



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



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Data Exclusivity/Patent Linkage in the Context of EU Generic and Biosimilar Applications

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Outlines

- Introduction to EGA and market shares for generic medicines
- Terminology
- New and old DE provisions
- DE vs patent period/ME
- Impact of DE/ME
- Applicability of DE
- DE and Paediatric Regulation
- Patent linkage

EGA - European Generic medicines Association

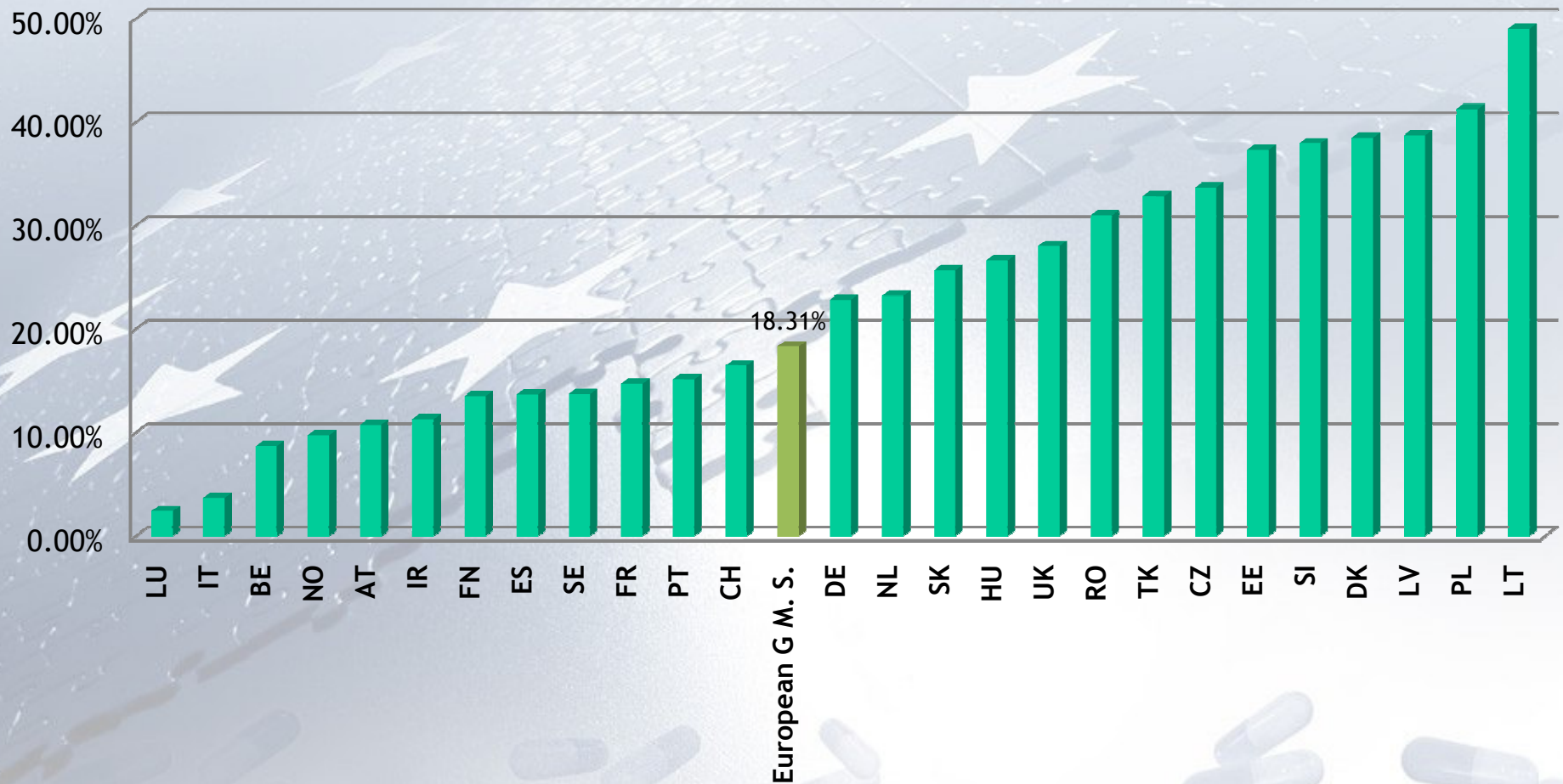
- Established in 1993
- Based in Brussels
- Pan European
- Generic & Biosimilar Industry
- Representing over 600 companies (excluding subsidiaries)
- Over 70 direct members
 - Companies
 - National associations





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Generic Market Share 2006 (value)

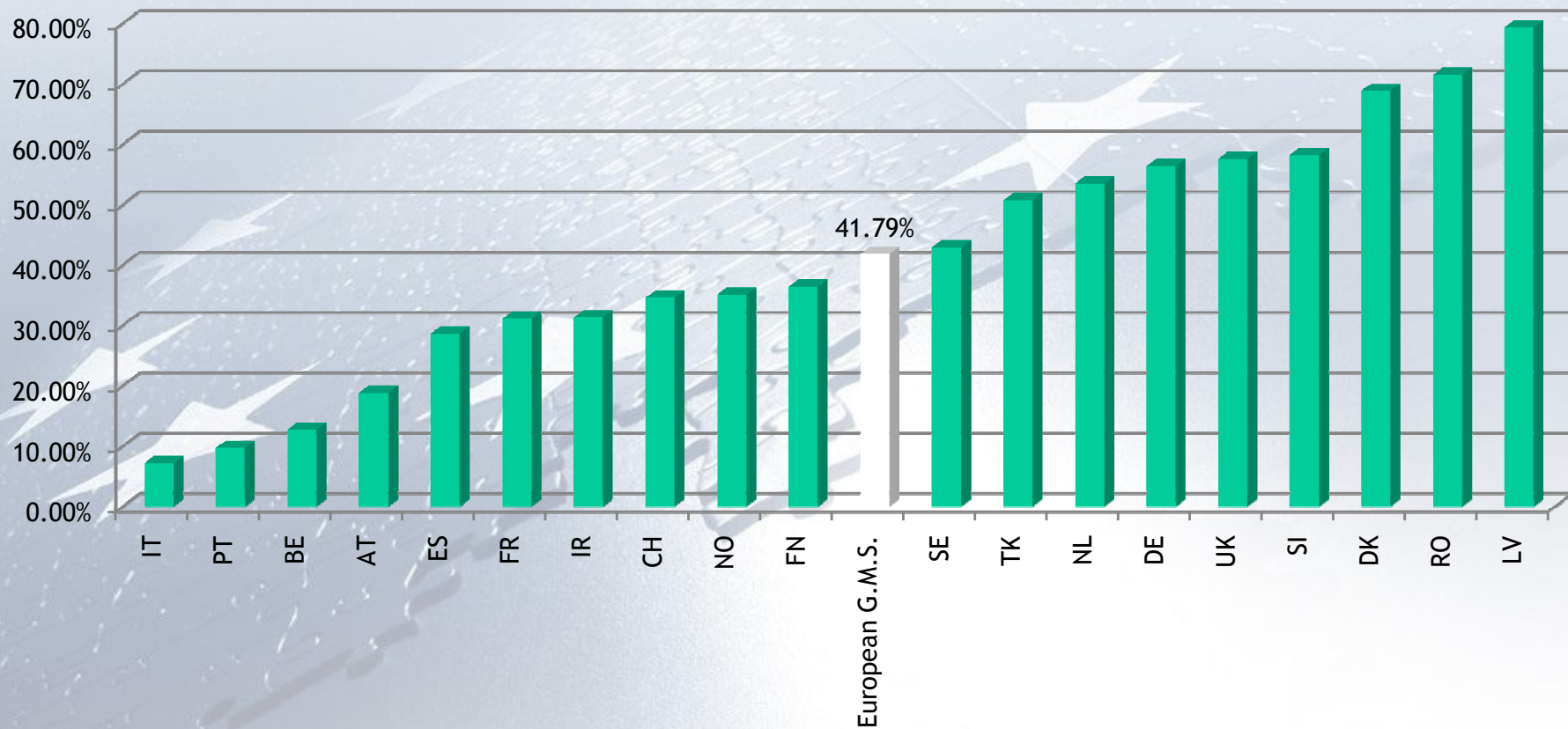


Source: EGA Market Review 2007



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Generic Market Share 2006 (volume)



Source: EGA Market Review 2007

Terminology

Data Protection

- **Misleading terminology**
 - Associated with protection of data of one's personal life
- **Data submitted to the regulators remain undisclosed vis-à-vis third parties**
- **Generic companies never have direct access to the pre-clinical and clinical data submitted by originator companies**
- **Generic companies do not use the originators' data**
- **Generic/biosimilar application cross-refer to originators' data**

Terminology

Data Exclusivity (DE)

■ Data exclusivity

- Completely independent of IP laws
- Administrative **Regulatory Exclusivity**
- Determines the length of time during which
 - the generic/biosimilar application **cannot cross-refer** to the originators' data and
 - the Regulatory Authorities **cannot rely** on originator's data to approve a generic/biosimilar version of the relevant originator product

6/10 DE Still Valid in Enlarged EU

■ 19 MSs: **6 years**

All new Member
States

(MSs), AT, DK, FI, SP
, EL, PT, IR,
+(EEA States: NO ,IS)

■ 8 MSs: **10 years**

BE, LU, FR, IT, DE,
NL ,SE ,UK



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New Data Exclusivity

- **Changes brought in by ‘EU Pharma Review’**
 - Change from 6/10 years to ‘8 + 2 + 1’
 - Harmonisation of Data Exclusivity
- **Prospective application i.e. applies to applications of originator products made after 30 October 2005 (DCP) and 20 November 2005 (CP)**

Data Exclusivity

‘8+2+1’ Formula

- Applies to all reference products (chemical & biological) independent of the registration procedures
- No additional data exclusivity for line extensions

0-8 years Data Excl.

2 years Market Excl.

(1 year ME)

Marketing
Authorisation of
Reference
Product

Generic or
biosimilar
Application

Assessment, approval, price
, reimbursement

Additional 1 year
Market Excl. if
significant new
indication
registered for
reference
product during
first 8 years

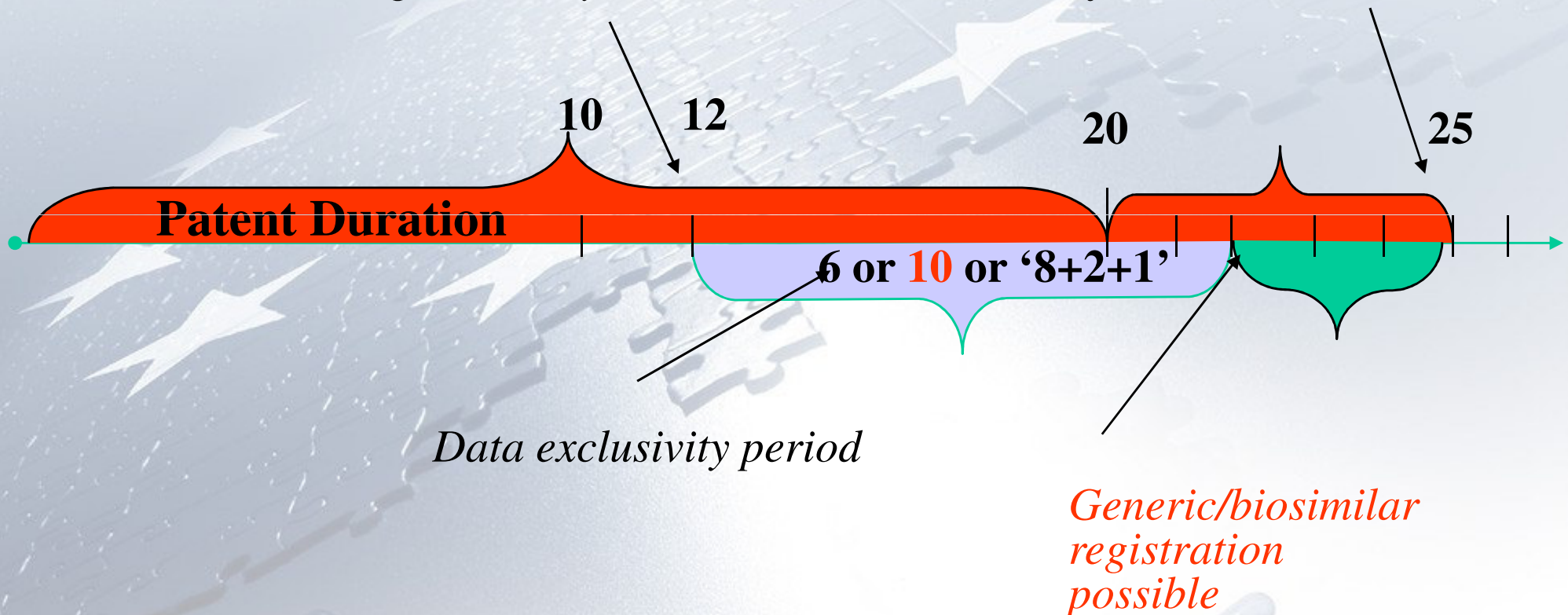
Data Exclusivity Total Spectrum in Practice

- 6 years (in 17 MSs +2) if reference product (RP) is nationally approved product or application of RP submitted before 1.11.05 (national/MRP/DCP)
- 10 years (in 8 MSs) if RP is nationally approved product or submitted before 1.11.05 (national/MRP/DCP)
- 10 years if RP is centrally approved product submitted before 20.11.05 (CP)
- '8 +2 + 1 formula' if RP application submitted after 1.11.05 (National/DCP) or 20.11.05 (CP)

Market Exclusivity for Originator: Maximum 15 years

e.g. the marketing authorisation is granted to originator in year 12

Maximum 5 years extension of Supplementary Protection Certificate (SPC)



- Submission of generic/biosimilar applications only possible after data exclusivity expiry

General Impact of Data Exclusivity

- No generic and biosimilar applications possible during DE periods
- DE period becomes a Market Exclusivity
 - When there is no patent or when weak patents are invalidated
 - When data exclusivity period goes beyond patent/SPC expiry

Impact of Data Exclusivity in Practice

- Usually patent protection - extended by Supplementary Protection Certificates - exceeds data exclusivity period
- When Data Exclusivity is the limiting date, generic companies are in a “race” to obtain Marketing Authorisations and get to market first
- About 5-10% of generic product launches are limited by Data Exclusivity under the 6/10 year rules

Change of Purpose of Data Exclusivity

■ 1987 Initial purpose

- DE as protection mechanism for insufficient protection of biotechnological inventions

■ 2004 Shift of purpose

- DE as additional market exclusivity mechanism
- Patents are challengeable. What about data exclusivity, especially in the context of ‘+1’ (significant clinical benefit)?

Date of Marketing Authorisation under 6/10 Years Rules

- **Where is date obtained from ?**
 - Usually generic companies rely on the date given by MA Holder on the application for Supplementary Protection Certificate
 - However, this date can be for a veterinary licence e.g. meloxicam
 - AstraZeneca case - omeprazole different MA dates given
 - Originator companies transfer MAs within their “group” so original date becomes less visible

Reliable Source of MA Date

- Generic companies asked to prove date of first authorisation in EU - they usually obtain written evidence from Regulatory Authorities
- **Openly shared database needed (EudraPharm ?)**
 - More transparency and easy accessible data would
 - *reduce administrative burden*
 - *minimise 'misinterpretation' and 'misuse'*

Regulatory Exclusivity - under Paediatric Regulation

- **Opportunity for generic companies**
 - ‘8+2+1’ years DE for paediatric indications and appropriate formulations following an agreed paediatric investigation plan (PIP)
 - Legal responsibility on EMEA

What do we Understand by Patent Linkage?

- Patent Linkage is
 - linking the marketing approval or pricing/reimbursement status of generic/biosimilar medicines to the patent status of the reference products (RP)

‘Trips-plus’ Provision

- **Linkage between patent status and generic registration has been identified as a ‘Trips-plus’ requirement**
 - i.e. a requirement that goes beyond what is mandated by the TRIPS (Trade-Related Aspects of Intellectual Property Rights) **Agreement.**

Patent Linkage Illegal in the EU

- US practices have no application in the EU regulatory system
- EU Pharmaceutical law clearly allows development, application and registration during patent period
 - **‘Bolar’ provision** (Article 10.6. of Directive 2001/83/EC as amended)

Some EU Attempts to Link Patents to Pricing & Reimbursement

- Latest judgement in Stada/Pfizer case: Court of Appeal /Sweden
- Court of Appeal stated that: *STADA's request for price was not directed to a potential customer, nor was it related to any business transaction; by submitting its request STADA has not e.g. accepted any obligation to sell the product or to transfer any other right to the product. In the opinion of the Court of Appeal, **STADA's request for price is in principle a preparatory action carried out in order to make possible subsequent offers.** The fact that the price in potential future sales of STADA's products to the pharmacies is determined by the application can thus not lead to the conclusion that STADA has offered the product to the pharmacies or anyone else through its price request. The Court of Appeal shares the opinion of the dissenting judge in the District Court that an offer in the sense of the Patent Act cannot exist unless the applicant's commercial intention is more concrete than in the present case. The fact that STADA, following remarks from the PBB, has amended its price request in certain regards does not change the assessment*
- *The conclusion of the Court of Appeal is thus that STADA's **request that the PBB should set a certain price for the medicinal product Sertralin STADA has not** - whether in its own right or in connection with the contacts between STADA and the PBB concerning price - **constituted any offer in the sense of the Patent Act.** Hence, Pfizer's action shall be rejected*

(unofficial translation)

Thank you



Acronyms

- **DE Data Exclusivity**
- **MA Marketing Authorisation**
- **ME Market Exclusivity**
- **SPC Supplementary Protection Certificates**
- **CP Centralised Procedure**
- **DCP Decentralised Procedure**
- **MRP Mutual Recognition Procedure**
- **TRIPS Trade Related Intellectual Property Rights**
- **MS Member State**