



Securing the Pharmaceutical Supply Chain
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PhRMA PRIORITY: a safe and secure supply chain



- Prevents the introduction of counterfeit drugs
- Prevents diversion of drugs already in the supply chain
- Means that patients get safe and efficacious medicines

HOW DO WE ASSURE SUPPLY CHAIN SAFETY & SECURITY?



- **We need a systems approach as there is no single “magic bullet”**
- **Innovative packaging technologies**
- **Maintain a Closed Supply Chain with the United States**
- **Examine and test new approaches such as serialization**
- **Improved wholesaler licensure**
- **Active enforcement against counterfeiters**

PhRMA ACTIVITIES



- **Established a work group on Electronic Drug Authentication**
- **Worked with other supply chain partner associations on various issues (RxSafeTrack, EPCglobal)**
- **Commented in depth to FDA**
- **Issued a White Paper in 2005 on the path forward to achieve electronic drug authentication**

PhRMA WHITEPAPER OUTLINES A PATH FORWARD



- **All package units of targeted prescription medicines should contain a machine- readable serial number that includes the company identifier. The applicable package-level to uniquely serialize includes the pallet, case, and item level.**
- **The machine- readable code can include bar codes or RFID tags. The chosen code should be robust and reliable in terms of readability and cost effective.**
- **Standards for serialization, tag data, and frequencies (in the case of RFID) must be developed in accordance with packaging hierarchy.**
- **An appropriate information technology (IT) infrastructure should be constructed that will allow the dispensing site, and other trusted parties, to query through a central data portal. Data will be routed to the distributed database where information on the package unit in question is kept. The dispensing site will receive a real-time signal back that the identification number is authentic for the product in question.**

PhRMA WHITEPAPER OUTLINES A PATH FORWARD



- **Electronic authentication should focus initially on the end-user dispensing site, but is not intended to exclude other supply chain participants. Targeted pilots should also be undertaken by the pharmaceutical industry with the goal of furthering the development of electronic pedigrees.**
- **Operating rules must be established regarding the point and time of authentication. Following dispensing of the package unit (or the opening of a container containing multiple dispensing amounts) steps should be taken to prevent the subsequent illegal use of that unit's serial number.**
- **Following successful demonstration of the viability of dispensing site authentication, this technology can be added to other partners in the supply chain, adding another tool to assure authentic pharmaceutical product flow from the manufacturer to the end dispensing site.**

ELECTRONIC AUTHENTICATION IS DIFFERENT



- **Package identification information is resident in the database**
- **An “electronic pedigree” is just a series of authentication steps**
- **Each trading partner authenticates and it’s registered in the database**
- **The “electronic pedigree” does not need to be passed forward but can be examined if the package is flagged because it did not have a prior authentication**

Where are we today?



- **Section 913 of FDAAA requires FDA to establish a standardized numerical identifier**
- **California requires serialization of item packaging beginning in January 2015**

Outstanding Questions



- **RFID/2-D Bar Code for serialization**
- **Product identifier within RFID**
- **Readiness of Supply Chain Partners**
- **Authentication or full scale Track and Trace**