



Making Medicines Affordable

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

**GS1 Healthcare Conference
Granada 11-14 February 2008.**

René Kappers, CIRM

**chair EGA Anti-counterfeiting HPA Group
member EGA Health Economics Committee**



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“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 !



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- 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 ?

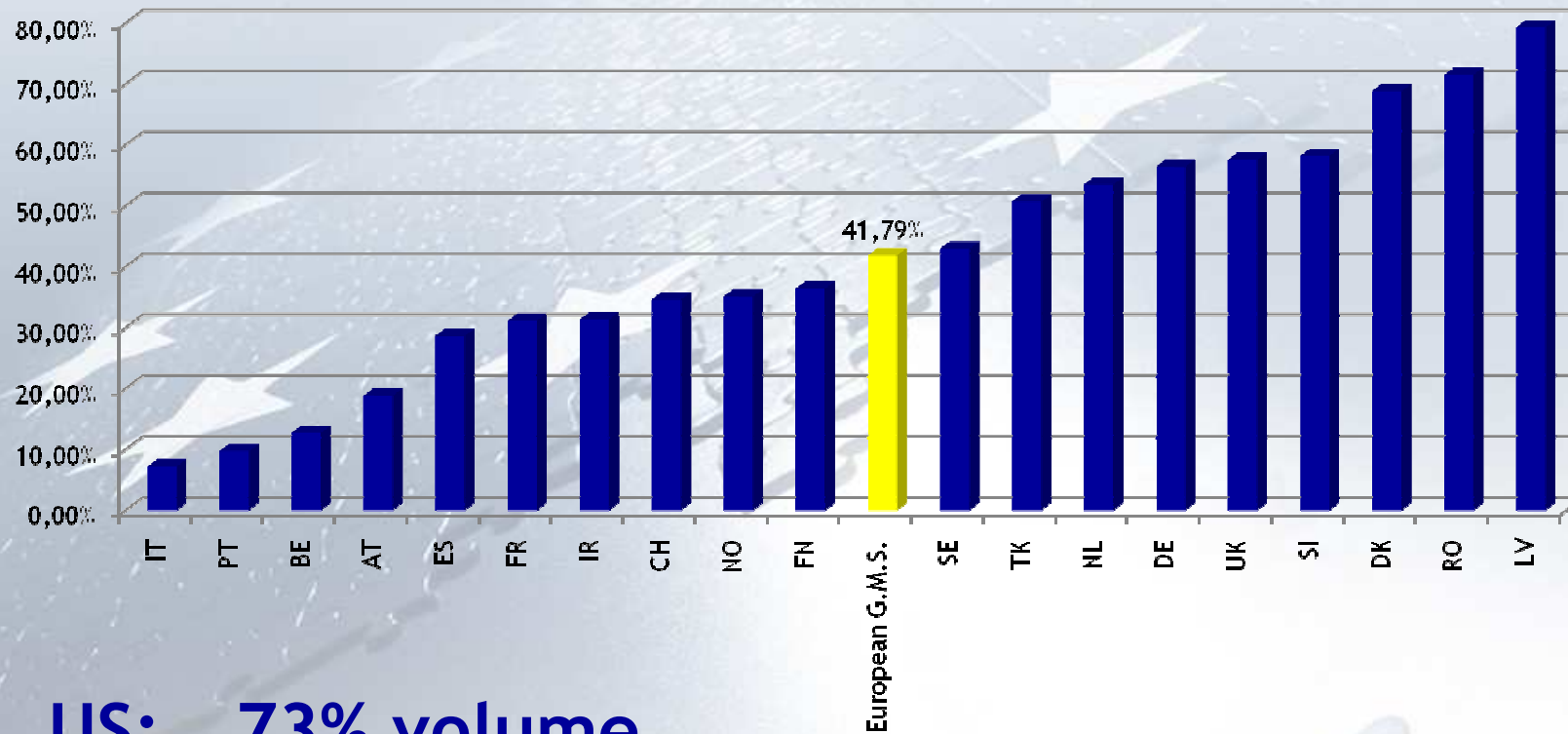
Topics

- 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)

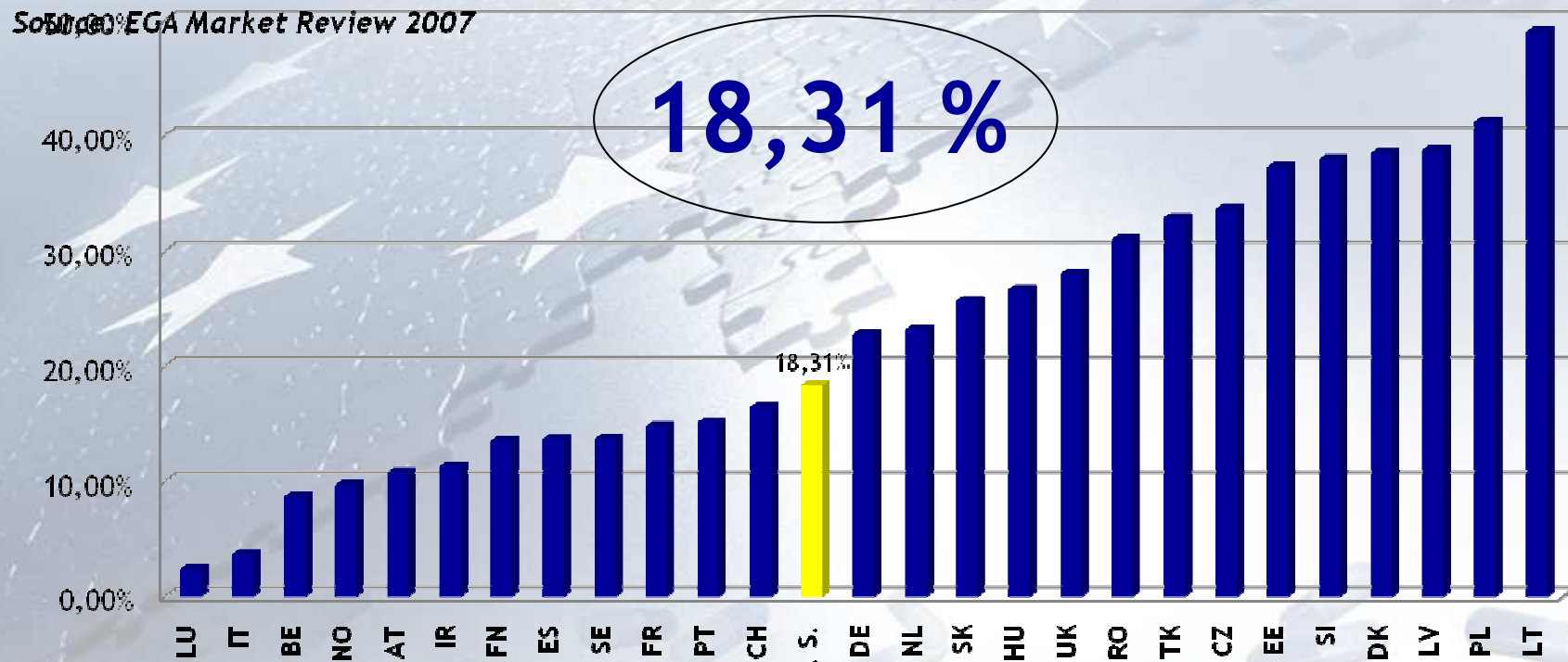
Generic Medicines Cover All Areas

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)





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

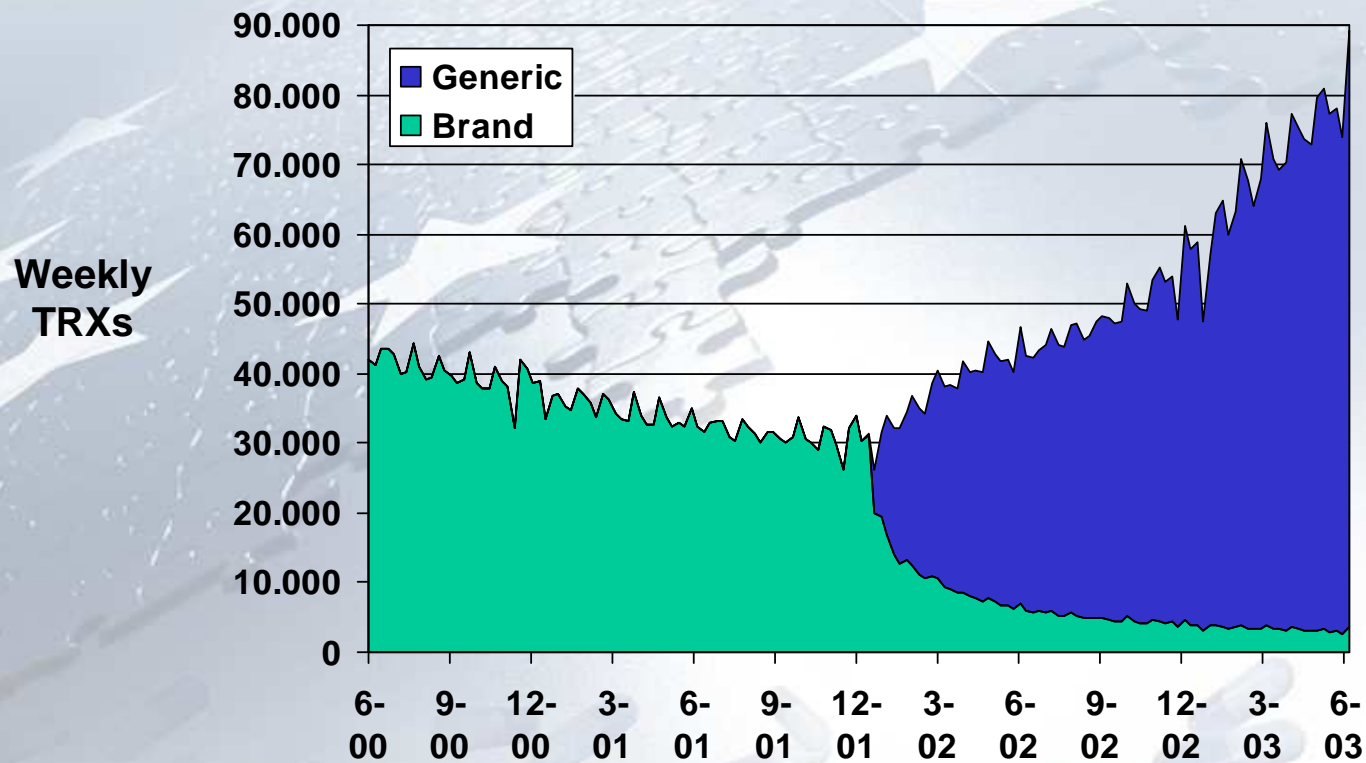
**WHO 55th Assembly
May 2002**

**Pharma Forum Progress
Report June 2007**



Generics add quality to more lives (1)

Market Growth Post-Generic Launch: Mevacor/Lovastatin



Ref: Israel Makov, IGPA 2003, Cascais
Source: IMS

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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!

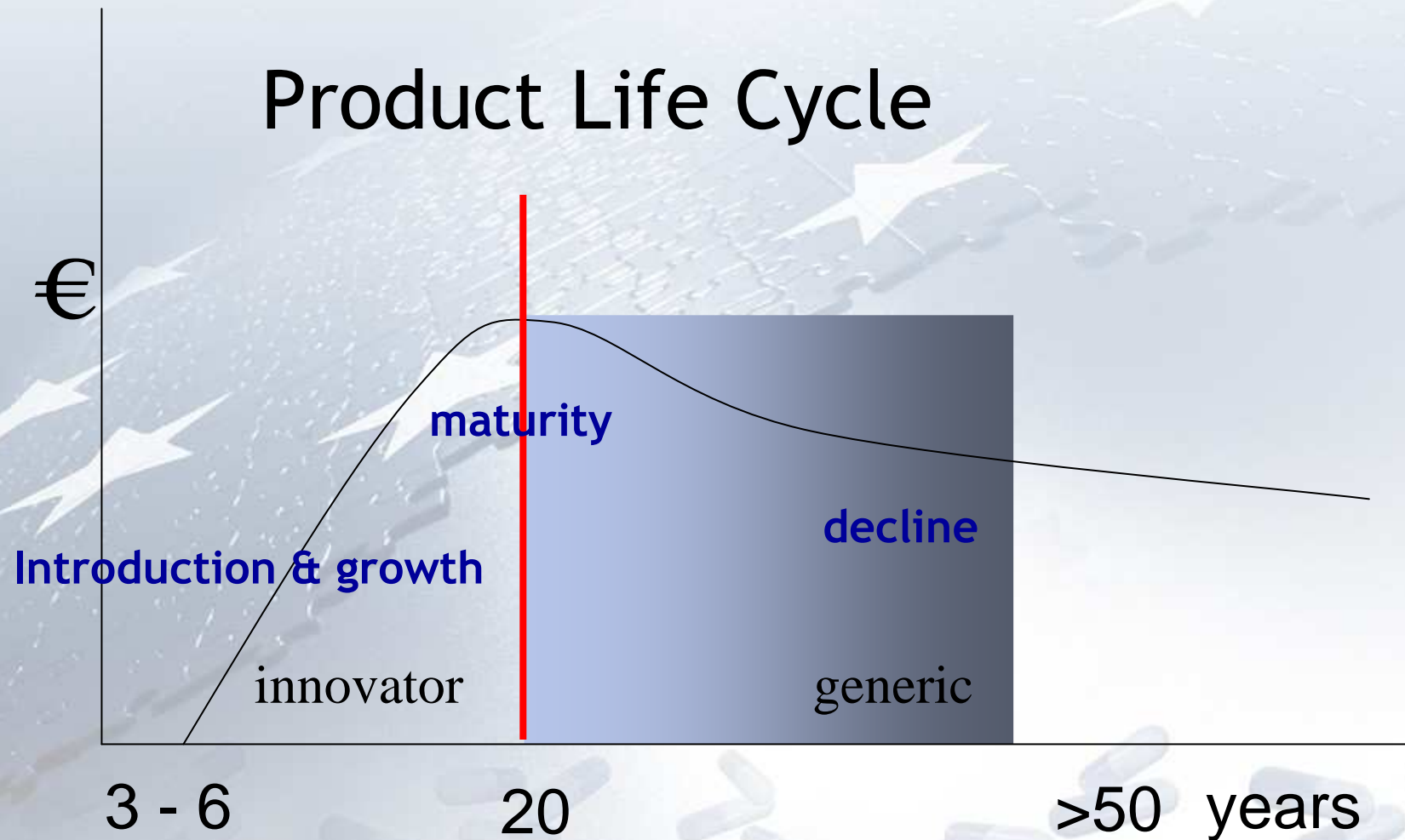
Thimothy F. Statham OBE

GM National Kidney Federation, UK

Brussels, 21 Nov 2007

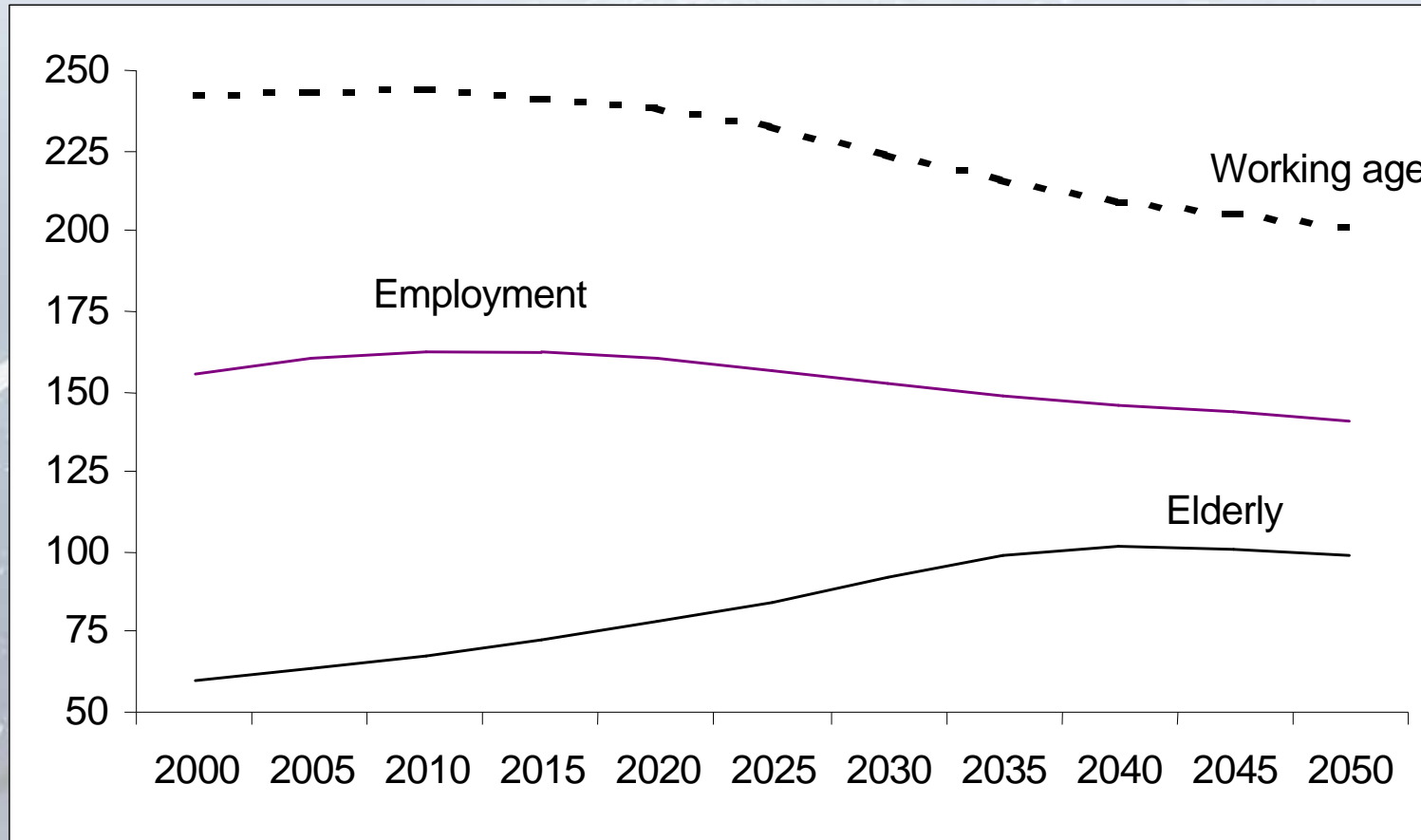
Generics do it on the other side

Product Life Cycle



Generics Future is Bright

Europe's Ageing Population

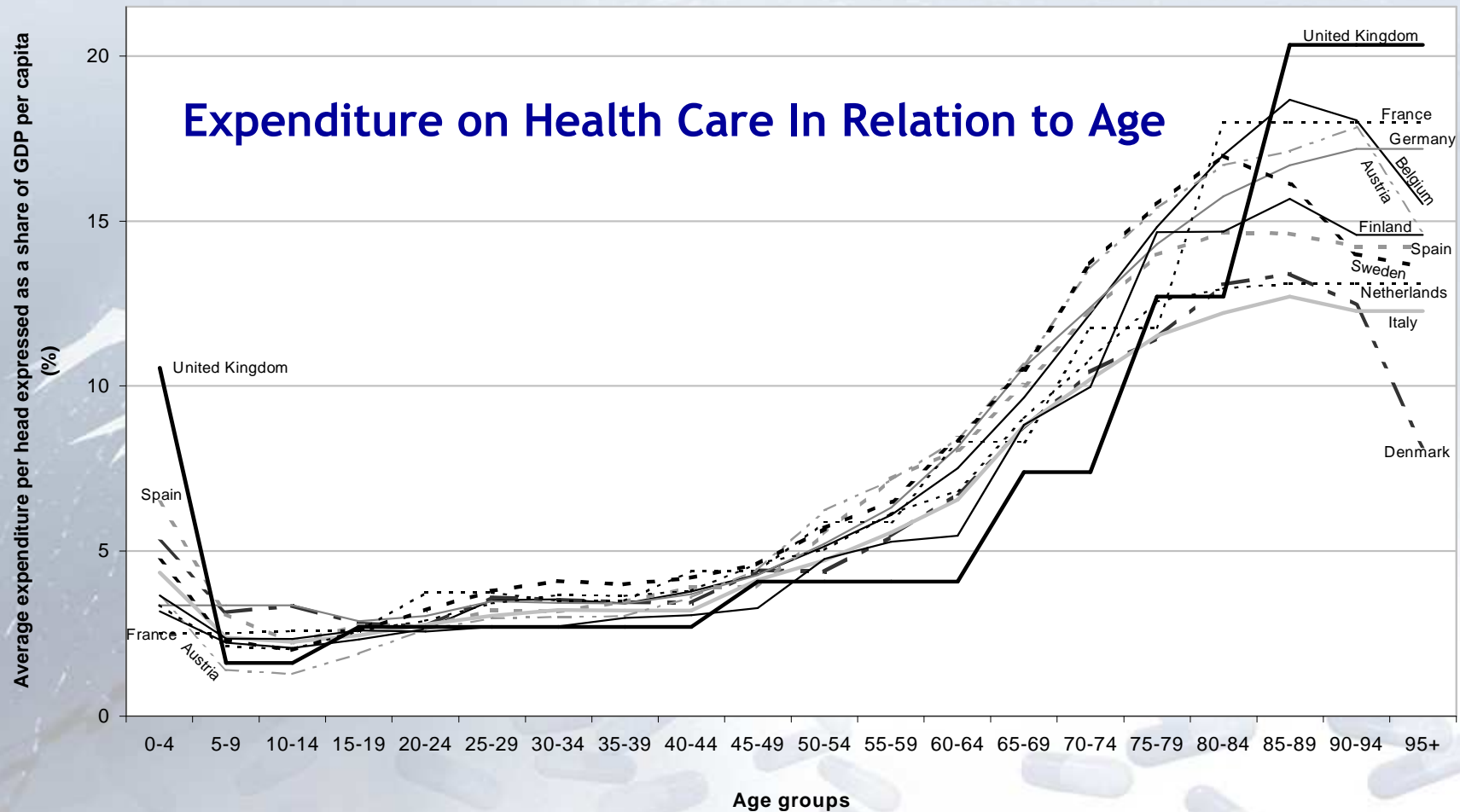




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Generics Future is Bright

Source: Economic Policy Committee (2001) "Budgetary challenges posed by ageing populations"



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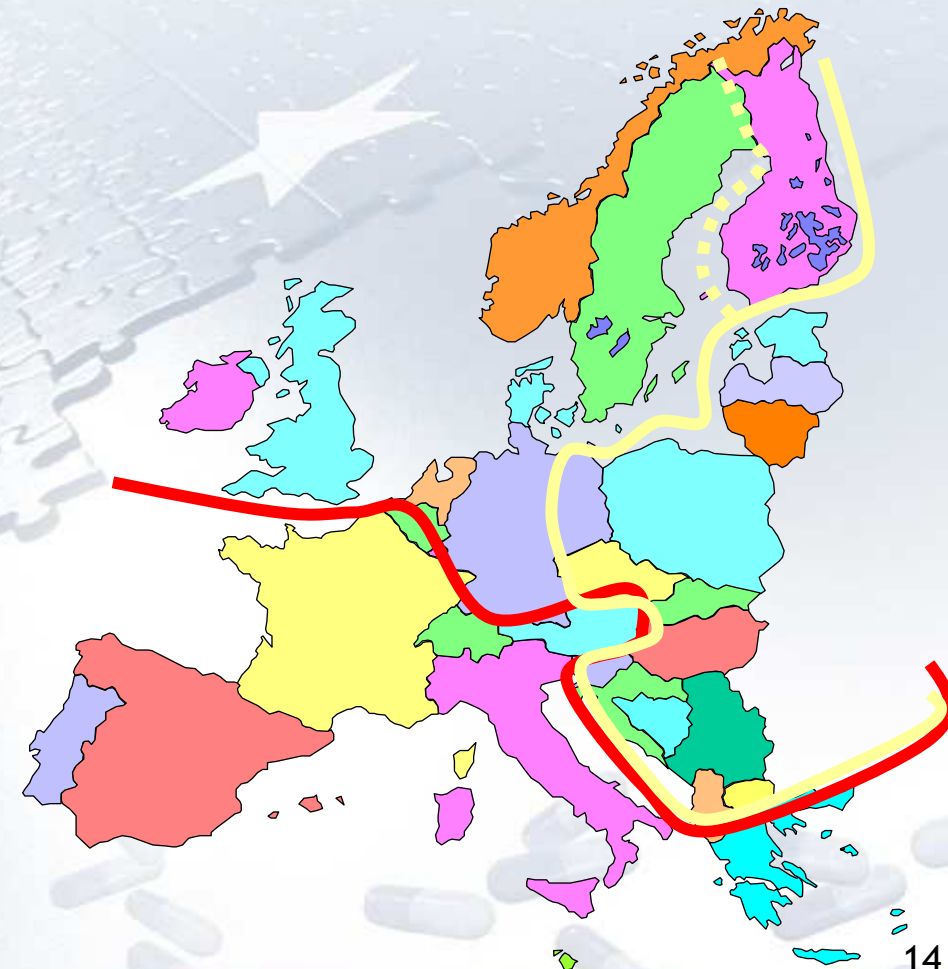


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Generics Future is Bright

Below "The Bidet-Line"

Country	costs	volume
United Kingdom	28 %	57 %
Netherlands	23 %	54 %
Germany	23 %	56 %
Denemark	39 %	69 %
Hungary	29 %	44 %
Poland	60 %	77 %
Csech Republic	34 %	60 %
Slovenia	38 %	58 %
Baltic states	50 %	77 %
Belgium	9 %	13 %
France	8 %	16 %
Italy	4 %	7 %
Spain	6 %	10 %
Portugal	15 %	9 %
Finland	14 %	36 %
Austria	11 %	11 %



Source: EGA 2007 Annual Market Review
FR, ES, HU, CR, Baltics, EGA 2006 Annual Conference

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Generics Goes Global

■ 1998: Zero True Global Companies

■ 2008:

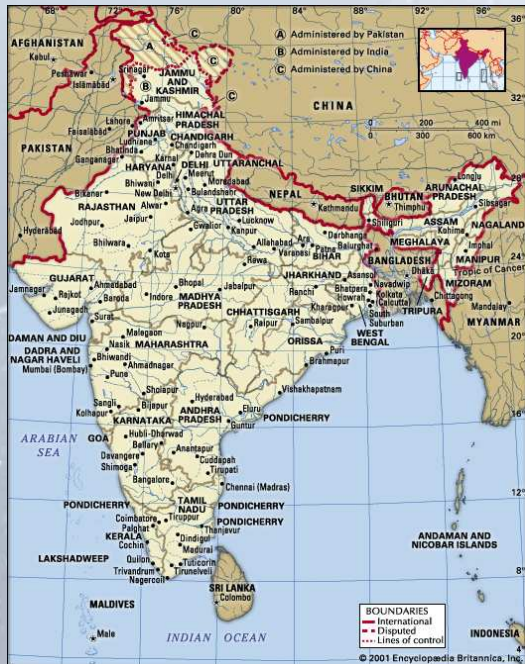
- Teva
- Sandoz
- Barr / Pliva
- Mylan / Merck Ag
- Hospira / Mayne
- Apotex
- Zentiva
- Actavis
- Ratiopharm
- Mayne / Faulding
- Ranbaxy
- Dr Reddy's
- Cipla

Ref: T.Erdei, Healthcare UBS, IGPA 2007 & Teva.



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Generics are Competition



China: 6.000 manufacturers

India: 12.000 manufacturers

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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

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 & Flexibel Enterprise Network

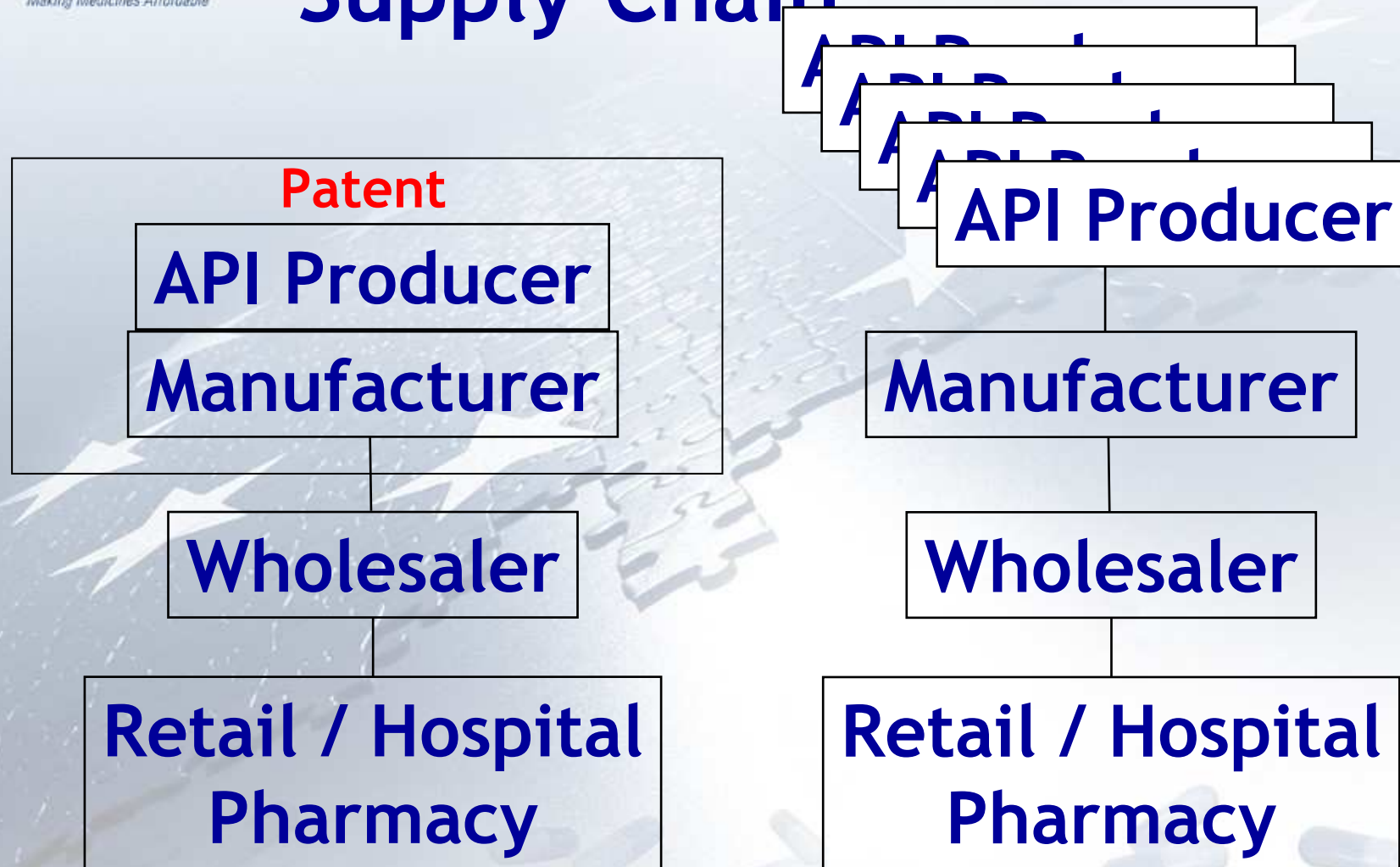


Pharma Industry is Two Industries

- 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.
Teva Annual Report, 12 Feb 2007.
Merck Ag carried 400 mol's 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



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 !!!



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**“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