Counterfeit drugs and product serialisation – standards, opportunities and strategy

by Andrew Love and Stephen McIndoe

Some other serialisation considerations

Reverse and abnormal process flows

It should be noted that reverse product flows and abnormal events can add significant complexity to the design of the business processes and information technology (IT) systems required to manage serialisation. In many implementation projects, the design and implementation of these business processes can take as much, if not more effort than the normal forward flow processes.

Product coding legislation

Product coding legislation requires manufacturers to apply machine-readable codes to product packaging. These codes typically contain information pertaining to the product, batch and expiry information, but no unique identifiers. Whilst this is not serialisation in itself, the solutions that must be implemented to meet these requirements can be significant building blocks for any future serialisation implementation if they are specified and selected appropriately.

Therefore, many organisations choose to manage the response to this product coding legislation together with serialisation to ensure the best long-term solutions are implemented.

The need for standards

It will be evident to you by now that serialisation requires many different stakeholders to receive, create, read, process and transmit information related to serialisation. For this to be achievable within the scope of a particular piece of legislation, standards must be defined and adhered to.

Many would further argue that, in order to avoid unnecessary complexity and cost, these standards should be international. Organisations, such as GS1, are working to achieve this goal.

Opportunities beyond legislative compliance

Whilst the primary objective of many organisations will be to meet the requirements of the emerging serialisation legislation, serialisation presents other opportunities. We have listed a few below, but there may be others within your particular organisation.

Improved compliance and persistence

Linking additional electronic information, tools and services to the coding on the pack allows pharma companies to help patients improve compliance and persistence. One approach to this would be to create a smart phone application which allows a patient to scan the machine readable coding on the pack via the smart phone camera and then not only gain access to product authentication information, but also to additional information and tools to help compliance and persistence.

Clearly, improved compliance and persistence not only leads to benefits for the patient, but also increased sales for the pharma company.

In the last article we talked about the basics of serialisation and the various serialisation models. In this third article in the series, we will discuss some other aspects, the important topic of standards, where serialisation can present opportunities to your organisation and what needs to be done to comply with the legislation.

Reduced impact of recalls

Unfortunately, recalls do occur and their impact on all stakeholders in the supply chain is significant, distracting organisations from their primary objective of providing efficient and effective supply of products to patients. Serialisation, particularly in the track and trace models, provides a number of significant opportunities.

- Identifying the minimum amount of product requiring recall.
- Identifying where all impacted product in the supply chain is located.
- Reducing unnecessary or fraudulent product returns.

Patient information

At the same time as providing useful additional services to the patient, pharma companies have the opportunity to gather information about product and patient use. This information is very valuable to pharma companies to help them ensure that their activities are targeted correctly.

More effective returns reimbursement

The models for payment of pharma products are complex in many supply chains, often involving many discount and rebate schemes. This, in turn, leads to a difficulty for pharma companies in knowing exactly how much to reimburse for returned product. Product serialisation, particularly in the track and trace models, offers the opportunity to significantly

improve the ability of pharma companies to reimburse the correct amount to the correct parties when product is returned for whatever reason.

Improved supply chain effectiveness

From a supply chain perspective, particularly in track and trace models, serialisation capabilities can be harnessed to provide improved supply chain visibility, leading to the following.

- Improved customer service, by ensuring the right product is in the right place at the right time.
- Improved efficiencies through such things as improved stock management.
- Improved supply chain design, through a better understanding of the actual product flows.

Impacts of serialisation

Serialisation legislation will require new capabilities to be implemented across many different functions of a typical company. The more obvious impacts include the following.

- **Packaging operations**, where serialisation will have to be applied to product packaging at one or more levels.
- In the more complex serialisation models, this operational impact will extend into the **distribution operations** in central and/or local markets, where information on individual sale and shipment transactions needs to be gathered and added to the serialisation information.
- Particularly in the more complex track and trace models, significant **IT capabilities** will be required to manage serial numbers and track information related to the product and its movement.

However, the impacts go beyond these. Below we list some of these additional impacts.

Commercial

- New customer support processes.
- New supply interruption risks.

Supply chain

- Modified supply routes.
- New data management processes.

Quality assurance and control

- New quality assurance requirements internally and externally.
- New processes and tools.

Procurement

- Additional third party packaging supplier requirements.
- New equipment and service provider management.

Legal

- New and extended liabilities.
- Complex legal interpretation of legislation.

Regulatory affairs

- New regulator relationships.
- Monitoring and influencing technically complex emerging legislation.

Corporate

- New business risk management.
- New governance.

Research and development

- New product design implications.

All these impacts need to be considered and the appropriate solutions put in place. Given that these impacts affect many different functions and third parties, there is a high risk that solutions will not work well together unless the design of the overall solution is carefully managed and governed.

What needs to be done?

Companies are faced with several specific issues when managing serialisation-related legislation, these include the following.

Identifying and interpreting the emerging and evolving legislation

Serialisation legislation, particularly in its early iterations, tends to be somewhat vague, incomplete and sometimes contradictory. Interpreting the legislation and predicting its impacts can present significant challenges, requiring specific serialisation knowledge as well as new legislative relationships with local legislators.

This is further compounded when considering the timelines allowed in the legislation. History has shown that timelines are often vague and subject to change. However, when implementation dates are finally set, they often do not allow enough time for robust implementation.

Given the uncertainties in requirements and timings, organisations need to ensure that there is a clear way of communicating their considered view of the legislative

requirements at any particular moment. Failing to do this will potentially result in individual functions or groups creating their own interpretations, which at minimum is wasteful of resources, but at worst results in capabilities being implemented which do not meet the eventual requirements of the legislation.

Understanding the full impact of these multiple pieces of legislation on the company and product supply chain

We have already discussed the potentially broad impact of the legislation on a typical organisation. It is important to engage all of the potentially impacted parties early in the impact assessment phase to ensure that comprehensive solutions can be defined.

A further challenge is that the multiple pieces of evolving legislation will often impact many of the same capabilities. Understanding these potential impacts and their likely evolution over time is key to ensuring effective solutions are defined and implemented in a timely manner.

Defining optimal solutions and implementation plans which strike the optimal balance between ensuring product supply and the caution that is prudent with this evolving legislation

There are often a number of supply chain configuration and technical options that can be brought to bear to deal with particular serialisation legislative requirements. Short-term tactical options have to be weighed against longer term strategic solutions.

Defining the timing of implementation plans, to a large extent, needs to be considered hand-in-hand with the solutions themselves. One risk that also needs to be considered is that of the "last minute rush" or "Y2K effect". By this, we mean the risk that, as so often is the case with this type of legislation, everyone waits until the last minute to implement solutions, only to find that the supply base cannot cope with the peak in demand, driving up costs and forcing companies into non-compliance.

Understanding the immature and evolving solution supply base and selecting appropriate implementation partners

Serialisation legislation is relatively new to the pharmaceutical industry, and, therefore, the solutions available from the supply base are correspondingly immature and, in many cases, evolving. Supplier selection will often be the start of a very long relationship, as solutions that are initially implemented will need to be supported and adapted to new requirements over time. There have already been several examples of suppliers that have come and gone as legislation has evolved or been delayed. Understanding the supply base and choosing the most appropriate suppliers will be critical to long-term success.

Defining complete requirements covering all aspects of the solution's lifecycle and then realistically judging the supplier's ability to meet these requirements also presents challenges.

Resourcing implementation projects with sufficient serialisation-specific knowledge to minimise the risk of wasted resources, delays and implementation failure

The specific challenge during the design, build, test and implementation phases of solution projects is to resource them with sufficient serialisation subject matter skills and knowledge to avoid common pitfalls, reduce wasted effort and the risks of delay and solution failure. Organisations need to plan for these resource requirements and build sufficient capabilities internally and secure access to sufficient external resources where appropriate.

Cross-functional governance

Given the cross-functional and cross-organisational nature of the impact of serialisation legislation, coupled with the significant product supply risk it presents, many organisations establish a cross-functional governance team to ensure the following.

- Decision making is taken with all impacted parties, at the right levels in each of the organisations involved.
- A "Target Response" is defined that specifies what the organisation must achieve and by when, given the current state of legislation and the organisation's considered view of how and when capabilities will be required.
- Changes to the Target Response are carefully managed and cascaded to all impacted groups.
- Appropriate cross-functional and cross-organisational resources are mobilised to address the issues in a coordinated and timely manner.
- Timely approval and funding of the program of activities is achieved.
- Progress, priorities, risks and issues are managed in an optimal way for the organisation as a whole.

Where to start

It is highly likely that one or more parts of your organisation are already working on this issue, perhaps in a coordinated

way, perhaps not. Initially, we would recommend continuing this work until the appropriate course of action has been decided. We would recommend a small and focused piece of work which has the following objectives.

- Understand the issue as it relates to your business.
- Understand the likely impact across your organisation.
- Identify, educate and mobilise an effective cross-functional governance team.
- Establish an effective legislative monitoring capability.
- Define an initial "Target Response".
- Define a plan of action.
- Identify any initiatives that are currently under way and define how they should proceed.
- Understand the high level budgetary implications.

From here, a programme of activity can be managed by the governance team to effectively manage the legislative risk.

Summary

From all of the above, there are some key learnings that should be borne in mind when defining your serialisation strategy.

- Recognise the significant supply risk and manage it accordingly, establishing senior cross-functional governance early.
- Mobilise your regulatory, legal and technical teams to establish effective access to, and interpretation of, the emerging legislative and technical standards.
- Actively interpret the evolving requirements and standards for the organisation using tools such as the 'Target Response'.
- Establish a programme of activity to build organisational and extended supply chain capability.
- Be realistic about the emerging nature of these capabilities and build in adequate time and resource to effectively test and iterate solutions.
- Design serialisation activities to closely couple related actions to minimise the possibility for errors due to abnormal events.
- Design both the normal processes and the regularly occurring non-standard events to avoid product supply quickly grinding to a halt.
- Ensure cross-functional teams are established to carefully design the interfaces between departmental and organisational boundaries.
- Ensure adequate time is allowed for packaging design changes to be made to accommodate serialisation features required.
- Be cautious about suppliers who have little practical experience in this area.

This concludes the third article on serialisation. In our next article, we will look at some of the learnings we have had from the numerous serialisation projects we have been involved in.

Stephen McIndoe is a Vice President at Be4ward and works with global healthcare companies to create award-winning world class packaging labelling and artwork capabilities. He is also co-author, with his colleague Andrew Love, of the book ***Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities.***

Andrew Love is also a Vice President at Be4ward. He was previously Head of Global Packaging Design at GlaxoSmithKline.