Counterfeiting, Coding and other Challenges

Using GS1 Standards to Combat Counterfeiting and Improve Patient Safety

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Christoph Krähenbühl, AstraZeneca Pack Coding and Product Security
AstraZeneca is a global, innovation-driven, integrated biopharmaceutical business

- We discover, develop, manufacture and market prescription medicines for six important areas of healthcare: cancer, cardiovascular, gastrointestinal, infection, neuroscience, respiratory and inflammation.

- We employ over 62,000 people (47% Europe, 31% Americas and 22% in Asia, Africa and Australasia).

- We invest over $4 billion in R&D each year and have over 11,000 people in our R&D organisation.

- Active in over 100 countries - growing presence in emerging markets (China, Brazil, India and Russia).

- In 2009, our worldwide sales totaled $32.8 billion (including 10 medicines with sales of over $1 billion.)
Counterfeit Drugs

The Experience of AstraZeneca
Counterfeiting is a lucrative business
For every US$1000 invested, counterfeit pharmaceuticals generates US$500,000 return*.

Pharmaceutical Counterfeiting is seen as **High Profit** with **Low Risk**.

So who may be involved?
- Unlicensed businesses
- Licensed business such as Distributors, Wholesalers
- Organised crime gangs

![Graph showing return on investment for different types of counterfeits: $7K for fake credit cards, $100K for counterfeit software, $500K for counterfeit drugs, and up to $500K for counterfeit drugs.](source: Visa/Master Card, Microsoft, AZ own data)
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Fake Drugs can hurt real Patients

* Source: Visa/MasterCard, Microsoft, AZ own data
The AstraZeneca Experience of Counterfeiting

Counterfeiting affects all types of products and all regions

WHO estimates on counterfeiting worldwide

- 30% counterfeit
- 20% counterfeit
- 10% counterfeit
- 1% counterfeit
Example of Counterfeits of Our Products

**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. Global response led to arrests worldwide. Court cases concluded.
Strategic Response to the Challenge

Product Security and PCSF Programme
AZ Global Product Security Strategy
Protect our patients from fake / illegally traded medicines
The historical AZ approach

Svärkopierad information på den nya etiketten:

- Hologram med perforeringar (försvarar avlägsning av etikett)
- Perforering (för öppning av förpackning)
- Etikett-nummer (i form av 2D-kod)
- Förpackningsnummer (i form av dels läsbara siffror samt i 2D-kod)

Så kontrolleras förpackningen:

1. Förpackningen dokumenteras och förpackningen unika data hanteras i tillverknings-systemet...
2. ...och lagras sedan i AZ-databasen.
3. Återförsäljaren kan sedan ”on demand” kontrollera förpackningens ursprung med databasen.

GRAFIK: TOMAS ÖHRKLING
Coding / Serialisation benefits

- **External Product Verification Services**
- **Today**
  - Supporting external coding requirements (Turkey, China etc.)
  - AZ verification over distance without divulging confidential information
  - Routine verification by pharmacists at time of dispensing
- **Enhanced Patient Safety, Supply chain and other business benefits**
Serialisation Solution in AZ

Global Roll-Out of PSDM – Product Security Data Management
UCN (Unique Carton Number)
ALMS – PSDM components

Packing Line

Segregated Network

Neri / Marchesini Labeller on Packaging Line

Systech Advisor

printers, cameras and control system (PLC)

(control system / Database)

Application of TESS

generate UCNs and apply to pack

UCNs from all lines aggregated by Guardian

lines securely isolated from corporate network

UCN records summarised in XML file

Site

Bridging Server

Systech Guardian

IBM Bridging Server

Axway Trusted File

UCNs

AZ Global

Corporate Network

AZIA

Axway Trusted File

PSDM (Axway Synchrony EPCIS)

Data Encryption and transfer through AZIA messaging service

Packing Line Site AZ Global

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Coding Requirements

Further Challenges
Pack Coding Radar

- EU Harmonised Coding
- US Serialisation & E-pedigree
- Sufficiently aligned
- Poor alignment or requirements unclear so far
- Out of line with AZ policy.
- Advocacy strategy needed

KEY
- Advocacy alignment
- Serialisation & E-pedigree
- EU Harmonised Coding
- Denmark coding
- Serbia ?
- Romania ?
- Slovenia coding
- Turkey Aggregation
- Korea s-code
- UAE
- France coding
- Turkey coding
- Japan s-code
- China Coding
- Brazil coding
- Argentina ?
- Colombia ?

Countries:
- Canada
- US/Canada
- EMEA
- AsiaPacific
- Latin America

- Sweden, Switzerland, Netherlands, Spain?
- Denmark coding
- Italy coding
- Korea coding
- UAE
- Korea RFID
- Korea s-code
- Hong Kong coding
- France coding
- Turkey coding
- Japan s-code
- China Coding
- Brazil coding
- Argentina ?
- Colombia ?

Timeline:
- 2010
- 2011
- 2012
- 2013
- 2014 onwards
GS1 standards – the answer?

Ensuring a global and interoperable solution with GS1 standards is clearly the answer …

- The GS1 standards have a true global reach
- Most manufacturers and suppliers are already incorporating GS1 standards into their products and processes
- Many of the requirements we see coming through from Governments (but other stakeholders, too) refer to the GS1 standards, examples:
  - India Export Coding
  - EFPIA advocating GS1 2D DM: GTIN, Batch, Expiry, S/N
  - Hospitals in Holland, Denmark, Switzerland
  - GS1 Sunrise in Canada
  - UK NHS Commercial Medicines Unit GS1 2D DM working group

AstraZeneca believes that the adoption of global GS1 standards will facilitate the pharmaceutical sector to efficiently manage new legislation and customer demands.

...however...
CEE multimarket pack
Challenges for everyone

Examples such as these raise a number of questions:

• Are the GS1 / GTIN rules on how to allocate GTINs clear enough?
• Has the guidance been fully understood, by industry, authorities and other stakeholders?
• Is the fundamental conflict being addressed between different uses of GTINs: 1) “pure” Trade Item, 2) use in the SGTIN in product security or 3) GTIN used as licence / reimbursement code?
• And also are we, as manufacturers, geared up to handling coding – not just code application but the critical data management requirements?

Let’s keep in mind: The aim is to deliver the right product to the right patient.

The most efficient and cost effective way to achieve this is through the harmonised identification of all pharmaceutical products using a unique, scan-able code that is part of one global standard.
Conclusion

Responding to the Challenges
An Ambitious Global Programme based on Global Roll-out of Serialisation capability

Key elements of a successful strategic vision are to:
• develop and implement an adaptable technical standard solution
• not focus on one specific requirement,
• work together with other stakeholders
• accept the challenge as an opportunity to move to a pro-active approach
• get the coding house in order.

AstraZeneca have a coherent and credible programme, aligned with mainstream thinking in the industry, that will support our long-term strategy but give us benefits along the way.

This puts us into a position to face the new and broader challenges presented to a globally sourced pharmaceutical company today.