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*Stora Enso Packaging Boards*  
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Food and Drug Administration  
Counterfeit Drug Task Force  
5630 Fisher's Lane, Room 1061  
Rockville, MD 20852  
USA

Dear Ladies and Sirs

Following your invitation for comments regarding the FDA Anti-counterfeit drug initiative, StoraEnso would like to share and present our efforts and developments related to supply chain solutions geared toward the Healthcare industry. Stora Enso has developed and is currently piloting an innovative brand protection and authentication solution which is branded PackAgent, providing advanced security against counterfeiting and diversion. The application is aimed toward manufacturers, folding carton suppliers, contract manufacturers, wholesalers, retailers, and consumers. While it is important to secure the authenticity of prescription drugs at counterfeit risk, the software can be equally used for any other serialized products in Life Sciences and Healthcare as well as other serialized products at risk to be counterfeited. It is currently piloted in real production and distribution environment involving a pharmaceutical manufacturer, converter, distributors, and pharmacies. The companies participating in the pilot will publish their pilot activities at the End of February by a press release.

When creating and designing the functionality of the PackAgent we have taken into account the following opinions and statements:

- 2D barcodes versus RFID for serialization

RFID enables automatized reading and such it offers reliable and time-efficient registration opportunities in logistics processes. But the automatized reading opportunity is dependant on factors like the radiation absorption by the product. Under the right circumstances RFID is superior to optical scanning of barcodes, for example. Possible limitations for the usage of RFID are the limited read range which is especially affected by metal and liquids contained in products. The implementation of RFID will also render additional costs both for infrastructure investments and item-costs for tagging. There are also concerns about the recyclability of packages in case they have RFID tags attached. PackAgent is unique in its flexibility in handling various Auto-ID technologies such as barcodes and RFID. The ID technology can be chosen freely for each product

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and packaging level. Examples of levels for ID applications: unit-dose pill, blister package, item level package, bundle case, transport box, pallet, container, transport vessel.

This offers the opportunity to use RFID in shipping and warehouse operations and, for example, 2-dimensional barcodes on item-level. PackAgent can also use the identification means as a security layer itself, so that an alert is triggered in case a number should be provided by an RFID tag but is read from a barcode, or vice versa.

The flexible ID approach of PackAgent supports automatic reading and supply chain streamlining by use of RFID on transport case level while it also allows a cost-efficient usage of serialized barcodes on item-level.

The usage of 2-dimensional barcodes would also easily overcome the concerns regarding privacy and possible unauthorized reading of products in the possession of consumers.

Depending on the length of the unique codes, possibly even 1-dimensional barcodes might be applied on packages.

We pled that the usage of serialized 2-dimensional barcodes will be made mandatory for item-level products which are in the scope of the drug pedigree mandate, while the usage of RFID in supply chain logistics is recommended.

- Authentication through ID verification or pedigree statement

Authentication of a product is done by verifying that a certain ID has been issued by a manufacturer and that it is currently existent in the market. Further comparison of product data with retrieved database data is possible -provided that this information is made accessible by the manufacturer. Further product data could be: product name, NDC, batch number, geographical market area, expiry date, etc. Further information about security features can be shared too in order to educate the person performing the authentication about the specifics of security features.

PackAgent is also providing a pedigree statement in electronic form where the involved parties, the product ID, and the transactions are verified and the pedigree statement is signed digitally by the authenticating party. Once a pedigree standard is established, PackAgent will comply with this standard. We are a member of EPC drug pedigree workgroup.

- Centralized database versus distributed database

PackAgent is based on the concept of a distributed database where each information generator maintains and controls access to their own information. In this way, the duplication of data is minimized and the information owners can explicitly grant or deny access to certain information. The access to information is defined by profiles created and maintained by the database owners. Information is exchanged peer-to-peer after a secured hand-shaking procedure for identification of communicating parties.

- Real-time address management for ID information providers

In order to find other parties having information regarding a certain ID, an internet-based communication protocol (WWAI protocol, patent pending) is used. The addresses are retrieved via a distributed search on internet. PackAgent is independent of the use of an object name server to look up the IP addresses of information providers. Neither it is necessary that all supply chain parties are pre-determined or pre-registered as information providers to the requester. It is

sufficient that PackAgent is activated on the servers which contain supply chain or product information for a certain ID in order to establish the contact. The contact is established by use of a secured handshaking procedure prior to the information exchange.

Since each reading of a serial number also represents a certain business process, it is theoretically possible that it can be re-analyzed as business information revealing certain amounts of goods which have passed along certain supply chain channels. Usage of a distributed address management and peer-to-peer information exchange does not allow for any party to reconstruct the total business flow unless the information owners explicitly permit this. In this way also the indirect business information is protected against business intelligence by third parties.

- Authentication performed by wholesalers, or retailers, or consumers  
PackAgent allows the authentication for any authentication checking party, provided that the brand owner is granting access to that information for the requesting party. PackAgent is also providing the opportunity to access a web-based interface where consumers can anonymously enter a product ID for authentication check. In this way, the consumers themselves can check the authenticity; they do not need to rely on the retailers' accurate authentication performance. This would then also allow consumers to check the authenticity of products delivered by internet pharmacies. Internet pharmacies do sometimes have a doubtful reputation. Allowing authentication check by consumers might help to clarify any doubts. Otherwise consumers have to rely on that an authenticity check has been performed even if they are not present at the moment of authentication check.

A service for SMS-based requests will be enabled, too.

- Global standards versus geographical confined standards  
Pharmaceutical supply chain is global and pharmaceutical products may be imported and exported via several countries before reaching its final distribution at the retailer. It would be a very difficult situation in case mandatory requirements for pedigree would be contradictory in different regions.

We pled that FDA will coordinate its regulating efforts for supply chain tracking and marking of drugs with corresponding offices in other regions to avoid contradictory regulations.

For RFID, we already know that there will not be a common standard for UHF in Europe, USA, and Asia. The allocated frequency bands are deviating and also the maximum power allowed for the reading process is differing. This strongly affects the reading performance so that the aimed automation in tracking of goods might be challenged. This issue is not in the hands of FDA to be solved but it should be kept in mind when assessing the technology feasibility.

- EPC as serialized code  
EPC is a well-suitable code for serialization. We believe that the industry partners will be able to establish a common coding system without mandating it. Creation of a monopolistic standard might have deteriorating effects.  
It is also important to distinguish between the EPC as a coding standard and the EPCglobal as a system for finding server addresses. The principal approach of the EPC global system is the use of an object name server for finding addresses and connecting to information providers. Any server that has information

regarding certain EPC will register its address to the ONS and can be looked up by requesting parties.

There is alternative ways available for localizing information providers. The WWAI protocol used in our PackAgent software would offer the users a lower risk of reverse business intelligence.

We support the EPC as a coding system but manufacturers should not be made dependant on sharing information in a way they are not comfortable with.

In addition, companies have currently to join as a member of EPCglobal in order to allocate EPC manager numbers. The fees related to this are not service-based but dependant on global group revenues of the companies which would establish a peculiar business situation in case the EPC would be mandated as a coding standard in the US.

- Additional Features

The validation of the pedigree and the verification of the ID issued by the manufacturer are considered to be secure protection against counterfeiting, especially when combined with additional security layers. Additional benefits arising from the use of a tracking and authentication system are:

- A recall can be issued on item-level. A recall message can be pushed forward to the current owners of the items or it can be passively fed to the system that the information will appear after the next reading event.
- Additional information can be provided to support various language alternatives for warning texts, medication information etc.
- Application of serialized ID (digital printing/laser marking on packages or labels)

Barcodes can be applied on labels which are attached to the packages, but it can also be written directly on the packaging material by digital printing or laser-marking technologies. These printed or written codes could not be rubbed off or released from the package. For laser-marking, the board used as package material will have to contain certain agents which itself could be an additional security feature.

Key take-away:

- For ePedigree, 2D barcodes are a cost-effective way for item-level serialization.
- ID verification provides Authentication, especially in case the information is used in combination with product information data
- A distributed database offers higher protection of information regarding business processes
- A distributed communication protocol for address management allows real-time identification to information providers without usage of an object name server.
- Consumers do have the option to verify an ID themselves, in addition to authenticity checks by supply chain parties.
- Global standards or globally coordinated regulations are recommended.
- EPC is well-suited as code for serialization, but it should be left to the industry to establish their standard.

We believe that our PackAgent authentication solution has addressed and solved the concerns presented in the FDA's Counterfeit Drug Task Force Interim Report when offering a software-based solution for verification of serialized IDs and providing an electronic pedigree.

We would welcome and appreciate any comments or on this subject and are available for further discussions. In case of any further questions, please do not hesitate to contact us.

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Best regards,

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