



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION



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Generic Medicines and Innovation

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Innovation, Competition & Patient Benefits

- Innovation and competition in the pharmaceutical sector can bring improvements to healthcare delivery for European patients and improve the competitiveness of EU
 - Important role for both the originator and the generic medicines industries in Europe
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Levels of Innovation?

- **“Incremental innovation”** - new dosage forms and new formulations
 - **“Stepwise innovation”** - different molecules of one chemical family offering some differences in properties, e.g. indications, side effects, and drug metabolism
 - **“Breakthrough innovation”** - real new approach to a disease / New Chemical Entity (NCE)
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Generics Stimulate Innovation

- EGA companies are principally involved in the development, production and marketing of affordable high quality off-patent medicines
 - These stimulate innovation through Competition and Financial Headroom for Innovation
(savings from use of competitive generic equivalents can be used to finance reimbursement of new truly innovative products)
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Generic Innovations

- **Generic companies improve existing production processes, resulting in improved pricing and medicinal products**
- **Several generic companies produce new formulations, methods of delivery, and dosage regimes**



Innovation in Generic Companies

- Several generic companies have produced their own NCEs, for example:
 - Azytromycin
 - Glatiramer Acetate
 - Deferiprone
 - Vinpocetine



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Breakthrough Innovation

- Breakthrough innovations are critically important in dealing with major diseases

“(...)in the last 20 years far too many “new drugs” have been only insignificant variants on those already existing, and real breakthroughs have been virtually absent.”

Professor M.N. Graham Dukes, Department of Pharmacotherapy, University of Oslo, Bulletin of the World Health Organization Volume 83, Number 5, May 2005, 321-400
“Priority medicines and the world” WHO - Ref. No. 05-021618

- Market environment in the EU needs to be built to encourage the necessary R&D for innovation

The focus in the EU has been on extending IP protection, but despite this Europe remains behind the USA as a source of innovation



New Focus for Pharmaceutical Innovation

The EU's emphasis should be focused on:

- Creating EU equal to USA National Institutes of Health
- Better links between science and business
- Increasing Private Public Partnerships (PPPs)
- Quicker access to the market for new approved medicines
- Reimbursement structures for added value of innovation
- Creating a Community Patent
- Strong generic competition in Europe

It is these type of factors that make the USA
a better place for R&D than Europe - not IP

“Stepwise & Incremental Innovations”

- These innovations can also provide important improvements for patients and should be evaluated according to their clinical advantages
 - Provisions are already made in EU pharmaceutical law to encourage this form of innovation:
 - a) 8+2+1 Data Exclusivity (DE)
 - b) +1 DE for OTC switch
 - c) +1 DE for new indications for well-established products
 - Soon to be adopted:
 - d) Paediatric Regulation - 6 months SPC extension for in patent
8+2+1 DE off-patent
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Pharma Properties Eligible for Patenting also Increased

1980s (5 properties)

1. Primary uses
2. Processes and intermediates
3. Bulk forms
4. Simple formulations
5. Composition of matter

1990s (18 properties)

1. Primary uses
2. Processes and intermediates
3. Bulk forms
4. Simple formulations
5. Composition of matter
6. Expansive numbers of uses
7. Methods of treatment
8. Mechanism of action
9. Packaging
10. Delivery profiles
11. Dosing regimen
12. Dosing range
13. Dosing route
14. Combinations
15. Screening Methods
16. Chemistry Methods
17. Biological Target
18. Field of use

Source: "Evolution of IPR & Pharmaceutical discovery and Development", Eric Larson, Sr Director, Groton Site Head, Pfizer Global Research & Development.

Viewed on 9/11/2005 at:

http://www7.nationalacademies.org/step/Larson_ppt.ppt



IP and P&R Must Stimulate Real Benefits for Patients

- Patent systems and price & reimbursement systems should seek to encourage real innovation aimed at improving patient care and not at preventing generic competition
 - Patent system in particular can encourage changes in chemistry with no real therapeutic advantage to patients
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Patents: Challenges for Payers

Salts & Esters

By changing the salt or ester in the chemical make-up of an active agent immediately prior to the market release, the originator company can present old products as “new” and create a new market to effectively prevent generic competition with no benefit to patients

Patenting various new versions of older medications can be used to create a complex array of IP protection to block registration of generic versions

Secondary Patents



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Added value of “Innovation”?

■ Losec MUPS vs. Losec

“Commission fines AstraZeneca €60 million for misusing patent system and the procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug Losec. The Commission has decided that AstraZeneca’s actions constitute serious abuses of its dominant market position in violation of EC and EEA competition rules.” EC: IP/05/737 Brussels, 15th June 2005

■ Chiral switching:

Nexium (esomeprazol) / Losec (omeprazol)

■ Switching to active metabolite:

Claritin (loratadine) / Aerius (desloratadine)

*“There is no clinical advantage to switching a patient from loratadine to desloratadine”
November 2003 journal American Family Physician*

■ Different formulations:

Doxazosin and mirtazapine

■ Different presentations: Ramipril



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Case Study: Nexium

- **Point of consideration: Clinical relevance of benefits vs. Cost implication on healthcare budget**
- **Discussions & emotions in the marketplace:**
 - *"If we had left it to R&D, Nexium would not have been developed. The project was driven by the marketing people,"* says Matthew Emmens, the former chief executive of Astra-Merck
 - In three trials conducted in Europe with GERD patients, there was no difference between Prilosec and two different doses of Nexium. With erosive oesophagitis, one of the trials showed similar results for both drugs. In the other trial, however, Nexium won a modest victory: while 20mg of Prilosec healed 86.9 per cent of patients after eight weeks, 20mg of Nexium was effective in 89.9 per cent of patients - a difference of 3 percentage points.
 - " The gastrointestinal expert who reviewed the drug for the Food and Drug Administration in 2000 was not convinced that Nexium was better. In terms of healing erosive oesophagitis, Hugo Gallo-Torres concluded: *"A superiority claim of Nexium over omeprazole [Prilosec] is NOT SUPPORTED,"* (his capitals).
 - The fiercest attack on Nexium came from Tom Scully, the US federal government official in charge of Medicare and Medicaid. At a medical conference this year, he told doctors: *"You should be embarrassed if you prescribe Nexium."* In a stinging rebuke to AstraZeneca, he said the drug was increasing costs without adding any medical benefit.

(Financial times, 22.10.03)



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Concluding Points

- Assessment must be made if innovation brings benefits to patients
 - Assessment of incremental innovation must establish if it seeks to restrict generic competition
 - The question that remains is: when and at what rate should countries pay for innovation?
 - This will probably differ between Member States according to the ability to pay e.g. 1-day instead of 3-times a day treatments but can it be justified on a cost benefit basis?
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