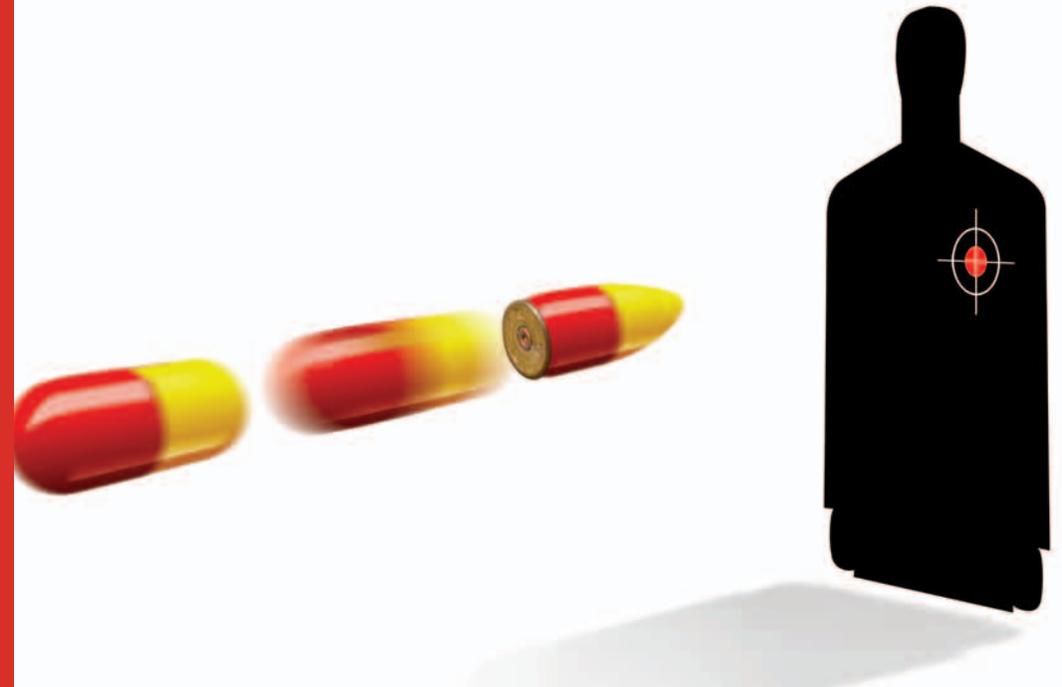


COUNTERFEIT DRUGS KILL!



**counterfeit drugs are silent killers
distributed by criminals**

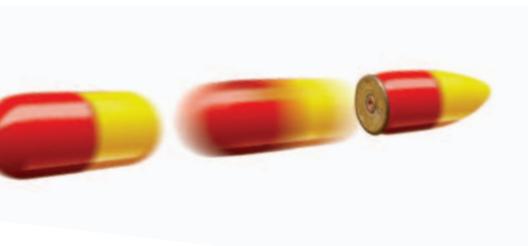
A GUIDE FOR HEALTH PROFESSIONALS

YOUR PHARMACIST... YOUR BEST GUARANTEE



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1- WHAT ARE COUNTERFEIT MEDICATIONS?

Counterfeit medications are in fact non-medicinal products manufactured illegally with no regards to the safety of their contents or inclusion of active ingredients that treat illnesses. Their sole purpose is to make money for the criminals who make and distribute them, selling them clandestinely often at less than the price of originals to enhance their marketing appeal.

Counterfeit medications are silent killers packaged to look like originals to create confusion among unsuspecting patients who buy and consume them to the detriment of their health.

The main concerns about counterfeiting medications involve neither intellectual property rights, nor adequate tax collection. This is first and foremost a public health issue as patients who use them tend to not improve their conditions or suffer even worse complications and potential death.

2- CURRENT STATUS IN LEBANON

The country is facing a problem of principle, definition and notion in terms of health:

- What's a patient? Is he/she a care seeker or a client?
- What's a drug? Is it a healthcare product or a consumer good?
- What's a pharmacist? Is he/she a healthcare professional or a simple trader?

Important questions remain unanswered by those in charge who are required to face a major challenge and make crucial choices.

When it comes to health, no matter how minimal details seem, they are in fact, of a great importance. The quality of health care depends upon the quality of medicinal drugs which relies on a chain of responsibility (manufacturing, importing, distributing and dispensing) that must be **respected and controlled**.

a- Pharmacies

The conditions for proper dispensing that provide quality control of medications are:

- Favoring the concept of the professional pharmacist whose priority is the patient's health, instead of the greedy merchant whose main concern is the lure of profit. The professional pharmacist:
 - Ensures or provides the dispensing of medication
 - Provides follow-up, especially for chronically ill patients
 - Provides patient education regarding the use of medicines (counseling)
 - Controls and approves the physician's prescription
 - Stops the abuse of drugs
 - Provides a secure service to the patient
 - Direct contact with the patient
 - Dominant confidence factor
- In addition, a good pharmacist is personally engaged with the patient and adheres to public health and professional ethics to ensure safety.

The amendment of article 80 of the law governing the pharmacy profession (according to which the pharmacist must dispense drugs at the price fixed by the Ministry of Public Health) provided pharmacists with leeway to maneuver prices at will, leading to unfair competition resulting in the following consequences:

- Professional pharmacists turned into traders, forced to attract "customers" by cutting prices in order to keep up with competition and lure patients to their "store"
- Pharmacists were stripped of their professional dignity
- Chaos reigned in terms of medication pricing
- Counterfeit and smuggled drugs made a breakthrough on a pharmaceutical market needing to compete among itself
- Sales of expired drugs thrived
- The national medications bill rose

Family education, conscience, ethics and professional training of many pharmacists have so far prevented the massive spread of counterfeiting and sub-standard medications, despite Lebanese laws and a health care system that effectively promote their prevalence.

Therefore, it is necessary to repeal – urgently – article 80 to fix



the system and eliminate unfair competition among pharmacists, in order to guarantee the safety of patients.

Pharmacists are at a pivotal final link in the healthcare chain and key at assuring the quality of drugs. Therefore, it is necessary to increase their awareness and to implicate them in the fight against counterfeit and sub-standard medications because their vigilance can prevent the introduction of counterfeit and questionable-quality medications in the pharmaceutical chain.

b- Hospitals

Hospital pharmacists are the guarantor of dispensing quality medications at hospitals:

- They should check and ensure proper adherence to rules, supply chains, management, storage, preparation of, and the control and dispensing of medications
- They should lead and/or participate in informing doctors on specifications of medications as far as content, quality and potential drug interactions
- They should lead and/or participate in every action that may contribute to the quality and security of medicinal treatments

Current Status:

- Hospital pharmacists lack all their basic privileges
- In most cases, they have no decision-making power when it comes to the choice of drugs appearing on the hospital guidelines (should such guidelines exist)
- In most cases, pharmacists cannot follow up on patient treatments because of easily offended physicians
- In some cases, they are not included in any of a hospital's scientific committees

c- Dispensaries

Dispensaries have not been subjected to regular or systematic examinations for 50 years, allowing some of them to freely issue counterfeit, questionable-quality and smuggled drugs. It is necessary to conduct a field survey on the number of dispensaries in the country, and the types of medications they are dispensing. It is also essential to separate politics and related interests from the health care system!



3- FACTORS FACILITATING COUNTERFEITING

Economical

- High prices of original drugs, largely due to the costs of bringing them to market after years of clinical studies as well as other factors
- Unfair competition, linked to size and "market share" of various pharmacies pricing at will instead of adequately regulated fixed rates
- Corruption, which tends to be rampant on various levels

Legal gaps

- Weak national regulatory system
- Weak enforcement
- Low penalties
- Denial of the problem by the government, industries...

Globalization

- Parallel trade
- Free zone for trade
- Repackaging

Other factors

- Technology: promotion and trade through internet
- Free delivery



4- HOW CAN WE EXPLAIN THE RISE OF MEDICINES COUNTERFEITING?

A rise in organized crime is at the root of an ever-growing counterfeit medications market, especially considering that this trade poses less legal and technical risks than narcotics trafficking. Some key highlights:

- Blockbuster medicines (i.e. medicines with high annual turnover) which represent strong stakes for counterfeiters
- New technology has made it easier to produce counterfeit products, especially in regards to copying labels
- Market globalization facilitates trading in counterfeit medicines, with the internet making it easier for patients to have direct access to self-prescribed medicines of often questionable quality

Regulation of medicines distribution is insufficient in many countries in terms of enforcement and sanctions; therefore, not dissuasive enough for counterfeiters.

5- WHAT ARE THE RISKS FOR HEALTH?

Counterfeit medications and healthcare products expose patients who use them to high risks, since they generally do not meet expected quality, effectiveness and security criteria.

- The use of a medicine which does not contain the correct dose of active ingredient (under-dose, over-dose or no active ingredient) or which may contain another active ingredient than the one claimed can damage patient health: no therapeutic effects, complications...
- The potential presence of toxic substances can also damage patient health
- In the case of internet sales, distribution channels do not follow legal pharmaceutical chains controlled by health authorities which means that neither quality nor preservation conditions are guaranteed
- Patients who buy medications – whether counterfeit or not – on the internet without a prescription do not benefit from any medical advice and can therefore misuse drugs (inappropriate or counter-indicated medicines, risky medicines interactions...). Internet-ordered medicines are mostly treatments for erectile dysfunction and anorexigens.

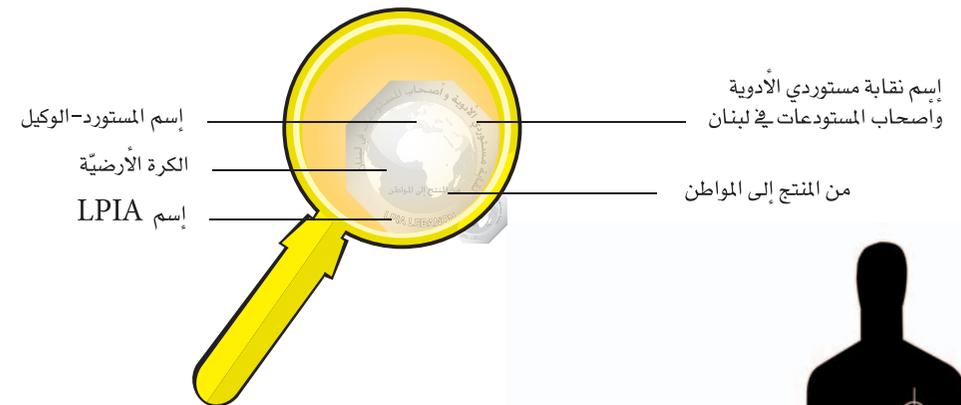


6- HOW TO RECOGNIZE A COUNTERFEIT PRODUCT



Below is an outline of only a few details which need to be looked out for:

- a surprisingly low price;
- batch number and expiry date that do not fit with those usually used by the pharmaceutical manufacturer;
- unknown distribution channel;
- packaging (i.e. medicine cardboard) which is not similar to the original;
- a patient reports new side effects: this is often the first way to detect counterfeit medicines;



- a patient complains about the quality of a medicine
 - Look for features such as hologram, colour-shifting ink or supplier's label
- Nevertheless, the packaging of some counterfeit medications



can really be well done and hard to detect from originals.

7- WHAT IS THE ROLE OF PHARMACISTS TOWARDS THEIR PATIENTS?

As key health promoters, pharmacists should warn patients about the risks of counterfeiting. They should pay attention to potential signs noticed by patients. In addition, pharmacists should discourage patients from using illegally imported medications (often sold outside the realm of pharmacies), since neither their preservation conditions nor their quality can be guaranteed. Pharmacists should explain why the right to dispense medicines is legally granted to pharmacists only, which essentially is to ensure that only licensed and regulated pharmacists provide quality medicines to the public.

8- ACTION PLAN

a- Actions of international organizations

- World Health Organization (WHO)
- IMPACT: International Medical Product AntiCounterfeiting Taskforce. IMPACT is a taskforce launched by the WHO to gather all the most important international actors in the fight against counterfeiting. IMPACT aims at coordinating global action against the counterfeiting of medical products in order to promote and protect public health.
- The WHO organized an international conference on combating counterfeit medicines leading to the Declaration of Rome in February 2006 (page 9)
- The WHO created a reporting form for counterfeit medicines for community pharmacies (page 10)
- Conférence Internationale des Ordres de Pharmaciens Francophones (CIOPF)
- The CIOPF organized a meeting intersession of French-speaking Orders in Beirut (February 2006) where the "Beirut Convention" was adopted, in which the pharmacist commits to secure the patients' health in terms of

counterfeit drugs (page 11).

The CIOPF created a position: "Référént Contrefaçon" (counterfeit specialist) whose mission is:

- To assure a coordination and exchange of information on counterfeit drugs between the French-speaking Orders
- To raise awareness and provide the public with information
- To develop appropriate vigilance and to collect data from the patients, health care professionals and the chain of distribution
- To collaborate with any organization having the same targets with the concern of protecting public health
- As preventive actions, traceability tools and authentication means of health products have been developed:
- Datamatrix (2-dimension barcode) is under implementation in Europe and will enable batch traceability. It includes a medicine codification (through the CIP code) of 13 numbers and the expiry date; an individualized box number can also be included;
- RFID (Radio Frequency Identification) which enables sale unit traceability. It is an electronic chip that can be read contact-less.
- Visible (holograms, variable-reflection inks) or hidden authentication means (i.e. chemical markers, hidden image) which are more complex to counterfeit.

b- Actions of the local organizations

- Lebanese Order of Pharmacists
- Increase public awareness: media
 - Television
 - Print press
 - Radios
 - Billboards



- Education and information:

- Brochures for pharmacists, doctors and the public
- Posters
- Conferences: health care professionals, customs, press, inspectors of the Ministry of Public Health
- Press conferences

- Other means:

- Better distribution of information and data at the national and the international level
- Enforcing of the law
- Better sensitization of the public
- Obtaining drugs through suppliers authorized by the Ministry of Public Health
- Creating declaration forms for the pharmacists
- Engaging political commitment and the will of the governments of the world to fight counterfeiting
- Reinforcing and protecting the pharmacy profession, the pharmacist being the key-person
- Involving the pharmacist in the fight against counterfeit -drugs

- Lebanese Pharmaceutical Importers Association

- Joint circular of the Lebanese Order of Pharmacists and the Lebanese Pharmaceutical Importers Association
 - Hologram
 - Advertising campaign
 - Brochure to the patients
 - Posters to the patients to be displayed in pharmacies

- Ministry of Public Health

- Confiscation of counterfeit drugs



- Issuing circulars signed by the Minister of Health, listing the confiscated counterfeit drugs and forbidding their utilization
- Collaboration with customs, the public prosecutor and the Lebanese Order of Pharmacists

9- WHAT IS THE PROCEDURE TO BE FOLLOWED FOR A PRODUCT SUSPECTED OF COUNTERFEITING?

How to act faced with a forged product?

- Download (from the Lebanese Order of Pharmacists website: opl.org.lb), fill in and return the declaration form on counterfeit drugs to the Drug Information Center (DIC). Fax: +961-(0)1-611342
- Centralize data through the Drug Information Center at the Lebanese Order of Pharmacists
- Convey the data to Dr. Ziad NASSOUR (counterfeit specialist to the CIOPF) who in turn will submit it, through the Lebanese Order of Pharmacists, to the Ministry of Public Health and to the concerned laboratories which will send the confiscated drugs for analysis
- The results of analyses will be communicated by the laboratory to the Ministry of Public Health and the DIC for data archiving
- Once the report is transmitted by the pharmacist, an internal procedure established by the Lebanese Order of Pharmacists is applied: information of health centers of the Ministry of Justice, the Ministry of Health and other concerned administrations (fraud, customs, specialized brigades)
- Counterfeit products spotted in distribution networks must be kept separately from other pharmaceutical products to avoid any confusion
- Any reception of spotted counterfeit products must be recorded at the time of its execution
- These products must be identified by a mention pointing out clearly that they must not be sold
- The competent authorities, the product license holder of the original product or the supplier must be informed without delay



10- WHERE TO FIND THE NECESSARY TOOLS TO INQUIRE?

Every party involved in the pharmaceutical chain (scientific offices, importing agents, Ministry of Health, community pharmacists, and hospital pharmacists) has a certain number of information:

- On the website of the Lebanese Order of Pharmacists: www.opl.org.lb

- Index of scientific bureaus
- Index of the suppliers (importers)
- List of drugs
- Circulars, information centers, alerts... on counterfeit drugs that the pharmacist can make available to patients

- On the website of the Ministry of Public Health:

www.public-health.gov.lb

- List of registered drugs
- List of the coefficients

- Through the scientific bureaus and the Lebanese

[Pharmaceutical Importers Association: lpia@inco.com.lb](mailto:lpia@inco.com.lb)

As part of prevention actions, an authentication tool for health products is developed: hologram, variable-reflection ink.

- On the website of the CIOPF: www.ciopf.org

- On the website of the World Health Organization: www.who.int

11- WHAT IS THE LEGISLATION APPLICABLE TO THE FIGHT COUNTERFEIT DRUGS?

The marketing of counterfeit healthcare products is an infraction to several legislations:

- Intellectual property rights code
- The law governing the practice of the pharmacist profession
- Customs code
- Public health code

The infractions can be notified by:

- Fraud repression services
- Customs services
- Police officers

Infractions to public health code can be notified by MOH inspectors or by OPL pharmacy inspectors.

Fight against counterfeiting relies partly on the cooperation between the OPL, the customs services and the MOH. Regular cooperation has been established.

The whole distribution chain involving importers, marketing authorizations owners, manufacturers, wholesalers and dispensing points are inspected either by MOH or OPL pharmacy inspectors.

Pharmaceutical companies are under the responsibility of pharmacists who are registered at the Lebanese Pharmacist Order and medicines have all been approved by the MOH through its technical committee.

This triple authorization architecture (company, pharmacist and product) and regular inspections on it, contribute to the fight against fake and counterfeit medicines.



CHARTRE DE BEYROUTH

DÉCLARATION

Adoptée à Beyrouth
18 Février 2006

LES PHARMACIENS S'ENGAGENT POUR PRÉSERVER LA SÉCURITÉ DES PATIENTS FACE AUX MÉDICAMENTS

Il y a un paradoxe au niveau mondial : nous investissons beaucoup pour découvrir et approuver des médicaments utiles pour la santé mais nous n'investissons pas assez pour contrôler les systèmes de distribution de ces mêmes médicaments.

Conscients de leurs responsabilités en tant que professionnels de santé, les membres de la conférence internationale des Ordres de Pharmaciens Francophones (CIOPF) constatent avec inquiétude le développement dans les médicaments d'origine douteuse ou contrefaits,

- Soit au niveau du circuit légal de distribution du médicament
 - Soit par les circuits illégaux de distribution : pharmacies par terre, ventes illégales sur Internet, etc.
- Parallèlement, la banalisation du médicament aux yeux du public est un facteur supplémentaire de risque pour la santé publique. Les médicaments ne peuvent pas être traités comme des produits commerciaux ordinaires : ils sont dangereux.

Dans le respect des recommandations de la Fédération Internationale pharmaceutique (FIP) sur les contrefaçons de médicaments(1), poursuivant leurs efforts pour préserver la sécurité des patients face aux médicaments, les membres de la Conférence Internationale des Ordres de pharmaciens Francophones (CIOPF) recommandent une attention et une responsabilisation de tous les acteurs.

LES MEMBRES CIOPF RECOMMANDENT AUX PHARMACIENS :

- D'exiger une chaîne spécifique de sécurité par le marquage des lots en utilisant des technologies permettant d'assurer la traçabilité depuis le fabricant jusqu'aux pharmacies de ville et hospitalières, d'une part des médicaments et d'autre part des intermédiaires qui sont intervenus dans la distribution d'un médicament.

- D'avertir les patients et le public en général des liens aux circuits illégaux du médicament : Pharmacies illégales, proposées sur Internet,...

Exemples de risques associés :

- Médicaments périmés :
- Absence d'emballage original : les médicaments sont présentes en vrac :
- Condition de transport inadéquates conduisant à une altération du médicament (température, ...) :
- Notice dans une langue étrangère :
- Médicaments contrefaits selon la définition de l'Organisation Mondiale de la Santé (OMS) ;
- Médicaments parfois non livrés (dans le cas d'achat sur Internet)

- De s'approvisionner auprès de sources fiables et respectant les bonnes pratiques de distribution.

- De veiller à ce que les conditions de conservation aient été respectées tout au long De la chaîne pharmaceutique et jusqu'au patient (risque de dégradation ou d'inactivation du principe actif, développement d'une toxicité,...)

- D'agir pour maintenir à l'officine la qualité et la sécurité du médicament en mettant en place des procédures internes d'assurance qualité et contrôles.

- De respecter les bonnes pratiques officinales, notamment en s'appuyant sur celles développées par la Fédération Internationale Pharmaceutique (FIP).

1- Fédération Internationale Pharmaceutique. Déclaration de principes de la FIP : les contrefaçons de médicaments.2003

2- Un médicaments contrefait est un médicaments qui est délibérément et frauduleusement muni d'une étiquette n'indiquant pas son identité et/ou sa source véritable. Il peut s'agir d'une spécialité ou d'un produit générique, et parmi les produits contrefaits, il en est qui contiennent les bon ingrédients ou de mauvais ingrédients, ou bien encore pas de principe actif et il en est d'autres ou le principe actif est en quantité insuffisante ou dont le conditionnement a été falsifié. Guide pour l'élaboration de mesures visant à éliminer les médicaments contrefaits. OMS Genève 1999.

- De veiller à ce que la dispensation des médicament se fasse dans des conditions assurant la sécurité du patient : analyse de la demande, questionnement du patient, délivrance accompagnée de conseils pharmaceutique et réalisée par un personne qualifié.

- D'avertir le public des dangers de l'automédication sans le recours préalable à un professionnel de santé.

- D'informer l'autorité national en charge de la lutte contre les contrefaçons de médicaments des cas rapportés par les patients ou suspectés par le pharmacien lui-même.

- D'informer les autorités en charge de la pharmacovigilance de tout effet indésirable inattendu rapporté par un patient ou identifié par le pharmacien.

LES MEMBRE DE LA CIOPF RECOMMANDENT AUX POUVOIRS PUBLICS :

- De renforcer la réglementation pharmaceutique

- De reconnaître les spécificités du médicament et le soustraire à une politique fondée sur les seuls critères de concurrence, d'ouverture des marches, de déréglementation ou de concurrence déloyale.

- D'encadrer la fabrication et l'importation des médicaments afin d'empêcher l'entrée de médicaments contrefaits dans la chaîne pharmaceutique

- D'établir une réglementation assurant une lisibilité de tous les acteurs intervenants dans la chaîne de distribution et de dispensation du médicament.

- De s'engager contre toutes les sources illégales de dispensation du médicament qui représentent dans tous les cas un niveau d'insécurité inacceptable pour les patients.

- De développer des stratégies transnationales et pluridisciplinaires de lutte contre les contrefaçons qui intègrent les professionnels de santé, les organisations professionnelles devant sanctionner les pharmaceutiques.

- D'exprimer leur volonté que les recommandations de l'Organisation Mondiale de la Santé (OMS) en matière de dons de médicaments soient respectées. Tous les circuits doivent offrir les mêmes sécurités aux patients.

LES MEMBRES DE LA CIOPF RECOMMANDENT AUX PATIENTS :

- De se rappeler que tout médicament peut être dangereux.

- D'éviter le recours aux médicaments sans l'accompagnement d'un professionnel de santé.

- De suivre les conseils du pharmacien pour chaque prise de médicaments.

- De se procurer leurs médicaments uniquement dans le circuit officiel de distribution du médicament.

- D'informer le médecin et les autres professionnels de santé de tous les médicaments utilisés.

- Dans le cadre de l'achat de médicaments sur Internet dans les pays où cette pratique est autorisée :

- De vérifier les éléments essentiels permettant une identification de la pharmacie en ligne : adresse postale, téléphone, fax, nom du titulaire, numéro d'inscription à l'ordre, numéro de licence,...
- En cas de doute, de contacter l'Ordre local pour vérifier le caractère légal de la pharmacie.



SIGNATAIRES DE CETTE DÉCLARATION :

LES ORDRES DES PHARMACIENS FRANCOPHONES PRÉSENTS À BEYROUTH
LE 18 FÉVRIER 2006

Le Président de la CIOPE : M. Jean Parrot

Pour les Ordres des Pharmaciens :

D'Algérie: M. Abdelfetah Meghezzi-Bekhouché

Du Bénin: Mme Moutiatou Toukourou

Des Comores: M. Mohamed Abdoulkarim

Du Congo: M. Hyacinthe Ingani

De la Côte d'Ivoire: M. Charles Boguifo

De la France: M. Jean Parrot

De la Guinée: M. Fodé Ousson Fofana

Du Liban: M. Ziad Nassour

Du Maroc: MM. Med Laghdaf Rhaouti et salaheddine Karim-El-Alaoui

De Mauritanie: M. Ousmane Bocoum

Du Sénégal: M. Yérém Diop

Du Togo: M. Sakariyaou Tidjani

De Tunisie: M. Ali Naas



Déclaration de Rome

CONCLUSIONS AND RECOMMENDATIONS OF THE WHO INTERNATIONAL CONFERENCE ON COMBATING COUNTERFEIT MEDICINES **DECLARATION OF ROME** **18 FEB 2006**

The participants of the WHO International Conference
"Combating Counterfeit Drugs: Building Effective International Collaboration",
gathered in Rome on 18 February 2006

DECLARE

1. Counterfeit medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.
2. Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.
3. Combating counterfeit medicines requires the coordinated effort of all the different public and private stakeholders that are affected and are competent for addressing the different aspects of the problem.
4. Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.
5. National, regional and international strategies aimed at combating counterfeit medicines should be based on:
 - a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on public health and providing the necessary tools for a coordinated and effective law enforcement.
 - b) Inter-sectoral coordination based on written procedure, clearly defined roles, adequate resources, and effective administrative and operational tools,
 - c) Creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public,
 - d) Development of technical competence and skills in all required areas,
 - e) Appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public.
6. The WHO should lead the establishment of an International Medical Products Anti-counterfeiting Taskforce (IMPACT) of government, non-government and international institutions aimed at:
 - a) raising awareness among international organizations and other stakeholders at the international level in order to improve cooperation in combating counterfeit medicines taking into account its global dimensions
 - b) raising awareness among national authorities and decision-makers and calling for effective legislative measures in order to combat counterfeit medicines
 - c) establishing effective exchange of information and providing assistance on specific issues that concern combating counterfeit medicines
 - d) developing technical and administrative tools to support the establishment or strengthening of international, regional and national strategies
 - e) encouraging coordination among different anti-counterfeiting initiatives.

The IMPACT shall function on the basis of existing structures/institutions and will in the long term explore further mechanisms, including an international convention, for strengthening international action Against counterfeit medicines.



Reporting form for counterfeit medicines detected in pharmacies

Definitions: A counterfeit medicine is deliberately and fraudulently mislabeled with respect to identity, composition and / or source. (Who)

Please tick the respective box or write in block letters

Rx	OTC	source of supply:	local wholesaler	re-import
			Other pharmacy	other source

Brand name: **main active substance:**
 (of suspected counterfeit medicine)

Strength:

Dosage form: package size:

Batch number: expiry date:

Is the medicine suspected to be counterfeit or substandard?

Counterfeit substandard

Why is this medicine suspected to be counterfeit?

How was the suspected counterfeit medicine detected?

Visual inspection Laboratory test

Other investigation (specify)

What measures were taken to prevent the risk of possible harm by the suspected counterfeit?:

What is the most likely source for the suspected counterfeit medicine?

What is the suspected country of origin of the counterfeit medicine?

Name of pharmacist (please print)	Name of the pharmacy:
Phone number	Street (or P.O.B.)
Date	Postal code and city:

Please send this reporting form to the Pharmaceutical Society of your country



Contact list

Lebanese Order of Pharmacists

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