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Consumer perspectives on Intellectual Property, Competition & Access to Medicines in Europe

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Current Model

The dominant current model...

- Relies heavily on **Intellectual Property** protection.
- Rewards R&D with **market exclusivity** and **monopoly prices**.
- No competition, which leads to **high prices, high profits, high costs** → **poor access**

Costs and Competition

European countries devote a high percentage of their health expenditure to medicines and...it is still growing

- **A decade ago**, no industrialised country spent more than **10% of its health budget on medicines**
- **Now** In Germany: **15.2 %** , Spain: **22.8%**, Finland **16.3%**, France: **16.6 %**, Italy: **20.1%** (US 12.48%)

Costs and Competition

Competition is vital to drive down prices, support broader access, and open the field to more innovation

- Generic market entry: **25% decrease in prices** within first year; 40% after two years.

Model of Litigation and Marketing

- Many **blockbusters** are going off-patent
- Originators have **profit-driven incentives** to hold on to market exclusivity
 - ➔ hinders competition
- **Business model** increasingly focused on litigation, excessive patenting, and marketing and promotion.
 - ➔ incentives structure contrary to citizen interests.

DG Competition

Pharmaceutical Sector Inquiry

Investigation conducted between late 2007-mid 2010

Serious concerns about:

- **slow generic entry**
- **weak innovation**

Could infringe on EC Treaty:

- **Art 81.** Prevent, restrict or distort competition
- **Art 82.** Abuse of a dominant position

Findings: DG Competition Report

- Revealed some **structural practices**
- Observed that pharmaceutical companies have...

...“designed and implemented strategies aimed at blocking or delaying generic entry”

AND

...used tactics that “reduce incentives to innovate” and “cause significant additional costs for public health budgets”.

Findings: DG Competition Report

- Calculated that EU health systems **could have saved more than 3 billion euros** between 2000 and 2007
- Found that originator companies **spend 15 times more on marketing, blocking tactics and litigation** than on discovering new beneficial medicines.
- Identified a **'toolbox' of tactics** employed by originator company to discourage, delay, and prevent generic entry into the market.

Practices: Originator-Generics

- i. **“Patent clusters”** → substantial barrier to potential generic manufacturers
- ii. Patent-related **disputes and litigation**
- iii. **Settlements** with generic companies
- iv. **Misleading claims** about inferior quality of generics in decisions on product authorisation, pricing and reimbursement status
- v. Launching **follow-on products** in order to displace generic medicines based on the original product

Follow-up: DG Competition Inquiry

- **Regulatory frameworks:**
 - Patents and patentability
 - Market authorisation
 - Pricing and reimbursement
- Enforcement of competition law: **Anti-trust cases**
- **Deterrence**

BUT, companies will still act according to the current framework of incentives:

Prioritising profits over public health needs

How to go forward

High prices and lack of competition are at the core of the debate about **Access to Medicines**.

IP protection provides incentives to:

- Engage in **anti-competitive** practices
- Develop strategies that hamper **innovation**

We need fair and effective competition to promote widespread access to essential medicines.

Thank you

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