# The Latest Developments, Technologies and Strategies in Anti-counterfeit and Tamper-resistant Packaging

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Making Pharmaceuticals
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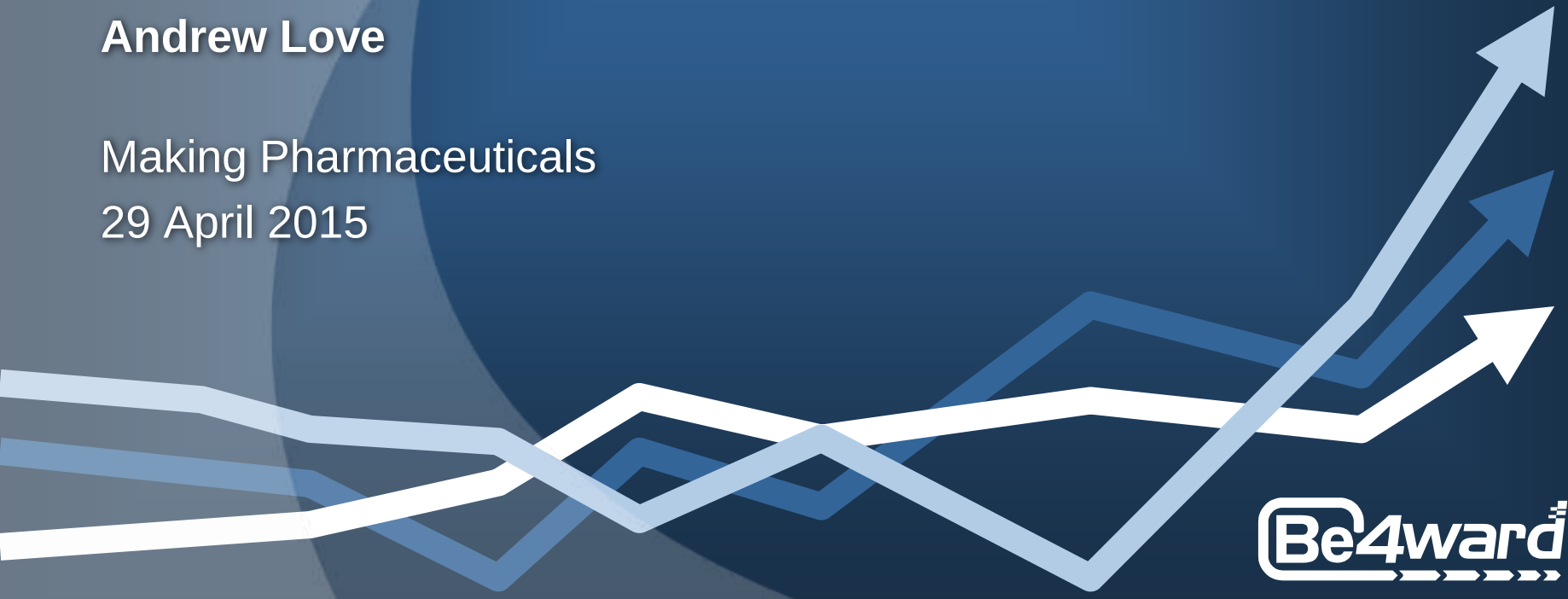

# Andrew Love

**2009 to current: Vice President Capability Development, Be4ward Ltd**, assisting a number of Pharmaceutical clients with packaging management related engagements.

## 2007 to 2009: headed GlaxoSmithkline's pharmaceutical Global Packaging Strategy

- Defining GSK's global supply chain strategies for each product dose form, standardising packaging equipment, components and SKUs

## 2001 to 2007: Global head of pharmaceutical packaging for GlaxoSmithkline

- Structural design, artwork and creative services, packaging legislation, complexity reduction, technical capability development and packaging supplier base development
- Across portfolio of 25,000 SKUs and 150,000 packaging components.
- Led Global Pack Management Project, a £25m re-engineering of GSK's product change management capability.
    - Implemented Product Lifecycle Management software to 4000 users in 160 markets
    - Ensuring timely & accurate product changes to meet product launches whilst maintaining product safety information.
    - Reduced information/artwork related recalls by 80%
    - Rationalised artwork supply from 250 studios to 4 global artwork service centres, one based off-shore in India
- Established GSK's global packing design capability to drive product standardisation, legislative compliance, effective packaging support to product launch and the company's capabilities to manage SKU portfolios
- Led definition of GSK's strategy for serialisation, authentication, anti-counterfeiting and product coding.

## Prior: GSK and specialty chemical industry in various supply chain/operational roles

- Experiences in merger integration, supply chain process and systems implementation, product acquisition and divestment, lean and six sigma deployment, and operational management.

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# Introduction – what is counterfeit pharmaceutical product?

- The WHO defines such product as SSFFC*:
  - substandard,
  - spurious,
  - falsely labelled,
  - falsified,
  - counterfeit
- This shows that there are a number of different types of product that could be considered counterfeit.

**World Health Organisation's taskforce on counterfeit product (the International Medical Products Anti-Counterfeiting Taskforce (IMPACT))*

The issue of counterfeit pharmaceutical product is growing on a world-wide basis, with increasing instances of identification and seizures being reported each year.

# What is the problem?

- Forecast sales for global Pharmaceutical market-place set to top $1.1tr in 2015[1].
- Counterfeit drugs now estimated to be the largest black market in the world at $200bn[2].
- Global issue - counterfeiters looking for opportunities around the world, employing complex global supply chains.
- India and China are the prime source for counterfeit product[3].
- Counterfeit medicines in EU
  - seized at outer EU border tripled from 2006 and 2009 to approximately 7.5 million items.
  - Over 30 million counterfeit medicines seized at internal/external EU borders over same period[4].
- In Africa, most pharma products are sold in informal African marketplaces. Borders are porous and control is difficult.
  - 10 day operation across Africa (supported by the World Customs Organisation) - 460 containers inspected, 1 billion fake products intercepted, half were pharmaceuticals[5].
- On-line Pharmacies
  - Significant source of counterfeit products.
  - The European Alliance for Access to Safe Medicines (EAASM) estimates that 97% of online pharmacies are illicit and there are over 50,000 fake pharmacy web-sites live at any time[6].

*What is real and what is fake?*


1. *Market trends in Pharmaceutical Packaging, Smithers Pira*
2. *www.havocscope.com*
3. *Bad Medicine. The Economist. 13 October 2012*
4. *European Stakeholder Model data*
5. *Operation Biyela 1, World Customs Organisation*
6. *European Alliance for Access to Safe Medicines (2008). The Counterfeiting Superhighway. www.eaasm.eu.*

# Why does the problem need to be addressed? Is it not just a response to high drug prices and essentially harmless?

- The types of issues found with counterfeit drugs include;
  - no active ingredients present,
  - mostly adulterated product,
  - manipulation or refilling,
  - poor storage,
  - expired product
  - cold chain interruption.
- Counterfeit drugs are intrinsically dangerous.
  - Result in putting the patients' safety at risk from products which are unsafe and/or not effective.
- Most popular drugs to be counterfeited:
  - pain killers, anti-inflammatory, anti-tuberculosis and anti-malarials.
  - Estimated that 1/3 of malaria drugs around world are fake, 30% of emerging market product is counterfeit.
- 2013 WHO estimate:
  - 100,000 deaths/year due to fake pharmaceutical product.
- International Policy Network estimate:
  - 700,000 malaria and tuberculosis deaths each year are attributable to counterfeit medicines[7].

- Legitimate pharmaceutical manufacturing facilities constructed and controlled to exceptionally high standards and subject to rigorous regulatory standards, licensing and inspections.
- This safeguard and assurance cannot be provided for products manufactured in fake pharmaceutical manufacturing facilities.

7. *Keeping it real: Combating the spread of fake drugs in poor countries. Health Issues, International Policy Network, London, Harris, J., Stevens, P., & Morris, J.*

# What is being done at a legislative/policy level?

- 2011 EU Falsified Medicines Directive and the 2013 US Drug Quality and Security Act
  - Defined strong legal frameworks for the manufacture and distribution of medicines.
  - Compliance with these rules are obligatory for pharmaceutical manufacturers and other supply chain partners in order to keep counterfeit medicine out of the legitimate supply chain.
  - European and US serialisation being introduced in 2017/18
- Further legislation is being developed, approved and implemented in many other countries (for example Serialisation legislation in Turkey, Argentina, Brazil and South Korea)
  - Targeted at prescription pharmaceuticals and products that are reimbursed by governments and other healthcare providers.
- Organisations such as the World Health Organisation (through their IMPACT taskforce) and the World Customs Organisation (WCO) are helping to define and shape solutions.
  - WCO have developed a secure on-line tool (IPM) to improve communication between the private sector and customs officers.
- Multiple influencing bodies championing specific causes, (for example EAASM and on-line pharmacies) or developing specific solutions.

# Typical activities pharma companies are engaged in to help reduce counterfeits?

1. Collaborating with local authorities and professional organisations
   - This would include involvement in Industry groups e.g. EFPIA and policy/legislative bodies to help define and shape relevant legislation and practices to help secure supply chains.

2. Cooperation with official bodies
   - Examples of this would include participating with WCO on seizure operations and the collaboration some PharmaCos undertook with EAASM on their fake pharmacy exercise.

3. Dedicated permanent cross-functional structure to coordinate and implement strategies
   - The impact and prevention of counterfeit product impacts many parts of a PharmaCo and extends outside the company to other supply chain partners. The establishment of appropriate governance bodies involving relevant functions and parties permits effective coordination of strategies.

4. Proactive securing of drugs
   - The use of technologies to protect product and help identify counterfeits.

5. A dedicated product security and investigation Team and laboratory
   - To support the comparison of real and suspected product to determine if the product is counterfeit.

# What technological solutions are being applied

- A number of different measures can be employed to combat counterfeiting of products:
  - Verification features
    - Included in or on the product and packaging to help determine if the product is genuine. These verification features can be overt or covert.
  - Tamper evident packaging
    - Usually through gluing or labelling the opening of the pack identified if the pack has been tampered with.
  - Serialisation and traceability
    - Providing a unique serial number for a specific pack that can then be used to authenticate the pack through the supply chain and ensure that the chain of custody is intact.

# There are two main types of Verification features

## Covert security features

- Not obvious and require analysis by specialist tools or some specific training to authenticate.
- Generally provided to facilitate forensic examination of products to determine the authenticity of suspicious product.
- Types vary from the simplest e.g. microtext that requires a magnifier to authenticate,….
- Up to specialist printing inks or fibre weaves in the materials that necessitate highly specialised equipment and skilled examination.

## Overt security features

- Visible to the naked eye
- Include many common technologies seen on many consumer items,
  - for example holograms, watermarks and colour changing inks.
- Their visible nature makes them easy to be copied by counterfeiters but can be considered as a first line of defence that are easy to use.

- Typically, the knowledge of what security features are applied is on a ‘need to know’ basis to keep knowledge about technologies or applications out of the hands of counterfeiters.
- Normal to apply a number of different combinations of features to make copying even more challenging - many companies consider features need to be regularly changed to stay ahead of counterfeiters.

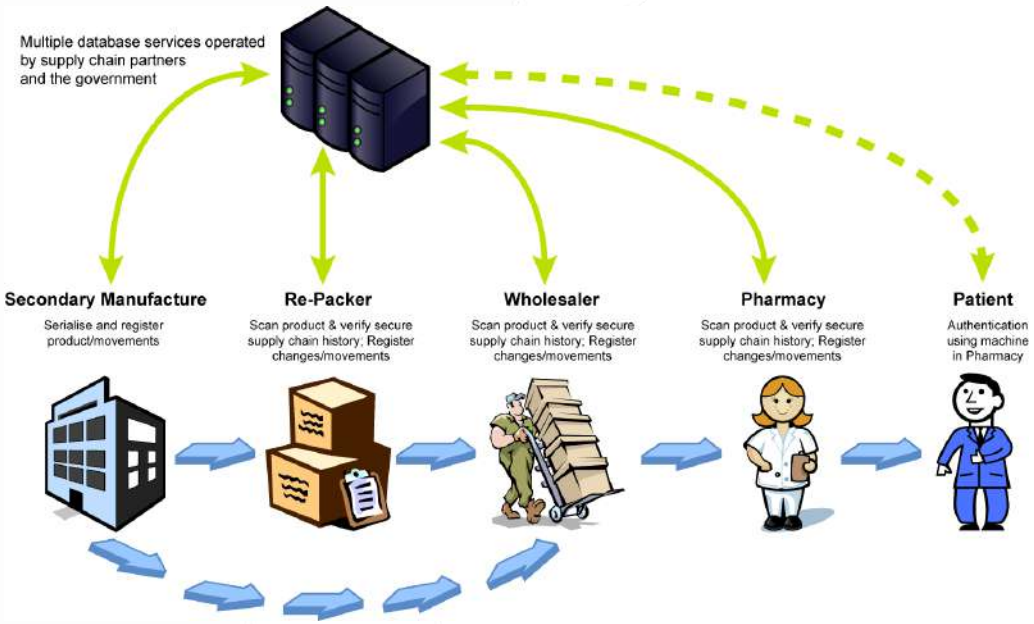
# Tamper evidence makes it visible if the pack has been opened

- Tamper evident packaging has been around for many years
- Included in EU FMD legislation - has to be applied to all pharmaceutical product for the 2018 deadline (subject to approval of delegated acts in 2015).
- Bottle closures and product cartons are main areas of application.
  - Bottle closure solutions are either an over wrap on lid or tear off part of lid that allows removal of cap.
  - There are four main carton solutions:
    - A cardboard ‘mechanical’ lock that destructs when opened
    - A tamper evident tear off seal applied across the opening
    - A glued flap
    - An over wrap


In all cases, the purpose is to provide a locking mechanism that, in opening, damages the packaging, showing it has been opened.

# At it's most complex, serialisation involves tracking individual packs and shippers across the supply chain

## *Illustrative full serialization model:*




## *There are two main models*

1. **Serialise and Authenticate**
   - Unique identification & publish
   - Authenticate at point of use
2. **Track & Trace**
   - As Serialise and Authenticate, plus
   - Aggregation
   - Supply chain transactions update

## *Full aggregation is required to achieve this:*

Serialized Doses ⇔ Serialized Units ⇔ Serialized Bundles ⇔ Serialized Cases ⇔ Serialized Pallets

***Manufacturers need to create the serialised product/shippers and associated data and then transmit this to someone.***

# Summary

- The threat to patients from fake medicines is real and growing - the healthcare community is taking action on a global basis to tackle the issue.
- Legislation is being implemented providing a framework for action - many groups and coalitions are tackling different aspects of the problem.
- Many new capabilities and technologies are being introduced to provide solutions
- However, there is no magic bullet and success lies in the considered application of multiple solutions to provide layers of protection.
  - As each new solution is introduced, counterfeiters will try to determine methods to overcome them,
  - so combating counterfeit product will be a continual battle
- It is essential that your company is playing a full and participative role in this continued threat to protect the lives of patients

# Be4ward

# Be4ward is a niche management consultancy with award winning success in delivering pack change and artwork capability

- Be4ward provides specialist consulting services to the global pharmaceutical industry
- Our team combines operational management experience, subject matter expertise and excellent consulting skills to help our clients deliver successful change
- Whilst we have in depth knowledge of the supply base in our areas of focus, we provide independent advice to our clients
- Our current areas of focus include:
  - **Packaging and artwork management**
  - **Product coding, serialisation and anti-counterfeiting**
  - Product complexity management, late customisation and postponement
  - Secondary packaging supply chain design
  - Post merger legal entity and brand integration
- Contact details:
  - PO Box 4151, Maidenhead, SL60 1DP
  - London, UK: 0800 098 8795, 0203 318 0395, fax 0203 318 0396
  - Montreal, Canada: 888 308 8657

***Our team have won many awards for their work, including the establishment of a world class global artwork capability for a Top 3 Pharma Co.***

# Fundamental elements of serialisation

- Uniquely identifying each product pack
  - With some form of serial number or product code/serial number combination: a “licence plate”
- Uniquely identifying each shipper (tray, bundle, case, pallet)
  - With some form of serial number or product code/serial number combination
- Representing the physical relationship between serialised items in a database
  - Which pack is in which shipper(s): “Aggregation” or “Association”
- Publishing this information to government systems and/or downstream supply chain partners to enable “track & trace” across the supply chain
- Providing verification service
  - To allow customers/users to check product is what it says it is

*All product/shipper marking needs to be in machine readable format for this to be practical.*