Initiative of the EU Commission: Follow up to the Public consultation on the future of the pharmaceutical sector

EU Regulatory Network
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Commission Communication on a strategy for the sector

- Identifying and addressing the challenges: *Safe, Innovative and Accessible Medicines. A Renewed Vision for the Pharmaceutical Sector*
- A comprehensive overview of the challenges and the Commission's proposals for action, across a wide range of areas (access to medicines, internal market, competitive EU industry, safety of medicines, globalisation, innovation and research, etc)

Outline

- The EU legal framework for pharmaceuticals: evolution and current regulatory challenges
- Key upcoming initiatives: agenda for 2008 onwards
- The issue of availability in small markets: reflections from a regulatory perspective

EU legal framework for pharmaceuticals

- Placing on the market of medicinal products subject to the granting of a marketing authorisation (MA)
- Progressive harmonisation of requirements for MA since 1960s, implemented across the EEA
- Overall system dependent also on the proper functioning of the network of competent authorities

Regulatory challenges

- Ensuring a high level of protection of public health: legal framework in constant evolution as a result of scientific and technical progress
- Addressing market fragmentation: a true single market in medicines
- Several layers of rules (Community and national legislation, guidelines, international harmonisation)

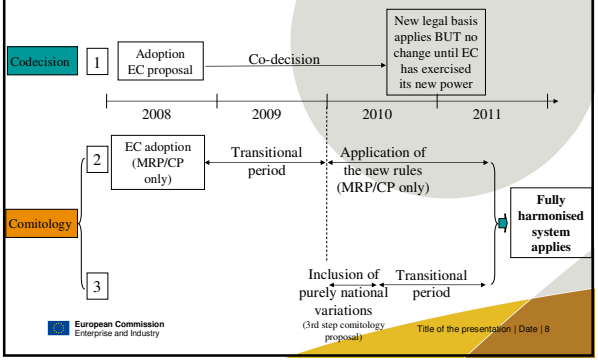
Regulatory challenges: current trends

- Ensuring availability of authorised medicines and affordability
- Competitiveness and innovation in Europe
- Evaluating the procedures for marketing authorisation and the functioning of the network of competent authorities
- Globalisation
- Simplification and better regulation

Addressing the challenges: key upcoming initiatives

- On-going: Revision of the variations framework
- "**Pharma package**" for adoption in October 2008:
  - Commission Communication on a renewed strategy for the pharmaceutical sector
  - Legal proposal on Safety of the supply chain
  - Legal proposal on Information to patients
  - Legal proposal on Pharmacovigilance

Variations: timing



Variations: next steps

Guidelines

- Different technical/scientific groups contribute to drafting
- EMEA coordinates this drafting
- Commission to finalise the first draft
- Broad consultation of Member States and stakeholders
- Legal scrutiny and adoption

Fees – Regulation to be amended

Globalisation poses new challenges for regulator and internal market

Example:
Counterfeit medicines and API

Counterfeit medicines: looking a different aspects:

1. Manufacture, Placing on the Market of Medicinal Products & Inspections	2. Actors in the supply chain	3. Manufacture, Placing on the Market of Active Substances & Inspections

Information to patients

- Clarify the legal framework how the industry can provide information on prescription-only-medicines to patients
- Keep the ban for advertisement for these medecines
- Keep in general the rules for OTC medicines

Pharmacovigilance

- Need to strengthen and rationalise the EU-system widely accepted by stakeholders

Conclusions

- Commission launching debate on the future strategy for the pharmaceutical sector, to ensure safe, innovative and accessible medicines
- Imminent adoption of a legislative package addressing certain of the current regulatory challenges
- Availability of medicines gaining visibility in the political debate and one of the challenges for the coming years