kezzler

Comments

FDA Docket 2005N-0510

FDA Anti-Counterfeit Drug Initiative Public Workshop and Vendor Display

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II. What Issues Are We Interested in Seeking Comment on at the Meeting Related to RFID and E-pedigree?

Please fully explain your rationale and reasons for your answers and comments to the following questions.

A. Implementation of RFID

1. What incentives are needed for more rapid and widespread adoption of RFID in the U.S. drug supply chain? How can these incentives be achieved?
2. What are the current obstacles to widespread adoption of RFID in the U.S. drug supply chain? How can these obstacles be overcome?
3. What is FDA's role in further facilitating adoption of RFID across the drug supply chain?
4. What is the timetable for widespread adoption of RFID across the drug supply chain, with and without additional incentives?

Kezzler thinks that the already existing compatibility between RFID and bar-coding is the key. RFID must in the first stages be used where it gives economical sense and bar-coding can be used for item-level identification. Kezzler believes that as the track and trace systems are implemented, and doing their intended job, a transition towards RFID will be seen. Today complete secure track and trace technologies using on other data carriers, such as bar-codes, are available on the open marked.

B. RFID Standard Setting

1. Who should set the standards for RFID? Currently we are aware of the efforts of only one organization, EPCglobal, to develop standards for the use of RFID in the drug supply chain. Are there other entities within the United States or abroad that are also developing standards for the use of RFID for the drug supply chain?

Should standards remain voluntary? Why?

In a phase of a new technology being adopted on an industry wide basis, as few restrictions as possible will ensure that the most efficient technologies and practises will emerge. It is necessary with some room for "trial-and-error" before technologies and practices adjust and settle.

C. Specific Drug Supply Chain RFID and E-pedigree Issues

We have been approached by a number of stakeholders for our advice and thoughts on various issues that have surfaced as a result of RFID pilot studies, standards development, and e-pedigree implementation. We would like to discuss these issues at the public workshop.

1. Mass Serialization

In the Counterfeit Drug Report, we advocated the use of mass serialization, which involves the incorporation of unique identifier numbers on each drug package in order to track the individual drug package as it moves through the supply chain. We still believe that this is an important element for the success of electronic track and trace in the drug supply chain.

It is _not possible_ to securely track any unit, be it single, pallet or SKU, without a unique identifier. The pedigree (tracking) must be initiated solely and inconclusively on the basis of the physical product itself _in situ_. There must be an "unbreakable" and unequivocal link between the product (its identity) and its pedigree.

To register an event in the pedigree, every time the physical product item must be authenticated. In order to achieve this securely, it must have a unique identity.

It is the flow of (physical) goods that must be secured, not the flow of the pedigree (as such), the _pedigree is the proof and documentation_ of such secure product flow.

At any time, being in possession of the physical product (single item) _only_, it shall be possible to unequivocally authenticate the product, and then subsequently produce the pedigree for that item.

From a practical and economical perspective there are mass-serialization technologies available today that can track in hierarchies. This means that by tracking the security number (identifier) of the pallet only, by default all its contents will be tracked automatically without actually "reading" these individually. This is possible since the relation(s) between the units in the hierarchy has been established and duly documented at the time of shipping from the manufacturer.

Without a product ID (and possibility for authentication, and hence possiblity to determine whether the drug item is genuine or not) illicit and counterfeited drugs can enter the supply chain undetected, and hence the ePedigree can be doctored and falsified, and effectively the ePedigree will give "proof" of authenticity of counterfeited and diverted drugs.

What numbering conventions currently are being used or considered for mass serialization?

The current numbering systems (conventions) utilize decimals or alphanumeric characters or a combination thereof.

Mass-serialization systems are data carrier independent, and in this respect the RFID renders no more than a bar-code.

Should there be a single numbering convention or are different conventions compatible?

Mass-serialization is a technology. Different technologies will make use of different numbering schemes for reasons of performance and security level. Restricting the way such a number is designed and constructed will inhibit development in this field. A numbering convention that will ensure the desired safety is the following rules:

1. **The identifier shall be unique for the item or unit it shall identify**
2. **The identification of the product item shall be unequivocally linked it to its pedigree.**
3. **The identifier should only contain decimal numbers or the 26 character in the Latin alphabet or combination thereof.**
4. **The minimum length for the identifier number is 8 for alphanumerics and 11 for decimals.**
5. **The identifier shall be a neutral in relation to the product, manufacturer or any logistical information.**

Should the national drug code (NDC) be part of the unique identifier or should the identifier be a randomly generated number?

No. It is important for safety reasons that there is no information contained in the identifier that can be interpreted to reveal information about the product. Preferably the identifier should be a randomly generated number.

An identifier shall upon authentication provide additional information about the product, such as for instance the NDC. In principle there are no limitations to the nature or amount of such information, and its updating frequency, i.e. for instance product recalls.

Concerns have been raised that use of the NDC raises privacy issues. What is the extent of these concerns and how should they be addressed?

Using a neutral mass-serialization technology there is no concern about privacy, as the identifier, only will authenticate the product itself.

What is the timetable for widespread mass serialization for prescription drug products, with and without additional incentives?

Secure mass-serialization technologies designed for this application that for instance uses bar-coding, are on the market today.

2. Universal Pedigree Fields

FDA regulations at 21 CFR 203.50 (currently stayed) list the information that must be provided in the pedigree. This is the minimum information that was also set forth in the PDMA. These requirements were established at a time when a paper pedigree was the only mechanism available for passing a pedigree. An e-pedigree not only requires additional information because of its technological nature, but it may also facilitate the inclusion of more information. In addition, some States are requiring that specific information be included in pedigrees passed with drugs sold in their State. Consequently, pedigree information required by one State may be different than the pedigree

information required in the next State where the drug is received. Some States now also require that all wholesalers (both primary and secondary) pass pedigrees.
Are there logistical concerns or barriers to passing a pedigree for a drug that moves from one State to another with different pedigree requirements?

No. In an electronic world the barriers are only imposed by the movement of the physical of the goods themselves. The pedigree is produced by recording a series of authentications of the product. The amount and nature of the information that is generated by the product and its identifier, is adjusted to the different states with ease.

Would a universal pedigree alleviate these concerns or barriers? How?

From a technical point of view the adoption of a universal pedigree is _not_ of high importance.

What common fields/information are the most important in a pedigree? Why? How can a universal pedigree be achieved?

The pedigree should have conventions/rules about the minimum required information, _but not the presentation format._

This will ensure that different pedigree systems will provide the same level of safety and information.

3. Data Management and Security

For e-pedigree transmission from manufacturer to dispenser to be successful, business partners must be able to share information specific for the product that is the subject of the pedigree. We are aware that there is a great deal of interest in the management and sharing of pedigree information among business partners.
One issue that has been raised is whether the data/ information should be stored in one central database or if a distributed approach (where each stakeholders system exchanges information with other systems) should be used. Can/should the pedigree information is passed and authenticated using either model?

A central database for identifiers should not be used (for a number reasons).

An approach with a central database will put too many restrictions on suppliers of such systems with regard to development and implementation. Experience has shown that "gargantuan" system architectures like this have never been successful when meeting technical and legal realities.

From a technical point of view this is a great disadvantage, and technologically a distributed model is far better.

The individual manufacturer must manage and be responsible for their own data that will be the master source for the pedigree.

The manufacturer will based on this model _grant access to information_ based on given criteria, and _accept recording a tracking event_ based on given criteria.

Today ID Management and Public Key Infrastructure (PKI) systems are the layer/access gate to the individual information source.

There are also serious doubts if such a central database from a technological point of view is feasible or even possible.

What types of encryption or other data security measures are available to ensure the authenticity of the information being passed and digitally signed? What measures can be taken to secure the databases themselves in either the central database or distributed approach?

There are many mature solutions and practises for protecting these kind of systems, of which encryption, access management and PKI system are pivotal.

III. What Issues Are We Interested in Discussing related to PDMA and E-pedigree?

B. Adoption of E-pedigree Across the Drug Supply Chain

It is very important to differentiate and conceptually strictly separate the ePedigree data source(s), and the access to it.
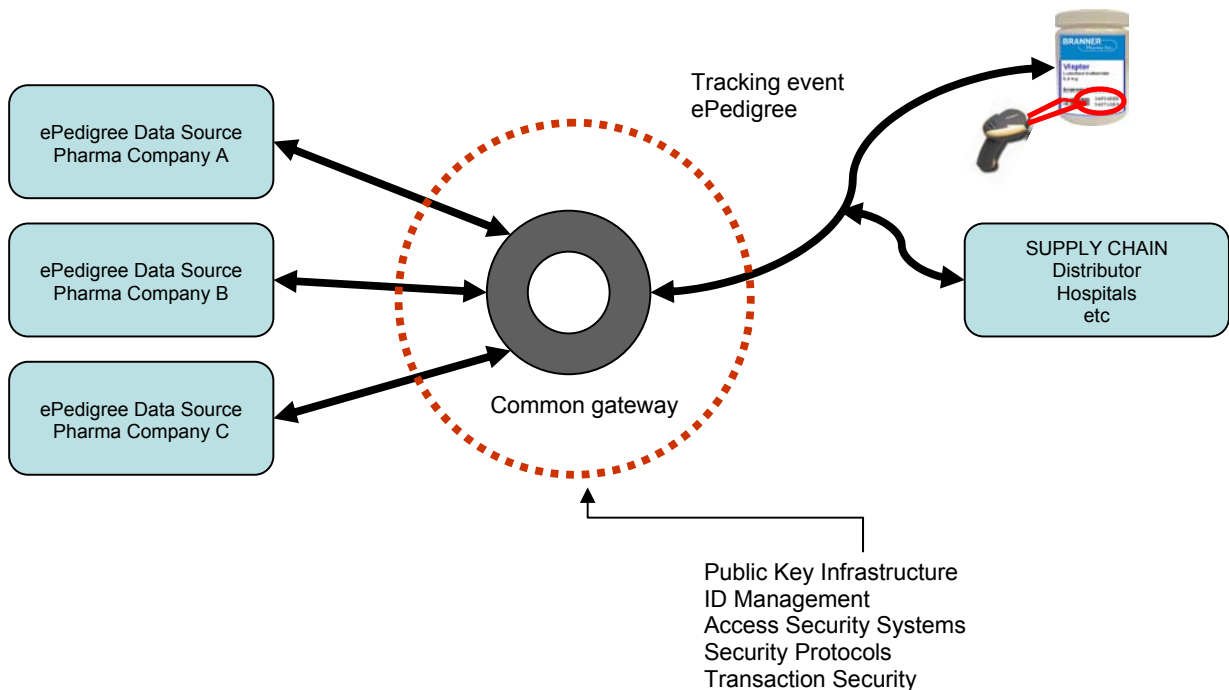
The solution infrastructure for access of the ePedigree common infrastructure should be provided respecting the following key aspects:

Availability, Authentication, Authorization, Confidentiality, Non-repudiation, Integrity.

This infrastructure can be perceived as the _common minimum_ supply chain policy. It gives the manufactures the possibility to collect and give other parties access to data but completely under their _own data control and management regime_

Further the distributed model gives the manufacturers the option to enforce their own internal supply chain policies that are not part of the official mandatory regulations. The data source can also be used for other applications and business processes that are private for the manufacturer. Using a central data base approach to perform these business processes are virtually impossible.

In the section below the term supply chain policy shall generally be understood to mean the rules of engagement for information access and exchange between parties

The efficient enforcement and operation of an industry supply chain policy relies on two or more parties interacting simultaneously so that their individual supply chain policy and appropriate protocols and parameters _combined and additively_ result in a negotiated _transient_ session where all polices are enforced for that given situation. This means that if a second and/or third party fulfils the parameters of the first parties policy, the transaction can be performed. This enables seamless policy-based interaction with all unknown parties for any given situation. This is very similar to the Public Key Infrastructure (PKI) and Identity Management concept. Two prominent advantages with the concept are realized as there is no need to have any prior agreement or approval with any party being a member of the infrastructure to interact, and secondly the members do not need to update or keep track of changing parameters for the other members.

This allows industry and company managed changes in policies (protocols) (even if expected to be relatively infrequent), and parameters that are expected to be changed frequently. Further the internal polices for an organization can be ensured to stay in line supporting the external industry policies.

Is there a difference in costs if the drug product has a unique identifier versus one that does not?

It is _not possible_ to securely track any unit and generate an ePedigree without a unique identifier. By using bar-codes and in-line printing systems the cost of such unique identifiers are expected to be relatively inexpensive and unburdensome.