“EGA, Coding, Auto-ID and Patient Safety”

GS1 Healthcare Conference

René Kappers, CIRM
chair EGA Anti-counterfeiting HPA Group
member EGA Health Economics Committee
“EGA, Coding, Auto-ID and Patient Safety”

THE Pharmaceutical Industry no longer exists.

It has matured into TWO separate industries, rooted into two different strategic global marketsystems.

Difference between Generics-Originators is not used in any other industry!
why are so few members from the generic industry active in GS1 Healthcare Projects?
why so low attention for GS1 initiatives directed to the generic industry?
? a communication mistake?
? do we understand the needs of the target audience correctly?
Topics

- Generics? Relevance, value, growth, future, breadth, its driver
- Core business compared
- Characteristics
- Auto-ID and generics
- Global Coding and generics
- Patient Safety
- Conclusions

Difference between Generics-Originators is not used in any other industry!
Generics are relevant

Generic Market Share 2006 (volume)

US: 73% volume

Source: EGA Market Review 2007; ES, FR, IR, share of 'unprotected market'. ES, FR share of 'protected market' is respectively 10% and 16% (Source EGA 2006 Annual Conference)
Generic Medicines Cover All Areas

Common Chronic Conditions treated with affordable generic medicines

- Cancer
- Viral Infections
- Diabetes
- Bacterial Infections
- Depression
- Osteoporosis
- High Cholesterol
- Epilepsy
- High blood pressure
- Rheumatism
- Asthma
- Pain Relief
- Gastro-intestinal disorders (i.e., heartburn, ulcers)
- Inflammation
Generics do it for less costs

Generic Market Shares 2006 (value)

Source: EGA Market Review 2007
Generics add value to Society

 Role of Generic Medicines

- “Pricing studies have shown unequivocally that generic competition is the most effective way to ensure lasting price reductions”

WHO 55th Assembly
May 2002

- “Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines.”

Pharma Forum Progress Report June 2007
Generics add quality to more lives (1)

Market Growth Post-Generic Launch: Mevacor/Lovastatin

Weekly TRXs

Ref: Israel Makov, IGPA 2003, Cascais
Source: IMS
Generics add quality to more lives (2)

- During patent period
  - 7% of the kidney patient not treated with Epoetin Alfa due to budgetary constraints

- After intro of biosimilar by Sandoz...
  - 100% treatment due to 20% price reduction!

Thimothy F. Statham OBE
GM National Kidney Federation, UK
Brussels, 21 Nov 2007
Generics do it on the other side

Product Life Cycle

- Introduction & growth
- Maturity
- Decline

- Innovator
- Generic

3 - 6 years
20 years
>50 years

€
Generics Future is Bright

Europe’s Ageing Population

- Working age
- Employment
- Elderly
Generics Future is Bright

## Generics Future is Bright Below "The Bidet-Line"

<table>
<thead>
<tr>
<th>Country</th>
<th>Costs</th>
<th>Volume</th>
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<tbody>
<tr>
<td>United Kingdom</td>
<td>28 %</td>
<td>57 %</td>
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<tr>
<td>Netherlands</td>
<td>23 %</td>
<td>54 %</td>
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<tr>
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<td>Denemark</td>
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<td>Csech Republic</td>
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<tr>
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<td>38 %</td>
<td>58 %</td>
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<tr>
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<tr>
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<tr>
<td>Finland</td>
<td>14 %</td>
<td>36 %</td>
</tr>
<tr>
<td>Austria</td>
<td>11 %</td>
<td>11 %</td>
</tr>
</tbody>
</table>

Generics Goes Global

- 1998: Zero True Global Companies
- 2008:
  - Teva
  - Sandoz
  - Barr / Pliva
  - Mylan / Merck Ag
  - Hospira / Mayne
  - Apotex
  - Zentiva
  - Actavis
  - Ratiopharm
  - Mayne / Faulding
  - Ranbaxy
  - Dr Reddy’s
  - Cipla

Generics are Competition

China: 6,000 manufacturers
India: 12,000 manufacturers
The Core Businesses

- Converting 'Local Patents' into Global Brands by
  - Multinational Companies
  - International Companies
  - Global Companies

- Converting 'Global Commodities' into Local Brands
  - Trans-national Enterprises
How to strategically organize

**Multinational**
- Corporate HQ
- Country HQ
- Subsidiaries
  - independent & loosely organized

**International**
- Re-create abroad
- Domestic clones
- Transplanted products

**Global**
- Standardized product
- Exported anywhere

Flaig, Integrative Manufacturing, APICS, 1993
How to strategically organize

A Transnational Enterprise

- Vision, Policy & Philosophy centralized
- Products tailored to local economy
- Decentralized implementation decisions
- Decentralized operational decisions
- International management teams
- Strong & Flexible Enterprise Network

Flaig, Integrative Manufacturing APICS, 1993
Pharma Industry is Two Industries

- Cost Driven Industry
- Full Competition
- Fierce Competition
- Breadth & Deep assortment
- Huge Annual 'Filings'
- "Business" Stakeholders

- R&D Driven Industry
- Mono / Oligopolistic
- ? Moderate to none
- "Small" assortment
- Normal Annual Filings
- "Science" Stakeholders

Teva got 1160 approvals regarding 89 components in 206 forms in 2007 in Europe.
Teva had 3166 approvals pending by 31 Dec 2007 in 30 European countries.
Merck Ag carried 400 mols in 3300 products; Hank Klakurka, Merck Ag, Istanbul 2007
Ranbaxy 614 filings/year globally. S; Brian Tempest, Ranbaxy, Istanbul 2007
Generics have a different Supply Chain.

- API Producer
- Manufacturer
- Wholesaler
- Retail / Hospital Pharmacy

- Patent

- API Producer
- Manufacturer
- Wholesaler
- Retail / Hospital Pharmacy
Generics Need a Different Supply Chain

- Mix
- Change-over
- Modifications
- Volume (-changes)
- (Re)-Routing
- Specifications
- Speed & Reliability
- Complexity
- Length
Generics, Coding & Auto-ID, Patient Safety. Conclusions

- Regarding the Claimed Increase of Patient Safety by Coding & Auto ID: we'll wait for the evidence
Generics, Coding & Auto-ID. Conclusions.

- Global Coding is a great enabler for a developing global business
- Auto-ID is the important enabler for greater dynamics while increasing accuracy in the supply chain
- Global Coding & Auto ID strikes right in the strategic heart of the generics pharmaceutical industry: Cost Reduction !!!
GS1 Healthcare and Coding & Auto-ID

... to recognise and to communicate its TRUE added value for the generic medicines industry: cost reduction!

... that strikes the hearts of our generic medicines industry executives

We Love Cost Reductions !!!

...to Increase the affordability of proven valuable health care
By The Way, re. Counterfeiting

- We disgust it as much as our colleagues do.
- We are actively cooperating in this serious matter with GS1, WHO / IMPACT, Council of Europe and the EU Commission.
- However, we still do not believe in 'technical' solutions ...because ...
- "Greed needs another Paradigm"
- Medical Supply Chain Integrity Pact
Medical Supply Chain Integrity Pact
(launched 20 September 2007)

Business with Licensed Partners Only!

To establish non-technological but ethical solutions to improve supply chain integrity while dealing with counterfeiting of medicines.
Medical Supply Chain Integrity Pact
(launched 20 September 2007)

Business with Licensed Partners Only!
You are Invited to Join !!!
“EGA, Coding, Auto-ID and Patient Safety”

Thank you very much.

René Kappers, CIRM
chair EGA Anti-counterfeiting HPA Group
member EGA Health Economics Committee
Annex.
Anti-Counterfeiting so far:

- **EGA actions:**
  - Established Anti-Counterfeiting High Priority Action Group, reporting immediately to the Executive Committee, i.e. to its president Mr. Emile Loof
  - Two position papers on anti-counterfeiting policy published
  - Active participation in the WHO IMPACT International Medical Products Anti-Counterfeiting Task Force (2006)
  - Active participation in the GS1 European Health Care Initiative and Global GS1 Health User Group (HUG) and -to a lesser extent- GS1 Healthcare activities
  - Active participation in the Anti-counterfeiting working group of Council of Europe
  - Contribution to and member of the RFID Experts Group initiative of DG INFSO
  - Recently joined as observer the EFPIA Anti-counterfeiting steering committee
  - Creation of the Supply Chain Integrity Pact together with GIRP and PGEU