

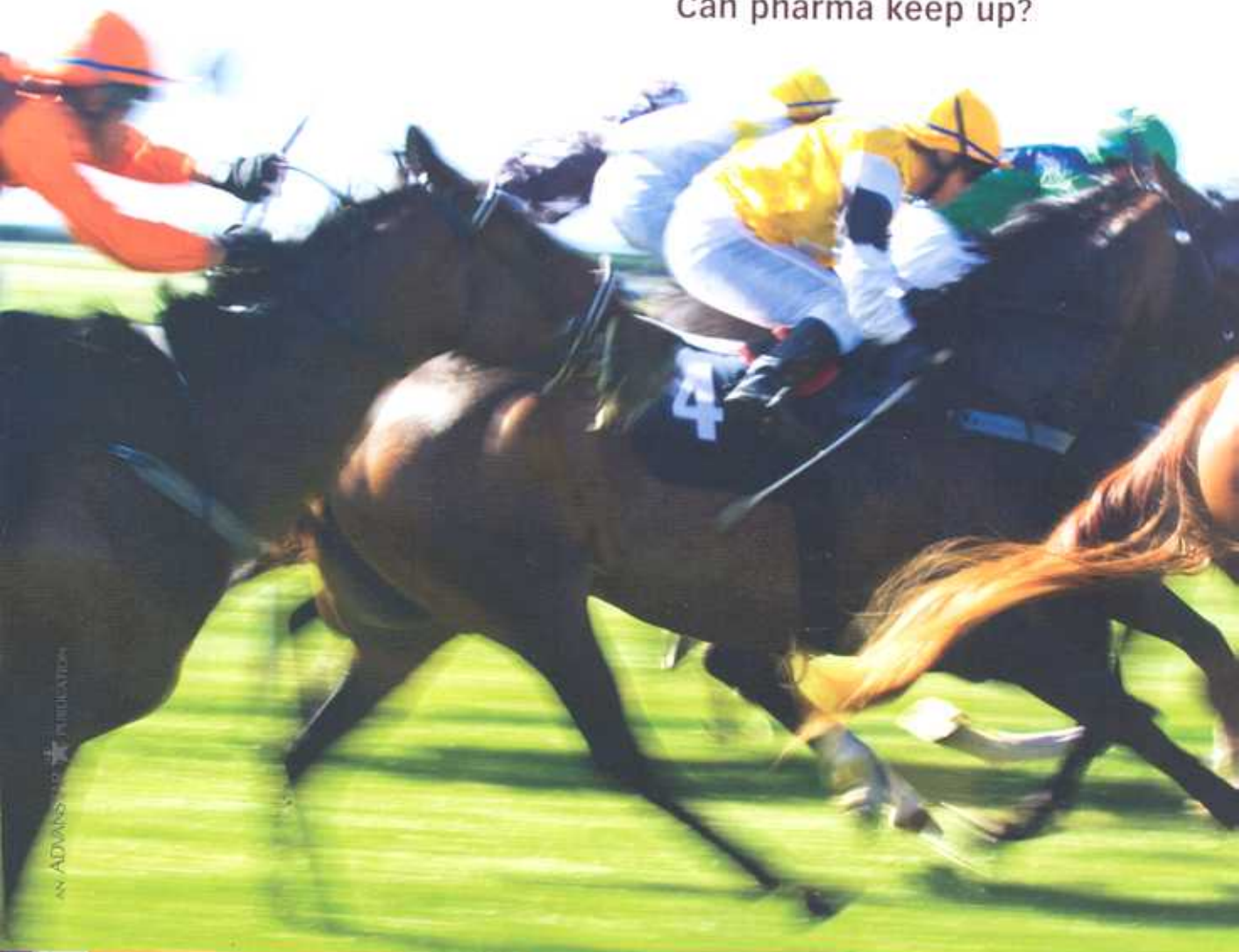
Advancing process solutions

Pharmaceutical Technology

EUROPE

Keeping pace with the counterfeiters

Can pharma keep up?



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fundamentally ones of patient safety, but semantics should not be allowed to derail their attempts to coordinate and harmonise the legal and technical approaches to anti-counterfeiting worldwide.

As the US is the biggest pharmaceutical market, the main driver for a mass rollout of serialisation worldwide will probably be the FDA, which has adopted the serialised National Drug Code (NDC) as a standard numerical identifier for serialisation. The data structure of the sNDC is compatible with GS1 standards and the resulting clarity will catalyse some action from drug companies.

Enforcing track-and-trace fully throughout the supply chain, however, will be a problem because of the inherent difficulty of reading codes or checking the authentication features for every pack at every transaction. One hundred percent coverage is impractical with any anti-counterfeiting system, but serialisation is a good start and the wider the net the harder it is for counterfeiters to evade it.

Companies just need to make sure they keep checking for holes.

Is the pharma industry ready?

Various false starts with different kinds of anti-counterfeiting technologies have led many companies to take a wait-and-see approach. Companies have invested to comply with national drug tracking regulations, such as those in France and Turkey, and have protected key products with targeted authentication initiatives, but many have not implemented serialisation across their entire product range. Most companies are now gearing up to do this, but will need to devote regular Board-level attention to anti-counterfeiting to develop and maintain momentum. Some companies have a person of real power with profit and loss responsibility in direct charge of product protection, but in most companies committed mid-level managers struggle to be heard above corporate background noise.

A core, global, interoperable framework with optional additional layers of local

flexibility is key to an anti-counterfeiting solution's success. Ubiquitous technologies tend to be quite long-lived, so once 2D codes become the standard data carrier, we will be using them for a while. The open standards on which serialisation is built will also allow integration of other complementary technologies such as RFID, which has yet to realise its potential, but offers many advantages, such as the ability to read multiple unit codes quickly and without unpacking shipping cartons. Many other technologies, such as on-dose technologies, are also being developed, and the worldwide rise of social networking and mobile telephony also holds interesting potential for the combination of authentication with marketing and customer interaction.

In the future, non-digital authentication will become ever more important; codes can be copied and RFID chips cloned, so we still need methods that can obtain a definitive authentic/fake answer to the question "Is this product real?" PTE

EU anti-counterfeiting legislation on its way

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With the increasing financial and technical means of counterfeiters, the number of counterfeit pharmaceuticals in the supply chain is growing at an alarming rate. Counterfeiters now have the ability to produce higher quality packages, which enables fake medicines to slip into supply chains more easily.

To combat this threat, the European Parliament and the Council of the EU are amending the current anti-counterfeiting directive (Directive 2001/83/EC), which is due to be completed before the end of 2010, to include a requirement for features that enable the identification, authentication and traceability of prescription medicines. Once this legislation is passed, all European member states will have to implement local

legislation within 24 months. Given the legislation's short timeframe, it is imperative that pharmaceutical manufacturers begin to examine and invest in a solution as soon as possible.

The only way a specific product can be identified, authenticated and traced effectively throughout the supply chain is to give it a unique identity. As such, serialisation, which assigns a unique identity via a unique identification number to each product through a vehicle such as RFID or 2D barcode, is the only solution that can comply with the directive.

Identification, authentication and traceability

Combined, identification, authentication and traceability initiatives make it significantly more difficult for counterfeit drugs to enter the supply chain and reach patients.

Identification allows a specific item to be tracked to the date and batch number that it was manufactured on.

Authentication is the ability to verify that a drug product genuinely came from the manufacturer or other legalised source within the supply chain. To authenticate a product, the pharmacy reads its serialisation code, which when linked to a database, can identify an individual pack and determine that it has not been copied, is in date, has not been recalled and is legally available for sale.

Traceability allows authorised individuals to verify samples of packs to confirm their authenticity before they are distributed, as well as locate and remove the packs from the supply chain if issues are detected. It can also help identify where in the supply chain a counterfeit drug entered.

Identification, authentication and traceability require very high quality serialisation data. If the data are not 100% accurate when the manufacturer applies the serialisation code to a product, then authentication by the pharmacy will be inaccurate. Aside from simply placing a unique number on a package,

serialisation technology must also allow a manufacturer to know which numbers have been assigned and placed on which of their products and batches; to be aware of which serialised products are in the supply chain or have been consumed; and to obtain updates regarding the status of specific serialisation numbers in the case of recall, illegal importation or theft.

For serialisation technology to provide such a high quality of data, it must have the ability to maintain control of the product throughout the packaging process. Because such large amounts of data are involved, companies need excellent quality control procedures regarding data integrity; otherwise, for example, there may be problems associated with missing information or overlapping ranges of serialisation numbers. To ensure data integrity is maintained throughout the packaging process, serialisation solutions must:

- control the numbers issued to a particular packaging line for a particular process
- assign and verify unique identification numbers at the item level, track items through the packaging process, and establish relevant parent-child relationships between item, case, and pallet
- assign numbers randomly rather than in sequential order
- accurately account for numbers that may have been assigned to packages that were rejected during packaging both on and off of the line
- associate serial numbers to the correct lot/batch information.

Configurability is key

Because of the emergence of identification, authentication and traceability initiatives, as well as the

unpredictability of future serialisation regulations, manufacturers should be examining solutions that can respond to current and new demands quickly and cost effectively. Ideally, the solution should be configurable because such solutions are scalable in that they can manage both small and large throughputs and are also capable of expanding as requirements (e.g., post-lot requirements for serialisation and OEE (Overall Equipment Effectiveness) etc.) are introduced. Configurable serialisation software can be assembled and realigned to quickly accommodate changing demands, allowing it to support a wide variety of packaging line functions and new requirements.

Manufacturers who choose configurable serialisation solutions that maintain the integrity of data throughout the packaging process are best positioned to meet both current and future regulations.

Customised solutions, on the other hand, are very rigid because they are built for one particular need. As such, new code must be written whenever there is a change of equipment on the line or if requirements on the line change. For example, if a manufacturer has been performing serialisation using 2D barcodes and then adds RFID to the line because of new requirements, the customised solution will probably require large changes, such as the writing of

new code to manage the new components. Writing new code requires many resources, is very time-consuming and requires the line to be re-validated, thereby shutting down the line.

Configurable solutions do not require new code to be written because they are designed with the necessary elements to address new functions — manufacturers can simply realign and rearrange these elements as required. This eases the need to handle multiple code schemas to comply with different regulations, enables in-house personnel to easily maintain the solution and also speeds implementation. Additionally, revalidation of the line is not required.

Conclusion

The only technology that supports all three of the European Parliament and Council's anti-counterfeiting initiatives is serialisation. However, implementing serialisation throughout the supply chain requires software capable of maintaining a high level of data integrity.

Manufacturers who choose configurable serialisation solutions that maintain the integrity of data throughout the packaging process are best positioned to meet both current and future regulations. PTE

Examples of authentication and data integrity

To protect patients and establish a barrier to counterfeit medicines, pharmacies in Belgium have begun to implement a specialist authentication system. This is a real-time system where a unique serialisation code affixed by the manufacturer to each pack of medicine — similar to a passport number — is read and authenticated by the healthcare provider before dispensing. The country's national pharmacy association, the regulator and the pharmaceutical industry can also input safety information into the system, which is delivered on their behalf at the time of dispensing. This system acts as a "final check" before the patient is handed a medicine, and confirms that the code has not been seen before (i.e., that the code has not been copied) and that the product has not been recalled and has not expired. Additional notifications, such as regulatory changes, can also be delivered using the same mechanism. All data is held securely, compartmentalised, and protected.



Anti-counterfeit product showcase

Browse our showcase of top anti-counterfeit technologies in this month's issue of *PTE Digital*

www.pharmtech.com/ptedigital0710