

**MASS SERIALISATION IN THE EUROPEAN
PHARMACEUTICAL INDUSTRY**

F R O S T  S U L L I V A N

***Working Together on Mass Serialisation:
Whose Responsibility is Ensuring Patient Safety?***

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Executive summary

International cooperation is required to tackle the explosion in unscrupulous traders who peddle fake medicines, with no regard for patient safety. Counterfeit drugs sold have been reported to harm patients either through therapeutic inadequacy, the build-up of resistance or through direct toxicity, which may even be fatal.ⁱ

It is estimated that the counterfeit drug trade is responsible for 10% ⁱⁱof the global medicine supply. There is no doubt that the presence of counterfeit drugs in the market poses a real threat to the health and well-being of patients.

There are a variety of approaches that can be taken to help secure the supply of medicines to patients. This paper discusses these approaches in some detail. It also examines why if approaches are available and so much is at stake there is still not enough decisive action being taken by the players in the industry to harness the problem.

The report reveals, that it is mass serialisation, a method by which a unique number is assigned to each saleable unit (pallet, case or individual package of drugs) that can provide the foundation for a workable solution to help combat the trade in counterfeit drugs. The application of the mass serialisation technology unlocks the key to authentication processes that can validate drugs at critical points in the pharmaceutical supply chain – which can often involve more than 20 stages – enabling assurance of product quality before dispensing and the opportunity to identify sources within the supply chain where counterfeits may have leaked in.

This process of serialisation has already been adopted in many other industry sectors, such as food and beverages, timber, and alcohol. A particularly important application is in the control, supply and distribution of pharmaceuticals.

Non-governmental organisations, such as the WHO and the European Federation of Pharmaceutical Industries and Associations (EFPIA)ⁱⁱⁱ are working actively to encourage adoption of mass serialisation. Frost and Sullivan finds however, that just a handful of European countries have fully implemented mass serialisation programmes and others are at various stages of the planning process.

As the issues associated with counterfeit medicines has a negative effect on a global scale for all involved in the supply chain a collective push towards a solution with tangible benefits for patient safety is urgently needed. And whilst the national schemes already in place should be praised, the effectiveness of mass serialisation as an anti-counterfeiting measure will be limited if it is confined to just a few countries and individual stakeholders.

Overall, Frost & Sullivan have found that there is a direct link between the willingness of governments to legislate and the implementation of mass serialisation programmes. There is a consensus that serialisation is one of the best measures to combat fake drugs.

This paper seeks to uncover the real issues that are prohibiting collective industry action to address counterfeit medicines. Within the paper we take a closer look at the benefits to industry of mass serialisation in addition to its ultimate gain of patient safety, and its uptake across different markets and industries. We also examine, why these benefits are largely unknown when they actually offer a real advantage, whose responsibility patient safety really is, where liability falls and if enough is being done from individual stakeholder point of view.

As the counterfeit drug market expands, and as national health systems become more aware of the financial cost and public health implications, Frost & Sullivan expect that more governments will be driven to legislate. Where legal responsibility for patient safety rests with all the participants in the pharmaceutical supply chain, there is a greater willingness to install systems that improve security of the supply chain.

To date, the goals have been reactionary – to limit revenue loss, and to enable enforcement of anti-counterfeiting laws. This largely ignores the many positive benefits to be gained from mass serialisation schemes, such as a secure supply chain, improved product recall, brand protection, point of sale security, and improved service to pharmacists and patients. With a few notable exceptions, the pharmaceutical industry has been slow to recognise the rewards. Frost & Sullivan believe that drug manufacturers are beginning to realise the potential benefits, both to their revenue and to their corporate image as responsible suppliers of pharmaceuticals.

The costs and time involved in a full global product recall are punishing; but the loss of public confidence in a manufacturers' products is probably even greater. Mass serialisation systems allow manufacturers to recall fake or sub-standard drugs quickly, efficiently and relatively cheaply. Effective mass serialisation systems limit the negative publicity associated with drug scares and minimise the threat of litigation if patients suffer from consumption of fake or unsafe medicines.

It is important to note that best practice examples from other industries (notably the food, automotive and beverage sectors) illustrate that mass serialisation can successfully be deployed cost effectively and to the benefit of all stakeholders.

Although there are financial costs involved in setting up mass serialisation systems, under the right conditions pharmaceutical manufacturers and governments stand to benefit significantly both in terms of the financial protection, returns, and ultimately in a better risk-reward profile, particularly in terms of winning back public trust.

Two approaches that utilise mass serialisation technology are widely discussed within this paper; authentication and track and trace. The advantages of authentication is that it operates only at two points in the supply chain (in and out), making it relatively simple and cost effective to apply and operate. Track and trace (yet to be implemented) has to cope with a validation step at each transfer within the supply chain which could involve up to 20 transactions in some cases.

Frost & Sullivan's research illustrates that the cost of deployment of an authentication solution need not be prohibitive. However, the investment required to implement track-and-trace technologies is estimated at over €400 million per single supply chain amounting to a total €10 billion investment for the European Union, combined with an estimated €500 million for operational costs.

For too long, the question of implementation of mass serialisation schemes has been dominated by discussions about the merits of different technologies and the establishment of standardised approaches. With the availability of universal solutions such as the authentication process currently operating in Belgium and Greece, that can read and interpret different coding systems, this argument can no longer be used to delay adoption of mass serialisation schemes.

This report concludes that while mass serialisation provides an effective and immediately available solution, its impact will not be felt on the global stage if only embraced by individual market participants or at a country level only. In an increasingly globalised world, combined with the proliferation of the Internet, solutions to combat the trade in counterfeits must be globally applied. An element of compulsion and collective action is needed by all market participants to combat drug counterfeiting and drive interest and uptake in patient safety solutions that make use of mass serialisation programmes. The responsibility for this ultimately rests with Governments who have the power to enact legislation.

References

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ⁱⁱ *Plos medicine - The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers* <http://medicine.plosjournals.org/perlserv?request=get-document&doi=10.1371/journal.pmed.0020100>, March 14, 2005, viewed April 23 2008

ⁱⁱⁱ <http://www.lif.se/cs/Compliance%20Officer/Bifogade%20filer/C3EF32C6-595D-4B5F-AA5F-DDB0941413AB.pdf> viewed 23 April