

**FIP Framework for Establishing  
National Guidelines for Pharmacists  
in Combating Counterfeit Medicines**

**2009**



## Foreword

This document has been developed by the International Pharmaceutical Federation (FIP). It aims to provide FIP member organisations with a framework facilitating the development of a national Guide for pharmacists in counterfeit medicines.

It is recommended that national guidelines of this nature should be a joint document between national associations of pharmacists or related professional groups and the ministry of health (or the national Drug Regulatory Agency). This tool should be considered as a first step to establishing and/or strengthening partnerships between pharmacists' organizations and other key stakeholders on counterfeit medicines, through an action plan established amongst the different partners.

This document was based on many references collected and used; here are 6 major ones:

1. WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) documents
  - Principles and Elements for National Legislation against Counterfeit Medical Products: an update with special reference to counterfeit medical devices
  - Counterfeit medical products and the Internet
  - National Drug Regulatory Agency Data Collection Tool for assessment of national situations
  - Sampling strategy for national drug regulatory agencies
  - IMPACT Communication Strategy
  - National Drug Regulatory Agency response to suspected cases of counterfeit medical productsFor more information and updates on IMPACT, please visit [www.who.int/impact](http://www.who.int/impact)
2. FIP Statement of Policy on Counterfeit medicines. Sydney 2003. Available on <http://www.fip.org>. Latest access on 14th November 2008.
3. World Health Professions Alliance. BE AWARE – Helping to fight counterfeit medicines, keeping patients safer. Geneva (Switzerland): 2007. Available on <http://www.whpa.org>. Latest access on 14<sup>th</sup> November 2008.
4. MHRA/RPSGB. Counterfeit medicines – Guidance for Pharmacists. London (United Kingdom): Available in English at: <http://www.rpsgb.org/pdfs/counterfeitmedsguid.pdf>. Latest access on 14<sup>th</sup> November 2008.
5. Afssaps/Ordre national des pharmaciens. Guide à l'usage des pharmaciens. Paris (France): 2007. Available in French at: <http://www.ordre.pharmacien.fr/upload/Syntheses/242.pdf>. Latest access on 14<sup>th</sup> November 2008.
6. CIOPF/Ministère de la Santé libanais/Ordre des pharmaciens du Liban/EmroPharm Forum. Counterfeit medicines kill: a guide for healthcare professionals. Available in English and in French at: <http://www.fip.org/combatacounterfeitmedicines>. Latest access on 14<sup>th</sup> November 2008.

In this document, useful information for pharmacists on combating counterfeit medical products is provided in the context of the recommended content framework of a national guide. National pharmaceutical associations will also find specific red box sections which will require their input in order to make the guide relevant for their pharmacists.

FIP requests all Member Organizations to send an electronic or paper version of their present and future Guides to [fip@fip.org](mailto:fip@fip.org) or at FIP, Andries Bickerweg 5, PO Box 84200, 2508 AE The Hague, the Netherlands.

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## Definitions of a counterfeit medicines and extension to counterfeit medical products

Several definitions of counterfeit medicines and counterfeit medical products are available worldwide.

Nevertheless, because of the patient-centered practice of pharmacists, it is important for pharmacists to know the WHO definition:

*A counterfeit medicine is a product which is "deliberately and fraudulently mislabeled 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.*

### Box 1: National definition of a counterfeit medicine

*National pharmaceutical associations should insert here the national definition of a counterfeit medicine if there is any, such as:*

*Law XXX has defined a counterfeit medicine as: YYY*

## Extent of the issue

### An international overview

Counterfeit medicine is a global issue. According to the latest WHO estimates [2]:

- Most developed countries with effective regulatory systems and market control (e.g. USA, EU, Australia, Canada, Japan, New Zealand) currently have a very low proportion, i.e. less than 1% of market value. However, we must keep in mind that indications point to an increase in the prevalence of counterfeit medicines even in developed countries;
- Many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more than 30% of the medicines on sale can be counterfeit. Other developing markets, however, have less than 10%; overall, a reasonable estimate is between 10% and 30%;
- many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value -this falls into the developing country range;
- Medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases.

### Stories, news and facts

*Counterfeit medicines have a long history. In the first century in Greece, Dioscorides first classified drugs by their therapeutic use, warned of the dangers of adulterated drugs, and advised on their detection. The phenomenon is not new, but through globalization, it increases: on the 17<sup>th</sup> Century, while the demand of Europe for Peruvian Cinchona bark, the first effective treatment of malaria increased, the incentive to adulterate it is increasing, especially as these "medicines" were not regulated. This increased adulteration has led to loss of confidence of the patients.[1]*

*The first time a case of counterfeit medicines was publicized was through the movie "The Third Man" (1949, directed by Carol Reed), where the main character, Harry Lime, peddled diluted penicillin in post-war Vienna.*

*Modern cases of counterfeit medicines have been discovered many years ago. For instance, the first case of counterfeit medicines was discovered in Nigeria as early as in 1968.*

## The regional situation

### Box 2: Information specific to the geographical region

National pharmaceutical association should insert here, any information pertaining to the prevalence of counterfeit medical products in their region.

For example, for an European organization, this text could be:

According to the latest European Union Customs data [4],[5],[6], the issue of counterfeit medicines is an increasing one:

	2005	2006	2007
Number of seizures	148	497	2 045
Number of seized medicines	560 598	2 711 410	4 081 056
Increase vs. previous year	+100%	+384%	+51%

Some of these seizures were meant for the European market. Some examples of past seizures, discovered in the legal chain (at wholesalers' or community pharmacy level) includes Cialis® (erectile dysfunction medicine), Lipitor® (anti-cholesterol medicine), Reductil® (anorexigen medicine), Spiropent® (asthma medicine), Plavix® (anti-aggregant medicine).

In addition, other counterfeit medicines were seized during their transit through Europe. For instance, between February and March 2006, 5 seizures of counterfeit Viagra were made at Charles de Gaulle Airport (France) representing more than 360 000 fake Viagra® pills. These counterfeit medicines were intended to be sold in Dominican Republic, Mexico, Burkina Faso and Togo.

In the view of these data, it is of importance for every pharmacist to be aware of the danger and to take part on the fight against counterfeit medicines.

## The national situation

### Box 3: Information specific to the national situation

National pharmaceutical association should insert here, any information pertaining to the prevalence of counterfeit medical products in their own country.

If there is no case of discovery of counterfeit medicines, a text should be written stating that the country has never been faced with counterfeit medicines but it could be relevant to highlight if possible, the counterfeit medicines cases that have been discovered in neighboring countries.

If counterfeit medicines have already been discovered, a table should be included and gather at least the following information:

- Types of medicines
- Where these products were found
  - Products in transit (not for the national market),
  - Products for the illegal national market,
  - Products within the legal distribution chain (and at which stage),
- Day of seizure,
- Circumstances...etc.

## What products are likely to be counterfeit?

A few years ago, the answer to this question would have been rather easy at least at European level: mainly life-style medicines (i.e. erectile dysfunction medicine). But as the European Commission stated in one of its last Memos on Counterfeit medicines [22], although medicines for erectile dysfunction (Viagra) continue to be the most popular counterfeited medicines, other serious medicines such as anticholesterol, anti-osteoporosis or medicines to control hypertension are also found as counterfeit medicines.

In the USA, the National Association of Boards of Pharmacy have created the “National Specified List of Susceptible Products,” available at <http://www.nabp.net/ftpfiles/NABP01/List.pdf>, which identifies 32 drugs that are most susceptible to adulteration, counterfeiting or diversion and that pose the greatest risk to public health.

The latest version of this list identifies:

1. Combivir® (lamivudine/zidovudine)
2. Crixivan® (indinavir)
3. Diflucan® (fluconazole)
4. Epivir® (lamivudine)
5. Epogen® (epoetin alfa)
6. Gamimune® (globulin, immune)
7. Gammagard® (globulin, immune)
8. Immune globulin
9. Lamisil® (terbinafine)
10. Lipitor® (atorvastatin)
11. Lupron® (leuprolide)
12. Neupogen® (filgrastim)
13. Nutropin AQ® (somatropin, E-coli derived)
14. Panglobulin® (globulin, immune)
15. Procrit® (epoetin alfa)
16. Retrovir® (zidovudine)
17. Risperdal® (risperidone)
18. Rocephin® (ceftriaxone)
19. Serostim® (somatropin, mammalian derived)
20. Sustiva® (efavirenz)
21. Trizivir® (abacavir/lamivudine/ zidovudine)
22. Venoglobulin® (globulin, immune)
23. Viagra® (sildenafil)
24. Videx® (didanosine)
25. Viracept® (nelfinavir)
26. Viramune® (nevirapine)
27. Zerit® (stavudine)
28. Ziagen® (abacavir)
29. Zocor® (simvastatin)
30. Zofran® (ondansetron)
31. Zoladex® (goserelin)
32. Zyprexa® (olanzapine)

Based on this list, it is therefore rather hard to determine a specific profile of medicines which are more likely to be counterfeit.

It is therefore important for every pharmacist to pay attention to every product they dispensed at the community or hospital pharmacies. Additional information will be provided in this document under “How to detect/suspect a counterfeit product?” (Page 7).

## What are the consequences for personal and public health?

### At patient level

Based on the WHO definition and the different reports provided by major international organizations, counterfeit medicines can include:

- No active pharmaceutical ingredients (API). As a consequence, patients are deprived of essential medicines for their therapy and may have a worsening medical condition.
- An insufficient amount of active pharmaceutical ingredients. As a consequence, the medicine may not be effective in treating the patient. Moreover, with sub therapeutic dosage forms leading to treatment failure, prescribers may consider increasing the dose for the non-respondent patients. In some cases, injuries or death to patients may thus occur due to non-intentional over-dosing caused by counterfeit medical products.
- An excessive amount of active pharmaceutical ingredients. In this case, the patient will be more likely to face drug adverse reactions.
- Toxic ingredients. These toxic ingredients can induce unusual symptoms that could deter diagnosis and effective management of medical conditions and in some cases, lead to death.

It is important to know that the difference in the amount of active pharmaceutical ingredients can either be due to an incorrect amount of API used in the manufacturing phase, to a drug delivery formulation which could not mimic the release profile of the original drug; for example, the pharmacokinetic profile of the drug in different patients groups might be different and could lead to unpredictable blood concentration of API. The pharmacological effects of adsorption, distribution, metabolism and excretion of drugs are especially critical for drugs with a narrow therapeutic index. For example: warfarin.

## Stories, news and facts

*Historically, in recent years, counterfeit medicines have led to the death of the patients, such as in the province of British Columbia (Canada) in 2007; the death of a woman was reported by the Coroner Service.[7] In India, in 1998, more than 80 children died from a counterfeit cough syrup which contained di-ethylen glycol instead of glycerin. WHO also reported cases in the 2008 IMPACT brochure [8]:*

*"In 2006 more than 100 patients have been killed in Panama by medicines manufactured with counterfeit glycerin. [...]"*

*"In 2004, fake medicines led to a trail of death in Argentina. Veronica Diaz was a healthy 22-year old woman, living in Viedma, Argentina, who had mild anaemia and was given injections of an iron-based preparation. In December 2004, she became very sick and died of liver failure after receiving the seventh of a 10-injection treatment. The medicines authority of Argentina, ANMAT, determined that she had been given a highly toxic counterfeit. [...] In May 2005 another woman died and a 22-year old pregnant woman was injected with the same counterfeit. She survived but gave birth to a 26 week premature baby."*

## At society level

Not only are counterfeit a danger for individual health, but they can also be a threat for public health and the community. If they do not contain the correct amount of APIs, patients receiving them as treatment may have a lower concentration than the therapeutic dose, enabling the emergence of anti-microbial resistance. Such a consequence could lead to the inefficacy of both original and counterfeit medicines.

Moreover, a pharmacotherapy may be considered as ineffective and a second-line treatment may be chosen based on the poor outcomes of the treatment, whereas such a conclusion is biased by the counterfeit product. Such a change in treatment could lead to increased expenditures in healthcare system through additional medical visits and second line treatments (which are often more expensive than the first line ones).

The inefficiency of these medicines can also lead to additional healthcare and therefore to increased cost for the entire society.

In addition to this direct threat to public health, counterfeit medicines when found in the legal distribution chain can also erode public trust in health systems.

## How to detect/suspect a counterfeit product?

### Visual inspection

First of all, it should be noted that in many cases, counterfeit products are rather similar in appearance to the original products. Therefore, their identification may require chemical analysis.

Nevertheless, for some counterfeit medicines, pharmacists could detect them by a visual inspection. To facilitate this inspection, the International Pharmaceutical Federation (FIP) together with the US Pharmacopeia and the International Council of Nurses (ICN) has developed a checklist for a visual inspection of medicines in order to identify suspicious products for further examination. Such signs include improper packaging, labeling, 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. It can be adapted for use by enforcement officers in other similar contexts.

See Appendix 1 – Visual inspection tool for this visual inspection tool.

### Box 4: Information specific to regulations for parallel import

*National pharmaceutical association should insert here, any information pertaining to the parallel importing regulations of counterfeit medical products in their own country.*

*If parallel import is allowed in your country, this paragraph will have to be adapted in accordance.*

*Parallel import of medicines can be defined as the process within the European Union by which a medicinal product authorized in other European Union Member States to be marketed in an EU country provided the imported products have no therapeutic difference from the equivalent national products. To achieve patient safety, this product might have to be repacked to introduce patient leaflets and information in the national language.*

### Selection of suppliers

In many cases, the infiltration of counterfeit medicines within the pharmaceutical distribution chain is made possible through an operator of this chain buying from an unauthorized seller.

Moreover, especially on market where medicines prices are highly regulated, having a medicine from the national market with an unusually low price, when compared to prevailing rates, should raise suspicions of pharmacists.

### **Patient reported information**

In 2004, in the UK, a patient complained to his pharmacist that some of his purchased tablets of Cialis® completely crumbled when he tried to cut them in half. The company, Lilly ICOS, was notified. An analysis of the suspect tablets revealed the presence of two active substances instead of just one.

Based on this example, it is clear that patients can be effective partners in detecting counterfeit medicines.

Through their everyday interaction with patients, pharmacists often come across such “complaints” by patients on their use of the medicines, including abnormalities of their medications such as difference in taste, color or medical response. In all cases, pharmacist should report to the relevant authority, including the national DRA where appropriate.

Moreover, when treatment unusually fails, pharmacists should consider counterfeit medicines as a potential reason for non-response or unexpected response in pharmacotherapy in the patients they care for, especially if the patient bought their medicine from an illegal or risky source (i.e. Internet, a foreign country with little regulation and enforcement, on the street market).

### **Technology for authentication**

In some countries and for some products, the manufacturers may be required to adopt anti-counterfeiting technologies such as a hologram, on the packaging of their products. Sometimes, some of them also adopt voluntarily these technologies.

#### **Box 5: Information specific to anti-counterfeiting technology**

*National pharmaceutical association should insert here, any information pertaining to current regulatory requirements of your country for product authentication and other anti-counterfeiting technology.*

*In addition to these visual authentication tools, some countries have developed an electronic system aiming to check whether a specific box (identified by an individualized number) has been legally produced by the original manufacturer and has never been dispensed in another dispensing outlets (community or hospital pharmacies, for instance). If such a system is established in your country, describe it, and mention what information is given when a counterfeit medicines is detected.*

In case of any doubt, please refer to section “What should pharmacists do when they encounter a suspected counterfeit medical product?” (Page 9)

## **What can pharmacists do to reduce the risks of buying counterfeit medical products?**

As part of the distribution chain, pharmacists have a shared responsibility to avoid any infiltration of counterfeit medicines within the legitimate pharmaceutical supply chain. Therefore, before buying products from a new supplier or distributor, purchasing pharmacists should check at the competent national authority (i.e. DRA or Ministry of Health) whether this supplier is a legal business entity and has the necessary authorization/licenses for its activities in your country.

A reliable distributor is usually a company with a long-term involvement in pharmaceutical products distribution and operates within established quality management systems with regards to its own suppliers and other clients. The traceability of medical products purchased from a reliable distributor is critical to ensuring a rapid response to any recalls from the market (for example community and hospital pharmacies) in the event of a discovery of counterfeit medical products.

Pharmacists who are responsible for purchasing medicines should refer to the national Good Distribution Practices (GDP) to evaluate and select their source of medicines. If no national GDP are available, they should refer to the WHO guidelines on Good Distribution Practices available on <http://www.who.int>.

Pharmacists should keep in mind that the fewer links there are between the producer and their pharmacy, the stronger the traceability of the product will be.

#### **Box 6: Information specific to the distribution practices**

*National pharmaceutical association should insert here, any information pertaining to adherence of existing national guidelines on good distribution practices. It will be useful to refer to the national requirements on the different type of authorized wholesalers and their restricted activities (e.g. wholesalers only for clinical trials are not allowed to sell medicines to community pharmacies).*

*It will be important to explain how pharmacists can check whether a wholesaler is authorized or not, based on the existing procedures of the national drug regulatory authority, where relevant.*

**Box 7: Information specific to the return policy practices**

National pharmaceutical association should insert here, any information pertaining to existing guidelines on return policy practices in their country.

Here is an example:

Return policies doesn't allow pharmacists to send back a medicine to a wholesaler, in order to maintain the distribution safe from any potential infiltration of counterfeits. It is therefore also advised not to allow any products to go back to the distribution chain (for instance from a patient through a community pharmacy and then through a wholesaler), as it could be a way of entrance of counterfeit medicines.

Moreover, the product return could impact the traceability of the medicines. Therefore, any return product should be destroyed and not be re-introduced in the pharmaceutical distribution chain.

**What should pharmacists do when they encounter a suspected counterfeit medical product?****Box 8: Information specific to the reporting procedures of counterfeit medical products**

National pharmaceutical association should insert here, any information pertaining to the procedure established by the national Drug Regulatory Agency (or the ministry of health) on how pharmacists can report suspected counterfeit products, preferably through a single point of contact (as recommended by the Council of Europe and IMPACT:

[http://www.edqm.eu/medias/fichiers/Model\\_for\\_a\\_Network\\_and\\_Single\\_Points\\_of\\_Contacts\\_SPOCs.pdf](http://www.edqm.eu/medias/fichiers/Model_for_a_Network_and_Single_Points_of_Contacts_SPOCs.pdf))

This part of the guide should give the contact details of this SPOC, the procedure and information needed to report a suspected case.

**Important issues to be considered by a pharmacist when facing a batch recall because of counterfeit medical product****Traceability needed and possible recall from patients**

When counterfeit medicines are discovered in the legal pharmaceutical chain, most of the time the Drug Regulatory Agency will generally proceed to a batch recall based on a risk analysis.

Batch number and expiry dates are important elements for any recall, and more precisely for such a case, as this is a first step to identify products which are at risk to be counterfeit.

In addition to these data, the DRA may inform pharmacists how to detect counterfeit medicines (i.e. visual inspection, hologram, RFID...).

In the stock of the community or hospital pharmacies, these data enable pharmacy staff to separate (potential) counterfeit medicines from original ones. It is therefore important to store these recalled products in a separate room and with proper information on them to avoid dispensing them, before destroying them or sending them back, based on the DRA instructions.

It is advised to check all coming orders from wholesalers, during the next days after the batch recall, in order to detect possible counterfeit products which were not withdrawn from the market by the wholesalers and/or which were already in their journey to the pharmacy.

Pharmacists should comply with the requirements of the DRA which could request to contact individual patients to proceed to a batch recall down to patients' levels.

In that case, batch number and expiry dates which should be recorded in the pharmacists computers (in patients records), will facilitate the recall down to the patient.

If these data are not recorded, the pharmacists will have to go back to the products dispensing data and may contact all patients which received their products for the last month (or 3 months) depending on the amount of doses dispensed.

**Communication to the public**

Whether it is a pro-active communication (pharmacists calling the patients to inform them) or a reactive communication (patients asking pharmacists for more details), a clear message should be given.

This message needs to be made out of reliable information, mainly from the DRA and the original pharmaceutical manufacturer. As a medicines expert, pharmacists should give precise information based on verified facts, and have a balanced message.

If patients are questioning about generics, try to make the distinction between generics and counterfeit products, as on one hand, generics are approved by the DRA and their quality is assessed by it, whereas on the other hand, counterfeit medicines are not controlled at all and their ingredients and way they are manufactured can sometimes be very different from what could be expected from licensed medicines. Pharmacists can refer to WHO definition to highlight these differences.

### **Consider disruption of treatment in regard to the risk of counterfeit medicines**

If a batch withdrawal is decided, there could be a risk of treatment disruption, because of the unusual increase of demand versus available stock.

In such a case, the pharmacist will have to evaluate the risks posed by the counterfeit medicines versus the risks of treatment disruption. In that case, he will take into account how serious the counterfeit issue is and how serious the condition being treated is (counterfeiting could for example be just slightly less of active substance, and the underlying condition could for example be becoming a rather important issue), as well as the medicines stock available (at his pharmacy but also at his wholesaler(s)) to replace counterfeit medicines.

Guidelines on this issue may also be provided by the DRA to help pharmacists.

## **Special focus on the Internet**

### **Background information**

A growing number of internet pharmacies have been established worldwide. Many of these Internet pharmacies are operated by brick-and-mortar community pharmacies that also serve consumers online. However, in addition to legal pharmacies there are also a large number of illegal providers. The main risk of the internet lies in the inability of the consumer to distinguish between legal and illegal providers. Many websites appear legitimate, but in fact they are a front for illegal operations. It is very difficult to detect these pages as they are generally well written and presented in such a way to gain the confidence of the consumer.

WHO estimates that medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases[2].

One of the latest reports from the European Alliance for Access to Safe Medicines (EAASM)[10] revealed that a frightening 62% of medicines purchased online are fake or substandard! These include medicines indicated to treat serious conditions such as cardiovascular and respiratory disease, neurological disorders, and mental health conditions. Whilst only 38% of the medicines received were found to be genuine branded medicines, of these 16% were illegal non-EU imports (genuine products, imported into the EU illegally from a non-EU country) and 33% did not have patient information leaflets, which in itself is also illegal and potentially dangerous to consumers' health.

A study from the German Association of pharmacists (ABDA)[11] also revealed that out of 24 orders for Propecia® made online, none of them required a prescription (although it is a prescription only medicine), and only 12 were received. Out of these 12, 6 medicines were counterfeit (4 without active pharmaceutical ingredients and 2 with a smaller amount of API than mentioned).

The risk of ordering counterfeit medicines through Internet is specific to this media. The unique features of the internet include its broad reach, relative anonymity, and the ease of creating and removing Web sites. Many sites are connected to other sites and have multiple links, which poses a challenge for identifying the origin of the individual web sites. When a patient goes to a brick-and-mortar pharmacy, he can be sure that this pharmacy is established where it claims to be, as the patient can physically enter the pharmacy. In contrast, the location of an e-pharmacy is rather difficult to check. It has been reported several times that e-pharmacies which stated to be established in Canada, were in fact running from outside Canada.[24]

Some clever counterfeiters have even a PO Box address in a country and a phone number but its correspondence is then eventually redirected to another country, where the legislation is either weaker or even not implemented. Moreover, when a brick-and-mortar pharmacy opens, the inspectorate (under the Ministry of Health or the drug Regulatory Agency) is able to inspect it, to determine if all the requirements (including the safety of supply, an adequate pharmacy staff...etc) are fulfilled.

Patients should know that the national requirements and standards of a legalized Internet pharmacy in their own country may not necessarily apply to other foreign Internet pharmacies established elsewhere and therefore should never buy their medicines from such unknown sources.

According to the latest report of the EAASM the vast majority of online pharmacies uncovered via search engines, email spam and online supermarkets are untrustworthy and will readily provide online buyers in Europe with illegal, substandard and / or counterfeit medicines.[10]

### Why do people buy their medicines online?

There are several reasons, why people order medicines online:

- They hope for a rapid delivery of medicine
- They are too embarrassed to discuss their condition with a doctor, a pharmacist or a nurse or other health-care professional
- They do not want their family or employer to find out about their condition
- They fear that the doctor may not prescribe them a certain medication
- They believe that the costs are lower
- They want to access to medicines which are not (yet) available in the national market
- In some cases, patients may have dependence to some medicines and Internet is a way to illegally obtain medicines without a prescription.

We need to understand that our patients also have an intuitive understanding of risks and they need to be provided with accurate information about the dangers of buying medicines online. This is a role that pharmacists can play in their daily interactions with patients; we need to be mindful and sharp to identify the needs and concerns of our patients in paying for their medicines and in obtaining a regular supply of affordable and quality medicine in their communities. Sufficient patient counseling about the proper channels in buying medicines should always be done to avoid misconceptions of the risks of buying medicines from the Internet.

### The danger of buying medicines online

Internet counterfeit medicines have already killed patients. For example, it has been reported that a 57-year old Canadian woman who lived in Quadra Island (British Columbia) was found dead at home due to her consumption of medicines bought on the Internet. The long term therapy medicines that she was taking contained very high levels of metals (aluminum, arsenic...etc). Due to their toxicity, she had a fatal cardiac arrhythmia. Her medicines were poorly manufactured and contained impure filler materials. The filler was likely contaminated by dangerous metals during production in Southeast and sold by a website based in Eastern Europe, possibly the Czech republic, as stated by the Regional Coroner [12],[13].

There are notable efforts made by a number of national authorities in raising awareness of the possible dangers of e-pharmacies for the trade of medical products and services over the Internet such as the French Agence Française de Sécurité Sanitaire des Produits de santé (Afssaps)[14], the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)[15], the Swiss Swissmedic[16], the British MHRA[17] or the European Commission[18]. Even in countries where Internet pharmacies are allowed, warnings are published by national drug regulatory agencies, like in Canada [19] or in the USA [20].

### Internet pharmacy in your country

#### Box 9: Information specific to the Internet pharmacy regulations

*National pharmaceutical association should insert here, any information pertaining to the regulations of Internet pharmacy in your country.*

*If Internet pharmacy is not allowed in your country, state it clearly. If Internet pharmacy is allowed in your country, please give some advice to identify a legal e-pharmacy.*

*These advices should include where to check if an e-pharmacy is officially registered, and if available, what label has been developed to identify legal e-pharmacies e.g. VIPPS (<http://www.nabp.net/index.html?target=/IP/intro.asp&>).*

*Here are some selected key messages that pharmacists can provide to their patients and customers:*

*"Determining whether a website is a legally established pharmacy is not easy, from a patient point of view and even from a pharmacist point of view. There is such a high chance of buying counterfeit medicines from the Internet that even I will not risk my life for them".*

*"For example, if this seller will provide you with prescription-only medicine (POM), it should raise your suspicion".*

*Here are other tips that should raise the suspicion of patients about an "e-pharmacy":*

- *Fast or sensational results are presented, supported by personal testimonials only*
- *Proposing medicines which are not authorized in your country (there could be a good reason for it!), or presenting new astounding new theories regarding diseases or secret recipes that should be passed on.*
- *The treatment is riskless or no side-effects are reported on the website.*
- *Everyone can use the medicine or take it on a lifelong basis*
- *If the "e-pharmacy" full address is missing (or only accessible through an e-mail address)*

## Special focus on raw materials for compounding medicines

### The case in Panama

In 2006, a manufacturer in a Panama government health program was producing cough and antihistamine syrup. The cough medicine was labeled as sugarless so that even diabetic patients could use it. Among its ingredients, there was glycerin, of which its quality was certified by a trader in Barcelona and the original manufacturer in China. It was only after a series of deaths occurred from the consumption of this cough syrup that it was discovered that these medicines were associated to the adulteration of diethylene glycol which is a widely used solvent for industry and a prime ingredient in some antifreeze liquids[8],[21], in the syrup. Unfortunately, the Panama manufacturer did not analyze this “glycerin”.

This dreadful story underlines how important it is to ensure the quality of the active pharmaceutical ingredient(s) and other excipients in all pharmaceutical preparations/dosage forms during manufacturing.

### Issues relating to pharmaceutical compounding at the pharmacy

#### Box 10: Information specific to the pharmaceutical compounding

*In many countries, pharmacists are allowed to make compounding medicines.*

*In that case, some guidelines should be established to ensure that the ingredients used for this activity are not counterfeited.*

*These guidelines could for instance include:*

- *Only buy ingredients from reliable sources*
- *Only buy ingredients with an authorized analytical certificate (analytical certificate released by a qualified person)*
- *Check the identity of the ingredients when receiving them.*

*National pharmaceutical association should insert here, any information pertaining to the compounding practices and standards in their country.*

## Anti-counterfeiting initiatives and other useful resources for pharmacists

### WHO and IMPACT

In February 2006, WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

IMPACT is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, nongovernmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups.

Since then, these groups have joined to improve coordination and harmonization across and between countries so that eventually the production, trading and selling of counterfeit medical products will cease. The mission of IMPACT is to promote and strengthen international collaboration to combat counterfeit medical products.

For more information regarding IMPACT's initiatives, please visit the WHO website at <http://www.who.int/impact/en>.

### FIP

The International Pharmaceutical Federation (FIP) mission is to “improve global health by advancing pharmacy practice and science to enable better discovery, development, access to and safe use of appropriate, cost-effective, quality medicines worldwide”. Therefore the FIP has been involved for many years in the fight against counterfeit medicines to protect patients' health.

In 1999, the FIP council adopted a statement on counterfeit medicines and updated its statement in 2003. This statement provides policy directions to combat counterfeit medical products and can be downloaded on the FIP website: <http://www.fip.org>

Since 2006, FIP has been actively involved in the WHO IMPACT and chairs the Working group on Communication. In addition, it has shared its expertise with the Council of Europe Committee of Experts on counterfeit medicines.

FIP has established an online resource center on combating counterfeit medicines: highlighting key information for patients, publications and international guidelines/tools that can be useful in policy development and advocacy against counterfeit medicines. This is accessible at: <http://www.fip.org/combatingcounterfeitmedicines>

## By regional organizations

### Box 11: Activities at regional levels

*National pharmaceutical association should insert here, any information pertaining to the different activities which they participate at regional levels, including FIP/WHO pharmaceutical forums, governmental regional organizations and other relevant organizations.*

## Pharmacists involved in counterfeiting

### Box 13: Information specific to penalties relating to counterfeiting

*National pharmaceutical association should insert here, any information regarding past prosecution of any pharmacists who have been proven guilty of an involvement in counterfeiting activities in your country, outlining their illicit actions and penalties awarded.*

## By national stakeholders (DRA and pharmacists association)

### Box 12: Activities at national levels

*National pharmaceutical association should insert here, any information pertaining to the different activities which they lead at national level. These could be a national conference for pharmacists, guidelines, press releases, public conferences, communication campaigns, opening a website dedicated to this issue, as well as the collaboration within working groups dedicated to counterfeit medicines.*

## Responsibility on counterfeiting issue

### Moral responsibility

In accordance to the Code of Ethics, pharmacists should think of their moral responsibility to protect their patients from counterfeit medicines. Such a moral responsibility is of course to be considered in addition to his legal requirements.

Indeed, pharmacists are trusted people by the community for health issues. The provision of medicines by the pharmacist is expected to improve or at least maintain health condition.

When a counterfeit medicine is distributed through the legal distribution chain to the patient, it could be seen from a patient's perspective, like an attempt to their health and his trust in his pharmacist could be weakened.

Therefore, the image of the pharmacist could be altered in such a case.

It is therefore of the interest of the patients and of the ones from the pharmacists to take part in the fight against counterfeit medicines.

### Stories, news and facts

In some very rare cases, pharmacists have been discovered to be involved in the manufacturing and the distribution of medicines they knew or suspected to be counterfeit.

For instance, in the city of Hamilton (Ontario, Canada), a 28-year old pharmacist was found to have sold counterfeit Norvasc®. Although he noticed the different appearance of the products, he assumed the changes had been made by Pfizer. Moreover, these medicines were provided by an unknown "wholesaler" and the pharmacist did not check whether this wholesaler was legally established in Canada. The manner of 4 deaths of patients taking counterfeit Norvasc® was inconclusive and the manner of death was noted as "undetermined", with the medical cause of death as "possible unauthorized medication substitution". In the judgment of the Ontario College of Pharmacists, it was mentioned that the entrance of counterfeit medicines within the pharmaceutical distribution chain was the result of the pharmacist failing to discharge due diligence in the purchase of the drug, which was described as an act of extreme carelessness and a significant departure from expected standards of care.<sup>[23]</sup> This judgment underlines that allowing entrance of counterfeit medicines in the distribution chain is not acceptable. Such activities disgrace the entire profession of pharmacists and should (and have been) condemned not only by the Court but also by local pharmacists associations.

## Key national legislations and/or relevant regulations

### Box 14: Information specific to key national legislation and regulations

National pharmaceutical association should insert here, any information regarding national law extracts and other regulation related to the manufacturing, distribution and sale of counterfeit medicines.

Also quote if applicable elements of the Code of Ethics of pharmacists and include information relating to punishment or other penalties related to counterfeiting of medical products. In some countries, pharmacists might be prosecuted for selling counterfeit medicines even if they do not do it knowingly. In that case, a specific paragraph should be written to present the legislation as well as to highlight the even greater interest of the profession to take part in the fight against counterfeit medicines.

## Where to find further information

Find more information on counterfeit medicines on:

- IMPACT website: <http://www.who.int/impact/en/>
- FIP website dedicated on counterfeit medicines <http://www.fip.org/combatacounterfeitmedicines>

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## Appendix 1 – Visual inspection tool

[Please note that this visual inspection tool is also available in French, Spanish, German and Dutch, on the FIP website: <http://www.fip.org/combatacounterfeitmedicines> ]

### 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 labeling 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 labeling and holograms.

	Yes	No	Other Observations
<b>1.1 Container and Closure</b>			
<i>Do the container and closure protect the drug from the outside environment e.g. properly sealed?</i>			
<i>Do they assure that the drug will meet the proper specifications throughout its shelf life?</i>			
<i>Are the container and the closure appropriate for the drug inside?</i>			
<i>Is the container safely sealed?</i>			
<b>1.2 Label</b>			
<i>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.</i>			
<i>If there is a carton protecting the container, does the label on the carton match the label on the container?</i>			
<i>Is all information on the label legible and indelible?</i>			
<b>1.2.1 The trade name:</b>			
<i>Is the trade name spelled correctly?</i>			
<i>Is the drug (trade name) registered in the country by the DRA (drug regulatory authority)?</i>			
<i>Is the drug legally sold in the country?</i>			
<i>Does the symbol ® follow the trade name?</i>			

	Yes	No	Other Observations
<b>1.2.2 The active ingredient name (scientific name):</b>			
<i>Is the active ingredient name spelled correctly?</i>			
<i>Do the trade name and the active ingredient name correspond to the registered drug?</i>			
<b>1.2.3 The manufacturer's name and logo:</b>			
<i>Are the manufacturer's name and logo legible and correct?</i>			
<i>Does the logo or hologram (if applicable) look authentic?</i>			
<i>Does it change colour when viewed from different angles?</i>			
<b>1.2.4 The manufacturer's full address:</b>			
<i>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.</i>			
<i>Is the manufacturer's full address legible and correct?</i>			
<i>Has the company or its agent registered the drug in the country?</i>			
<b>1.2.5 The drug strength (mg/unit):</b>			
<i>Is the strength – the amount of active ingredient per unit – clearly stated on the label?</i>			
<b>1.2.6 The dosage form (e.g., tablet/capsule):</b>			
<i>Is the dosage clearly indicated?</i>			
<i>Is the indicated drug under this dosage form is registered and authorized for sale in the country?</i>			
<b>1.2.7 The number of units per container:</b>			
<i>Does the number of tablets listed on the label match the number of tablets stated on the container?</i>			
<b>1.2.8 The batch (or lot) number:</b>			
<i>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.</i>			
<i>Does the numbering system on the package correspond to that of the producing company?</i>			

	Yes	No	Other Observations
<b>1.2.9 The date of manufacture and the expiry date:</b>			
<i>An expired drug should not be sold under any circumstances.</i>			
<i>Are the manufacture and expiry dates clearly indicated on the label?</i>			
<b>1.2.10 Storage information:</b>			
<i>Are the storage conditions indicated on the label?</i>			
<i>Has the drug been properly stored?</i>			
<b>1.3 Leaflet or package insert:</b>			
<i>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.</i>			
<i>Is the package insert printed on the same coloured or same quality paper as the original?</i>			
<i>Is the ink on the package insert or packaging smudge-proof?</i>			

### 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.

	Yes	No	Other Observations
<b>2.1 Uniformity of Shape:</b>			
<i>Are the tablets/capsules uniform in shape?</i>			
<b>2.2 Uniformity of Size:</b>			
<i>Are the tablets/capsules uniform in size?</i>			
<b>2.3 Uniformity of Colour:</b>			
<i>Are the tablets/capsules uniform in colour?</i>			
<b>2.4 Uniformity of Texture:</b>			
<i>Tablets can be film-coated, sugar-coated or enteric-coated.</i>			
<i>Do the tablets have a uniform coating?</i>			
<i>Is the base of the tablets fully covered?</i>			
<i>Are the tablets uniformly polished, free of powder, and non-sticking?</i>			
<b>2.5 Markings (scoring, letters, etc):</b>			
<i>Are markings uniform and identical?</i>			
<b>2.6 Breaks, Cracks and Splits:</b>			
<i>Are the tablets/capsules free of breaks, cracks, splits or pinholes?</i>			
<b>2.7 Embedded surface spots or contamination:</b>			
<i>Are the tablets/capsules free of embedded surface spots and foreign particle contamination?</i>			
<b>2.8 Presence of empty capsules in the case of a sample of capsules:</b>			
<i>Is the sample examined free of empty capsules?</i>			
<b>2.9 Smell</b>			
<i>Does the medicine smell the same as the original?</i>			

