efpia
European Federation of Pharmaceutical Industries and Associations

Mass Serialisation and e-Pedigree - Its effects on the supply chain

EFPIA Discussion Document

Much is currently being discussed about the merits and de-merits of mass serialisation of medications. However, what is not currently clear is how all the 'much talked about capabilities' are realised and what effects these 'capabilities' have on the various medications supply chain partners.

In the final analysis, mass serialisation is one technique for providing increased patient safety (when used in conjunction with healthcare products). There are other means of achieving the same objectives some with less reliability and many with more cost. One such scheme is the much debated 'pedigree' scheme proposed and used in the US. While this has the potential to assist with tighter control of the supply chain, it is far from ideal in either ICT terms or in terms of physical product identification. (product remains identified at batch level only). Mass serialisation however provides the capability to not only identify individual packs but to provide multiple opportunities to check and verify product. The more times we check and verify the product, the more we tighten the control on the supply chain and thus, the more we improve patient safety. Mass serialisation enables track and trace technology, enable instant product recall notification and allows for dispensing errors to be cut dramatically (in theory to zero) by enabling product to be checked prior to administration. All of this depends on mass serialisation as a first and important step towards increased patient safety. Without the individual serialisation of the product, most of these concepts are difficult or impossible to practically achieve.

Pack Serialisation (sometimes referred to as 'partial mapping')

This is the first and critical step.

Mass serialisation of unit of use medications involves the following:

- The equipping of production lines with real-time in-line coding equipment to mark each pack with a code (currently expected to be a DataMatrix code)
- The equipping of the production lines with vision equipment to check the readability or perhaps quality of the code printed on the pack
- The equipping of the production lines with software systems to supply completely unique (guaranteed to be unique) product codes (e.g. GTIN, Serial Number, Expiry and Batch) to each pack as required during manufacture
- Linkage with a database (databases) that will enable each printed code to be checked for uniqueness and status (e.g. the EFPIA PILL)

This will eventually provide a marketplace full of product that is uniquely coded at pack level. This in turn provides the ability to check that the code applied on the pack indicates that pack to be 'known/unknown', 'unused/used', 'on recall/not on recall' etc.

Cases of product will have no indication upon them as to the packs contained within (other than knowledge of the product type, expiry, batch and number in the case) thus it is not possible to track product within the supply chain when the product is grouped in multiples (e.g. cases/pallets etc)

The supply chain partners have no visibility of specific packs at any time. The only time that unique pack codes can be checked/located/verified etc is when they are individual packs and the codes are available to scan. Only then can we address the issues of pack validity, dispensing, product recall, administration error etc.

There is no way of knowing which packs are contained within specific shipments and therefore, with a mass serialisation system as described, any database system used for pack verification etc, will have to be updated at the point of pack manufacture and not the point of pack shipment.

Mass serialisation of this nature allows for relatively easy identification, and verification, of pack level items from the point of manufacture to the point of dispensing. Mass serialisation of this nature thus allows for a significant increase in patient safety through the ability to verify the product being dispensed for both 'validity' and 'accuracy' thus significantly reducing the ability to dispense counterfeit or problematic product and significantly reduce the potential for medication error (wrong medication dispensed). Mass serialisation of this nature also allows extremely accurate product recall processes to be implemented which in turn would increase the % of product capture during a recall process and should also ensure that no product subject to a recall can be dispensed to a patient.

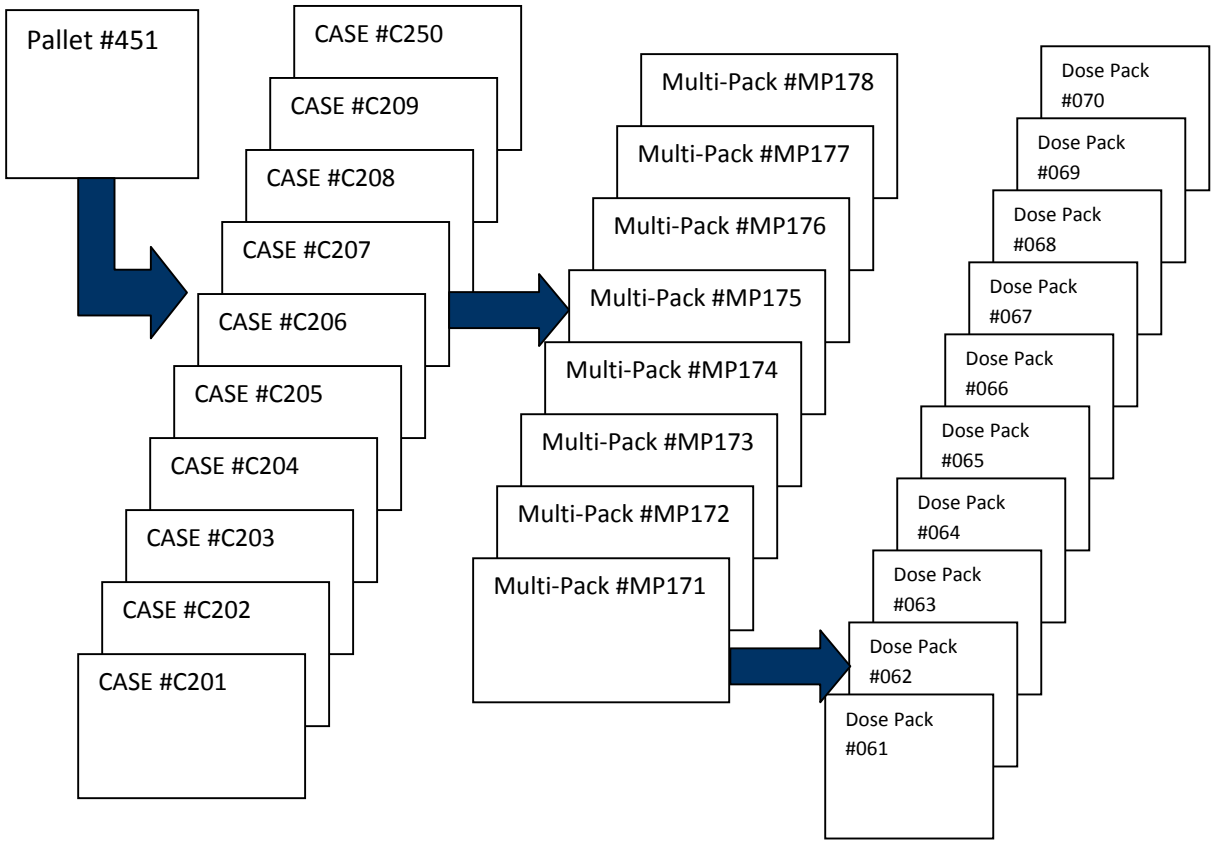
Aggregation (sometimes referred to as 'complete mapping')

The next logical step for full supply chain traceability.

Aggregation is the process by which one associates item serialised code with the code of the container into which they are packed. Thus, pack codes could be associated with the codes of the cases they are packed into and the case codes associated with the pallet code (normally SSCC) onto which they are built. There is no limit to the number of packing levels (packing hierarchy) that aggregation can in theory support, however practically a packing hierarchy of more than six levels would be unusual.

Aggregation allows us to understand which exact items, down to the individual serial number, are packed into any nominated container (e.g. box, case, shipper, pallet)

For example



By way of example only, we can see from the partial view of goods packed on this pallet above that reference to:

- Pallet #451 will reveal fifty cases numbered (#C201 thru #C250).
- Anyone of those fifty case ID's will reveal a further eight Multi-Pack ID's (in our example, case ID #207 has revealed Multi-Pack ID's #MP171 thru #MP178).

- Each Multi-Pack will reveal the presence of ten Dose Packs (in this example, Multi-Pack #MP171 has revealed that it contains the ten Dose Packs, #061 thru #070 inc.)

Thus this pallet has 4000 unique items packed onto it (50 cases x 8 multi-packs x 10 items). By selecting any container (pallet, case or multi-pack) unique number we can easily find out by working down the packing hierarchy, which specific packs are contained within that container vessel. Likewise, given any unique item code, or sub-container code, we can easily find out by working up the aggregation hierarchy, which pallet/case etc a specific item is packed in.

Aggregation provides the supply chain partners between the manufacturer and the point of final distribution (e.g. the pharmacist) with the ability to understand precisely which items, at a unique pack level, they have within their possession. This allows for highly accurate recall management and also allows for the potential to create what has been referred to as a product pedigree, that is, a detailed understand of each change of custodianship that an item encounters between original shipment (from the manufacturer) and final distribution (to the patient). To be completely clear, building a product pedigree does not require that aggregation be employed, however without it the supply chain partners between manufacture and final distribution point would be required to unpack every container and scan every individual pack item passing through their hands – this is an improbable outcome and at best, exceptionally expensive to achieve.

Aggregation however is considerably harder to achieve at a manufacturing level than the simpler mass serialisation of just packs, and unless the supply chain is able to accept the concept of 'inference'[(1)], offers questionable benefit to the supply chain. To aggregate items during manufacture it is required that each stage of containerisation of the product (e.g. packs into cases, cases into pallets) is monitored by extra vision systems to collate the unique container codes with the unique item codes being packed into it. Theoretically this is a straightforward task, however it is fraught with challenges such as handling and reading items at speed, handling rejects, allowing QA sampling, returns etc) and incurs significant extra expense in terms of vision systems and software complexity. Eventually it may be possible to streamline the process of aggregation by the use of RFID tagging which in theory would allow us to assemble a series of containered items and then read/analyse which unit packs where contained within them. e.g. be able to read all 50 cases code on the pallet and associate them with the pallet code having previously read all 80 pack codes within each case etc. As yet, RFID still has some technical challenges to overcome before it can be used as liberally as this (RFID has a number of application specific and substrate/product substance specific compatibility issues to contend with and thus is not yet as readily usable as the printed code. It should be noted however that when it is able to overcome these issues RFID technology, cost permitting, will be able to offer significant overall benefits to the supply chain).

Using aggregation allows the manufacturer to update any database system used for pack verification at the point the product is shipped. This is because we can identify which unique packs are shipped when a specific pallet or case is shipped.

(1) Inference is the concept of essentially trust that when reading the unique code associated with a container (e.g. pallet, case etc) that it is acceptable to infer the unique contents of that container from the container code via a database enquiry. To minimise the potential for misuse, each container would need to be provided with some form of overt tamper evidence. Also, the database system responsible for building and holding the product tracking history and thus pedigree information can be enhanced with the ability to apply knowledge based rules to container code enquiries. e.g. is a container code is scanned in for receipt at location D but had already been scanned in for receipt at location N without being scanned out for despatch, it is reasonable to assume that something of 'potential interest' has occurred and that at least one of the containers may be dubious. Many more rules and heuristics can be used to help bolster a supply chain when tracking is employed, however without acceptance of the concept of inference, most tracking enhancements of value add is negated.