



*Making Medicines Affordable*

## POSITION PAPER

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"Business with Certified Partners Only"

Position Paper on Anti-counterfeit Policy

19 JULY 2006



Making Medicines Affordable

## 1. Introduction

The EGA firmly believes that counterfeiting medicines is a serious criminal offence<sup>1</sup>. Counterfeit medicines are deliberately and fraudulently mislabelled with respect to their identity and/or source. Counterfeiting can apply to both patented, branded and generic medicines.

The European Generic medicines Association, EGA, represents EU based companies that together produce and market almost 50% of all prescription medicines dispensed in the EU-25. EGA is an active member of the Council of Europe's ad hoc Group on counterfeit medicines, and was a member of the WHO anti-counterfeiting group from 1998 to 2000.

The EGA and its members are aware of the fact that in 2005 alone 781 cases of counterfeited medicines were reported by the Pharmaceutical Security Institute, PSI<sup>2</sup>. However, it appears to the EGA that these cases mainly concern 'patented branded pharmaceuticals'. Surveys of the EGA members in 2006 revealed no recent case of counterfeited generic medicines within the EU-25. As a result, we conclude that, due to the high standards of the supply system and of the regulatory procedures in the European Union, the incidence of counterfeited generic medicines in general in the EU-25 is limited in scope. Moreover, due to their low price in comparison to originator products, generic medicines are not likely to be counterfeited in the EU-25. However, there are cases of counterfeited generic medicines outside the EU, especially in Russia.

The EGA is also aware of the fact that there is no scientific proof of any causal relationship between counterfeited medicines and patient accidents in the UK over the past years as reported to the Patient Safety Agency of the NHS<sup>3</sup>. In spite of repeated requests, no other scientific proof appeared to be available to the EGA either.<sup>4</sup>

## 2. General comments

Anti-counterfeiting measures are, in the opinion of the EGA, a responsibility of all sides of the pharmaceutical industry as counterfeiting is a threat to the excellent reputation of EU health care systems, to the trust of health care professionals in our products, to the reputation of EGA's suppliers and, finally, to the safety of consumers. EGA agrees that the currently available analyses show an upward trend in the number of counterfeit cases and in the variety of pharmaceuticals involved, and that with unchanged policies the future outlook shows a further likely increase<sup>5</sup>.

All measures proposed until now to secure pharmaceutical products and their supply chains have been of a technological nature ranging from bar-coding to nano-printing, and from RFID-tagging to odour-application<sup>6</sup>.

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<sup>1</sup> Declaration of Rome, WHO international Conference on combating counterfeit medicines, Rome 18 Feb. 2006.

<sup>2</sup> Harvey Bale, The view of pharmaceutical manufacturers, International Conference on combating counterfeit drugs: building effective international collaboration, Rome 18 Feb. 2006, slide5.

<sup>3</sup> Prof. Cousins, NHS Patient Safety Agency: "For which problem is this a Solution ?", GS1 meetings, London, Brussels, 27-7, 13-9-2006.

<sup>4</sup> GS1, Global Health Care User Group meeting, Rome 21-23 March 2006.

<sup>5</sup> WHO, Counterfeit medicines, Fact sheet no. 275, rev. Feb. 2006

<sup>6</sup> EFPIA, Combating Counterfeit medicines and protecting patients through a partnership approach, Position paper, EFPIA, May 2005.



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Currently one of the basic prerequisites for acting against counterfeiting is precise identification and correct immediate tracking and tracing<sup>7</sup>.

However, the investment required to implement these technologies is estimated at over €400 million per single supply chain, amounting to a total €10 billion investment for the EU-25 combined with an estimated annual €500 million for operational costs for the EU-25.

If we consider that generic medicines manufacturers work to a highly competitive business model with small margins and a broad range of products, the cost burden of implementing these technologies will be very high and could make some medicines too unprofitable to continue being produced. This will reduce competition and raise the prices of drugs, with the consequent negative effects for healthcare systems.

Nevertheless, since criminal behaviour and a lack of integrity are the basic origin of counterfeiting, it is very doubtful whether technological measures will stop counterfeiting. It is clear that in this digital era technology-based measures are very easy to copy and paste, and can be transmitted via the internet at the speed of lightning to other jurisdictions where reproduction of these technology-based safety measures is a matter of very little time and money.

Therefore, the EGA is of the opinion that the only result of technology based anti-counterfeit measures is a brief delay of counterfeit product entry. Furthermore, EGA proposes to support enhancement of legal measures enforcement.

### 3. What can manufacturers do to reduce the risk of counterfeiting?

Since technology based anti-counterfeit measures are mainly aimed at authenticating genuine products, we would like to emphasise that measures to prevent counterfeiting (eg, market surveillance, strict control of distribution chain, strict control on printed packaging materials, strict control of waste and batch remainders, etc) are of major importance.

Bearing all of the above in mind, the EGA advocates anti-counterfeit measures from a very different nature or paradigm. We propose a multiple approach to fighting against counterfeiters. Manufacturers can contribute by:

- Minimising counterfeiting risk by using safer production processes (see below);
- Implementing procedures on how to investigate suspect samples;
- Improving cooperation with authorities in case of confirmed counterfeits;
- Employing technology for authentication of genuine products as mentioned in point 2;
- Strengthening market surveillance (see below);

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The Stockholm Network, A sick business. Counterfeit medicines and organised crime, The Stockholm Network, London 2004.

Harvey Bale, The view, 2006

WHO, Fact sheet 275.

WHO, Anti-counterfeit technologies for the protection of medicines, Draft proposal, 2006.

<sup>7</sup> EGA has been participating since April 2004 in the development of global standards for identification by GS1 through active participation in the GS1 Global Healthcare User Group and in the GS1 European Health Care Initiative. EGA has organised an Identification Developments Network where 14 EGA members are participating.



**Minimising counterfeiting by safer production processes** consists of assuring that printed packaging materials (including films or electronic masters) provided by external printers can not be diverted; that all excess, rejected, returned or expired products, including those retained by third parties and customers, are properly disposed of; that bulk finished product and packaging materials are securely stored to prevent their diversion to illegal manufacturers and packagers; and that all third parties involved (eg, contract manufacturing/packaging) are properly controlled. Compliance with these measures must be monitored by internal audits of own facility and external audits of printed packaging suppliers, third parties, licensees, and service providers.

**Improved market surveillance** can be achieved by close monitoring of adverse events, by evaluating marketing data (eg, unexpected drug demands exceeding normal drug supply or unexpected decline of drug demands in certain regions) and, finally, by routine sampling from local markets.

In the opinion of the EGA, the area of the supply chain that is most vulnerable to counterfeits entering the stream of commerce is with secondary wholesalers, and not through transactions between legitimate manufacturers and the primary distributor. In other words, wholesalers can also contribute to the fight against counterfeiting by securing the supply chain. That concept is called the "normal chain of distribution": drugs that do not travel outside the normal chain of distribution would be exempt from more burdensome anti-counterfeit measures.

In this context EGA is of the opinion that 'certification' of partners in the pharmaceutical supply chain is a better solution and better way to operate not only with regard to sustainability, but also from the cost-benefit standpoint:

- ISO 9001 certification (or equivalent) offers mutual benefits to all partners in the supply chain and in the health care system.
- Self-auditing as well as periodical audits by independent auditors creates a self-confident corporate culture of integrity where counterfeiting has no room to flourish.
- Additional auditing by Inspectorates or criminal investigation agencies is easier to fulfil at less cost both for the agencies and the companies involved.

Because of the mutually rewarding outcome of the proposed **'Business with Certified Partners Only'** model of anti-counterfeiting measures, EGA strongly believes this system will:

- Improve the business process of the company;
- Create a sustainable integrity amongst all partners in the pharmaceutical care of the European Union;
- Create a competitive advantage for EU based 'certified' companies in business situations with other jurisdictions;
- Contribute to the EU being the most competitive economy.

Therefore, implementation of (ISO) certification is a self-rewarding anti-counterfeit measure with minimal costs to the EU health care systems.

**In conclusion, an important contribution to the fight against counterfeiting is to secure the supply chain by introducing safer business processes through a variety of measures ranging from business certification and market surveillance to electronic pedigrees.**