

**HDMA Response to Key Food and Drug Administration (FDA)  
Questions on EPC/RFID  
Anti-Counterfeit Drug Initiative  
Docket No. 2005N-0510, 71 Federal Register 1759 (January 11, 2006)**

*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?*

The FDA should continue its active participation in the industry's standards development process, and should encourage industry efforts to address issues identified in that process. The standards need to be developed and supported by all sectors of the healthcare supply chain. The FDA should actively encourage adoption of the standards once developed.

*What are the current obstacles to widespread adoption of RFID? How can they be overcome?*

There are a number of obstacles to widespread adoption of RFID in the pharmaceutical supply chain. Data management and data sharing issues are significant. Due to these issues HDMA recommends that the industry continue to investigate whether a central data base should be used for pedigrees. The industry needs to come to an agreement on the rules of engagement for data sharing. Progress is being made in this area by HDMA through a study underway in its Healthcare Foundation Research Initiative on "Managing the Elephant in the Room: The Case for Data Sharing."

There are a number of standards that are still under development for the use of RFID and product data. Standards for serialization numbering to be used on RFID tags, item level tagging of products in the pharmaceutical supply chain, the frequency of tag use and pedigree messaging are some of the standards that are in development and need to be completed. Once the standards are developed, the read rates of tagged items will need to be at or near 100% while the products are moving through the supply chain.

Industry and regulators need to develop a coordinated roll-out plan for the tagging of items in the pharmaceutical supply chain. Based on a study completed by the HDMA Healthcare Foundation, HDMA recommends a phased-in approach for tagging pharmaceutical products to include:

- Drugs more likely to be counterfeited
- Drugs with special handling or storage needs
- Products used in the hospital environment

During this phased-in approach, two sets of processes, technologies and infrastructure will need to be put in place for the limited duration of the roll out. Industry and

regulators would need to continue to work together to agree on standards and a recommended roll-out plan for the industry.

*What is FDA's role in facilitating RFID?*

The FDA should offer guidance in the area of RFID and its possible effects on proteins, biologics and refrigerated products. Additional guidance is needed from FDA in the areas of product labeling and electronic recordkeeping. HDMA continues to believe that RFID holds the most promise for mass serialization in the pharmaceutical supply chain. HDMA believes that 2-D bar codes only serve a role as a redundant technology to RFID tagging. HDMA encourages FDA to support standards setting work conducted by EPCglobal and by participating in the Healthcare and Life Sciences Business Action Group. Additionally, the FDA should develop a public education program on the benefits of how RFID and serialization will help protect the drug supply.

*What is the timetable for widespread adoption of RFID across the supply chain, with and without additional incentives?*

The industry is moving forward with RFID/EPC implementation in terms of the development of standards and the number of companies currently engaged in RFID pilots. There are a number of issues that have been identified previously and will be addressed as part of pilot studies, industry studies such as the HMDA Foundation study on data management and data sharing is one example of research in this area. The industry will be in a stronger position to draw conclusions as more information is gathered and analyzed. These issues need to be resolved before standards can be developed and incorporated in software products and business processes.

*Who should set the RFID standards?*

The standards should be a collaborative effort of industry, associations, regulators and solution providers participating at standards setting bodies.

*Is there a role for Federal leadership by FDA to advance the standard setting efforts?*

HDMA encourages the FDA to support standards setting work conducted by EPCglobal by to continue participation in the Healthcare and Life Sciences Business Action Group. Uniform standards for electronic pedigree and technology are critical. As part of the work at EPCglobal, the FDA could have input on business practices such as the appropriate use of inference in the reading of tags in the supply chain. The intent is to allow efficiencies in the supply chain processes, while allowing track and trace to remain intact.

*Is there a role for other Federal entities?*

Guidance is needed from the DEA on the numbering scheme with respect to any existing regulations as industry begins tagging of controlled substances.

*Should standards remain voluntary?*

Yes. Standards development bodies should include an open and equitable process allowing for widespread industry support and participation.

*What mass serialization numbering conventions are being used/considered?*

EPCglobal has developed a serialization working group. This group's goal is to create a recommendation for the numbering standard to be used on the RFID tag in the healthcare supply chain. This process has made great progress this year. The group is considering conventions that would identify the manufacturer and a unique item serial number or using the NDC and a unique item serial number.

*Should there be a single numbering convention only?*

Yes. If multiple numbering conventions are permitted, system complexities would increase as well as the possibilities of errors (operations/logistics).

*Should the national drug code (NDC) be part of the unique identifier? What privacy issues does the NDC raise?*

As part of the work in the EPCglobal Healthcare and Life Sciences serialization working group the use of NDC as part of the unique identifier is being evaluated. The use of NDC raises patient privacy concerns for patients undergoing specialized treatments in areas such as HIV and oncology. Potential security concerns associated with the use of the NDC have also been raised.

*What is the timetable for widespread mass serialization? With and without additional incentives?*

Based on industry supported data, a phased in approach for tagging products meeting specific criteria is highly desirable. HDMA, through a study conducted by the HDMA Healthcare Foundation, recommends a phased-in approach for tagging pharmaceutical products to include:

- Drugs more likely to be counterfeited
- Drugs with special handling or storage needs
- Products used in the hospital environment.

This approach seems to be the most appropriate approach toward industry roll-out of mass serialization.

*What is the status of e-pedigree solutions across the drug supply chain?*

E-pedigrees are not a standard requirement in states' pedigree legislation. Distributors believe the solution to counterfeit activity revolves around tightening the supply chain.

However, in order to comply with the varying pedigree laws in the most efficient manner possible, distributors are investing in e-pedigree solutions.

First, we want to be sure that we all have a consistent interpretation of what is meant by “e-pedigree.” An e-pedigree, or electronic pedigree, is an electronic business transaction containing specific detailed information about a product(s) chain of custody. A “pedigree” refers to the documentation required by regulators/agencies regarding a product’s chain of custody history from point-of-manufacture to point-of-dispensing. Distributors are making every effort to meet regulatory requirements by working on an electronic pedigrees. However, there are issues that need to be addressed in order to efficiently utilize e-pedigrees:

- Unique product identification is not utilized due to a lack of availability of the technology standards;
- State pedigree deadlines are ahead of the standards-making process necessary to produce supply-chain interoperability between vendor e-pedigree software. As a result, there is a risk of e-pedigree document incompatibilities that would inhibit the normal and proper movement of pharmaceuticals through the supply chain. Messaging standards are under development but are not currently available;
- Utilizing the NDC, lot number, and expiration date do not provide sufficient granularity to uniquely identify the product at the item level—mass serialization would be required;
- There is no uniform standard of data required to meet state pedigree regulations. The industry needs one uniform standard across all states. unique product identification is not utilized due to the current lack of standards and the use of multiple and incompatible technologies.

*To what extent are stakeholders using e-pedigree?*

Distributors have made significant investments and continue to focus on identifying and implementing required business modifications to support the use of e-pedigree where required by law. Distributors are now in the initial phases of implementing e-pedigree solutions in order to meet state regulatory requirements such as those of Florida and California.

HDMA hosted a meeting in the summer of 2005 with several industry stakeholders including manufacturers, distributors, retailers, standards development organizations, boards of pharmacy and regulatory agency participants. The focus of the meeting was to develop model requirements for pedigree regulations. Significant progress has been made in the development of an e-pedigree messaging requirement to comply with existing regulations. The group will be meeting again to review EPCglobal pedigree messaging standard and progress on issues such as use of NDC, mass serialization, and drop shipments.

*When is it expected to be used?*

The e-pedigree interim measures are first expected to be used in certain states. For example, Florida's law contains a pedigree implementation date of July 1, 2006 which presents several challenges to distributors including data capture at the point of receipt and shipment, inventory management processing, manual intervention and additional quality control processes. Distributors are making every effort to comply. However, the implementation barriers such as data management/sharing issues, interoperability of software solutions, and mass serialization will continue to exist beyond the implementation date.

*What is the experience to date of interoperable e-pedigree solutions across the drug supply chain?*

We do not believe that HDMA is the appropriate entity to answer this question. Accenture the project manager of the industry proof of concept pilot, Project Jumpstart Cap Gemini, project lead for the Drug Security Network pilot or other groups/industry analysts such as Forrester and Gartner would be better positioned to address this question. To the best of our knowledge most pedigree pilots have been in a closed loop system, thus avoiding interoperability issues.

*What is the feasibility of a paper and e-pedigree system co-existing across the drug supply chain?*

HDMA has always believed that a fully electronic pedigree solution with unique product identification is the most promising solution to combat counterfeit products in the healthcare supply chain. Paper pedigrees have been forged in previous domestic counterfeiting situations and are an inefficient and costly answer to a larger problem. Paper pedigrees *essentially halt* the efficient distribution of drugs given the volume of products delivered and the sophisticated automation technology utilized to do so safely and efficiently.

*Can the authenticity and validity of the pedigree be maintained in such a system? How?*

HDMA has always been a proponent of electronic pedigree in combination with unique product identification and that RFID holds the most promise to enable unique product identification in the pharmaceutical supply chain. Unique product identification, such as mass serialization, is a way to ensure the electronic pedigree identifies each item and its chain of custody. HDMA believes that with EPC/RFID and electronic pedigree the authenticity and validity of the pedigree will be able to be maintained.

*What capabilities would be needed?*

For an electronic pedigree system in combination with unique product identification, industry standards which are currently under development need to be completed and implemented in systems across the supply chain (manufacturer, distributor, point of

dispensing). Products would need to be tagged at the point of manufacture with EPC/RFID tags and each point in the supply chain would need to implement equipment to read the tags. Infrastructure and systems would need to be developed to handle the information. The time and cost to achieve this is significant.

*How much will an e-pedigree system cost?*

E-pedigree software cost will vary by software vendors. Significant additional costs would be incurred for the following:

- New computers necessary to execute the E-pedigree software
- New database software and storage systems to hold pedigrees
- New or upgraded network infrastructure to accommodate the increased throughput requirements to construct and maintain pedigrees
- Integration of the e-Pedigree software into existing systems
- Modification of business processes and their associated system changes to create, track and maintain pedigrees
- Changes and upgrades to e-commerce software and hardware to accommodate the exchange of pedigree documents with trading partners.

*How much will a paper pedigree system cost? What infrastructure is needed?*

HDMA does not support the implementation of paper pedigrees.

*What is the difference in costs if the drug product has a unique identifier versus one that does not?*

HDMA is still evaluating costs, and the ability to determine the difference between costs with or without the unique identifier has yet to be determined. However, it should be very clear that regardless of costs, a unique identifier is imperative if the system is going to work as intended.

*What is the timetable for widespread adoption of e-pedigree across the drug supply chain, with and without additional incentives?*

This is dependent on the availability of standards, including a national unified pedigree as well as the industry developing a consistent roll-out plan for the tagging of products and the implementation of readers, infrastructure and systems. A timetable cannot be developed because we are still determining how to prepare e-pedigrees. In all likelihood, there will be unforeseen problems that may require months, or longer, to identify.

*Are there logistical barriers to passing a pedigree for a drug that moves from State to State with different pedigree requirements?*

Paper pedigree isn't supported by HDMA and its members. States have different requirements for pedigrees, including differing requirements for which entity or entities

must initiate and/or provide a pedigree and information to be contained on the pedigree. Different state requirements are extremely burdensome to the industry, increasing the complexity and opportunities for error. Different state requirements could prevent distribution of a product that doesn't comply with that state's regulations. Emergency situations that require mass movement of product among states in a short period of time is an example of when problems could occur.

*Would a universal pedigree help?*

Yes, one universal pedigree, harmonized across all states should be required. However, it is essential that industry and government collaborate to develop the requirements of the universal pedigree.

*What common fields/information are the most important in a pedigree?*

A "pedigree" refers to the documentation to produce a product's chain of custody history from point-of-manufacture to point-of-dispensing. An e-pedigree, or electronic pedigree, is an electronic business transaction containing specific detailed information about a product(s) chain of custody. Below are the data elements we believe are most important in a pedigree:

- Legend Drug Name
- Strength
- Dosage Form
- Container Size
- Manufacturer
- Quantity
- Invoice quantity, date
- Sold to name, address
- Ship to name, address
- Purchase date and invoice number
- Recipient name

Although many states have specified additional information that they require for inclusion on paper or e-pedigrees, we believe that much of that information will have little or no value for recording the transaction history of the product, particularly once an RFID system is in place. Further, the more data that are required, the longer it will take to complete standards and the more complex maintaining the RFID system will be. Should we reach agreement on moving forward with a nationwide standard for pedigree requirements, HDMA encourages revision of the actual pedigree data in this light.

*How can a universal pedigree be achieved?*

Universal pedigree can be achieved by collaboration among industry and government to develop the appropriate requirements. Criteria needed to develop for an electronic

solution working with appropriate solution providers and standards bodies. Promotion of the use of the universal pedigree across the supply chain, the states all other stakeholders needs to occur.

*If there is to be a central database, who should host it?*

At the current time, industry seems to be moving towards a decentralized data model. There a number of issues that would need to be resolved before a central database could be implemented. One significant issue is the rules of engagement for access to the data. The industry needs to come to an agreement on the rules of engagement for utilizing a central database. Progress is being done in this area by HDMA through its Healthcare Foundation Research Initiative on “Managing the Elephant in the Room: The Case for Data Sharing”. The initiative has three separate phases. Phase I will conclude by September of '06 with the intent to have the entire project completed by the 4<sup>th</sup> quarter of 2007.

*If not extended, would the rule ensure an effective track and trace capability to combat drug counterfeiting? If not, why?*

HDMA continues to believe that a system incorporating item level mass serialization utilizing radio frequency identification and electronic product codes (RFID/EPC) provides the most effective track and trace capability to continually secure the healthcare supply chain. Item level mass serialization would need to be rolled-out across the supply chain to truly have effective track and trace capability.

*Although the Federal Register notice did not touch on implementation steps within warehouses once RFID is available, HDMA would like to offer the following information for the FDA's consideration.*

Once mass serialization, standards, and other developmental processes are completed, distributors would need to take many steps, including the following, to implement RFID within their warehouses:

- Evaluate, purchase, and test new computers to execute the RFID software
- Purchase or develop new database software and storage systems to hold pedigree information
- Create new or upgraded network infrastructure to accommodate the increased throughput requirements
- Integrate the RFID software into existing systems
- Modify business processes and their associated system changes to create, track, and maintain pedigrees
- Change and upgrade to e-commerce software and hardware to accommodate the exchange of pedigree documents with trading partners.

It should also be noted that most of the additional steps referenced above cannot take place concurrently with the development of other RFID features. It is only after standards are set and RFID is widely available, that distributors can begin to assess and carry the changes that will be needed to effectively implement RFID within their warehouses. Such implementation efforts may include purchasing equipment compatible with final RFID standards, determining how best to reconfigure warehouses, train staff, and execute other business and process changes that RFID will require. In other words, we cannot just “flip the switch” and start implementation as soon as the tags are on the drugs. This conversion will need careful planning and execution over a reasonable transition time frame if distribution centers are to implement an RFID system and assure its accuracy, while continuing the timely distribution of products to dispensers and their patients.