



Pharmaceuticals Anti-Counterfeiting How secure is your Supply Chain?

The World Health Organization (WHO) estimates that up to 30% of branded drugs sold in developing nations are counterfeit.

It's estimated for example that more than 700'000 people die every year due to complications caused by counterfeit Tuberculosis and Malaria vaccines.

Significant margins between cost of manufacturing and sales price remain a lucrative incentive to sell counterfeit drugs through several channels, resulting in a market thought to be worth between \$75 billion and \$200 billion a year. The counterfeiting industry operates across borders and is not afraid of law enforcement or the deadly consequences their products might have.

The upshot of all this, poses three major risks to the pharmaceutical industry:

- Non-compliance to regulatory requirements addressing counterfeiting.
- Risk of recall and liability suits.
- Potentially catastrophic and irrecoverable risk to reputation, brand and market.

The complexity with counterfeit drugs

Counterfeited drugs are not only an issue in developing countries but also in the western world. Tracking and detection of sources of counterfeit drugs is difficult, and more so as only few countries are willing to share data and information to address the issue. And even if data is available, pharmaceuticals companies usually generate data that is unstructured and hence not analysable or attributable. Many organizations are facing challenges in managing globally collected counterfeiting cases from analysis to verdict and on to corrective, preventive and legal prosecution actions. Thus, the aim of having full control and full transparency over the counterfeiting risks appears to be far away for most.

Addressing these challenges by implementing proactive and rigorous anti-counterfeiting measures must therefore now be considered one of the first and most critical steps in establishing a secure supply chain strategy for every pharmaceutical company.

Securing the Supply Chain

Typical actions to address counterfeiters include

- Globally aligned and workflow supported case management.
- Fulfilling regulatory obligations to report on the counterfeiting cases and corrective actions.
- Data profiling and legal action on illicit traders and collaborating with governments, customs and law enforcement agencies.

These measures do what is required in a more or less efficient way, but are reactive in nature.

Proactive and preventive measures that make counterfeiting more difficult in the first place are:

- Enforcing serialization.
- Non-clonable packaging and hurdles against re-packing.
- 2D barcoding, RFID chips.
- Improving drug delivery and drug pedigrees.
- Consumer education and information on security features.

How Deloitte can help

In Deloitte's point of view the anti-counterfeiting management is a step in the journey to increase the maturity of the secure supply chain. Delivering the above stated measures is efficient and effective; however, it requires a joined-up strategic and operational vision across the supply chain. Deloitte recommends developing a proactive vision to secure the supply chain while investing into the efficiency of the reactive measures.

Our recommended holistic approach is to go for a journey that starts with anti-counterfeiting and continues with elements of packaging management and serialization and leads to modern product lifecycle management capability.

We help you to design end-to-end processes and link those to the capabilities of a secure supply chain. Such a capability is e.g. data profiling that helps you gaining high transparency.

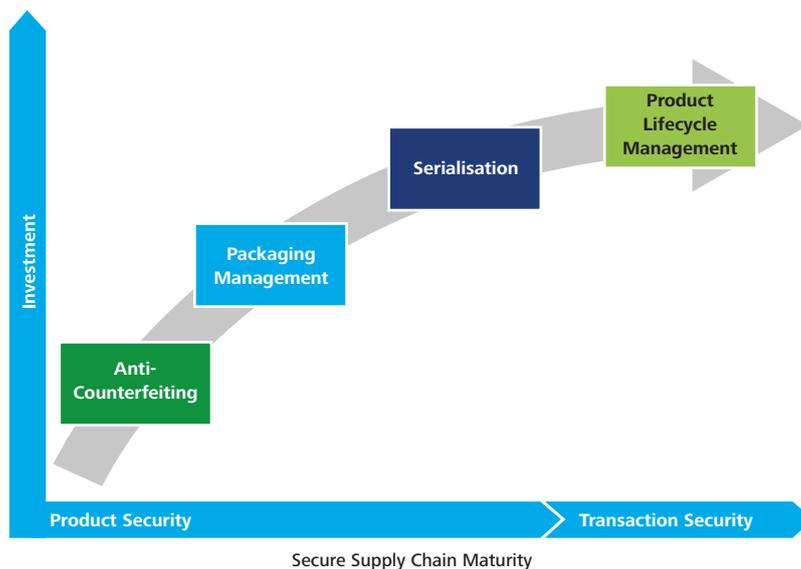
This will help to move your supply chain from a pure product security onto a transaction security focus with which you will be able to fully realize security and efficiency benefits and increase your company's competitive advantage.

Our integrated Supply Chain offering allows us to provide services to you in a wide breadth of domains with true subject matter expertise and experienced industry insights.

Typical benefits

We help our clients generate significant value:

- Protection to reputation and markets by reducing the compliance risks due to counterfeited drugs by up to 80 percent.
- Ensuring compliance and reduction of liability risks.
- Simplified design and development process information flows and reduction of non-value-added steps (and related cost) by up to 70 percent.
- Addressing organizational deficiencies preventing an effective or efficient counterfeiting handling.
- Establishing a solid anti-counterfeiting drill down tracking system to easily identify origin, manufacturer, and API's along with consolidated case management.
- Creating a case for change towards a holistic perspective on product data management along the lifecycle, outlining specific benefits, cost and support the selection of the right solution for your business.



Your Contacts

At Deloitte, we leverage a global network of more than 400 dedicated Anti-Counterfeiting, Product Development and Lifecycle Management practitioners. We use detailed, industry-specific process models and state of the art technology based on years of hands-on experience. We also understand that each industry and business model faces unique challenges in implementation.

Our professionals have the experience, track record, deep industry background and leading practice knowledge to tailor anti-counterfeiting solutions and services for organizations in your industry.

Phil Symonds

Switzerland Life Science Partner
 Tel: +41 58 279 71 80
 Mobile: +41 79 876 47 44
 Email: phsymonds@deloitte.ch

Wolfram von Ehren

Supply Chain Director
 Tel: +41 58 279 68 21
 Mobile: +41 79 654 00 77
 Email: wvonehren@deloitte.ch

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/ch/about for a detailed description of the legal structure of DTTL and its member firms.

Deloitte Consulting AG is a subsidiary of Deloitte LLP, the United Kingdom member firm of DTTL.

This publication has been written in general terms and therefore cannot be relied on to cover specific situations; application of the principles set out will depend upon the particular circumstances involved and we recommend that you obtain professional advice before acting or refraining from acting on any of the contents of this publication. Deloitte Consulting AG would be pleased to advise readers on how to apply the principles set out in this publication to their specific circumstances. Deloitte Consulting AG accepts no duty of care or liability for any loss occasioned to any person acting or refraining from action as a result of any material in this publication.

© 2014 Deloitte Consulting AG. All rights reserved.

Designed and produced by The Creative Studio at Deloitte, Zurich. 34053A