The European Commission's 2008 Pharmaceutical Package

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The “Pharma package”

- Commission strategic communication
  Identifying and addressing the challenges: *Safe, Innovative and Accessible Medicines.*

  A Renewed Vision for the Pharmaceutical Sector
- Legal proposal on Counterfeit Medicines
- Legal proposals on Pharmacovigilance
- Legal proposals on Information to patients

Challenges for the European pharmaceutical sector

- Europe has been losing ground in pharmaceutical innovation.
- Shortcomings in the availability of medicines have been identified.
- The sector is more and more globalised.
- Scientific breakthroughs revolutionize the way medicines are developed and prescribed.

Answers of the European Commission

1. To make further progress towards a single and sustainable market in pharmaceuticals
2. To take on the opportunities and challenges of globalisation
3. To make science deliver for European patients

Make further progress towards a single and sustainable market in pharmaceuticals

- Three legislative proposals and an impact assessment of the application of the Clinical Trials Directive
- Follow-up to the Pharma Forum: pricing, reimbursement and relative effectiveness
- Improve the availability of medicinal products
- In-depth monitoring of the functioning of markets

Proposal on “counterfeit” medicines

- The issue at stake:
  - increase of seizures of counterfeit medicines
  - legal supply chain targeted
  - from lifestyle to life-saving drugs
- New risk profile with negative consequences for public health, economy, internal market
- The proposal in the framework of a wider strategy against counterfeits

Proposal on “counterfeit” medicines –Key items

1.	2.	3.
Product characteristics and **‚Good Manufacturing Practices‘ (GMP)**	**Actors in the supply chain** and **‚Good Distribution Practices‘ (GDP)**	**Active Substances** (incl. Inspections)

Directive amending Directive 2001/83/EC

Proposal on “counterfeit” medicines
Product characteristics and GMP

- Obligatory (and harmonised) **safety features** allowing identification and authenticity checks and tracing
  - Scope: prescription medicines and risk-based
  - Characteristics set out in implementing measures
  - Specific rules for the removal or cover-up of the feature
- Obligation on manufacturers to **report** any suspicion of counterfeit

Proposal on “counterfeit” medicines
Actors in the supply chain and GDP

- Definition of “**trader**” assorted with certain obligations (records, audit, notification)
- Clarification of rules on “**introduction**” and **exporting wholesalers**
- **Audits** of suppliers by purchasers
- Compliant wholesale distributors registered in a **EudraGDP** database
- Obligation on distributors to **report** any suspicion of counterfeit

Proposal on “counterfeit” medicines
Active substances

- **Importation of APIs** from third countries only if
  - Confirmation on GMP compliance from exporting country
  - Confirmation not required if exporting country has an equivalent control and enforcement mechanism
- Obligatory **audits** by MAHs
- **Notification** of manufacturers and importers

Legal proposal on pharmacovigilance
Key items

- Clear tasks and responsibilities for all parties
- Improved decision-making procedures and efficient use of resources
- Proactive and proportionate risk management avoiding unnecessary administrative burden and providing for stronger link between safety assessments and regulatory action
- Strengthened transparency, patient involvement

Legal proposal on pharmacovigilance
Tasks and responsibilities

- **EMEA** general coordinating role reinforced
- New EMEA committee for PhV
- Increased cooperation and work-sharing among **Member States**
- **MAH** to operate a PhV system which may be documented in a PhV Master File
- Strengthened obligations of MAH as regards continuous monitoring of safety information and update of MA

Legal proposal on pharmacovigilance
Decision-making procedures

- Revision of current **Art 107 procedure** (Community procedure for safety issues of national products)
- Scope of procedures to cover **all products concerned** to ensure single assessment of the safety issue
- Rules to ensure the (harmonised) **regulatory follow-up** as regards the marketing authorisation
- New **roles** for PhV committee and CMD

Legal proposal on pharmacovigilance
Risk management

- **Risk management plan** for all products, proportionate to risks and information available
- List of **intensively monitored products**
- **Adverse reaction reporting**: enlarged definition of ADRS; all reports to Eudravigilance; patient reporting
- **PSURs**: benefit-risk reassessment vs. line-listing; requirement proportional to risk; harmonisation of frequency of assessments allowing single assessment of related products

Legal proposal on pharmacovigilance
Transparency, patient involvement

- **Eudravigilance** database: single point to receive and share reports
- European and national safety **web portals**
- Coordination by EMEA of **communications** on safety issues
- New section in **product information** for rapid identification of critical messages
- **Patient involvement**: adverse reaction reporting, public hearings, more info through increased transparency

Legal proposal on information to patients

- The issue at stake:
  - no common rules on non-promotional information: divergent practices on the provision of information to patients across the EU
  - patients increasingly empowered and proactive users of healthcare: increased demand for information
- Long-standing debate (G-10, Review 2001-2004, Pharma Forum)
- Commission report and Council conclusions

Legal proposal on information to patients

- Commission has concluded that there is a need to take **action at EU-level** in order to address the shortcomings of the current pharmaceutical legislation in the area of information on medicinal products to the general public
- While maintaining **ban on advertising**
- **Scope**: information provided by the pharmaceutical industry as regards prescription medicines
- Amendments to Directive 2001/83/EC and Regulation (EC) No 726/2004

Legal proposal on information to patients
Key items

- Types of information to be disseminated
- Channels for the dissemination of information
- Quality criteria and conditions to be fulfilled
- Specific rules on Internet websites
- Monitoring and enforcement

Cumulative application of these rules to allow **workable distinction between advertising and information**