

RPS Policy Statement

Falsified Medicines Directive (FMD)

Definition

For the purposes of this paper, the term 'falsified medicine' is used to define a drug that:

- contains none of the stated active ingredient
- contains a different dosage than advertised
- contains another drug
- is created from substandard active ingredients or excipient
- is deliberately sold or branded in a way to lead buyers to believe it is a different product.

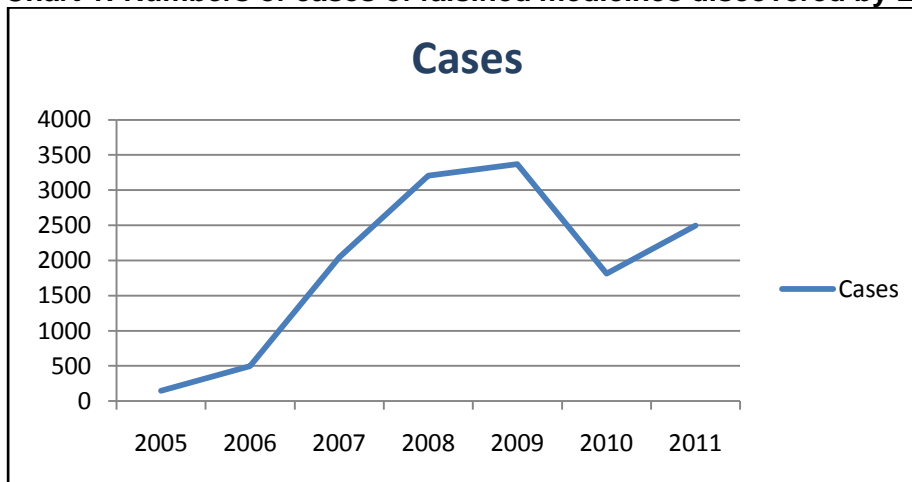
This is the term adopted by the European Parliament, whereas the World Health Organisation prefers to use 'spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines' and other organisations use 'counterfeit'.

This paper will use 'falsified' unless quoting another body.

Background

The instances of falsified medicines being discovered in Europe are increasing at a dramatic rate. Medicines are now the second largest category of falsified items imported into Europe, whereas they didn't warrant a separate category in 2004 because numbers were so low. The chart below displays an increasing trend in individual cases, and numbers of falsified items discovered.

Chart 1: Numbers of cases of falsified medicines discovered by EU customs



Charts 1 and 2 demonstrate a substantial rise in the number of cases, over the most recent six-year period where figures are available. There is an unexplained dip in 2010, for which there is no explanation, but the underlying trend suggests ongoing instances of falsified medicines being introduced into the EU.

Source: EU Taxation and Customs Union

Chart 2: Number of falsified medicines recovered by EU customs

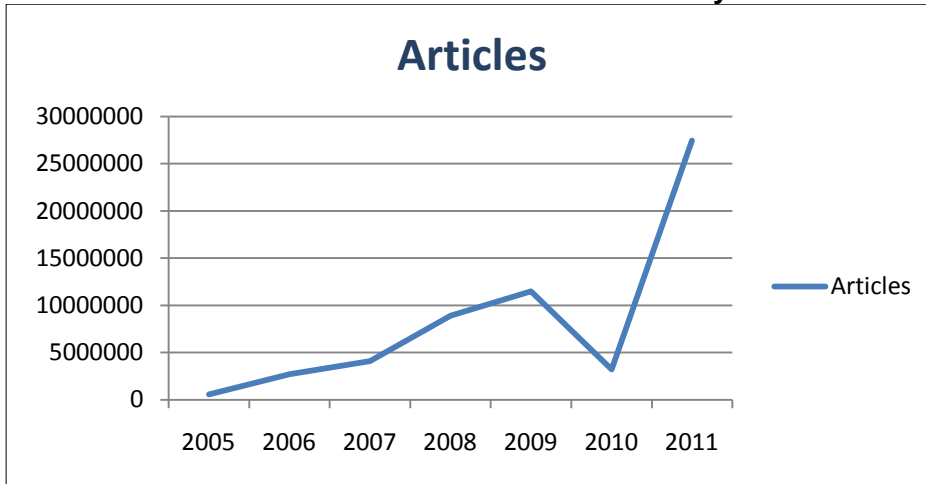


Chart 2 demonstrates an even stronger increase in the number of falsified medicines entering the EU. The figure in 2010 is unique in not defining an exponential increase in volume of counterfeit medicines.

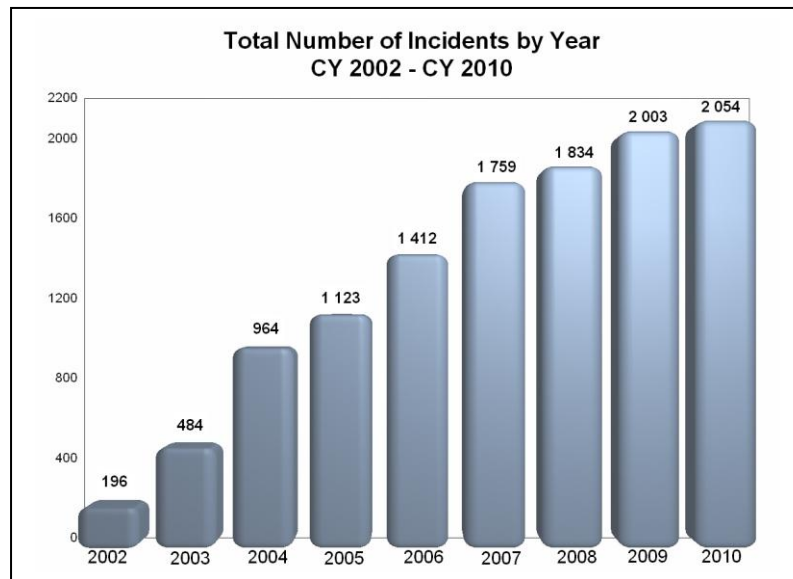
Source: EU Taxation and Customs Union

The figures above are highly likely to include medicines purchased via the internet, from suppliers outside the EU.

Chart 3: Number of falsified medicines discovered in the global legitimate supply chain

Chart 3 demonstrates a substantial increase in numbers of falsified medicines being found in the global legitimate medicine supply chain.

The increase in discovered falsified medicines may be partially due to an increased awareness of the issue amongst all stakeholders in the legitimate supply chain. The significant rise in incidents indicates a high likelihood of falsified medicines continuing to be targeted at the EU from the rest of the world.



Source: Pharmaceutical Security Institute

The European Commission Taxation and Customs Union cites two countries being predominantly the greatest exporters to the EU: China (68%) and India (28%) are by far the greatest exporters with Hong Kong (1.5%) the third greatest exporter.

Falsified medicines are found in every region of the world. In a statement in 2011, the World Health Organisation said:

Increasing international trade of pharmaceuticals and sales via the internet has further facilitated the entry of counterfeit products into the supply chain.¹

This follows on from its comment in 2006:

Counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way, in the form of tablets or capsules that look right, but which do not contain the correct ingredients and, in the worst case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality.ⁱ

The WHO IMPACT Counterfeit Medicines Working group estimates that parts of Latin America and some countries in Africa and Asia have a 30% counterfeit medicine rate amongst the legitimate medicine chain. In the former Eastern Bloc it is 20% and medicines purchased from illegal internet sites have a 50% counterfeit rate.ⁱⁱ

The Westminster Government has expressed concern to the RPS about the rising incidence of falsified medicines. It is understood that the MHRA is keen to introduce an effective recall system that is able to identify individual packs.

Some European Member States have either introduced or commenced their own response to this issue.

The instances of EU customs seizing counterfeit medicines are increasing, as the table below demonstrates:

Falsified Medicines in the UK

There have been 15 known incidents of falsified medicines entering the UK between 2005-2011, seven of which were seized before reaching patients. Nine were recalled but it is unclear what proportion of those medicines was actually returned. It is understood that over half a million packs remained in the hands of patients in one incident alone.

Date	Product	Indication	How Discovered	Action
2005	Lipitor	Cholesterol reduction	Information from an EU regulator	Batch recalled
2005	Cialis/ Viagra	Erectile Dysfunction	MHRA investigation	Seized before reaching patients
2005	Lipitor	Anticholesterol	MHRA investigation	Seized before reaching patients
2005	Celebrex	Arthritis	MHRA investigation	Seized before reaching patients
2006	Lipitor	Cholesterol reduction	MHRA investigation	Batch recalled
2006	Lipitor	Cholesterol reduction	MHRA investigation	Batch recalled
2006	Propecia	Hair Loss	Wholesaler	Seized before reaching patients
2007	Zyprexa	Anti psychotic	By repackager	Batch recalled
2007	Casodex	Prostate cancer	MHRA investigation	Batch recalled
2007	Plavix	Anti platelet	MHRA investigation	Batch recalled
2007	Plavix	Anti platelet	MHRA investigation	Batch recalled
2007	Plavix	Anti-platelet	Industry Laboratory	Seized before reaching patients
2008	Enbrel	Rheumatoid Arthritis	Marketing Authorisation Holder	Seized before reaching patients. Diverted authentic product in falsified Packaging
2009	Seretide Evohaler	Asthma	Information from EU Customs Office	Batch recalled
2011	Truvada and Viread	HIV	Licensed repackager	Seized before reaching patients. Diverted authentic product in falsified packaging

Source: MHRA

Progress to Date

Conversations on the issue of counterfeit medicines commenced several years before any action was taken by the European Parliament. These conversations commenced before 2005 when the European Commission (The Commission) decided to take action.

The Commission decided that action needed to be taken to resist the exponential growth in falsified medicines and guard against the increased potential of them entering the medicine supply chain in Europe. The issue was understood to be endemic amongst branded medicines and almost non-existent amongst generics. In light of this, the Commission's proposal is for this legislation to only refer to branded medicines but with the potential to be expanded to include all generics for when there is evidence of falsification.

The Commission formalised its endeavours by introducing legislation in 2008. It chose to amend an existing Directive - 2001/83/EC - relating to the introduction of falsified medicines into the medicine chain.

Once satisfied with the new text, the European Parliament was asked to consider the new Draft Directive, which it accepted on 16th January 2011.

The Commission has now been tasked by the European Parliament to devise the best practical solution to address the Parliament's wish to provide an effective defence against falsified medicines. It will be using the new Delegated Legislation process for the first time. Some countries outside Europe recognise falsified medicines as an issue that requires action. Nigeria and Ghana both have voluntary schemes whereby manufacturers place a unique, identifying barcode on every pack of medicine. Patients are able to scan the barcode with a mobile phone and send to the manufacturer to confirm the pack's authenticity.

India has just announced that it is to adopt a similar scheme.ⁱⁱⁱ

The RPS has made a clear statement on medicines safety: It aims to make Great Britain the safest place to take medicines. It will be necessary to engage in a programme to restrict the incidence of falsified medicines if we wish to fulfil this statement.

A consultation by the European Commission took place in 2013 to seek views of all stakeholders on the most effective systems and processes required to deliver the measures set out in the Directive.

The European Commission has now commenced the creation of Delegated Acts which it aims to complete by January 2014, where it will set out the processes used to verify medicines and secure individual packs.

The first measures included in the Directive come into force in July 2013, where manufacturers will be expected to have enhanced QA processes in place, set out in the Good Manufacturing and Distribution Practice Directive.

The main aspects – verification and the tamper-proof seal - of the Directive will be introduced in the UK in 2017.

Royal Pharmaceutical Society Position

The RPS will identify, recognise and develop partnerships with relevant stakeholders to ensure that the FMD is implemented to enhance patient safety.

Pharmacists should not be receiving counterfeit medicines in their pharmacies. The RPS believes that nothing should come between a patient and the medicine they require. Falsified medicines do just that. They also introduce an element of doubt into the legitimate medicine

supply chain. Patients must be confident that the medicines they receive from their pharmacies are safe and fit for purpose.

Falsified medicines are taken in good faith by patients, often with serious or life-threatening illnesses. The impact on patient care cannot be over estimated. Their use can result in reduced therapeutic benefits, increased adverse affects and contribute to unnecessary morbidity and mortality.

On balance, it is likely that the European Parliament will introduce a system that as currently proposed, adds a higher level of integrity to the medicine supply chain. To pursue its aim of being the safest place in the world to take medicines, the RPS must support any reasonable initiative that may achieve this aim.

The RPS believes:

- the Directive must eliminate falsified medicines from the supply chain and further enhance patient safety
- there must be no unacceptable delay in the supply of medicines to patients
- the system is fully tested before introduction, fully compatible and fully integrated with existing pharmacy software systems
- the IT system must be robust and reliable, with appropriate failsafe and back-up systems
- working practice is integrated with existing pharmacy work streams, to minimise pharmacy workforce pressure, add professional value and enhance patient care
- patient confidentiality is secured through adherence to NHS and professional guidance at all points in any new processes and procedures
- any new commercially sensitive data generated or accessed within the pharmacy must remain confidential and secure
- patient safety and confidence in their medicines would be further enhanced by extending the use of original packs with tamper proof seals
- the potential patient benefits of the verification system should not be compromised by a lack of support and resources
- the point of authentication should be decided locally in the best interests of the patient.

Additional Points to Consider

The Directive requires systems to be in place enabling recall of falsified medicines at individual patient level.

If scanning at the point of dispensing is introduced, it must be interoperable with existing pharmacy systems, to reduce the need for additional pharmacy hardware and resources. Use of a system that displays information on the medicine being dispensed, in addition to verifying authenticity, will reduce picking errors and provide an additional reason for pharmacists to use the system

In addition to reducing the incidence of falsified medicines, the correct system will also provide pharmacists with an additional resource that enhances dispensing accuracy. Research from Australia demonstrates a 50% reduction in dispensing errors after a barcode system was implemented in 2004.^{iv}

The Westminster Government must undertake preparatory work at an early enough stage to allow for new hardware and workflow planning by pharmacists and pharmacies, and to minimise costs.

IT systems suppliers must also be engaged with as soon as possible to ensure that integration with existing systems used in pharmacies, will be as seamless as possible.

The introduction of any necessary hardware or software will have cost implications for pharmacy. These financial and contractual changes must be addressed prior to implementation of the Directive. There must be a clear indication of potential costs per pharmacy as soon as possible, to allow for business planning. Delaying this vital piece of work is likely to put unacceptable levels of strain upon pharmacies, pharmacists and their staff.

Stakeholders must engage with prescribers at the earliest opportunity to ensure that prescribing behaviours recognise pack sizes wherever possible. This can provide an interim stopgap until the Westminster Government facilitates whole pack dispensing.

Wholesalers must ensure the integrity of all transport used to distribute medicine.

It is likely the UK will make itself more prone to attack by counterfeiters if Home Nation implementation appears to be less rigorous than the rest of Europe. The UK may also be regarded as the best route for counterfeit medicines to enter Europe, depending upon how fully we participate.

A Directive that isn't fully implemented could also place additional burdens on those who export medicines to mainland Europe. UK exporters may be compelled to provide documentation guaranteeing the provenance of every consignment. This will be an unnecessary burden on business and potentially slow down the medicine supply chain.

The General Pharmaceutical Council will be required to review all relevant regulations in light of the Directive. We will seek assurances that it will be ready to respond in an appropriate manner at the commencement of the new regulations.

The RPS will:

1. Monitor developments with the Delegated Acts to highlight opportunities for pharmacy and ensure that all professional issues are addressed.
2. Continue to influence public policy across GB and in Europe to minimise the risk to patients through falsified medicines, in accordance with our aim to ensure that Great Britain is the safest place to take medicine.
3. Continue to press the Westminster Government for Original/Whole pack dispensing.
4. Continue to press for the creation of a Directive that does not disrupt pharmacy practice, strengthens the integrity of the medicines supply chain, and uses IT solutions to maximum advantage for pharmacy.

ⁱ WHO SFFC web pages: http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/

ⁱⁱ WHO IMPACT brochure: <http://www.who.int/impact/FinalBrochureWHA2008a.pdf>

ⁱⁱⁱ Indian Ministry of Health and Family Welfare: <http://mohfw.nic.in/WriteReadData/l892s/GS1%20barcode%20requirements%20for%20medicines-drugs-49916377.pdf>

^{iv} PJonline report on the FIP Congress, India, 2011: http://www.pjonline.com/files/rps-pjonline/pdf/FIP_Online.pdf

Falsified Medicines Cross-Board Working Group August 2013

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Review

August 2015 (or if upon review or amendment to relevant legislation)