Intellectual Property and Pharmaceuticals

Access to Medicines and Bioethics

WIPO Seminar, 2-3 May 2007
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Agenda

• SAFS

• Pharmaceuticals & Biotechnologies
  – Pharmaceutical Industry

• Access to Advanced Therapies
  – Slovak Republic „Case“
Slovak Association of Research Based Pharmaceutical Companies

- Established in 1997
- Exclusively R&D companies “Big Pharma“
- Max 30 % of local generic turnover in value is allowed
- 22 members, 55 % of total SK market value (14 bill. SKK)
- 2 professionals: ED, PR
- Board: 5 members elected every 2 years
- EFPIA of member since 2004 (EU federation of Pharmaceutical Industry and Associations)
What you can’t see with your naked eye

May be even more hidden than you thought...
Pharmaceuticals & Biopharmaceuticals
No. of New Molecules and Biotech Product Worldwide 1990-2004

Source: CMR International
NME Approvals are Declining – Biologics are Filling the Void

Source: FDA, K. Kaitin – Tufts Center for the Study of the Drug Development
Origin of New Chemical or Biological Entities (1986–2005)

Source: SCRIP – EFPIA calculations (according to nationality of mother company)
Of the top 10 worldwide products in 2005, 7 originate from the US against 3 from Europe.

**ORIGIN OF THE TOP 40 COMPANIES BY R&D INVESTMENT, 2004-2005**

- Europe: 12
- USA: 16
- Japan: 11
- Others: 1

**NEW CHEMICAL AND BIOLOGICAL ENTITIES LAUNCHED IN THE PAST FIVE YEARS, 2001-2005**

- Europe: 51
- USA: 61
- Japan: 23
- Others: 14

Source: UK Department of Trade and Industry, The 2005 R&D Scoreboard - EFPIA calculations

Source: SCRIP, 2005 - EFPIA calculations
United States Leads the World in Biopharmaceutical Development

Note: Comparisons were completed in June of each year. Some compounds will be at different phases for different indications.
Source: Adis R&D Insight Database, customized run (December 2005).
What are the reasons?

R&D Costs of a New Drug
( mil. USD)

Pharma R & D investments by regions

Pharmaceutical R&D Expenditure in Europe, USA and Japan
(€ Million, Current Exchange Rates), 1990-2005

Source: EFPIA member associations, PhRMA, JPMA
Shares of Top 5 Sectors in Total R&D Investment
(Top 942 Companies by Main World Region in 2004)

[Bar chart showing shares of top 5 sectors in total R&D investment by region: EU, Japan, USA, Rest of World.]

Source: The 2005 EU industrial R&D investment scoreboard, European Commission
Although Europe’s biopharmaceutical sector is growing Europe practically missed out on the first wave of biotech start-ups in the 1980s, most European biotech companies are significantly smaller than their US counterparts.

*2004 data; Source: Ernst & Young, ‘Beyond Borders, The Global Biotechnology Report 2006’ (data relate only to publicly traded companies)
What is critical for success?

Investments

Supportive environment for innovation

» Drug Legislation
» IPR
» Economic considerations/ Health and HC as priority – motivating rewards for innovators
» Solved Ethical Considerations (or at least open public discussion..)
European Union

Drug legislation

• **Directive 2001/83/EC** on the Community Code relating to medicinal products for human use

• **Regulation (proposal) on advanced therapy medicinal products** amending Dir. 2001/83/EC and Reg. (EC) No. 726/2004

  Passed EP in first reading on 25 April, 2007

IPR

• **Directive 98/44/EC** on the legal protection of biotechnological inventions
EU – Ethical Considerations

Advanced Therapy Regulation passed thanks to adoption of “Compromise package of amendments“. With the compromise package, the subsidiarity and Member States’ national legislations on ethics will be fully respected.

Indeed, the European assessment and decision will not deprive a Member State of its right to reject a product based on their ethical values.
„Case“ Slovak Republic and Access to Advanced Therapies

- EU Drug Legislation - transposed
- IPR – transposed
- Investments to health and HC?
- Ethical considerations?
SK – strict ethical regulations on bioresearch

  § 26, bod 10) Research without health indication cannot be provided on living human foetus or zygota
• Criminal Act 300/2005 coll.
  § 161 - more detailed provisions, up to 15 yrs jail

• Stem cell research, tissue engineering, gene and cell therapy?
What about Slovak patients?

- Strong need of public education and discussion based on scientific facts not emotions only....
- This could lead to less conservative approaches and more friendly environment for research and production investments

Otherwise

- Some of “Advanced Products” should be accessible just thanks to free movements of goods or patients across EU....
Thank You for Attention

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