Implementing effective technologies

TECHNOLOGIES TO SECURE THE SUPPLY CHAIN

The research-based pharmaceutical industry is committed to contribute to securing the legitimate supply chain. Given the complexity of the supply chain, this is an essential, but arduous effort that requires an efficient, multi-faceted strategy. As IFPMA, EFPIA and PhRMA state in their joint position paper, "**no single solution will prevent counterfeiting. Rather, a holistic approach** comprising the use of covert and overt anti-counterfeiting features, a well-regulated, secure supply chain and appropriate laws and penalties to deter and punish counterfeiters is necessary to provide maximum patient protection".

Four types of technologies provide the foundation for authenticating medicines. These technologies are essential tools for securing the legitimate supply chain and ensuring the authenticity of medicines, though additional caution is always necessary.

OVERT TECHNOLOGIES

These technologies are visible to the naked eye, and require end-users and healthcare providers to be familiarised with them. They are often incorporated within tamper-evident features, such labels that transfer "VOID" onto the surface of the container when peeled off. This avoids the reuse of genuine components for falsified products. Another example are holograms, which typically incorporate images with the illusion of three-dimensional construction, thus combining three-layered security features.

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COVERT TECHNOLOGIES

These technologies can only be seen by specially equipped individuals. Therefore, verification is checked on a "need to know" basis, with security value deeply connected to secrecy. These often include using special inks for invisible printing, including ink visible only under ultraviolet light, infrared fluorescent pigments, and thermosensitive inks.

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CHEMICAL MARKERS

These are a subset of covert technologies that require laboratory testing to assess authenticity. They include a wide range of methods, ranging from chemical taggants, detected only by highly specific reagent systems, to more complex protein and DNA taggants.

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TRACK AND TRACE MODELS AND TECHNOLOGIES

These technologies utilize serialization, which assigns a unique identifier to an item like a pack, case or pallet. This identifier is stored in a database, enabling authenticity checks and product tracking. Many countries have already issued traceability regulations, though significant resources and investments are required for total implementation of track and trace models.

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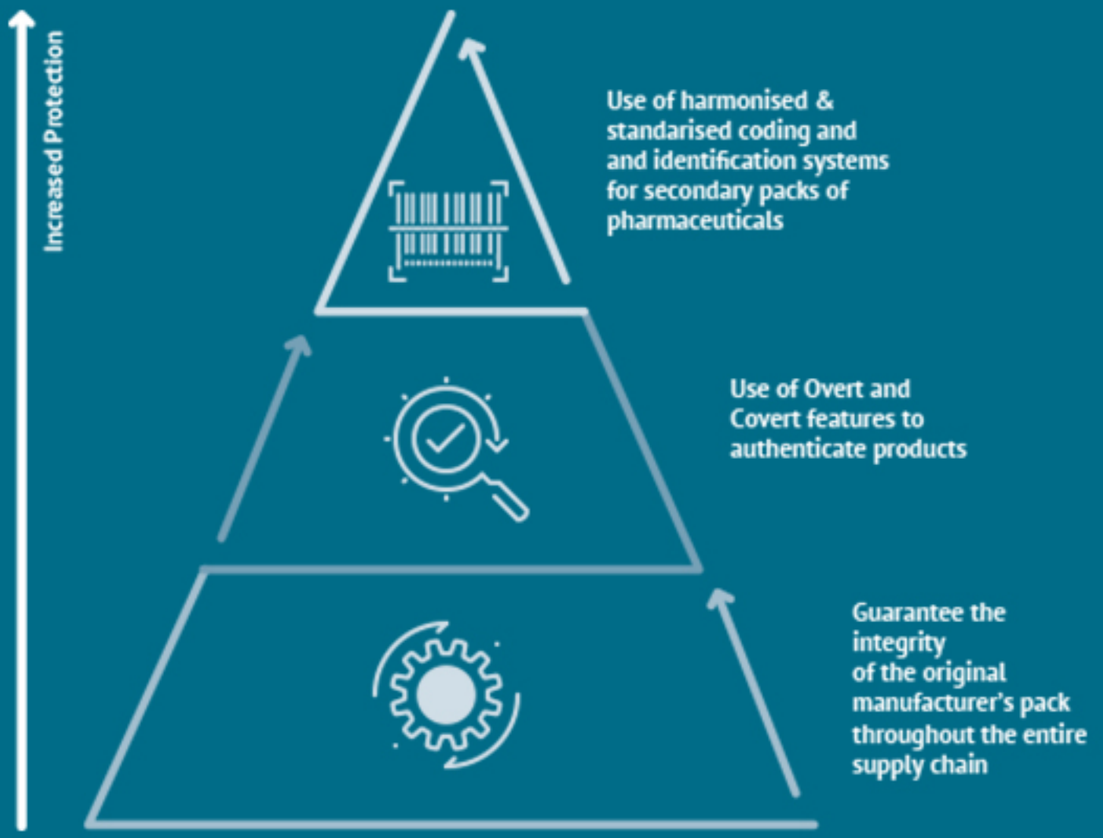
PRINCIPLES AND STRATEGIES TO PROTECT THE LEGITIMATE SUPPLY CHAIN

There are three key principles for an efficient technological anti-counterfeiting strategy, according to EFPIA's "White Paper on the Anti-Counterfeiting of Medicines". These are: tamper-evident packaging; overt and covert authentication features; and a harmonized coding system to enhance product identification at the individual pack level.

These three principles must be applied throughout the legitimate supply chain to ensure greater product security and patient safety.



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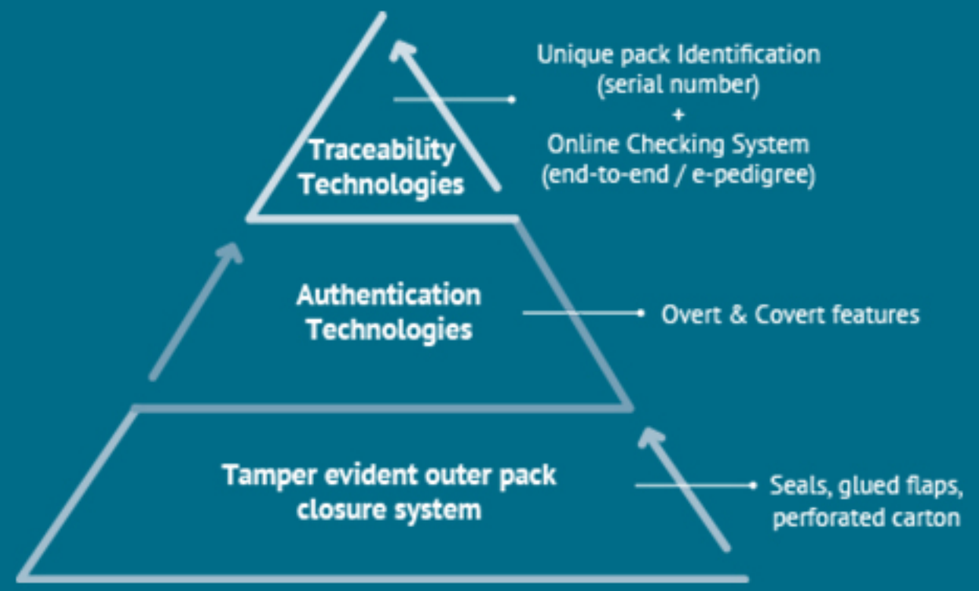
PRINCIPLES AND STRATEGIES TO PROTECT THE LEGITIMATE SUPPLY CHAIN

Serialization and product verification systems are an increasingly common measure to protect the legitimate supply chain worldwide. These systems assign a unique identifier to an item like a pack, case or pallet, which is stored in a database, along with other information about the item. Items are then scanned and verified against the database to ensure authenticity and provide tracking information throughout the legitimate supply chain.

These systems must be implemented in a step-wise, scalable manner – including realistic timelines and suitable consultation with relevant stakeholders – given the significant resources and investments in capital equipment and software systems necessary. These systems **should also use globally recognized common standards** to minimize fragmentation and increase international harmonization, while also providing sufficient flexibility to accommodate various packaging and supply chain differences. Additionally, these systems should be tested ahead of implementation.



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Further, EFPIA, IFPMA and PhRMA believe that serialization initiatives should conform to internationally recognized standards. For example, the GS1 2D barcode allows manufacturers to deploy a single set of standards across their operations and with supply chain partners. In contrast, using multiple standards complicates operations, increasing costs and introducing a higher risk of error. Using GS1 standards also ensures that a single barcode can be used across multiple countries.

Beyond patient safety, serialization and product verification systems also allow for additional supply chain benefits. Potential advantages include:

- Allowing for automated checking of expiry dates
- Better pharmacovigilance
- Reduced medication dispensing errors
- Reduction in the number of fraudulent reimbursement claims
- Preventing recalled products from being supplied to the patient
- More efficient handling of product returns
- Improved logistics such as stock management processes for pharmacies