



May 7, 2008

**To:** European Commission  
Enterprise and Industry Directorate-General, Pharmaceuticals

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**Subject:** Response to "Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use"

**Background:** Authentix is a private company that provides anti-counterfeiting and anti-diversion technologies and services to a wide range of industries and to many governments. Our programs are global and we currently employ approximately 110 people. [www.authentix.com](http://www.authentix.com)

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The increased globalization of the pharmaceutical trade means that getting drugs from the point of manufacture to the patients they are meant to help involves an increasingly complex supply chain. Drugs frequently change hands multiple times before reaching the patients they are intended for, and are often repackaged by legitimate third party operations at which time original packaging is discarded along with any countermeasure features and tracking information that may have been present. The complexity and weak controls over the pharmaceutical supply chain have made pharmaceuticals a vulnerable target for unauthorized distribution, counterfeiting and possible terrorist attack.

There are fundamental areas that the EC can influence that would lead to near term improvements to the integrity of the supply chain and patient safety.

- Dramatically increase the penalties for counterfeiting and unauthorized distribution of medicines and medical devices. These illegal activities create life-threatening situations and the penalties should be commensurate with the crime. The risk/reward equation still favors taking the risk.
- Require all medicines and medical devices to have tamper evident security features that remain intact from the time product leaves the manufacturer to when product reaches the patient. The current practice, where repackaging of product occurs as a consequence of the parallel trade industry, results in the loss of original manufacturer packaging. Not only does this undermine manufacturers attempts to secure their products and protect patients, but it also creates a supply of "discarded" original packaging material that can then be used as packaging for counterfeit product. This major flaw in current drug distribution practices should be addressed with urgency.

- Strengthen licensing requirements and oversight for distributors of drugs and medical device products. Raise the standards to weed out “garage” operations.
- Develop stronger communication programs to raise public awareness to the real threat of counterfeit medical products and the risks posed by purchasing these products through the Internet.
- Strongly encourage the combination of physical authentication factors in concert with move toward serialization and tracking. There is a false perception that once product is serialized at the unit level it will be possible to prevent counterfeiting and diversion. Although serialization and the associated tracking and verification programs that are being discussed will be a big step forward in improving patient safety, it is also inevitable that serial codes from legitimate product will be copied and used on counterfeit product. The capability to authenticate both the serial code and the physical item quickly, definitively, and in the field, will be a critical component of a complete product surety initiative. A variety of mature authentication technologies that can be integrated into packaging components, inks used for serial code application, and the dosage form, currently exist. As track and trace programs mature, and scrutiny of the supply chain increases, there will be a higher incidence of “exceptions” that are found and quarantined and which will require rapid investigation and disposition. It is the combination of digital (serialization) programs along with physical authentication capability that will ultimately help lock down the supply chain.

### General Comments

A momentum is developing across the pharmaceutical industry and across the globe toward improving product surety and patient safety. However, there is a danger that patient safety will suffer from fragmented approaches and expensive implementation strategies that will actually delay the implementation of effective programs. For example, at the same time as the EC is seeking this public consultation, the FDA is also seeking public consultation, California is trying to establish compliance with an e-pedigree requirement, legislation has been introduced in the US Congress for a national e-pedigree program (potentially superseding California), Turkey is seeking compliance with its own e-pedigree requirement, and EFPIA is pursuing a slightly different type of tracking system. The multitude of different initiatives and associated requirements, and the uncertainty of which ones will prevail, presents the healthcare industry with a dilemma that not surprisingly, has led to delays and inaction toward building out enabling infrastructure.

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Now is the ideal time to be building a harmonized, global approach to improved patient safety rather than heading down divergent paths. The EC can take a leadership position in bringing together key organizations and agencies including The World Health Organization (WHO), The European Medicines Agency (EMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), the United States Food and Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America, (PhRMA), the Ministry of Health, Labor, and Welfare, Japan (MHLW), and the Japan Pharmaceutical Manufacturers Association (JPMA) to engage together to establish a harmonized global approach that can be deployed broadly. The International Committee

for Harmonization (ICH), which was established to harmonize aspects of drug development between the US, Europe, and Japan, could also play a key role in establishing a common foundation for product surety and patient safety.

The two key technical elements of the product surety strategy would include: 1) unit level serialization, and 2) unit level physical authentication. A global, harmonized approach to drug safety should initially be carried out with the central goal of verifying drugs at the most critical transaction in the drug's journey - when drugs are dispensed to patients. This is essentially the "book-end" approach being proposed by EFPIA. Although the cost and complexity of the "book-end" approach is significantly lower than the ePedigree approach, which follows product through the supply chain, it still requires two significant and challenging developments: 1) all products must be serialized at the unit level and 2) an industry wide data routing and data management system must be established. Although both of these objectives are challenging and costly they represent only a fraction of the cost and complexity of enabling a full supply chain pedigree system. Undertaking this initial step would enable near term improvements to patient safety through point of dispensing verification, provide significant learning, and enable subsequent development of follow-on supply chain pedigree programs.

First, at the point of manufacture, drugs would be serialized with a unique item-level serial number printed on each individual unit of the drug in the form of a scannable code and a human readable alphanumeric. The combination of a scannable barcode (eg. 2D datamatrix) and a corresponding human readable alphanumeric will enable anyone along the supply chain (eg. from manufacturer to patient) and in any region (eg. with or without electricity) to access the unique identification number on every unit of product. The basic structure of the code should be established as a global standard through a group such as GS1, however the structure should also be expandable to allow for forward compatibility should larger data handling needs arise. The item level serial code associated with the drug should reside in a manufacturer-controlled database. An industry wide data routing system, similar to those in use for banking and credit card transactions, will be required to enable verification of information within each manufacturers data management system.

At the point of dispensing (eg. pharmacy, hospital, etc.), the item serial number would be scanned and the information routed to the manufacturer's database for verification. The number would be checked against the serial codes in the database and either an "approval" or "denial" would be sent back to the point of dispensing. Multiple checks of the same serial number at the time of dispensing would raise a flag, triggering a "denial" for any future attempts to dispense. Questionable product would be put aside for further investigation and disposition based in part on physical authentication.

In addition to the points of dispensing, other potential inspection points such as corporate security, distribution centers, wholesaler sites, and returns centers could also be registered in the system and recognized as non-dispensing points and different business rules established.

Like credit cards and ATM cards, this should be a global system that can be used throughout all regions of the world.

In developing regions that lack computer infrastructure, products could be checked through a cell phone text message. Cell phone verification would be highly advantageous for countries that have fragmented pharmaceutical distribution systems and poor regulatory and enforcement structures.

Another important component of this global approach are overt and covert product authentication features that are applied by the manufacturer to both the product packaging and even the product itself. These physical security features provide the manufacturer with various options for conducting rapid field investigations. In certain regions, the manufacturer may also wish to educate the consumer to look for certain overt security features.

To make this happen, the EC, EFPIA, EMEA, FDA, PhRMA, MHLW, JPMA, and WHO would need to work together to establish an industry data exchange infrastructure that would underpin the broad implementation of unit-level serialization.

Using the “bookend approach” that involves only the beginning and the end of the drug distribution process makes for a streamlined approach that can be implemented using existing barcode technology (eg. datamatrix), barcode readers, and cell phones.

Applying this type of phased strategy would effectively lay the foundation for future implementation of a “closed loop” track and trace system that would track drugs as they move through the supply chain. Over time this system would be forward compatible to work in conjunction with RFID or other emerging technologies as they mature and become ready for use in the marketplace.