

# Safeguarding the integrity of the medicines supply chain in Europe

## Counterfeiting

### A global problem

During 2005, many individual criminals and criminal organisations have remained active in the counterfeiting, diversion and theft of pharmaceuticals. The Pharmaceutical Security Institute (PSI) has documented a 27% increase in incidents reported to its Counterfeit Incident System (CIS) in 2005.<sup>i</sup> Moreover the number of countries experiencing counterfeiting, theft and diversion has increased 17% between 2004 and 2005. The 973 incidents in 2005 were traced to 101 countries. The types and therapeutic categories of counterfeit pharmaceutical products that have been identified has also continued to grow. In the 973 recorded incidents, 687 different pharmaceutical products were identified. This represented a 23% increase over 2004.<sup>ii</sup>

*"The data disclosed that virtually any type of pharmaceutical is subject to counterfeiting."*<sup>iii</sup>

The WHO estimates that 8% to 10% of the medicines in the global medicine supply chain are counterfeit, reaching as high as 25% in some countries.<sup>iv</sup>

The largest counterfeit market with close proximity to the EU is Russia, where it is estimated that 12% of medicines are counterfeit.<sup>v</sup> Crime relating to pharmaceuticals in the Eurasia region in general continues to grow dramatically accordingly to the PSI. In 2005, the region recorded 175 total incidents. This represents a 216% increase over 2004. 102 of these incidents were in Russia and 30 in the Ukraine – both of which have land frontiers with the EU. Analysis of the therapeutic categories of drugs associated with the incidents in Eurasia reveals a predominance of counterfeit drugs in the anti-infectives category.

Table 1

#### TOP TEN RANKED BY COUNTERFEITS SEIZED/DISCOVERED

	Country	Seizures/Discoveries
1	<b>Russia</b>	<b>93</b>
2	China	87
3	South Korea	66
4	Peru	54
5	Colombia	50
6	United States	42
7	<b>UK</b>	<b>39</b>
8	<b>Ukraine</b>	<b>28</b>
9	<b>Germany</b>	<b>25</b>
10	Israel	25

Incidents reported to PSI Counterfeiting Incident System: PSI 2005 Situational Report

Separately from the PSI, the Russian Ministry of Health claims to have identified 211 batches of counterfeit medicine. All of the counterfeit batches were found in the legitimate supply chain.<sup>vi</sup>

Following the enlargement of the EU, the WHO warned that an increase in the risks of counterfeits entering the supply chain was "obvious".<sup>vii</sup>

In February 2006 the WHO International Conference On Combating Counterfeit Medicines declared:

*"Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective"*<sup>viii</sup>

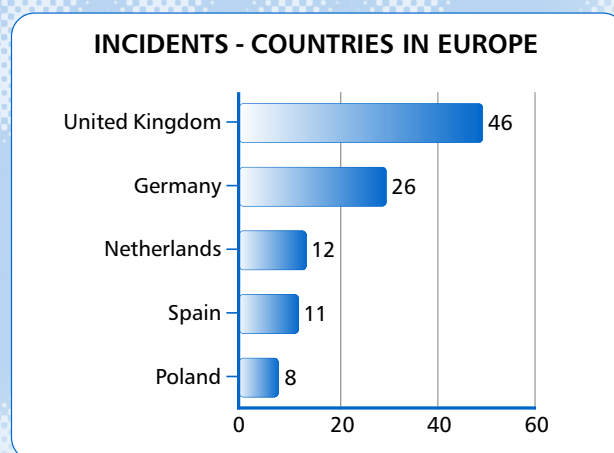
### Europe

Dr. Nils Behrndt, Deputy Head of Pharmaceuticals Unit, DG Enterprise and Industry has stated at the WHO International Conference On Combating Counterfeit Medicines in February 2006 that in the EU, in the four years 2001 to 2005, there have been 27 incidents involving counterfeits in the legitimate supply chain<sup>x</sup>. These breaches of the medicines supply chain are a clear indication of the increasing sophistication of those involved in counterfeiting in the EU.

Alexander Vladychenko, Director General for Social Cohesion in the Council of Europe has stated that:

*"Counterfeit drugs are on the verge of becoming a silent pandemic"*<sup>x</sup>

Table 2



Incidents in Europe reported to PSI Counterfeit Incident System: PSI 2005 Situational Report

According to the Pharmaceutical Security Institute in 2005, the EU experienced a significant increase in incidents recorded in their Counterfeit Incident System. Eighteen European countries were involved in incidents and the region jumped from 43 incidents in 2004 to 130 in 2005. This represented an approximate 300% increase in a year.<sup>xi</sup>

## Short-Line Wholesaling – Parallel Trading

Parallel trading is the common parlance for short-line wholesaling activities. Pfizer is concerned about the potential for counterfeit medicines to enter the supply chain via the activities of parallel traders as has been the case in the UK (see Case Study) and the Netherlands. The complex and fragmented nature of the EU medicines supply chain presents multiple opportunities for counterfeit medicines to enter the legitimate supply chain. Over 140 million medicine packs are parallel traded each year in the EU and they can travel through as many as 20-30 pairs of hands before finally reaching the patient.<sup>xii</sup> Graham Satchwell, a former British Police Detective Superintendent, has argued that, in his opinion, through parallel trade, counterfeiters may have discovered an easy route for selling counterfeit products into the legitimate distribution chain.<sup>xiii</sup>

**This complexity can be explained by a number of factors:**

- The growth of the EU in recent years. The supply chain has now become more fragmented with effectively 25 pharmaceutical markets in Europe.
- A dramatic increase in the number of parallel traders has increased the flow of medicines throughout Europe. For example, there has been a doubling of the number of parallel traders holding licenses to trade in Pfizer products from around 60 in 2000 to well over 120 in 2006.
- A dramatic increase in the number of parallel trade licenses. For example, by the end of 2005 over 6000 parallel import licenses had been granted across Europe for Pfizer products alone compared to 1000 in 2000.
- No unified system of track and traceability.
- No supra national authority has responsibility for the pan European distribution system.
- The repackaging process involved in parallel trading removes many of the security features which the industry has invested in.

There is evidence linking counterfeits with parallel trading. The respected Dutch pharmacy journal, *Pharmaceutisch Weekblad*, reported that counterfeit medicine found in the Netherlands at the end of 2004 entered the legitimate supply chain through parallel import.<sup>xiv</sup>

**In addition, the Dutch Healthcare Inspectorate on behalf of the Minister of Public Health, stated in the report of its audit of the Dutch distribution system that:**

*"More stringent checks are required from pharmaceutical distributors for counterfeit pharmaceutical drugs to include supplier and customer authentication."*<sup>xv</sup>

## Focus on the United Kingdom

The United Kingdom, with 46 incidents in 2005 (of which 39 were confirmed to involve counterfeit), the UK again ranked among the top ten countries worldwide (as seen in Table 1). This incident total represented a substantial increase over the incident total of 17 recorded for 2004.<sup>xvi</sup>

## Case Study: Counterfeit Lipitor in the UK supply chain

In July 2005 counterfeit Lipitor 20mg was found in the UK supply chain resulting in a recall of a batch of 120,000 packs of Lipitor 20mg. MHRA issued the recall after 70 counterfeit packs of medicine claiming to be Lipitor 20mg and using the same batch number as the genuine product were found in two separate licensed UK wholesalers, one a short-line wholesaler (parallel trader) and the other a full-line multinational wholesaler. It is understood that the short line, parallel trading wholesaler imported the counterfeit Lipitor 20mg from outside the EEA, an illegal activity in its own right, and subsequently sold these medicines to the large full line multi-national wholesaler who in turn supplied the counterfeit medicines to pharmacies across the UK. The extent to which the counterfeit Lipitor 20mg had penetrated the UK pharmacy system is clearly demonstrated by the fact that over 50% of the medicines returned from pharmacy following the MHRA recall notice were proven to be counterfeit.

Only days after this incident a second batch of counterfeit Lipitor, this time 40mg, was found on the same premises of the UK licensed short-line parallel trader. The UK regulator, the MHRA, was alerted to the possibility of counterfeit Lipitor 20mg being available in the UK by the Dutch regulator, after the Dutch seized a significant quantity of the same counterfeit Lipitor in the same UK livery in a Dutch pharmacy.

The incidents above are indicative of the low barrier to entry into the legitimate medicines supply chain. The ease of entry was most recently demonstrated by an undercover investigation presented on British television 'Tonight' programme in January 2006.<sup>xvii</sup> The programme demonstrated how, for a relatively small fee and using false names, a wholesaler dealing license was easily obtained, giving the investigative journalist authorised access to the entire European legitimate medicines supply chain.

**UK concern about increasing risk from counterfeiting has lead the MHRA to adapt its anti counterfeiting strategy to include:**

- The operation of Europe's largest medicines surveillance scheme to spot check 'at risk' medicines.<sup>xviii</sup>
- Increased checks by MHRA inspectors when inspecting pharmaceutical distributors.<sup>xix</sup>
- Increased international collaboration.<sup>xx</sup>

## Counterfeit Risk Factors for Europe

- Legally sanctioned repackaging of original manufacturers' medicine
- Plethora of wholesaler intermediaries (parallel traders)
- Low barrier to entry to medicine supply chain
- Lack of supra national control of EU medicines supply

## Further Information

MARTIN.SWEENEY@PFIZER.COM  
European Trade Group, Pfizer Ltd, Walton Oaks  
Dorking Road, Tadworth, Surrey KT20 7NS

i The Pharmaceutical Security Institute (PSI) manages a secure database, called the Counterfeiting Incident System, (CIS) which captures incidents of counterfeiting, diversion, and theft of pharmaceutical products worldwide. Each new report, if known to be unrelated to a previous submission, is listed as an "incident". CIS reports come from a variety of sources, including open media reports, PSI member company submissions, and public-private sector partnerships.

ii PSI Situational Report 2005

iii PSI Situational Report 2005

iv <http://www.who.int/mediacentre/factsheets/fs275/en/>

v Association of International Pharmaceutical Manufacturers (AIPM) and the Coalition for Intellectual Property Rights (CIPR), April 2002

vi PSI Situational Report 2005

vii Independent on Sunday, London, 18 January 2004

viii Declaration Of Rome, 18 Feb 2006, Conclusions And Recommendations Of The WHO International Conference On Combating Counterfeit Medicines

ix WHO Conference, Rome, 16–18 February 2006

x WHO Conference, Rome, 16–18 February 2006

xi PSI Situational Report 2005

xii Haigh, J., IMS Global Consulting, quoted in 'Parallel Trade in Medicines', Social Market Foundation, June 2004

xiii Satchwell, G., 'A Sick Business', The Stockholm Network, November 2004

xiv Croonen, H., (2004): *Nep-Cialis bevat Sildenafil*. *Pharmaceutisch Weekblad* 139, 40 pp 1300-1302

xv Kingma, J.H., (2005): *Dutch Health Inspectorate*, October 2005

xvi PSI Situational Report 2005

xvii *Is your medicine Fake? A tonight special*. Channel: ITV January 9th 2006

xviii Nimo Ahmed, Head of Intelligence, MHRA Hospital Doctor 27 April 2006

xix Nimo Ahmed, Head of Intelligence, MHRA Hospital Doctor 27 April 2006

xx Nimo Ahmed, Head of Intelligence, MHRA Hospital Doctor 27 April 2006

