Track & Trace at Novartis Pharma AG

Scott Cameron
GS1 Healthcare Conference, Tokyo – October 29, 2008
Agenda

- Novartis Company Profile

- Track & Trace
  - Drivers
  - Concept
  - Novartis Pilot
  - Complexity and Sophistication
Our focus is on patients

Our purpose is to care and cure. We provide medicines to treat and prevent diseases, ease suffering and improve quality of life.
Novartis is a world-leading healthcare company

- Ranked as one of the fastest-growing pharmaceutical companies
- One of 20 largest companies by market capitalization
- Among most respected companies globally

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<th>Key figures¹</th>
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<tr>
<td><strong>2007</strong></td>
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<td>Net sales:</td>
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<td>Net income:</td>
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<td>R&amp;D investment:</td>
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<th>Sales by region – 2007</th>
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<td>Rest of the world</td>
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<td>Americas</td>
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<td>Europe</td>
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¹ Excluding Consumer Health discontinued operations

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We have a broad healthcare portfolio

2007 net sales by division

Pharmaceuticals

New and better medicines with improved efficacy and fewer side-effects

Vaccines and Diagnostics

Human vaccines and diagnostic tools to protect against life-threatening diseases

Sandoz

Generic pharmaceuticals that replace branded medicines after patent expiry and free up funds for innovative medicines

Consumer Health

Readily available products that enable healthy lifestyle choices

- OTC (Over-the-Counter)
- CIBA Vision
- Animal Health

¹ Excluding Consumer Health discontinued operations
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  - Complexity and Sophistication
Drivers for Track & Trace functionality

- Patient Safety
- Compliance (Legal Requirements)
- Brand Protection
Track & Trace concept: Technological hurdle against criminal activities

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<td>• Numbering</td>
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Authentication Features
• Holograms
• Security Inks
• Watermarking
• Serialization
• ...
Challenging Regulatory Environment

California: Effective Date of E-pedigree Law postponed to January 2015

Turkey: New Track & Trace law in place – effective January 2009/2010

Jan '09: unique numbering
Jan '10: pedigree
all sales packs: Rx + OTC

EFPIA Trial
2008

Unique numbering & e-pedigree for all sales packs by Jan 2015 - Rx only

Track & Trace – law in place
Track & Trace – law discussed
Serialization – law in place
Serialization – law discussed
Machine-readable coding – law in place
Data concept along the supply chain

*Solution for data exchange is required (many diverse technologies)*

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Novartis Supply Chain

- **PharmOps**
  - Packing
  - Factory stock

- **Country Organization**
  - Distr. Center
    - In
    - Stock
    - Pick
    - Out

- **Wholesaler**
  - Distr. Center
    - In
    - Stock
    - Pick
    - Out

- **Pharmacy / Hospital**
  - Refill Stock

* :Places where trace data gets recorded

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Packaging: Serialization of packaging hierarchy

Process Requirement: Must work at line speeds of up to 400 packs /min.

- Manufacturer
- Product
- Production date
- Part number
- Random part Nr.
- Authentication Nr. ID Level 4
- Authentication Nr. ID Level 3
- Authentication Nr. ID Level 2
- Authentication Nr. ID Level 1
- Product status
- Log file

Supply chain monitoring
Database

Authentication & e-pedigree

Authentication Nr. ID Level 4:
Pallet

Authentication Nr. ID Level 3:
Shipping case

Authentication Nr. ID Level 2:
Display carton

Authentication Nr. ID Level 1:
Individual package

Commercial Pilot:
Barcode & RFID
(UHF Gen2)
Packaging: Complex & sophisticated retro-fit of Lines required
Novartis Pharma – U.S. Market only: 45 Packaging Lines (own & 3rd parties)
Packaging: Novartis Pilot Operational

Unique Serialization of Sales Packs - 250 bottles per minute
Distribution: Integration of complex, global Supply Network

Production Sites & Distribution Centers - operated internally or by 3rd parties
The magnitude of the Effort - U.S. Market only

*Item-level Serialization & Pedigree*

- Over 300 packaging configurations sold on the U.S. market
- 45 packaging lines (incl. 23 operated by contract packagers) at 15 sites in 6 countries produce for the U.S. market
- 75…85 MUSD estimated cost to comply for total U.S. volume through implementation of serialization capability (packaging) and pedigree capability (distribution centers) - operating cost not included
- Similar implementation cost for RFID vs. 2D – but vastly differing operating cost
- Although a standardized approach is taken each implementation has unique features
  - Competing priorities for line time; must not disrupt supply
  - Varying line speeds, line automation equipment, floor space availability
- Novartis pilot to cover packaging, distribution and IT required involvement of 45 individuals
Conclusion
The learning for Novartis

- Implementing Track & Trace is time consuming, complex and costly.

- Emerging technology

- Without globally harmonized standards Track & Trace implementation will be sub-optimal.
  - Standards for data carrier & content for serialization: Business Stakeholders and GS1
  - Pedigree standards (e.g. push vs. pull)

- Continued discussion/ alignment between regulatory bodies and pharma business partners is required.
Thank You!
Novartis Pilot Operational
Unique Serialization of Bundles - 250 bottles per minute
Novartis Pilot Operational

Unique Serialization of Shipping Cases - 250 bottles per minute