Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

WIPO Symposium:
Test Data Protection - generic and biosimilar industry perspective

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Generic Medicines: Key to Healthcare Sustainability and Patient Care

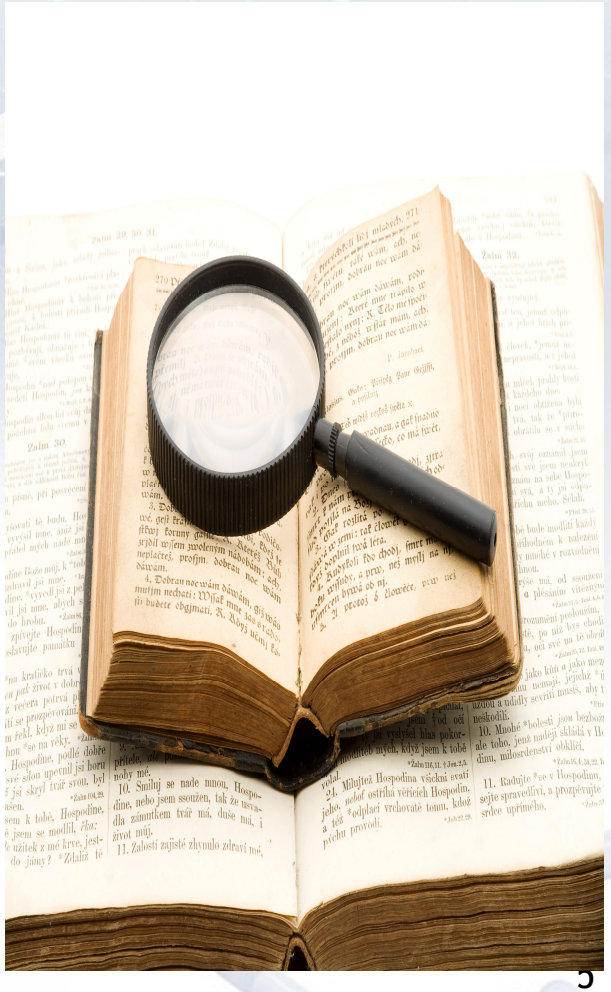
- EGA represents over 700 companies in 34 European countries
- Generic medicines companies employ over 150,000 people in the EU
- Generic medicines account for nearly 50% of packs dispensed in the EU and 18% of pharmaceutical expenditure
- Generic medicines bring savings of over €25-30 Billion per annum in the EU 27
- Generic medicines companies cover a full spectrum of pharmaceutical needs
- Generic medicines companies also undertake incremental innovation

Terminology: Data Protection/ Data Exclusivity

- **Misleading terminology**
- 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 after expiry of exclusivity**

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



Data Exclusivity and TRIPS

WHO Briefing Note-Access to Medicines- March 2006

- **Article39.3 requires countries to protect <u>undisclosed</u> registration data**
  - i) against disclosure and
  - ii) against unfair commercial use
- **Article 39.3 does not make any reference whatsoever to exclusivity or exclusive rights**

What is Meant by 'Unfair Commercial Use'? (WHO)

- ***'Does the use of bioequivalence studies instead of full clinical trials represent 'unfair commercial use'?***
- ***'Clearly, there is no 'unfair commercial use' by the generic company'***
  - *Never use of originator data*
  - *Never access to originator data*
- ***'Even if regulators would use those data, this is not commercial use, since the regulatory agency is not a commercial organisation.'***

Carlos Correra - 2002

- **The term 'unfair commercial use' refers to, and prohibits practices such as industrial espionage, but was not meant to provide exclusive rights**
  - Carlos M. Correra: Protection of data submitted for the registration of pharmaceuticals: implementing the standards of the TRIPS Agreement

http://www.southcentre.org/

WHO Briefing Note

- Data Exclusivity classified as a '**TRIPS PLUS Measure**'
- *'Legal and public health experts believe that TRIPS requires data protection, but not data exclusivity - and national laws do not need to be more stringent or more restrictive than TRIPS'*

March 2006

Impact of Data Exclusivity

- **DE period becomes Market Exclusivity**
  - When there is no patent or when weak patents are invalidated
  - When a country has no patent law
  - When no patents are granted for originator
  - When data exclusivity period goes beyond patent/SPC expiry
    - The EU- About 7% of generic product launches were limited by Data Exclusivity (not by patent/SPC) (*EC Report on Pharmaceutical Sector Inquiry 2009*)

Impact of Data Exclusivity in Developing Countries

- Interpreting that TRIPS requires implementation of DE has serious worldwide implications on access to medicines
- *'Essential drugs are not simply another comodity- TRIPS safeguards are crucial'*

WHO Globalization, TRIPS and Access to Pharmaceuticals 3 March 2001

Data Exclusivity in the EU

- **1987 Initial purpose**
  - DE as protection mechanism for insufficient protection of biotechnological inventions
    - **6 years** DE with a possibility to extend to 10 years (individual decision of each country); no longer than patent
    - 10 years for biotech/ high tech products
- **Overview before a change in 2004**
  - **6 years in 19 MSs** (+2): AT, BG, CZ, CY, DK, EST, EL, FI, HU, IR, MLT, LV, LT, PL, PT, RO, SP,SK, SLO, (NO, IS)
  - **10 years in 8 MSs** (BE, LU, FR, IT, DE, NL, SE, UK)
  - **10 years for biotech/ high tech** products

2004- General Increase of Length of DE in the EU

- **Significant revision of pharmaceutical legislation in 2004**
  - Increase of basic DE to 8+2(+1)
  - Additional exclusivity
    - **1 year DE** for new indication for well established use substance (WEU)
    - **1 year DE** for change of classification (eg, OTC switch)
- **Final achievement seen by the European Commission as a balance between originator and generic medicine industry**

Balance Reached in 2004

- **Exclusivity 8+2(+1)**
  - Harmonised for both types of products (generics/ biosimilars), all MA procedures and all countries
- **1 year DE for new indication for well established use substance (WEU)**
- **1 year DE for change of classification (eg, OTC switch)**

- **No additional data exclusivity for line extensions** (*new indication, new strength, new form etc as a part of so called: "Global Marketing Authorisation"*)
- **Bolar provision**
- **No patent linkage in Marketing Authorisation process**

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

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

Global Marketing Authorisation' Concept

- **No data exclusivity for line extension:**
  - any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall be considered as belonging to the same global marketing authorisation
  - even if authorised through a separate procedure and/or full dossiers and/or under a different name

Intention to Mix the US and the EU System Stopped

US system:

- 5 year DE
- 3 year DE for each new indication
- Patent linkage in Marketing Authorisation (MA)
  - 4 year DE if Orange Book patent is challenged

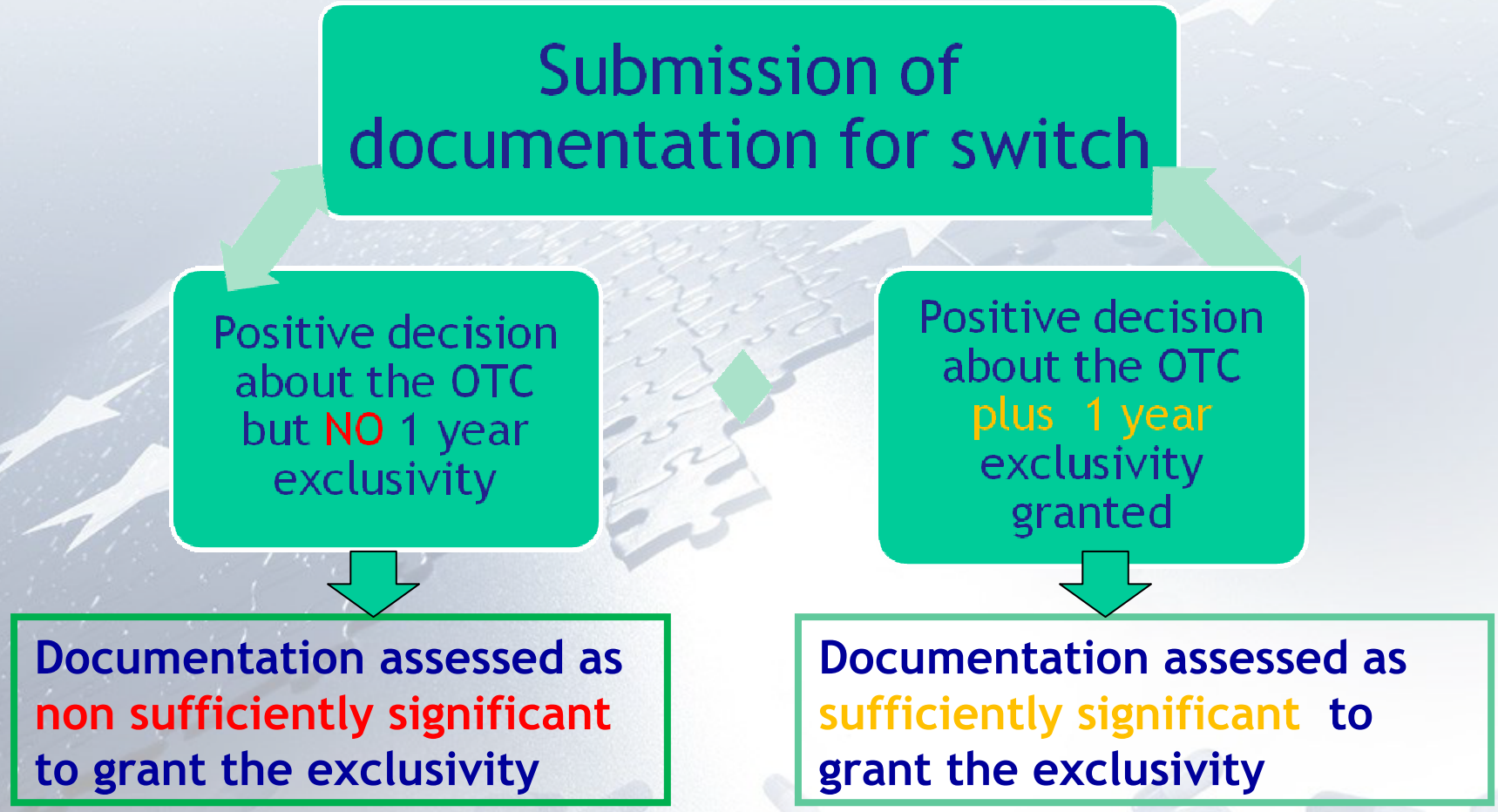
EU system:

- 8 DE+2 ME+(1ME)
  - + 1 year ME for entire product (only once) if new indication brings a significant clinical benefit in comparison with existing therapies
  - No data exclusivity for line extension
- 1 year DE for new indication
  - if significant trials
- No patent linkage in MA

Intention of Rewarding a Significant Innovation

- **1 Year Data Exclusivity for New Indication of Well Established Use (WEU) Substance** if ***significant pre-clinical or clinical studies***
  - 1 year DE refers exclusively to the data concerning the new indications
- **1 year of Data Exclusivity for changing clasification (eg, OTC switch)**
  - If a change of classification based on ***significant pre-clinical tests or clinical trials***

Possible Scenario for Changing a Classification

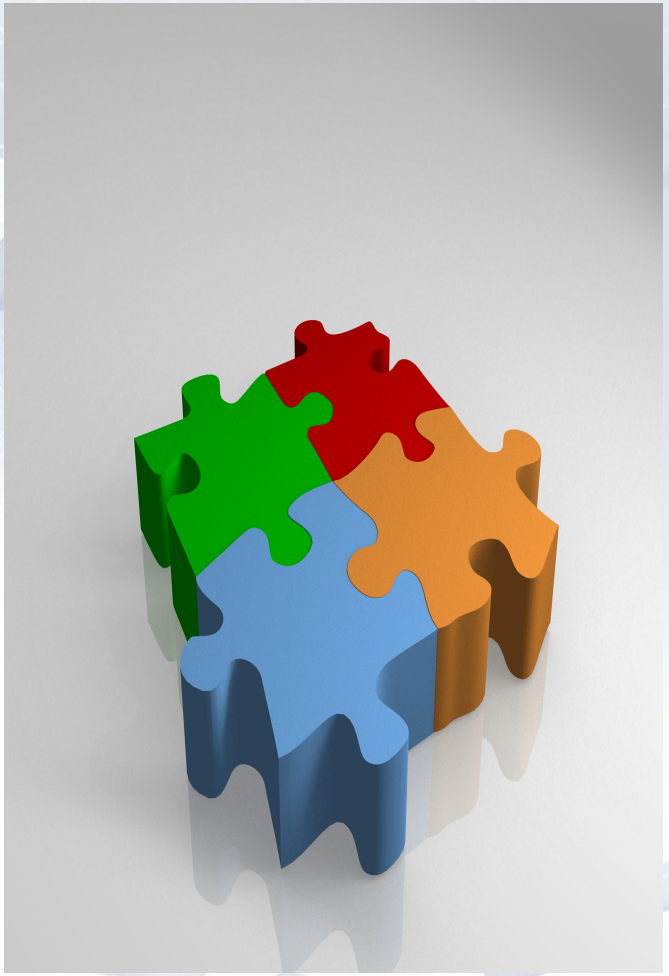


Current Experience with the OTC in the EU

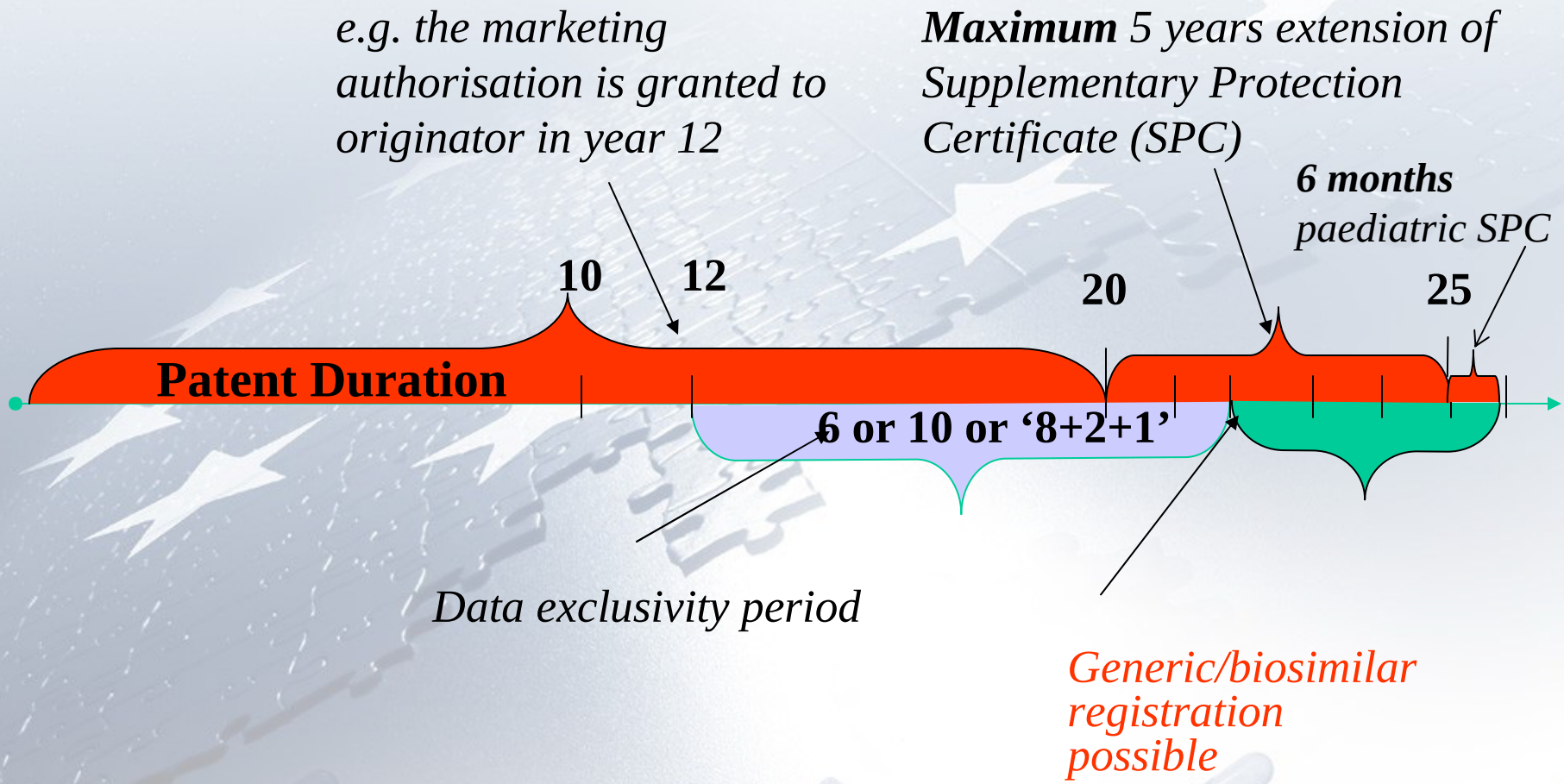
- **Three cases via Centralised Procedure:**
  - Viagra-erectal dysfunction- refusal
  - Orlistat- weight loss aid- OTC accepted but no 1 year DE
    - *Justification: Studies provided were not relevant and necessary to change a classification, did not give more insight into the safety of orlistat*
  - Pantoprazole- OTC accepted but no 1 year DE
    - *Justification: Studies provided were not relevant and necessary to change a classification*

Various Possibility of Market Protection in Addition to DE

- **Data Exclusivity is only one of several existing mechanisms of protection**
  - Patent
    - including a possibility to patent an indication (*so called "second medical use patent")*
  - Supplementary Protection Certificate (SPC)
    - max 5 years
  - SPC extension due to paediatric trials
    - 6 months
  - 10 years market exclusivity for orphan medicines



Parallel mechanism to achieve 15 years Market Exclusivity for Originator:



Submission of generic/biosimilar applications possible after data exclusivity expiry

Sector Inquiry

Neelie Kroes, European Commissioner for Competition

"The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible."

8 July 09

Conclusion of the Sector Inquiry (1)

- **Data exclusivity used as a anti-competitive tool**
  - Originator companies had a low success record (19%) in cases concerning data exclusivity, i.e. when they claimed that marketing authorisation for a generic product cannot yet be granted due to data exclusivity rules protecting the originator product.

Conclusion of the Sector Inquiry (2)

- The combined use of life-cycle instruments may increase the likelihood of delays to generic entry. Delays due to the use of several instruments may sometimes be cumulative.

Conclusion of the Sector Inquiry (3)

- **Intervention and litigation by originator companies in administrative proceedings for generic medicines delay generic market entry on average four months.**
  - The sector inquiry produced evidence that such practices generated significant additional revenues for originator products

Untitrust investigation into Lundbeck

- **The European Commission has opened a formal antitrust investigation into Lundbeck**
  - potential breaches of EU rules on restrictive business practices and on the abuse of a dominant market position
  - To investigate unilateral behaviour and agreements by Lundbeck which may hinder the entry of generic citalopram

Conclusion (1)

- Art 39.3 of TRIPS should not be interpreted as an obligation to introduce Data Exclusivity
- Current EU system gives the highest protection by Data Exclusivity in the world

Conclusion (2)

- **Every system of protection in each country should be developed on its own:**
  - After careful assessment of other existing IP protection tools
  - Without mixing the elements from other systems
  - Taking into consideration its own health care and economics factors within the flexibility of TRIPS.

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Thank you for your attention!

Acronyms

- DE Data Exclusivity
- MA Marketing Authorisation
- ME Market Exclusivity
- SPC Supplementary Protection Certificates
- CP Centralised Procedure
- TRIPS Trade Related Intellectual Property Rights
- MS Member State
- EU European Union