editorial

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Helping secure the global pharmaceutical manufacturing supply chain

Pharmaceutical counterfeiting is a global problem whether it is on our door step or on the other side of the world, and the differentiation between the two is increasingly narrowing in a rapidly growing multinational manufacturing base and global supply chain.

The pharmaceutical manufacturing sector and its supply and distribution chains are complex; constantly evolving to meet new demands from a variety of stakeholders – be that physician led, advances in treatments such as those delivered by biotech, or in response to global market influences, such as state regulation and new technologies.

Issues facing the pharmaceutical manufacturing industry

The common issue for both governments and manufacturers is safety. Each side must accept different levels of responsibility for ensuring that patients, wherever they may be, are protected from the dangers of being supplied with counterfeit medicines.

With many organisations involved, including the World Health Organisation, one might expect the solution to be built upon a joint approach – incorporating co-ordinated centralisation, global standards and designed with the full support of all the commercial stakeholders. A key problem is who exactly is responsible for what and, more crucially, the liability that stems from that responsibility.

It is no surprise, therefore, that manufacturers are currently taking an independent and individual approach, whilst at the same time actively engaging and contributing to the general debate at the highest level. Driven by concerns to protect the patient, the brand and shareholders, it is natural to see the need for them to be proactive. It is easy to be cynical, but one should not underestimate the potential catastrophic public health effects if there were a loss of public confidence in any number of core patented drugs.

Common sense tells us that two clear and complementary routes will prevail. At a logistical level this means securing supply chain integrity with Track & Trace and ePedigree solutions. The other is mass serialization, something GS1 and EPCglobal have taken a lead role on but has rapidly gained a life of its own, where individual 'item level' packs are uniquely identified.

What is interesting is that both rely on the core concepts of lifecycle, visibility and security of data (albeit logistic level versus item level). Whilst both can successfully co-exist, they perform very different functions, significantly influencing a wider anti-counterfeit strategy. It is important to differentiate the roles they play and the direct contribution to mitigate risk from a pharmaceutical company and patient perspective.

Putting the patient at the centre of the equation

Whilst it is essential to ensure supply chain integrity and continuity of data flow, this process involves multiple parties, some of whom are not within the control of the manufacturer. For this reason, the most direct relationship is actually between the

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manufacturer and the patient or at the very least the pharmacy at point of dispensing.

As a patient, maintaining trust in the prescriber and pharmacy is paramount. This is fine when there is a personal contact but not quite so achievable if you are sourcing your medication via the Internet.

Solutions that enable verification and authentication, whether in the legitimate supply chain as a part of track and trace or direct verification at the point of dispensing, are highly desirable and bring a range of benefits. Product unique identification and chain of custody and ownership, when combined with data intelligence, bring the visibility needed to show which products are genuine and which are not – with this comes the ability to root out and track counterfeit goods.

In Europe, EFPIA are making major progress to their goal of implementing a live Product Verification Project in 2009. Primarily, their proposal is based on delivering enhanced product packaging security through coding and verification – a vision that seeks to deliver an end-to-end (Manufacturer to Pharmacy point of dispensing) solution.

At the heart of this is the need to have an agreed European standards based codification approach. In the proposal this takes an EPC-type approach utilising a GS1 GTIN or Pseudo GTIN in the product code structure. The content of the code: GTIN, serial number, expiry date and batch code provides for totally unique product identification. The batch and expiry data allow for product recall and other alerts.

At this stage it is important to highlight that Electronic Product Code™ (EPC) should no longer be regarded as synonymous with Radio Frequency Identification (RFID) tag only data. A true pervasive computing approach is in essence 'data carrier agnostic' so that any suitable carrier can be considered whether RFID, Data Matrix or other barcode. In the EFPIA proposal the Data Matrix two-dimensional barcode is the carrier of choice.

The key to the system is the secure codification by the manufacturer of the packaged product and the verification process that follows. Although the EFPIA route is not initially intended to support supply chain Track & Trace capabilities, it does indeed enhance and facilitate this at the relevant phase.

It also becomes clear that, in building up Pedigree data and Track & Trace records, a natural and persuasive synergy has to be achieved.

It should be made clear that these proposals have not been created in isolation because several European countries have already implemented technically similar coding approaches such as Belgium, and Italy with its Bollini code – implementations less to do with counterfeit and more healthcare cost reconciliation issues.

Of course, this should not ignore other elements that are critical to the long-term success of an anti-counterfeit and patient safety strategy. A layered approach where there are a variety of other anti-counterfeiting technologies covert or overt, many at packaging level such as special inks and nanoparticles or holograms, and tamper evident seals. All still have a role to play.

It is of note that the Europe Community, which is actively looking at this issue from a regulatory and legislative standpoint, has the advantage of the US learning experience and this has greatly informed the debate and potential routes forward; but it is important to stress that there is still active debate in progress – much of it on a global level, with particular focus on those countries where current or pending regulation has created compliance deadlines.

In some cases, however, these deadlines seem to come and go as the realities and complexities of these projects hit home. Maintaining the momentum for tier 1 pharmaceutical manufacturers, who have invested significantly in this space, goes without question. But for tier 2 manufacturers there seems (understandably) to be little enthusiasm to play in this space when the goal posts keep moving.

The World Health Organisation WHO IMPACT group and their various committees have been major players in this, and have given the debate a sense of urgency and purpose by bringing together experts and stakeholders from around the globe. There are few illusions that at a global level there will ever be a 'one solution fits all' approach, but a coherent strategy is achievable.

In essence the key is to put in place compliance frameworks without compromising some of the fundamental functionality that each distinct solution focuses on. As such they are core building blocks on which to base any approach – each is clearly identifiable, manageable and interoperable. Crucially these 'blocks' give scope for solution vendors and pharmaceutical companies to work together to create solutions, with the reassurance that the compliance framework is being adhered to.

Data integrity – supply chain and beyond

Fundamentally, the solutions that the technical framework should be built on rely upon digital information technologies linked to: business processes, making product visible and the applications and data intelligence that help makes sense of it all. More efficient global collaboration between different agencies with regard to counterfeiting activity surveillance and investigation is already built and paying dividends. As the USA has found, the deeper you look the more you find.

Aligned to this is the security of these systems such as the databases, the communication networks and other vendor technologies. These enable the creation and management of crucial elements, such as the serial numbers, and the generation of non-repudiable records at every stage from manufactures through distribution and supply chain.

The success of authentication and supply chain ePedigree solutions absolutely depends on maintaining high levels of data integrity.

Complex data and identity relationships are formed throughout every stage of the product's lifecycle – from manufacturing and packaging to entering and exiting of the supply chain. A unique identity given to a product at item level is a primary part of that 'parent child' relationship, but visibility of this may only be required by certain users and authentication events. The ability to record and analyse data at varying levels of granularity is critical to any long-term anti-counterfeit strategy.

Finally, it is all very well putting in place compliance and regulatory strategies to secure the safe manufacture and supply of medicines, but it is the loop holes through which anti-counterfeiters and criminals can exploit weaknesses that present the biggest challenge. Their resources should not be underestimated such is the profit to be made versus the risk.

It is imperative that an anti-counterfeit strategy has to be robust and also allow for the evolution of both business processes and technologies.

Sources

- EFPIA – European Federation of Pharmaceutical Industries and Associations.
- MHRA – Medicines and Healthcare Products Regulatory Agency – anti-counterfeiting strategy 2007–2010.
- GS1 – GS1 is a leading global organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world.
- EPCglobal – EPCglobal is leading the development of industry-driven standards for the EPC to support the use of RFID in today's fast-moving, information-rich, trading networks.

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