SupplyScape

Response to:

PUBLIC CONSULTATION
IN PREPARATION OF A LEGAL PROPOSAL
TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE GENERAL
CONSUMER GOODS, PHARMACEUTICALS

May 8, 2008

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1 SupplyScape – from MIT Theory to Commercial Reality

SupplyScape Corporation is a leader in developing and applying new technologies to secure the safety and value of the global pharmaceutical supply chain. The company was founded by software technology experts and members of the Massachusetts Institute of Technology (MIT) Auto-ID Lab who led the university's groundbreaking effort on electronic track and trace technologies, collaborating with government regulators, industry associations and commercial organizations to bolster the safety and security of products in pharmaceutical distribution.

SupplyScape is a trusted advisor to industry in the areas of serialization structure, management and execution. The company actively participates in World Health Organization's International Medical Products Anti-Counterfeiting Task Force (IMPACT) forums and conferences. The company's field experience includes implementing European compliance and serialization strategies for 800 prescription drugs, 200 production lines, and 80 manufacturing plants and distribution centers.

SupplyScape runs the largest pharmaceutical authentication footprint in the United States. It is used by numerous pharmaceutical companies throughout the entire supply chain. More than 4 million serialized drug product authentications have been performed using SupplyScape's authentication network.

SupplyScape invented the electronic drug pedigree – an electronic record that traces a drug's chain of custody through the supply chain. The company contributed its electronic pedigree specification to the GS1 EPCglobal™ Drug Pedigree Messaging Standard (DPMS) initiative and worked with the standards organization and industry to develop and ratify this new standard in just over a year. More than 125 companies across the pharmaceutical industry are implementing EPCglobal DPMS standard ePedigrees, based on SupplyScape intellectual property. By 2007, more than 300 million drug bottles were pedigreed using SupplyScape's electronic pedigree software.

Using serialization, authentication and electronic pedigree as the technology foundations of our solutions, SupplyScape is solving anti-counterfeiting problems in the United States today. 100 companies across the pharmaceutical supply chain rely on SupplyScape to protect the integrity of their prescription medicines, including 10 of the top 15 global pharmaceutical manufacturers and 6 of the top 10 biotechnology companies.

2 Counterfeiting – Addressing a Multidimensional Problem

2.1 Different Forms of Counterfeiting

Counterfeiting is a complex, multidimensional problem. To comprehensively address the problem, one needs to understand the various kinds of counterfeiting. SupplyScape believes an effective anti-counterfeiting solution must focus on the following counterfeit types.

- **Substandard product with fake Active Product Ingredient (API)** – substandard product may be manufactured by the legal manufacturer and have the original packaging, but will not meet quality standards due to fake active ingredient (s) supplied to the manufacturer.

- **Completely fake product** – completely fake product refers to product never produced by the legal manufacturer. In this case, both the drug product and its package have been made by a counterfeiter. The fake product may have zero active ingredient, inadequate quantities of active ingredient or even harmful ingredients.

- **Relabeled product** – relabeled product refers to product originally manufactured by the legal manufacturer but with tampered labels. Usually, the product is up-labeled to a higher dose than the original label so that it can be sold for a higher price.

- **Substitution of content** – substitution of content refers to the situation when a counterfeiter obtains the original package or immediate container and fills that with fake product.

- **Adulterated product** – adulteration refers to the addition of foreign substances to make the original product impure or inferior. E.g., water may be added to dilute liquid drugs and increase the overall quantity.

- **Unauthorized re-pack** – repacking of expired products, recalled products, drugs designated for destruction and samples would fall under this category. The re-packaging of product illegally moved from one country to another would also fall under this category.

2.2 Principles of an Effective Anti-counterfeiting System

An effective anti-counterfeiting system will have multiple solution dimensions. The key tenets of such a solution would include proactive capabilities, provide multiple levels of counterfeit protection, be based on industry standards, and provide functionality to secure the product, supply chain and validity of trading partners.

2.2.1 Proactive Approach

It is imperative to protect the safety of patients and prevent counterfeit drugs from entering and remaining in the supply chain. Most solutions currently on the market are reactive in nature. They come into play only after it has been determined that counterfeit drugs have reached the patient – and by then, they may have already harmed the patient. Proactive solutions help prevent counterfeit drugs from getting into the supply chain, detect counterfeit drugs if they do get into the supply chain, and preclude counterfeit drugs from reaching patients.

2.2.2 Provide Multiple Levels of Counterfeit Protection

An effective anti-counterfeiting system will prevent the supply chain from being breached and even deter counterfeiters from faking the product or package. Three levels of counterfeit protection should be provided by anti-counterfeiting solutions:

- Prevention – Enable prevention of entry of counterfeit product in the supply chain.
- Detection – Enable detection of counterfeit product in supply chain.
- Investigation – Enable investigation of counterfeiting incidence once it has occurred and been identified.

2.2.3 Secure the Product, Validity of Trading Partners and the Supply Chain

To ensure that patients receive legitimate drug product, it is necessary to secure not only the physical product but the validity of trading partners participating in the legitimate supply chain. In addition, a comprehensive solution seeks not only to address counterfeit product, but the method by which counterfeit product enters the legitimate supply chain. This is where a concept called pedigree plays a significant role.

By highlighting who has had the product, where it has been, and for how long, companies get better accountability and control over where their products are outside their organization. Illegal diversion can be detected, vulnerability points identified, and appropriate actions taken to protect the integrity of products.

2.2.4 Standards-based Interoperable Solutions

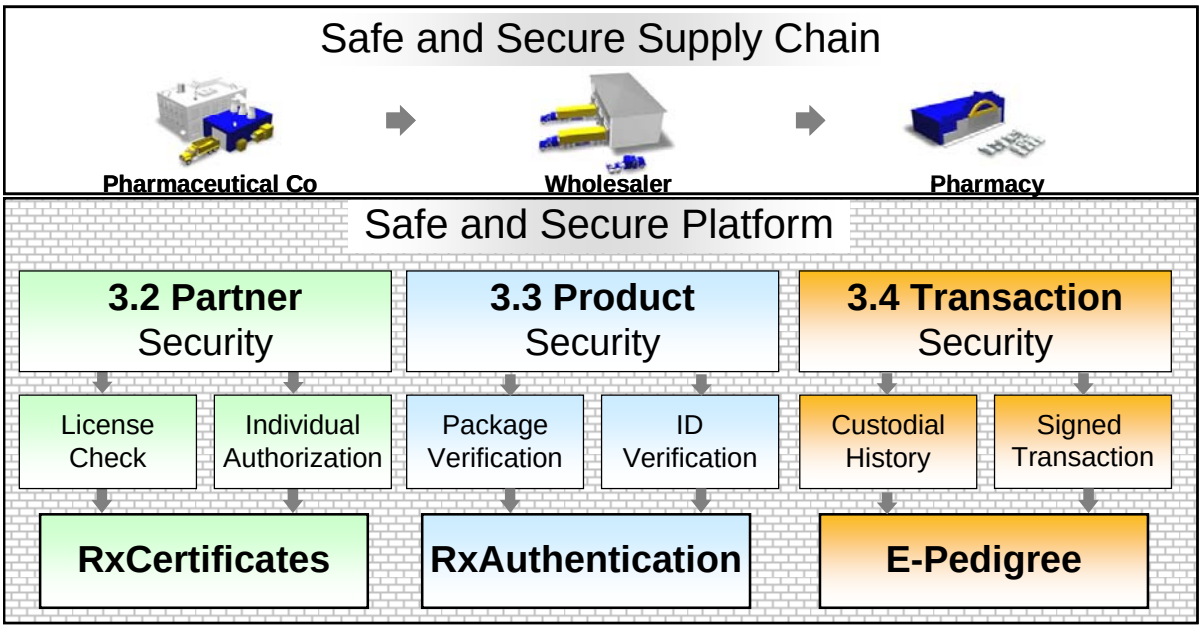
Adherence to industry standards is integral for interoperability and fosters widespread adoption across the supply chain. In addition, standards-based solutions can provide a structure for future extensibility, and they can help reduce project risk and minimize costs based on widespread use and experience. This contrasts with proprietary solutions, which would require implementation by every participant in the supply chain to be useful – an assumption that is unrealistic.

3 A Holistic Approach to Combating Counterfeiting

3.1 Safe and Secure Supply Chain

SupplyScape is committed to a safe and secure supply chain. We believe that in order to ensure the authenticity of the product reaching the patient, it is essential first to ensure the product is handled only by authorized trading partners, and then to secure the physical product and maintain the integrity of the transactions involving the product. The following diagram (Figure 1) illustrates an industry-tested integrated model.

Figure 1. Holistic Approach to a Safe and Secure Pharmaceutical Supply Chain



A holistic, integrated approach secures all 3 – product, partner and transaction. It provides tools to prevent the supply chain from being breached, detect counterfeit products present in supply chain, and support criminal investigations by creating a legal record trail back to the counterfeiter.

3.2 Ensuring Partner Integrity through Certificates

3.2.1 Licensing of Partners

The product should be handled by licensed, authorized trading partners only. This requires extending licensure requirements to all supply chain entities handling the product. The licensure may be done by the state or outsourced to a trusted third party. However, in addition to one time licensure, the validity of the license needs to be checked periodically, most effectively during every transaction. For example, the validity of license should be checked before digital signatures are provided to a trading partner. Only trading partners with valid licenses should be allowed to access authentication databases and the identity of trading partners should be verified whenever they access an authentication database. Similarly, the validity of trading partner's license should be checked before receiving product from them.

3.2.2 Individual Authorization

Within a licensed trading partner, only authorized individuals should be allowed to handle the product. Only authorized individuals should be able to digitally sign and certify chain of custody records.

3.2.3 Certificates

Certificates issued by a legitimate certificate authority can ensure the integrity of trading partner and the individuals handling the product at the trading partner. A certificate authority acts as a trusted third party and can perform the following checks before issuing digital certificates:

1. Validity of license of trading partner
2. Identity of the individual requesting digital certificate
3. The individual requesting certificate is employed by trading partner and authorized to sign on their behalf.

While the certificate authority function and processes can be done manually, it is most effective to implement them through an Information Technology network. A certificate authority is crucial to maintaining supply chain integrity as it ensures counterfeiters are not able to access and falsify chain of custody records or authentication databases

3.3 Ensuring Physical Security of Product through Authentication

3.3.1 Components of Product Security

3.3.1.1 Package Verification

Multiple anti-counterfeiting options are available today to pharmaceutical manufacturers that can be applied to the packaging of the product. These anti-counterfeiting packaging features can be overt, covert or forensic.

1. Overt features are visible to the naked eye and include features like holograms and color shifting inks. Overt features can be used by the general public to verify the authenticity of the package. However, as these features become more widely used, they may be copied by counterfeiters. Overt features essentially enable detection of counterfeiting but provide only limited ability to prevent counterfeiting or investigate counterfeiting once it has happened.
2. Covert features are not visible to naked eye and include features such as watermarks, microtext and invisible printing. Covert features can be used by field inspectors to detect counterfeit product. As they are more difficult to fake than overt features, they provide better detection ability than overt features.
3. Forensic features require testing in the lab and involve adding trace chemicals, biological markers or microscopic particles to actual product or package. Forensic features are harder to fake than overt and covert and hence provide best detection ability out of the three categories.

3.3.1.2 ID Verification

Another tool to ensure authenticity of package is to uniquely identify the package by serializing every package. The serial number may be sequential or random. A random serial number is much harder to guess and hence provides greater security than sequential serial numbers.

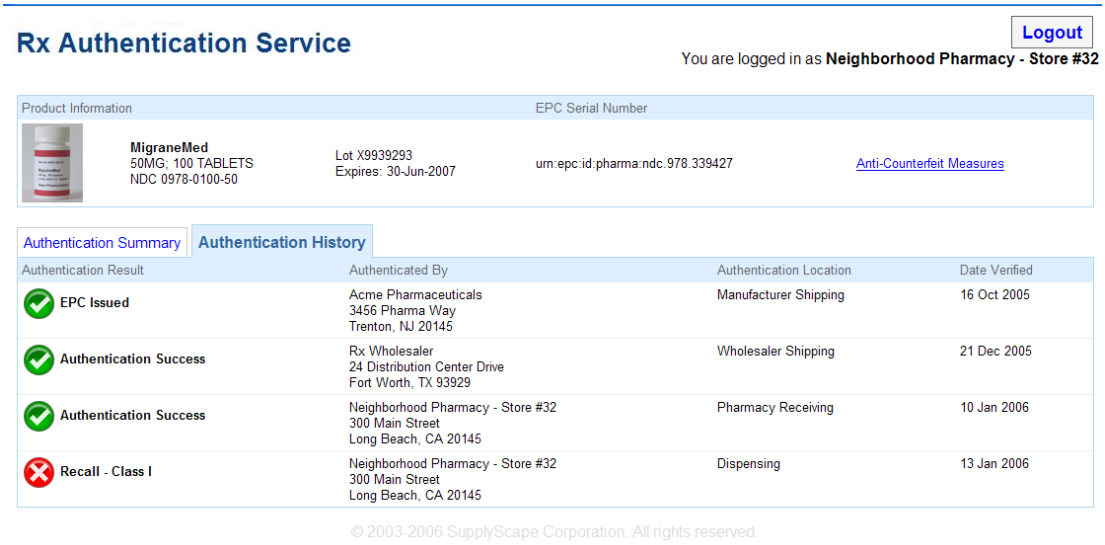
3.3.2 Authentication

Authentication is a means to affirmatively verify the anti-counterfeiting features or the serial ID on the package against the information provided by the manufacturer. The manufacturer may provide this information through a central data base or through a database maintained by the manufacturer himself. In general, authentication should be performed by any supply chain entity before receiving the product (or at the time of receipt of product).

3.3.2.1 Utility of Authentication

By themselves, overt/covert/forensic anti-counterfeiting features and package serialization provide the ability to detect counterfeit product. The detection ability is available only while the product and the package remain together in the supply chain, and before counterfeiters have learned to fake the anti-counterfeiting features. However, when anti-counterfeiting features and serialization are combined with an authentication mechanism, the system can then provide greater preventive and investigative capabilities. If every supply chain partner is required to authenticate the anti-counterfeiting features and/or serial numbers before accepting the product, then fake product can be detected and prevented from entering the supply chain. Authentication by every trading partner can also create a record of possession of a product which can be a valuable investigative tool if a counterfeiting incidence happens. The accompanying graphic (Figure 2) illustrates an authentication service which provides a record of possession.

Figure 2. Authentication Service Example



3.3.2.2 Limitations of Authentication

Anti-counterfeit features and the serial ID are both marked on the package of the product. Therefore, the package and product have to stay together for authentication to work effectively. If a counterfeiter can get the original package with valid serial number and valid anti-counterfeit features, then authentication may not be able to identify the counterfeit. Authentication may not help with substandard product resulting from fake API being provided to the manufacturer, as the product will have valid anti-counterfeit features and valid serial ID at all times.

3.4 Ensuring Transaction Integrity through Pedigree

3.4.1 Components of Transactional Security

3.4.1.1 Chain of Custody History

Chain of custody history refers to a record of all previous ownerships and transactions that a product has been through. Many times, ownership may not be the same as physical possession. For example, in case of consignment inventory, product is owned by one company but stored by another company. Therefore, in addition to the record of ownership, custodial history should also include a record of physical possession. Chain of custody history provides a valuable investigative tool but its utility can be limited if the data is not secure and the counterfeiters have the ability to change the data.

3.4.1.2 Digital Signatures

Digital signatures are an integral component of ensuring transaction integrity. Every trading partner who initiates the transaction should certify that the information provided by the trading partner is true and accurate. The certification backed by digital signatures can enforce accountability in the supply chain. Digital signatures protect against forgery and can ensure the integrity of data has not been compromised as the product moves through the supply chain. Digital signatures bind the trading partner to the data provided by them, proving the transaction is authentic. Due to these characteristics, digital signatures convert chain of custody records into non-repudiable legal documents.

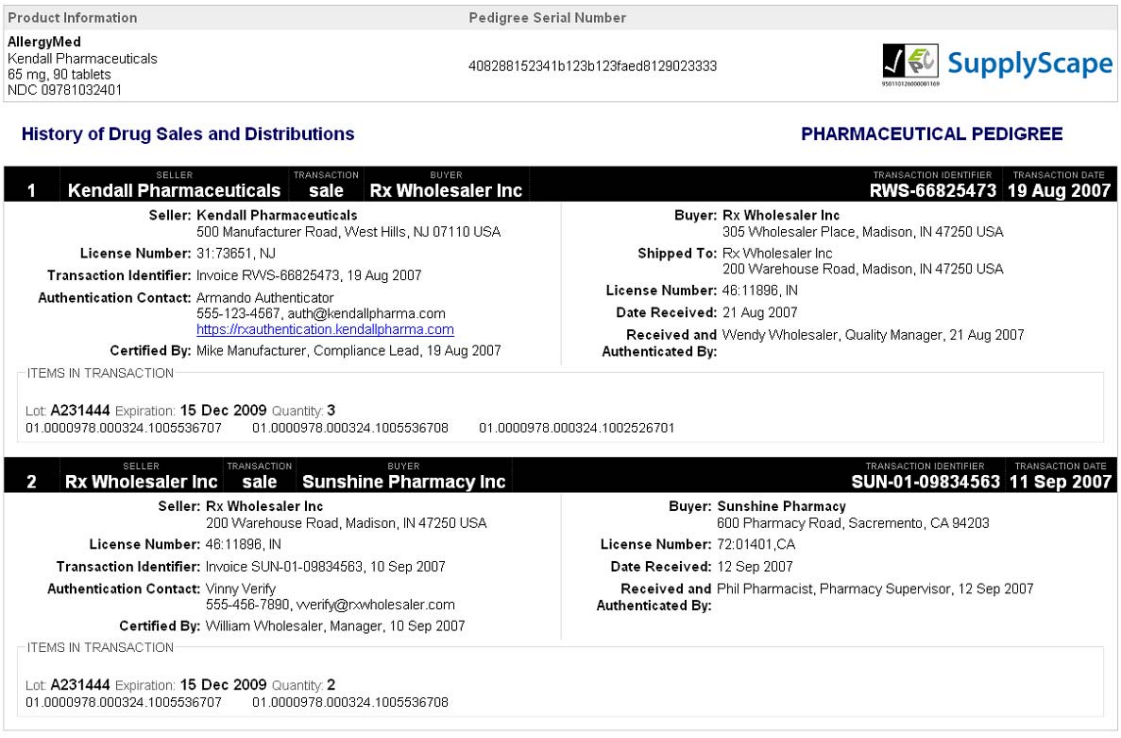
3.4.2 Electronic Pedigree

"Electronic Pedigree" is commonly understood to mean an electronic chain of custody record, containing information regarding each transaction that results in a change of ownership of a drug, from sale by a manufacturer, through acquisition and sale by supply chain intermediaries, until final sale to a pharmacy. The Pedigree may also record every change of possession of the drug. Pedigree should have a certification under penalty of perjury from each supply chain entity that the information contained in the pedigree is true and accurate. A pedigree can also include information on the repackaging of a drug.

3.4.2.1 Utility of Pedigree

Chain of custody by itself is primarily an investigational tool to trace the path of product once a counterfeiting incidence has happened. However, when chain of custody history is combined with digital signatures and is required to be authenticated before every transaction, it becomes a preventive and diagnostic tool. This is what the electronic pedigree accomplishes by combining the chain of custody history with digital signatures. Digital signature ensures that data on pedigree is accurate and has not been forged. As fake product is not likely to have a pedigree, if electronic pedigree is required for every transaction and has to be authenticated before the transaction is complete, then any fake product would be detected before it enters the supply chain and thus prevented from compromising the supply chain. An example of a pedigree locked by digital signatures is shown in Figure 3.

Figure 3. Electronic Pedigree Example



Product Information	Pedigree Serial Number
AllergyMed Kendall Pharmaceuticals 65 mg, 90 tablets NDC 09781032401	408288152341b123b123faed8129023333

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History of Drug Sales and Distributions — **PHARMACEUTICAL PEDIGREE**

#	SELLER	TRANSACTION	BUYER	TRANSACTION IDENTIFIER	TRANSACTION DATE
1	Kendall Pharmaceuticals	sale	Rx Wholesaler Inc	RWS-66825473	19 Aug 2007

Seller: Kendall Pharmaceuticals
500 Manufacturer Road, West Hills, NJ 07110 USA
License Number: 31:73651, NJ
Transaction Identifier: Invoice RWS-66825473, 19 Aug 2007
Authentication Contact: Armando Authenticator
555-123-4567, auth@kendallpharma.com
https://rxauthentication.kendallpharma.com
Certified By: Mike Manufacturer, Compliance Lead, 19 Aug 2007

Buyer: Rx Wholesaler Inc
305 Wholesaler Place, Madison, IN 47250 USA
Shipped To: Rx Wholesaler Inc
200 Warehouse Road, Madison, IN 47250 USA
License Number: 46:11896, IN
Date Received: 21 Aug 2007
Received and Authenticated By: Wendy Wholesaler, Quality Manager, 21 Aug 2007

ITEMS IN TRANSACTION

Lot: **A231444** Expiration: **15 Dec 2009** Quantity: **3**
01.0000978.000324.1005536707 01.0000978.000324.1005536708 01.0000978.000324.1002526701

#	SELLER	TRANSACTION	BUYER	TRANSACTION IDENTIFIER	TRANSACTION DATE
2	Rx Wholesaler Inc	sale	Sunshine Pharmacy Inc	SUN-01-09834563	11 Sep 2007

Seller: Rx Wholesaler Inc
200 Warehouse Road, Madison, IN 47250 USA
License Number: 46:11896, IN
Transaction Identifier: Invoice SUN-01-09834563, 10 Sep 2007
Authentication Contact: Vinny Verify
555-456-7890, vverify@rxwholesaler.com
Certified By: William Wholesaler, Manager, 10 Sep 2007

Buyer: Sunshine Pharmacy
600 Pharmacy Road, Sacramento, CA 94203
License Number: 72:01401,CA
Date Received: 12 Sep 2007
Received and Authenticated By: Phil Pharmacist, Pharmacy Supervisor, 12 Sep 2007

ITEMS IN TRANSACTION

Lot: **A231444** Expiration: **15 Dec 2009** Quantity: **2**
01.0000978.000324.1005536707 01.0000978.000324.1005536708

Pedigree can also be extended backwards in the supply chain from the manufacturer to the source of active product ingredients. This can help deal with counterfeiting of active ingredients and prevent substandard products from entering the market.

3.4.2.2 Limitations of Pedigree

Electronic pedigree is intricately linked with digital signatures. If digital signatures are absent, then the chain of custody record can be falsified significantly reducing the effectiveness of the tool.

3.5 Holistic Anti-counterfeiting Approach Summary

The following chart summarizes the benefits provided by electronic track and trace technologies in an integrated approach.

Figure 4. Benefits of Anti-counterfeiting Technologies

Anti-Counterfeit Protection Level	Electronic Track & Trace Technology	Benefit
Prevention	Electronic Pedigree Certificates	Prevent large scale introduction of counterfeit product into supply chain
Detection	Electronic Pedigree Authentication Serialization Certificates	Identify counterfeit product in the supply chain before it is dispensed to patients
Investigation	Electronic Pedigree Certificates	Provide legal chain of custody record of drug transactions for criminal investigation and resolution

4 Response to Key Ideas for Better Protection of Patients against Counterfeit Medicines

Please find below SupplyScape's response to specific key ideas put forth by the Commission for better protection of patients against counterfeit medicines. This response is guided by the holistic approach to anti-counterfeiting outlined in previous sections.

4.1 Tightening Requirements for Manufacture, Placing on Market of Medicinal Products, Inspections

4.1.1 Subject All Actors of the Distribution Chain to Pharmaceutical Legislation

(A) Supply chain visibility is critical to effective anti-counterfeiting. The supply chain is only as strong as the weakest link. If certain players in the supply chain are exempt from wholesaler requirements, then authentication records or chain of custody records will be incomplete. The resulting record gaps will hamper investigation as the financial and physical flow of a counterfeit product can be hidden from investigators.

(B) All actors in the distribution chain should be subjected to regular audits. Regular audits by qualified auditors will ensure that all trading partners meet certain minimum standards for manufacture, handling, storage and distribution of product. SupplyScape supports licensure and certification of all trading partners to ensure only authorized trading partners handle the product. Regular audits can be an important component of a licensure and certification program.

4.1.2 Tightening Rules on Inspections

(A) Counterfeiting is a problem that goes beyond national boundaries. Manufacturers buy active ingredients from third world countries outside the EU. Many contract manufacturers are also located in third world countries. However, the inspection standards in these countries may not be as strict as in the EU. In order to prevent fake active ingredients or substandard products with fake active ingredients from entering the EU supply chain, it is important to conduct inspections in third world countries. All suppliers, irrespective of location, should be subject to equally stringent inspection requirements. Even with strict inspections, there is no certainty that it is the inspected product which will show up in EU. There is a need to enhance visibility from the supplier of active ingredient through its passage in the supply chain to entry into the EU and to the manufacturer. In order to ensure that only the inspected product makes it to the EU, chain of custody record keeping requirements may be extended back up to suppliers in third world countries.

(B) Inspection provisions should be extended to all parties in distribution chain. This will ensure the participation of all players in maintaining security of supply chain and will make it harder for counterfeiters to breach supply chain and introduce fake product.

(C) Inspections can become more effective by having more complete and authentic information. Inspections efficiency can also be improved with continual access to information for analysis. In this way, inspections can be precisely targeted.

4.1.3 Improving Product Integrity through a Unique Seal, Supported by a Ban on Re-packaging

(A) Pharmaceutical manufacturers have adopted multiple methods such as holograms, color shifting ink or serialization to secure the product. Tools such as authentication and pedigree take advantage of the features applied by manufacturers by requiring supply chain partners to verify the features on the product against the information provided through pedigree or authentication.

However, these anti-counterfeiting features are on the packaging of the product. Effective functioning of authentication and pedigree systems requires that the original product and original packaging stay together. Once the original packaging is opened and separated from the product, the utility of the anti-counterfeiting features is lost and authentication or pedigree systems can not be used. In fact, the situation becomes worse than having no anti-counterfeit features. The original packaging can be misused by counterfeiters to pass off fake product. As the authentication systems and pedigree systems check against the anti-counterfeit features on the package, they may not be able to detect fake product in original packaging. Allowing repackaging may lead to fake product moving undetected through supply chain. Due to these factors, a ban on repackaging significantly enhances security of supply chain.

(B) Having a unique tamper evident seal on every product which may be opened only by the end user or marketing authorization holder will ensure that the authentic product remains together with authentic packaging. Hence adoption of these provisions is recommended.

(C) Counterfeiting is a rising problem and counterfeiters have been known to fake even cheap products like glycerin (as evidenced by death of children in Panama due to consumption of syrups containing fake glycerin). Measures such as using a unique tamper evident seal, ban on repackaging and allowing only the end user to open the package, represent comparatively low cost solutions (as compared to mass serialization for example). Therefore, instead of a risk based approach, these measures may be adopted for all products as the minimum acceptable level of security.

4.1.4 Centrally Accessible Record to Facilitate Traceability of Batches

A complete record of transactions (pedigree) is a very important prevention, detection and investigational tool. As mentioned earlier in Section 3.4, if every supply chain partner is required to authenticate against chain of custody information before receiving product, then they can detect fake product at receipt itself and prevent it from being introduced in the supply chain. This provides a significant deterrent to counterfeiters trying to sell fake products into supply chain. When pedigree information is backed by digital signatures, then it assures that the product has been handled by certified trading partners and the pedigree data has not been tampered with. If there is a case of counterfeiting, having a complete pedigree enables the investigators to trace the path of the product through the supply chain and identify the source of fake product.

While having a complete record of transactions is a good idea, the concept of a centrally accessible system has some shortcomings.

(A) A centrally accessible system requires high levels of network connectivity. All the supply chain entities should be able to access the system for pedigree information or to update the pedigree with new transactions. This represents a significant challenge considering the large number of supply chain partners involved. In addition, network connectivity is not uniform across EU. There is significant disparity between countries in terms of technology adoption and IT capability.

(B) A central database represents a single point of failure and is likely to be a target for hackers and counterfeiters. Counterfeiters may be able to bring the entire system to halt by concerted attacks such as ‘denial of service’ attacks.

Counterfeiters may be able to avoid detection by not getting on the centrally accessible system. The centrally accessible system requires the bad guys i.e. counterfeiters to cooperate with the rest of the supply chain.

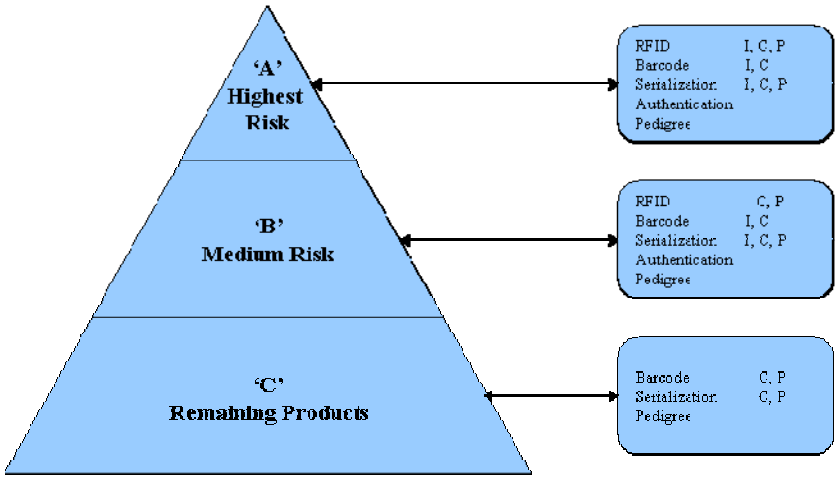
In view of above considerations, it may be a better idea to send the record of transactions along with the product. In that case, the record will be available to the trading partner who needs it instead of being available to everyone. The complete record would be available in a consolidated form with the end point in the supply chain, i.e., the pharmacy, and may be used to pursue an investigation if required.

4.1.5 Mass Serialization for Pack-tracing and Authenticity Checks on Case by Case Basis

Mass serialization enables identification of an individual pack. When combined with authentication and/or pedigree, serialization ties the chain of custody record to the appropriate individual product. This provides much greater granularity and traceability compared to identification at batch level. Some of the major considerations around mass serialization are:

(A) Cost of serialization and risk based approach to serialization – Serialization is a comparatively costly endeavor, especially when compared to some of the other anti-counterfeiting technologies such as optically variable inks. Putting a serial number on every pack can add significantly to the cost of the individual pack. The risk of counterfeiting and the wholesale price of certain drugs, e.g., generics, may not justify pack serialization. Due to these considerations, manufacturers have tended to follow a risk based approach where the level of security provided to a product depends upon its risk profile. For products at high risk of counterfeiting, high level of security is provided by adopting multiple anti-counterfeiting technologies. However, for products at lower risk of counterfeiting, only certain technologies may be adopted. An example of risk based approach is shown below (Figure 5).

Figure 5. Risk-based Approach to Serialization



Key : I – Item Level, C – Case, P – Pallet

(B) Harmonization of serial numbers – There are multiple states in EU who already have pack serialization requirements. However, each state has its own serial number scheme and there is no consensus on number scheme. This limits the pack traceability to within each member state. In order for an EU-wide traceability system to work, there is a need for a common serial number scheme. A common serial number scheme will allow product to be tracked even when it crosses borders. A common number system will also prevent duplication of serial numbers. In addition, a common serial number scheme will enable manufacturers to deploy one single serialization management system for the entire EU, thus driving down cost of serialization deployment.

(C) Harmonization of data carriers – Similar to issue of serial numbers, there is a no consensus between different member states on which barcode symbology to utilize to print the serial number on to the pack. This requires additional hardware and software throughout the supply chain to print or read serial numbers.

(D) Development of EU wide label – The commission has proposed a ban on repackaging as one of the key ideas to fight counterfeiting. If such a ban is implemented, then as parallel trade is still legal, it would mean that the label on the package with all its data, including the serial number, should be legally acceptable in any EU member state. In addition, trading partners across EU

should be able to read the label in an efficient, automated manner. Due to these considerations, there is a need for a standardized EU label with a specified data, layout, and location on the pack.

4.2 Tightening Requirements for Manufacture, Placing on the Market of Active Substances & Inspections

SupplyScape is in agreement with the commission that risks to the patient health and safety may originate at very early stages of the production chain. This has been particularly borne out by some of the recent cases of counterfeiting. For example, in Panama more than 100 children died when contaminated cough syrup was administered to them. Investigations showed that the cough syrup had toxic diethylene glycol instead of glycerin as one of the ingredients. The counterfeit glycerin originated from a third country. Similarly, in the U.S., more than 80 deaths were linked to the administration of heparin contaminated with a cheap chemical that mimicked the effects of heparin. Investigations showed that contamination occurred at an active ingredient supplier in a third world country.

(A) Based on study of past counterfeiting incidences similar to those mentioned above, SupplyScape supports regular audits and enhanced inspections of active ingredient suppliers. In addition, as evidenced in the contaminated heparin case, the active ingredient may contain toxic chemicals which may evade detection unless specifically looked for. This may require utilization of more discriminating analytical techniques.

(B) Active ingredient may go through a network of suppliers, brokers and traders before arriving at the drug manufacturer. Due to this complexity and despite regular auditing and inspection of active ingredient suppliers, inspected active ingredients may not reach the intended drug manufacturer. The same anti-counterfeiting principles and tools applied to finished drug products should also be applied to active ingredients.

5 Summary

SupplyScape appreciates the opportunity to contribute to the European Commission's Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines consultation.

SupplyScape's recommendations are based on real world experience - systems successfully implemented and in use today protecting the safety of patients in the United States. SupplyScape's E-Pedigree solution is enabling pharmaceutical manufacturers, wholesale distributors, and pharmacies to secure the integrity of prescription drug transactions and comply with regulatory requirements of the states, such as California, and the federal government. SupplyScape's Certificate Authority issues Florida-compliant digital certificates for ePedigree systems. SupplyScape's Rx-Authentication network is being used to verify the authenticity of drug product packages for a growing number of prescription medicines.

At the core of SupplyScape's recommendations is a holistic, integrated approach that not only secures the physical product, but also maintains the integrity of the transactions involving the product and ensures the product is handled only by authorized trading partners. The approach is proactive and focuses on preventing counterfeit drugs from entering or remaining in the supply chain. Additionally, this approach aids in investigating and resolving counterfeit incidences once they have occurred.

The approach described in Section 2 of this document is applicable regardless of technical sophistication. While information technology networks increase productivity, the basic tenets of prevention, detection and investigation over a wide variety of counterfeit scenarios are applicable regardless of whether the processes are automated or not.

For additional information or questions regarding this submission, please contact Robin Koh by email at rkoh@supplyscape.com, or by telephone in the Unites States at 781-503-7403.