplace.
- Suggest that health professionals be vigilant in case more counterfeits are circulating.
- Warn the relevant authorities in your workplace that counterfeit medicines have been found
- Spread the word that the criminals are being sought: this sometimes dissuades further action.
- Verify whether any patients have not responded to or had an unexpected response to medicines.
- Reassess possibilities that other counterfeit medicines may be present.
- Follow up with patients if counterfeit has been confirmed to discuss next steps in treatment.
- Address any questions and concerns patients may have through information and discussion.

# Sample media questions and answers

This document can be used as a prompt when dealing with the media. Health professionals talking to media should at all times maintain patient confidentiality. Answers should be adapted to the local situation.

## General questions

### 1. What is a counterfeit/fake medicine?

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. What kinds of medicines are likely to be counterfeited?

Counterfeiting can apply to both brand name and generic products, prescription medicines and over the counter medication, as well as to traditional remedies. They may contain different ingredients, both harmless and toxic, or different quantities of ingredients.

### Examples of the kinds of medicines that have been counterfeited (non-exhaustive list)

Analgic	Cholesterol-reducing
Anaesthetic	Erectile stimulant
Antacid	Hormones
Anti-asthmatic	Immune booster
Anti-depressant	Oncology treatment
Antimicrobial	Osteoporosis treatment
Anti-malarial	Vaccine
Antiretroviral	Weight loss
Cardiac	Wound healing

### 3. What is the scale of counterfeit medicines worldwide?

It is difficult to determine the actual scale of counterfeit medicines worldwide. It is estimated that the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries, to between 10-30 percent in developing countries, depending on the geographical area. It is estimated that medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases .

### 4. Why do people make counterfeit medicines?

Making counterfeit medicines is a criminal activity that endangers people's lives for the sake of huge profits.

### 5. What is the punishment for a counterfeiter?

Punishment for counterfeit varies widely according to countries, and can range from a small fine to imprisonment and a fine. In some countries enforcement is not strong and counterfeiters get off very lightly.

### 6. What can people do to fight counterfeit medicines?

**Health professionals** can talk to patients and colleagues to raise awareness. They should report any suspect medicines and reach out to any other patients who might have taken the medicines too.

**Patients** should: Be aware that counterfeit/fake medicines exist. Purchase their medicines from safe sources. Suspect any unnaturally low-priced medicine. Be attentive to packaging and presentation of medicines. Notice any unexpected reactions to the medicine.

The **media** can help by reporting responsibly and accurately on the danger of purchasing medicines from unsafe sources, by spreading the word to warn patients if counterfeit medicines have been found.

**Authorities** can fight counterfeit medicines by supporting health professionals, putting proper legislation in place, financing secure health systems, working with police and customs, and ensuring that legislation is enforced.

## Country-specific questions

### 1. What medicine was found to be counterfeit in this country?

(Answer accordingly. In general, it is better to use the name of the active ingredient and the condition the medicine treats, rather than the brand name, to avoid loss of confidence in the product)

### 2. How was the counterfeit/fake medicine discovered?

(Answer accordingly. It may be a patient who reported no effect/bad effects, it may be a health professional who identified a counterfeit, it may be the police, or another source.)

### 3. Were any lives lost?

(Answer accordingly.)

### 4. What has been done to stop more such medicines from harming other people?

(Answer accordingly. You may need to check with the relevant authorities what you can or cannot say for legal reasons)

## For further information



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### **World Medical Association**

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### **Other useful references**

[www.who.int/impact/](http://www.who.int/impact/)  
[www.who.int/medicines/services/counterfeit/en/](http://www.who.int/medicines/services/counterfeit/en/)