



MEDEV – WHO meeting in Budapest 24-25 September 2007



Workshop on Biosimilars Introduction and Setting the Scene



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Disclaimer

The opinions presented here are exclusively those of the author.

They are not necessarily identical with those of the Department, the Main Association of Austrian Social Security Institutions, its Advisory Committees or its management, nor with those of the individual members of the MEDEV Committee.

The term „generic“ is used here to designate essentially similar products for which bioequivalence has been shown



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Biosimilars – the Payer's Perspective

- ▶ Definition
- ▶ Advantage for payers
- ▶ Prerequisites for realising economic potential
- ▶ Applying lessons learned



Definition

What is a biosimilar medicine?

A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the 'biological reference medicine'). The active substance of a biosimilar medicine is similar to the one of the biological reference medicine.

Biosimilar and biological reference medicines are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional.

The name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine.

Questions and Answers on biosimilar medicines (similar biological medicinal products)
European Medicines Agency, London, 22 June 2007, Doc. Ref. EMEA/74562/2006



FDA

„I will further use FDA's informal term *follow-on protein products* to refer to proteins and peptides that are intended to be sufficiently similar to an approved product to permit the applicant to rely on certain existing scientific knowledge about the safety and effectiveness of the approved protein product. Follow-on protein products may be produced through biotechnology or derived from natural sources.“

Statement of

Janet Woodcock, M.D.

Deputy Commissioner, Chief Medical Officer
Food and Drug Administration

Before The Committee on Oversight and Government Reform
United States House of Representatives

"Follow-on Protein Products" , March 26 , 2007



Why Biosimilars Now?

Somatropin:

The European Commission granted a marketing authorisation valid throughout the European Union for **Omnitrope** to Sandoz GmbH on 12 April 2006

Epoietin alfa:

The European Commission granted a marketing authorisation valid throughout the EU for Binocrit to Sandoz GmbH on 28 August 2007.

The European Commission granted a marketing authorisation valid throughout the EU for Abseamed to Medice Arzneimittel Pütter GmbH & Co KG on 28 August 2007.

The European Commission granted a marketing authorisation valid throughout the EU for Epoetin alfa HEXAL to HEXAL Biotech Forschungs GmbH on 28 August 2007.



It's the Prices....

Average Cost for methotrexate: **25,05 €**

Average Cost for Biologicals used in
rheumatoid arthritis

(ATC L04AA11,12,14,17): **966,26 €**

Source: Datawarehouse PEGASUS of the Federation of Austrian Social Insurance Institutions, costs per prescribed pack, excluding VAT. This does not include hospital drugs.



Some more Prices

Average cost (excl. VAT) in Austria in 2006 for a package of

Colony-Stimulating Factors (L03AA):	> <u>850 €</u>
Interferon alfa (L03AB 04,05,10,11) (pegylated & non-pegylated):	> <u>660 €</u>
Interferon beta (L03 AB07, 08):	> <u>950 €</u>
Erythropoietin-Stimulating Agents (ESA's, B03XA):	> <u>730 €</u>

Source: Datawarehouse PEGASUS of the Federation of Austrian Social Insurance Institutions, costs per prescribed pack, excluding VAT. This does not include hospital drugs.



Advantage for Payers

New drugs should offer medical and/or economic benefit

From an economic point of view, biosimilars play a role similar to that of generics:

*“They offer no medical benefit (per definition), they do not meet any unmet **medical** need.*

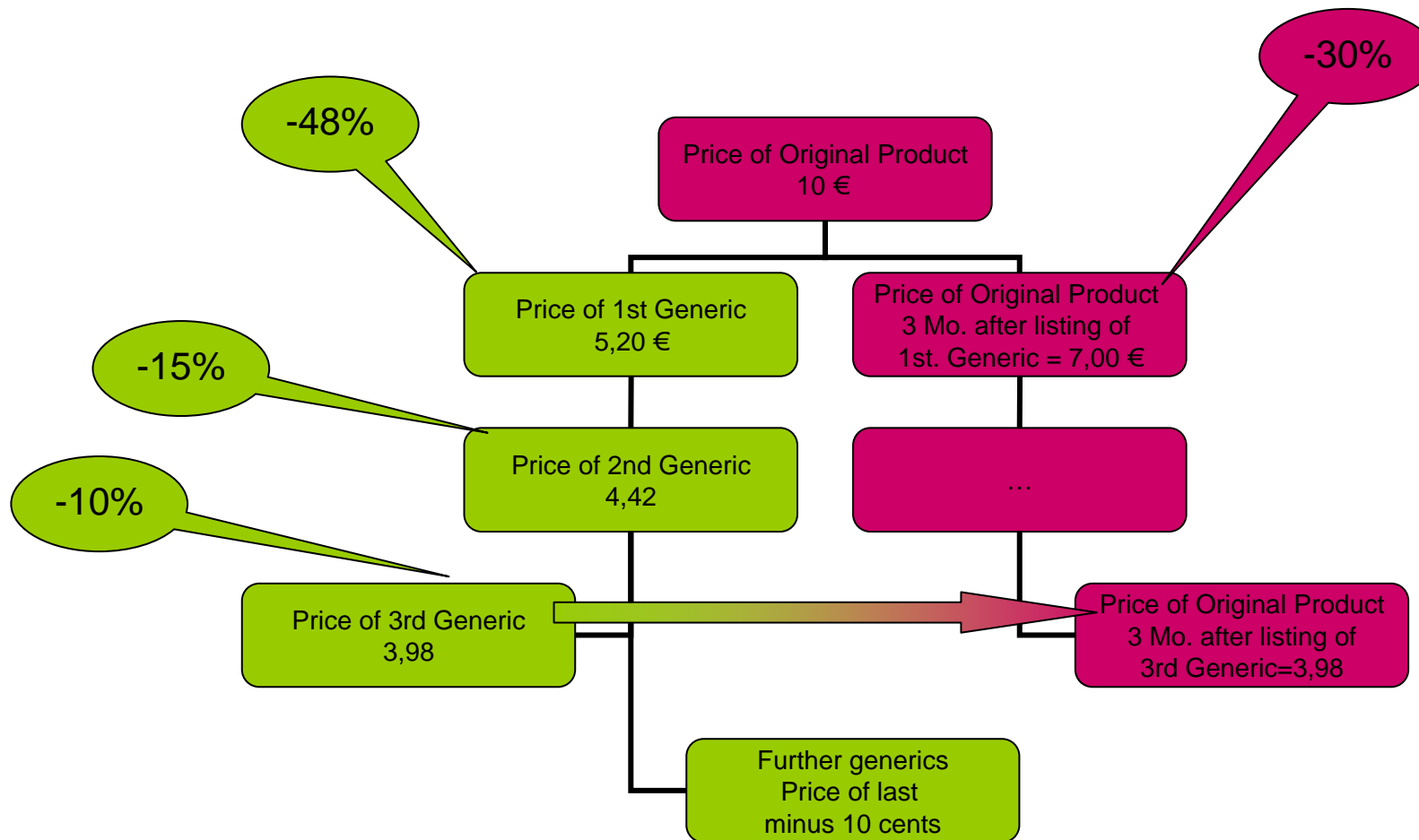
*Therefore they must offer **economic benefit** = “Economic innovation”*

Peter Wieninger, Department of Pharmaceutical Affairs, Main Association of Austrian Social Insurance Institutions

„Headroom for Innovation“?



Pricing of Generics and Subsequent Price Reductions of Original Products According to Legal Criteria and Rules Set up by the Pharmaceutical Committee





Savings per Mio Covered Persons

Somatropin:

Expenditures per million covered persons in 2006 :
€ 914.333

Price Reduction by 10%, Market Share of 10% would lead to savings of **€9.143** per million covered persons

Price Reduction by 40%, Market Share of 40% would lead to savings of: **€146.293** per million covered persons

Source: Datawarehouse PEGASUS of the Federation of Austrian Social Insurance Institutions, costs per prescribed pack, excluding VAT. This does not include hospital drugs.



Potential Savings per Mio Covered Persons

ESA's: Expenditures 2006 per million covered persons:

€5 533 466

Price Reduction by 10%, Market Share of 10% would lead to savings of:

€55 334

Mio euro Per Million covered persons

Price Reduction by 50%, Market Share of 50% would lead to savings of:

€1 383 366

Mio euro Per Million covered persons

Source: Datawarehouse PEGASUS of the Federation of Austrian Social Insurance Institutions, costs per prescribed pack, excluding VAT. This does not include hospital drugs.



Prerequisites for realising economic potential

- ▶ Market access
- ▶ Perceived Usefulness of Biosimilars
- ▶ Biosimilars should be capable of being used instead of the reference product – otherwise market mechanisms may not apply.
- ▶ **Nomenclature of biosimilars.** This should ensure that doctors can look up and find biosimilars at the same ATC position as the originator products in their databases.
- ▶ **Pricing of biosimilars.** The price differential needs to be relevant and attractive for payers to embrace biosimilars.
- ▶ Trust and Transparency.



Potential Counter-Strategies

- ▶ Developing new products
- ▶ Emphasizing arguments for strict marketing authorization criteria
- ▶ Emphasis on insecurity
- ▶ Price cuts?



Lessons Learned

Biosimilars need to be seen as equal to the reference products with regard to the quality, safety and efficacy in order to gain acceptance from prescribers. Doctors need reassurance that biosimilars can be used instead of the reference products – in fact, that they are interchangeable, despite efforts by the originator companies to question this.

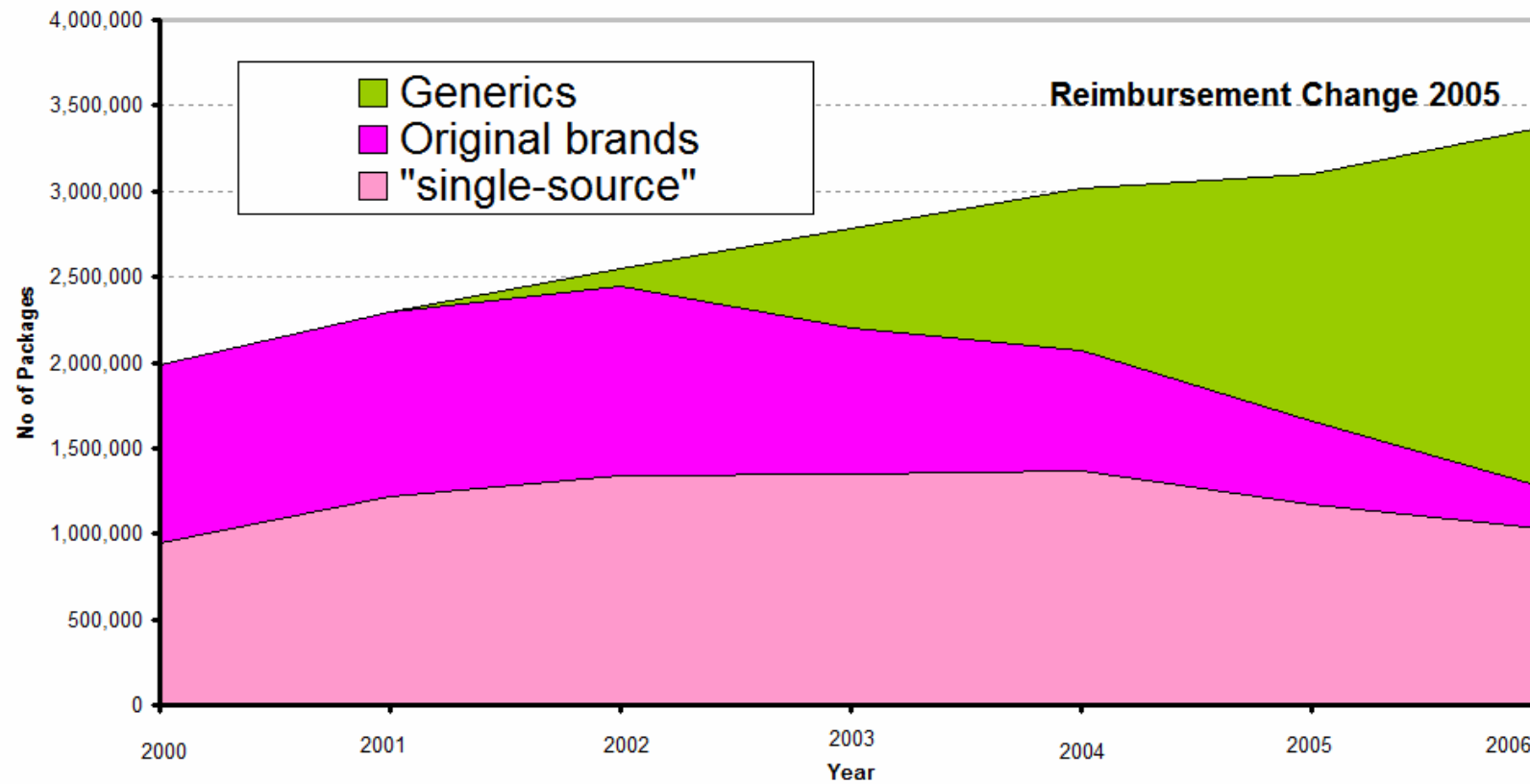
Discussions on “switchability”, “interchangeability” “substitutability” have lead to more confusion than clarity.

In our experience, the situation after patent expiry can lead to confusion and insecurity among doctors when being asked to prescribe generics. We all need to make an effort to avoid this kind of lose-lose situation with biosimilars. This includes even the makers of the originator products, because the money saved on biosimilars ultimately helps make innovations affordable.



Market Dynamics of Generics

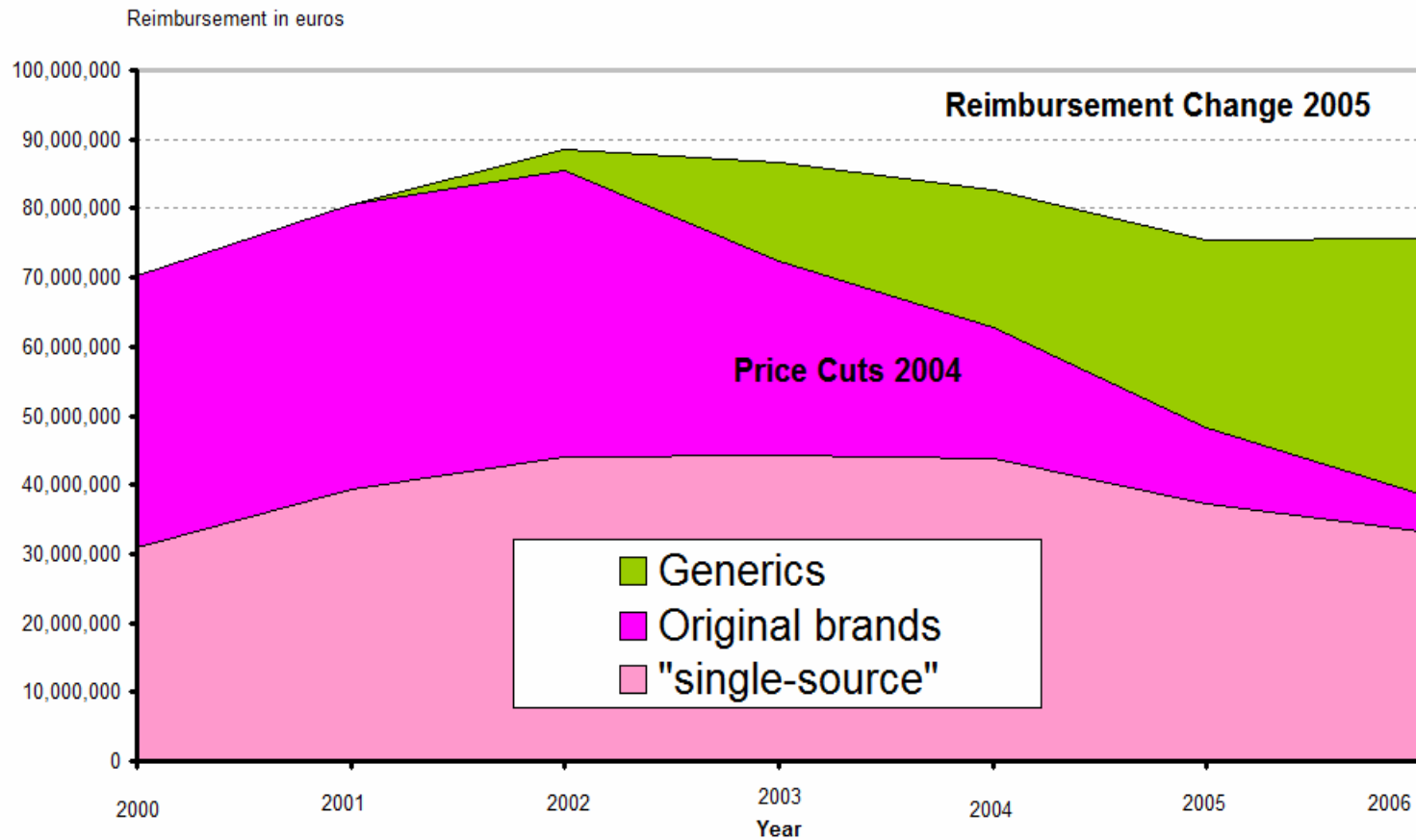
Reimbursement of Statins





Market Dynamics of Generics

Reimbursement of Statins





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Thank you!

