



Royal
Pharmaceutical
Society
of Great Britain



Counterfeit Medicines Advice for Healthcare Professionals

Guidance for Pharmacists and Dispensing Doctors

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 community 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.

UK Situation

Over 750 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 and / or the instigation of criminal proceedings.

Factors associated with increased counterfeiting:

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

Counterfeit Medicines Advice for Healthcare Professionals

Guidance for Pharmacists and Dispensing Doctors

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. The 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.

Action to be taken:

Pharmacists or dispensing doctors worried about a counterfeit medicine need to do certain things to minimise / prevent harm to patients:

- Contact the MHRA on the counterfeit hotline by:
 - E-mail: counterfeits@mhra.gsi.gov.uk
 - Phone: on the 24 hour counterfeit hotline 0207 084 2701
 - Clicking the green icon on the MHRA website homepage: www.mhra.gov.uk
- Await MHRA instructions – conducting unilateral action may prove ill-advised, unnecessary, confusing and counter-productive
- If a drug alert and recall notice is received, be prepared to:
 - Check the current stock held in the dispensary 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 or dispensing doctor should make a record of this (recording patient contact details, reason for patient's suspicion, product name, dosage, batch number and expiry date would be extremely helpful) and inform the MHRA immediately.

Dispensing doctor's practices are covered in the same alert system as pharmacies.

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 and / or in unusually large quantities (particularly in a large quantity of the same batch number), 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 an altered expiry date. Counterfeiters commonly purchase 'short-dated' products and then alter the labels
- 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
- Notwithstanding the obvious differences in the packaging of legitimate parallel imported products, 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 subtle changes in the product's package (compare with previously purchased 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

Counterfeit Medicines Advice for Healthcare Professionals

Guidance for Pharmacists and Dispensing Doctors

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)
- 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

Counterfeit medicines around the world are often first detected by patients

Report all suspicious approaches or known information on counterfeits to the MHRA through the counterfeit hotline:

- E-mail: counterfeits@mhra.gsi.gov.uk
- Phone: on the 24 hour counterfeit hotline 0207 084 2701
- Clicking the green icon on the MHRA website homepage: www.mhra.gov.uk

In 2007, one phone call to the MHRA from a suspicious wholesaler led to the interception and seizure of 15,000 packs of a counterfeit cancer medicine and nearly 20,000 packs of counterfeit anti-platelet medicines before they could reach pharmacies and patients.

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

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

RPSGB

The RPSGB recognises 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 so have an important role in helping prevent counterfeits reaching patients.

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

The RPSGB has developed an internet pharmacy logo and more information on this can be found at www.internetpharmacylogo.org. This logo will help the public identify bona fide internet pharmacy and indicates that a website is operated by a registered pharmacy in Britain. By clicking on the logo visitors will be taken to the RPSGB's website, where they can verify the registration details of both the pharmacy and the pharmacist(s) behind the site.

The logo looks like this:



Each individual logo contains the pharmacy's *unique seven digit registration number*, issued by the RPSGB.

A legitimate online pharmacy should:

- Clearly display the name, address and owner of the pharmacy business
- Have a physical address in the country where it claims to be located
- Require patients to provide a medical history evaluation before supplying them with a medicine
- Require a prescription signed by a UK-registered doctor for obtaining prescription-only medicines
- Have a telephone number that patients can call to speak to a pharmacist
- Have a privacy and security policy

British pharmacy premises are all registered with the RPSGB and are listed on its Register. You can check this here:

www.rpsgb.org/registrationandsupport/registration/searchourregisters/

Counterfeit Medicines Advice for Healthcare Professionals

Guidance for Pharmacists and Dispensing Doctors

MHRA

Whilst the UK legitimate pharmaceutical supply chain is tightly regulated it is recognised that no supply chain is impenetrable – whatever the regulatory and surveillance safeguards that may be in place. The Minister of State (Public Health) launched the MHRA's Anti-Counterfeiting Strategy in London in November 2007.

This strategy sets out a three year plan to combat counterfeit medicines and devices through a sustained programme of *communication, collaboration and regulation*

Communication:

Ensuring both the public and healthcare professionals have sufficient information about counterfeit medicines, how to avoid them, and how to report any suspicions to the MHRA – this guidance is part of that effort.

Collaboration:

The Agency will continue to host the UK Anti-counterfeiting Stakeholders (ACS) meeting between Regulators, Law Enforcement and Industry / Trade which ensures an awareness and recognition of the threat from counterfeit medicines / devices whilst encouraging collaboration and increased vigilance.

The MHRA fully participates in all relevant international initiatives to tackle counterfeit medicines / devices which impact upon the UK, including the World Health Organisation (WHO), International Medical Products Anti-counterfeiting Taskforce (IMPACT), EU Commission work in this area, EU Heads of Medicines Agencies enforcement officers and the Council of Europe.

Regulation:

The MHRA is thoroughly examining all aspects of the supply chain with key stakeholders in view of recent incidents of counterfeits reaching patients and will make necessary recommendations for change.

The MHRA will maintain targeted market surveillance projects throughout the supply chain on the medicines most at risk from counterfeiting. They will thoroughly investigate all reports of counterfeit medicines, and where appropriate, prosecute and confiscate the assets of those involved.

DDA

The Dispensing Doctors' Association (DDA) fully supports all action to eliminate counterfeit medicines. As the vast majority of medicines dispensed by doctors are sourced from wholly reputable wholesalers the DDA works closely with them to ensure that the highest standards are maintained and instances of counterfeit medicines being found in dispensing doctors' dispensaries are therefore extremely rare.

Further Information

If you are worried about counterfeit medicines, or want more information, you can:

- Visit the MHRA website at www.mhra.gov.uk and click on the green icon on the right hand side of the screen labelled "Reporting a counterfeit product" – this will take you to the counterfeit information page
- Visit the RPSGB website at www.rpsgb.org
- Visit www.internetpharmacylogo.org
- Send an email to counterfeit@mhra.gsi.gov.uk
- Visit www.dispensingdoctor.org

Telephone the MHRA 24 hour counterfeit hotline on 020 7084 2701