



European Federation of Pharmaceutical
Industries and Associations

WHITE PAPER

ON

THE ANTI-COUNTERFEITING OF MEDICINES

EFPIA Anti-Counterfeiting Group

Updated 2 November 2010

A. Introduction

This updated EFPIA White Paper is intended to express the views of the European-based innovative pharmaceutical industry associated within the EFPIA to combat counterfeiting effectively in order to

- address the need to further develop the European legislation, in particular the draft Falsified Medicines Directive
- focus on key European stakeholders and promote international collaboration and political will to reduce the amount of counterfeit medicines reaching patients
- define the role of suppliers, drug manufacturers, wholesalers, distributors, pharmacies and repackagers in the combat against counterfeit medicines
- focus on effective and affordable solutions of supply chain control to achieve transparency
- recommend rules and messages for communication to the various stakeholders
- address the need to reduce the distribution of counterfeits via the internet.

B. Background to the 2010 White Paper

EFPIA issued its first White Paper on “The Anti-Counterfeiting of Medicines” in November 2005. That paper focussed on the need to further develop European legislation against counterfeit medicines as well as focussing on effective and affordable solutions for transparent supply chain control. Since the publication of the 2005 White Paper considerable progress has been made in these, and other, areas:

- The Commission has published its legislative proposal for preventing the entry of falsified medicinal products in relation to their identity, history or source into the legal supply chain.
- EFPIA has successfully piloted its product verification system in Sweden. The pilot demonstrated how a cost-effective serialization and coding system can prevent counterfeit medicines from reaching patients.
- The World Health Organisation (WHO) created IMPACT (International Medical Products Anti-Counterfeiting Taskforce) in 2006. The taskforce has been active in forging international collaboration that (1) seeks global solutions to this worldwide challenge and that (2) raises awareness of the dangers of counterfeit medical products. In particular, WHO IMPACT has delivered¹:
 - Draft principles and elements for national legislation against counterfeit medical products;
 - Significant anti-counterfeiting operational training programmes in partnership with Interpol, customs and other stakeholders. Key

¹ The WHO IMPACT programme added a lot of value to the fight against medicinal product counterfeiting. However, it is currently being examined by a multi-stakeholder working group to redefine its principles and key priorities. The working group is scheduled to report its conclusions at the WHA assembly in 2011.

examples here include Operation Mamba in East Africa and Operation Storm in South East Asia;

- A guide setting out processes and techniques for countries developing an investigative capacity to combat pharmaceutical crime, in particular, identifying, investigating and prosecuting individuals and companies that import, manufacture, supply and export counterfeit medical products;
 - Revised WHO guidelines on good distribution practices (GDP) that include measures to prevent counterfeit medicines; and
 - Guidelines for a rapid response plan for national drug regulatory authorities to deal with suspected counterfeit medical products.
- In April 2010, the Council of Europe adopted a Convention on counterfeiting of medical products and similar crimes involving threats to public health ("Medicrime" Convention).

While good progress has been made, there is still much to be done. Key next steps include significantly reducing the amount of counterfeit medicines sold over the Internet, the promotion of European and global harmonisation of product verification systems, and unblocking the politically driven debate around definition of counterfeited drugs at WHA.

C. Executive Summary

1. European Legislation

In October 2008, the European Commission published its proposal for a Directive amending Directive 2001/83 as regarding the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source. Proposed actions include:

1. Strengthening product protection measures
 - The proposal provides a legal basis for the Commission to render obligatory specific safety features (such as a serialisation number) on the packaging of prescription medicines based on the risk of the product being counterfeited.
2. Ensuring reliability in the wholesale distribution of pharmaceuticals
 - Restrictions on manipulating, removing, tampering with, or over-labelling of safety features on the packaging
 - Obligatory audits of supplying wholesale distributors
3. Defining clear obligations for starting materials
 - Strengthened requirements for imports of active pharmaceutical ingredients (API) from third countries

EFPIA has welcomed the legal proposal as an important starting point for measures to tackle the problem of counterfeit medicines in the legitimate supply chain.

Clearly, the basic principle to effectively prevent the infiltration of counterfeit medicines into the legitimate supply chain is to guarantee the integrity of the original

package throughout the distribution chain from the time it leaves the original manufacturers' hands until it reaches the patient.

EFPIA supports the principle of applying safety features on the outer packaging and considers that all prescription medicines must be subject to the same level of security. The introduction of safety features on only some prescription medicines will move the threat to those not protected and weaken efforts to eliminate the problem of counterfeits. In principle, the same is valid in analogy for any pharmaceutical drug.

To protect patients from counterfeits, the basic level of security on all prescription only medicines should be a combination of tamper-evident packaging and a unique code for each medicine pack, based on one harmonised coding solution across Europe. A unique serial number would enable pharmacists to verify each pack at the point of dispensing thus making a significant contribution to greater product security and patient safety.

2. International collaboration

EFPIA will continue to be the focal point at the European level for engagement of key stakeholders at the national level. The four main categories of stakeholders are government, industry, users and payers. Industry recommends a number of preventative measures as essential to an anti-counterfeiting programme: adaptation of structures, cooperation, awareness and political will. As counterfeiting is a problem affecting international supply chains, a strong collaboration with other pharmaceutical industries' associations is needed. The leading role here is with the IFPMA in Geneva.

3. Role of the health agencies, manufacturers, repackagers, wholesalers, distributors and pharmacies

As the originator of the product, the manufacturer has an obvious role to play in product authentication and supply chain control efforts (new technologies, procedures for counterfeit prevention). Repackagers must also contribute actively to the safety of the supply chain, and so must wholesalers and distributors, through auditing and alert systems. Pharmacies must be a part of the scheme to protect customer health and safety. The role of the health agencies must be clear in how to organize the regulatory oversight to all measures for securing the supply chain taken according to the European legislation. This role should consider the penetration of counterfeited drugs into the legitimate supply chain as well as any other uncontrolled penetration.

4. Supply chain control

All stakeholders in the supply chain should participate in a product verification system in order to ensure that patients receive only genuine pharmaceutical products. Regulatory tasks should include auditing of the supply chain, a licence system for the sale of medicines over the Internet, a certificate system for wholesalers, and safeguards for the supply of packaging material. Supply chain controls should ideally be harmonised between countries to minimise complexity and cost for all pharmaceutical manufacturers. In addition, this will allow for much easier verification of legitimate or counterfeit medicines that are shipped across borders.

5. Communication

All stakeholders are invited to raise public awareness of the dangers of counterfeit medicines, in particular the dangers to patients associated with purchasing medicines over the Internet. Balanced reporting will include communication to the specialised media and healthcare professionals. Industry may organise alliances and partnerships with healthcare associations / experts as well as with patient organisations. The importance of purchasing medicines through certified distribution channels is already a key message. Member States should be encouraged to adopt stronger criminal measures to combat counterfeiting, which threatens public health and safety.

Product specific communications should only be undertaken by the public authorities working with the relevant manufacturer.

1. European legislation

1.1. Legal System

As a general principle, the legal system must facilitate close cooperation both nationally and trans-nationally between the different authorities dealing with anti-counterfeiting. One important example is to ensure the obligatory exchange of information between, customs, public health authorities, police and right holders. Legislation must be reviewed and amended to accommodate and facilitate this type cooperation.

EFPIA welcomes the European Commission proposal on falsified medicinal products as an important starting point for measures to tackle the problem of counterfeit medicines in the legitimate supply chain. EFPIA is also encouraged by the commitment shown by the European Parliament and the Council to legislate rapidly on this important matter.

Effective legislation to tackle the threat of counterfeit medicines entering the legitimate supply chain should include a number of elements:

- Infiltration of counterfeit medicines into the supply chain is best addressed if the integrity of the original package is maintained throughout the entire supply chain, from the time it leaves the original manufacturers' hands until it reaches the patient. If products are repackaged the effectiveness of any anti-counterfeit features incorporated into the original packaging is seriously compromised. EFPIA urges that repackaging be prohibited in principle as a key step in preventing counterfeits entering the supply chain. If repackaging is to be allowed to continue, there must be clear rules on what would constitute "equivalent" safety features and clear provisions on liability.
- EFPIA supports the principle of applying safety features on the outer packaging and considers that all prescription medicines must be subject to the same level of security. The introduction of safety features on only some prescription medicines, will move the threat to those not protected and weaken efforts to eliminate the problem of counterfeits.
- The core elements for an efficient technological anti-counterfeiting strategy based on the integrity of the pack include:
 - Tamper-evident packaging or tamper-resistant closures for all medicines
 - Strengthening product identification at individual pack level through a harmonised coding standard
 - Use of overt, covert and forensic authentication features
- The basic level of security on all prescription only medicines should be a combination of tamper-evident packaging and a unique serial number for each medicine pack. A unique serial number would enable pharmacists to verify each pack at the point of dispensing thus making a significant contribution to greater product security and patient safety. With regards to the fact that medicines in Europe move across borders, any serialization system should be harmonized across Europe and based on a 2D data matrix code, called 'data matrix ECC 200'.

Legislation should work to ensure a clear understanding of the roles and responsibilities of all the authorities dealing with anti-counterfeiting both nationally and at a European level. The legislation dealing with counterfeiting must be enforced consistently. This will also require the backing of national governments and the European Parliament to ensure sufficient resources are available to do so.

The original Marketing Authorisation Holder (MAH) will continue to act responsibly in contributing to the fight against counterfeit medicines.

In particular the EFPIA supports the following:

- A clear definition of “counterfeit medicine”, “substandard medicine” and “pharmaceutical crime”, to understand the true extent of the problem at global level and align the information exchange between different countries and authorities.
- With regards to the definition of counterfeit medicines and in the light of the recent discussions at WHA assembly 2010, EFPIA considers the WHO definition of counterfeit medicines from 1995 as still adequate, as it focuses exclusively on public safety.
- strengthening and harmonising the criminal law dealing with counterfeiting, in particular harmonised sanctions commensurate with the level of the crime, currently not yet available but essentially needed in order to avoid that criminals escape from one country to the next country. Furthermore the obligation to report suspicious cases to the national health agencies within a few working days should be harmonized
- complete codification of existing Member State legislation which has been recommended by the Council of Europe
- Signing and ratification of the convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health. (Medicrime Convention)

1.3. Medical Authorities

Pharmaceutical counterfeits represent a major risk to patients' safety and health. For this reason, the Medical Authorities, who are entrusted by governments with the task of monitoring and securing the safety of pharmaceutical preparations have a major role to play in the joint efforts to combat pharmaceutical counterfeits.

At the moment, the role of the medical authorities, as defined by national and Community legislation, is on the whole too narrowly defined. Currently, it is focussed on approval of new drugs as well as on GMP inspections at manufacturers but does not include responsibility for public health and safety in relation to counterfeits and supply chain channels. Their responsibility also varies between Member States and often does not allow them to actively and effectively take action against these illegal activities that represent a major threat to patients' safety and public health. To change this situation three priorities have to be tackled:

- A more collaborative role of the medical authorities with traditional law enforcement or to increase their investigative and prosecutor capacity to stop counterfeits from reaching patients
- Amend the current laws to allow regulatory authorities to hold counterfeiters criminally accountable for damaging or threatening public health.
- Include reporting of counterfeits in the existing voluntary alert systems to the national authorities.

1.4. Customs

The EFPIA needs to further develop its cooperation with customs authorities to combat the international threat to public health and safety coming from counterfeit medicines. In order to facilitate speedy action by customs officials it would help to remove the current obstacles preventing the transfer of information between customs and the rights holders. This would enable a faster response from the rights holder which would in turn permit customs officials to act quickly. We need to encourage the industry to make use of the EU Customs Watch notices to halt suspicious shipments and to inform right holders about potential infringements. In particular, we would suggest that

- Each company files Applications for Action with EU Customs for key IP rights (e.g., corporate trade mark and high risk product trade marks)
- Each company provides EU Customs with appropriate risk analysis information (e.g., information about authorised exporters and importers; normal routes of supply; known counterfeiters and routes used by counterfeiters)
- Each company uses EU Customs Red and Yellow Alert notifications in relation to specific shipments or new trends
- "Sector-specific training" is provided to Customs (e.g., Offered by PSI)

1.5. Police

Local, regional, and national police forces are integral in the investigation and collection of evidence to identify and prosecute counterfeiters. A harmonised set of rules must be established for the police to operate efficiently at a consistent level across Europe and internationally. This should include:

- Further collaboration with Europol to provide it with further industry knowledge useful in investigating and prosecuting counterfeiters
- Clarifying responsibility for investigations and giving the police the appropriate authority.
- Increased availability of seizure orders and prosecution.
- Improved trans-national cooperation between forces
- Systematic cooperation between the police and other authorities, in particular the Medical Authorities, and private intellectual property right owners.

2. International collaboration

2.1. Key Stakeholders

There are many key stakeholders at local, national and international level that are essential to effective international collaboration. EFPIA is positioned as a focal point at the European level and is able to act as the central body coordinating members' actions at the national level.

There are five main categories of key stakeholders, which are Government, Industry, Right Holders, Users & Payers. A variety of stakeholders exist within each category, too many to list in this paper. The main ones are listed for information in Attachment 1

2.2. Effective Anti-Counterfeiting Programmes

The EFPIA acknowledges the work carried out by the Council of Europe Committee of Experts on pharmaceutical questions and its multisectoral Ad Hoc Committee on counterfeit medicines. The same applies to the very comprehensive work produced by Dr Jonathan Harper. We agree with all of the recommendations & binding instruments in the Harper Report.

EFPIA has recommended the following preventative elements as essential to an anti-counterfeiting programme:

- Adaptation of structures and systems to detect counterfeits at international and multisector level e.g. rapid reporting systems and due dates for the reporting of suspicious cases at least on a national level
- Identification of liaisons for an information network, e.g. single points of contacts identified on a national level
- Raise awareness of all stakeholders, e.g. by creating internet pages on anticounterfeiting by each stakeholder, mainly manufacturers, distributors and agencies
- Create and maintain political will to support concerned agencies and centres, a task for the governments on national level
- Encourage national, regional and international cooperation, a task for associations on a stakeholder level
- Enable forensic analytical testing, a task for the industry and for control laboratories on a national or regional level as they have the technological know how e.g. supply test methods, provide analytical techniques, provide test samples, provide reference materials, Information on usefulness of analytical techniques, Information on impurity profiles

2.3. The EFPIA Coding Pilot Project

The pharmaceutical supply chain in Europe has become increasingly complex over the past few years with an increase in the number of wholesaler intermediaries and traders involved in the flow of medicines to their final destination. This has resulted in decreased transparency and increased risk of counterfeits entering the system. Some national governments are starting to mandate the identification and traceability of medicines in individual countries. The measures to individually identify

each product means that mass serialization of medicines will become a reality in Europe over the next 4-5 years. However, there is currently no industry or stakeholder recognized standard. The result of a nation-by-nation approach would mean less security of supply as manufacturers and other stakeholders may need to comply with a number of different coding solutions across Europe. As a result, it is essential that the system is harmonized and interoperable at EU level. This way, a pharmacist in any country can check whether the pack has been dispensed before, whatever its country of origin.

Between September 2009 and February 2010, EFPIA conducted a pilot in Sweden to demonstrate that it is possible to have a unique coding system across the EU. The goal of the pilot was to test a product verification system based on the use of a two-dimensional data matrix bar code on each package of medicine dispensed to patients. Overall, the pilot involved the dispensing of 110,000 packs across 180 dispensing points across Stockholm. The results of the pilot showed that the product verification system has been checked successfully. In addition, the results strongly indicate that the proposed EFPIA model is viable, proportionate, secure and cost-effective.



2D Data Matrix
ECC-200

Based on these positive results, EFPIA has recommended the implementation of such a standardized and unique coding solution for medicines at the European level and considers this to be the most effective and technologically sound system for the present time. However, the adoption of a '2D Data Matrix' system does not prevent the adoption of other technologies such as RFID (Radio Frequency Identification) at a later stage.

Using mass serialisation at pack level provides other benefits over and above improved counterfeiting prevention. Maximising these should help to encourage widespread use of identification systems and assist all stakeholders. The coding system enables the pharmacist to automatically read the batch number and expiry date, significantly reducing the risk of dispensing errors and improving product recall procedures. It can also facilitate reimbursement for pharmacists and national authorities alike. This offers major advantages in reducing fraud and increasing market transparency.

It has been suggested to print the serial number in a human readable form. As stated in the EFPIA Guideline (European Pack Coding Guidelines – February 2009), it could be beneficial, but this should not be mandatory, it should only be an option left to the discretion of the manufacturer.

3. Role of Manufacturers, Repackagers, Wholesalers, Distributors and Pharmacies

3.1. Manufacturers

As the originator of the product, the manufacturer is the logical starting point for product authentication and supply chain control efforts. Additionally, the manufacturer is already GMP certified, is regularly GMP audited and routinely performs incoming material control procedures.

Additionally, manufacturers are encouraged to:

- Conduct worldwide investigations within their area of competence and in liaison with the respective national police and customs authorities.
- Seek to protect the supply chain through careful analysis of new technologies and the scalable deployment of these technologies consistent with the known level of risk associated with not only the pharmaceutical product but also the geographic area.
- Address products or regions with the highest counterfeit risk first.
 - If considered at risk, individual packages should be marked with overt and covert technologies for authentication
 - A technology evolution plan should be developed in case the chosen technology is defeated.
 - Tamper evident features should also be included.
- Manufacturers should be prepared to play a role in determining the cost/benefit performance of anti-counterfeiting technology initiatives and to participate in officially sanctioned initiatives on new technological requirements.
- Manufacturers should have effective procedures in place that prevent counterfeiters from obtaining non-used material from trial batches and previously used machines and tools

3.2. Repackagers

Parallel trade is a legal practice in the European Union. However, repackaging practices can lead to serious weaknesses in the integrity of the supply chain when original safety features are removed. The use of safety features on the packaging help ensure that the pack has not been opened or tampered with, and along with verification at the point of dispensing, is critical to ensure integrity of the content of the pack. Removal of these features makes it easier for counterfeits to enter the supply chain undetected. Therefore the simplest method of avoiding this would have been a ban on repackaging.

However, to date the Commission does not wish to see such measures. EFPIA strongly believes that, should repackaging be allowed to continue, robust inspection and audits by regulatory authorities are required to ensure that this activity is strictly controlled and scrutinised.

It is also important to clarify obligations on the repackager to replace mandatory safety features. The strict obligations mentioned below should also entail a transfer of liability to the repackagers for all errors caused by repackaging.

- If the product is repackaged, the original pack serial number should be cancelled in the database by the repackager and a new number provided. The original and new numbers must be linked in the database to enable the product to be tracked in case of recalls or other safety issues.
- Other safety features, including mandatory tamper-evident packaging and any discretionary features included by the manufacturer, should be replaced with similar features guaranteeing an equivalent level of protection.²
- Destroying all original safety packaging that was removed from the original package to prevent counterfeiters from accessing it

² These should be defined on the basis of an approved list, categorising the features on the basis of criteria still to be determined.

3.3 Wholesalers and Distributors

Currently, a single medicine pack may pass through many hands both physically and through trading between the time that the originator places the product on the market in the first Member State and the time at which that product is dispensed to a patient in a subsequent Member State. This complexity, which results in the splitting up of batches multiple times and products from the same batch being shipped to several destinations, facilitates the introduction of falsified medicinal products into the supply chain.

All supply chain actors should take responsibility for ensuring the safe supply of genuine medicines. All trade partners including repackagers and relabellers should be strictly liable for all errors, in particular those that result in counterfeits entering the legal supply chain.

Traders and brokers (active in the supply chain beyond the original manufacturer/marketing authorization holder's group of companies and wholesalers) should be required to obtain a wholesale license.

3.4 Pharmacies

As the member of the supply chain closest to the patient, pharmacies are critical locations for product authentication and patient safety with regard to counterfeit medicines. Their role should include:

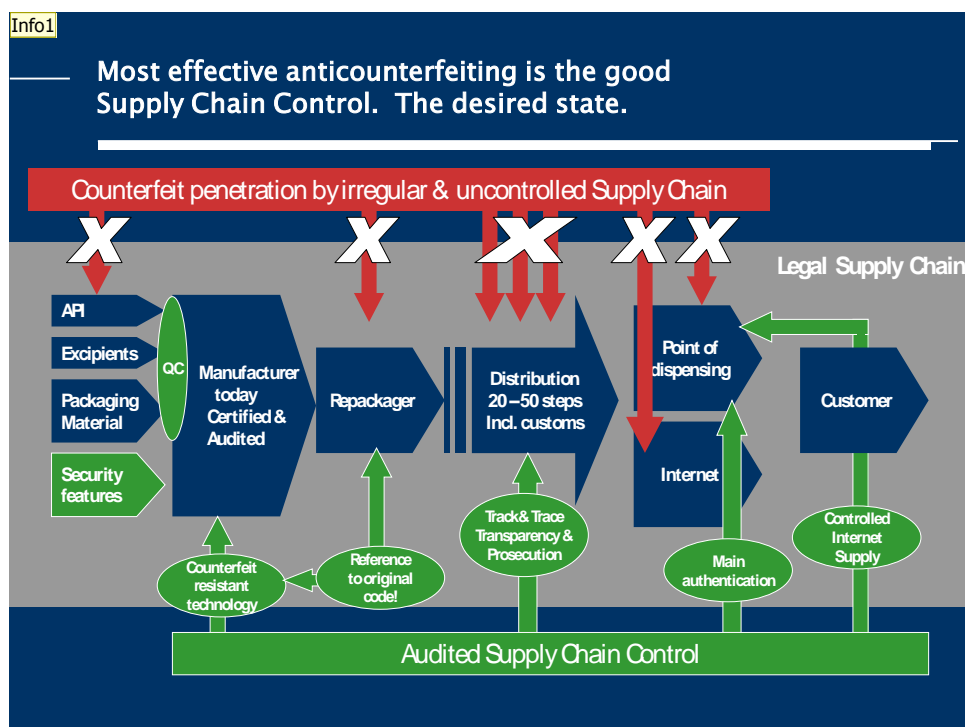
- Participation in a pan European point of dispense medicines verification system

4. Supply Chain Control

The suitable starting point of any supply chain control should be at the drug product manufacturer's level as there are GMP certificates available, quality systems in place, as well as established control of all incoming starting materials such as actives, excipients, packaging materials and security features.

The drug product manufacturer therefore will be a major partner in any system of supply chain control and authentication of drug products in the market.

The supply chain control is most effective if the system is at least designed supra-nationally. All stakeholders in the supply chain, drug manufacturers, wholesalers, distributors and pharmacies have to be legally obliged to participate in a supply control system.



Tab 1. The desired state of the legal supply chain: a “closed shop”

4.1. Regulatory tasks

4.1.1. Auditing

Any supply chain control has to be audited to ensure that the implemented measures are working in the desired way. Governments or authorities should be responsible to set the legal framework for extending the existing GMP auditing system by including auditing of the supply chain. The existing Good Manufacturing Practices (GMP) and the WHO amended Good Distribution Practices (GDP) 2010, could work as an adequate basis for this.

4.1.2 Internet

EFPIA shares the deep concern of many stakeholders related to the risks to patients from illegal online pharmacies and calls for an effective and tangible response to the sale of counterfeit goods over the internet.

EFPIA will initiate a dialogue with global Internet providers in order to generate a catalogue of requirements how to make Internet drug selling safer. This might include:

- Information campaigns by various stakeholders e.g. health agencies or industry to increase consumer awareness about the fact that counterfeiting is a real scourge that is growing via new distribution channels offered by the Internet.
- Certification logos for internet pharmacies to assist patients in verifying the licensing status of online pharmacies.
- Tackling illegal pharmacies through their suppliers such as such as domain name registrars (E.g. ICANN) and search engines (E.g. Google).
- On-going work with European and international organisations to pool expertise among all stakeholders and to examine the myriad of problems associated with unlicensed Internet pharmacies.

4.1.3. Wholesalers

A license or certificate system for wholesalers can also contribute to raise the hurdle for counterfeiters. If pedigrees are required, it should be considered that paper based pedigrees can be penetrated by counterfeiters, therefore electronic systems are preferable.

4.1.4 Suppliers

Suppliers can also contribute to raise the hurdle for counterfeiters. They should be fully integrated into the existing Quality Assurance system, e.g. GXP auditing and ISO certification. Suppliers of packaging material should ensure the identity and credibility of their customers. The access to printed packaging material and to security features shall be controlled by suitable measures e.g. documentation of customers or the check of the credibility of the customers.

4.2. Industries' tasks

Verification Systems - All stakeholders in the supply chain shall consider establishing a product identification system in order to ensure the transparency of the supply chain enabling the identification of the origin of a pharmaceutical production. Hereby it is important that the EU introduces clear standards for a coding solution that ensures harmonisation and interoperability across the EU, to support regulatory and law enforcement activities. EFPIA encourages the European Commission to review the ongoing work by the pharmaceutical industry in identifying a cost effective and inclusive system that consciously reflects the needs and requirements of the end customer. The solution proposed by EFPIA is proportionate and cost effective for all stakeholders. It is important that any solution is seen as inclusive for all stakeholders in order to effectively meet their needs and secure their support.

4.2.2 Technology and Process

The verification system shall be based on a pan European Barcode standard. This standard should be able to work on the basis of the EPC (Electronic Product Code). The EPC is the only available global product standard description, which is also compatible with different bar coding standards and with RFID (Radio Frequency

Identification). Due to its current development status, the introduction of RFID-tags across the supply chain is highly expensive and not necessary for the present purpose.

The content of the barcode information shall comprise at least manufacturers name, product name, batch number and expiry date. The bar code number shall be randomized in order to make copying of sequential numbers for counterfeiters impossible.

5. Communication

Industry supports initiatives to provide patients with information about counterfeit medicines. While all stakeholders should be encouraged to raise public awareness about the dangers of counterfeit medicines, product specific communications should only be undertaken by the appropriate public authorities working in conjunction with the relevant manufacturer.

Industry recommends communication on counterfeit medicines be targeted mainly vis-à-vis specialised media and healthcare experts in order to contribute towards balanced reporting. Existing industry activities concerning political involvement and development of technical solutions should be communicated proactively.

5.1. Alliances and Partnerships

Industry can organize alliances and partnerships with healthcare associations / experts as well as patient organizations. Common approaches have to be identified with the various key stakeholders. Messages to be communicated will depend on the respective alliance, while emphasising the importance of public health and safety.

What seems to be useful is the development of guidelines in the form of templates or tool kits which develop awareness, increased vigilance and as a consequence can set up a reporting system on suspected counterfeit medicines.

On their websites, patient organizations can alert consumers to counterfeit drugs.

The main message will be to stress the importance of purchasing medicines through certified distribution channels. Due to practical reasons, authentication of products should be done by wholesalers and pharmacies. Patients and consumers can only play a limited role in this context. What seems to be realistic is a telephone "hotline" access to report anomalies detected concerning a product, dosage form, patient leaflet or package.

Local authorities responsible for authorization and regulation of medicines have to be involved in these common efforts.

5.2. Messages to public authorities / European and national Authorities

Main industry message towards European and national authorities should be, that increased penalties will help to deter counterfeiting and more adequately punish those convicted. Member States are to be encouraged to adopt legislative measures on stronger criminal measures as foreseen in the EU proposal for a Directive (July 2005) which is currently under revision by DG Justice. Industry also asks public authorities to increase investigative activities, especially at customs level (see messages to stakeholders above).

5.3. Communication within the Supply Chain

Industry has to advocate the proposals for technical solutions with the other members of the supply chain as indicated in the sections above and to be developed in a business case.

ATTACHMENT 1

Main categories of Key Stakeholders

- **Government**

- EU Institutions and Offices

- EU Commission and EU Parliament

- DGs for Health & Consumers, Enterprise & Industry, Justice Freedom & Security, Research, Trade, Taxation & Customs Union ("Taxud")

- OLAF (European Anti-Fraud Office)

- OHIM (Community Trade Mark Office)

- Health Agencies

- National Health Agencies

- European Medicines Agency (EMA)

- Council of Europe

- Parliamentary Assembly

- Public Health Committee

- Ad hoc Pharmaceutical Questions group

- Committee of experts on minimising public health risks posed by counterfeiting of medicinal products and related crimes.

- EDQM (European Directorate for Quality Medicines) network

- OMCL (Official Medicines Control Laboratory) network

- Law Enforcement Agencies

- EU Customs – DG Taxud & Task Force Experts

- Interpol

- Europol

- World Customs Organisation (WCO)

- National enforcement agencies

- FDA foreign offices

- Other

- WHO IMPACT

- World Health Assembly

- OECD (Paris)

- UNECE (United Nations Economic Commission Europe)

- ICC (Paris)

- **Industry**

- EFPIA

- Wholesalers/Distributors/Retailers/Suppliers/Forwarders

- PSI (Pharmaceutical Security Institute)

- IPEC – Europe (International Pharmaceutical Excipients Council)

- APIC (Active Pharmaceutical Ingredients Committee)

- CEFIC (European Chemical Industry Council)

EGA (European Generics Association)
AESGP (Association of the European Self-Medication Industry)
GIRP (European Association of Pharmaceutical Wholesalers)
FECC (European Association of Chemical Distributors)
PhRMA (Pharmaceutical and Research Manufacturers of America)
IFPMA (International Federation of Pharmaceutical Manufacturers and Associations)

- **Right Holders**

AIM (Association des Industries de Marques)
AIPPI (Association Internationale pour la Protection de la Propriété Intellectuelle)
ECTA (European Community Trademark Association)
MARQUES

- **Users**

Users are identified as an important collaborative partner in any anti-counterfeiting programme as they can help to increase awareness about the existence of counterfeit medicines and the risk of buying drugs through unauthorised channels. Users include patient organisations and institutions, healthcare professionals such as doctors' organisations and medical councils, pharmacists' organisations and nurses' organisations. At European level they vary in size and focus and are too numerous to list here.

- **Payers**

Payers are recognised as an important stakeholder and include organisations such as health and care insurers, medical industry insurers and re-insurers and the providers of subsidised medicines programmes. The way how they are included depends on the ordinances given at national level how to implement the legal proposal of the European Commission.