



Making Medicines Affordable

How Future EU Legislations Could Enhance Patient Access to Affordable Healthcare

Elke Grooten

Director Pharmaceutical Policy EGA

To Ensure Timely Patient Access to Affordable Generic Medicines

- Immediate market access for generic medicines after patent expiry
- Increased market volume for generic medicines





Making Medicines Affordable



**European Commission Communication
(December 08):**

***“Safe, Innovative and Accessible
Medicines:
a Renewed Vision for the
Pharmaceutical Sector”***

December 2008 Communication

■ ***“Many Member States recognise that generic medicines play an important role in helping:***

- *to limit their healthcare expenditure in their reimbursement and prescribing practices*
- *To enable sustainable treatment of more patients with less financial resources*
- *To create financial headroom for innovation*

Action Point

■ ***All actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively”***

EC Pharma Sector Inquiry



Neelie Kroes, former
Commissioner for COMP

“Market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market”

“When it comes to generic entry, every week and month of delay costs money to patients and taxpayers.”

8 July 09

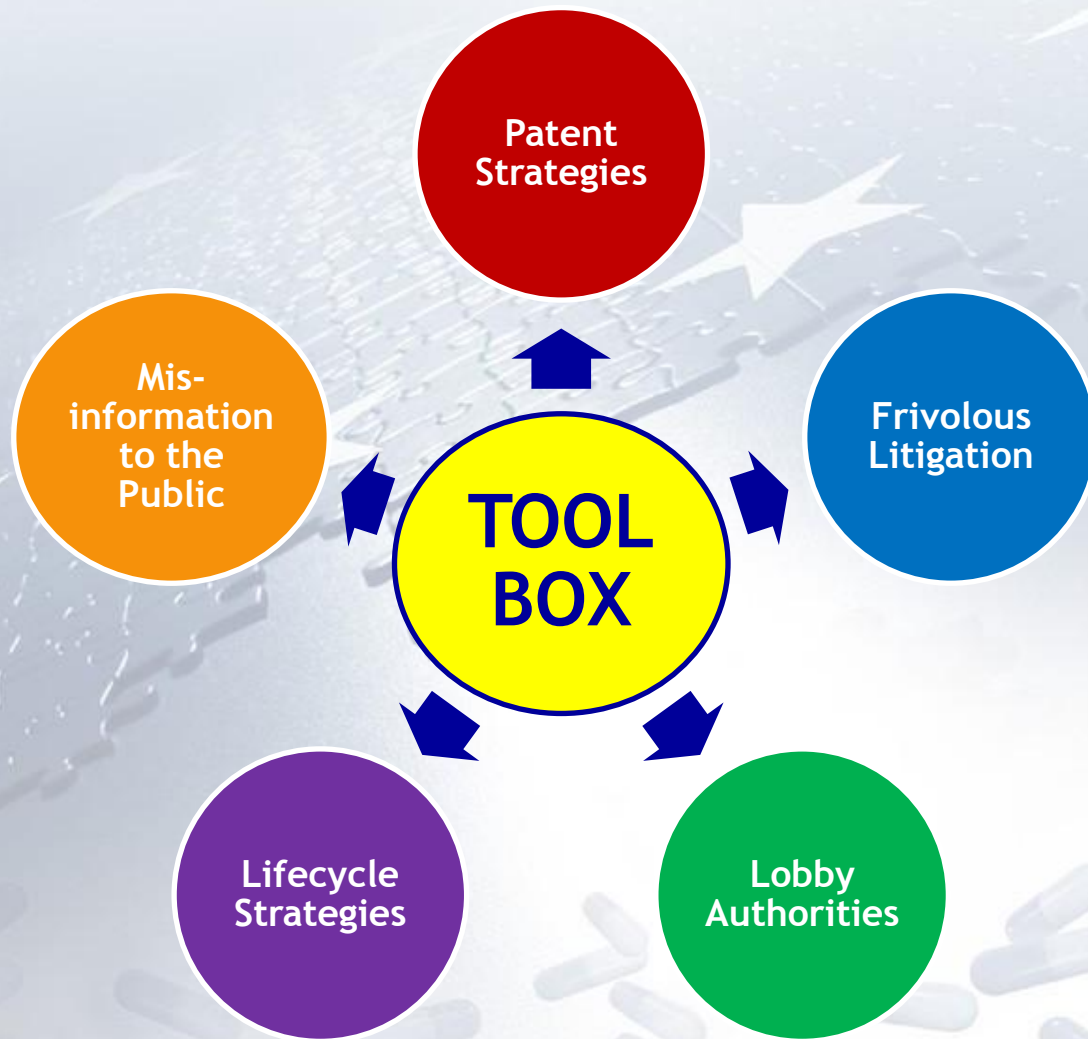


Making Medicines Affordable

Some Remarkable Findings

- On average, generic entry delayed for 12 months
- Up to 1300 patents around 1 molecule
- Generic companies win majority of litigation cases
- Average duration of litigation case: 2.8 years
- Total litigation cost for analysis for 2000-2007 is over €420 million
- In 75% of EPO opposition cases, patent revoked or restricted
- “Interventions” before authorities delayed generic entry on average by 4 months
- 98% of court cases about interventions won by generic companies
- Originator companies use of marketing power to switch patients

Delaying Strategies Used by Originator Companies



Source: Final report Sector Inquiry, July 09

European Commission Recommendations



Patent Strategies

- Strong Support for EPO Reform “RAISING THE BAR” on quality patents
- Accelerate opposition and appeal procedures
- Limit time period to file voluntary divisional patents
- Rapid Establishment of Community Patent

*Role
Parliament
and Council*



Legislative Proposal on Community Patent

European Commission Recommendations

**Frivolous
Litigation**

- Rapid Establishment of Unified Litigation System
- National courts to grant preliminary injunctions with care in order not to delay generic entry without proven patent infringement

**Role
Parliament
and Council**

**Legislative Proposal on
EU Patent Court**

European Commission Recommendations

**Mis-
information
Campaigns**

- Member States to take action in line with Pharmaceutical Legislation providing correct information on authorised medicines
- Misbehaviour effectively sanctioned by authorities

*Role
Parliament
and Council*

**Legislative Proposal on
Industry Information to
Patients**

European Commission Recommendations

**Lobby
Authorities**

- Shorter price and reimbursement (P&R) for generic medicines
- Ban of patent linkage in all regulatory procedures
- P&R agencies should not look at bio-equivalence and efficacy
- Third party submissions should be well documented (burden of proof), made transparent and not delay the application

**Role
Parliament
and Council**

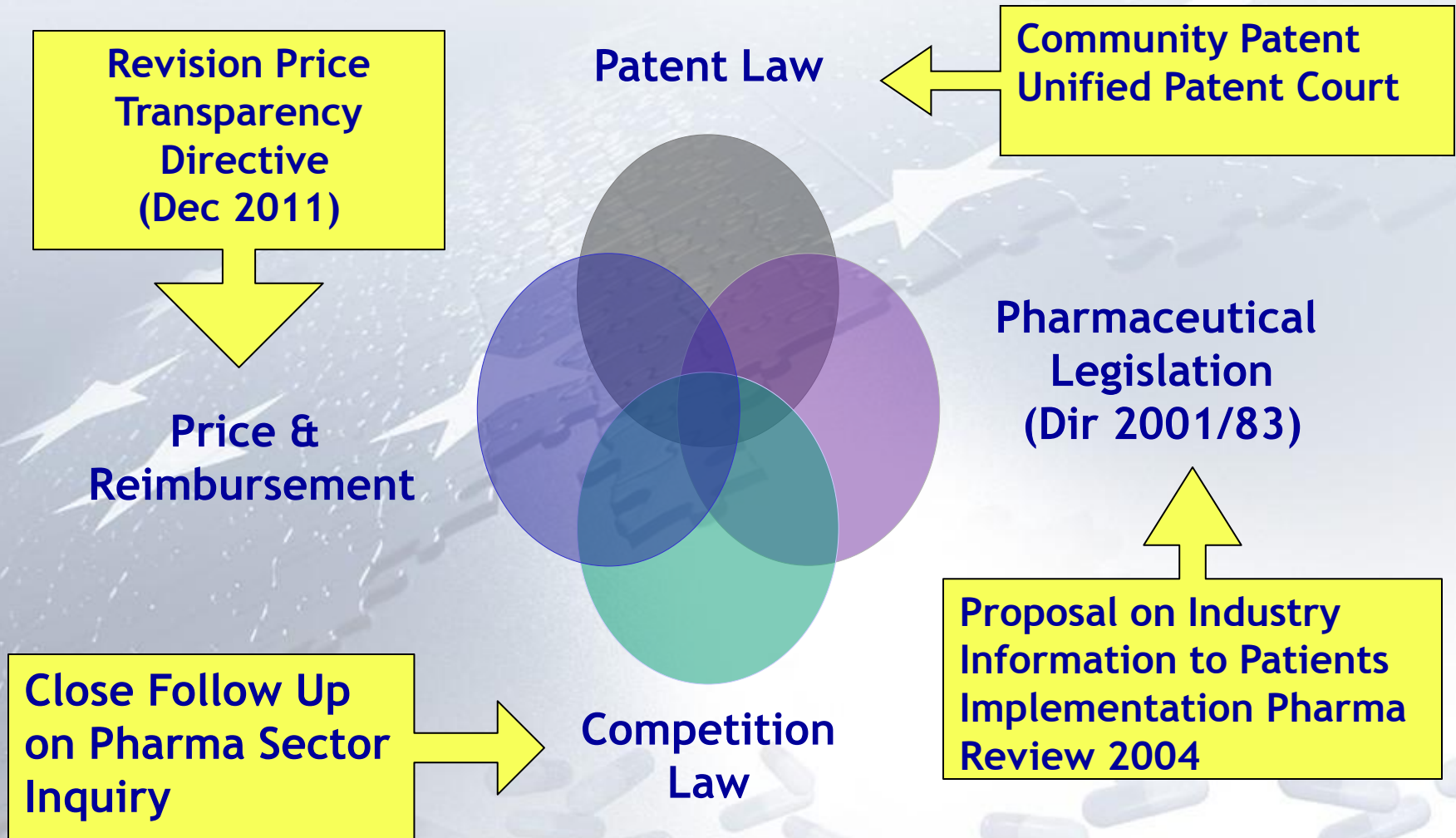
**Revision Price
Transparency Directive**

European Commission Recommendations

Lifecycle Strategies

- Streamlining of clinical trials with regard to relative effectiveness assessment (=HTA): proof of added therapeutic value for obtaining price and reimbursement

Legislative Framework Needed to Get EU System Right



Rapid Implementation of Recommendations Would:



- Foster Innovation
- Increase competition
- Improve the image of the sector
- Improve patient access to affordable treatments
- Ensure healthcare sustainability

The Time is Now !



Making Medicines Affordable

Thank you

www.egagenerics.com

