



# Become part of the solution

## Counterfeit and substandard medicines

## threatening patient safety

WHO estimates that counterfeit medicine sales range from around 1% in developed countries to over 10% in developing countries and that medicines purchased over the internet from sites that conceal their physical address are counterfeit in over 50% of cases.<sup>1</sup>

Counterfeit and substandard medicines are a very real and increasing threat to patient safety that needs to be addressed by all stakeholders. For example, 1647 million packs of medicine were sold in Germany in 2002 – if, as WHO estimates, 1% of these medicines were counterfeit then a staggering 16.4 million packs of counterfeit medicines were sold in Germany in that year.<sup>2</sup>



The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach US\$ 75 billion globally in 2010, an increase of more than 90% from 2005.



Not surprisingly there has been a noteworthy and necessary increase in the attention being paid to the threat of counterfeit and substandard medicines. The public sector in particular is examining the problem more actively. For example, The Council of Europe has made an extended investigation into the problem and is determined to provoke action in its member countries. The European Parliament is also calling for action and counterfeit medicines are seen as an increasing threat by MEPs.

Most notably, WHO's IMPACT initiative will further raise the profile of counterfeit medicines and look to work with patient safety organisations world wide.

The pharmaceutical industry is also responding to the increasing threat to patients, with the safemedicines.org initiative in the US and EFPIA in Europe.

However, further action must be taken to raise the profile of safe medicines and campaign for more effective measures to protect patients.

### WHAT IS THE PROFIT MARGIN FOR COUNTERFEITERS?



#### HEROIN

Cost: 1 kilo = €2,000  
Street value: 1 kilo = €40,000  
**Profit: 2000%**



#### VIAGRA

Cost: 1 kilo = €100\*  
Street value: 1 kilo = €70,000  
**Profit: 70,000%**

\*Counterfeit active ingredient

### WHAT IS NEEDED

Combating counterfeit medicines requires the coordinated effort of all the different public and private stakeholders that are affected and are competent in addressing the different aspects of the problem.

Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.

### WHAT THE EU SAYS<sup>3</sup>

- ★ counterfeit medicines have increased 1000% between 1998–2004
- ★ that in 2003 100m counterfeit articles were seized at external EU borders, with a value of \$1bn
- ★ between 2001–2005 197 cases of counterfeit medicines identified in the pharmaceutical supply chain
- ★ 170 counterfeit medicines were identified in illegal distribution channels over the past 5 years in the EU Member States.

## About the European Alliance for Access to Safe Medicines

The Alliance is a new, pan-European patient safety initiative, campaigning for the exclusion of counterfeit and substandard medicines from the supply chain. The Alliance aims to represent all interested parties – patient groups, health professionals, academics, non-governmental organisations, the pharmaceutical industry and policy-makers.

### MISSION STATEMENT

The European Alliance for Access to Safe Medicines is an independent voice campaigning to remove counterfeit and substandard medicines supply to better ensure patient safety.

### OBJECTIVES

To increase awareness of the dangers of counterfeit and substandard medicines, to successfully campaign for improved legislation, enforcement and patients' rights to safe medicines.

### STRATEGIES

- ★ Be the recognised independent, inter-sectoral voice representing European patients' rights to access safe medicines.
- ★ Raise public awareness of the dangers of counterfeit and substandard medicines, based on one key consideration – patient safety.
- ★ Build a network of 'influencers of change' charged with promoting the establishment of a secure supply chain, driving legislative change where necessary.
- ★ Be proactive in devising and implementing safe medicines initiatives and tactics.

### KEY ISSUES THE ALLIANCE ADDRESSES

The Alliance is taking action to increase access to safe medicines by:

- ★ involvement in the ongoing anti-counterfeiting activities of the European Commission, European Parliament, WHO and Council of Europe – enhancing patient safety through policy and legislation
- ★ participating in the wider debate on counterfeit and substandard medicines through our website, conferences and the media
- ★ raising public awareness and reducing consumer exposure to the risks of purchasing medicines online



## Alliance organisational structure

The direction and actions of the Alliance will be governed by the board of executives. An executive board of seven, elected from the members and supporters' group, will provide the communications drive and direction.

The members and supporters' group will contain partners from both independent and industry backgrounds. The members and supporters' group will never have more funding partners than non-funding partners.

The actions of the Alliance will be carried out by the executive board, with logistical and marketing support from a professional marketing communications agency.

"I am delighted to be heading-up the Alliance and welcome the opportunity to really make a difference to patient safety in Europe. Other interested organisations and individuals are welcome to join the Alliance as supporters and their feedback and suggestions will be presented at executive board meetings."

Jim Thomson  
EAASM Chair

### References

1. Fact sheet N°275 Revised 14 November 2006 [www.who.int/mediacentre/factsheets/fs275/en/](http://www.who.int/mediacentre/factsheets/fs275/en/). Date accessed: July 2007
2. [www.euro.who.int/pharmaceuticals/Topics/Overview/20020425\\_2](http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020425_2). Date accessed: July 2007
3. Dr Nils Behmdt, Deputy Head of Pharmaceuticals, Unit DG Enterprise and Industry. WHO meeting, Rome, February 2006