



Making Medicines Affordable

The Biosimilar Framework in the European Union

Japan Generic Medicines Association Seminar
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Outlines

- Introduction to EGA
- 'The Birth' of the Legal Framework for Biosimilar Medicines in the European Union
- When Can Biosimilar Medicines Applications Take Place?
- What are the Data Requirements?
- INN/International Non-proprietary Name
- Post-Authorisation
- Biosimilar Medicines in the Market Place
- EGA Vision

Generic Medicines: Key to Healthcare Sustainability and Patient Care



- EGA represents over 700 companies in 34 European countries
- Generic medicines companies employ over 130,000 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 Billion per annum in the EU 27
- Generic medicines companies cover a full spectrum of pharmaceutical needs
- Generic medicines companies also undertake incremental innovation

Biosimilar Medicines Europe's New Opportunity

- *“Biosimilars offer new opportunities both for the growth of our generic industry and for the control of our national health expenditure.”*

Günter Verheugen,
Vice-President EU Commission
April 2006





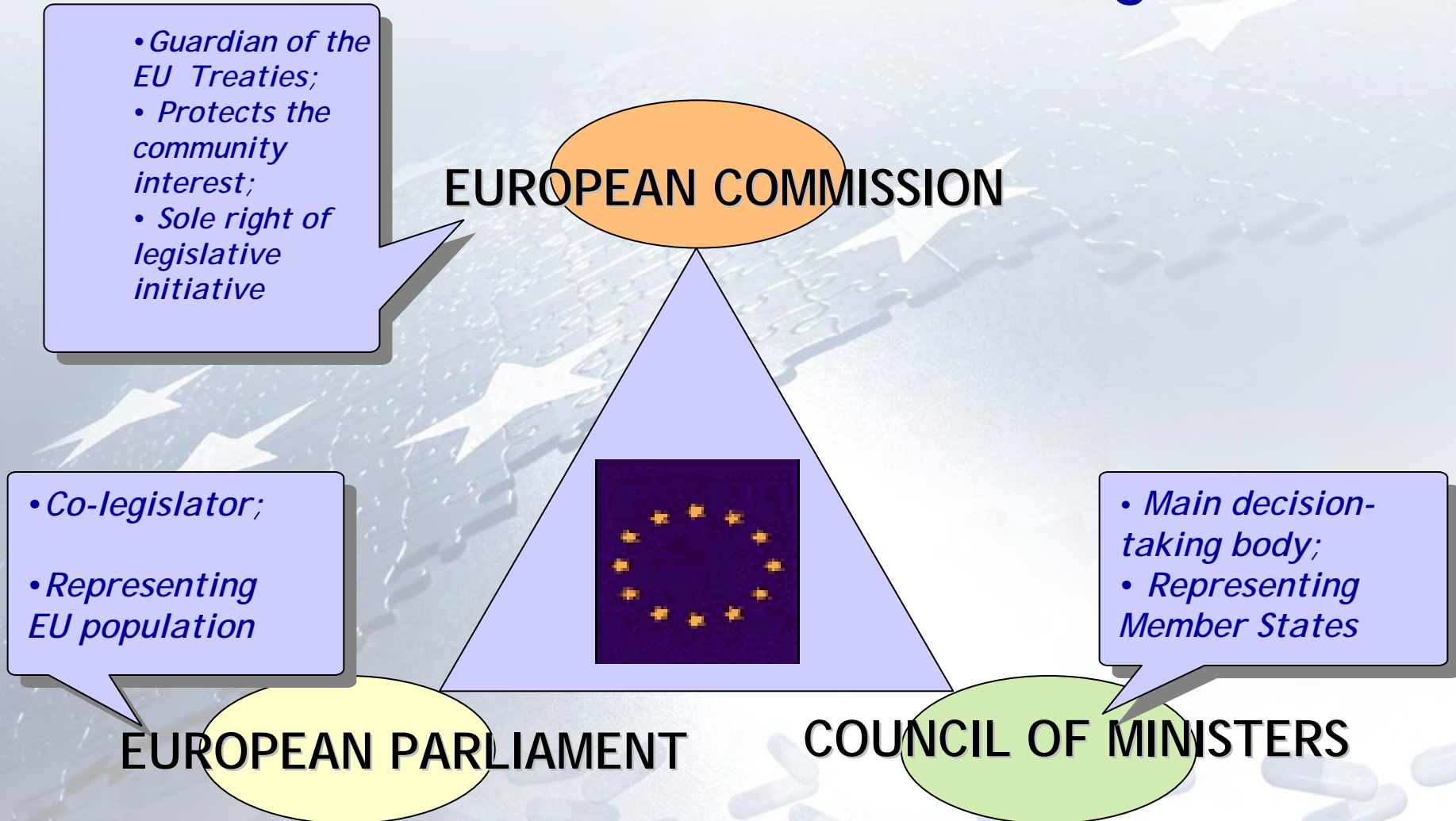
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'The Birth' of the Legal Framework for Biosimilar Medicines in the European Union

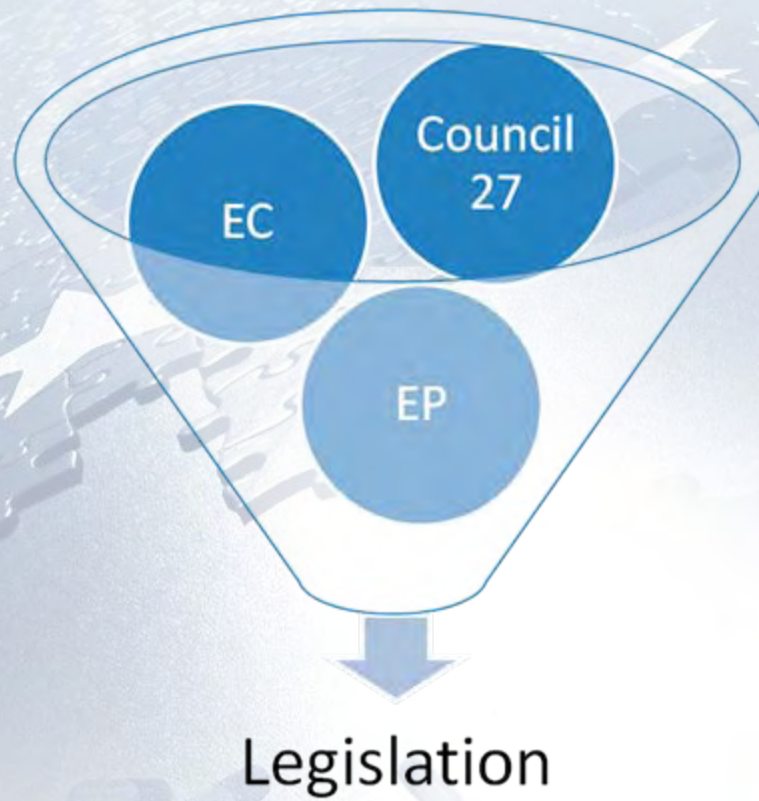
European Union (EU) 27 Member States Diversity, Complexity



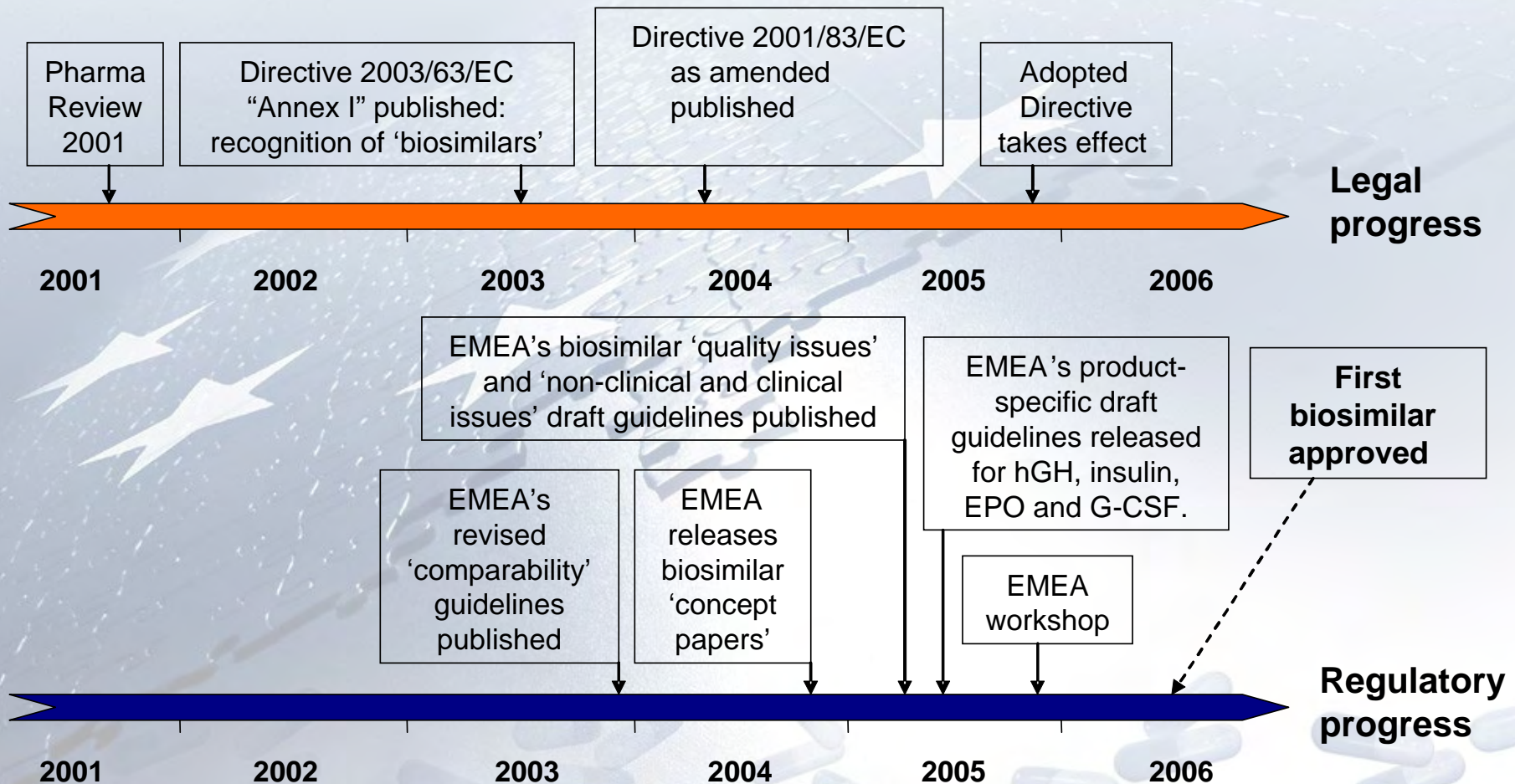
Overview of the EU 'Institutional Triangle'



Remember!



Legal & Regulatory Pathway Carefully Developed Over Time



EU Framework for Biosimilars Combines:

■ Legal certainty

- Clear legal basis
- Abbreviated data package

----->key for
investments

■ Flexibility

- Case by case approach
- General and product specific guidelines

-----> adjustments of data
requirements (science,
technology, experience)



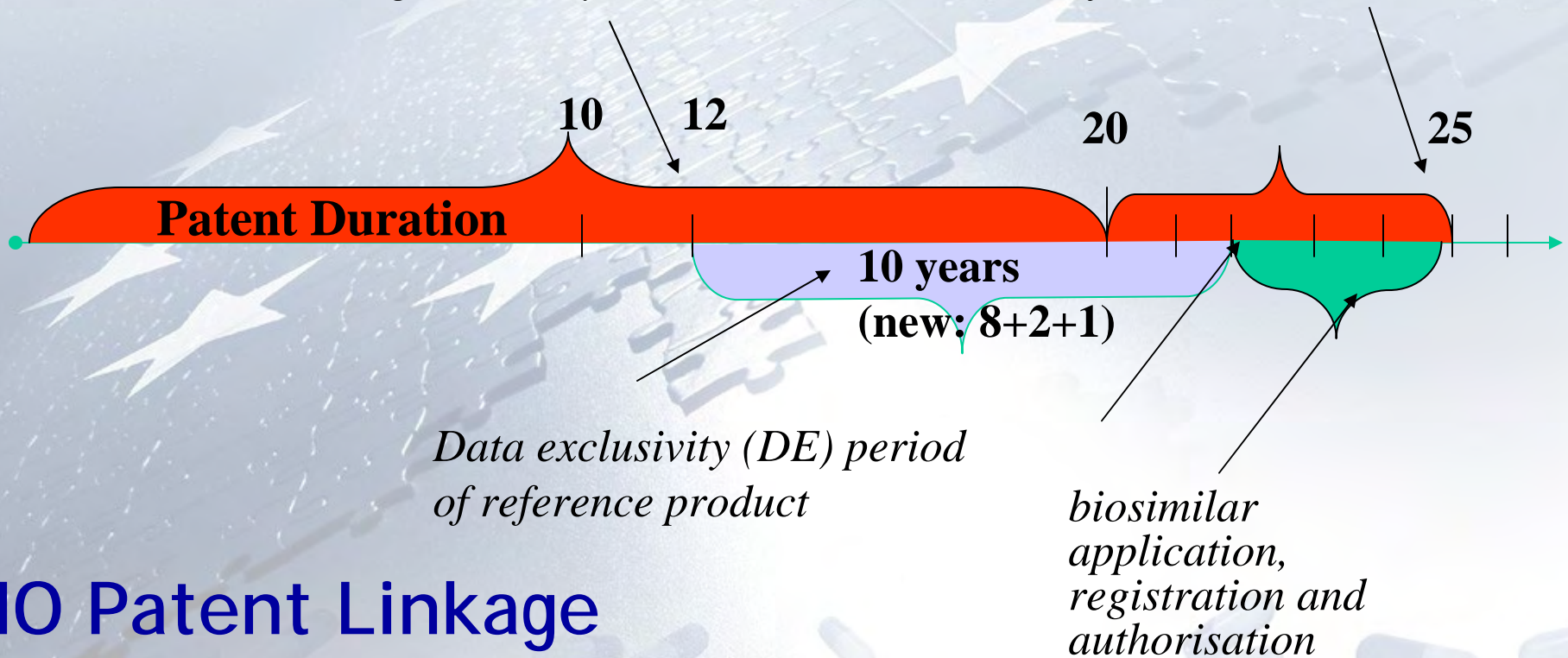
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When Can Biosimilar Medicines Applications Take Place?

Maximum Market Exclusivity for Reference Product: 15 Years

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

Maximum 5 years extension of Supplementary Protection Certificate (SPC)



Data exclusivity (DE) period of reference product

biosimilar application, registration and authorisation

NO Patent Linkage

- Submission of biosimilar applications only possible after DE expiry



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Which Products are Covered?

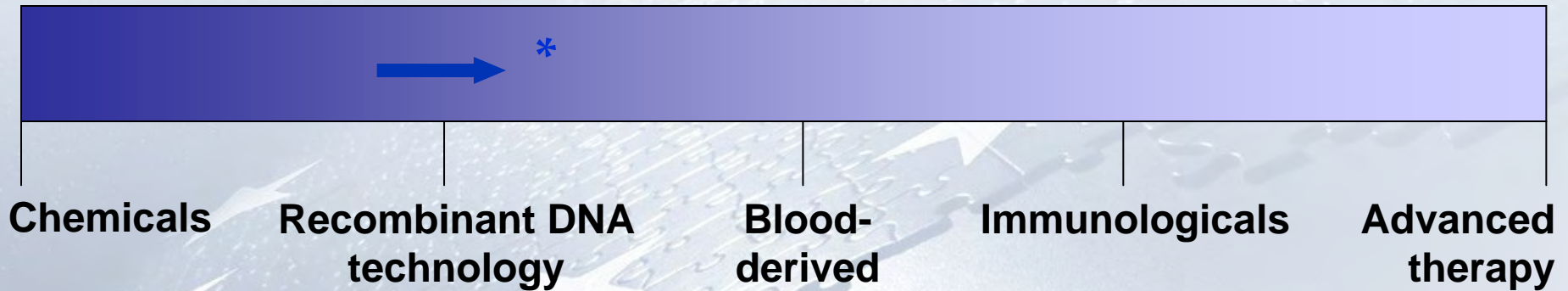
Legal Perspective

- In principle the concept of “similar biological medicinal (biosimilar) products” applies to **any biological medicine**
- ‘Generic approach’ is legally not excluded

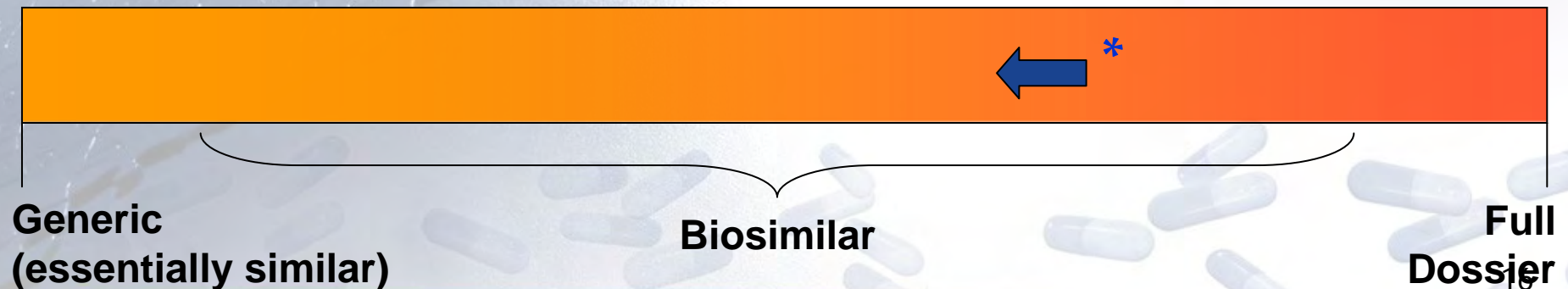
Spectrum of Complexity

(source: Dr. John Purves/EMA)

Science



Legislation



* Future Developments ?



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What are the Data Requirements?

Regulatory Perspective

- For the type and quantity of data to be provided, the EU legislative framework refers to detailed guidelines
- **But guidelines are NOT mandatory before submission and approval**
- **Guidance follows science**
 - Guidance is built on experience gained through scientific advice procedures and assessment of marketing authorisation application
 - Guidelines do not have legal force - but a justification for non compliance must be provided

Example: Omnitrope[®] Approved before Somatropin Guidance

■ Omnitrope Positive Scientific Opinion

26 Jan 2006

■ Adoption of guideline

22 Feb 2006

■ Approval of Omnitrope

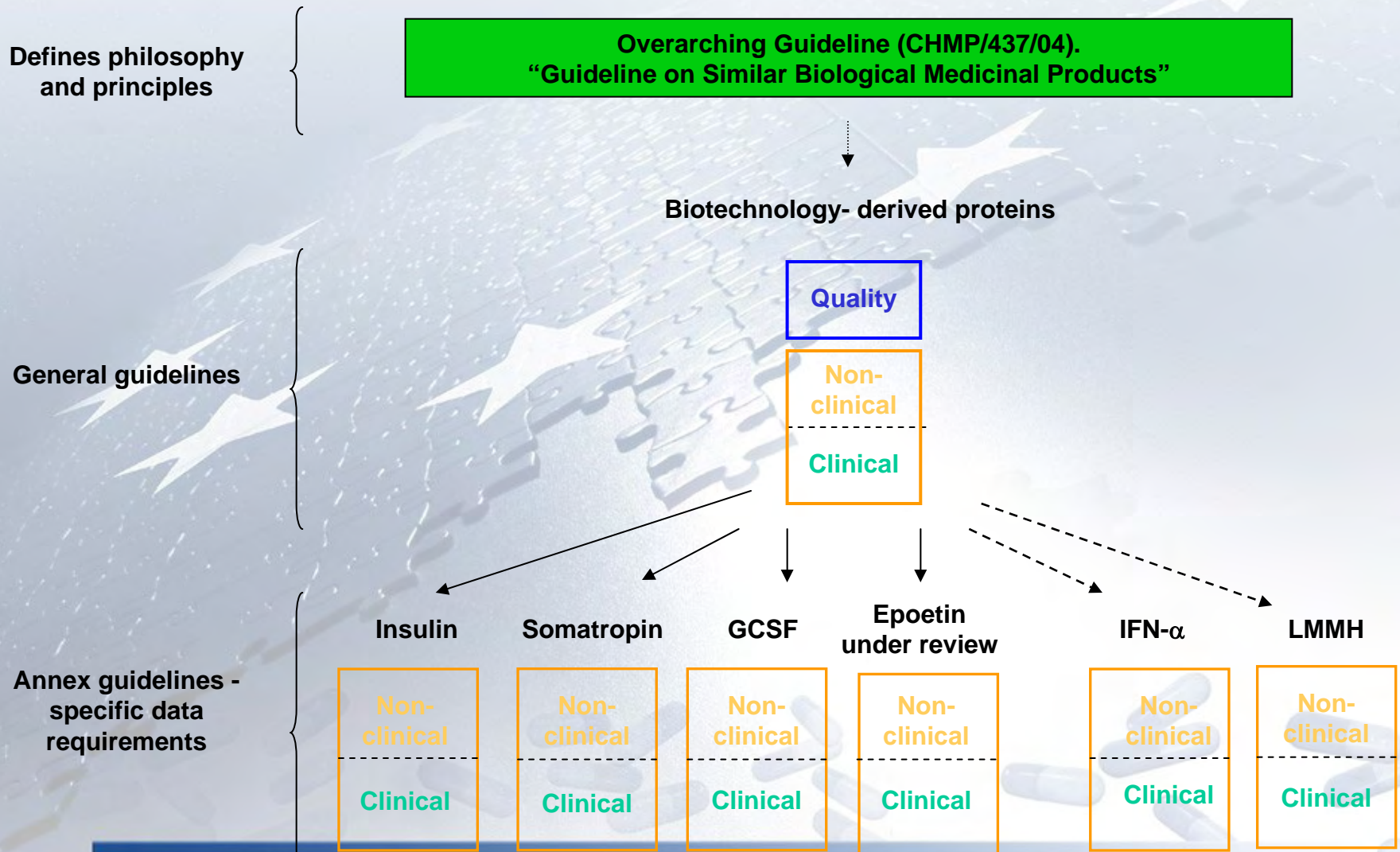
18 April 2006

■ Came into effect

1 June 2006

Current EU Biosimilar Guidelines

<http://www.emea.europa.eu/htms/human/humanguidelines/multidiscipline.htm>



Source: P. Richardson EMEA-EGA 6th symposium on biosimilar medicines

High Level Scientific Evaluation by EMEA and European Commission Approval

EMEA





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INN International Non-proprietary Name

Purpose of INN



World Health
Organization

■ Classification / nomenclature

- Identification of **pharmaceutical substances**

■ WHO Guidance on INN - broad scope

- Pharmacopoeia, labelling, product information, drug regulation, basis for product names (generics)...



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INN is NOT...

- Identification of a drug product or its impurities
- Statement of therapeutic equivalence and/or substitution
- Means of managing the practice of medicine
- Traceability and pharmacovigilance apply to drug products

Current INN Policy

- **INNs for glycosylated rDNA proteins**
 - Core name based on Amino Acid sequence
 - Greek letter added: 'differences in glycosylation'
- **Difficult to define 'differences'**
 - eg, batch to batch differences

INNs for Biologicals

■ EU reflections for consideration at WHO level:

- INNs should have “high level” utility - identification
- Up to Regulatory Authorities to assess Benefit / Risk
- AA sequence basis for INN
- Presence/absence of glycosylation compared to native protein

■ Discussions continue



Nomenclature: Same INN Decision lies with Regulators

With regard to the nomenclature of biosimilars, we do not endorse the idea that any difference in glycosylation automatically leads to a different INN. We have serious doubts that this stance could be scientifically justified. We are also concerned that the WHO is promoting a double-standard policy on biosimilars.

G.Lalis/Director General EC -Statement on WHO INN Policy at
EGA Annual Conference Paris 2 June



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Post-Authorisation

Pharmacovigilance

■ Company Risk Management System must be in place

- Risk Management Plan

- Pharmacovigilance activities

Routine pharmacovigilance

PASS

- Risk minimisation activities

Labelling (counter-indication, advice, warning)

Traceability of ALL Biologics

All biological drugs need to be monitored

- An adverse reaction report **for any biological drug** should always include
 - full name of the biological drug
 - batch number
- Where information is missing, Member States/MAHs should ensure that reports are followed up for completion

G. Lalis/Director General EC on Pharmacovigilance for Biosimilars

EGA Annual Conference Paris 6/08

Furthermore we **have written to Member States'** regulatory authorities to take necessary measures to ensure

- a method to link suspected adverse reaction reports to specific products (such as a unique product identifier) and
- to ensure that prescribing doctors know which glycoprotein has been given to their patient.



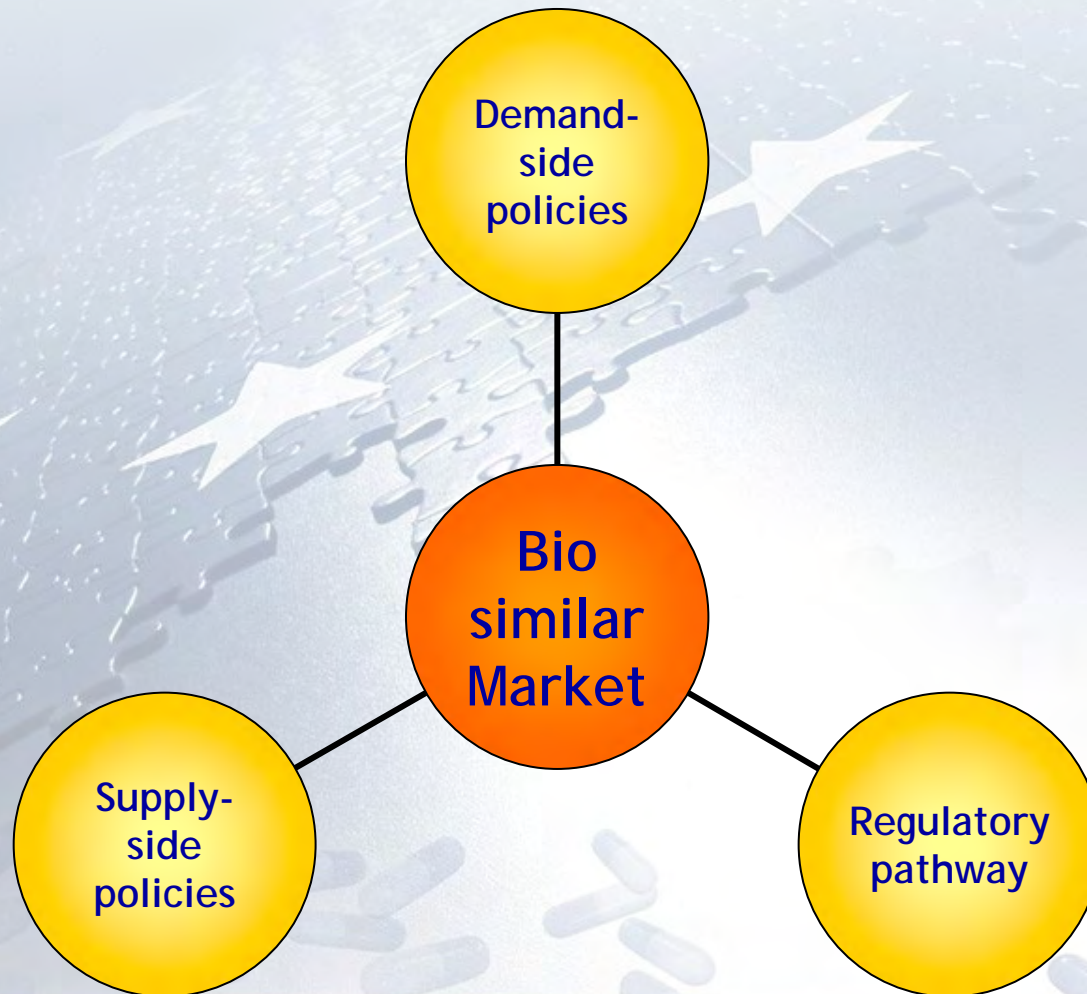
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Biosimilar Medicines in the Market Place

Biosimilar Drugs in the EU Market Place

- National pricing approvals and reimbursement have been agreed without any major barriers
- Market in-roads are made
- Patients and healthcare professionals are catching up
- But scare tactics still ongoing by certain interested parties

Understand the Environment for Biosimilar Medicines...



The Market Players



Message from the European Commission

..... *'we are confident that if a product goes through all the steps and meets all the requirements and gets at the end an approval through a Commission Decision, it means that this product is as safe and efficacious as any other product authorised by the European Commission in the EU'.*

N. Rossignol at 6th EGA symposium on biosimilar medicines 2008



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EGA Vision

Global Development for Biosimilars

- **Streamlining the development process**
 - Avoids repetition of unnecessary trials
 - Increases access through affordable medicines
 - Increases competition
 - Market competition from biosimilar drugs will drive the biotechnology industry to do what it does best - discover new drugs that enhance, sustain, and save lives.

ありがとうございます。



Thank you very much.



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Acronyms

- EGA European Generic medicines Association
- EU European Union
- EMEA European Medicines Agency
- CHMP Committee for Medicinal Products for Human Use
- EC European Commission
- WHO World Health Organization
- MS Member State
- MAA Marketing Authorisation Application
- MAH Marketing Authorisation Holder
- DE Data Exclusivity
- ME Market Exclusivity
- INN International Non-Proprietary Name
- ADR Adverse Drug Reaction
- RMP Risk Management Plan
- PASS Post Authorisation Safety Study