Directorate-general
Enterprise and Industry

PHARMACEUTICALS in the EU HEADING FOR THE FUTURE

DGRA Conference, Bonn
17 June 2008
Martin.terberger@ec.europa.eu

Pharma Communication: 'Have your Say' initiative

- Commission commitment to listen to all stakeholders: open debate
- Public Consultation July-October 2007
  (Consultation paper in 22 EU languages)

=>104 contributions received

- Commission Communication planned for October 2008

- What did stakeholders say?

- How does the Commission respond? What is the Commission vision and action plan for the sector?

- What did stakeholders say?

- How does the Commission respond? What is the Commission vision and action plan for the sector?

What did stakeholders say?
3 major challenges for the sector

- Globalisation
- Functioning of the EU single market
- New scientific developments

What did stakeholders say?
Globalisation: challenges and opportunities

- Global health challenges:
  - Counterfeiting
  - Quality of starting materials/active substances
  - Clinical trials in non-EU countries
- International competition
- New opportunities on new markets

What did stakeholders say?
Functioning of the EU single market

- Fragmentation:
  - National pricing and reimbursement decisions
  - Strategic decisions of companies to invest in certain markets and not in others
  - Competition? (sector enquiry)

- Potential for improvement of existing regulatory framework (better regulation)

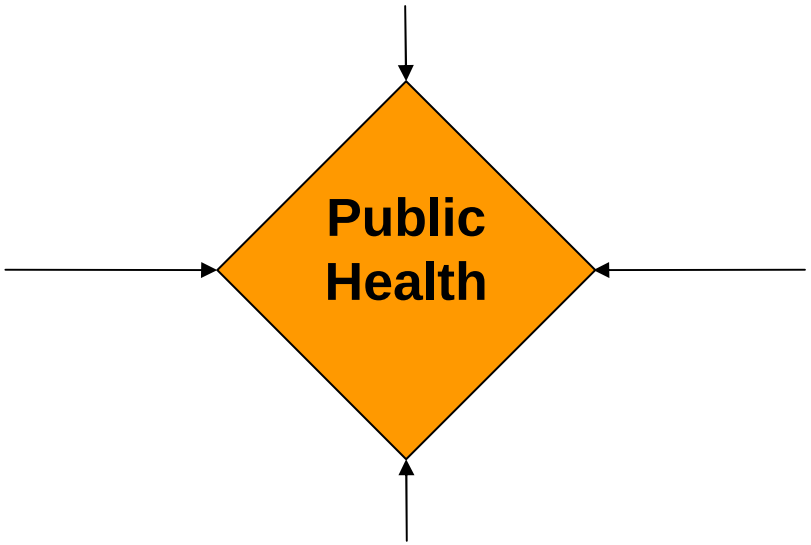
What did stakeholders say?
New scientific developments

- More and more complex medicines, using living materials (genes, cells, tissues…organs)
- Borderline with other sectors (medical devices)
- Personalised medicine, pharmacogenetics
- Nanotechnologies

What did stakeholders say? Underlying Drivers

Policy
- Political priorities
- Regulatory framework
- International collaboration

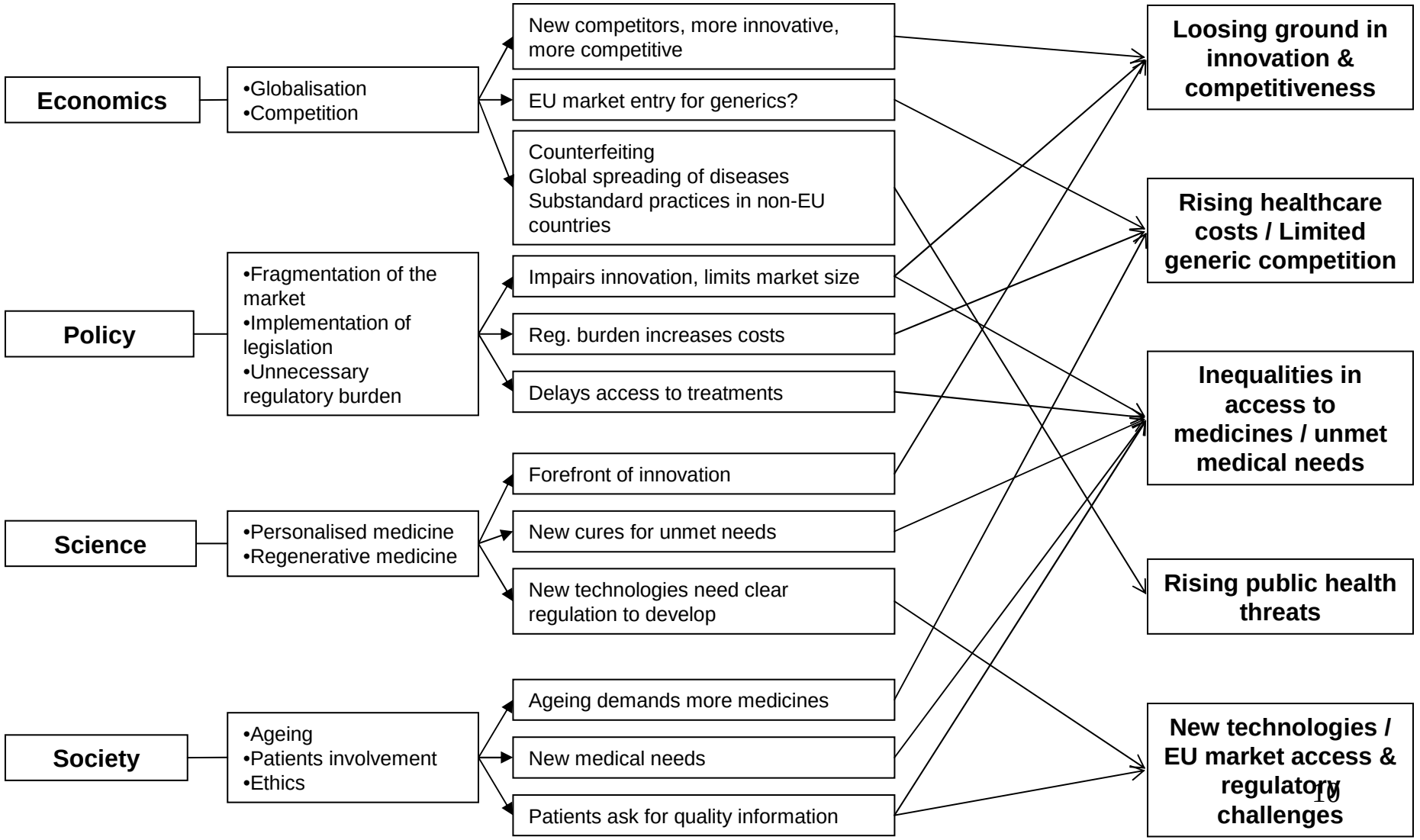
Economics
- Globalisation
- Competition



Society
- Ageing
- Patients involvement
- Ethics

Science
- New technologies/therapies
- Unmet medical needs

What did stakeholders say? Underlying Drivers



- *What did stakeholders say?*

- How does the Commission respond? What is the Commission vision and action plan for the sector?

Response/Vision

Improve functioning of the EU single market

Foster international collaboration and convergence

Make science deliver for EU patients

Response/Vision

Improve functioning of the EU single market

- Better Regulation
- Protect/empower EU patients
- Coordination with Member States

- Variations
- Pharmacovigilance Strategy
- Safety of the supply chain
- Information to patients

The ‘Variations’ project

- Commission flagship for Better Regulation
- Radical and concrete approach to simplification:
  - Inclusion of purely national authorisations (co-decision)
  - Design space (ICH)
  - ‘Do and Tell’ & annual reporting
  - Grouping of variations
  - Worksharing
  - Type IB by default instead of Type II
  - Clear fixed deadlines for Member States to review/approve variations

Variations: current state of play

- Codecision:
  - proposal adopted in March
  - progress made under SL Presidency
  - EP timeline to be defined
  - FR Presidency could be decisive

- Comitology:
  - Meetings with MS on 3 April, 2 June and 10 June (**agreement**)
  - EP/Council Scrutiny (3mths) -> 13/9/2008
  - Formal adoption by Commission in October 2008
  - Application by Q4 2009

Pharmacovigilance strategy

Proposal to better protect public health by strengthening and rationalising EU Pharmacovigilance

- Improving the data, information, and decision-making on safety issues
- Resource savings by increasing the efficiency of the system

Pharmacovigilance legislative strategy

Concrete examples

1. Simplification of 15-day (expedited) reporting of single case reports
2. Literature monitoring for case reports
3. Informing about the company's PhV system
4. Proportionality of Periodic Safety Update Reports (PSURs)

Safety of the supply chain

Problems

- 380% increase of seizures of counterfeit medecines at EU borders
- Trend towards fake life-style and life-saving drugs
- Legal supply chain targeted
- Packs of counterfeit medicines have reached patients to a significant extent

Safety of the supply chain

Objectives

- prevent manufacturing, importation and distribution of
  - counterfeit or low quality active substances
  - counterfeit medicines
- protect legal distribution chain against counterfeit medicines

Information to patients

Problems

- Divergent practices of Member States
- Patients ask for more information on medicinal products
- Web based technologies need a clear framework

Information to patients

Objectives of Commission projects

- Maintain ban on advertisement of POMs
- Clear guidance to pharmaceutical industry
- Clear quality criteria to avoid advertisement through the backdoor

Response/Vision

Foster international cooperation and convergence	•Trilateral EU-US-JP (ICH) •Global cooperation •Transatlantic dialogue

•ICH

•Transatlantic Cooperation (TEC)

•International strategy
(JP, Canada, India, Russia, China, Brazil)

Transatlantic cooperation

Simplification is pursued on different levels

- Upstream regulatory dialogue on draft legislation
- Harmonisation of guidelines
- Cooperation on technical standards
- Administrative and scientific processes

Transatlantic cooperation

International guidelines - Example “(e)CTD”

- "Common Technical Document" has reduced administrative burden
- eCTD has potential to simplify process further, but requires upfront investment and coordination

Transatlantic cooperation

Agreed Transatlantic priorities

- Pilot joint inspections
- Pilot exchange of inspection schedules and results on APIs
- Collaborate on dedicated production facilities
- Joint work on biomarker development and validation

Response/Vision

Make science deliver for EU patients

- Stimulate R&D
- Support SMEs

- Advanced Therapies Regulation
- Innovative Medicines Initiative
- SME Regulation
  - >250 companies have received the SME status
  - >4 million Euros has been spent in SME fee reductions

- *What did stakeholders say?*

- *How does the Commission respond? What is the Commission vision and action plan for the sector?*

- Other points highlighted by stakeholders

Other stakeholders' points

- A better system for Clinical Trials
- A more « proportionate » framework for OTC medicines
- A faster market access for generics
- Pricing and Reimbursement

CONCLUSION

Conclusion (1/2)

2008, **a year of delivery**:

– Variations
(comitology (done) and codecision (FR Presidency))

– Pharma Package (Autumn):
  - Pharma Communication
  - Info to patients
  - Pharmacovigilance
  - Counterfeit

Conclusion (2/2)

2009, **a year of political changes**:

- New European Parliament
- New Commission

- Pharma Communication should provide a blueprint for next Commission review of concepts and negotiations

Thank you