Packaging Patient Protection

Recommendations for new legislation to combat counterfeit medicines

European Alliance for
Access to Safe Medicines

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The insidious rise of counterfeit medicines in Europe

The severity of Europe's counterfeit medicines challenge is rising inexorably. Despite the unrelenting efforts of committed medicines regulators, international police and myriad stakeholders dedicated to protecting Europe's patients from the harm of fake drugs, the European community as one faces an escalating trial on this vital matter.

It is fundamentally impossible to declare the true magnitude of medicine counterfeiting on an international scale due to its clandestine nature. However, the information available reveals a shocking rise in the recorded incidence alone.

In 2008, an EU-wide customs operation uncovered more than 34 million illegal medicines in just 8 weeks. Until new, bespoke legislation is introduced to halt this progress, there is little reason to expect anything other than a rapid and sustained augmentation; as has happened in recent years.

Vice-President of the European Commission (EC) Günter Verheugen committed to tackling this unacceptable heightening of risk to European patients and healthcare systems. His mission is squarely aligned with the core aims of the European Alliance for Access to Safe Medicines (EAASM), established in 2007, to rally against this danger to patients.

The EAASM recognises, therefore, the unique opportunity afforded by the EC's proposal for a European Pharmaceutical Package for new legislation that maximises the protection of patients against the insidious hazards imbued by counterfeit, fake, substandard and other non-genuine medicines, whether branded and generic.

A complete ban on medicines repackaging would immediately secure the supply line in full between manufacturer and patient, ensuring total safety and trust in the regulated distribution chain. In the unfortunate absence of this, however, patient safety deserves nothing less than stringent new legal provision that excludes wholly any opportunities for counterfeit operations to sully Europe's lifeblood.

The EAASM stands shoulder to shoulder proudly with its partners in commending this report to all with a vested interest in defending patient safety. In particular, we seek to reach those with the power and opportunity to uphold the rights of Europe's citizens to access safe medicines.

This report outlines and clarifies the means of creating a much-needed safe harbour inclusively and cost-effectively for the international distribution and supply of safe medicines.

We hope that European Parliament takes the appropriate action to reflect not just this spirit but also the very letter of whatever laws are required to achieve patient safety in Europe.

Jim Thomson, Chair, EAASM

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Introduction

In December 2008, the European Commission (EC) announced the results of the first coordinated, cross-border action on customs control targeting illegal medicines entering and travelling through the EU – the MEDI-FAKE initiative.

In just 8 weeks, customs across 27 Member States seized more than 34m illegal medicines, including 2.2m counterfeit tablets at Brussels airport alone – 1.6m were painkillers and 600,000 were anti-malaria pills – plus a single consignment of 400,000 counterfeit drugs at Le Havre.[1]

According to reports, the World Health Organization (WHO) estimates medicine counterfeiting to be worth in excess of €20bn; the increase in reported incidents in recent years however leads some to forecast this as €40bn in 2010, representing around 10% of global medicine sales.[2]

The risk to Europe's patients is rising seemingly with little to abate it, despite intensified efforts by some medicines watchdogs. The WHO believes that more than 50% of medicines offered by websites that conceal their physical address are fakes.[3] Research conducted in 2008 by the EAASM (*Counterfeiting Superhighway*) puts this proportion higher, at 62%.[4]

It is widely accepted that we cannot know the true magnitude of medicine counterfeiting. Yet taking the much-quoted '1% of all medicines in developed Western markets' as being counterfeit, in the UK, for example, reports equate this with more than 8m packs worth approximately £425m per year.

The UK's Medicine and Healthcare products Regulatory Association (MHRA) is regarded as one of the most active and competent drug regulators in Europe in overseeing supply chain security. Between April 2008–March 2009, the agency helped to seize more than £10m worth of unlicensed and counterfeit medicines, playing a role in 23 convictions for counterfeit-related incidents of which 9 resulted in custodial sentences totalling 32 years, 6 months.[5]

This provides a clue to the scale of the challenge; however, while pharmaceutical regulation should ensure a minimum effective level of protection for patients wherever they are located in Europe, many, if not the majority, of drugs watchdogs in other Member States are under-resourced by comparison. Distribution chain regulation is often governed principally by 'soft law' (ie guidelines on good distribution practice etc).

A consequence is major divergence between Member States in the regulatory oversight of supply, and, therefore, in the level of protection afforded to patients.

The EAASM welcomes this vital opportunity to provide these key insights and recommendations in the fervent hope that new regulation is introduced – with key provisions made in the interim – to close off the gaps in European drug supply, destroying the impetus for counterfeit operations and affording patients safe access to authentic, proven medicines; which should be a right by law.

What is the current* sentiment among MEPs and European Parliamentary political candidates towards the counterfeit medicines crisis?

That Europe's patients are placed in escalating danger by the implacable violation of regulated supply chains with counterfeit medicines is now a widespread acceptance held by many. In May 2009 the EAASM, in order to gauge sentiment among lawmakers on the issue, commissioned ComRes to seek the opinions of MEPs and European Parliamentary candidates.

The responses, outlined opposite, convey a truly empathetic view by lawmakers on the health risks to Europe's citizens, and a robust resolve to take whatever action is required to prioritise and protect patient safety with minimal delay.

These are the views on counterfeit medicines of 140 incumbent MEPs (May 2009) and candidates standing for election to European Parliament.

*May 2009

On taking action

- ★ **95%** of MEPs and candidates surveyed now consider the risk posed to Europe's patients by counterfeit medicines 'serious', and **9 in 10 support action to stop the trade in counterfeit medicines** in the EU
- ★ 85% believe that the **new European Parliament should take steps** to counter trade in counterfeit medicines in the EU; furthermore, **93%** believe strongly (or very strongly, 60%) that **all measures should be taken** to achieve this

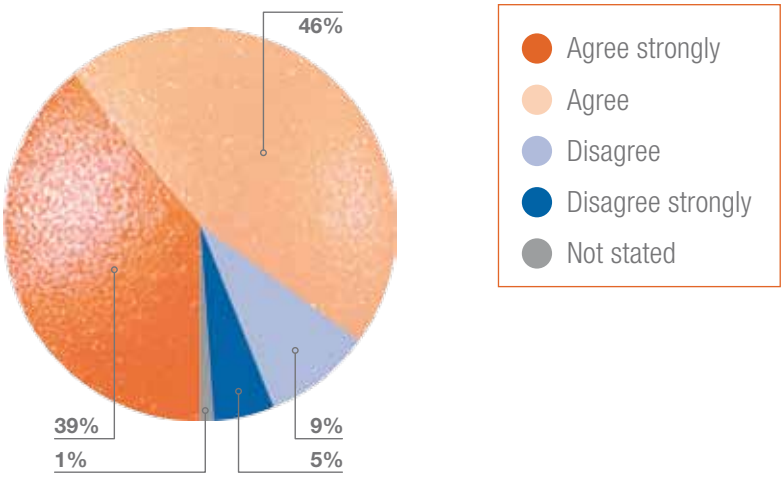
On patient safety versus free movement of goods

- ★ More than one-third (**34%**) surveyed feel that **patient safety always outranks free movement of goods**, while a further **25%** consider this to be true in the majority of cases
- ★ Another **34%** believe that **patient safety is – at the very least – equally important** as the free movement of goods in the EU

On the application of security technologies

- ★ **Two-thirds** polled say that such measures as **tamper proof seals, holograms and unique pack codes should be applied to all medicines** – both generic and branded
- ★ **59%** feel that **all medicines available from pharmacies should be protected** in this way
- ★ **71%** are sure that **particular focus should be placed on medicines commonly counterfeited**

Following the election in June 2009, the new European Parliament should take steps to counter trade in counterfeit medicines in the EU



On the practice of repackaging (in the absence of a ban)

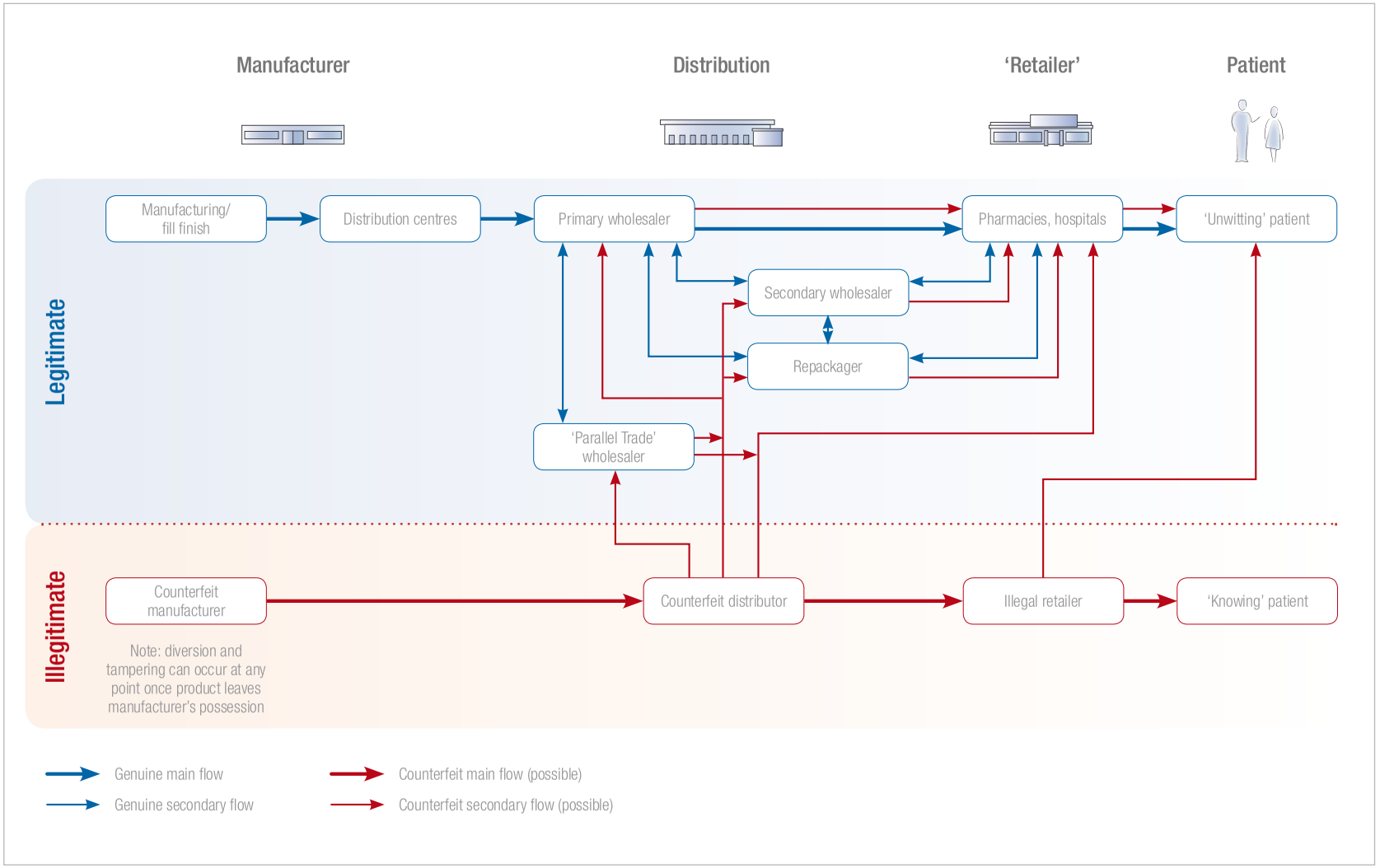
- ★ Respondents agreed by more than **2 to 1** that the **medicines repackaging process brings health risks to Europe's patients**
- ★ **82%** support (or strongly support, 25%) the **obligation for safety features to be replaced with equivalents** when repackaged
- ★ **76%** support (or strongly support, 26%) the implementation of **measures that reveal where medicines have been repackaged** from the original packaging
- ★ The opinion of nearly **2 in 3 (64%)** MEPs and candidates surveyed is that **liability for protecting patient safety should lie with the repackaging organisation**

The EAASM was heartened by the notable clarity and consensus among lawmakers in seeking to end the scourge of fake medicines in Europe. Chiefly, the results reveal unification underlining the prospect of new legislation to protect Europe's patients from the intensifying risk of medicine counterfeiting.

How counterfeit medicines can enter the legitimate supply chain

This diagram indicates the potential routes by which illegal, counterfeit and substandard medicines may penetrate today's regulated distribution and supply lines, on which Europe's patients and healthcare systems depend for safe, effective treatments.

Data collated in recent years indicate a clear and rising trend in Europe for counterfeit medicines to enter, and be traded through Europe's legitimate supply chains; real evidence now exists that fake medicines have reached patients via authorised pharmacies.



Protecting Europe's patients against the risks of counterfeit medicines

Why new legislation is needed

In the battle against the rise of counterfeit medicines, even the most dynamic and best-resourced European drug regulators struggle to keep pace with criminal developments.

For all European Member States – in particular those where resources are not so readily available to build an effective defence on behalf of citizens and patients – there is at present a dearth of legal weaponry to prevent and deter the infiltration of counterfeit medicines into regulated supply chains.

This poses a threat to human health worldwide. New legislation to protect regulated supply lines and establish appropriate oversight will serve to rebuild the confidence of distributors, healthcare professionals and patients in the authenticity and safety of the medicinal products Europe places directly into the hands of its citizens.

The EC has rightly acknowledged the sinister and escalating risks associated with the propagating plague of counterfeit medicines, and is acting to develop a framework for legislation that will tackle the problem.

Therefore the EAASM, as a leading independent and representative voice for patient safety on this matter, is able to offer guidance and consultation in order to encourage the development of a truly effective and sensitive solution; fresh, powerful legal provision for enhanced patient protection.

The EAASM recognises the Commission's accountability for the smooth and equitable functioning of the internal market for medicinal products while also ensuring a high level of public health protection in the European Union.

In the regrettable absence, therefore, of measures to restrict in full or even curtail the process of medicines repackaging and redistribution between Member States, the EAASM hopes to see implemented a highly robust package of legal measures to protect patients and ensure their safety.

What follows is a series of clear recommendations with that goal in mind.

EAASM Recommendations

1. Recommendation: The EAASM seeks a clear disassociation of specific proposals relating to the key – yet much broader issue – of general internet regulation from the European Pharmaceutical Package and the Rapporteur's response to it.

Rationale: While the EAASM recognises the internet as the central means for the sale/purchase of counterfeit medicines, seeking provision for clear, enforceable regulation of transactions via the worldwide web is potentially a fringe ambition from the perspective of the European Pharmaceutical Package.

Internet regulation is highly complex, requiring extensive impact assessment and other in-depth politico-legal discussions. The EAASM believes that the proposed European Pharmaceutical Package is not the most suitable conduit through which to address in full the controversial issue of internet regulation, which deserves an independent inquiry and separate report.

This will be a key focus in 2010 for the EAASM. Therefore, it advocates the EC's statement of 10th December 2008 that, *'the Commission does not, for the time being, propose harmonised specific rules for Internet sales of prescription medicines'*.[6]

The EAASM also acknowledges the Council of Europe's (CoE) current activities in this area, and advocates any measures that serve to bolster the protection of European patients from the risks of counterfeit medicines purchased online. The CoE expects to release the results of its work in 2010.

2. Recommendation: The EAASM seeks to define the term 'equivalence' with reference to the level of safety protection and security categorisation of Europe's prescription medicine packs.

Rationale: Original manufacturers may choose to develop and apply technologies using in-house resource and expertise. Alternative solutions exist for organisations to purchase solutions from independent technology providers. However, every safety measure reapplied by third parties should provide security 'equivalent' to these original measures (see box, left).

What is 'equivalence'?

Where safety seals and security technologies protecting original prescription medicine packs are removed or breached in the process of repackaging, it is vital before patients receive these packs that the 'equivalent' level of protection and assurance of authenticity afforded by the original manufacturer is reapplied. This should be effected by any party breaking the seals, removing or covering up one or more original security feature(s) on prescription medicine packs.

The term 'equivalence' should, therefore, refer to a set of safety and security criteria – agreed universally by all key stakeholders and provided for in revised legislation – versus any specific technology.

This way, each safety and security feature breached or removed from a pack for the purpose of repackaging, or any other reason prior to the patient receiving it, should be replaced with those providing the *equivalent* degree (or category) of protection, even if this is not necessarily achieved via the exact same means as the original; although, this may well occur. Equivalence, therefore, should mean the *same in essence, if not exactly identical technology*. This ensures that:

i) The core principles underlining the safety and security of all prescription medicine packs in Europe are agreed and protected in law for the benefit of patients;

ii) Innovation is encouraged in security technology, conferring advantages for European healthcare systems and companies.

Provided each technology solution is legally compliant with these criteria, encouraging competition and innovation in this arena avoids applying time-effectiveness limits on 'static' technologies.

As the concept of equivalence forms the backbone of security provision for prescription medicine packs in Europe – and is therefore (from a policy perspective) something of a precursor to discussion on ultimate measures – its definition should be established with minimal delay, through comitology.

3. Recommendation: The EAASM advocates universal agreement (by all holders of manufacturing and marketing licences) to apply, at the very least, a 'minimum categorisation by law' of effective traceable and tamper-proof anti-counterfeit technology.

Rationale: The EAASM recognises that security technology provision mandated legally for medicine packs should be inclusive and achievable by all parties in all Member States in an authorised position to package, or repackage a medicine. Therefore, while many pharmaceutical manufacturers may choose to apply a range of security measures (both overt and covert in nature) at the point of pack origination, patients and healthcare systems should also be protected at all times by legislation that obliges the application of minimum security features, deemed to be effective, acceptable and affordable.

The EAASM suggests the following simple but effective pack security measures, which can be implemented cost-effectively:

- ★ tamper-evident packaging
- ★ unique 2D data matrix

These measures should ensure product security, protecting medicine packs as they enter the European marketplace and then again at the final point prior to dispensing by pharmacy. Such technologies will reveal whether an authentic, original pack has been opened and repackaged, while the 2D matrix will assure the pharmacist or final dispenser of authenticity.

The unique pack number (contained within the 2D data matrix) would correspond to the specific product and its presentation (including dose and other specific details) within that pack. This would oblige would-be counterfeiters to find the unique matching code for every individual pack and its specific contents.

Advantages conferred by this system include:

1. a means of delivering safe and effective medicines to Europe's **patients**
2. the facility to alert **pharmacists** to official product recalls or changes
3. the opportunity to tackle reimbursement fraud for the benefit of **payors**
4. assistance in identifying product packs that have expired etc.

Ultimately, these measures disrupt the economic model of the counterfeiter, as they prevent numerous packs with the same code from being dispensed.

Pharmaceutical manufacturers will share the details of these 'minimal' security measures with an approved and authorised group of technology providers and manufacturer/ marketing licence holders, in order to promote patient safety.

However, it is patently unacceptable for original manufacturers to reveal details of *covert* security technology applied at source, which should of course remain as such throughout the product's journey through the European supply chain.

Pharmaceutical companies should expect repackagers to reapply the 'minimum security categorisation' with the same or 'equivalent' overt technology, but shall not reveal details of any covert measures for reapplication.

It should be noted that Recommendation 3 does not in any way negate the requirement for the implementation of Recommendation 2 as regards the replacement by 'equivalents' of *additional* overt security features applied to packs, above and beyond the 'minimal' measures as identified in Recommendation 3.

This is vital in encouraging original manufacturers to protect prescription medicines with a level of overt security appropriate to their own security risk assessments for individual products. Medicines deemed to be at risk of counterfeiting may require overt security features over and above those set out in Recommendation 3, whereupon original manufacturers will apply these in meeting their duty to protect the public.

In summary, therefore, if an original manufacturer deems additional overt security features as necessary then these – supplementary to the 'minimal' measures – should be replaced by repackagers in line with Recommendation 2.

Implementing this measure largely negates the need for a centrally-managed 'at risk of counterfeiting list' of prescription medicines. It will also allow the original manufacturers to modify pack security measures in line with their own ongoing risk assessments.

Cost – accessibility and inclusiveness is a key priority

Cost should not, as far as possible,become a prohibitive factor in the implementation of minimum security measures for any manufacturer or other party in the business of packaging (or repackaging) and/or distributing medicines for Europe's patients. While the EAASM recommends the provision in law for the application of minimum security categorisation, solutions must be flexible, scaleable and accommodating to suit actors of all sizes and means, and in all Member States.

In this regard, the suggested measures of tamper-evident packaging with unique 2D data matrices provides basic, affordable yet effective security for patients and healthcare systems.

Initial, ballpark estimates provided to the EAASM by globally-established pharmaceutical manufacturers are as follows (Nb these estimated costs are based on the immediate risk assessment and could be phased):

For a typical medium-sized pharmaceutical company with an approximate annual turnover of €2.3bn, the dual security measures are estimated to cost between €23m–€34m, which could be spread over 60 months. Many pharmaceutical companies already spend far in excess of this amount to ensure their medicine packs are protected by several security technologies, including overt and covert features.

Under the EAASM's proposals, a legal requirement for the dual security measures (2D barcode and tamper-evident packaging) would negate the need for more expensive and exclusive solutions; although they would remain an option for interested companies.

Actors unable for any reason to develop the dual security measures in-house should procure them instead from a variety of existing independent technology providers.

The EAASM believes that such measures could protect Europe's patients, healthcare systems and pharmaceutical manufacturers effectively from the health dangers, significant risks and inequities of medicine counterfeiting activities. The simple, cost-effective dual technology solution is also a means to tackle the issue without undue delay.

4. Recommendation: The EAASM strongly advocates the introduction and provision in law of 'continuing accountability' along the medicines supply line. That is, every actor to package or repackage a medicine for European patients should hold full liability for the authenticity of that pack and the entirety of its contents at the time of release to another actor.

Rationale: In the absence of a ban on medicines repackaging in Europe, and without costly 'gold-plated' track and trace systems, it is imperative that all actors opening and repackaging medicines anywhere in the supply chain takes full responsibility in the eyes of the law for the authenticity of that pack during the entire period of their 'ownership', before releasing it to another actor having (re)applied all due equivalent security technologies. The pharmacist, or final dispenser, should act as the 'goalkeeper' for the patient.

In this way, counterfeit – or suspected falsified – medicines will be identified at the very earliest opportunity, with each actor in the supply chain taking full responsibility for 'handing on' a safe, original and authentic pharmaceutical product.

Without 'continued accountability', the chances of counterfeit, fake or other non-genuine medicines and medicine packs reaching patients increases. It also becomes more difficult to identify vulnerabilities and weak spots in distribution.

5. Recommendation: The EAASM believes that Europe's patients should be enabled to recognise medicines that have been repackaged. Patients should also be empowered with the right to choose an original pack over a repackaged medicine.

Rationale: Patients should not be expected (or given any responsibility) to identify potential counterfeit, fake or other non-genuine products supplied inadvertently through the regulated supply chain. However, the provision of a label (or similar), where appropriate, revealing to the end user that the medicine box has been repackaged – and therefore may contain information and possibly also contents different from that produced by the original manufacturer – is an added step in improving patient safety.

A warning label might convey the following information and guidance:

- ★ this medicine has been repackaged since leaving the original manufacturer
- ★ the pharmacist or other *authorised* dispenser can validate its authenticity and safety
- ★ if in doubt, please request an original medicine pack and inform the national medicines regulatory authority

If a patient is unhappy about taking a prescription medicine that has been repackaged, they should be able to reject the pack in favour of an original product.

> *"It is imperative that all actors opening and repackaging medicines anywhere in the supply chain take full responsibility in the eyes of the law for the authenticity of that pack during the entire period of their 'ownership'"*

6. Recommendation: The EAASM supports the establishment of an Active Pharmaceutical Ingredient (API) Guarantee, as proposed in the European Pharmaceutical Package.

Rationale: Patient safety is further protected by measures that ensure the originality and safety of APIs supplied for medicines; this includes producer assessment and investigation, where appropriate.

> *"Patient safety is further protected by measures that ensure the originality and safety of APIs supplied for medicines"*

The EAASM supports the proposals noted below that seek to ensure consistent high quality of all APIs, and in particular those manufactured outside the EU:

- ★ obligatory audit of API manufacturers
- ★ assurance that imported APIs have been manufactured to EU-level safety standards
- ★ obligatory enhanced inspections by Member States, in particular those countries where public health protection with respect to regulatory framework, control and supervision is not equivalent to the EU

7. Recommendation: The EAASM is keen that a set of interim measures is agreed and implemented as a matter of significant urgency, providing protection while the European Parliamentary process arrives at a final legislative solution to protect European patients through the European Pharmaceutical Package.

Rationale: The health and wellbeing of Europe's patients are already today at notable risk from dangerous counterfeit, fake, substandard and other non-genuine medicinal products entering the legitimate supply chain. The lack of universally applied security technologies also increases the likelihood that patients purchasing medicines online will receive a counterfeit product. Delay in action serves to increase this risk.

For the expedient protection of patients in Europe, the EAASM hopes that the basic infrastructure providing for 'minimum security categorisation' and 'equivalence' can be agreed in comitology.

If no action is taken until European Parliament has concluded all deliberations and implemented a new legislative package that is definitive for the foreseeable future, the danger to patients from counterfeit medicines will have intensified markedly if current trends continue as expected.

In Summary

The EAASM believes that European patients should hold a right protected by law to access safe medicines. They should be able to do this safe in the knowledge that the legal system provides effective protection against the risks and dangers of counterfeit and substandard medicines entering the regulated supply chain through European trade. These Recommendations to policy-makers support the achievement of that vital goal for patient safety.

Protecting patient safety: Stakeholder points of view

Many of us have already been – are today, or could be tomorrow – patients requiring prescription medicines to attain and maintain good health. We must rely on the secure provision of safe, effective healthcare products via regulated supply lines to achieve this. Therefore each of us, as citizens in Europe, shares a common goal in seeking this universal assurance and safety guarantee.

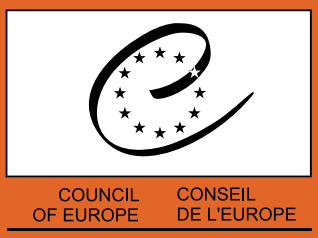
The EAASM, as a leading independent voice on the issue of counterfeit medicines and patient safety in Europe, presents in this report its recommendations for stronger, more sensitive legislation to protect patients' rights to access safe medicines.

While independent from the EAASM, united in this cause are other stakeholders whose submitted contributions are presented on pages 16-22. These include opinions on several different anti-counterfeit stances and technology solutions, some in trials and others already operational.

We could not reasonably include the views of all who seek a safer environment for Europe's patients, but we aim to reflect a range of opinion supplementary to, yet independent from, the EAASM's formal recommendations.

Council of Europe draft Convention on counterfeit medical products

In order to protect Europe's patients, the Council of Europe (CoE) is preparing a draft Convention on the counterfeiting of medical products and similar crimes involving threats to public health. We have outlined here not only the key aims of the Convention, but have also explained the context and process behind its development.



Main features of the draft Convention

The focus of the draft Convention is the threat to public health posed by counterfeit medical products and medical products which are manufactured or distributed without proper authorisation and/or in breach of safety standards.

Hence, the issue of intellectual property rights (IPR) is not dealt with in the Convention, which shall be applied without prejudice to the possible criminal prosecution of infringements of such rights.

The draft Convention obliges States Parties to criminalise the following **intentional** acts:

- ★ the manufacture of counterfeits
- ★ the falsification of documents accompanying medical products
- ★ the supply of, offer to supply, or trafficking of counterfeit medical products
- ★ the advertising and promotion of counterfeit medical products
- ★ the unauthorised manufacture or supply of medical products
- ★ the placing on the market of medical devices that are not in compliance with conformity requirements

The draft Convention also provides for a framework for international cooperation, measures for coordination at national level, preventative measures and protection of victims and witnesses. Additionally, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Party.

As is the case for several other CoE Conventions, and considering the global dimension of pharmaceutical crime, this Convention could be open for participation by non-Member States other than the Observers, giving the Convention a potentially universal vocation.

Convention formation process

Preparation of the CoE draft Convention followed the events and discussions listed below:

- ★ the Parliamentary Assembly Recommendations 1673 (2004) on *'Counterfeiting: problems and solutions' and 1794 (2007) on 'The quality of medicines in Europe'*
- ★ the declaration of the G8 Summit in St Petersburg, entitled *'Combating IPR piracy and counterfeiting'* (16 July 2006)
- ★ the declaration of the International Conference, *'Europe against counterfeit medicines'* held in Moscow (23–24 October 2006)
- ★ the conclusions of the High-level Conference of the Ministries of Justice and the Interior on *'Improving European Cooperation in the Criminal Justice Field'* in Moscow (9–10 November 2006).

The Committee of Ministers took the decision to establish a Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP), comprising 11 specialists with additional participation from the CoE Parliamentary Assembly – plus several Member States' delegations as Observers.

On 23 April, 2008, the PC-S-CP produced a report on the feasibility of an international legal instrument in the field of counterfeiting of medical products and similar crimes. It held a series of six meetings in Strasbourg to prepare the draft Convention. The last meeting took place on 2–4 February, 2009, when a draft text of the Convention was adopted.

The draft was then submitted for negotiation in a plenary ad hoc committee (PC-ISP) with the participation of all CoE Member States and Observers. At its most recent session (October 12-16, 2009), the European Committee on Crime Problems (CDPC) steering committee adopted the text of the Convention.

The Committee of Ministers (the CoE's deciding body) has been asked formally to adopt it, and it is foreseen that the new Convention will be offered to Member States for signature in 2010.

Details may be viewed on the CDPC Pharmaceutical Crime website, accessed via www.coe.int.

During research for the EAASM's *Counterfeiting Superhighway* report, prescription medicines were purchased online (without a prescription). Subsequent expert visual and chemical analysis revealed that 62% were counterfeit products (ie illegal and potentially dangerous and clinically substandard).

IAPO: key ideas for better protection against the risks of counterfeit medicines

Following the release of the EC's document outlining key ideas for better protection of patients in Europe against the risks of counterfeit medicines, and further to the Council of Europe's Convention on Counterfeit Medical Products (see pp 16-17), the International Alliance of Patients' Organizations (IAPO) presents its response and outlines priorities, as the only global alliance representing patients of all nationalities across all disease areas:

1. **Patient-centred healthcare** – All strategies developed to combat counterfeit medicines should align with the principles of patient-centred healthcare, considering their impact on the patient in terms of access to safe, good quality and appropriate treatments and information. Only through the involvement of patients and their representative organisations can these strategies be truly patient-centred.

2. **Regulatory framework** – IAPO strongly supports the development of appropriate regulations and effective enforcement regarding medicines manufacture and the medicines supply chain with appropriate consideration of their impact, especially on access to quality and safe medicines.

3. **Broader anti-counterfeiting strategies** – In addition to new legal measures that prevent counterfeit medicines reaching patients, a responsible communications strategy should inform patients and the public of the risks, facilitating vigilance. Patients and their representative organisations should be involved in global, European and national initiatives.

4. **Medicine counterfeiting is a global issue, demanding the attention of all countries** – Medicine counterfeiting is a cross-border problem, and while the EU is increasingly vulnerable it is also a significant problem in regions such as Africa. Not only can we not be complacent, but we have a duty to support these other regions.

Conclusions

Counterfeit medicines have become an increasing threat to public health over the past few years and it is therefore vital that strategies to combat their proliferation are given appropriate attention, political commitment and resources to ensure effective development and implementation at the earliest opportunity. Unless we act now, the reach and severity of the problem will only worsen.

A European, patient-centred approach should aim to ensure a strong regulatory environment that is well enforced, with each decision judged against its likely impact on patients' timely access to safe, good-quality treatments. A responsible 'risk and vigilance' communications strategy is an essential complementary measure.

About IAPO: Spanning more than 40 countries and 50 disease areas, IAPO's 200-strong membership represents an estimated 365m patients worldwide.

* The EAASM advocates the implementation of new measures, including anti-counterfeit technology solutions, that ehance patient protection against exposure to fake medicines. A variety of such technologies are already in European operation or trials, however the EAASM does not necessarily or actively endorse any specific anti-counterfeit technology or solution provider.

EFPIA Pilot Coding Project*

The logic of the European Commission's (EC) proposal is indisputable. Europe's citizens must be protected from the infiltration of counterfeit medicines, for their own safety and to maintain confidence in the traditional supply chain.

Introduction

In September 2009, EFPIA launched its Pilot Coding Project to test a pharmacy-based verification system, using a small data matrix on each medicine pack dispensed. The project uses a 2-dimensional barcode, similar to those now found on airline boarding passes. This contains a unique product identifier, allowing pharmacists to verify the status of every pack in the pilot at the time of dispensing.

This will increase confidence that a product being dispensed is safe and authentic. A simple barcode reader will also allow pharmacists to automatically detect the expiry date of any product and – in the case of a recall – the batch number.

Background to the EFPIA Pilot

The project is a direct response to the Commission's Draft Directive on counterfeiting, and will run for approximately 3 months in more than 30 pharmacies in the greater Stockholm area, assessing more than 100,000 packs. It encompasses both wholesaler and retail pharmacies.

The EC's proposals set out a legal basis for ensuring that safety features are obligatory on medicine packs, permitting tracing and authentication. Improved identification of packs entering pharmacies and being dispensed to patients will make a valuable contribution to tackling the threat from counterfeit medicines.

However, it cannot wholly eradicate the problem; a comprehensive series of measures is required to protect public health effectively, including harmonised product serialisation and the universal use of safety features.

Ensuring product integrity

The use of safety features to ensure packs have not been opened or tampered with, along with verification at the point of dispensing, will help to ensure pack integrity. Where existing safety features have been removed, it becomes easier for counterfeits to enter the supply chain undetected.

The simplest method of avoiding this is a ban on repackaging. This would guarantee to preserve the integrity of the original packaging throughout the entire distribution chain, thereby preventing the medicinal contents from being tampered with. However, to date the Commission does not wish to see such measures. EFPIA strongly believes, therefore, that should repackaging be allowed to continue then robust controls are required to ensure astute regulation and scrutiny of the practice.

An optimum approach to product verification

Of the Commission's proposals, point of dispensing verification offers clear scope for improving both supply chain security and patient safety. The Commission has not yet set out how it envisages traceability working, but there are clear criteria for success.

Paramount is that systems are harmonised across Europe, requiring national coding systems to be interoperable and based on common standards. If the safe and free movement of medicines across borders is to become a reality, such a co-ordinated approach to identification and verification is vital.

This way, any pharmacist in any country can verify whether the pack has been dispensed before, independent of its country of origin. Without this standardisation and interoperability, there is a risk that national identification and verification systems will be fragmented, limiting their ability to verify a product's provenance to only national product codes – presenting the problem of identifying counterfeits crossing borders.

With parallel trade accounting for around 10% of all pharmaceutical sales in Europe, the ability to verify products that have moved cross border is essential.

To ensure its success, the solution must gain support from all stakeholders to address their needs effectively. Imposing high-end or expensive solutions throughout the supply chain is likely to generate resistance. EFPIA's proposed solution is realistic, proportionate and cost-effective, and will need minimal investment.

Finally, the solution should be timely. The Commission's proposals mean that Europe's Member States will have to embrace mass serialisation, but with no set timelines or guidelines on the appropriate technology.

EFPIA's project will provide proof of concept; a system using proven technology that can be deployed rapidly, while addressing the key requirements of interoperability and standardisation in a proportionate and affordable manner. This represents a practical solution to the challenge of implementing unique pack identification that all actors can embrace.

It cannot provide the total protection of a ban on repackaging, but provides a practical, pragmatic and achievable approach that improves protection for Europe's citizens.

Colin Mackay, Director, Communications and Partnerships, EFPIA

Security solutions – additional positions

EAASM members, supporters and funders advocate the application of a minimum categorisation of traceable and tamper-proof anti-counterfeit measures, and are keen to engage in debates over appropriate solutions. However the EAASM retains an independent and unbiased perspective on the relative *pros* and *cons* of systems already in use or testing.

Views and comments on this page outline those from a range of stakeholders as expressed in a meeting (September 2009) at European Parliament, hosted by MEP Jorgo Chatzimarkakis. Organisers Aegate brought together representatives from the research and generics industries, GIRP, pharmacy associations and the Rapporteur, Marisa Matius, to discuss workable approaches to the EC's proposed anti-counterfeiting directive.

- Dr Domenico Di Giorgio of the **Italian Medicines Agency** supported the 'unofficial' World Health Organization estimate that less than 1% of medicines in keenly regulated markets are counterfeit.
- John Chave, Secretary General of the **Pharmaceutical Group of the European Union**, urged action on the basis of precaution, noting that even 1% represents a sizeable volume of potentially lethal substances. He also warned against a risk classification system for a medicine's vulnerability to counterfeiting. "There's a danger that if you single out certain medicines as risky, you merely push the counterfeiters to other medicines. A risk-based system may also confuse patients. Do we create an implied guarantee that medicines without safety features are thereby safe and free from counterfeiting?"
- Hugo Carradinha, of the **European Generic Medicines Association**, saw the 1% estimate as reason not to "kill a mouse with a tank", noting that counterfeiters are attracted chiefly to high-profile, high-priced brands at present.
- Dirk Broeckx, Secretary General of the Belgian pharmacists association, **APB**, discussed its drug authentication service initiated in 2006, which he said could be used to "convey pharmacovigilance data or expiry warnings rapidly".
- Monika Derecque-Pois, Director General of the **European Association of Pharmaceutical Full-line Wholesalers**, said 2D barcodes "are the only way forward", although radio frequency identification may also become useful. She called for all actors in the medicines supply chain to be fully licensed, for greater transparency in the licensing system.
- German pharma group **Ursapharm** noted the high costs for smaller producers of adding traceability features, potentially necessitating expenditure on cameras and scanners for production lines plus specialist software. Claudia Glasgow highlighted technical challenges in adding barcodes to small medicine boxes (eg eye drops) while complying with labelling guidelines.
- Simon Simoens, of the **Katholieka Universiteit Leuven**, said that identifying substandard drugs helped to avoid litigation cases against pharmacists, as well as labelling errors. He noted that cost-effectiveness for any particular system depends on a market's volume of counterfeit medicines.

What happens next?

This report, *Packaging Patient Protection* published in 2009 by the EAASM, is an urgent call to action.

The evidence that medicine counterfeiting is on the rise, that it endangers the lives of Europe's patients and that already today it is perforating regulated supply lines by breaching existing security measures is incontrovertible.

Only with new legal provision and enhanced regulatory governance can patient safety be restored and protected effectively.

The EAASM believes that a patient's right to access safe, effective medicines should be provided for, and protected in law. The recommendations in this report support the achievement of that vital goal.

References

1. Europa Press Releases. Customs: Millions of illegal medicines stopped by "MEDI-FAKE" action. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1980&format=HTML&aged=0&language=EN&guiLanguage=en. Date accessed: September 2009. **2.** Counterfeit Medicines: the pills that kill (www.telegraph.co.uk), 2008. Available at: http://www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-that-kill.html. Date accessed: September 2009. **3.** World Health Organization. Fact sheet No 275. Counterfeit Medicines. Revised 14 November 2006. Available at: www.who.int/medicines/services/counterfeit/CfeitsFactSheetJuly09.pdf. Date accessed: September 2009. **4.** European Alliance for Access to Safe Medicines (2008). The Counterfeiting Superhighway. Available at: www.eaasm.eu/Media_centre/EAASM_reports. Date accessed: September 2009. **5.** Medicines and Healthcare products Regulatory Agency. Personal communication: 14 September 2009. **6.** Europa Press Releases. Protecting the legal supply chain against counterfeited medicines. Available at: http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/781&format=HTML&aged=0&language=EN&guiLanguage=en. Date accessed: September 2009.

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"Everything we are suggesting today builds on the needs and interests of patients. European citizens should benefit from safe, innovative and accessible medicines" Günter Verheugen, EC

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