Note: At its 2nd meeting on 28 and 29 October 2008, the Council of Europe EDQM Committee of Experts on minimising public health risks posed by counterfeiting of medicines and related crimes endorsed inviting the WHO IMPACT Working party “Communication” to submit the enclosed document comprising a model approach “Counterfeit medicines in Europe: risk communication strategies for Drug Regulatory Authorities” for a possible endorsement at the 3rd General Meeting of WHO IMPACT, Hammamet, Tunisia, on 3-5 December 2008.
The Committee of Experts on minimising public health risks posed by counterfeiting of medicines and related crimes, co-ordinated by the Council of Europe’s European Directorate for the Quality of Medicines & HealthCare (EDQM), was entrusted with a comprehensive programme of activities dealing with training programmes, model approaches, management of specific knowledge, and networking through Single Points of Contact (SPOCs). After the transfer of the pharmaceutical activities to the EDQM, the Committee of Experts succeeds the former Ad hoc Group on Counterfeit Medicines (Council of Europe Partial Agreement in the Social and Public Health Field).

At its 2nd meeting on 28 and 29 October 2008, the Committee of Experts on minimising public health risks posed by counterfeiting of medicines and related crimes inter alia

- approved the model approach dealing with “Counterfeit medicines in Europe: risk communication strategies for Drug Regulatory Authorities”,
- in the frame of the membership of the Council of Europe at the WHO IMPACT General Meetings, invited the WHO IMPACT working party “Communication” to submit the enclosed document on “Counterfeit medicines in Europe: risk communication strategies for Drug Regulatory Authorities” for possible endorsement at the 3rd General Meeting of WHO IMPACT, Hammamet, Tunisia, on 3-5 December 2008.

General information

The mission of the European Directorate for the Quality of Medicines & HealthCare (EDQM) is to contribute to the basic human right of access to good quality medicines and healthcare, and to promote and protect human and animal health. It contributes effectively to combating the counterfeiting of medicines and related crimes involving threats to public health by:

- Establishing and providing official standards which apply to the manufacture and quality control of medicines in all the signatory states of the Convention for the elaboration of a European Pharmacopoeia and beyond, the European Pharmacopoeia, covering 2000 medicinal substances,
- Ensuring the application of these official standards to substances used for the production of medicines,
- Co-ordinating a network of approximately 100 Official Medicines Control Laboratories in 35 countries to collaborate and share expertise between Member States and effectively use limited resources,
- Establishing ethical and quality standards for the collection, storage and use of blood components relevant to blood transfusion and for organ transplantation, including tissues and cells,
- Collaborating with national and international organisations in efforts to eliminate illegal and counterfeit medicinal and medical products,
- Providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care.

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1 www.edqm.eu
2 See Appendix [18]
1. Introduction

Ensuring healthcare of adequate quality is a prime task of all governments. The obligation to do this is usually part of the national constitution or dependent specific legislation. It is therefore an obligation for governments to maintain a safe system of healthcare. The Drug Regulatory Authorities (DRA) are usually in charge of the licensing of medicines and inspection of the production sites and distribution channels. Inspection procedures may need to be adjusted to take into account the possibility that counterfeit medicines may enter the regular distribution chain.

Prevention is an important element in all healthcare systems. Prevention is always better than cure. Pro-active information, e.g. campaigns, to influence the behaviour of people are particularly useful in healthcare and this holds also true in the prevention of counterfeit medicines. Awareness among several stakeholders on counterfeit medicines should be raised in general even if no counterfeit medicines have been discovered on the legal pharmaceutical market.

In case of a suspected or verified counterfeit medicine, communication within the authorities and with other stakeholders has to be effective in order to prevent health damage.

This document contains a model approach for a pro-active information strategy on counterfeit medicines (item 2.) and a reactive communication strategy about incidences of counterfeit medicines (item 3.).

For general information, please refer to References a-b.

The Committee of Experts on minimising public health risks posed by counterfeiting of medical products and related crimes, co-ordinated by the Council of Europe European Directorate on the Quality of Medicines & HealthCare (EDQM) developed this model approach intended to facilitate the writing and implementation of a procedure at national level by outlining basic principles and providing examples.

This work takes account of the conclusions of the Seminar Counteract the Counterfeiters! Limiting the risks of counterfeit medicines to public health in Europe by adequate measures and mechanisms, organised by the former Council of Europe Ad hoc Group on Counterfeit Medicines, in Strasbourg, France, on 21-23 September 2005\(^3\), regarding the seminar programme item « Public health »:

*Inter alia*, the seminar participants called for public health protection through
- raising awareness through positive communication avoiding scaring people,
- discouraging the public from purchasing medicines via illegal distribution channels,
- training of healthcare professionals to communicate the counterfeit medicines risk to patients,
- considering counterfeit and substandard medicines in the systems which are in place to survey medicines’ safety on the market,
- enabling the traceability of a medicine to patient level in case of a medicine recall.

On the basis of the conclusions of the above seminar, a programme of activities was set up aiming at the development and implementation of practical tools in the field of counterfeit medicines and related crimes in the frame of the programme of activities of the Council of Europe and its EDQM. Among the activities proposed was the development of the present pro-active information strategy on counterfeit medicines and of a reactive communication strategy on incidences of counterfeit medicines.

The pro-active information (‘awareness raising’) and the reactive communication protocol on new cases of suspected or verified counterfeit medicines are closely related in that they are both meant

\(^3\) http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/pharma_and_medicine/Presentation_Seminar_CountMed%20public.asp#TopOfPage
to give information on counterfeit medicines and the associated health risks. The differences between both approaches are as follows: the communication protocol defining when, how and who to inform of new cases of suspect or verified counterfeit medicines is intended to be used when a counterfeit medicine has actually been detected on the market as follow-up and reaction to the incidence. The pro-active information aims at making the general public, patients, professionals and partners in the pharmaceutical distribution chain aware of the issue of counterfeit medicines in a proactive way, contributing to the prevention of harm and of new cases in the long run.

This model approach deals with counterfeit medical products. However, other medical products such as medical devices, tissues and blood products are equally at risk of being counterfeit. The tools in this model approach can also be used for the prevention of risks posed by other medical products, although minor adjustments may be necessary to allow for different legal environments.

In most cases the Drug Regulatory Authority (DRA) is part of, or linked to the Ministry of Health (MoH). The present model approach applies also to situations where the DRA shares communication activities with or sources them out to the MoH.

2. Pro-active information strategy on counterfeit medicines

2.1 Stakeholders

There are several stakeholders in the public and private sectors and the general public sharing concern of medication safety that have to be aware of the possibility of counterfeit medicines appearing on the market. These stakeholders comprise the general public, patients and/or patient organisations, healthcare professionals such as pharmacists, doctors and nurses, including students of these professions, the medicines’ production and distribution chain, such as manufacturers and wholesalers, and the media, such as radio, television, the Internet and newspapers. The DRA are key stakeholders. The DRA is as well sender of information for internal and external use as recipient of communication.

2.2 Key messages

The DRA should therefore, as a first step, take the initiative to launch an information campaign aimed at the general public on the ways and means of preventing damage to health caused by counterfeit medicines. Alternatively, the DRA could participate in initiatives taken by other stakeholders resulting in joint information campaigns. The goal of these campaigns should be to prevent the public from buying medicines outside the regular distribution channels and to spot cases of counterfeit medicines as soon as possible. The key messages of the information campaign should be:
- Buy medicines from your pharmacy only (where legally permitted, this includes regulated internet pharmacies).
- Report ineffective medicines and quality problems to your pharmacist.

Examples of such initiatives can be found in Appendices [1] to [8]. Appendices [9] to [13] focus on counterfeit medicines over the Internet.

Other stakeholders than the above mentioned pharmacists should be informed to make sure that they are aware of the message to the public and are prepared to answer questions that may come up. Also, the role of these stakeholders in facilitating the detection of counterfeit medicines should be highlighted. Examples can be found in Appendices [1], [14] and [15].

4 For the purpose of this document, the term medicines is used as a synonym for medical products.
5 The DRA is encouraged to designate a dedicated reporting point for the general public to report about suspect medicines and to publish information about the reporting point.
6 Reporting of adverse effects and quality defects according to national and supranational legislation are not within the scope and focus of this document. Health professionals and stakeholders of the manufacturing and distribution chain are called to adhere reporting requirements as applicable.
Finally, the DRA should evaluate the effect of the information campaign and re-launch the campaign, reinforcing the conveyed messages, when public awareness comes below a predefined level.

3. Reactive communication strategy on incidences of counterfeit medicines

DRAs and other involved services of the MoH may have to face a situation where a suspected or verified counterfeit medicine is found in the pharmaceutical distribution chain.

In order to improve the efficiency of communication in this case, it is highly recommended to DRAs to establish a procedure for communication. Some DRAs have already prepared such a procedure.

3.1 Stakeholders

The below stakeholders (A-E) and processes related to the information flow are outlined in Chart, following page.

Several stakeholders should be targeted in this procedure:
1. the DRAs themselves and other MoH-related services (A). This would encompass the different services within the DRAs, such as the Single Point of Contact (SPOC), (see Appendix [16], the medicines enforcement officers, the Official Medicines Control Laboratory (OMCL) and the press and communication officers;
2. the general public including the patients (B);
3. the media (C) at large: such as general public press (e.g. newspaper, radio, television and new information technologies media like Internet magazines), and professional press;
4. healthcare professionals (D) (e.g. pharmacists, physicians, nurses). Apart from individual healthcare professionals, this category also encompasses their respective representative bodies;
5. the distribution chain (E) from the manufacturer to the dispensing point (e.g. community pharmacies, hospitals), including full-line and other wholesalers, as well as other retail shops in case of an “Over The Counter” (OTC) medicine.

It should be noted that pharmacists should be considered under both healthcare professionals (D) and stakeholders of the distribution chain (E).

Based on this definition of stakeholders, several actions should be expected from these partners. A specific strategy customised for the targeted stakeholders should be drawn up and implemented. Customised communication for the different stakeholders should be based on a basic communication from which key message(s) should be extracted and adapted to the needs for information of the respective stakeholder.

3.2 Information flow

Information flow is described in the following Chart:
An example of a press release can be found in Appendix [17]. Moreover, when the case of a counterfeit medicine has been sentenced, it is of interest to publish the court’s decision in order to deter people from counterfeiting medicines. (See Appendix [18]).

3.3 Responsibilities of stakeholders

When receiving information stakeholders are expected to react appropriately. In the table below the follow-up actions are listed.

<table>
<thead>
<tr>
<th>Who</th>
<th>Actions expected of stakeholders as regards the communication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> DRA and other MoH related services</td>
<td>Organise a taskforce on the case including all relevant experts&lt;br&gt;Organise information flow (two-way): within the DRAs&lt;br&gt;at national level&lt;br&gt;at international level with other partners&lt;br&gt;Take decisions and communicate them</td>
</tr>
<tr>
<td><strong>B</strong> General public and patients</td>
<td>Act responsibly, i.e. follow the advice of healthcare professionals</td>
</tr>
<tr>
<td><strong>C</strong> Media</td>
<td>Cooperate and relay message</td>
</tr>
<tr>
<td><strong>D</strong> Healthcare professionals</td>
<td>Provide care (i.e. in case of adverse effect of the counterfeit medicine) and relay information to the patients (and refer them to reliable sources of information)</td>
</tr>
<tr>
<td><strong>E</strong> Manufacturers and distributors</td>
<td>Recall the product and replace them if needed. Part of the recall process is the isolation of products which are suspected of being counterfeit, as well as communication on the recalls.</td>
</tr>
</tbody>
</table>
4. References

a) IMPACT: http://www.who.int/impact

b) FIP website on counterfeit medicines: http://www.fip.org/combatcounterfeitmedicines
5. Appendices

Le médicament est ...

un produit actif

Pour être efficace, c'est-à-dire traiter ou prévenir une maladie, un médicament contient un ou plusieurs principes actifs. De ce fait, il peut avoir des effets secondaires aussi apprêts effets indésirables. Ce n'est donc pas un produit médicamenteux.

sous contrôle

De sa fabrication jusqu'à sa délivrance dans les pharmacies, le médicament est contrôlé par les autorités de santé. Sa qualité (composition, conditions de fabrication, de conservation et de distribution) est ainsi garantie pour votre sécurité.

généralement prescrit par votre médecin.

De nombreux médicaments, soumis à prescription obligatoire, nécessitent une ordonnance. Lors de la consultation, votre médecin (ou tout autre prescripteur autorisé) prescrit le médicament adapté à votre maladie, en prenant en compte les éléments de votre dossier médical et les éventuels traitements en cours.

dispensé par votre pharmacien

Qu'un médicament nécessite ou non une ordonnance, il est toujours délivré par votre pharmacien, garant de sa qualité. Vous bénéficiez ainsi des conseils d'un professionnel du médicament, qui vérifiera également qu'il n'y a pas d'incompatibilité avec les autres médicaments que vous prenez.

Le médicament contrefait ....

echappe à tout contrôle

Ne pas soumis aux contrôles des autorités sanitaires et des professionnels de santé, son efficacité et sa qualité ne peuvent être garanties.

est risqué pour votre santé

Un médicament contrefait peut présenter une composition différente de celle du médicament d'origine : absence, surdosage ou sous-dosage, principes actifs ou présence de substances toxiques. Ainsi, le médicament peut être inutile, nocif ou dangereux pour votre santé.

peut circuler sur internet

Les médicaments en vente sur Internet sont proposés par des professionnels qui ne sont pas les internautes. Pour vous, c'est dangereux :
- ils n'ont pas le contrôle nécessaire pour garantir l'efficacité et la sécurité de vos médicaments;
- ils ne respectent pas les critères de qualité qui garantissent leur efficacité et leur innocuité (absence de caractère nocif).
Farmaci veri, farmaci falsi

"Un farmaco contraffatto è (...) un farmaco la cui etichettatura è stata deliberatamente e fraudolentemente preparata con informazioni ingannevoli circa il contenuto o l'origine del prodotto. La contraffazione colpisce tanto i farmaci di marca quanto quelli generici; un farmaco contraffatto può contenere le sostanze attive, sostanze diverse da quelle attive, nessuna sostanza attiva, quantità insufficienti di sostanza attiva o può essere contenuto in una confusione contraffatta."

La contraffazione è un vero e proprio crimine, e la sua gravità non è limitata al danno economico verso un marchio commerciale, problema che per altri tipi di contraffazione è sicuramente il principale: quando la contraffazione colpisce un farmaco, diventa un problema di salute pubblica.

L’assunzione di specialità medicinali, contenenti sostanze inattive, si traduce in problemi molto seri qual è, ad esempio, la morte legata all’assunzione di falsi vaccini che non proteggono dalla meningite, o all’assunzione di falsi antibiotici che non debellano le infezioni respiratorie, o addirittura causano shock allergici. Inoltre, quando lo scopo di quei falsificati sono farmaci salutevoli, la semplice inefficacia del medicinale contraffatto diventa potenziale causa di eventi tragici.

L’inefficacia di un medicinale non è l’unico problema della contraffazione. L’incidenza di chi produce questi preparazioni fa sì che anche medicinali tutti altrettanto che critici, come uno scirocco per la tosse, possano diventare pericolosissimi, a causa del possibile utilizzo di sostanze tossiche al posto del principio attivo, come è purtroppo accaduto qualche anno fa.

Si tratta di un problema che sta assumendo dimensioni mondiali e ciò viene documentato da recenti dati divulgati dagli organismi di controllo internazionale.

L’Organizzazione Mondiale della Sanità (OMS) stima al 6% la quantità di medicinali falsi presenti sul mercato mondiale. È chiaro che non si tratta quindi di un problema circoscritto alle vendite di farmaci nei paesi in via di sviluppo: al contrario si è rivelato essere diffuso anche nelle reti dei paesi occidentali, che fino ad oggi erano ritenute pressoché immuni dal problema. Lo dimostrano i recenti sequestri di stampe contraffatte nelle farmacie del Regno Unito.

In Italia, il fenomeno sembra essere limitato alle tipologie di farmaco che arrivano ai pazienti attraverso reti parallele e illegali, o attraverso l’acquisto via internet. Infatti è bene ribadire che non ci sono garanzie sui medicinali acquistati on-line su siti esteri, tanto più che nel nostro paese la vendita di medicinali via internet è esplicitamente vietata. Non c’è ovviamente modo di certificare gli anabolizzanti (o presunti tali) che alcune paesi diffondono in segreto, fuori da ogni controllo medico e farmaceutico. Per queste attività, l’impegno delle nostre forze giudiziarie è comunque rilevante: il solo Comando Carabinieri per la Tutela della Salute, nel periodo 2002/2006, ha sequestrato oltre un milione di filetti illegali provenienti dalle reti non controllate, contenenti farmaci di qualità non conforme agli standard.

L’Agenzia Italiana del Farmaco (AIFA) sta dedicando una particolare attenzione alla lotta internazionale alla contraffazione. Nell’ultimo triennio è stata rafforzata la cooperazione con enti internazionali come il Consiglio d’Europa (l’Italia detiene la vicepresidenza del gruppo ad hoc sulla contraffazione di medicinali), e l’OMS, col quale ha organizzato la conferenza “Combatting counterfeit drugs: building effective international collaboration”. L’evento è stato coniugato con l’apprendimento di tutti gli enti interessati al processo (organizzazioni internazionali, agenzie farmaceutiche, industrie, distributori, pazienti e professionisti sanitari), riuniti per trovare una piattaforma comune per la lotta a questa moderna “epidemia”. Durante il convegno internazionale è stata concordata l’adozione di un “piano di azione comune” per contrastare il fenomeno della contraffazione dei farmaci. Una delle iniziative intraprese ha previsto l’istituzione di una taskforce internazionale (sotto la direzione dell’OMS) denominata IMPACT – International Medical Products Anti-Counterfeiting Taskforce – di cui fanno parte organizzazioni, istituzioni, agenzie, industrie farmaceutiche, associazioni di categoria che, a vario titolo, operano nel settore farmaceutico. Gli scopi di questo organismo informale di cooperazione internazionale...
sono quelli di condividere esperienze, identificare problemi, concordare soluzioni, coordinare azioni comuni per contrastare il fenomeno della contraffazione dei farmaci e dei prodotti farmaceutici. L'Italia è membro effettivo di IMPACT fin dalla fondazione, avvenuta nel luglio 2006 a Roma. Oggi le attività italiane nel gruppo sono focalizzate soprattutto sulla formazione degli investigatori, per i quali l'AIFA sta sviluppando un manuale di casi esemplari e riferimenti, che verrà pubblicato in cooperazione con il Consiglio d'Europa.

A livello nazionale, la mancanza di coordinamento tra i vari attori coinvolti, così come la differenza tra le normative in paesi anche confinanti, rappresenta senz'altro un ostacolo da abbattere per poter efficacemente combatte re il fenomeno. A tale scopo, l'AIFA ha di recente formalizzato la costituzione del tavolo tecnico sulla contraffazione dei medicinali - che riunisce la stessa Agenzia, l'Istituto Superiore di Sanità, il Ministero della Salute e i Carabinieri per la Tutela della Salute, un reparto specifico dell'Arma impegnato sul versante del crimine sanitario.

Il tavolo tecnico, istituito ufficialmente dall'AIFA nel maggio 2007 dopo circa due anni di attività informale, rappresenta un punto di incontro tra chi gestisce i processi autorizzativi e di controllo sui farmaci, chi fornisce il supporto analitico e tecnico e chi sul territorio va alla ricerca delle possibili contraffazioni, per rafforzare ancora di più il controllo, già alto, sulla nostra solidità catena di distribuzione farmaceutica (già efficacemente protetta con il sistema della tracciabilità dei farmaci attraverso i bolli, che rende difficilissima l'entrata di prodotti sospetti nelle nostre farmacie).

L'istituzione formale del gruppo di lavoro, che prende il nome di IMPACT Italia, rappresenta anche la realizzazione di un progetto già delineato dal Consiglio d'Europa* e si configura come un punto di contatto unico (single point of contact) per rivolgersi per le questioni inerenti la contraffazione dei medicinali, che si posa rapidamente interfacciare con i propri omologhi esteri per agire tempestivamente sui casi sospetti, attivando i laboratori e le forze di polizia interessate. L'individuazione di un Coordinatore AIFA delle attività anti-contraffazione, cui indirizzarsi in caso di sospetti, rende ancora più lineare la procedura di gestione italiana della problematica e pose il single point of contact come un modello da seguire e un buon esempio di fattiva collaborazione con tutti gli attori coinvolti. A breve, il tavolo tecnico inizierà un confronto con le altre istituzioni pubbliche e private del settore: industrie e distributori, dogane e investigatori di altre forze (come Guardia di Finanza e Polizia) che verranno chiamati a cooperare ai diversi progetti, per creare insieme una rete efficace di monitoraggio del fenomeno, in grado di intervenire tempestivamente quando si verifichino situazioni sospette.

Tra i risultati già conseguiti dal tavolo tecnico italiano ci sono progetti che riguardano la formazione degli investigatori, e numerose iniziative di studio e informazione. Va segnalato un programma di campionamento sui siti internet sospetti, che vendono a prezzi concorrenziali alcuni farmaci per i quali la presenza di contraffatti in altri Paesi è supportata da una vasta casistica. L'obiettivo dello studio, realizzato con l'OMS, e che vede il coinvolgimento di altre strutture esterne, è raccogliere dati per effettuare una analisi informativa sul pubblico e per supportare in maniera rigorosa una campagna di informazione sui rischi reali cui va incontro chi si affida a fonti non controllate per acquistare prodotti medicinali.

Bibliografia

4. www.coe.int/ (ultimo accesso verificato il 18/04/2007).

*A Contatti: d@ingegneri@atp.it

Agenzia Italiana del Farmaco
Nota Informativa de 13/04/2006

Para: Divulgação geral
Contacto no INFARMED: Centro de Informação do Medicamento e dos Produtos de Saúde (CIM); E-mail: cimi@infarmed.pt; Telef: 800 222 444 (linha verde)

A Comissão Europeia divulgou recentemente um alerta relativo a falsificações da substância activa rimonabant, que estão a ser vendadas em diversos sites da Internet. A substância activa rimonabant destina-se a tratar a obesidade e factores de risco que lhe estão associados, bem como a cessação tabágica. A autorização do medicamento está ainda pendente da demonstração de qualidade, segurança e eficácia no âmbito da Agência Europeia de Medicamentos, a EMEA. Doentes que adquiram cópias não licenciadas e falsificadas ou cópias ilícitas de rimonabant podem estar a colocar a sua saúde em risco.

A venda de medicamentos contraresta através da Internet, e através de outros meios, tem vindo a aumentar nos últimos anos, merecendo uma especial atenção por parte das autoridades reguladoras e dos profissionais de saúde em todo o mundo.

De acordo com informações recolhidas recentemente junto dos Estados membros da União Europeia (UE), 170 medicamentos foram identificados como alvo de contrafação através de canais ilegais de distribuição, nos últimos 5 anos. O mais utilizado tem sido a Internet. Entre os casos identificados encontra-se os medicamentos "lifestyle", as hormonas de crescimento utilizadas na musculação e sedativos. Cópias não autorizadas ou falsificações de medicamentos licenciados para o tratamento da disfunção eréctil e para infeccções virais (como o caso do Tamiflu) também estão presentes nas listas dos falsificadores. Entre os produtos contrafeitos podem ainda encontrar-se alguns que não contêm qualquer substância activa do medicamento em causa ou até com a substância activa errada.

Em Portugal, os medicamentos apenas podem ser comercializados nas farmácias e nos locais de venda de medicamentos não sujeitos a receita médica autorizados pelo INFARMED. Importa referir que, em matéria de comprovação da qualidade de medicamentos, o nosso País é parte integrante do sistema europeu da qualidade de medicamentos. Em Portugal, essa garantia é assegurada pelo INFARMED, enquanto autoridade reguladora, no nível do serviço prestado pelos fabricantes, distribuidores, farmácias, serviços de saúde e profissionais de saúde.

O INFARMED colabora com a Agência de Segurança Alimentar e Actividades Económicas em inspeções regulares aos locais fora do circuito normal de distribuição e dispensa de medicamentos e que possam ilegalmente tentar comercializar produtos não conformes. Qualquer situação suspeita é de imediato comunicada às autoridades competentes, para investigação e ação.

O INFARMED divulga também informação sobre medicamentos aos cidadãos em geral e aos profissionais de saúde em particular, a quem cabe igualmente informar e aconselhar os cidadãos, nomeadamente na consulta médica e na dispensa de medicamentos por parte do farmacêutico. A informação é divulgada através de diversos meios, nomeadamente publicações regulares e na página na Internet, e reuniões e sessões de informação.

No que concerne à compra de medicamentos pela Internet, o INFARMED tem repetidamente referido que os cidadãos apenas devem adquirir medicamentos em estabelecimentos autorizados para esse efeito. A compra de medicamentos através da Internet comporta riscos, por não estarem sujeitos ao normal controlo de segurança, qualidade e eficácia bem como à intervenção do médico e do farmacêutico. Esta aquisição é desaconselhada pelas autoridades de saúde e do medicamento a nível mundial.

Os Estados membros da UE cooperam no combate à contrafação de medicamentos. Para uma maior protecção dos utentes e da indústria contra as actividades de contrafação criminal, as agências do medicamento da UE, a Comissão Europeia e a Agência Europeia de Medicamentos encontram-se a analisar a situação, trabalhando com parceiros internacionais, designadamente a Organização Mundial de Saúde e o Conselho de Europa, na definição de mecanismos e de acções, e formas de cooperação internacional necessárias à salvaguarda da saúde pública neste domínio.

O INFARMED recomenda:

Não adquirir medicamentos através da Internet. O risco associado à utilização de medicamentos é muito elevado. A venda pela Internet não possibiltiza aos utentes o acesso a medicamentos sujeitos a controlos rigorosos, com segurança, qualidade e eficácia demonstradas, tal como sucede no circuito normal do medicamento.
Guideline on medicines and the Internet

The Internet is gaining in significance as a source of information about medicines and a channel for ordering them. Offers on the Internet for the purchase of medicines and the information relating to illness that can be found there can nevertheless constitute risks. In issuing this guideline, Swissmedic is therefore providing information regarding these risks and the legal background, as well as offering tips for obtaining information and ordering medicines from the Internet.

Swissmedic strongly recommends that for questions relating to health, you should consult qualified specialists such as your doctor or pharmacist. These persons are best placed to assess your personal state of health and to recommend the appropriate treatment. Personal contact is not only a better way of assessing a patient’s condition but also means that examinations can be carried out, which is not possible on the Internet.

Legal mail order within Switzerland
The sale of medicines via the Internet represents a special case in terms of mail order business. Basically, obtaining medicines by mail order is prohibited in Switzerland. The competent Cantonal authorities may, however, grant exceptional authorisations to appropriate suppliers, under specific conditions. To obtain medicines by mail order nevertheless requires a medical prescription for each order. This also applies to medicines that are otherwise sold without a prescription. In this way, it is possible to guarantee that specialist advice has been obtained before the order is placed.

Ordering medicines within Switzerland has an advantage: it means that the medicines come from official distribution channels authorised by Swissmedic. To date, the authorities - in collaboration with the pharmaceutical companies, wholesalers and pharmacists - have been able to prevent counterfeit medicines from being distributed in Switzerland.

Obtaining medicines from abroad over the Internet
The purchase of medicines advertised on the Internet can be dangerous for your health. Globally, hundreds of counterfeit, bad quality and ineffective medicines or prescription-only medicines available without prescriptions are offered on the Internet. The range of medicines available worldwide, to treat every possible type of illness, is immense.

The legislative authorities have nevertheless made it possible to obtain medicines abroad legally. An individual may import medicines corresponding to one month’s supply for his or her personal use but not on behalf of third parties. The calculation of one month’s supply is in accordance with the manufacturer’s indications for the medicine in question. For medicines containing narcotics such as hypnotics (sleeping pills), tranquillisers or strong analgesics (painkillers), a prescription issued by a Swiss physician must accompany the order dispatched.

1 Legal basis: Art. 27 of the Swiss Law on Therapeutic Products (HMG; SR 812.21).
2 Legal basis: Art. 20, para. 2, letter a) of the Swiss Law on Therapeutic Products (HMG; SR 812.21) and Art. 36, para. 1 of the Ordinance on Establishment Licenses (AMBV; SR 812.212.1).

The exemption provisions were initially intended for tourists having obtained medicines legally in their home countries. For that reason, the permitted quantity was established as one month’s supply.
Costs relating to the import of medicine from abroad

When comparing costs, it is essential to take into account the following elements in addition to the cost of the medicine. In addition to the dispatch costs, Value Added Tax (VAT) is normally levied on goods imported into Switzerland. In addition, a processing fee is charged for imported goods.

Other factors are also involved, but are frequently underestimated:

- Medicines available on the Internet are at times more expensive than those available from Swiss pharmacies.
- It is impossible to claim reimbursement from your medical insurance scheme.
- Medicines obtained via the Internet cannot usually be returned.
- The transport of medicines is at the recipient’s risk.
- If the order is not received, the buyer alone bears the risk.
- If imported illegally, the medicines may be confiscated and a fee levied for administrative costs (see following page).

Risks

- **Health risk**: the greatest risk when obtaining medicines from the Internet concerns your health. Without advice from a physician or pharmacist, self-diagnosis and self-medication can constitute a risk. It is not impossible that your illness could become worse if it is treated with the wrong medicines or those that are not effective. The principle of “even if it doesn't help, it can’t do any harm” is only valid to a highly limited extent when it comes to your health. The interaction of a medicine with another that you are taking can lead to severe side effects or even result in death.

- **Quality of the medicine**: The quality and composition of medicines obtained from the Internet cannot be guaranteed. Falsified potency drugs, “natural, purely herbal medicines” containing only chemical active substances or toxic impurities, and medicines without an active substance of any kind are all encountered frequently. Even for a medicine actually containing the stated active substance, inappropriate storage or transport may have a negative effect on it.

- **Untested treatments / medicines**: The number of miracle cures offered on the Internet is massive: to lose weight, to build up muscles, to strengthen the immune system and even to fight cancer. For reasons of health protection, Swissmedic strongly advises against the use of treatments other than those commonly used in Switzerland or medicines that have been tested. The offers in question often fail to deliver what they promise. “Slimming cures” frequently contain only diuretics that only seem to reduce your weight. Taking anabolic steroids to build up muscles can lead to health risks such as liver damage, an increased risk of heart attacks, and for men shrunked testicles, sperm production problems or even feminisation with the growth of breasts, or for women masculinisation (lower voice, body hair, disrupted monthly cycle, etc.).

- **Internet providers**: it is important to realise that a provider of medicines on the Internet above all wants to sell the products. Offers by international providers on their websites are often misleading:
Even if they state that the company and the dispatch of their products are legal, this is not necessarily the case.

Creating an online prescription based on the information provided by the person making the order does not make it legal to obtain the medicines from the Internet, nor does it offer security.

Although Internet pharmaceutical suppliers often claim that they are located in Great Britain, Canada or the USA, the medicines may come from, for example, India, China, Thailand, or from various different sources that are difficult to control in small, tropical states.

The checklist for patient information provided later in this guideline can also be of assistance to you when assessing an Internet pharmaceutical supplier.

**Legal measures in the case of illegal import**

If imported medicines are dispatched in quantities that exceed one month's supply, importation is forbidden and the goods are seized by customs.

Non-declared goods are also usually detected thanks to experienced postal and customs staff. The Swiss Customs Service and Swissmedic collaborate closely regarding illegal imports.

Upon the seizure of goods by customs, Swissmedic initiates an administrative procedure that results in the loss (usually destruction) of the medicine. Although only the costs for the work carried out are charged, these costs are, in our experience, at least CHF 300.- and must be borne by the person who placed the order in Switzerland.

In case of repeated offences or the importation of medicines that represent a threat to health, criminal proceedings against the person placing the order are also possible. The importation of medicines with the intention of reselling them is in particular vigorously pursued by Swissmedic, since trading with medicines is subject to stringent requirements (notably the need for a licence).

**Medical information on the Internet**

The persons who are best placed to provide you with information that is appropriate to your personal situation are those with medical qualifications. Given patients' increasing need to obtain additional information from the internet, Swissmedic wishes to provide the following recommendations.

The internet can certainly be helpful, but it does not replace consulting a person qualified in medicine. Discuss the information you have found on the internet with your physician, pharmacist or druggist.

For reliable information on a medicine, the patient information and the specialised information provided for physicians on medicines that are authorised in Switzerland can be found at http://www.documed.ch or http://ch.odd.b.org. This information has been officially reviewed and is accurate. The specialised information nevertheless requires expert medical knowledge. We therefore advise you to discuss any queries with a person qualified in medicine.

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3 Legal basis: Art. 68, para. 1 of the Law on Therapeutic Products (HMIG; SR 812.21)

4 Legal basis: Art. 2, para 1 and Art. 3 in relation to letter V of the relation to Letter V of the Annex to the Ordinance on fees for therapeutic products (HGeBv. SR 812.214.5)
For information on illnesses, health and medicines we recommend that you use the following check list:

Check list for health information on the Internet

1. Who is responsible for the website?
   • Does it include a credible professional qualification and the name of the author or the organisation?
   • Does it have a (complete) contact address?
   • Is a credible company/person responsible for the website? You can find out the name of the 'holder' and the 'technical contact' of a website by typing the URL (the domain name, such as www.name.com) into service sites that provide information on who is behind a site. You can find such sites using www.google.ch, for instance, using the keywords "Domain Whois" or "Domain Dossier".

2. Is the information published reliable, complete, and up to date?
   • In principle, you can assume that sites by public organisations such as the World Health Organisation (WHO), Swissmedic, the Swiss Federal Office of Public Health (BAG), the FDA, professional organizations or the non-governmental foundation "Health on the Net" (www.hon.ch) constitute reliable sources of information.
   • Does the site provide balanced information, including details of both the advantages and risks of the medicine?
   • Is the information up to date, or could it be outdated?
   • Does it contain links to reliable sites?
   • So-called quality labels are not necessarily a guarantee for the credibility of a website and the reliability of the information contained in it.

3. Does the information correspond to your needs?
   • Find out who is targeted by the information (qualified medical personnel, companies, the general public/patients, potential buyers)
   • Does it answer your questions?
   • Are the site provider's interests purely scientific?

Check on all these questions, and remain wary. Compare information that you have obtained from the Internet with information from other sources, and discuss it with your physician or pharmacist. Never provide your personal details on the Internet unless you are certain that the operator complies with security and data protection standards.

Things that should make you suspicious:
   • If the site promises fast or sensational results, usually supported by personal testimonials
   • If the medicines are not authorised in Switzerland, Europe or the USA
   • If the site includes astounding new theories regarding diseases or secret recipes that should be passed on. The apparent plausibility of a theory usually says nothing about its medical substance.
Medicines claimed to be "natural" does not mean that they are not potentially dangerous. The most powerful toxins, for example, are those found in nature.

Claims that a treatment presents no risks, or a lack of information regarding side effects

Claims that the medicine is suitable for anyone, or can be taken on a lifelong basis without any risk whatsoever

Claims that taking this medicine alone is enough to bring about a cure

Sites without the provider's full address, e.g. with an e-mail address only

An aggressive selling approach

Other recommendations

If you feel unwell and need medical advice or a specific medicine, consult a qualified person nearby.

Buy only medicines that are authorised by Swissmedic. You can see this thanks to the Swissmedic sign, in a circle, on the packaging of the medicine. In addition, all authorised medicines are listed on the Swissmedic website (www.swissmedic.ch), in a list under the section Therapeutic Products / Authorised medicines, procedures and effective ingredients.

To date, no counterfeit medicines have been found in legal distribution channels in Switzerland (pharmacies, drugstores, medical practices). Use this reliable, easily accessible channel within Switzerland to obtain your medicine and the corresponding medical advice.

Please note:

If you discover any evidence of medicines coming from Switzerland that are not authorised in Switzerland and that are offered on the Internet for import or export, you can notify Swissmedic (at market.surveillance@swissmedic.ch or by traditional mail).
IGZ waarschuwt: Kopen van medicijnen op internet risicovol


Ook wijst de inspectie op het gevaar van internetdokters. Deze kennen de patiënt vaak niet en zijn dus ook niet op de hoogte van bijvoorbeeld ander medicijngebruik. Ook daarmee loopt de patiënt gezondheidsrisico. In enkele gevallen heeft dat al tot de dood van patiënten geleid. De tuchtcreht heeft Nederlandse artsen verboden medicijnen via internet te schrijven aan patiënten die zij zelf niet kennen of gezien hebben. De inspectie adviseert mensen zoveel mogelijk bij hun eigen huisarts een recept te halen en voor het geneesmiddel naar een "normale" apotheek te gaan.

Plaatsvervangend Inspecteur-generaal Nico Oudendijk noemt de handelswijze van sommige internetsites die medicijnen verkopen ronduit "crimineel". Vaak opereren die netwerken vanuit het buitenland en bieden medicijnen aan op Nederlandse sites. Wekelijks onderschept de douane in ons land honderden buitenlandse pakketjes met illegale medicijnen. De afgelopen tijd heeft de inspectie een groot aantal zaken van verdachte medicijnverkoop op internet samen met de Fod Economische Controle Dienst aangepakt. Meerdere verdachten zijn inmiddels door de rechter of het tuchtcollege voor de gezondheidszorg veroordeeld.


De inspectie vindt dat bij medicijnverstrekking via internet er altijd sprake moet zijn van een behandelsrelatie tussen de patiënt en de arts. Het recept van een arts is de basis voor de verstrekkering door een apotheek. Alleen deze echt bestaande apotheek, die ook via internet verkoopt, kan nagaan of nieuwe medicijnen in combinatie met eerder voorgeschreven pillen geen gevaar voor de patiënt vormen. Zo kunnen gezondheidsrisico's voor de patiënt vermeden worden. Begin dit jaar waarschuwde de IGZ ook al voor advertenties met illegale medicijnen in dagbladen en op advertentiesites.

Bijlagen:
igz film waarschuwing medicijnen [4811Kb]

Vorige pagina
Print pagina
Singapore, Health Sciences Authority: Consumer guide to protection against counterfeit and illegal medicines.

CONSUMER GUIDE TO PROTECTION AGAINST COUNTERFEIT & ILLEGAL MEDICINES

Introduction
Buying medicines from unauthorised sources exposes consumers to the risk of illegal and counterfeit medicines. Though these medicines may be cheaper, they will however pose serious threat to health as they may contain undeclared potent medicinal ingredients, no ingredients or even wrong amounts of ingredients!

Read on to find out what are illegal and counterfeit medicines, how you can identify them and protect yourself.

What are illegal medicines?
Illegal medicines are medicines that are not authorised for sale in Singapore. They may be counterfeits or those containing medicinal ingredients that require regulatory approval. In addition, the safety, quality and efficacy of such products cannot be vouched for.

For instance:
- Adulterated traditional medicines
- Unapproved Western medicines
- Counterfeit medicines

What are counterfeit medicines?
These are medicines that may be presented in a manner so as to resemble or pass off as real medicines when in fact they are not. All counterfeit medicines are illegal medicines!

Dangers of illegal & counterfeit medicines
Illegal medicines often contain undeclared medicinal ingredients that may bring about side effects in susceptible patients. They may also interact with other medicines that the patients are taking and bring about adverse effects.

As counterfeit medicines may contain no medicinal ingredients, wrong ingredients or wrong amounts of ingredients, they may cause undesirable side effects, disrupt medical treatment or result in drug resistance. In serious cases, they may even result in death!

The risk is even greater if the product contains a prescription medicine, the consumption of which has to be under close medical supervision.

Foren-CIM/003
Tips on how to identify a counterfeit medicine

Counterfeit medicines often contain one or more of the following anomalies, whether on the packaging or on the medicines:

- Missing logo or holograms, different layout of the hologram or packaging
- Faded or different packaging colours
- Missing text, different font-type, different font size, poor quality print
- Omission of expiry dates, batch numbers
- Lack of safety seal on the box or bottle
- Different shape, size or colour of the tablets or capsules
- Different markings such as different logos or words printed or embossed on the medicine
- Different taste, texture or consistency of the medicine

In addition, if you notice any difference in the effectiveness of your usual medicine, it is time to raise the red flag!

How to avoid buying illegal & counterfeit medicines

- Do not buy from dubious sources such as street peddlers or via the internet as the safety, quality and efficacy of such medicines cannot be vouched for.
- Always obtain your medicines from licensed clinics and pharmacies
- Know your medicines! Always check the colour, texture, shape and taste of your medicines after obtaining them to ensure that they are not different from your usual supply
- When in doubt, consult your doctor or pharmacist if you notice the following:
  - Your usual medicine looks / feels / tastes different!
  - Your body responds differently to your usual medicine such as, appearance of new symptoms, adverse reactions etc

Be rational. If the price of your usual medicine seems too good to be true, then it probably calls for suspicion!

What to do if you suspect a medicine is illegal or counterfeit

Stop taking the medicine and seek medical advice should you feel unwell.

You can report the incident to your pharmacist or doctor who will then inform the Health Sciences Authority (HSA) accordingly.

Alternatively, you may report the case directly to HSA at:

Enforcement Branch
Enforcement Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-03 Heleos
Singapore 138667
Tel: 68663485
Fax: 64789065
Email: hsa_is@hsa.gov.sg
News
22.10.2008

STOP PIRACY DAY: Thanks for your vote!
The first Swiss STOP PIRACY day will be on 25 October 2008. STOP PIRACY Day is an initiative by the STOP PIRACY association with the support of, in particular, Interpharma, Swissmedic, Microsoft, pharmaSwiss and SAFE to show appreciation to those who purchase only original products, thus undermining the global counterfeiting industry.
07.10.2008

October 25 is STOP PIRACY Day
Exactly right for the original – STOP PIRACY day is October 25 in Switzerland. A variety of events will be taking place: Many pharmacies are offering to check medications bought over the internet for authenticity at no fee and no penalty. Select retail stores will offer software at special prices, and a competition with superb prizes will be held. The goal of the action is to sensitize the internet-shopping public. In addition, the pharmaceutical, music, film and software businesses want to thank those who do not consume counterfeited products.
03.10.2008

Workshop “Counterfeiting and Piracy: From problem to solution”
The goal of this workshop is to examine the problem of counterfeiting and piracy of IP-protected products in depth from various points of view. Presenters will analyze the background of counterfeiting and piracy and report on their experience in various industries sectors as well as from the point of view of consumers. In addition, the latest legal measures for combating counterfeiting and piracy will be presented and the practical application by federal and criminal authorities will be discussed. A concluding round table will discuss the question: "Can the fight against counterfeiting be won? What do we need to do?" (link to program schedule and registration form, in German only).
01.07.2008

 Destruction of counterfeited watches and DVD's: Buying counterfeited goods isn't worth it anymore: Swiss Customs can now destroy imported counterfeits
New regulations for combating counterfeiting and piracy entered into force in Switzerland today. With them, importing counterfeited trademark and design goods into Switzerland—even for private use—is now illegal. To highlight the entering into force of the new regulations, the Swiss Anti-Counterfeiting and Piracy Platform STOP PIRACY, the Central Office for Precious Metal Control, the Swiss Watch Industry FH, and the Swiss association for combating piracy (SAFE) held a destruction action of counterfeited Swiss watches and pirated DVDs (see press release in German, pdf 109 KB or in French, pdf 109 KB).
26.06.2008

Press conference "Improved protection for intellectual property as of July 1, 2008"
Legal measures for dealing with counterfeited goods and piracy products will be more
comprehensive in Switzerland begin ning July 1. They reflect current developments and a e con users as well. A joint press conference about the changes was held by the Federal Institute of Intellectual Property, Federal Councilor Eveline Widmer-Schlumpf and the STOP PIRACY association (Media release, pdf 41 KB).

24.06.2008

New flyer for STOP PIRACY
The new flyer for STOP PIRACY is now available. It gives information about the dangers of counterfeited and pirated products, valuable tips about how to recognize imitations and encourages people to 'take the wind' out of the sails of pirates and counterfeiters! (Flyer, pdf 142 KB).

12.06.2008

Invitation to the Press Conference
"Intellectual property will be protected even better in Switzerland as of 1 July 2008"
At a press conference on June 26, the Swiss Federal Institute of Intellectual Property and the organization STOP PIRACY, a cooperative initiative by the public and the private sector against counterfeiting and piracy, will be explaining the content and effects of the new legislation against counterfeiting and piracy (Invitation, pdf 138 KB).

00.05.2008

Statistics
EU statistics for 2007 (pdf 227 KB) are now available online.

25.04.2008

Swissmedic provides information on the risks of obtaining medicines from the Internet
Hundreds of counterfeited medicines, of poor or ineffective quality, are being purchased globally over the Internet. The Swiss Agency for Therapeutic Products (Swissmedic) has issued a new guideline (pdf 60 KB) explaining the legal background on Internet trade, informing of the risks involved, and offering tips on how to find information about medicines on the Internet.

22.04.2008

Last Stop
The St. Galler Tagblatt reports about the confiscation and destruction of counterfeited goods destined for private use (Article in German, pdf 812 KB).

02.04.2008

Colloquium on the counterfeiting of pharmaceutical products
On Friday, May 23, 2008 a one-day colloquium concerning the counterfeiting of pharmaceutical products will be held in the tower of the Federal Statistical Office in Neuchâtel. The one-day event has been organized by various organizations under the auspices of STOP PIRACY (including: Institute for combating economic criminality, Institute of criminal authorities for Western Switzerland, University of Neuchâtel, Institute for health law, University of Applied Sciences Western Switzerland, Swiss Agency for Therapeutic Products-Swissmedic, and Federal Institute of...
20.03.2006

**Customs is the Last Stop for Fakes**

The "Südostschweize am Sonntag" newspaper recently published an article on the future confiscation of counterfeit articles at the Swiss customs, including a comment by Felix Addor, Deputy Director General of the Federal Institute of Intellectual Property and Vice-President of STOP PIRACY, and Andreas Tschöpe (Foundation for Consumer Protection). The article also includes tips on how to recognize fakes (see Article, in German, pdf 187 KB).

19.03.2006

**iPhone**

Yokiland has been selling original Apple Phones since the beginning of March - even though Apple does not distribute the cell phone in Switzerland yet. At the same time, counterfeits from China are for sale (20 Minuten in German, see story in German, pdf 42 KB, and photo pdf 102 KB. © by www.20min.ch).

06.03.2006

**Statistics**

Federal Customs Administration statistics for 2007 (pdf 149 KB) are now available online.

06.01.2006

**CD-Rom "Music and Copyrights"**

The University of Neuchatel and SUISA have produced a CD-Rom titled "Music and Copyrights." The multimedia product for PCs, in French, uses a fun, interactive format for the younger generation to teach about copyrights in the field of music and raise awareness about authors rights and the fight against piracy. The CD is available free of charge through the University of Neuchatel media, communication and marketing service. E-mail or contact SUISA, Avenue du Grammont 11bis. 1007 Lausanne, telephone 021-614-3232 E-mail.

07.12.2007

**Anit-Counterfeiting and Piracy Conference, University of Geneva**

The Law Faculty of the University of Geneva in collaboration with the STOP PIRACY Association has organized a one-day conference on the topic of counterfeiting and piracy. The schedule and program (French only, pdf 202 KB) for the February 15th, 2008 conference is available online in a printable version.

01.12.2007

**STOP PIRACY president and vice-president interviewed by SWISS magazine**

SWISS magazine spoke with President Anastasia Li-Treyer and Vice-President Felix Addor of

STOP PIRACY on the global trade in counterfeited goods. Read their interview here (in German, pdf 102 KB).

02.11.2007

OECD

Work on the first phase of the OECD project on counterfeiting and piracy has been completed, and a draft of the study report about “The Economic Impact of Counterfeiting and Piracy” can be found at OECD.

03.10.2007

STOP PIRACY – Counterfeiting and Piracy in Sight

In Switzerland, representatives of the private sector and the administration have teamed up to fight counterfeiting and piracy in the framework of STOP PIRACY. Today’s member assembly was focused on the public campaigns aimed at waking the public up to this issue Media Release (pdf 51 KB)

25.09.2007

Statistics

EU statistics for 2006 (pdf 282 KB) are now available online.

01.07.2007

Founding of STOP PIRACY Association

The Swiss Anti-Counterfeiting and Piracy Platform was transformed into a legal association on July 1, 2007. This represents a new phase for the initiative which was launched by the Federal Institute of Intellectual Property and the ICC Switzerland as an effort to combine efforts from the private and public sectors.

08.06.2007

Workshop

STOP PIRACY, the Swiss Anti-Counterfeiting and Piracy Platform, announces a workshop titled “Fighting Counterfeiting and Piracy on the Internet” (invitation in French or German, pdf 316 KB) to be held June 22, 2007 at the World Trade Institute, Hallerstrasse 6, 3012 Bern. The time is 9.00 till 16.00 hours.

11.05.2007

International Exhibition of Inventions

The International Exhibition of Inventions took place in Geneva April 18-22, 2007. Among the exhibitions, the STOP PIRACY stand was highly visible (see photos, pdf 122 KB).

04.05.2007

www.stop-alla-pirateria.ch

Information about the Swiss Anti-Counterfeiting and Piracy Platform in Italian is now available.

13.04.2007

**Muba**

STOP PIRACY teeshirts a big hit at the customs authority stand. [Photos](#) (pdf 220 KB) from the event (by kind permission of Rahel Gäss, Karin Märki, and Patricia Leuenberger).

10.04.2007

**Trademark Piracy**

Article on trademark piracy printed in the Jan./Feb. 2007 "persönlich" magazine in [German](#) (pdf 924 KB), by kind permission of the editor-in-chief.

23.03.2007

**Statistics**

Federal Customs Administration [statistics for 2006](#) are now available online.

21.03.2007

**VICTORINOX**

VICTORINOX successfully fights product pirates at CeBIT. Press release in [German](#) (pdf 15 KB).

16.02.2007

**Interview with Thomas Pletscher**

Moneyscat-Interview in [German](#) with Thomas Pletscher, Secretary-General of the Swiss Section of the International Chamber of Commerce ICC, Monday, 12 February 2007.

16.01.2007

**STOP PIRACY launched**

"STOP PIRACY," the public awareness campaign by the Swiss Anti-Counterfeiting and Piracy Platform was launched today, Tuesday January 16, 2007, as part of a press conference in Zürich. More information about the event and the topic can be found in the [press folder](#).

09.01.2007

**Press conference for STOP PIRACY**

Product piracy is a problem causing an estimated two billion francs damage annually to the Swiss economy. In an effort to combine the forces of business and government to more effectively fight this phenomenon, the Federal Institute of Intellectual Property (IGE) and the Swiss chapter of the International Chamber of Commerce (ICC Switzerland) have founded the "Swiss Anti-Counterfeiting and Piracy Platform". On January 16, 2007 a press conference for the platform will take place at the Zürich Airport with the participation of Federal Councillor Christoph Blocher and other experts from business and government. The conference will introduce the platform as well as present information on the beginning and content of a poster campaign and other activities. For further information contact ins.sieder@pi.ch

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Health Information Sources

Licensed physician and pharmacist – reliable sources

Official Health institutions – easy to check source, reliable information

Medical libraries, academic sources – information mostly in scientific language

Health professionals’ organisations – check within your country first, may use scientific language

Consumer and Patient Support Associations – likely to use consumer friendly language

Non-profit institutions – easily checkable if renowned

Commercial companies – likely to give information only about their own products

Individually posted information, other sources – difficult to check, could be unreliable

[Suspicious signs]

- Claims of fast, guaranteed or sensational results
- Miraculous cure or secret formulas
- Claims of no risks or absence of information on side effects
- Experts or personal testimonials
- Claims of efficacy for a wide range of conditions or for every person
- Sites without complete address only e-mail indicated
- Aggressive commercial behaviour, e.g. you cannot leave the site

Learn about Quality Information Tools

Check with health authorities in your country about the existence of quality tools such as a seal, accreditation system or other local initiatives.

< Codes and Symbols >

Check with health authorities in your country about the existence of quality tools such as a seal, accreditation system or other local initiatives. 

Medical products and the Internet – a guide to finding reliable information

Health On the Net Foundation <www.hon.ch>
Internet HealthCare Coalition <www.ihc.net>
DISCERN <http://www.discern.org.uk>
MedCIRCLE
Quality Criteria for Health Related Websites, European Commission communications

Websites offering medicines and/or medical services

Check with your health authorities, if either prescription or selling through the Internet are allowed.
Verify, if the selling point is licensed to provide or sell those products and services (check with Health Authorities)
Make sure, you are dealing with licensed Health professionals.
The major problems in the field of Medicines and the Internet are the overflow of information and an abundance of risky offers.

To help you with the right choice:

The Council of Europe and [to insert partner] gives you the following practical tool.

Check the topics inside.

Internet can be helpful but does not replace the consultation with a health professional.

Don’t forget to discuss and share the information obtained from the Internet with your doctor or pharmacist.

In some countries medicines may only be sold in licensed pharmacies and they must have the proper marketing authorization. National medicines regulatory authority or the European Medicines Evaluation Agency (EMEA) are responsible for these issues.

In order to practice, physicians and pharmacists must be registered in their respective professional societies.

EMEA:
http://www.emea.eu.int/exlinks/exlinks.htm

Other European regulatory bodies:
http://www.who.int/medicines/information/websites/infdra.shtml

Check the World Health Organisation user guide available at:

Avoid Risks or Your Health!

Illegal sale settings/Foreign sites

Illegal practices

Be aware: Incorrect diagnosis, insufficient, misleading or wrong counseling, Medicines inappropriate and harmful for your condition, inadequate treatment.

Misleading information

Be aware: Lack of information, biased information, wrong information, products with the same name may be different in different countries.

Seek Safe Medicinal Products!

Buy only medicinal products approved by a competent authority!

Quality medicines are dispensed by licensed persons and licensed sale channels, which are controlled by a responsible authority.

If you need a prescription or any medical advice be sure to contact a licensed health professional.

Committee of Experts on Pharmaceutical Questions - Council of Europe
F - 67075 Strasbourg Cedex
Tel: + 33 (0) 3 88 41 20 00
Fax: + 33 (0) 3 88 41 27 81
http://www.coe.int/T/E/Social_Cohesion/soc-sp/Public_Health/Pharma_and_Medicine/presentation%20pharma.asp#TopOfPage

Medicines & Internet

The major problems in the field of Medicines and the Internet are the overflow of information and an abundance of risky offers.

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Internet can be helpful but does not replace the consultation with a health professional.

Don’t forget to discuss and share the information obtained from the Internet with your doctor or pharmacist.
Commission warns about fake drugs on the internet

The European Commission has issued a warning that fakes of the medicine rimonabant are currently being sold via several websites. Rimonabant has been developed to treat obesity and related risk factors and smoking cessation. The medicine is still under evaluation by the European Medicines Agency (EMEA). The product will only receive marketing authorisation by the European Commission once its quality, safety and efficacy have been satisfactorily established by the EMEA scientific committee, and this approval is still pending. Once approved, the company intends to market rimonabant under the name Acomplia™. Patients who buy unlicensed and counterfeit or illicit copies of rimonabant may be putting their health at risk. This latest example underlines European Commission concern that criminals are taking advantage of the anonymity of the internet to sell fake, adulterated and unlicensed medicines to an unsuspecting public, putting lives at risk as well as undermining the pharmaceutical industry.

Commission Vice-President Günter Verheugen responsible for enterprise and industry products said: “I am alarmed at the ever increasing number of counterfeit medicines sold via the internet. This represents a real danger to the health of patients. The Commission is working with European and international partners to do everything possible to ensure legal methods for marketing of medicines are respected and enforced.”

Counterfeitors try to bypass the foreseen regulatory pathways of licensing and supervision by competent authorities. According to a recent survey by the Member States, 170 medicines were identified to be counterfeit in the illegal distribution channels over the past 5 years. Such illegal trade often occurred through the internet. Among the cases identified, lifestyle, growth hormones for bodybuilding use and sleeping drugs played a particular role. Unauthorised copies and fakes of licensed medicines for the treatment of erectile dysfunction (e.g. Viagra®, Cialis®) and viral infections (e.g. Tamiflu®) have also been on the sales lists of criminal counterfeiters. Counterfeits may include fakes which do not contain any of the medicine or the wrong medicine. At the same time, they may damage the image of a product and companies investing in the research and application of these products, while criminals try to make money without taking any responsibilities and risks.

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7 Developed by Sanofi Aventis
8 market authorisation holder: Pfizer
9 market authorisation holder: Lilly ICOS
10 market authorisation holder: Hoffmann La Roche
To be marketed in the EU, all medicines must undergo a rigorous evaluation for authorisation to demonstrate that they are effective, adequately safe and of high quality. This is ensured by a robust regulatory system for the authorisation of new medicines. The EU also has a strong legal framework for the licensing, manufacturing and distribution of medicines. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including the legitimate sale over the Internet.

Member States enforcement services closely cooperate to combat fake medicines. To further protect patients and industry from criminal counterfeit activities, the Commission is currently analysing the situation and working together with Member States, the European Medicines Agency and international partners on what further actions may be necessary to safeguard public health.

26/07 BfArM warnt vor Arzneimittelfälschungen aus dem Internet

Erstellt: 16.10.2007

Pressemitteilung 26/07


Durch die Überwachungsbehörden veranlasste Untersuchungen dieser verschreibungspflichtigen Arzneimittel, die u. a. auf verschiedenen Internetseiten wie pillenpharm.com, usa-medz.com und emediline.com angeboten wurden, haben ergeben, dass es sich bei den dort verkauften Produkten um Fälschungen handelt. Besonders bedenklich ist, dass entweder statt des deklarierten Wirkstoffes ein anderer hochwirksamer nicht deklarieter Bestandteil oder der deklarierte Wirkstoff in viel zu geringer Konzentration enthalten ist. Vor der Einnahme dieser Arzneimittel, die in kleinen Plastiktütchen verpackt versandt werden, muss grundsätzlich gewarnt werden.

Das BfArM empfiehlt daher nach den Worten seines Leiters, Prof. Dr. Reinhard Kurth, „Arzneimittel nicht aus unsicheren Quellen über das Internet zu erwerben. Dies betrifft besonders rezeptpflichtige Arzneimittel wie zum Beispiel auch Medikamente zur Behandlung von Erektionsstörungen, da sie wegen möglicher Risiken der Verordnung und der Kontrolle durch den Arzt bedürfen“.

„Wenn Sie den Verdacht haben, Ihnen könnte eine Fälschung vorliegen, sollten Sie das Produkt auf keinen Fall einnehmen und Ihren Arzt oder Apotheker fragen“, rät Prof. Kurth.

Ausgabejahr: 2007
Swissmedic met de nouveau en garde contre les contrefaçons d’antigrippaux.


Swissmedic met de nouveau en garde contre les contrefaçons d’antigrippaux

Encouragé par les risques potentiels liés à la grippe aviaire, le commerce illégal sur Internet de produits vendus sous l’appellation de l’antigrippal Tamiflu ne cesse de croître.

Or, comme le montre la récente analyse réalisée par les laboratoires de Swissmedic, certains de ces produits sont en fait des contrefaçons. Les contrefaçons de médicaments présentent des dangers considérables pour la santé. Swissmedic déconseille donc la prise de médicaments provenant de sources non contrôlées.

On trouve partout dans le monde sur Internet une pléthore de médicaments vendus sous le nom de Tamiflu. Reste que seule la préparation originale destinée à lutter contre la prolifération des virus de la grippe dans l’organisme humain vendue sous ce nom de marque est officiellement autorisée en Suisse par Swissmedic. Soumise à ordonnance, elle est distribuée par l’entreprise Roche.

L’analyse en laboratoire d’une préparation vendue sur Internet comme du Tamiflu a révélé des résultats inquiétants : au lieu du principe actif original oseltamivir, le produit concerné contenait une faible dose de paracétamol, un principe actif antipyrétique et analgésique inapte à enrayer une infection virale chez l’homme, accroissant ainsi notablement le risque pour la santé. D’autres autorités sanitaires en Europe ont également découvert des contrefaçons similaires.

Distinguer une contrefaçon de l’original

Dans le cas d’espèce, le faux Tamiflu vendu sur Internet ne comporte aucune notice d’emballage. Les maigres informations fournies avec le produit sont partiellement erronées et ne répondent en aucun cas aux exigences actuelles auxquelles doivent satisfaire les médicaments soumis à autorisation. Elles font également l’impasse sur les indications essentielles concernant les précautions à observer lors de la prise du médicament ou sur ses effets indésirables possibles. De même, les informations sur le titulaire de l’autorisation, la posologie ou la date de péremption font défaut. La contrefaçon est clairement reconnaissable - même pour les profanes - puisque la préparation est livrée dans un sachet plastique et non dans l’emballage en carton habituel. Il manque également sur les gélules l’impression de la raison sociale de l’entreprise et du dosage (voir illustrations ci-contre).

Aucune contrefaçon de médicament n’a pour l’instant été constatée dans les centres de distribution officiels de Suisse. En accord avec d’autres autorités européennes de contrôle des médicaments, Swissmedic continue toutefois de vérifier par échantillonnage si des contrefaçons de Tamiflu sont proposées dans des canaux de distribution non autorisés. Swissmedic déconseille expressément l’achat de médicaments provenant de sources non contrôlées, en particulier sur Internet ou par l’intermédiaire de personnes qui ne sont pas des professionnels de la santé. Comme l’atteste l’exemple du « Tamiflu » à base de paracétamol,
l’achat de produits pharmaceutiques sur Internet présente un risque certain pour la santé. Swissmedic a publié sur ce sujet un guide complet intitulé « Internet et les médicaments », à télécharger sur son site Web (www.swissmedic.ch /Hot Topics).

Communiqué de presse
2006
Swissmedic · Hallerstr. 7 · Case postale · CH-3000 Berne 9 · www.swissmedic.ch · Tél. +41 31 322 02 11 · Fax +41 31 322 02 12
Dans un communiqué daté du 21.12.05, Swissmedic avait déjà mis en garde contre les risques de contrefaçons de l’antigrippal Tamiflu.
Lien : http://www.swissmedic.ch/Archiv/Faelschungsthematik.pdf
Pour toute information complémentaire, contacter :
Monique Helfer, responsable Communication, tél. 031 322 02 76.
Gélules de Tamiflu : contrefacon à gauche, préparation originale à droite
Emballage de Tamiflu : contrefacon (à gauche), original (à droite)
Health Canada reminds consumers about the risks of buying drugs online. 


OTTAWA - Health Canada is reminding Canadians about the potential dangers of buying prescription drugs online, following the July 4th release of the British Columbia Coroner's report on the death of a woman which was attributed to prescription drugs purchased online.

While legitimate online Canadian businesses are an option to consider, the online purchase of any drug poses the potential for serious health risks, especially when drugs are shipped directly to Canadian consumers from sources outside of Canada. Consumers should be aware that some Internet sites may falsely claim to be Canadian, and consumers can identify if a drug has been shipped to them from a foreign country by checking the shipping information on the exterior of the package.

Buying drugs from an Internet-based business that does not provide a street address and telephone number may pose serious health risks because consumers have no way of knowing where these companies are located, where they get their drugs, what is in their drugs, or how to reach them if there is a problem. Buying drugs on the Internet may also pose financial risks: the product may not be shipped at all, or if it is coming from another country, it could be stopped and refused entry at the border by Canadian authorities.

If you order from these sites, you may get counterfeit drugs that may contain the incorrect dose, the wrong ingredients, dangerous additives, or no active ingredients at all, which could result in potentially serious health risks. Even if these drugs do not harm you directly or immediately, your condition may get worse without effective treatment.

In order to minimize the risk of purchasing counterfeit drugs, consumers who choose to purchase their medication via the Internet should not do business with any Web site or company that:

- refuses to give a street address, telephone number or way of contacting a pharmacist;
- offers prescription drugs without a prescription;
- offers to issue a prescription based on answers to an online questionnaire;
- claims to have a "miracle cure" for any serious condition; or
- sells products that are not approved for sale in Canada.
- sells products that are being provided directly to consumers from foreign sources.

If you order prescription drugs without being examined and monitored by a health care practitioner, you may be misdiagnosed, and miss the opportunity to get appropriate treatment that would help you. You may also put yourself at risk for drug interactions, or harmful side effects that a qualified health professional could better foresee.

In order to minimize risk, Canadians should only take medication that has been prescribed to them by their doctor. Patients should be aware of the name of the drugs they are taking and be familiar with their usual colour, size, shape and any imprints or markings on the drug. Patients who are concerned that they may have received counterfeit drugs should consult their physician immediately.

Counterfeit products may have one or more of the following characteristics:

- labels with spelling mistakes;
- labels with no Drug Identification Number (DIN) or Natural Product Number (NPN); or
• product having different taste or flavour than the product normally used.

Consumers who may have encountered suspected counterfeit health products are encouraged to contact Health Canada by calling 1-800-267-9675.

In Canada, pharmacies are regulated by the provinces. If you have questions about whether an Internet pharmacy is legitimate, please contact the licensing body in your province or territory.

For more information, please visit the It's Your Health articles:

• Buying Drugs Over the Internet
• Buying Medical Devices over the Internet

The Possible Dangers of Buying Medicine Online (see next page)
People can be confident that Web sites that are VIPPS-approved are legitimate. Legitimate pharmacies that carry the VIPPS® seal are listed at www.vipps.info.

Drugs purchased over the Internet by an American patient who was told that the products were manufactured in the United States and were being sold from Canada. The drugs he actually received are fake "knockoffs" from India.
On this page:

- Set Your Sites High
- Know Your Medicines
- Be Aware of Counterfeit Medicine
- Protect Yourself

The Food and Drug Administration cannot warn people enough about the possible dangers of buying medications online. Some Web sites sell medicine, such as prescription and over-the-counter drugs, that may not be safe to use and could put people's health at risk. The current system of federal and state safeguards for protecting consumers from using inappropriate or unsafe drugs has generally served the country well. But FDA says that the best way consumers can protect themselves is to become educated about safe online shopping.

**SET YOUR SITES HIGH**

Buying such prescription and over-the-counter drugs online from a company you don't know means you may not know exactly what you're getting. While many Web sites are operating legally and offering convenience, privacy, and the safeguards of traditional procedures for dispensing drugs, consumers must be wary of "rogue Web sites" that aren't operating within the law. A Web site can look very sophisticated and legitimate but actually be an illegal operation.

These sites often sell unapproved drugs, or if they market approved drugs, they often sidestep required practices meant to protect consumers. Some Web sites sell counterfeit drugs. Although counterfeit drugs may look exactly like real FDA-approved drugs, they are not legitimate and are of unknown quality and safety. If you're considering buying medicine over the Internet, look for Web sites with practices that protect you. If there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required, you should be especially wary.

**Safe Web sites should**

- Be located in the United States.
- Be licensed by the state board of pharmacy where the Web site is operating (visit www.nabp.info for a list of state boards of pharmacy).
- Have a licensed pharmacist available to answer your questions.
- Require a prescription from your doctor or other health care professional who is licensed to prescribe medicines.
- Provide contact information and allow you to talk to a person if you have problems or questions.

The National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites™ Seal, also known as VIPPS® Seal, gives a seal of approval to Internet pharmacy sites that apply and meet state licensure requirements and other VIPPS® criteria.

People can be confident that Web sites that are VIPPS-approved are legitimate. Legitimate pharmacies that carry the VIPPS® seal are listed at www.vipps.info

**Unsafe Web sites**

- Typically don't know your medical history or the details about your current illness or condition.
- Send you drugs with unknown quality or origin.
• Could give you the wrong medicine or another dangerous product for your illness.
• May sell prescription drugs even without a prescription—this is against the law!
• May not protect your personal information.

KNOW YOUR MEDICINES
Before you get any new medicine for the first time, talk to your doctor about any special steps you need to take to fill your prescription. In addition

• Any time you get a prescription refilled, check the physical appearance: color, texture, and shape of the drug. Even if all of these characteristics appear to be okay, there may be a problem if the medication doesn't taste like it has in the past.
• Pay special attention to altered or unsealed containers or changes in product packaging.
• Alert your pharmacist, or whoever is providing treatment, if you notice any differences or anything unusual about the product packaging.
• Make sure that you only use drugs that have been prescribed by your health care provider who is licensed in the United States to prescribe medications.

Be aware that some medicines sold online

• Are too old, too strong or too weak.
• Aren’t FDA-approved.
• Aren’t made using safe standards.
• Aren’t safe to use with other medicines or products.
• Aren’t labeled, stored, or shipped correctly.

BE AWARE OF COUNTERFEIT MEDICINE
Counterfeit drugs are fake or copycat medicines that can be difficult to identify. The deliberate and fraudulent practice of counterfeiting can apply to both brand name and generic products, where the identity of the source is often mislabeled in a way that suggests it is the authentic approved product. Counterfeit drugs may

• Be contaminated.
• Not help the condition or disease the medicine is intended to treat.
• Lead to dangerous side effects.
• Contain the wrong active ingredient.
• Be made with the wrong amounts of ingredients.
• Contain no active ingredients at all or contain too much of an active ingredient.
• Be packaged in phony packaging that looks legitimate.

For example, counterfeit versions of the FDA-approved weight loss drug Xenical, which contains the active ingredient orlistat, recently were obtained by three consumers from two different Web sites. The agency announced in May 2007 that none of the capsules that the consumers received contained orlistat. In fact, laboratory analysis showed that one capsule actually contained sibutramine, which is the active ingredient in Meridia, a prescription drug also approved by FDA to help obese people lose weight and maintain weight loss.
Using medication that contains an active ingredient other than what was prescribed by your licensed health care provider is generally unsafe.

FDA also became aware recently of a number of people who placed orders over the Internet for

- Ambien (zolpidem tartrate)
- Xanax (alprazolam)
- Lexapro (escitalopram oxalate)
- Ativan (lorazepam)

Instead of the intended drug, several customers received a product that contained haloperidol, a powerful anti-psychotic drug. As a result, some sought emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms and muscle stiffness—all problems that can occur with haloperidol.

FDA continues to be proactive in aggressively protecting consumers from counterfeit drugs. The agency is working with drug manufacturers, wholesalers, and retailers to identify and prevent counterfeit drugs. FDA also has created an internal task force to explore the use of modern technologies and other measures that will make it more difficult for counterfeit drugs to get mixed up with, or deliberately substituted for, safe and effective drugs.

Generally, medications that have not been purchased with a prescription from a state-licensed pharmacy located in the United States may be unsafe and ineffective. But remember, even those drugs that are purchased from a state-licensed pharmacy Web site cannot be guaranteed safe and effective.

**PROTECT YOURSELF**

- Only buy from state-licensed pharmacy sites based in the U.S. (preferably from VIPPS-certified sites, when possible).
- Don't buy from sites that sell prescription drugs without a prescription.
- Don't buy from sites that offer to prescribe a medication for the first time without a physical exam by your doctor.
- Check with your state board of pharmacy or the NABP to see if an online pharmacy has a valid pharmacy license and meets state quality standards.
- Sites ending in ".com" are usually commercial sites selling products (they may be either legitimate or rogue sites). Sites that end in ".gov" (government), ".edu" (universities or medical schools), and ".org" (not-for-profit groups) may be good sources of health information.
- Use legitimate Web sites that have a licensed pharmacist to answer your questions.
- Look for privacy and security policies that are easy to find and easy to understand.
- Don't give any personal information, such as a social security number, credit card information, or medical or health history, unless you are sure the Web site will keep your information safe and private.
- Make sure that the site will not sell your personal information, unless you agree.
- Report Web sites that may be problematic. You can do this by visiting [www.fda.gov/buyonline](http://www.fda.gov/buyonline) and clicking on "Notify FDA about problem websites."
**ALERT:** For a list of drugs that you should NOT buy online because of special safety restrictions, visit [www.fda.gov/cder/consumerinfo/dontBuyonNet.htm](http://www.fda.gov/cder/consumerinfo/dontBuyonNet.htm)

To see a press release called "FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet," visit [www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html](http://www.fda.gov/bbs/topics/NEWS/2007/NEW01663.html)

To see a press release called “FDA Says Consumers Continue to Buy Risky Drugs Online,” visit [www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html](http://www.fda.gov/bbs/topics/NEWS/2007/NEW01735.html)

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*Date Posted: July 2, 2007*

*Updated Nov. 2, 2007*
France, Afssaps/Ordre national des pharmaciens: "Guide à l'usage des pharmaciens".
Contexte général

3 Qu'est-ce qu'une contrefaçon ?
3 Etat des lieux
5 D'autres produits de santé sont-ils susceptibles d'être contrefaits ?
5 Quel est le principal vecteur de vente de produits contrefaits en France ?
6 Quelles sont les risques pour la santé ?
6 Comment expliquer la progression de la contrefaçon ?

Cette brochure, élaborée conjointement par l'Ordre national des pharmaciens et l'Atssaps, a pour objectif de sensibiliser, d'informer et d'impliquer le pharmacien dans la lutte contre la contrefaçon.

Repères pour le pharmacien

7 Comment reconnaître une contrefaçon ?
7 Quel est le rôle du pharmacien vis-à-vis de ses patients ?
8 Où trouver les outils nécessaires pour s'informer ?
9 Quelle est la procédure à suivre pour un produit suspecté de contrefaçon ?
11 Quelle est la réglementation applicable pour lutter contre la contrefaçon ?

La contrefaçon des produits de santé est, en effet, en fort développement à travers le monde. Elle représente aujourd'hui environ 10% du commerce mondial de médicaments.
Contexte général

Qu'est-ce qu'une contrefaçon ?

Selon le Comité National Anti-Contrefaçon, la contrefaçon est « l'action de reproduire par copie ou imitation une œuvre littéraire, artistique ou industrielle au préjudice de son auteur, de son inventeur », ce qui prête à confusion auprès des consommateurs.

La définition de l'Organisation Mondiale de la Santé (OMS) précise qu'un médicament contrefait est un médicament qui est délibérément et frauduleusement muni d'une étiquette n’indiquant pas son identité et/ou son origine véritable.

La contrefaçon peut viser une spécialité de référence (produit de marque) ou un médicament générique. Elle peut se manifester sous différentes formes :
- présentation et/ou composition identique ;
- composition différente (absence, sous dosage ou surdosage de principe actif, présence d'ingrédients nocifs) ;
- conditionnement falsifié (emballage contrefait, permettant par exemple de « repousser » la date de péremption de médicaments périmés).

État des lieux

En France

Jusqu'à aujourd'hui, aucun cas de contrefaçon de médicament n'a été notifié en France dans le circuit de distribution autorisé des médicaments.

À chaque niveau de la chaîne pharmaceutique française (fabricants, exploitants, dépositaires, grossistes répartiteurs, pharmacies d'officine, pharmacies à usage interieur, pharmacies mutualistes ou de secours minières), une vigilance renforcée s'impose. De plus, des pays voisins sont déjà concernés (Royaume-Uni, Pays-Bas et République tchèque).

Au sein des collectivités et départements d'Outre-Mer, cette même vigilance doit être appliquée compte tenu de la situation géographique (insularité) et de la particularité des frontières (Mayotte, Guyane, Saint-Martin).
En effet, la vigilance de chacun est requise pour éviter l’introduction dans la chaîne pharmaceutique de produits contrefaits achetés auprès d’une entreprise non habilitée à vendre des spécialités pharmaceutiques.

**Au niveau européen**

**Exemples de contrefaçons identifiées depuis 2004**

<table>
<thead>
<tr>
<th>Médicaments contrefaits</th>
<th>Pays concernés</th>
</tr>
</thead>
<tbody>
<tr>
<td>CALUS® (médicament du dysfonctionnement érectile)</td>
<td>Royaume-Uni et Pays-Bas</td>
</tr>
<tr>
<td>LPTNOR® (médicament hypochloestérémie)</td>
<td>Royaume-Uni</td>
</tr>
<tr>
<td>REDUCIL® (médicament anorexigène)</td>
<td>Royaume-Uni</td>
</tr>
<tr>
<td>SPROFENT® (spécialité aréolaire dans le traitement de l’asthme)</td>
<td>République tchèque</td>
</tr>
<tr>
<td>PLAVIX® (médicament antiagrégant plaquettaire)</td>
<td>Royaume-Uni</td>
</tr>
</tbody>
</table>

Ces cas de contrefaçon sont d’autant plus préoccupants qu’ils ont été découverts, pour la plupart, dans le circuit autorisé de distribution des médicaments, chez les grossistes-répartiteurs et dans les pharmacies de ville.

**Exemple de saisies douanières**

Des quantités de faux Viagra® ont été interceptées par les douanes françaises entre février et mars 2006, au cours d’opérations de transit :

<table>
<thead>
<tr>
<th>Dates de saisies par les douanes</th>
<th>Quantités interceptées</th>
<th>Destination</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 février 2006</td>
<td>30 000 comprimés</td>
<td>République Dominicaine</td>
</tr>
<tr>
<td>3 mars 2006</td>
<td>50 000 comprimés</td>
<td>Mexique</td>
</tr>
<tr>
<td>9 mars 2006</td>
<td>1 992 comprimés</td>
<td>Burkina Faso</td>
</tr>
<tr>
<td>14 mars 2006</td>
<td>240 480 + 39 480 comprimés</td>
<td>Togo</td>
</tr>
</tbody>
</table>

Au total, plus de 360 000 comprimés de faux Viagra® en transit ont été interceptés en 2 mois.

**Au niveau mondial**

Les médicaments contrefaits ont petit à petit envahi tous les marchés. Les pays en voie de développement (en Afrique, en Asie et en Amérique Latine) en sont les premières victimes. En voici quelques exemples marquants :

- En 1990, à Hatt, une solution anti-infectieuse diluée dans un solvant toxique (100 victimes) ;
- En 1995, au Niger, de faux vaccins utilisés au cours d’une épidémie de méningite (2500 victimes de la méningite dues à l’absence de protection conférée par le faux vaccin) ;
- En 1999, auCambodge, des antipaludéens contrefaits (30 victimes) ;
- Actuellement, au Cameroun, 70% des médicaments antipaludéens en circulation seraient des contrefaçons.

Quant aux USA, la contrefaçon des médicaments y atteint aujourd’hui un niveau important en raison, notamment, des fortes différences de prix des médicaments avec les pays voisins et des nombreuses disparités en termes de couverture sociale et de revenus.
D'autres produits de santé sont-ils susceptibles d'être contrefaits ?

La contrefaçon peut également concerner d'autres produits de santé, tels que les dispositifs médicaux, les réactifs, les cosmétiques, les biocides, ...

Des cas de contrefaçon ont été constatés dans le domaine du dispositif médical. Même si, contrairement au médicament, l'Afssaps n'intervient pas directement dans le processus de mise sur le marché des dispositifs médicaux qui relève des organismes notifiés européens mais seulement après la mise sur le marché, elle inspecte les fabricants et les distributeurs.

Aussi, une action auprès des distributeurs de dispositifs médicaux a été menée en février 2004 par l'Afssaps (communiqué de presse, point d'information, ...) afin de les sensibiliser aux risques de la contrefaçon.

Quelques exemples de contrefaçons de dispositifs médicaux constatées :
- En 2004, en France : contrefaçons de deux marques de lentilles de contact (Proclear®, Surevue®);
- En 2005, en Irlande : contrefaçons de préservatifs de la marque Durex®;
- En 2006, aux USA : contrefaçons de bandelettes de mesure de la glycémie dans le cadre d'un traitement du diabète. Ces fausses bandelettes ont montré des valeurs erronées de glycémie provoquant des surdoses ou sous-doses lors de l'administration de l'insuline chez les patients diabétiques, mettant en danger leur santé.

Quel est le principal vecteur de vente de produits contrefaits en France ?

Internet est le principal vecteur de vente de produits contrefaits puisqu'il permet aux contrefacteurs d'accéder facilement à des millions de consommateurs. Internet n'étant pas contrôlé, on ne peut, de ce fait, vérifier ni la qualité ni l'origine des produits vendus. A ce jour, le droit français n'autorise pas la vente de médicaments sur Internet.

Aujourd'hui, plus de la moitié des médicaments proposés sur des sites Internet, notamment à adresse physique difficilement identifiable, seraient des contrefaçons. Les messageries des internautes sont quotidiennement inondées par de nombreux courriels publicitaires sous la forme de « spams » incitant à la consommation de médicaments susceptibles d'être contrefaits.
Quels sont les risques pour la santé ?

Les médicaments et autres produits de santé contrefaits sont de nature à induire un risque grave chez les patients qui en consomment car ils ne répondent pas, dans la plupart des cas, à la qualité, l'efficacité et la sécurité attendues.

- La consommation d'un médicament ne contenant pas la dose de principe actif attendue (sous-dosage, surdosage, absence) ou intégrant un autre principe actif, met en danger la santé du patient ; absence d'effets thérapeutiques, complications...
- La possible présence de substances toxiques est source d'aggravation de l'état de santé du patient.
- Dans le cadre de la vente sur Internet, les modes de distribution n'utilisant pas, en règle générale, les établissements de la chaîne pharmaceutique régulièrement contrôlée par les autorités sanitaires. Dans ces conditions, ni la qualité, ni les conditions de conservation des médicaments ne peuvent être garanties.
- En achetant librement sur Internet des médicaments soumis à prescription médicale, qu'ils soient contrefaits ou non, le patient ne bénéficie d'aucun suivi médical et court ainsi le risque de mauvais usage (médicament inadapté ou contre-indiqué, risques d'interactions médicamenteuses, ...). Les médicaments les plus souvent commandés sont généralement les produits du dysfonctionnement érectile (Viagra®, Cialis®) ou les anorexigènes.

Comment expliquer la progression de la contrefaçon ?

- une implication croissante du crime organisé dans la contrefaçon qui présente moins de risque que le trafic de drogue ;
- les médicaments « blockbusters » (médicaments générant un chiffre d'affaires très important) représentent de forts enjeux pour les contrefacteurs compte tenu de leur potentiel ;
- une production frauduleuse de produits contrefaits, depuis la fabrication des principes actifs jusqu'à l'étiquetage du produit fini, plus aisée grâce aux progrès de la technologie actuelle ;
- la mondialisation des marchés facilitant le commerce des produits contrefaits ;
- le développement d'Internet qui facilite l'accès aux consommateurs, notamment dans le cadre de l'auto-prescription ;
- une réglementation régissant les systèmes de distribution de médicaments insuffisante dans de nombreux États en termes d'application et de pénalités ; elle ne constitue pas une force de dissuasion suffisante pour les contrefacteurs.
Repères pour le pharmacien

Comment reconnaître une contrefaçon?
Sans pouvoir établir une liste exhaustive des caractéristiques d'une contrefaçon, certains détails doivent éveiller l'attention :
- prix anormalement faible ;
- numéro de lots et dates de péremption ne correspondant pas à ceux employés par l'exploitant de manière habituelle ;
- circuit de distribution ne pouvant être établi ;
- conditionnement secondaire (carton d'emballage du médicament par exemple) non conforme ;
- signalement par un patient d'effets indésirables nouveaux : c'est souvent le premier moyen de dépistage des contrefaçons ;
- signalement d'un patient concernant un défaut de qualité d'un médicament.
Cependant, certaines contrefaçons peuvent être extrêmement bien faites et délicates à détecter.

Quel est le rôle du pharmacien vis-à-vis de ses patients ?
Dans le cadre de sa mission d'information et d'éducation pour la santé, le pharmacien doit, en tant qu'intélocuteur privilégié, mettre en garde ses patients sur les risques de la contrefaçon. Il doit rester à l'écoute d'éventuels signalements formulés par ses clients.
Où trouver les outils nécessaires pour s'informer ?

Chaque acteur de la chaîne pharmaceutique (fabricants, exploitants, dépositaires, grossistes-répartiteurs, pharmacie d'office, pharmacie hospitalière) dispose d'un certain nombre d'informations :

**Sur le site Internet de l’Afssaps : [www.afssaps.sante.fr](http://www.afssaps.sante.fr)**

- Répertoire des établissements pharmaceutiques, qui permet de savoir si un établissement est autorisé par l’Afssaps.
- Répertoire des spécialités pharmaceutiques, qui permet de vérifier leur autorisation de mise sur le marché en France, les éventuelles autorisations d’importations parallèles délivrées par l’Afssaps, ...
- Communiqués de presse, point d’information, alertes, ... sur la contrefaçon (ex : « mise en garde sur les risques liés à l’achat de médicaments sur Internet » ...) que le pharmacien peut mettre à disposition de ses clients.

**Sur le site Internet de l’Ordre des pharmaciens : [www.orpacpharmacien.fr](http://www.orpacpharmacien.fr)**

- Annuaire de l’ensemble des pharmaciens exerçant en France ainsi que leur lieu d’exercice, ce qui permet de vérifier si un pharmacien exerce sa profession en toute légalité.

L’examen de l’ensemble des données permet à tout pharmacien de vérifier aisément la régularité des propositions commerciales qui peuvent lui être faites. Il convient en effet pour les pharmaciens de connaître les acteurs autorisés de la chaîne pharmaceutique et de rejeter tout fournisseur suspect ou toute transaction commerciale illicite.
Via le fabricant de produits pharmaceutiques
Dans le cadre des actions de prévention, des outils de traçabilité et des procédés d'authentification des produits de santé sont développés :
- le marquage DATAMATRIX (code barre à deux dimensions), en cours d'instauration en Europe, assurera une traçabilité par lot. Il comprend une codification (code CIP) à 13 chiffres, le numéro de lot et la date de péremption ; il peut inclure éventuellement un numéro de série par boîte ;
- le marquage RFID (Radio Frequency Identification) qui permet notamment une traçabilité par unité de vente. Il s'agit d'une puce électronique permettant une lecture à distance des informations qu'elle contient (ex : utilisé aux USA pour le Viagra®, Pfizer) ;
- les procédés d'authentification visibles (hologrammes, encres à réflexion variable) ou invisibles (marqueurs chimiques, images cachées) plus complexes à contrefaire.

En cas de contrefaçon avérée, l'exploitant se rapprochera de l'Afssaps pour élaborer un plan de communication adéquat en vue d'informer les personnes concernées.

Quelle est la procédure à suivre pour un produit suspecté de contrefaçon ?

Vis-à-vis de l'Afssaps
- Tout pharmacien responsable d'un établissement de distribution en gros, d'un établissement de fabrication, exploitant ou importateur, doit transmettre à l'Afssaps, conformément aux Bonnes Pratiques de distribution en gros des médicaments à usage humain, tout signalé rapporté du fait de ses propres observations ou faisant suite à des éléments qui lui ont été rapportés. Une attention particulière sera portée sur un défaut de qualité d'un médicament pouvant faire suspecter une contrefaçon : une modification de taille, de couleur, de forme, de goût, de texture (par exemple comprimés plus friables), de packaging, ou encore la production d'un effet imprévu ou inhabituel.
- Les pharmaciens d'officine et les pharmaciens hospitaliers sont également invités à prévenir l'Afssaps en cas de doute sur un produit.

Comment ?
En téléchargeant le formulaire prévu à cet effet (en ligne sur le site Internet de l'Afssaps) et en le renvoyant à l'adresse suivante :
- par fax : 01 55 87 40 82
- par courrier à l'Afssaps
  Unité des Enquêtes Spéciales de la Direction de l'Inspection et des Établissements
  143, bd Anatole France - F-93265 Saint-Denis cedex
- Pour toute urgence : 01 55 87 40 81

Guide à l'usage des pharmaciens
Dès le signalement transmis par le pharmacien à l’Atssaps, une procédure interne établie par l’Atssaps est mise en application : information des pôles santé du ministère de la Justice, du ministère de la Santé et des autres administrations concernées (fraudes, douanes, brigades spécialisées...).

Obligations en matière de stockage et d’information
Les Bonnes Pratiques de distribution en gros des médicaments à usage humain (cf. BPDG : chapitres 6.21 à 6.24) prévoient également que le pharmacien des établissements de distribution ou de fabrication, exploitant ou importateur, remplisse les obligations suivantes :
- Les produits contrefaits repérés dans les réseaux de distribution doivent être conservés séparément des autres produits pharmaceutiques pour éviter toute confusion.
- Toute réception de produits contrefaits repérés doit être enregistrée au moment de son exécution.
- Ces produits doivent être identifiés par une mention indiquant clairement qu’ils ne doivent pas être vendus.
- Les autorités compétentes, le titulaire de l’autorisation de mise sur le marché relative au produit original ou l’exploitant doivent être informés sans délai.

Il paraît clair que ces mêmes recommandations de stockage s’appliquent aux pharmaciens en charge de la dispensation.
Quelle est la réglementation applicable pour lutter contre la contrefaçon ?

La commercialisation de produits de santé contrefaits constitue une infraction à différentes réglementations :
- le code de la propriété intellectuelle ;
- le code de la consommation ;
- le code des douanes ;
- le code de la santé publique.

Les constats d’infractions relèvent :
- des services de la répression des fraudes ;
- des services des douanes ;
- des officiers de police judiciaire.

Les infractions au code de la santé publique peuvent être constatées par les inspecteurs de l’Afnssap et les pharmaciens inspecteurs des DRASS.

La lutte contre la contrefaçon repose en partie sur la coopération de la DGCPE* et des douanes avec l’Afnssap. Une coopération régulière s’est développée.

L’ensemble de la chaîne pharmaceutique d’importation, d’exploitation, de fabrication, de distribution en gros et de vente au détail est soumis aux contrôles des inspecteurs de l’Afnssap ou des pharmaciens inspecteurs de santé publique des DRASS.

Les établissements pharmaceutiques sont sous la responsabilité des pharmaciens inscrits à l’Ordre national des pharmaciens et les spécialités pharmaceutiques font chacune l’objet d’une Autorisation de Mise sur le Marché.

Ce triple régime d’autorisation (établissement, pharmacien, produit) et les inspections régulières, dont ils font l’objet, participent à la lutte contre les faux médicaments et les contrefaçons.


* Direction générale de la concurrence, de la consommation et de la répression des fraudes.
www.afssaps.sante.fr

www.ordre.pharmaciens.fr
1. Introduction
Counterfeit medicines are those medicines that are described as “deliberately and fraudulently mislabelled with respect to identity and / or source.” Counterfeiting can apply to both branded and generic products. 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” (WHO definition).

Counterfeit medicines can harm patients in two ways: individually and at the societal level. Taking adulterated substances or lack of treatment can harm an individual, from unexpected adverse reactions to toxicity and / or anaphylaxis. Counterfeit medicines can also be life threatening and have caused deaths in Africa and Asia. For example, inert antibiotics will not cure an infectious disease, nor will “vaccination” with a counterfeit vaccine protect from illness. Improper treatments are a risk to public health, either through increased disease transmission or through the development of antibiotic resistance.

In addition, the credibility of a national healthcare system can be harmed if counterfeit medicines get into the legitimate supply chain, which may lead to patients becoming irrationally fearful of perfectly safe treatments.

2. UK Situation
Over 650 million prescriptions are written annually in the UK. Only a small number of counterfeit medicines have reached the legitimate pharmaceutical supply chain since August 2004. This guidance needs to be viewed in that context. The Government, through the Medicines and Healthcare products Regulatory Agency (MHRA), takes each such case very seriously, investigating all allegations of counterfeit medicines in the UK, the vast majority of which are not associated with the legitimate supply chain. The MHRA will take regulatory action where breaches are identified – which may take the form of revoking licences or the instigation of criminal proceedings.

3. Causes of counterfeiting:
- Technology to produce everything from labels to active pharmaceutical ingredients is now widely available
- Blockbuster "lifestyle" medicines that have created a demand for illicit use
- Cottage industries that use unemployed skilled labour
- Globalisation of markets has made distribution of counterfeit products easier
- The internet provides counterfeiters with easy access to consumers and markets
- An increase in self-prescribing culture
- Weak regulations, in terms of enforcement and penalties, governing the medicine distribution systems in many countries do not provide a strong enough deterrent for counterfeiters
- Organised crime has become increasingly involved in counterfeiting as it becomes more profitable with lower risks than other drug crime

4. Consequences of counterfeiting:
Counterfeiting has significant social and economic consequences. Most importantly, patients may not get safe or effective products and consequently may be at significant risk. On the economic side, legitimate manufacturers of pharmaceutical products suffer from patent and copyright infringement as counterfeiting, in reality, 'hijacks' the brand. Government is affected through loss of taxation revenue and undermining of the national healthcare system. Considerable resources are required to combat the practice of counterfeiting. In addition, health plans for the NHS are being defrauded and compromised.

5. Defective Medicines Report Centre (DMRC)
The Defective Medicines Report Centre (DMRC) receives and assesses complaints and reports of actual or suspected defects in medicines for human use. It also co-ordinates any necessary actions resulting from such allegations, including those involving counterfeit medicines.

The Centre provides an assessment and communication system operating between suppliers (manufacturers and distributors), users of medicines and other regulatory authorities. It receives reports of defective medicines from pharmacists, practitioners, manufacturers, distributors and the general public.

Manufacturers and importers must report any quality defect in their medicine. Other users are also encouraged to do this, while under new guidelines distributors must also report any such defects to the MHRA.

Where a defect is considered a risk to public health, the licence holder withdraws the affected medicine from use and the MHRA issues a 'drug alert' letter. Alerts are classified from 1 to 4 depending upon the risk presented to the public health by the defective product. Class 1 is the most critical and would include incidents, for example, of serious mislabelling, microbial contamination or incorrect ingredients which present an immediate threat to the health of patients. This
would require an immediate recall whereas a Class 4 alert, the least critical, would advise of ‘caution in use’.

The DMRC is also part of the European Rapid Alert System which disseminates information on medicine quality issues within EU Member States.

**Reporting a suspected defect**
Suspected defects can be reported by using the online form available at [www.mhra.gov.uk/home/idcplg?idcService=SS_GET_PAGE&nodeId=550](http://www.mhra.gov.uk/home/idcplg?idcService=SS_GET_PAGE&nodeId=550) or by phoning the MHRA on 0207 064 2574

6. **World Health Organisation (WHO)**
Counterfeit medicines are currently estimated to make up between 6% to 10% of the world wide market in medicines with annual sales in the region of $35 billion. WHO has developed a web-based system to track counterfeit medicines which enables countries to rapidly transmit information regarding sales of fake medicines. This website is available at [http://218.111.249.28/ras/default.asp](http://218.111.249.28/ras/default.asp). The reporting form asks users to enter the country where the medicine was identified, as well as how the medicine was encountered – whether at a hospital, pharmacy or via other means. The form also requires other information about the medicine, such as its name, classification, packaging information and dosage form.

The Rapid Alert System (RAS) aims to:
- Minimise the adverse impacts of counterfeit medicines
- Monitor actions taken by countries
- Rapidly distribute alert notifications about counterfeiting incidents
- Promote intensified surveillance of counterfeit drugs in high-risk areas such as markets, rural areas and unlicensed outlets
- Stimulate swift follow-up action on reported cases
- Encourage public warnings and increased awareness about fake medicines

7. **Action to be taken**:
Pharmacists worried about a counterfeit medicine need to do certain things to minimise / prevent harm to patients:
- Submit a report to the MHRA who will conduct definitive tests for counterfeits as quickly as possible
- Await MHRA instructions – conducting unilateral action may prove ill-advised, unnecessary, confusing and be counter-productive
- If a drug alert and recall notice is received, be prepared to:
  - Check the current stock held in the pharmacy and return any potential counterfeit medicines in line with guidance issued
  - If possible, interrogate the PMR systems to reveal which individual patients are on that particular medicine and when it was dispensed
• Contact those patients who have been supplied with that particular medicine within the suggested timeframe to check on their medication.

If a patient is concerned that they have a counterfeit medicine then the pharmacist should make a record of this and inform the MHRA immediately. Dispensing doctor’s practices are covered in the same alert system as pharmacies.

8. Tips for evaluating product sources & detecting counterfeit medicines

• Establish the integrity of the source prior to need
  Where possible, establish a list of approved suppliers.

• Require that any alternative source of supply provides the following as a minimum:
  • A pedigree back to the previous source
  • Certification that it is not a diverted product
  • Certification that any actions by the alternative source will not alter any original manufacture warranties or guarantees
  • Certification that the product has been stored and handled consistent with product labelling requirements

• If a product is being offered at an unusually cheap price, treat with extra caution.

• Consider developing a list of key pharmaceutical products that will not be purchased from sources other than the manufacturer, or authorised distribution channel.

• Look for signs of a removed or switched product label
  One common practice by counterfeiters is to remove the original label and replace it with a counterfeit label. To do this, they use lighter fluid, acetone or some other solvent which may leave a tacky residue on the container. Also, the label may be faded or discoloured along the edges due to the solvent.

• Look for an altered expiry date
  Counterfeiters commonly purchase ‘short-dated’ products and then alter the labels.

• Look for subtle changes in the product’s package (compare with previously purchased products), not withstanding legitimate parallel imported products
  Examine the package for differences in paper texture, size and thickness of the labels, also the gloss or finish on the paper. Look for differences in fonts and font sizes, print colour or raised print. Examine all printing on flaps and surfaces of the box in comparison with previously purchased products where possible. Look for overt security features such as holograms or colour shifting inks. Finally, look for breaks or tears in the sealing tape and seals.

• Look for variations in the size of the container (compare with previously purchased products), not withstanding legitimate parallel imported products
  Look for differences in container length, diameters and shapes. Examine for variations in diameters of bottle openings or lids. Examine for variations in the thickness of glass or plastic containers and for variations in container colour tints.

• Listen to patients
  The majority of counterfeit medicines are first detected by patients.

• Compare the physical characteristics of the product
Look at colour, tablet or capsule markings, shape and thickness of the medicine. You can also weigh the product to see if there are wide variations.

Report all suspicious approaches or known information on counterfeits to MHRA on 0207 084 2574.

Pharmacists should always purchase medicines from reliable, trusted wholesalers and suppliers – due diligence checks should be conducted regularly and systems reviewed.

9. What is being done to stop the business of counterfeit medicines?

**RPSGB**
The Practice Committee of the RPSGB recognised the need to provide information to both pharmacists and patients around counterfeit medicines. Although the number of counterfeit medicines entering the legitimate supply chain in the UK is extremely small, pharmacists are very closely involved in the repercussions of counterfeiting.

The RPSGB Inspectors are involved, in collaboration with the MHRA, in a UK wide medicine surveillance scheme. Inspectors pick targeted medicines off the shelves of community pharmacies which are sent to the MHRA for testing and analysis.

The RPSGB are considering the development of an internet pharmacy logo and more information will be provided to both pharmacists and the public in due course.

**MHRA**
Whilst the UK legitimate pharmaceutical supply chain is tightly regulated and has one of the best international records for being difficult to breach, it is recognised that no supply chain is impenetrable – whatever the regulatory and surveillance safeguards that may be in place. The MHRA operates a comprehensive anti-counterfeiting strategy, working with partners and stakeholders to ensure that the current safeguards work effectively and that vigilance against counterfeit medicines entering the legitimate supply chain is maintained. The key elements of this strategy include:

- The operation of Europe’s largest medicines surveillance scheme in conjunction with the RPSGB to spot check medicines on the UK market and then undertake laboratory analysis to test for authentication
- Increased checks by the MHRA inspectors for counterfeits when inspecting pharmaceutical manufacturers and distributors
- Collaborative international enforcement action and a training and education / awareness raising program amongst law enforcement agencies and pharmaceutical stakeholders (conducted domestically, at European level and internationally between respective national medicines regulators)
This is a long-term strategy, which is backed by investment and a significant commitment of resources to minimise the risk of counterfeit medicines reaching patients.

**International**

The European Commission, EU Heads of Medicines Agencies, Council of Europe and WHO are undertaking development of anti-counterfeit strategies. The UK, through the MHRA, is closely involved in all of these initiatives.
Strasbourg, 17/03/08

Note for the Editors

The European Pharmacopoeia and the EDQM (a Directorate of the Council of Europe notably in charge of the secretariat of the European Pharmacopoeia) have a mission to protect and promote public and animal health, through the elaboration of quality standards of medicines for human and veterinary use. Medicines need to be safe, effective and of good quality in order to produce the expected therapeutic effect. The EDQM works closely with its international and European partners to strengthen measures in order to ensure that substandard or counterfeit medicines do not reach the marketplace. The EDQM’s networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. Since December 2006, the EDQM took over activities of the Council of Europe in the domains of blood transfusion and organ transplantation.

COMBINING FORCES TO PROTECT PATIENTS FROM COUNTERFEIT MEDICINES AND PHARMACEUTICAL CRIME: A MODEL FOR A NETWORK AND SINGLE POINTS OF CONTACT (SPOCS) ACROSS DISCIPLINES AND BORDERS

Counterfeiting of medical products and other related pharmaceutical crimes put public health in danger in Europe and worldwide. Rapid and effective communication and concerted co-operation amongst officials in a country and across national borders are a pre-requisite to contain and prevent harm to patient’s health, disrupt supply of suspect counterfeit medical products, prosecute and deter criminals, and to avoid damage to healthcare systems. Often, communication and co-operation are hampered by the lack of adequate structures and procedures for concerned health and law enforcement.

The conclusions of the Council of Europe 2005 and 2006 international conferences on counterfeit medicines (link1) called for the establishment of a network of dedicated contact persons (SPOCs) within authorities involved in combating counterfeit medicines and other forms of pharmaceutical crimes. Inspired by the above conclusions, the Council of Europe Ad hoc Group on Counterfeit Medicines developed a model for a network and SPOCs and adopted it in June 2007. This model establishes a network of entities responsible for the management of notifications of medical products suspect of being counterfeit or of other pharmaceutical crimes. The entities involved comprise drug regulatory authorities including the official medicines control laboratories, customs, police and justice authorities. The importance of co-operation with industry, health professionals and other stakeholders is recognised.

The European Directorate for the Quality of Medicines and HealthCare (EDQM) is pleased that the 2nd General Meeting of the WHO International Medical Products Anti-counterfeiting Taskforce (IMPACT), Lisbon, 12-13 December 2007, endorsed the model for a network of single points of contact (SPOCs) enhancing its outreach and applicability to a global level. The EDQM, assisted by its Network of Official Medicines Control Laboratories (OMCL Network), has a worldwide reputation in standard setting and surveillance programmes for pharmaceuticals and contributes significantly to the Council of Europe programme of activities targeted at combating counterfeit medical products.

EDQM is supporting its expert bodies entrusted with a programme of activities dealing inter alia with public health oriented multi-sectorial prevention and risk management strategies to fight counterfeit medicines and pharmaceutical crimes, including the development of and training on best practices and the support to the elaboration and implementation of relevant national legislation and international legal instruments. Responding to the situation in Europe and keeping pace with criminal inventiveness require multisector and multorganisation counterstrategies: the EDQM will contribute through its programme of activities to improving networking and co-operation in member states through inter alia a network of SPOCs.

The network will serve your interest in safe and genuine medicines – your observations of suspect medical products are important: Communicate them to your doctor or pharmacist or the national drug regulatory authorities.

Model see next page
Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique

AD HOC GROUP ON COUNTERFEIT MEDICINES (P-SP-PH/CMED)

PROTECT PATIENTS FROM COUNTERFEIT MEDICINES AND PHARMACEUTICAL CRIME: A MODEL FOR A NETWORK AND SINGLE POINTS OF CONTACT (SPOCS) ACROSS DISCIPLINES AND BORDERS
Background

Counterfeit medicines and pharmaceutical crime in general are fast upcoming phenomena which directly involve public health and do need a multidisciplinary, multisectorial and cross-border approach. The basic principles of an adequate approach are collaboration and responsibility. Collaboration can be set up ad hoc for isolated cases but should be structured within a network. Within networks, single points of contact (SPOCs) should collaborate to meet the pre-set objectives.

In the conclusions of the Council of Europe 2005 and 2006 international conferences on counterfeit medicines the participants called for the establishment of a network of Single Points of Contact for speeding up effective co-operation and public health protection in the case of suspect/confirmed cases of counterfeit medicines.

The Council of Europe Ad hoc Group on Counterfeit Medicines developed a model for a network and SPOCs which is presented in this document.

The Council of Europe Ad hoc Group on Counterfeit Medicines programme of activities comprises calls for the development of practical tools in the field of counterfeit medicines and other pharmaceutical crimes for authorities and other stakeholders involved in combating counterfeit medicines and other pharmaceutical crimes. The Ad hoc Group is of the view that international co-operation should be facilitated through an operational network of SPOCs and through standard procedures at regional and global levels.

Definitions

Central Reporting Point: located at the SPOC authority where all information on pharmaceutical crime is centralised and information is disseminated to network partners on a need to know basis. Stakeholders (such as pharmacists, patients) should report information to the Central Reporting Point of the Drug Regulatory Authority

National SPOC: operates as contact point within the international network and belongs to the DRA.

Network: formal or informal collaboration between SPOCs at national level.

Networking: activities between network members consisting of operational management and information exchange in relation to pharmaceutical crime

Official Medicines Control Laboratories: national medicines control laboratories, preferably organised in a supranational network, are important partners and should be involved on a regular or ad hoc basis.

Pharmaceutical crime: any crime with medicinal products or health products comprising counterfeiting, adulteration, tampering, manufacture/distribution and possession of unlicensed medicines, diversion, trafficking and pharmaceutical crime through the internet

12 An example of a network of Official Medicines Control Laboratories (OMCL) is the OMCL Network co-ordinated by the European Directorate for the Quality of Medicines (EDQM) and Healthcare Link : News of the European Directorate for the Quality of Medicines - Pharmacopoeia on the WWW
**Signal**: any appearance of a problem with medicinal or health products which can be considered as pharmaceutical crime

**Single Point of Contact (SPOC)**: an entity responsible for the operational management of a signal in their own area of responsibility and the exchange of information

**Responsible person or SPOC for industry (RP)**: the pharmaceutical industry is part of the network but has no enforcement authority. Pharmaceutical industry staff is often an important part to the case and are involved on an *ad hoc* basis. Each company should provide a RP or SPOC

**Purpose**

This model should be the basis for
- establishing the concept of a SPOC network at regional and global levels;
- countries checking their existing networks or to establishing new SPOC networks at regional and global levels.

**Structure of the network**

SPOCs and a network are inseparably linked with each other. A national network should be set up by and between the main national authorities who are competent for handling pharmaceutical crime. For most countries the official authorities are DRA, Police, Customs and Justice. It is proposed that the National SPOC is located within the DRA.

The OMCL network is an important partner to the network and should be involved on a regular or ad hoc basis.

**Objectives of the national network**

1. Regular and ad hoc meetings should be organised and a secretariat installed. All information should be collected and stored in a structured secure database at the level of the SPOC and the
network. The network uses a Rapid Alert Form\textsuperscript{13} if necessary. The network shall create procedures for handling routine pharmaceutical crime signals (e.g. internet post office parcels) and set up online training by e.g. secure website.

3. The network is responsible for an annual report which reflects all data collected in relation with pharmaceutical crime, the recognition of new trends in pharmaceutical crime, initiatives taken for improving legislation, training programs set up for the different network partners and awareness programs to the different stakeholders.

4. The network actively updates its references at international level and sets up procedures for co-operation, information exchange, data collection and management.

5. Stakeholders should notify any signal to the Central Reporting Point of the Drug Regulatory Authorities who informs the network if necessary.

Profile and function of a SPOC within a national network

The National SPOC should have the following knowledge:

1. The SPOC should have a broad knowledge on medicinal products.

2. The SPOC should be experienced in enforcement in the area of pharmaceutical crime (including field investigation in pharmaceutical crime).

3. The SPOC should have a good knowledge of medicines legislation and Intellectual Property Rights.

4. The SPOC should have a basic knowledge in criminal law and investigation (e.g. handling of evidence).

All SPOCs should have the following competences and tasks:

1. The SPOC represents the co-operation partner as contact point within the network.

2. The SPOC manages incoming and outgoing information and - if required- reports a case to the other national SPOCs on a need to know basis.

3. The SPOC handles the information flow in accordance with the applicable legislation on data protection legislation. Confidential information such as patient names and/or names of notifiers etc should not be included in the information.

4. The SPOC develops and applies a model procedure for managing counterfeit cases and pharmaceutical crime cases within his/her authority.

5. The DRA SPOC co-ordinates the risk assessment of a pharmaceutical crime signal. The signal shall be identified, analysed, evaluated, and treated. The risk management procedure shall be continuously reviewed and improved. In any case, the protection of public health has priority.

6. The operational SPOC takes the lead in investigation when appropriate.

7. The SPOC may set up a Pharmaceutical Crime Unit consisting of an operational and an intelligence section.

\textsuperscript{13} Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: \url{http://www.coe.int/t/e/social_cohesion/soc-sp/Notification_E.doc}
The SPOC has the competence of giving detailed information to other SPOCs in the international and national network. Regarding information flow, it is important to differentiate between information (analysed and interpreted data) and evidence (information being relevant for proceedings and which may be used in court). Information should only be exchanged between SPOCs and between countries having regard to privacy laws and legal procedures. However, no legal procedure should prevent fast information exchange in life threatening situations.

A SPOC needs not necessarily to be a single person, but also may be an entity such as a group or a department within an agency. If the SPOC consists of several persons, then only one e-mail address and one phone/fax number needs to be indicated in order to ensure precise contact and to avoid unclear responsibility.

**Reporting procedure for SPOCs**

The model procedure on how to manage counterfeit medicines on a national level has been described in the “Guidance of the management of counterfeit medicines – Co-operation structures and model procedure”: diagram, see Attachment.

At international level, the national SPOC may use a Rapid Alert Form\(^\text{14}\) for reporting pharmaceutical crime to other National SPOCs.

The information exchange procedure is based on this model procedure and describes the conditions for communicating a case or signal of counterfeit medicines to an international SPOC network of National SPOCs:

- Counterfeit medicine(s) reached legal distribution channels;
- Counterfeit medicines’ batches were distributed internationally.

**Network implementation**

With a view to effective implementation of a network at regional and global levels it is recommended to
1. establish a list of National SPOC’s
2. list of all SPOC’s for each country

**SPOC system – how is it kept alive**

A successful example of a well maintained network is the Rapid Alert Database of representatives of each country to whom alerts/defective product recall notifications are addressed. This list is regularly updated by fax by the inspections sector of EMEA.

Once established, the SPOCs list should be updated regularly by a supranational body, for example by a periodical questionnaire asking to update the coordinates to the National SPOC’s. The updated contact list will then be distributed to the SPOC’s either through fax transmission through access to a secure database.

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\(^\text{14}\) Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Link: [http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc](http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc)
Clarify product characteristics and the medicinal product’s distribution status

Is the medicinal product legally marketed?

Yes

Does it comply with the approved marketing authorisation?

Yes

Close the case

No

Assess the risk for public health and develop a strategy for measures to be taken (including information management)

Co-ordination and taking of appropriate enforcement action

Signal

Transfer of information within network and evaluation of signal

Is the medicinal product legally marketed?

No

Yes

Does it comply with the approved marketing authorisation?

No

Yes

Immediate action (e.g. seizure of product, recall, dissemination of information)

Other administrative action (e.g. prohibition of distribution, suspension or revocation of establishment license or marketing authorisation, close-down of establishment)

Penal action (e.g. fine, arrest, imprisonment)
Press release: Recall of Counterfeit Casodex batch
Printer friendly version (new window)
Related information:

MHRA pages:
* Counterfeit medicines and medical devices
* Drug Alerts

Press release
Date: 01 Jun 2007
Time: 14:00
Subject: Medicines Alert and Recall of Casodex
Contact: Press Office 020 7084 3535/3564 or press.office@mhra.gsi.gov.uk
Out-of-hours 07770 446 189

The MHRA has been alerted to a counterfeit batch of Casodex (Bicalutamide) 50mg tablets (batch number 65520). This drug is used in the treatment of patients with prostate cancer. The MHRA has issued a drug alert to recall this product from the market, to minimise the risk to patients.

The MHRA was contacted by a wholesaler, who was offered a suspicious batch of Casodex by another wholesaler. This is now subject of a Class 1 medicines recall, today, 01 June 2007. We take this very seriously and a criminal investigation is being carried out.

Patients should contact their pharmacist as soon as possible if they are taking this medication, with the batch number of 65520. They should take their medication with them, so their pharmacist can check it and return it to the licensed manufacturer, AstraZeneca, for further examination. At present there is no evidence of patients having any adverse reactions specifically related to the counterfeits. Patients should consult their GP if they have any treatment or health concerns.

Notes to Editor

1. Casodex contains the active ingredient called Bicalutamide. This drug is used in the treatment of patients with prostate cancer. The MHRA is working in conjunction with AstraZeneca the licence holder.

2. The MHRA investigation is continuing into this case. At present we are investigating the possibility of links with the counterfeit drug recalls of Zyprexa (24 May 2007) and Plavix (25 May 2007)

3. The initial laboratory tests on the seized counterfeits (batch 65520) show that the samples contain approximately 75% of the labelled active ingredient. A counterfeit may also contain harmful ingredients. Work is ongoing to obtain more information about any additional ingredients in these counterfeit tablets, but in the meantime we have issued a recall to minimise the risks to patients.

4. Counterfeits are notoriously difficult to detect with the untrained eye and even experts sometimes require full forensic laboratory tests to determine whether a suspect product is indeed a counterfeit.

5. What are parallel imports? Parallel imported products are often sold at lower prices in the EU and are allowed to be imported and relabelled for sale in the UK. Parallel imported products have a marketing authorisation issued by the MHRA. The repacking and relabelling of parallel imports are
inspected by the MHRA but the importation and re-distribution takes place outside the original manufacturer’s supply chain.

Download documents:

* Class 1 Drug Alert (action now - including out of hours): Counterfeit parallel imported product - Casodex Tablets 50mg (Bicalutamide) (45Kb)
* Press release: Recall of Counterfeit Casodex batch (40Kb)

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An investigation by the Medicines and Healthcare products Regulatory Agency (MHRA) has today led to the sentencing of a man to four and a half years' imprisonment at Kingston Crown Court. He was convicted of four offences under the Medicines Act and Trade Marks Act. Three other men have also been found guilty, one of whom was also convicted of money laundering offences. The offences concerned the conspiracy to smuggle and supply counterfeit medicines into and, in some cases, out of the UK.

The men were charged with masterminding the industrial-scale supply of counterfeit medicine between 2002 and 2005, involving millions of pounds worth of counterfeit Viagra, Cialis and Propecia. These seizures resulted in the MHRA unravelling the biggest conspiracy of the supply of counterfeit medicines thus far in the UK. The seizure of over £1,500,000 of counterfeit medicines was intended to be supplied to customers through this conspiracy.

In the autumn of 2002, counterfeit Viagra was seized by HM Revenue & Customs at Stansted airport. This was followed by a number of other seizures at Stansted and Heathrow airports where false descriptions for a variety of products e.g. “Vitamins C & E”, “Calcium for Kids” and “Samples of Mineral Supplements for Dogs” were used. The counterfeit medicines were filtered for sale through licensed wholesalers to pharmacies in the UK and through internet sites operating both in the UK and overseas. In 2004 counterfeit Cialis made its way into the regulated supply chain reaching patient level, this lead to a recall of that product from the UK market.

The investigation traced a complex network of individuals, companies and bank accounts facilitating the movement of these medicines. Over that period of time, the men conspired together with the common purpose to profit from these counterfeits. The men were part of the UK distribution arm of a global counterfeiting ring, operating from China, India and Pakistan, and extending to the Caribbean and the USA.

Mick Deats, Head of Enforcement at the MHRA said, “The MHRA treat every report of a counterfeit medicine as a serious incident. We will continue to use every power at our disposal to prosecute those engaged in this illicit activity and confiscate the proceeds of their crimes. This successful prosecution should serve as a clear signal to those contemplating the supply of counterfeit medicines. The public are strongly advised to avoid buying medicines online, where the risk of being provided with counterfeit medicines is greatly increased.”

Notes to Editor
1. Mr Ashish Halai (DOB 13.07.74) of 1 Nicholas Road, Elstree, Borehamwood, Herts, WD6 3JY pleaded guilty on 24 February 2007 to four counts.

Mr Gary Haywood (DOB 16.03.48) of 63 Waterfall Way, Barwell, Leicester; Ashwin Patel (DOB 01.03.82) of 196 Chaberlayne Road, London, NW10; and Zahid Mirza (DOB 14.08.60) of 17 Milverton Gardens, Ilford, Essex were all found guilty on various counts

Details of the verdicts per person are attached in Annex A.

2. An overview of each defendant’s involvement in the conspiracy is outlined in Annex B.
3. All names, addresses, occupations a dates of birth were provided by the defendants at the time of questioning/arrest.
4. The trial at Kingston Crown Court has been heard over six and a half months, during which time, evidence was received by the jury from witnesses both in person and via live satellite link from the USA and Mexico.
5. One of the defendants, Zahid Mirza, absconded from trial on 30 August 2007 after being found guilty of five offences. A warrant has been issued for his arrest.
6. The sentencing of Gary Haywood, Ashwin Patel and Zahid Mirza will take place on date to be confirmed at Kingston Crown Court.
7. Confiscation hearings will take place on a date to be confirmed.
9. The MHRA will be hosting a major international conference about counterfeit medicines on 22 November 2007 at the Hilton London Metropole. It will bring together key organisations, high-profile international speakers and strategic ideas on the problem of counterfeit medicines. The event will focus on international co-ordination efforts and the UK strategy and response to this issue.
10. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem.
11. Where appropriate the MHRA will use the Proceeds of Crime Act 2002 to determine whether or not benefits were accrued through criminal activity and will recoup illicit earnings if the individual is found guilty.

Annex A

Ashish Halai (31)
Businessman
1 Nicholas Road
Elstree, Borehamwood
Herts WD6 3JY

Charged counts 1 to 9
Pleaded guilty 24/2/07 counts 1 - 4

Gary Haywood (58) (In custody)
Salesman
63 Waterfall Way
Barwell
Leicester
Charged & found guilty on all 11 counts listed

Ashwin Patel (24)
University graduate
196 Chaberlayne Road
London NW10

Charged counts 1 to 9
Found guilty counts 1, 2, 3, 4, 6, 7, 8
Found not guilty counts 5 & 9

Zahid Mirza (45)
Businessman
17 Milverton Gardens
Ilford
Essex

Charged counts 1, 2, 3, 4, 7, 8
Found guilty counts 1, 2, 3, 4, 8
Found not guilty count 7

COUNT 1
Conspiracy to evade the prohibition on the unauthorised use of a trade mark in relation to goods, contrary to section 92 (1) of the Trade Marks Act 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to offer or expose for sale goods, namely medicinal products, which bore, or the packaging of which bore, the manufacturer's trademark sign "Viagra" and with a view to gain for themselves or others, or with intent to cause loss to another, and without the consent of the proprietor,

COUNT 2
Conspiracy to place a medicinal product on the market, contrary to Schedule 3(1) of the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to place a relevant medicinal product, namely Sildenafil Citrate in tablet form, on the market without holding a Community or United Kingdom marketing authorisation in respect of that product.

COUNT 3
Conspiracy to evade the prohibition on the unauthorised use of a trade mark in relation to goods, contrary to section 92 (1) of the Trade Marks Act 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to offer or expose for sale goods, namely medicinal products, which bore, or the packaging of which bore, the manufacturer's trademark sign "Cialis" and with a view to gain for themselves or others, or with intent to cause loss to another, and without the consent of the proprietor.
COUNT 4
Conspiracy to place a medicinal product on the market contrary to Schedule 3(1) of the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to place a relevant medicinal product, namely Tadalafil in tablet form, on the market without holding a Community or United Kingdom marketing authorisation in respect of that product.

COUNT 5
Conspiracy to evade the prohibition on the unauthorised use of a trade mark in relation to goods, contrary to section 92 (1) of the Trade Marks Act 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to offer or expose for sale goods, namely medicinal products, which bore, or the packaging of which bore, the manufacturer's trademark sign "Propecia" and with a view to gain for themselves or others, or with intent to cause loss to another, and without the consent of the proprietor

COUNT 6
Conspiracy to place a medicinal product on the market contrary to Schedule 3(1) of the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 and section 1(1) of the Criminal Law Act 1977.

Between 1 January 2002 and 12 October 2005 conspired together with ASHISH HALAI and with other persons known and unknown to place a relevant medicinal product, namely Finasteride in tablet form, on the market without holding a Community or United Kingdom marketing authorisation in respect of that product.

COUNT 7
Conspiracy to evade the prohibition on wholesale dealing, contrary to section 8 (3) (a) and section 45(1) of the Medicines Act 1968 and section 1(1) of the Criminal Law Act 1977

Between 1 January 2002 and 12 October 2005 in the course of a business conspired together with ASHISH HALAI and with other persons known and unknown to sell, or offer to sell, a medicinal product, namely a quantity of Sildenafil Citrate in tablet form, except than in accordance with a wholesale dealer's licence.

COUNT 8
Conspiracy to evade the prohibition on wholesale dealing contrary, to section 8 (3) (a) and section 45(1) of the Medicines Act 1968 and section 1(1) of the Criminal Law Act 1977

Between 1 January 2002 and 12 October 2005 in the course of a business conspired together with ASHISH HALAI and with other persons known and unknown to sell, or offer to sell, a medicinal product, namely a quantity of Tadalafil in tablet form, except than in accordance with a wholesale dealer's licence.

COUNT 9
Conspiracy to evade the prohibition on wholesale dealing, contrary to section 8 (3) (a) and section 45(1) of the Medicines Act 1968 and section 1(1) of the Criminal Law Act 1977

Between 1 January 2002 and 12 October 2005 in the course of a business conspired together with ASHISH HALAI and with other persons known and unknown to sell, or offer to sell, a medicinal product, namely a quantity of Tadalafil in tablet form, except than in accordance with a wholesale dealer's licence.
product, namely a quantity of Finasteride in tablet form, except than in accordance with a wholesale dealer's licence.

COUNT 10
Concealing, disguising, converting, transferring or removing the proceeds of criminal conduct, contrary to section 93C of the Criminal Justice Act 1988

Between 1 January 2002 and 24 February 2003 knowing or having reasonable grounds to suspect that property, in whole or in part, represented the proceeds of his criminal conduct did conceal, disguise, covert, transfer or remove such property from the jurisdiction for the purpose of avoiding prosecution for an offence to which this Part of this Act applies or the making or enforcement in his case of a confiscation order.

COUNT 11
Concealing, disguising, converting, transferring or removing the proceeds of criminal conduct, contrary to section 327 of the Proceeds of Crime Act 2002

Between 25 February 2003 and 21 March 2006 knowing or suspecting that property, in whole or in part, represented the proceeds of his criminal conduct did conceal, disguise, convert, transfer or remove criminal property from England and Wales.

Annex B

Defendants - background
Ashish HALAI 33 years old [dob: 13 July 1974]. A Kenyan citizen, he settled in this country with his family when much younger. He was the lynchpin of the British arm of the conspiracy and came to the attention of the MHRA in July 2005. From his business base in North London, he and the co-conspirators used a variety of companies, both actual and bogus, including Stormgrand Ltd, as fronts to distribute vast quantities of counterfeit medicines in the UK and abroad. HALAI travelled the world in search of suppliers and buyers. He ensured that the conspiracy ran smoothly in the UK.

Gary HAYWOOD is 59 years old [dob:16 March 1948] like Mr HALAI was a pivotal conspirator. He promoted himself as a qualified pharmacist with extensive experience in the pharmaceutical industry. One of his many bogus claims was that he had been a prominent Pfizer employee. He like Mr HALAI used a variety of company names to cover his tracks. Mr HAYWOOD used off-shore bank accounts to hide his money. He also used forged documents to further the conspiracy. He was the intermediary who dealt with the counterfeiters abroad and in particular a counterfeiter based in China who readily supplied “made to order” fakes which would then be smuggled into the UK. The contents of these parcels would be disguised using false descriptions e.g. “sample C&E vitamins” “Sample of fishprotein” “calcium for kids” and “Sample of Protein for Dogs”- so as not to attract attention by the authorities. In this way over some 6 months HAYWOOD smuggled into UK about 500,000 fake Viagra tabs. In July 2003, MHRA officers seized over 120,000 fake Viagra tabs including packing material, fake product leaflets etc. Mr HAYWOOD left the country before MHRA investigators could interview him, a warrant for his arrest was issued and he was arrested at Heathrow airport in March 2006 disembarking from a flight from Singapore. He has since remained in custody.

Ashwin PATEL 25 years old [dob: 01 March 1982] is the youngest of the conspirators and HALAI is his brother-in-law in what is considered to be a close knit family. PATEL became HALAI’s “right-hand” man and was a trusted member of the conspiracy. Mr Ashwin PATEL was instrumental with others in the supply of counterfeit Cialis through a company named IMPERAZO

Zahid MAHMOOD MIRZA, 46 years old [dob14 August 1960] is based in Pakistan. Mr MIRZA was a key player in the supply of counterfeit Viagra from Pakistan and through a bogus UK company fake Cialis in the UK. He was the sole Director of a UK company named IMPERAZO;
the only real trade it did was in counterfeit medicine. Mr MIRZA is also linked to foreign companies that have been involved in the sale of counterfeit Viagra in the UK.