

The image shows two gold-colored padlocks hanging from a blue background. The padlocks are positioned in the upper right quadrant of the page, with their keys pointing upwards. The background is a solid blue color with some subtle lighting effects, suggesting a metallic surface or a clean, industrial environment.

# Double Security

Roland Meylan at AlpVision highlights the ways in which serialisation and authentication complement one another to improve patient safety

The pharmaceutical industry and its associated regulatory authorities have now clearly made the distinction between 'track and trace' and authentication solutions. The former is based on standardised numbering systems that can be exchanged universally. The latter, authentication, serves to uncover counterfeiting. Both should increase patient safety in helping to ensure delivery of only genuine medicine as prescribed. This article describes how these two features are complementary and why serialisation alone cannot assure protection against counterfeiting.

## PATIENT SAFETY & THE FIGHT AGAINST FRAUD

Currently, it is widely accepted that patient safety will be increased by a combination of various features addressing different needs. They will also help to combat fraud on the part of counterfeiters, dishonest patients or members of the medical profession (pharmacists, physicians, wholesalers and pharma sub-contractors). There are three core elements to consider in the development of an effective patient safety policy. Firstly, a tamper evident seal or tamper-resistant closure shows up

without doubt if a medicine box or vial has been opened or not. It prevents, for example, the sale of used medicine, or the use of genuine secondary packaging or containers being filled with fake or expired medicine.

Secondly, serialisation of batches or individual items allows rapid recall of medicine in the event that a problem is suspected as well as the prevention of dispensing the wrong medicine to the patient. In the case of fraud, it can for example avoid unjustified reimbursement of medicine or fraudulent modification of

expiry dates. This is provided that a track and trace system is in place that can locate a specific item or batch and that can also show up if an item has been sold, reimbursed by insurance, or still on sale within the supply chain. Such a track and trace system has sophisticated IT requirements; it also needs reliable data acquisition processes at the various points of passage of the pharmaceutical products, from the factory up to the dispensing point.

Thirdly, an authentication feature allows genuine or fake verification, for example

**Figure 1:** Serialisation using barcodes or matrix codes cannot be used to assess which item is genuine and which is fake, in the case where the fraudulent replication is well executed. Only additional efficient authentication features can securely guard against counterfeiting.



between two items that are strictly identical and with matching identification features. It helps combat counterfeiting of medicine by criminal organizations who are equipped with the same manufacturing facilities as the genuine pharma manufacturers.

### PRODUCT SERIALISATION UNDERWAY

Some countries, such as Turkey, Brazil, US and France have introduced, or plan to introduce in the near future, pharmaceutical product traceability via serialisation mandatory in government directives. For example, from 31 December 2010 France will enforce the adoption of a batch serialisation system based on human readable characters and an ECC 200 datamatrix code using the GS1-128 coding (1). In January 2011 two-dimensional barcode readers should be in place in all pharmacies and points of passage of medicines along the supply chain. According to specialists, the new batch identification to be introduced by 1

**Figure 2:** Example of the coding adopted for a pilot project conducted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) held in Sweden between September 2009 and January 2010 (2). It shows both human readable and machine readable information. GTIN is a global trade number provided by the GS1 non-profit organisation; the coding shows a batch number, the expiry date and an individual serial number. This information is also contained in the 2D barcode for machine readability.



January 2011 will cover only part of the production of pharmaceuticals and not all pharmacies will have installed 2D barcode readers. However, in view of the existing human readable information on the packaging, manual recording of the batch serialisation code of an item remains possible at any point in the supply chain. No centralised system is currently defined and pharma manufacturers are only required to record this information on their own premises.

The main issue concerning traceability systems based on item or batch serialisation is the improvement of patient safety, for example through the capability to rapidly recall suspicious batches. Protection against basic fraudulent behaviour is also reinforced, preventing expiration date extension and reducing the risk of the wrong medicine being supplied to patients. Some of these projects included implementation of RFID tags, first recommended by the US Food and Drug Administration (FDA) in 2000, but now abandoned because of its high price tag and its lack of industrial feasibility, when applied at the level of the individual dose. However, RFID is increasingly used for inventory control in stores, warehouses and shipping areas.

### WILL SERIALISATION HELP TO COMBAT COUNTERFEITING?

There has been some confusion over whether or not a serialisation code could serve as an authentication feature if it is recorded in a central database and used to flag a position item on delivery to the patient. The EFPIA stated, for example, that the results of its anti-counterfeit product verification pilot project proved to be successful (3). The idea behind this is for protection against fraudulent replication, which includes copied serial codes on products.

Fake items will be rejected when verified against the database at a point of passage in the supply chain or on delivery to the patient, the status indicating 'already passed or delivered.'

However, this solution contains two major drawbacks. Firstly, nothing would prevent a fake replication from being the first to be verified against the database. As a result, the item position would be taken up, causing rejection of the genuine product presented later on. Secondly, danger occurs if the supply chain certification constitutes the only means to prevent counterfeits. This can drive the counterfeiters' attacks onto the supply chain and would inevitably lead the criminal industry to fake the system or to render it unusable. Corruption and intimidation are most likely to be used and given that dishonest people may be part of the supply chain up to the dispensing point, this system would not be effective (4). In other words, the securing of the supply chain, the 'medicine pipeline', is not sufficient to ensure that what is 'inside' is made up of genuine products and not fakes.

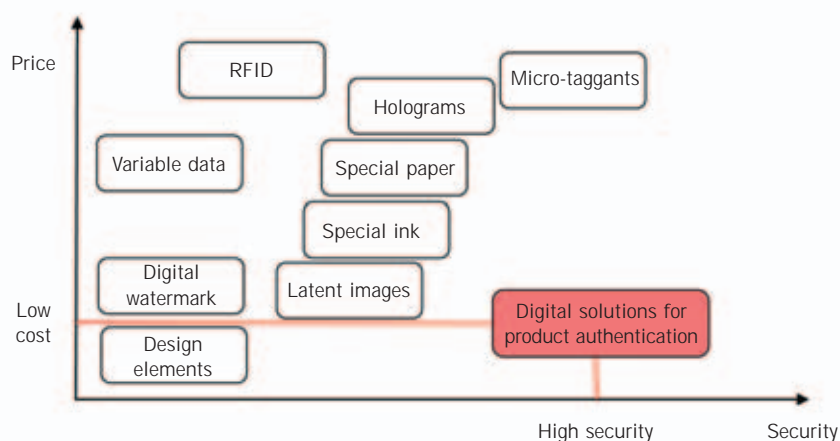
Consequently, more and more experts now agree that only a combination of the three elements mentioned above should be considered. For example the International Authentication Association (IAA) issued the following statement on 22 July 2010 (5):

"US policy makers have missed a golden opportunity to make authentication technologies mandatory for intellectual property (IP) anti-counterfeiting strategies. Although the newly published US Joint Strategic Plan on IP Enforcement is a welcome step in the right direction, the IAA is disappointed to see the only reference to authentication methods is the proposal to establish a mandatory requirement for a track and trace system for pharmaceuticals and medical products. Although the plan indicates that track and trace 'allows for authentication of the product', in reality track and trace systems do not authenticate products."

### OVERT & COVERT AUTHENTICATION FEATURES

If the adoption of serialisation results from a reaction on the part of

Figure 3: Cost versus security of various authentication features.



pharmaceutical manufacturers while waiting for detailed specifications to be issued by the regulatory bodies, anti-counterfeiting measures can be implemented proactively, given that the selection of authentication technologies and processes remains the prerogative of pharma manufacturers.

Many pharmaceutical companies have added visible security features to their packaging to prevent counterfeiting. These include holograms, kinegrams, embossing, micro printing, moiré or

special ink, such as optical variable ink. However, these visible features provide not only minimal security, but they also require training for effective authentication.

During a recent pharmaceutical packaging and labelling conference, a pharma spokesman reported that his company had discovered that a counterfeited medicine included holograms on secondary packaging, while the genuine medicine did not. Consequently, patients were demanding the one with hologram, as it looked safe.

The use of covert features – invisible to the naked eye – will produce a higher level of protection, due to the inability of counterfeiters to identify the presence of such features. Covert security should never be disclosed; to prevent leaks it should only be known to a limited number of trustworthy persons. As in other industries, the digital or software revolution opens exciting new possibilities for on-packaging and on-dosage protection solutions (6). Compared to the cost of security elements or substances, the cost of digital or software based security solutions is much lower. The typical cost per item would be smaller than a tenth or even a hundredth of a Euro cent, in the case that production volumes are considerable.

### CONCLUSION

Serialisation for track and trace combined with covert authentication

features on tamper evident pharmaceutical packaging or individual doses of medicine can contribute to patient safety, through the delivery of genuine medicines as prescribed. Considerable investment in sophisticated IT solutions will be necessary at the pharmaceutical manufacturing level to both fulfil the various additional marking requirements, as defined by different regulatory bodies for tracking and tracing of medicine, and to manage efficient authentication programmes with the purpose of defending their IP through actions aimed at halting the illegal manufacture of counterfeited medicine. Standardisation on serialisation and central track and trace solutions will need to be further developed and harmonised. It is the patient who will ultimately pay the price for the measures taken to prevent both counterfeiting and misuse of medicine, as well as other fraud such as multiple medicine reimbursement or fake prescriptions.

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### About the author



Roland Meylan is a co-founder of AlpVision and today serves as its Corporate Communications

Manager. He holds an MSc in signal processing and digital communication from the Swiss Federal Institute of Technology in Lausanne, Switzerland, as well as a postgraduate qualification in Business Administration from IMD Lausanne International Business School. He started his career at the graphic division of Bobst SA, a leading supplier of equipment for the folded carton packaging and flexible materials industries. Roland also worked in electronic communication over international data transmission networks, the forerunners of the internet.

Email: [roland.meylan@alpvision.com](mailto:roland.meylan@alpvision.com)