

Counterfeiting, Coding and other Challenges

Using GS1 Standards to Combat Counterfeiting and Improve Patient Safety

GS1 Healthcare Conference, Amsterdam October 2011
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.
- Active in over 100 countries - growing presence in emerging markets (China, Brazil, India and Russia).
- 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.
- In 2009, our worldwide sales totaled \$32.8 billion (including 10 medicines with sales of over \$1 billion).



Counterfeit Drugs

The Experience of AstraZeneca



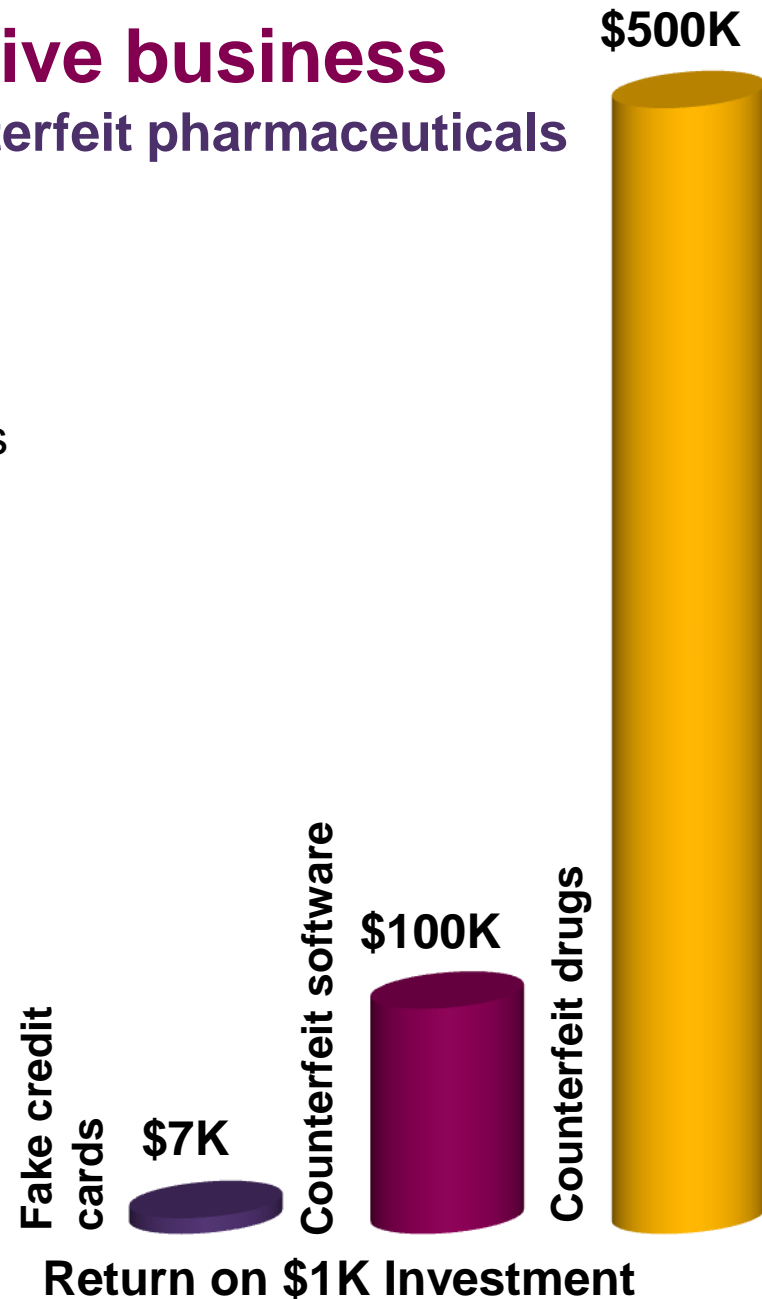
Counterfeiting is a lucrative business

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**



* Source : Visa/Master Card, Microsoft, AZ own data



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Fake Drugs can hurt real Patients



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The AstraZeneca Experience of Counterfeiting

Counterfeiting affects all types of products and all regions



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.



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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, the court heard.

'Patients at risk'

The counterfeit medicines contained only a fraction of the correct dosage.

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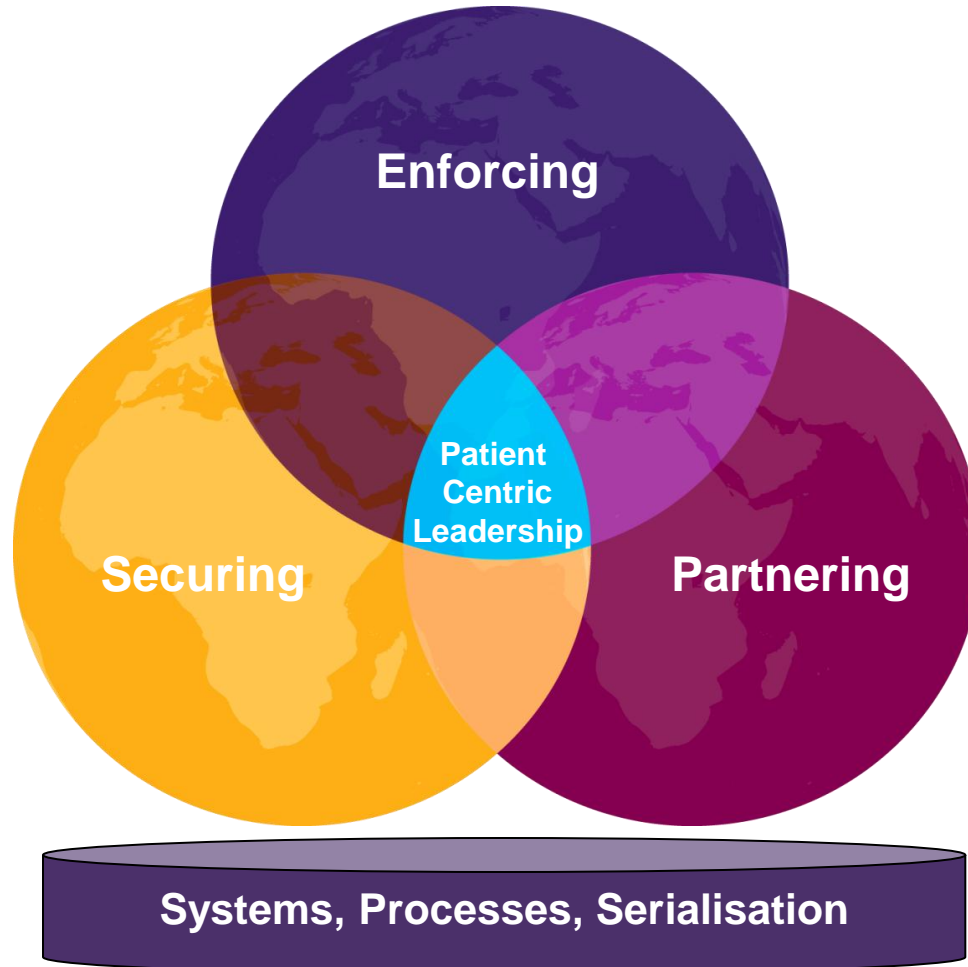
Strategic Response to the Challenge

Product Security and PCSF Programme



AZ Global Product Security Strategy

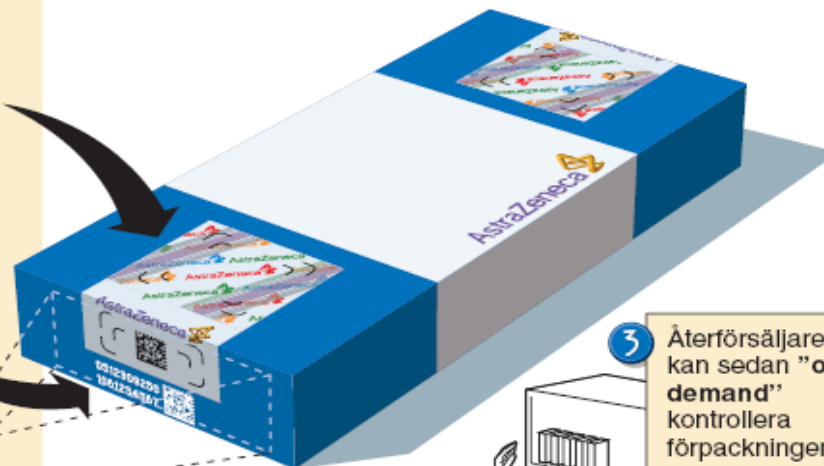
Protect our patients from fake / illegally traded medicines



The historical AZ approach

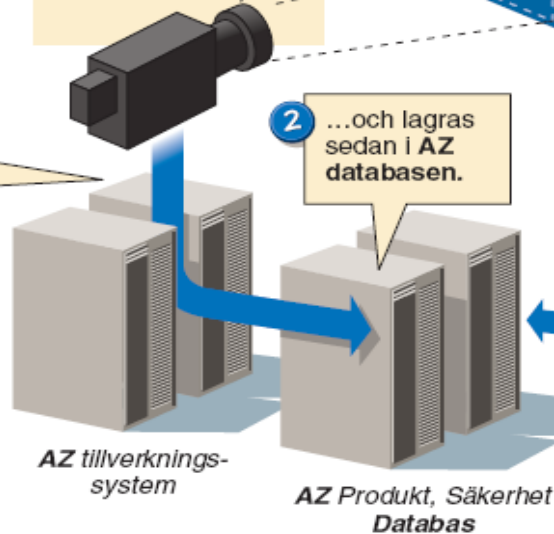
Svårkopierad information på den nya etiketten:

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



Så kontrolleras förpackningen:

1 Förpackningen dokumenteras och förpackningens unika data hanteras i tillverkningssystemet...

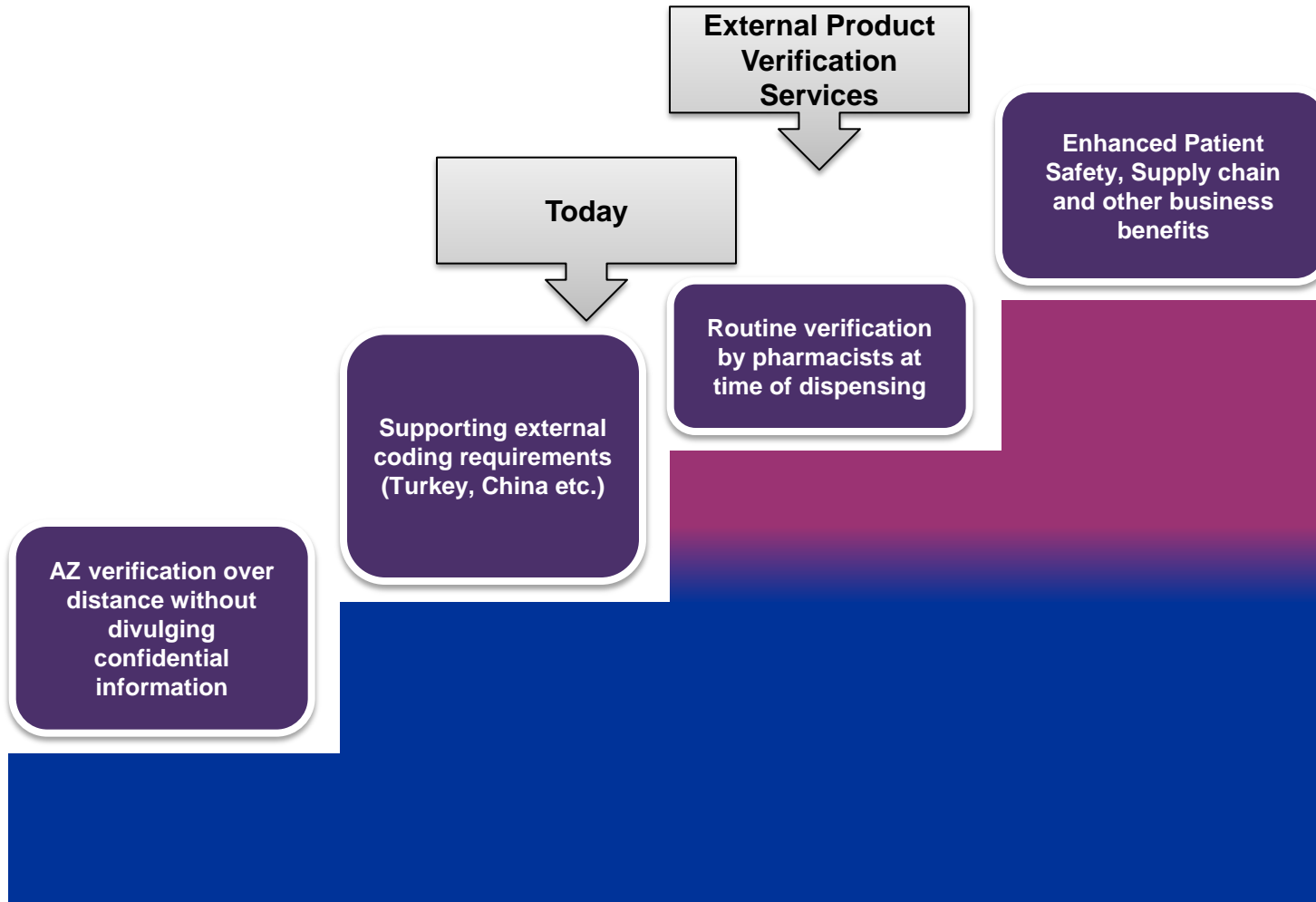


3 Återförsäljaren kan sedan "on demand" kontrollera förpackningens ursprung med databasen.



GRAFIK: TOMAS ÖHRLING

Coding / Serialisation benefits



Serialisation Solution in AZ

**Global Roll-Out of
PSDM – Product
Security Data
Management**



UCN (Unique Carton Number)

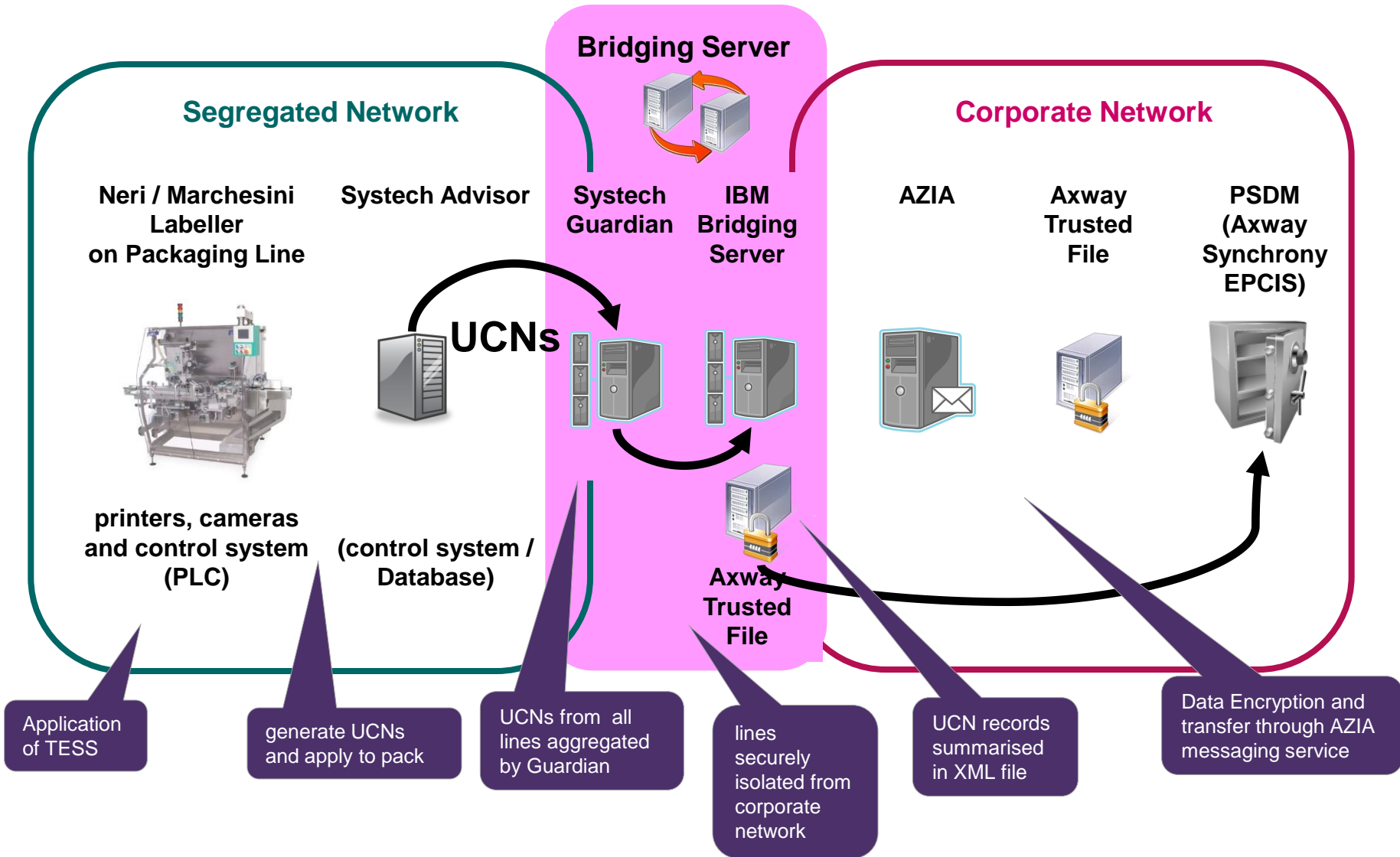


ALMS – PSDM components

Packing Line

Site

AZ Global

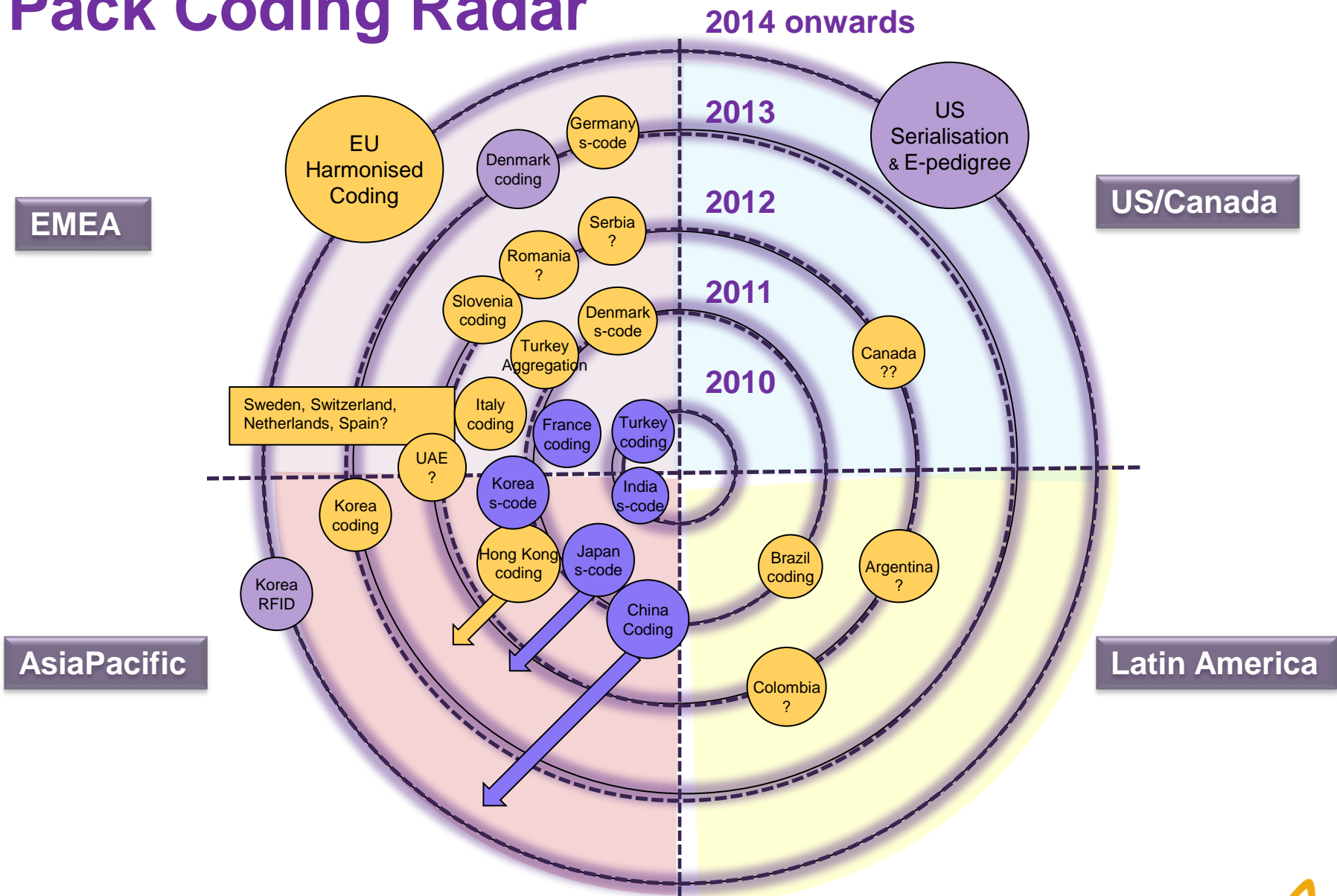


**Coding
Requirements**

Further Challenges

4

Pack Coding Radar



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

FASLODEX™ 250 mg

injekční roztok/oldatos injekció/
injekcinis tirpalas
fulvestrantum/fulvesztrant/
Fulvestrantas

Injekční roztok v předepsané sílce, intramuskulární použití. Pouze k jednorázovému použití. 1 předepsaná sílka (5 ml), 1 bezpečnostní jehla (Galaxy®), 1 dávková injekční stříkačka (Galaxy®).
Číslo injekční stříkačky: Fulvestrantum, intramuskulární léčba. Každá ampule obsahuje 1 předepsanou dávku (5 ml), 1 bezpečnostní jehlu (Galaxy®).
Injekční roztok v předepsané sílce, variabilní ražení. Také sterilizované v injekční lahvičce, 1 ampule (5 ml), 1 bezpečnostní jehla (Galaxy®).

AstraZeneca

Uchovávejte v chladničce. Uchovávejte předepsanou sílku v původním obalu, aby byla chráněna před světlem. Uchovávejte mimo dosah a dohled dětí. Více informací připravte si u svého lékaře, lékárníka nebo zdravotní sestry. Hlídejte si své zdraví. Pokud se objeví jakýkoli nežádoucí účinek, informujte svého lékaře. Pokud se objeví jakýkoli nežádoucí účinek, informujte svého lékaře. Pokud se objeví jakýkoli nežádoucí účinek, informujte svého lékaře. Pokud se objeví jakýkoli nežádoucí účinek, informujte svého lékaře.

Jedna předepsaná sílka obsahuje 250 mg fulvestrantu a 5 ml roztoku. Každá ampule obsahuje 1 předepsanou dávku (5 ml), 1 bezpečnostní jehlu (Galaxy®), 1 dávková injekční stříkačka (Galaxy®).

Účinná látka: fulvestrantum (5 ml roztoku) 250 mg. Každá ampule obsahuje 1 předepsanou dávku (5 ml), 1 bezpečnostní jehlu (Galaxy®), 1 dávková injekční stříkačka (Galaxy®).

FASLODEX 250 mg
injekční roztok

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Před použitím si prosím přečtěte příbalovou informaci. Úplný návod k aplikaci přípravku FasloDEX a použití bezpečnostní jehly naleznete v příloženém Návodu pro použití.
Használat előlt olvasd el a mellékelt tájékoztatót. A FasloDEX beadására és a biztonsági tű alkalmazására vonatkozó részletes használati utasítást a mellékelt alkalmazási előírás tartalmazza.
Prieš vartojimą perskaitykite pakuotės lapelį. Visi nurodymai kaip vartoti FasloDEX ir kaip naudoti saugią adatą pateikti pakuotėje esančioje vartojimo instrukcijoje.

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FASLODEX™ 250 mg

injekční roztok/oldatos injekció/
injekcinis tirpalas

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10000120001072

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.