EXCELLIS
HEALTH SOLUT

DELIVERING INNOVATION & DRIVING EXCE

Medinorma Workshop 19th April 2018

La sérialisation en pratique: retour d'expérienc

Serialisierung in der Praxis: Lernen vom Auslan

Serialisation in Practice: Learning from Abroad

3C EXCELLIS EUROPE

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Content

- Introductions
- Fake Medicines in Europe – No Problem?
- Serialisation: A Global Response
- EU-FMD in Detail
- A “Good Pack” in the Serialised World
- Side-effects
- In conclusion

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Christoph Krähenbühl

- **Senior Director at Excellis Europe**, European subsidiary of Excellis Health Solutions, with HQ in UK (Manchester) and Brussels (Belgium)
- European Medicines Verification Organisation **EMVO Management Team**, supporting the EMVS establishment and roll-out across Europe
- Previously Expert on **EFPIA's Coding and Serialisation team**
- Leadership in Serialisation Projects since 2006, as **Global Project Lead** and **Product Security Manager at AstraZeneca (HQ UK)**, one of the early adopters and global leaders in pharma serialisation.

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Excellis Health Solutions: A brief History

- **Excellis Health Solutions 2010**: Founded in US
- **December 2015 : Acquisition of 3C integrity**
- **European leadership** in serialization consultancy for pharma
- **European offices** in Manchester, UK and Brussels, Belgium
- Established **thought leadership** position: EFPIA, EMVO, GTT
- **Strong partner network** through the EU pharma Eco-system
- 100 employees: **WW structure, Pan-European team**
- **Holistic approach** to serialization : Enterprise integration from mfg, IT to supply cha
- 3C Excellis recognized as **Best Specialised Pharma Consultancy** and **Serialization Expert of the Year 2016 and 2017**

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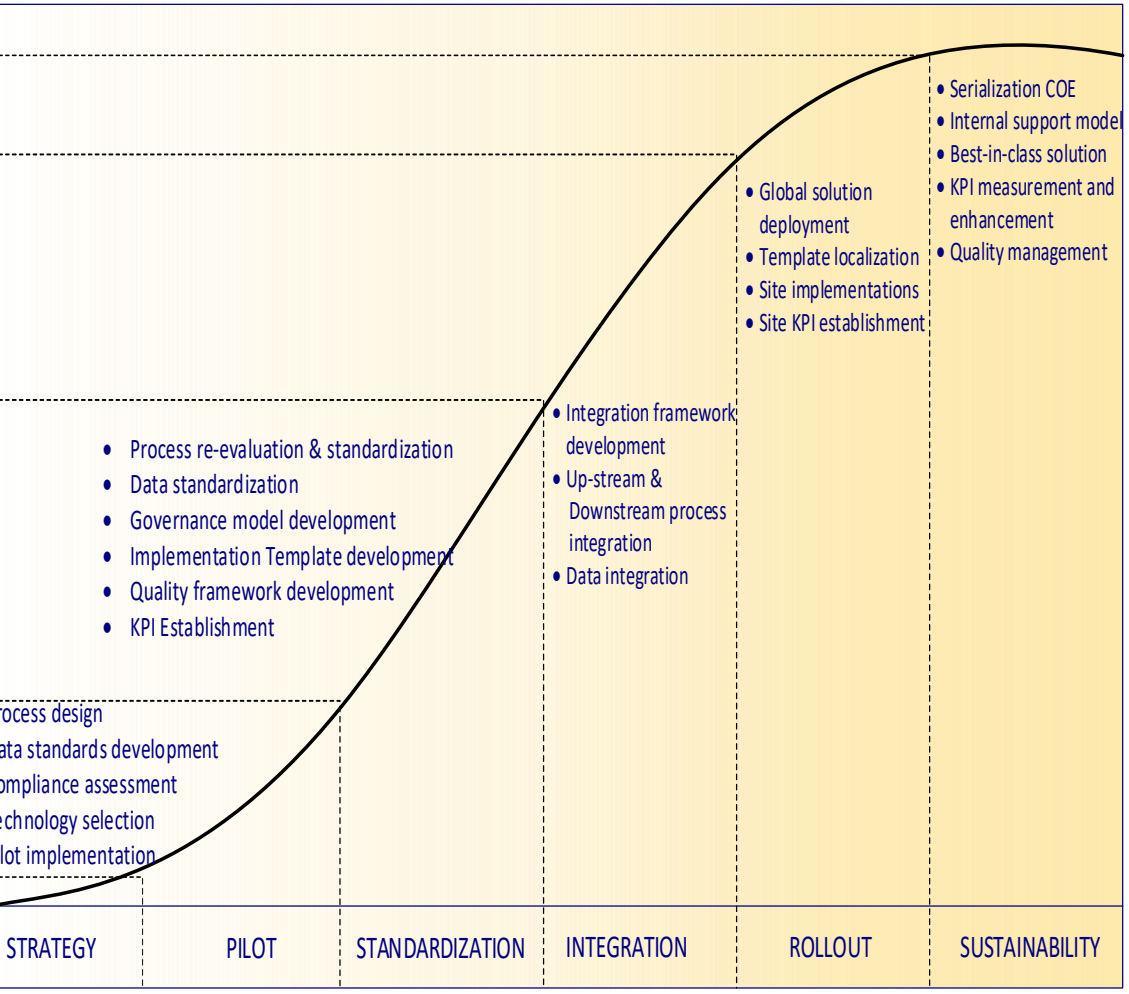
3C Excellis in the Industry : from strategy to sustainability



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AstraZeneca Casodex case, 2007

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3 April 2011 Last updated at 18:44

164 Share

Man jailed for £4.7m counterfeit medicine fraud

A man has been jailed for eight years for his part in what has been described as the most serious fake medicine fraud in the European Union.

Peter Gillespie, 64, from Hertfordshire, was part of a £4.7m plot to bring two million doses of counterfeit drugs from China to the UK.

He was convicted of conspiring to defraud pharmaceutical wholesalers, pharmacists and members of the public.

He was convicted by a jury at Croydon Crown Court.

By mimicking authentic, properly manufactured and tested medicines, Gillespie illegally infiltrated the regulated system designed to protect the public and pharmaceutical industry, he court heard.

Peter Gillespie was part of a plot to import drugs from China to the UK

'Patients at risk'

The counterfeit medicines contained only a fraction of the correct

- UK 2007: €2.8m of counterfeit Casodex was found in the legitimate UK supply chain.
- Made in China, in French packaging with sub-potent products.
- AZ's largest counterfeit based recall across Europe
- Global response led to arrests worldwide.
- Court cases concluded: 8 year jail

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ghts on falsified medicines in the legal supply chain in: *Regulatory Rapporteur – Vol 14, 4, April 2017*

***l Hargreaves**, Expert Inspector, and **Christopher Morris**, Intelligence Analyst; Medicines Healthcare products Regulatory Agency, UK.*

hile the risk of falsified medicines penetrating the legitimate supply chain to patient level ery low, the financial gains are substantial and so there are continued attempts being de to penetrate the supply chain. The EU Falsified Medicines Directive (2011/62/EU) was oduced to lower the risk and raise awareness, but it is only part of the story in the fight inst falsified medicines. Operationally, it is the inter-agency and inter-country cooperation ough Europol, INTERPOL, WGEO, etc, that is at the forefront of the detection and vention of falsified medicines from penetrating the legitimate supply chain."

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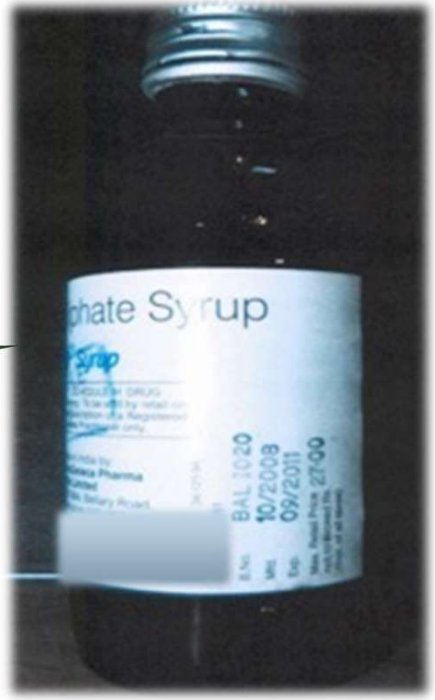
Some real incidents

Injectable (China) found to contain tap water



Cough syrup (India) contained sugar and E. coli

IV Formulation (Philippines) had been used & contained Penicillin G.

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Verification of Sales Pack is critical

Counterfeit

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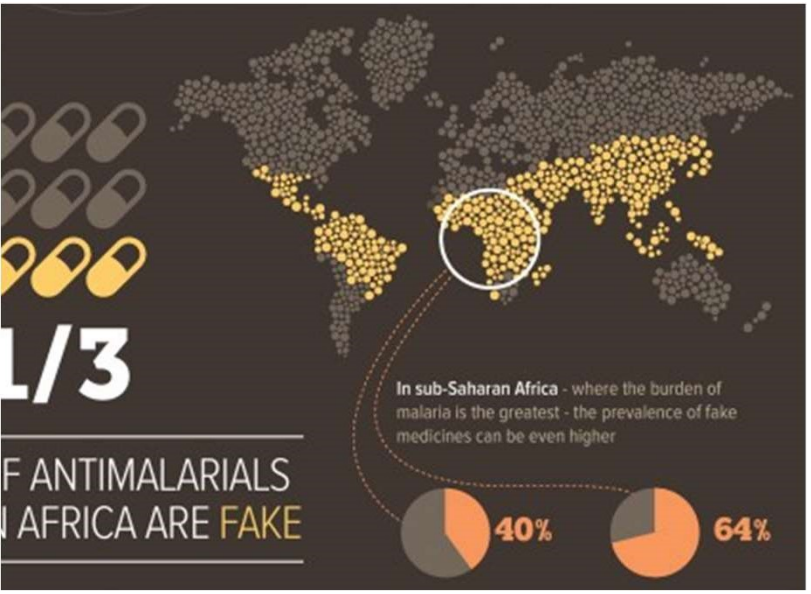
mpact of Counterfeit drugs



Direct Impact on Patient

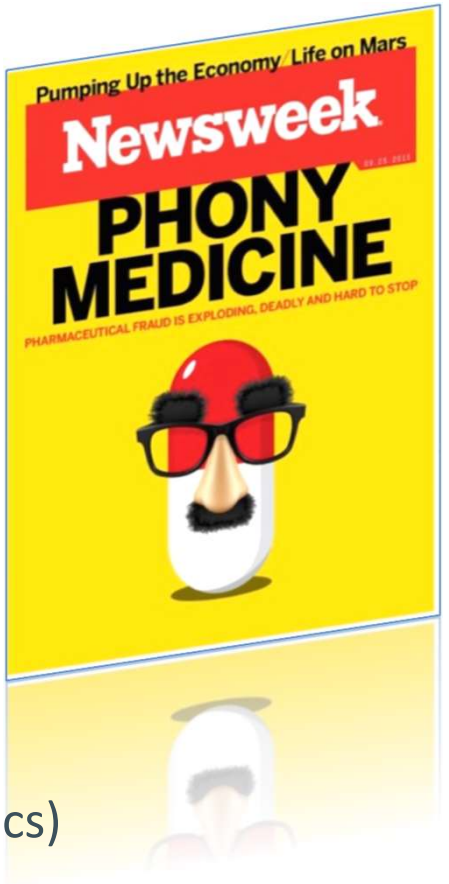
- No therapeutic benefit
- Over or under dosage
- Harmful effects including death

Impact on Brand Owners

- Adverse events
- Loss of revenue
- Loss of brand
- Loss of reputation

Wider Impact on Society

- Loss of efficacy (Malaria drugs, Antibiotics)



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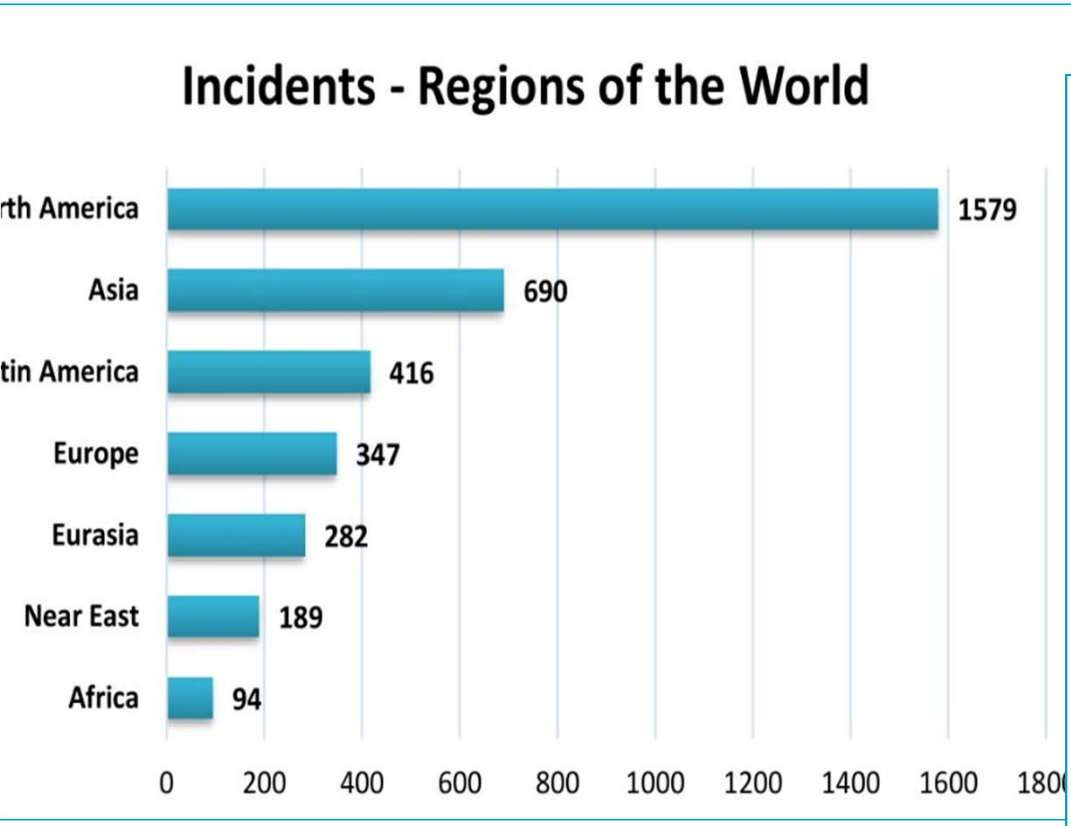
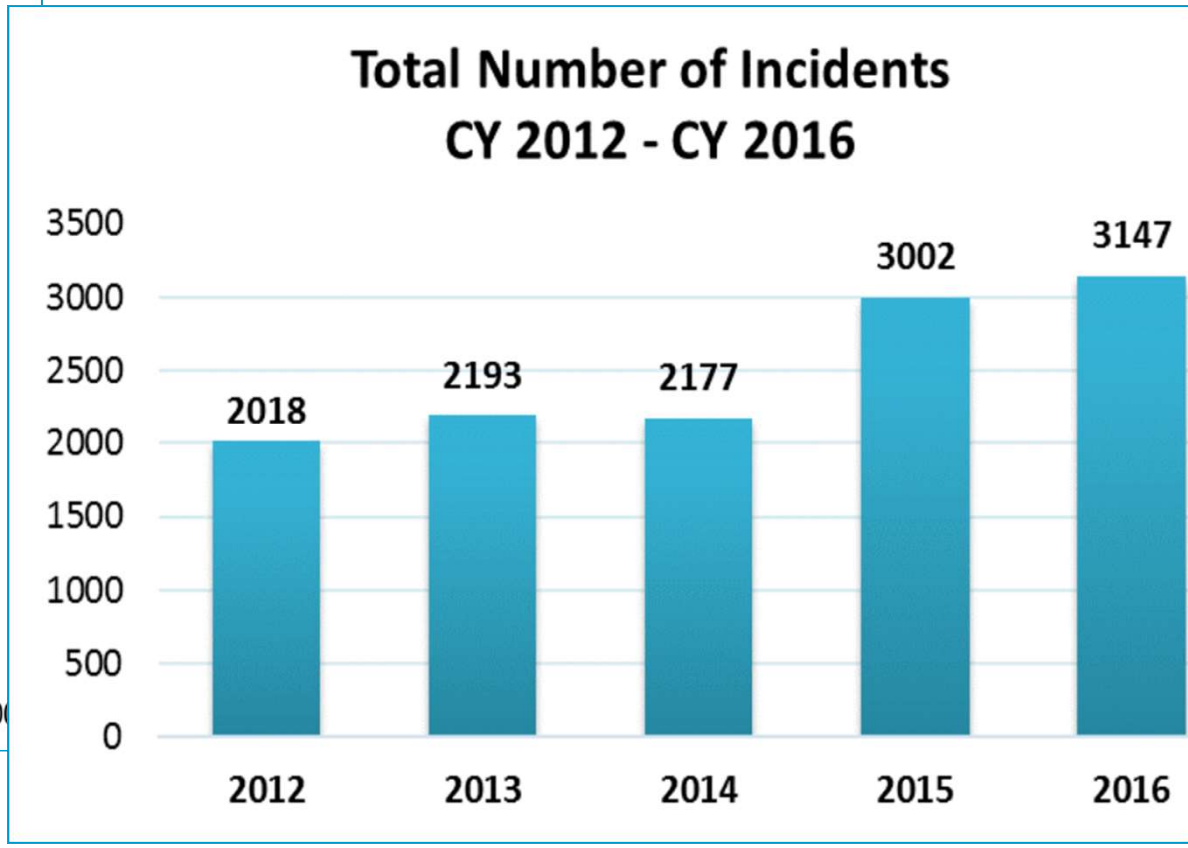
Counterfeiting cases worldwide (2016)





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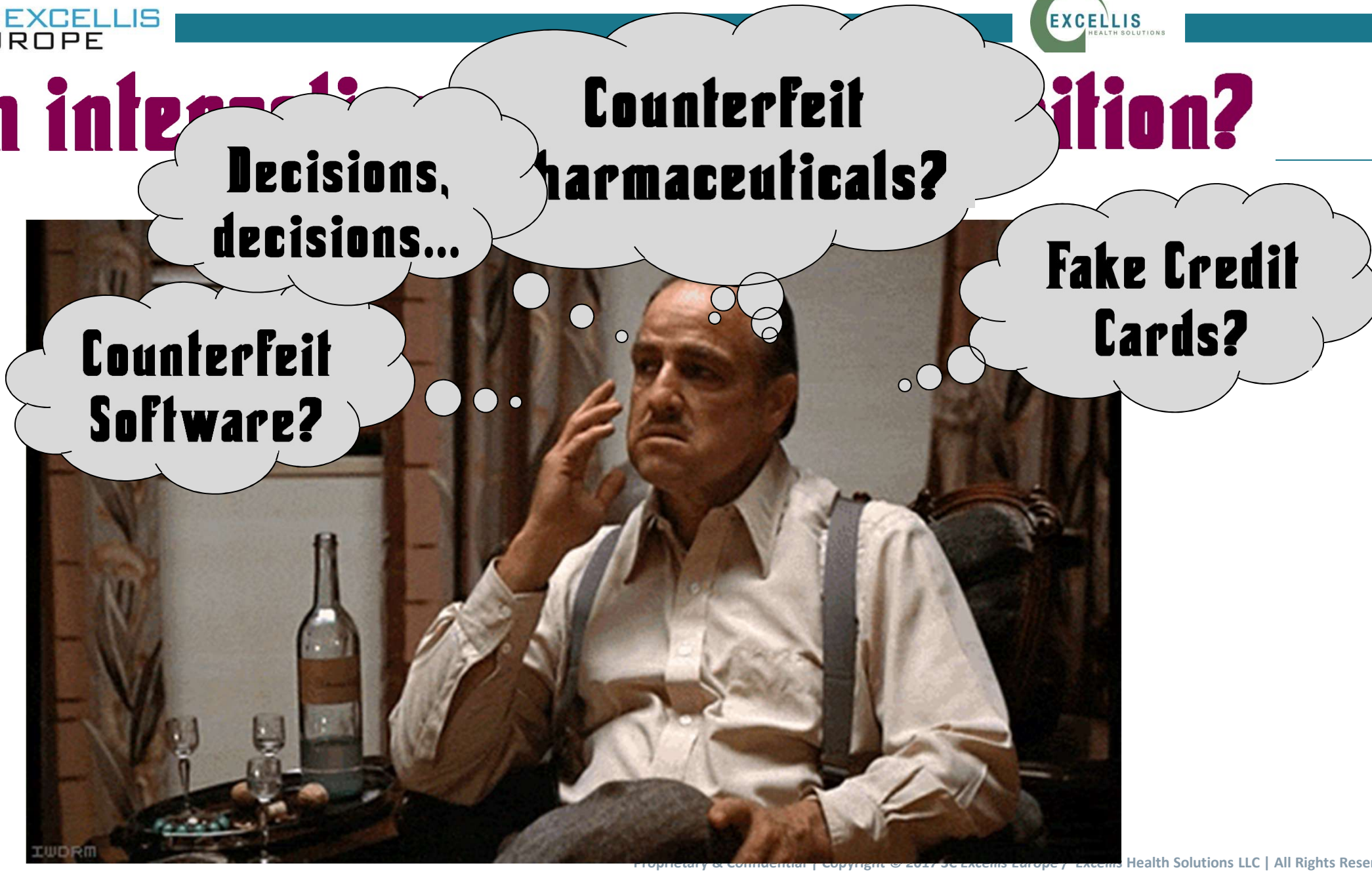
An inter… …ition?



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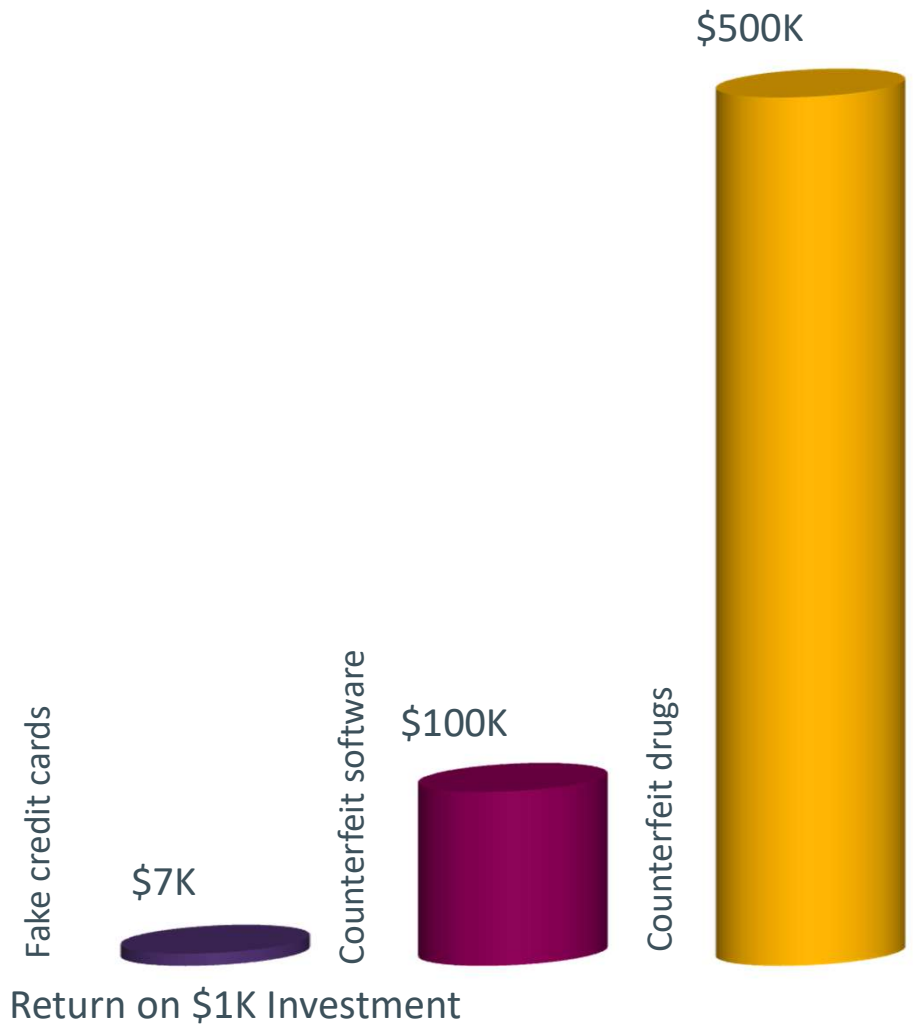
ounterfeiting Medicines: High return – low risk

r every $1000 invested, counterfeit
harmaceuticals generates $ ½ Million return*

harmaceutical Counterfeiting is seen as High Profit
ith Low Risk

o who may be involved ?

- Organised crime gangs
- Unlicensed businesses
- Licensed businesses: Brokers, Distributors, Wholesalers



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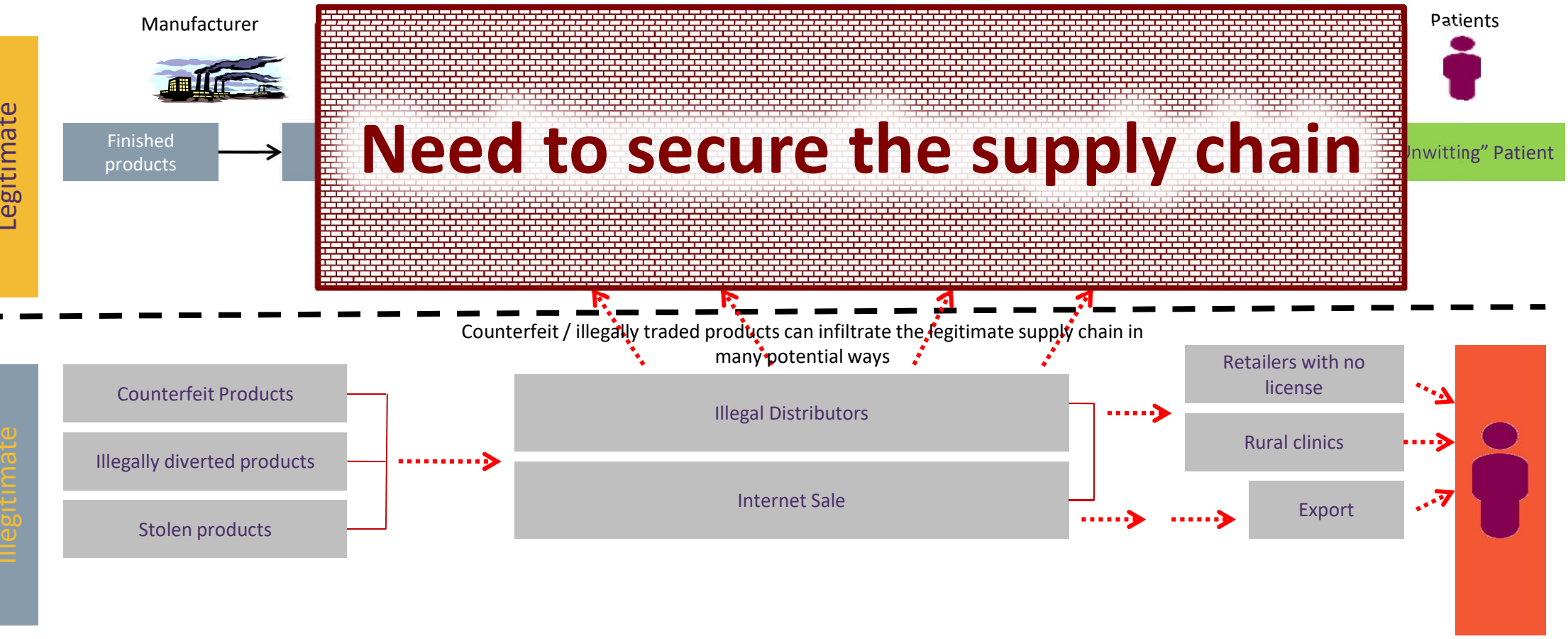
How counterfeit / illegally traded product gets in the supply chain and reaches patients



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Good intentions…

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A Chinese policeman walks across a pile of fake medicines seized in Beijing. The rapid growth of Internet commerce has led to an explosion of counterfeit drugs sold around the world, with China believed to be the biggest source of fake medicines in the world.

AFP/GETTY

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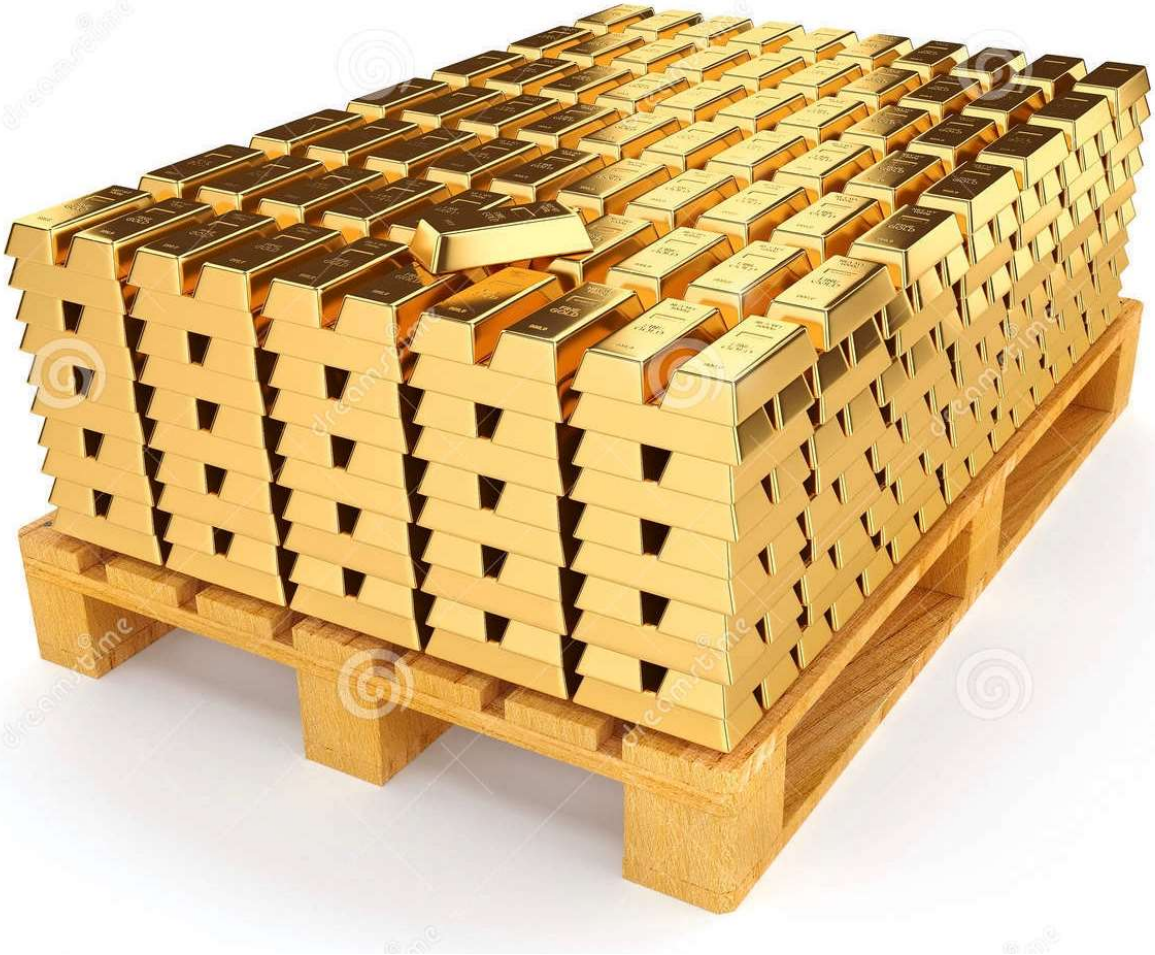
The $1M Palette



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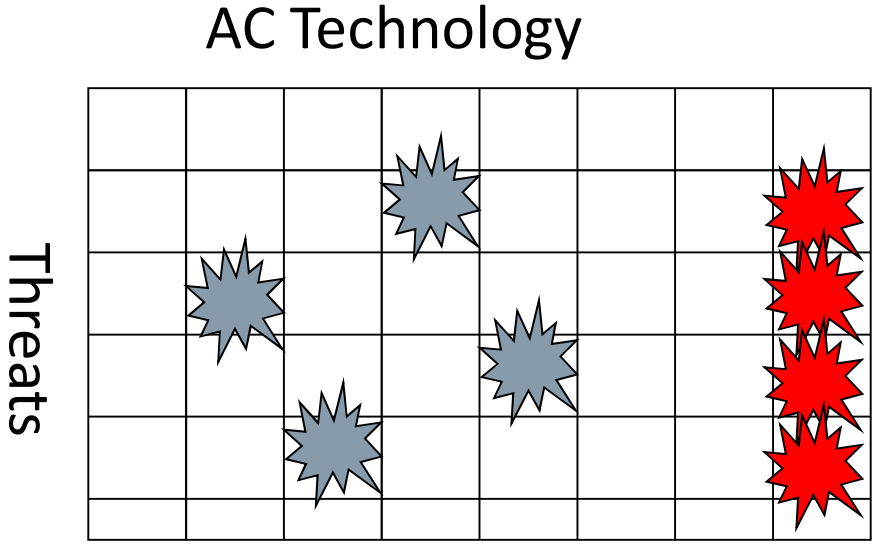
Strategies to fight counterfeiting and other threats



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erialisation fundamental concept: Unique Identifier

Data-Matrix code, developed to ISO-standards

Key data elements:

- Product code (GTIN/NTIN)
- Randomised unique serial number

Global uniqueness guaranteed

- Expiry date
- Batch number
- National health number (where necessary)

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 180500
S/N: 12345AZRQF1234567890

2D DM as data carrier of ch

Compact, Robust, Cost-effec

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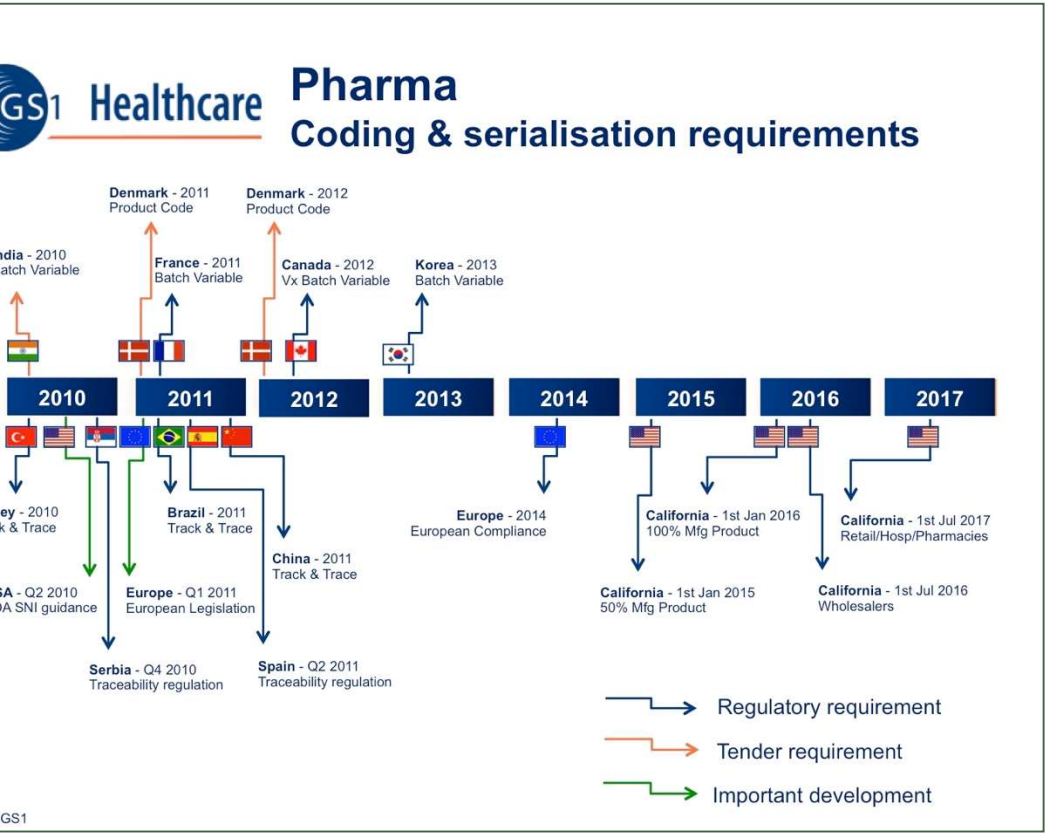
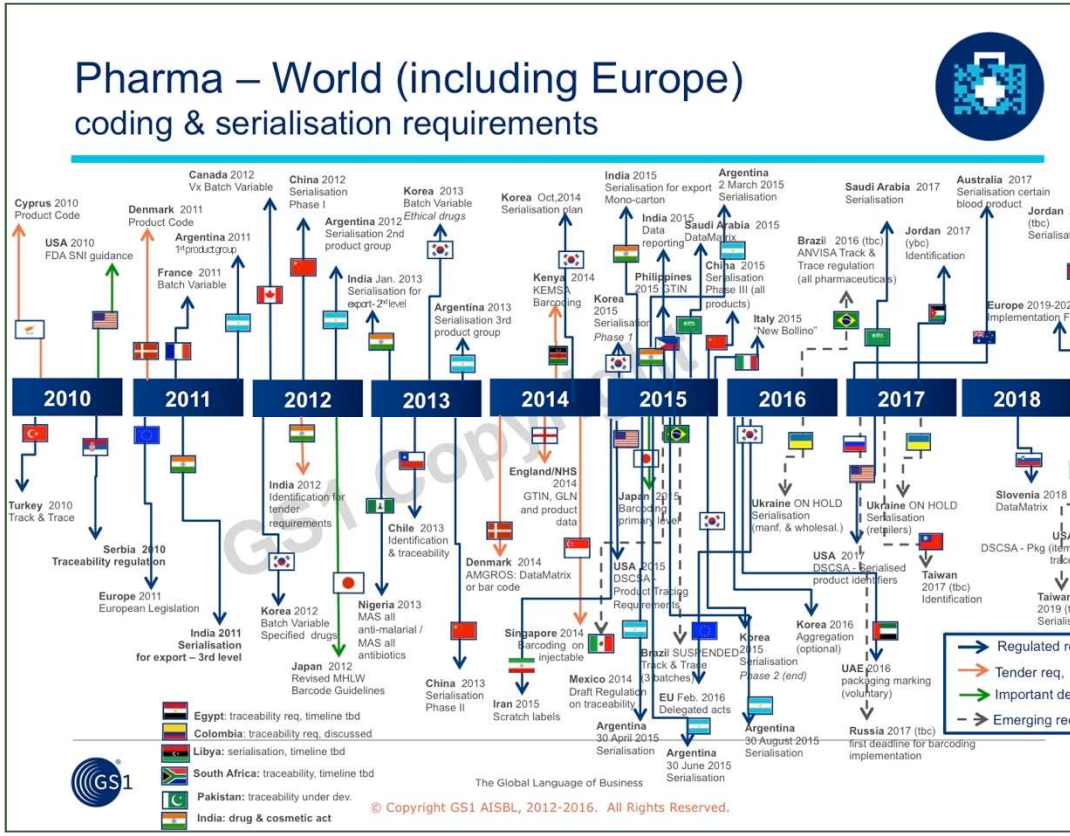
erialisation: From Success to Challenge

10



2017



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rket	2005	2010	2011	2012	2013	2014	2015	2017	2017	2018	2019	2020	2021	2023	2025	202x
geria										5	5	5	5	5	5	5
gentina			6	6	6	6	6	1	6	6	6	6	6	6	6	6
menia																1
stralia	1	1	1	1	1	1	1	2	5	5	5	5	5	5	5	5
erbaijan								5	5	5	5	5	5	5	5	5
arus																1
zil										9	9	9	9	9	9	9
nada				1	1	1	1	4	4	4	4	4	4	4	4	4
le					1	1	1	1	1	1	1	1	1	1	1	1
na							9		9	9	9	9	9	9	9	9
ypt										5	5	5	5	5	5	5
, EEA + CH (excluding BE, IT,), but see Note 3 for BE											6	6	6	6	6	6
lia (Export)			7	7	7	7	7	9	9	9	9	9	9	9	9	9
n							5	5	5	5	5	5	5	5	5	5
an							2	2	2	2	2	2	2	2	2	2
dan									2	3	3	6	6	6	6	6
zakhstan																1
rgyzstan																1
anon										3	3	8	8	8	8	8
nan										3	5	5	5	5	5	5
ssia									5	8	8	8	8	8	8	8
udi Arabia							3	3	5	5	8	8	8	8	8	8
uth Korea							5	9	9	9	9	9	9	9	9	9
wan								3	3	3	5	6	6	6	6	6
rkey		8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
raine								8	8	8	8	8	8	8	8	9
ited Arab Emirates									3	3	3	3	3	3	3	3
ited States							4	4	6	6	6	9	9	9	9	9

Data Standard Guidance, general
Data Standard Guidance, Product Coding
Coding: Product and Batch/Lot
Coding: Product and Batch/Lot; data reporting
Item Level Serialisation (no data reporting requirements)
6) Item Level Serialisation and data reporting required
7) Item Level Serialisation and Aggregation (no data reporting required)
8) Track & Trace; single point data reporting
9) Track & Trace, complex reporting requirements
10) Under Discussion, no requirements yet

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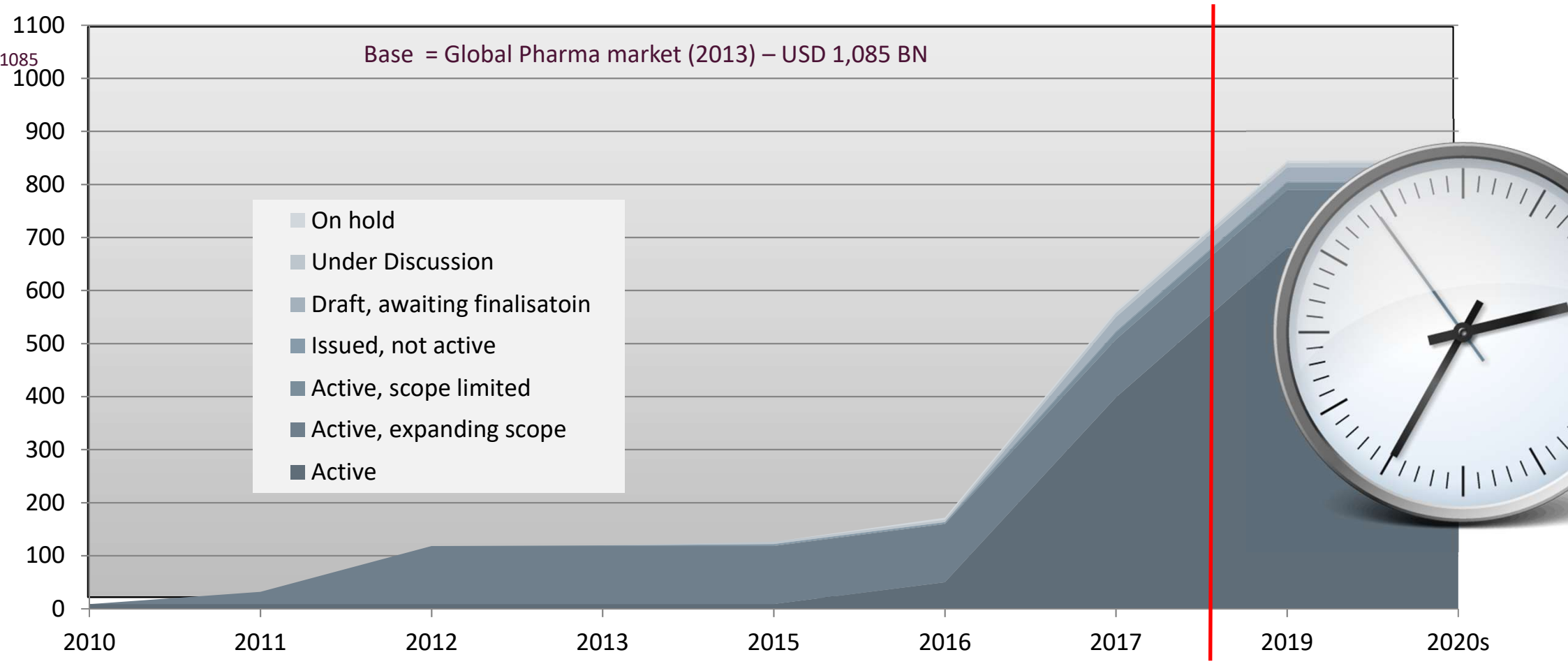
Pharma Sales subject to SER / T&T requirements



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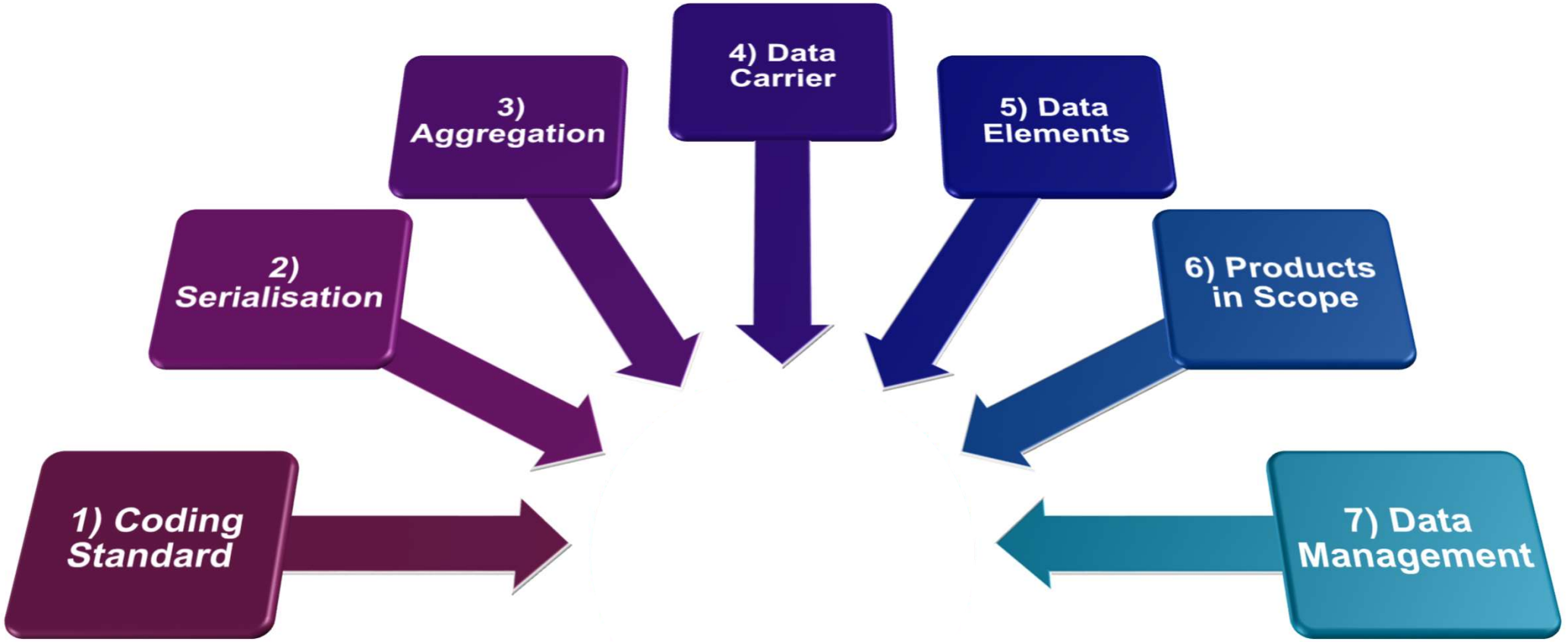
A silver cloud on the horizon – Emerging Global Standard



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EU-FMD Logo - genuine online pharmacies

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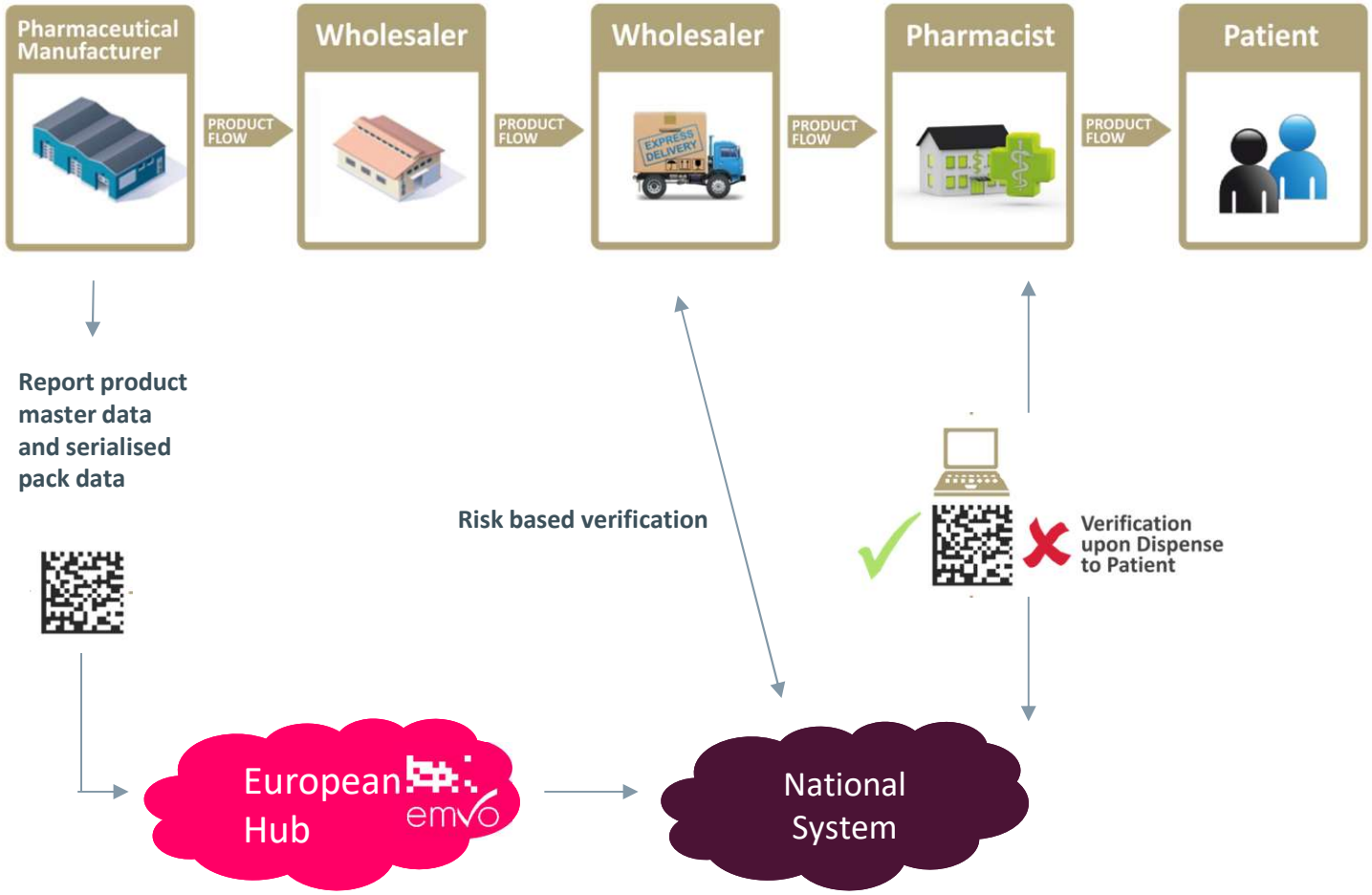
Systematic “Point of dispense verification”



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Stakeholder Impact

Manufacturers

Requirement (routine operation)		Pharma - Brand Owner and Generics	Pharma - CMO	Parallel Distributors	Wholesaler/Distributor	Pharmacist	National Competent Authorities
1)	**Pay for EMVS ("Bearing the costs for the system")**	Yes	*no - Marketing Authorisation Holders pay*	Yes			
2)	**Apply Unique Identifier**	Yes	Yes (requested by customer)	Yes			
3)	**Apply Anti-Tampering Device**	Yes	Yes (requested by customer)	Yes			
4)	**Connect to European Hub: Upload UIs**	Yes	*no - will be done by customer*	Yes			
5)	**Connect to EMVS to Decommission UIs**			For "consumed" packs (Hub)	For packs exported from Europe (National System)		
6)	**Connect to EMVS: Verify UIs**			Verify (EU-Hub)	higher risk shipments (NMVS)	voluntary check is possible (NMVS)	
7)	**Connect to NMVS: Decommission UIs**				"Early dispense" for institutions	Yes: Point-of-Dispense	
8)	**Process Alerts**	Where relevant		Where relevant	Where relevant	Where relevant	
9)	**Receive Reports to allow Overview/Supervision**						Yes

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The road to EU-FMD Compliance: 9th Feb 2019

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Europe-wide scope of EU-FMD “Safety Features”

Safety Features consist of 2 elements:

1 Unique Identifier

2 Tamper Evidence

Rx **Must** carry the safety features

All Prescription Medicines (Rx) are in scope….

…apart from those on the Whitelist

Currently white-listed:

- Radionuclides
- medicinal gases
- IV solutions in ATC therapeutic subgroup B05B ‘blood substitutes and perfusion solutions’
- contrast media
- homeopathic medicinal products

Over the Counter Medicines (OTC) are out of scope…

...apart from those on the Blacklist

Currently black-listed:

- 2 strengths of Omeprazol

OTC **Must Not** carry the safety features

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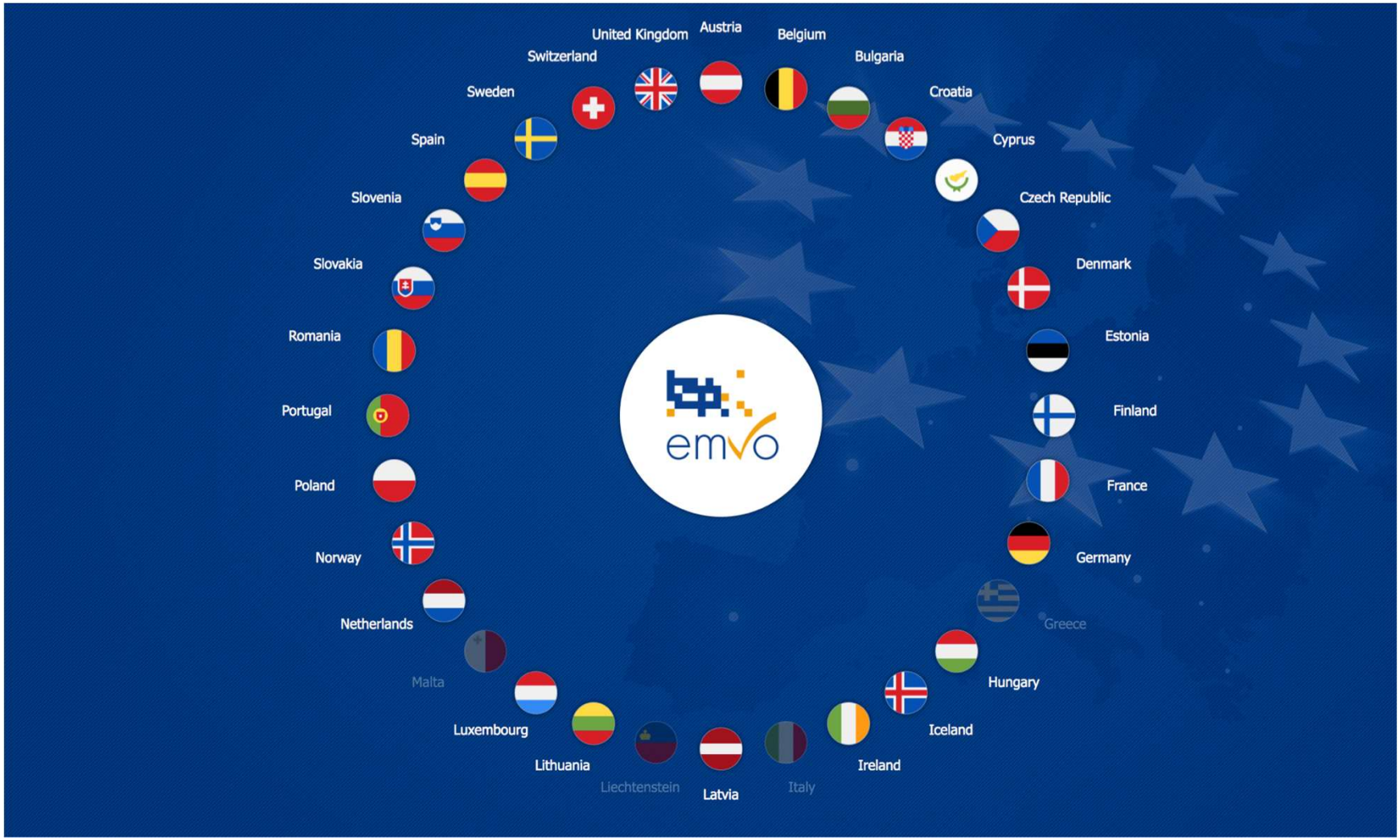
FMD – Countries in Scope



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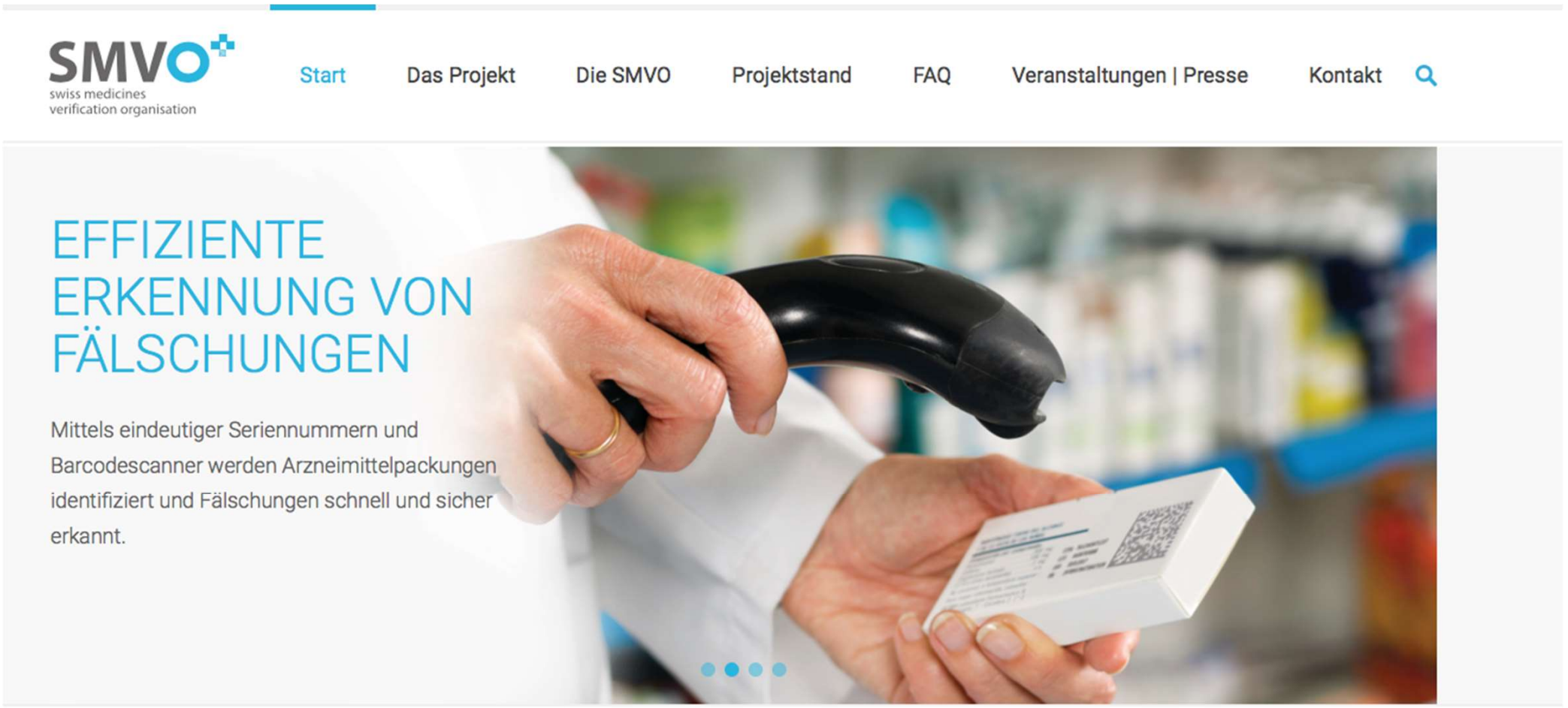
Switzerland (www.smvo.ch)



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Status SMVO

Projektstand in der Schweiz (9. April 2018)

- Entscheid für den Blueprint Servcie Provider ist getroffen worden: Solidsoft Reply.
- Die Statuten der künftigen Swiss Medicines Verification Organisation (SMVO) wurden ausgearbeitet und mit allen Stakeholdern und den Behörden abgestimmt.
- Gegenwärtig wird noch geprüft, wie sich verbandsfreie Unternehmen an die Arbeit der SMVO einbringen können und wie die in den Statuten berücksichtig werden kann.
- Die betroffenen Verbände haben ihre grundsätzliche Unterstützung zugesagt und die definitiven Statuten wurden verabschiedet.
- Erfolgreiche Durchführung von zwei Software-Provider-Workshops am 28. / 29. März 2018 mit über 60 Teilnehmern.
- **Die Gründung der SMVO erfolgte am 4. April 2018.**

Nächste Schritte

- Gründung der SMVS GmbH.
- Versand der Beitrittserklärungen an die pharmazeutischen Vertriebsgesellschaften.
- Aufbau und Moderation der Expertengruppen in Zusammenarbeit mit der SMVO.
- Planung Pilotbetrieb / Terminplanung
- Gewinnung von Pilotteilnehmern (SW-Häuser, Abgabeberechtigte und Grossisten)
- Verfügbarkeit von serialisierten Packungen sicherstellen
- Aufbau der SMVS Organisation zur Sicherstellung eines nachhaltigen Betriebs .

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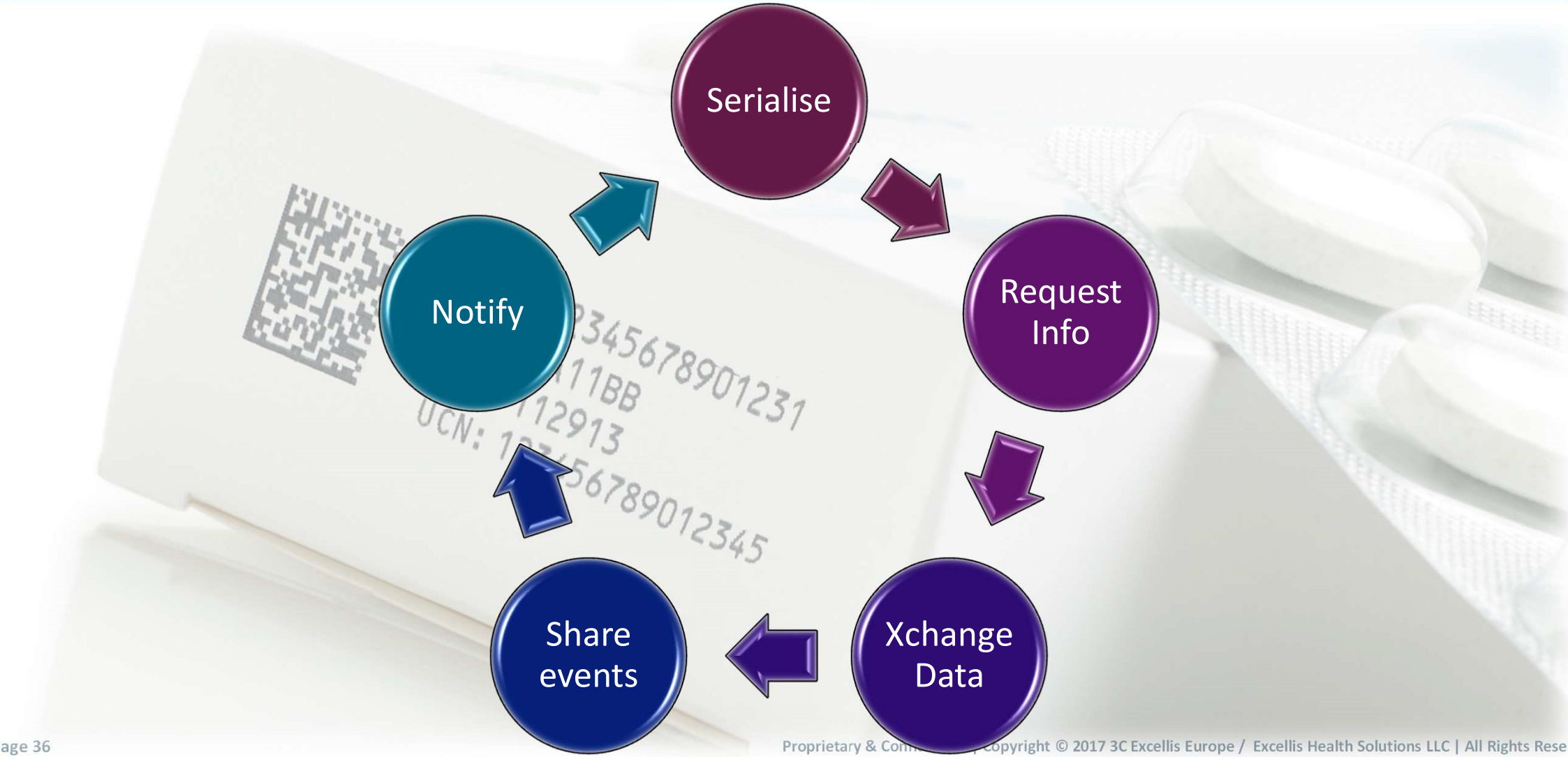
To protect patients, we need to get the pack right



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What is a “good” pack?

Before Serialisation

Confirm that batch of pharmaceutical product has a suitable pedigree demonstrated throughout the manufacturing supply chain and has been made to GMP

Correct API, composition, dosage form, strength

Confirm Product License Holder (certificate number, valid…)

Batch (number, prod/exp date, shelf life, primary/secondary pack as specified, storage conditions, temperature range….)

Quality analysis (specs, accepted by competent authority, COA)

Pack Labelling (Batch variable data, PIL….)

After Serialisation

All of the previous plus:

- Item-level variable data quality (correct data? SN uniqueness/randomness/sparseness?)
- Code carrier quality (barcode grade)
- Barcode vs. HR data
- Physical Items vs. serial numbers
- Item-aggregation reconciliation (Rejects? Samples?....)
- Number of packs produced vs. serial number uploaded to corporate repository
- SNs reported to compliance requirements:
  - Right numbers
  - Right report format
  - Received ok

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Serialisation Project Challenges

- Limited internal **bandwidth**…: implementing a major project like serialisation that touches many parts of the organisation
- Limited internal **knowledge**….: limited internal knowledge and experience of the particular challenges of serialisation
- How to understand the details and **impact of the requirements** in the many markets where the company operates
- Understanding what needs to be done to be **Serialisation-ready: Best Practices**

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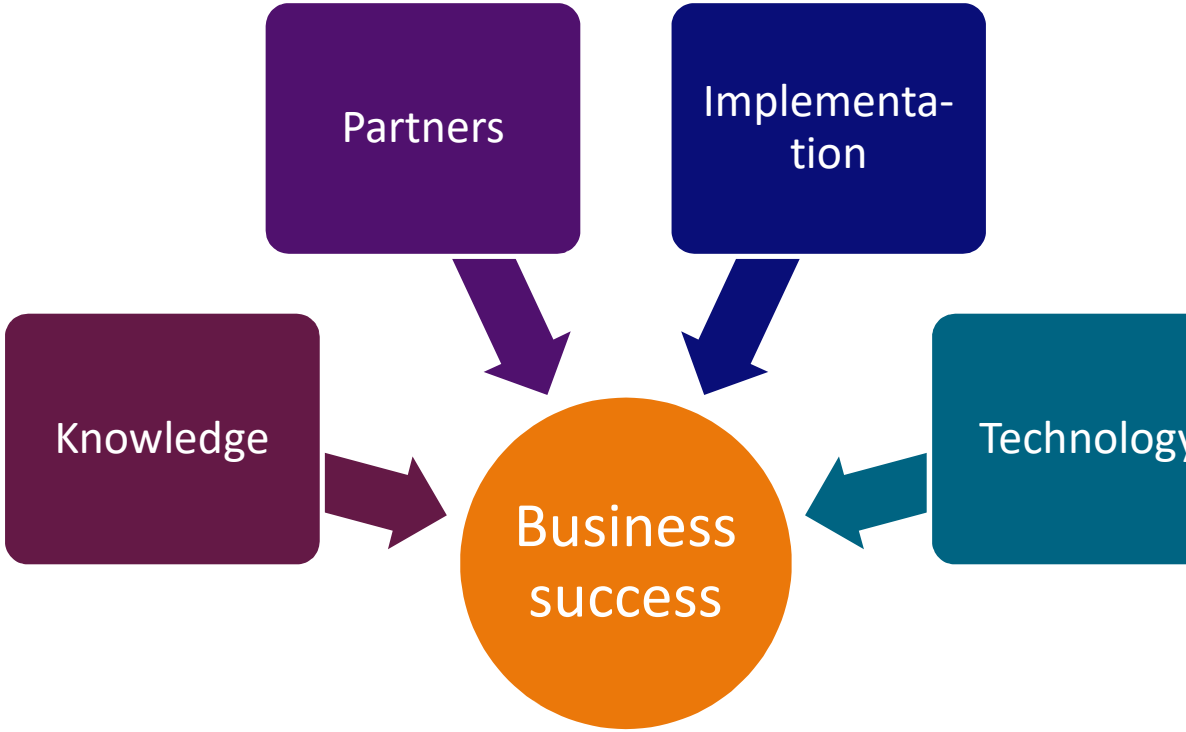
EU FMD Quick Start Guide: Readiness

erialisation
echnology stack

Master data and product coding

Partner integrated framework

comprehensive project



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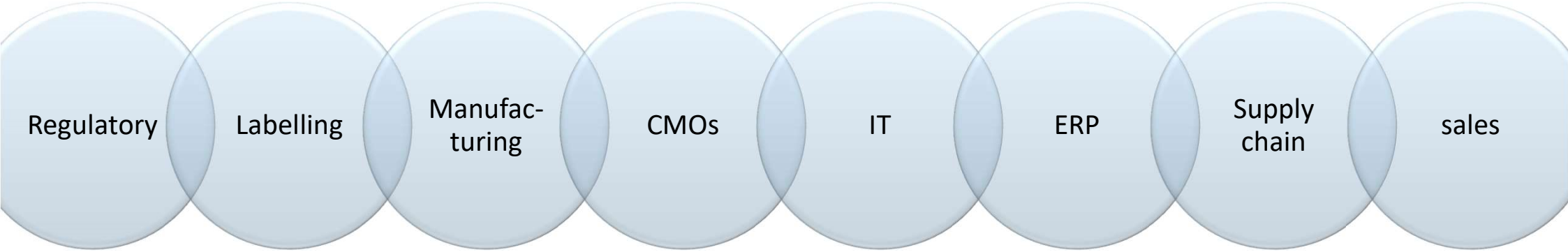
Take away :

- Serialization is a **regulatory imperative**: No compliance, no sales !
- Secure your **external supply chain: CMO** at at risk
- Serialization is still **evolving** - today : Turkey, Korea, **US-DSCSA**, **EUFMD** , new regulations (**Russia),** some regulations changes: Brazil, China, India….) .
- Serialization is a **enterprise program**!
- No time for trials: use **proven suppliers** and **expert consultancy** to secure your right do business and protect your investments.



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Serialization Data Creates Benefits

What is Generated?

Processing a single batch of 10,000 units:

Before Serialization

1 Transaction to Create a Batch
+
1 Transaction to Pick a Pallet
+
1 Transaction to Ship a Pallet
+
1 Transaction Send an ASN
=
4 Transactions
2KB of Storage

After Serialization

10,000 Transactions to Provision Serial Numbers
+
10,000 Transactions to Commission Serialized Products
+
10,000 Transactions to Aggregate Serialized Products
+
10,000 Transactions to Pick Serialized Product
+
10,000 Transactions to Ship Serialized Product
+
10,000 Transactions to Send Serialized Product Information
=
60,000 Transaction

Benefits from Use of Data Generated

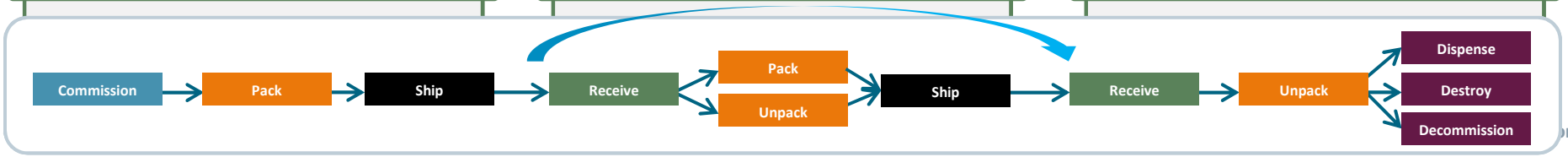
Life Sciences

- *Optimizing Recalls and Returns*
- *Inventory Optimization*
- *Supply Chain Visibility*
- *Operations Monitoring*
- *Addressing Illegal Diversions*

Healthcare and Retail

- *Improved Patient Safety*
- *Optimizing Recalls and Returns*
- *Improved Workflow*
- *Systems Interoperability*
- *Reimbursement*

Events Captured Across The Supply Chain



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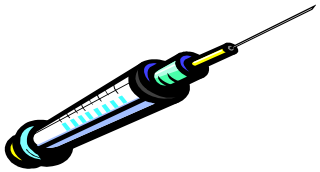
National Centre for Hereditary Coagulation Disorders (NCHCD) Ireland (GS1 Case Study)

Bar coded medication is delivered to the Hospital

Hospital (GLN)

Stock Fridge (GLN)

Patient receives CFC (clotting factor concentrates)



Prepare product (GTIN)

Issue Fridges (GLN)

Check Product V Patient and issue

e: Feargal McGroarty, National Haemophilia
m Project Manager, St. James's Hospital
n

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NCHCD Realised Business benefits

- ✓ Since Cold Chain delivery started all products verifiably delivered between 20-50 Celsius
- ✓ Product wastage reduced from €90,216 to zero
- ✓ Documentation errors reduced from 12 to zero
- ✓ Over € 5 Million worth of medication stock removed from supply chain
- ✓ € 426,000 worth of stock rotated between Hospitals and NCHCD
- ✓ Mock Recall of all (100%) Medication within 10 minutes
- ✓ Realtime recall alert
- ✓ Timeliness of infusion
- ✓ Prescription compliance (2000iu instead of recommended 1750iu)
- ✓ Automatic compliance (no manual record keeping)
- ✓ Electronic diary
- ✓ Realtime Alerts for specific bleeds
- ✓ Patient empowerment

e: Feargal McGroarty, National Haemophilia
m Project Manager, St. James's Hospital
n

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Value Beyond Compliance

nufacturer

- pply Chain Visibility
- oduct Diversion
- turns & Recalls
- tient Access
- ntracts & argebacks
- der Fulfillment

Wholesaler

- Process Automation
- Performance Monitoring
- Inventory Management
- Quality Management
- Integrated Services

Healthcare

- Operational Transformation
- Utilization/ Outcomes
- Reimbursement
- Adherence
- Patient Safety

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The “Five Rights”

1 Right patient

The patient’s identity must be verified against the prescription to ensure the right patient is receiving treatment;

2 Right medication

The provider must verify that the right medication is used;

3 Right dose

The right dose should be confirmed against the prescription;

4 Right time

Medications should be given at the right time; and

5 Right route

Medications that can be given in different ways, such as intramuscularly or intravenously, must be given via the right route;

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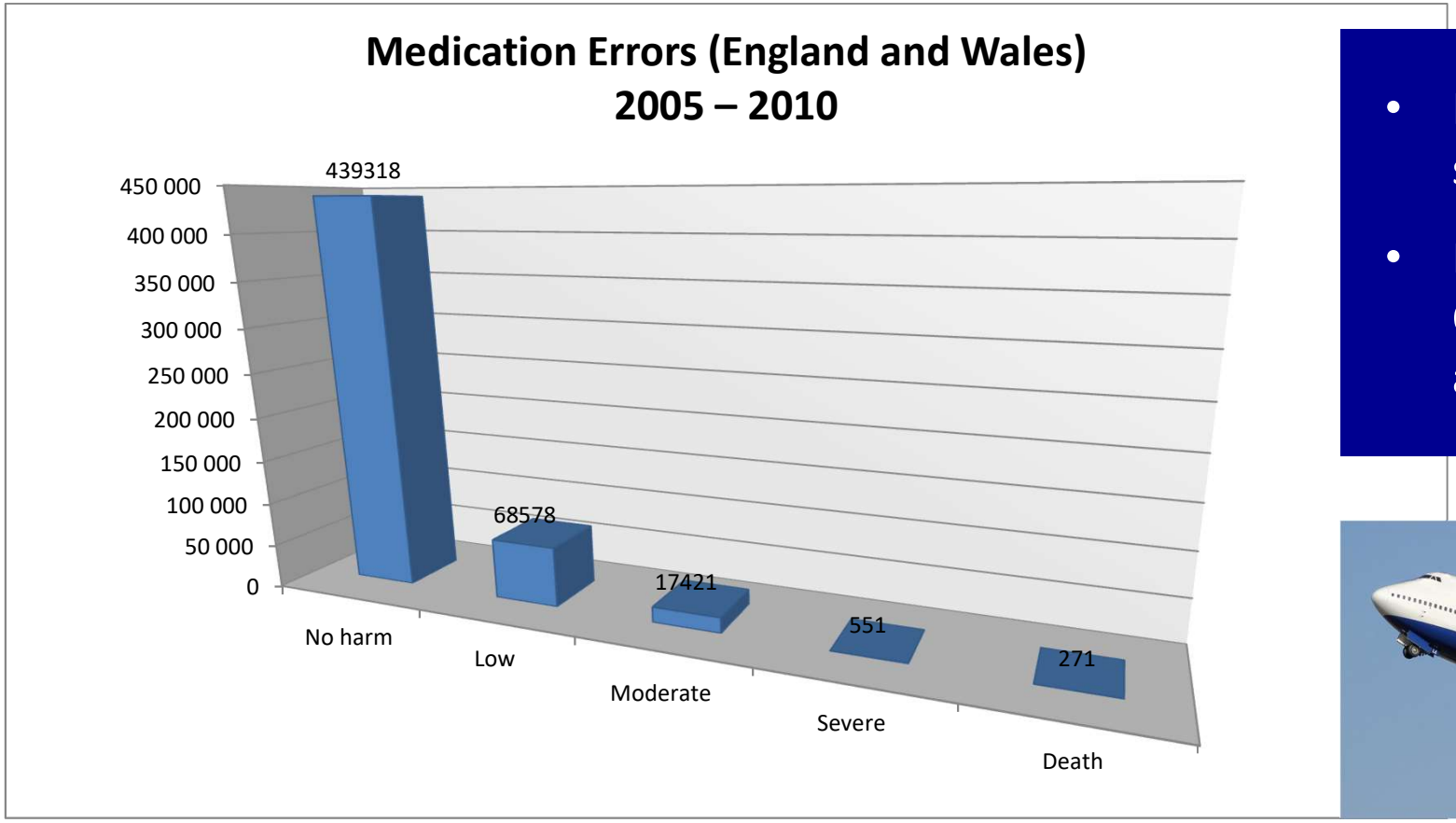
edication Errors



- Incidents annually (UK): S severe and 45 fatal
- Extrapolated to EU, 2012 Over 400 fatal Incidents annually

ousins D, Gerrett D, Warner B. A review of Medication Incidents reported to the National Reporting and Learning System in England and Vales over six years (2005 – 2010) Br J Clin Pharmacol 2012 (in press)

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Content

- Introductions
- Fake Medicines in Europe – No Problem?
- Serialisation: A Global Response
- EU-FMD in Detail
- A “Good Pack” in the Serialised World
- Side-effects
- **In conclusion**

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Strategic Goals for Serialisation / Traceability

New Opportunities Additional Business Value	• Advanced customer requirements • Patient engagement and support • Marketing • Stepping stone to e-health
Improve Business Operations: Process Integrity	• Improved Supply Chain Control • Enhanced Supply Chain Visibility • Improved reverse logistics • Meet special customers, e.g. Hospitals
Pro-active Brand Protection: Product Integrity	• Enhance perception of products • Pro-actively address potential threats • Shape Industry Response • Collaborate in shaping standards
Meet Legislation/ Regulations	• Comply with Regulations • Delay investment until Information is firmed up • Wait and see approach

+ $$$

- $$$

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Thank you very much

Additional information, questions, and assistance please contact:

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