

EFPIA Pilot Coding Project

Introduction

In September, EFPIA launched its coding pilot project, testing a pharmacy-based verification system using a small data-matrix on each medicine pack dispensed. This will run for approximately four months in 25 pharmacies, and will assess more than 100,000 packs. The project uses a two-dimensional barcode, similar to those found on airline boarding passes. This contains a unique product identifier, allowing pharmacists to verify the status of every pack in the pilot at the time of dispensing. Scanning the data matrix code with a simple barcode reader, the pharmacists will also allow to automatically detect the product expiry date and the batch number. This will increase confidence that the product being dispensed is safe.



Background to the EFPIA Pilot

The project is a response to the European Commission's Draft Directive on counterfeiting, aimed at reducing the risks of counterfeit medicines entering the legitimate supply chain. The proposals set out a legal basis for ensuring that safety features are obligatory on packs, allowing them to be authenticated and traced.

The logic of the Commission's proposal is indisputable. Europe's citizens need to be protected from the infiltration of counterfeit medicines, for their own safety as well as to maintain confidence in the legitimate supply chain. Improved identification of medicine packs entering the pharmacy and being dispensed to patients will make a valuable contribution to tackling this threat.

However this cannot wholly eradicate the problem; other measures are also required. To eliminate counterfeits and protect public health means having a comprehensive series of measures. These include harmonised product serialisation, the universal use of safety features and a ban on repackaging.

Ensuring Product Integrity



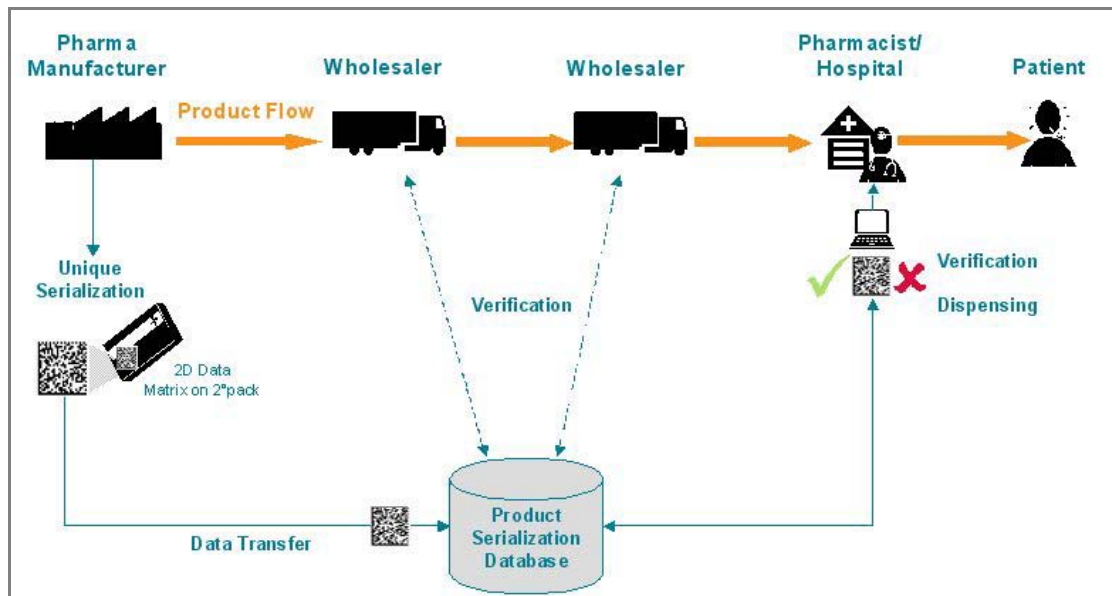
The use of safety features on the packaging, to show the pack has not been opened or tampered with, along with verification at the point of dispensing will ensure pack integrity. Where existing safety features have been removed it becomes easier for counterfeits to enter the supply chain undetected. The simplest method of avoiding this would be a ban on repackaging, as this would help guarantee that the integrity of the original packaging has been preserved throughout the entire distribution chain and the product has not been tampered with. However, to date the Commission does not wish to see such measures. EFPIA strongly believes that, should repackaging be allowed to continue, robust inspection and audits by regulatory authorities are required to ensure that this activity is strictly controlled and scrutinised.

An Optimum Approach to Product Verification

Of the measures proposed, a product verification system at the point of dispense¹ (i.e. Pharmacy or Hospital) offers good scope for improving both supply chain security and patient safety. The Commission has not set out how they envisage traceability working, but there are clear criteria required to ensure success. Paramount is that the system is harmonized and interoperable across Europe. If the free movement of medicines across borders is to

¹ The concept supported by EFPIA consists of individually marking each medicine pack with a unique code at the point of manufacture. This code will be verified in the pharmacy immediately prior to the release of the pack to the patient. This is known as the "Point-of-Dispense (PoD) Verification" concept.

be safe, a coordinated approach to identification and verification is essential. This needs all national coding systems to be interoperable and based on common standards such as those defined by GS1.



This way, any pharmacist in any country can verify whether a pack with the same serial number has been dispensed before, irrespective of its country of origin. Accredited full-line wholesalers would also be able to have the option to access to the database to check the status of the product at any time if in doubt, either before sending a product to the pharmacists or upon return of the product by the pharmacists. Without standardization and interoperability, there is a risk that the national identification and verification systems will be fragmented. This will limit verification of a product's provenance to national product codes and create the problem of identifying counterfeit products crossing borders. With parallel trade accounting for around 10% of all pharmaceutical sales in Europe the ability to verify products that have moved cross-border is essential.

Furthermore, the solution needs to garner the support of all stakeholders by addressing their needs effectively. Imposing high-end or expensive solutions throughout the supply chain is likely to generate resistance. The proposed EFPIA solution is realistic, proportionate and cost-effective. This pilot project encompasses both wholesalers and retail pharmacies in the trial process, and will generate learnings from all actors.

Finally, the solution needs to be timely. The Commission proposals mean that Member States will have to embrace mass serialization, but without setting timelines or guidelines on the appropriate technology. This could create a situation where the numbers of counterfeit medicines in the supply chain continues to increase, while Member States initiate potentially incompatible solutions at different speeds, without addressing the needs for interoperability and standardization.

The EFPIA project will provide proof of concept; a system using proven technology that can be deployed rapidly. It will also address the key requirements of interoperability and standardization in a proportionate and affordable manner. This is a practical solution to the challenge of implementing unique pack verification that all actors can embrace. It will not offer the total protection that a ban on repackaging would provide, but offers a practical, pragmatic and achievable approach that provides citizens with additional protection from this threat.