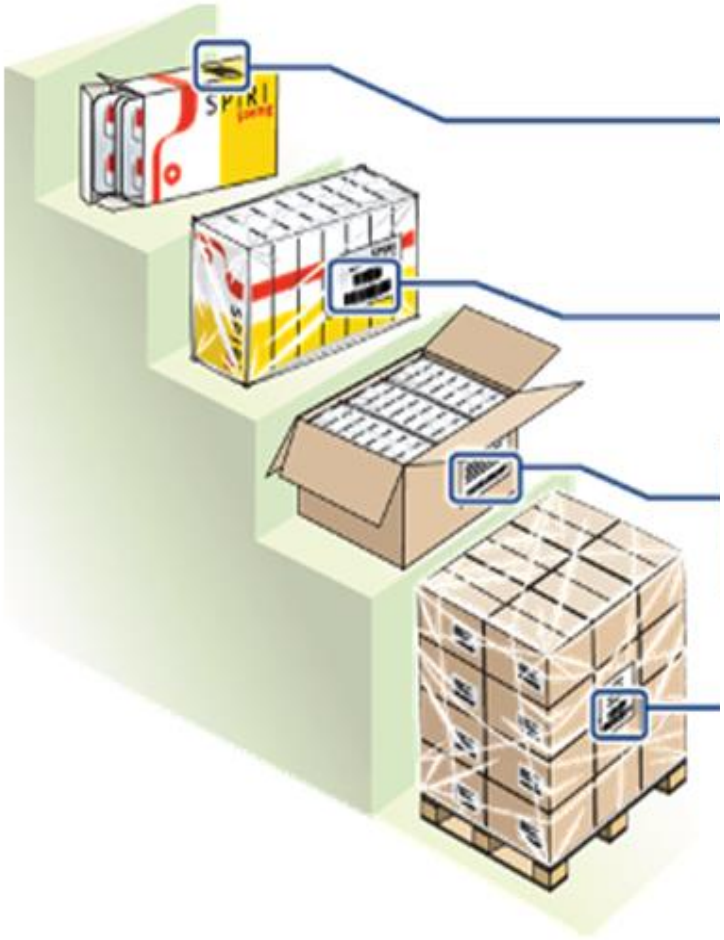
Serialisation
End User View

Agenda

- What is serialisation?
- Why do we serialise?
- Regulatory landscape and challenges
- Approaches to serialisation

WHAT IS SERIALISATION?

Packaging Levels



Lowest saleable unit or **secondary pack**. Serialisation of just this component = Point of Dispense Authentication (PoDA). The identity is a combination of serial number + GTIN(1). Except for the markets where it isn't!

If required, some SKUs are **bundled** – if used, these need unique identification and form part of the hierarchy for Track & Trace (T&T) – which might be a serial number / GTIN or just a unique tracking mark, depending on whether the bundles are traded

Secondary Packs or **bundles** are packed into a **shipper case** which needs to carry a unique idenitification (either SSCC(2) or serialised GTIN – sGTIN depending on the market)

Shipper Cases are loaded onto a **pallet** and the pallet carries a unique identifier (usually an SSCC number)

1. Global Trade Item Number – unique to the product
2. Serial Shipping Container Code – **not** the same as a serial number!

Product Serialisation

Each production line will require modification or additional equipment in order to be able to serialise product.

Some lines will just need to serialise / code: So, labeller (coder) is “all” that is needed

Some lines will need the capability to associate (for countries requiring Track and Trace): So bundler / case packer / palletiser could all be required

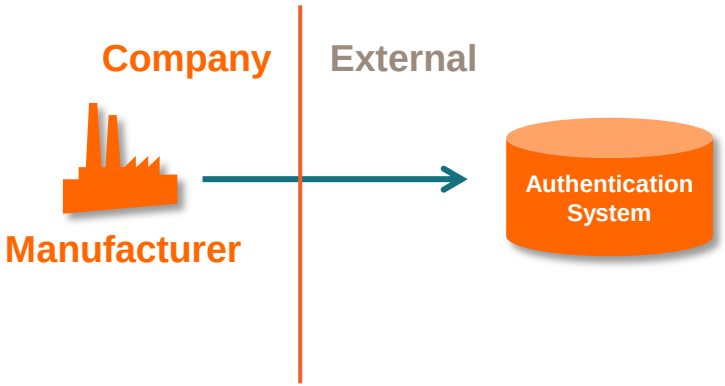
Serialise

Associate

VIDEO

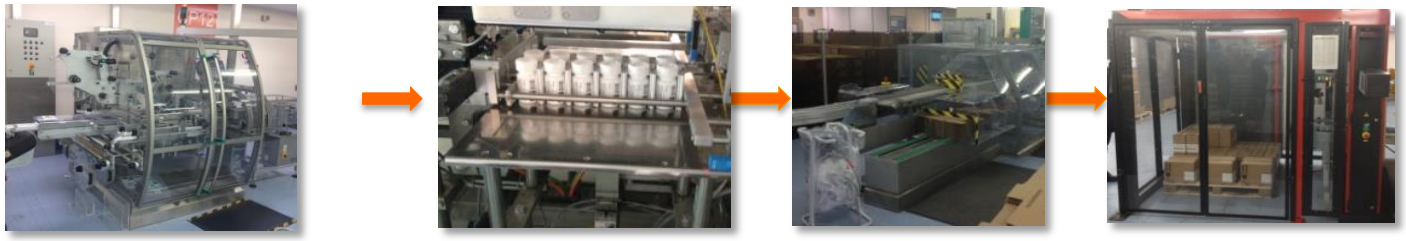
Reporting

- Print unique serial numbers on the product
- Serial numbers are sent to a system which tracks the product once it leaves the manufacturer, through the supply chain.



So simple?

What it really looks like



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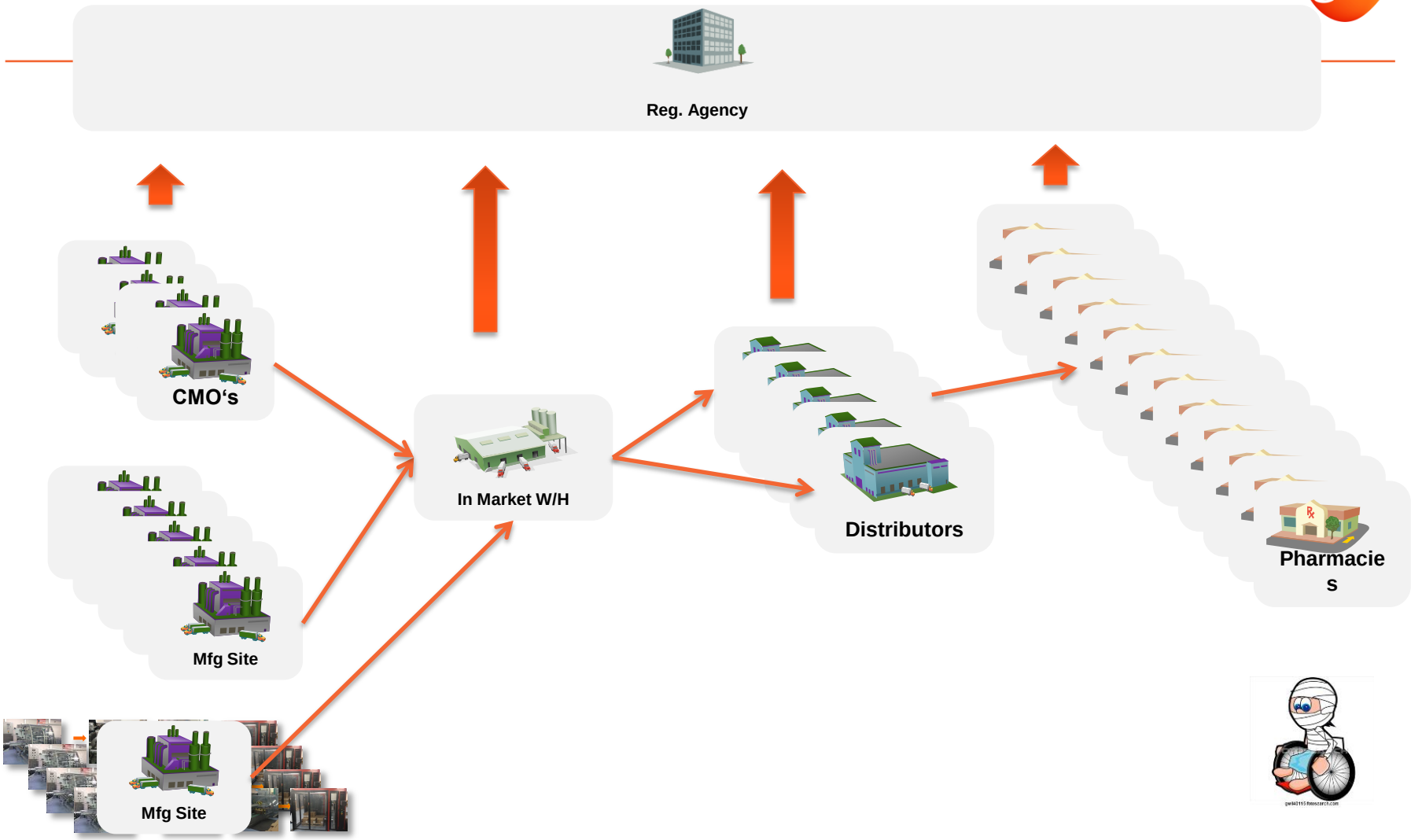

WHY SERIALISE?

Because we have to

- Global pharma market ~ US$900bn
  - US ~350bn
  - EU ~280bn
  - Asia/Africa/Australia ~100bn
  - Japan ~100bn
  - Latin America ~50bn
- Key serialisation markets represent >90% of the product by value
- Don’t serialise, don’t supply!

Because we should

- Falsified Medicines represent US$75bn of wasted investment in healthcare drugs, usually by people who can ill afford it
- Falsified and substandard malaria drugs caused an estimated **122,350 deaths in African children in 2013**. Other studies identified poor quality antibiotics, which may harm health and increase antimicrobial resistance
- Around 30% of drugs in low income countries could be falsified or substandard (~1% in western countries)

The Global Pandemic of Falsified Medicines: Laboratory and Field Innovations and Policy Perspectives
Supplement to the *American Journal of Tropical Medicine and Hygiene*, published online April 20, 2015

REGULATORY LANDSCAPE

Current Markets Driving Activity

DQSA (Drug Quality and Security Act) 21 U.S.C. 1 et seq.
2015 – lot level
2017 – serialised Produict, but…
2023 – pack level (T&T)

Directive 2011/62/EC of the European Parliament and the Council (European Falsified Medicines Directive)
2019 – pack level (PoDA)

Chinese Regulatory Authority, the State Food and Drugs Administration (CFDA)
2012 – phase 1 – T&T
2013 – phase 2 – T&T
2015 – phase 3 (all products) - T&T
SUSPENDED

Brazilian Law RESOLUTION-RDC No- 54, 10 DECEMBER 2013
2015 – pilot – 3 batches (T&T / full reporting)
2016 – all products (T&T / full reporting)
SUSPENDED

The Korea Food and Drug Administration (KFDA) Health and Welfare Notification 2011-58
2015 – PoDA
2016 – Reporting, but delayed until Jan 2017
???? – T&T
NOV 2016 – RFID for Narcotics

Kingdom of Saudi Arabia: Saudi Food and Drug Authority
2015 – coding
2017 – PoDA

Note: Turkey & Argentina already have successful T&T operation, generally implemented with local “in-market” redressing. Markets above **do not** allow this

AND; Russia, UAE, Pakistan, India…..

Regulatory Challenges

- Timing
  - Often regulators require change much faster than we can accommodate it
    - Packaging line changes = 12+ months just for equipment procurement
- Complexity
  - Some markets have very complex interactions through the supply chain
    - Brazil require the MA holder to report on all transactions through the supply chain (though the distributors certainly don't like the idea of it)
- Uncertainty
  - Although laws are in place early (e.g. EU directive, 2011), detailed regulations and ways of working tend to come late (e.g EU delegated acts, 2015-ish) and often technically complex details are very late in the day (e.g. Korean reporting, due 1 Jan 2016, no specific details available until late 2015, so enforcement suspended until 2017)
- Market Pressure
  - Korea, wholesalers want aggregation in reporting
  - US wholesalers pushing for aggregation early – they have to verify all returns for resale by Nov 2019

HOW DO WE APPROACH THE PROBLEM?

What's the best approach?

- Balance risk and cost
  - Do enough to ensure that you can secure market supply, but not so much that you drive significant additional cost
- Be compliant
  - Do what the regulators are asking for, rather than second guessing what might happen (delay etc).
  - Because if you get it wrong, you'll never recover!

What's the best approach?

Common Approach

- Business change (it's a huge impact)
- Artwork, line cutover etc.
- Centrally co-ordinated

Common Equipment Standards (incl validation)

- Small number of key vendors – standard equipment enabling flexibility in deployment
- Define and mandate a standard validation approach (or watch timelines recede into the distance

Standards Based

- Alignment to GS1 standards to ensure compatibility in industry (wherever possible)
- A solution (processes, equipment, software & documentation set) which can be repeated

Simplification

- External interfaces (CMOs and markets) will be simplified by using a single common design and a single standard platform

CONCLUSION

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- Serialisation is and will continue to have a significant disruptive impact on business – it isn't just packaging and we are only just getting to grips with the impact on the rest of the supply chain
- It needs to be done because your business will not survive without it, but more importantly because it will have an effect on lives
- Regulations are complex, evolving and demanding
- Delivering successfully requires a disciplined, standards driven and common approach across manufacturing sites and the rest of the supply chain.