Making Medicines Affordable

POSITION PAPER

Position Paper on Anti-Counterfeit Policy

In response to

the European Commission Consultation on DG ENTR Study on Distribution Channels Part I 'Combating Counterfeit Medicines'

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1. Introduction

Counterfeiting is a serious economic problem in today's world. Furthermore, counterfeiting of pharmaceuticals is a criminal and reprehensible crime: it puts people's lives at risk and undermines the confidence of the public in Europe's vital healthcare systems.

Originator pharmaceuticals with high added value are the main target of counterfeiters. Generic medicines are currently not counterfeited in the European Union[1], though this may change. This is due to the low prices of generic medicines resulting from the fierce competition on the European market.

To the best of EGA's knowledge, no harmful patient accidents due to the administration of counterfeit medicines have been reported in the EU. The existing systems seem to be capable of capturing counterfeit medicines before they reach the patient. In fact, this is a great compliment to the EU system and its relevant institutions. Licensing, marketing approvals, medicines evaluation boards, audits and inspectorates together with the actual dispensing pharmacists are reaching their main goal: the safeguarding of European pharmaceutical care. Intelligence and enforcement work by Member State competent authorities is another crucial and effective safeguard.

In these activities, the EU and Member State competent authorities and the pharmaceutical industry work together as partners. We share a common concern and objective to defeat the criminals who prey on citizens and damage the reputations of our companies. Since the current systems and partnerships are working well in the battle against counterfeiting in the EU, it is rational to strengthen the existing relevant systems and to fill in any gaps rather than seek to establish new systems.

The lack of auditing of certain partners in the legitimate supply chain can be viewed as an omission in the total system of quality control against counterfeit medicines.

[1] *The EGA held internal surveys amongst its members in 2006 and 2007. The 2006 survey resulted in zero reported cases of counterfeiting. The anonymous 2007 survey reported three cases of limited counterfeiting of generic medicines in Uzbekistan, Russia and the Ukraine.*

2. Topics for discussion

Other additional issues warrant further discussion: definition of counterfeiting, technology, costs, the Internet, reimbursement and differences between the counterfeiting of medicines in the European Union vs developing countries.

2.1 Need for a proper definition of counterfeited medicines:

The EGA is very much in favour of the definition of counterfeit drugs developed by the WHO**:** *"a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and 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".*[2]

In this context, it is important to note that medicines which are not patented can be counterfeited: counterfeiting **is essentially a trade mark issue and not a patent issue**.

Counterfeiting is not a reason **to increase intellectual property protection**. Measures to tackle counterfeiting need to be taken in the area of criminal enforcement (penal sanctions), drug regulation (reinforce control by the drug regulatory agencies, improve the regulation related to good manufacturing and distributing practices) and enforcement (by regulatory and law enforcement authorities); and **NOT by increasing levels of intellectual property protection,** which would be wholly ineffective as well as unjustified.

2.2 Costs

Mandatory application of "better technology" as a panacea against counterfeiting is, in the EGA's opinion, not effective. In today's digital world every technical solution can be copied and duplicated. The experience of banknotes and passports shows that counterfeiting will take place as soon as the "added value" is sufficiently lucrative.

The high cost of widespread implementation of "better technology" solutions can have serious financial implications. In particular, the implementation of "global" anti-counterfeiting databases could significantly increase the cost of pharmaceuticals and hamper healthcare budgets. In the EU alone, an estimated 20 billion packs of prescription medicines are dispensed annually.

2.3 Internet

The Internet is an important enabler of communication between business partners in a globalising market. Malicious parties in this transaction space are easily making use of these systems and infiltrating the legitimate supply chain with counterfeit products. A legitimate, proven and reliable internet pharmacy system must be created to protect both patients and prescribing physicians.

[2] *WHO/EDM/QSM/99.1, p.8*

2.4 Reimbursement

Reimbursement of pharmaceuticals in the EU can act as a protective measure since all Member States have some sort of socialised medicine. Generic medicines, by their very nature being the least expensive pharmaceuticals available, are often the first choice of reimbursement systems. However, the lack of governmental promotion of affordable generic medicines could encourage people to seek "cheap" originator drugs, making the system vulnerable to counterfeit entrants. The positive reputation and quality, safety and efficacy of proven bioequivalent generics must be made clear and visible to patients in all EU Member States as a tool against counterfeiting expensive originator pharmaceuticals.

In addition to this, there is a distinction to be made in developed countries between countries with reimbursed medicines versus countries with non-reimbursed medicines. In a reimbursed market (as in all EU Member States), "poverty" is not the driver to seek cheap alternatives. Rather it is the uninsured/poor who seek cheap drugs.

2.5 Need to distinguish between counterfeiting in developing countries and in the European Union

It is important to recognise the difference between counterfeiting of medicines in the European Union and in developing countries. Both need appropriate and different solutions.

- **In developed countries,** counterfeiting affect mainly the so-called **"life-style" drugs.** In addition, in rich markets, the counterfeiting industry may count on quite sophisticated technologies, both for manufacturing and for distributing (in some European countries and in the US, e-commerce is starting to play a role in the distribution of fake pharmaceuticals).

- **In developing countries,** high drug prices and the counterfeiting of medicines are linked. Essential and life-saving drugs may be affected by counterfeiting, as with antibiotics, anti-malaria drugs. Quite often, the "quality" of these counterfeits is poor. However, for life-saving drugs that are not available or affordable through the regular distribution channels, there is a desperate need-driven demand, allowing them to be successfully placed on the black market despite their poor appearance. Measures to tackle this problem include:

  (1) assuring the availability and affordability of essential medicines: a public policy to make quality essential medicines available to those who are in need: if access is not ensured, there will still be room for black market activities.

  (2) reinforcing the regulatory capacity of the national authorities.

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3. Conclusion and recommended actions

Anti-counterfeiting policy for medicines, in the EGA's view, should be aimed at maintaining and, where necessary, strengthening the strong professionalism of today's healthcare systems and its legitimate supply chain. Gaps in the existing systems should be recognised and filled. Good manufacturers, reliable wholesalers, importers and traders, along with the dispensing professionals who are able to authenticate pharmaceuticals, are the composite parts of the ideal supply chain. New provisions to control the Internet and greater promotion of generic medicines should be effectively incorporated into existing systems. Law enforcement and effective sanctions are also indispensable.

The conclusions and recommendations proposed here are only a potential solution for the EU and other developed countries. These measures will probably not protect the developing countries where the problem is the greatest because their regulatory structure is weaker, their border controls are less stringent, and the possibility of reading and controlling any coding will in general not be available.

Specific measures recommended:

1. Appropriate strengthening of the current GMP and GDP certification systems for all partners in the supply chain.

2. **Certification must be transparent to partners in business, to authorities and to professionals. This certification is properly and effectively provided by the competent authorities' work in licensing and regulation of manufacturers, wholesalers and pharmacists, and in enforcing GMP and GDP. Enforcement can ensure that all in the supply chain are dealing only with "Certified Partners", ie those approved and licensed by the competent authorities. Thus, the authorities, industry and the supply chain can work in partnership to ensure supply chain integrity, which is the crucial pre-requisite of an effective anti-counterfeiting strategy in the medicines market.**

3. Doing "Business with Certified Partners Only" should be the standard harmonised practice; additional checking or auditing of non-certified companies must be mandatory.

4. All pharmaceutical actors should introduce codes of conduct and make a joint declaration to deal only with Certified Partners as defined above (ie approved and/or licensed by the competent authorities).

5. Specific attention should be given to the role and licensing of wholesalers, secondary wholesalers, pharmacists and parallel importers which have been identified as vulnerable entry points of counterfeit products into the supply chain.

6. The EGA supports other measures proposed in the US such as ensuring that:

    a. printed packaging materials provided by external printers cannot be diverted;
    b. bulk finished products and packaging materials are securely stored to prevent their diversion;
    c. all third parties involved in packaging are properly controlled;
    d. all excess, returned or expired packages are properly disposed of.

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7. The development of a global coding system for the principal reason of enhancing patient safety and compliance should be continued. When complete, it should be applied primarily to "commercially interesting" medicines (ie high priced, on-patent life-style products) at the choice of the manufacturer, recognising that this may have a secondary role in the work against counterfeiting. It is, however, important to realise that coding systems can themselves be copied and they cannot be relied upon as a primary defence against counterfeiting. Any code or codes should be based on the open access principle.

8. The creation of specific rules and security systems for the selling of pharmaceuticals by the internet.

9. The enforcement and adequate sanctions and punishment of "pharmaceutical crime".

10. Finally, the EGA supports consumer education through a public information campaign sponsored by the national health authorities on the risks entailed in using counterfeit medicines. Aim: to explain where to buy safe medication and to encourage people to use these legal distribution channels in both developed and developing countries.