Instrument for Pre-Accession Programme IPA

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The Role of the European Commission

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Topics

- 1. European Union Competence
- 2. Roles and Responsibilities of European Bodies
- 3. Role of the European Commission in Pharmaceuticals

European Commission Enterprise and Industry

EU Competence - TFEU

- 1. Exclusive competence (Art. 3)
 - Only EU to legislate and adopt legally binding acts
 - Customs union
 - Common commercial policy
 - Conclusion of international agreements...
- 2. Shared competence with MS (Art. 4)
 - EU and MS to legislate and adopt legally binding acts
 - Internal market
 - Common safety concerns in public health matters ...
- 3. Actions to support, coordinate actions of the MS (Art. 6)
 - Protection and improvement of human health ...

There is a difference...

European Union since 1957

- 27 Member States
- Mandate:
 - Common market
 - Harmonised legislation
 - Intergovernmental cooperation
 - Trade Agreements: 3rd countries

Relevant Institutions/ Bodies:

- European Council
- European Commission
- Council
- European Parliament
- European Court of Justice...
- EMA (European Medicines Agency)
- ECDC (European Center for

Prevention and Control)

Council of Europe since 1949

- 47 Member Countries
- Mandate:
 - Human rights (European Human Right Convention)
 - Rule of law (criminal & civil)
 - Pluralist democracy

Relevant Bodies:

- Committee of Ministers
- Parliamentary Assembly
- European Court of Human Rights
- DG I: Human Rights & Legal
- DG III: Social Cohesion

 EDQM: European Directorate for the Quality of Medicines & Healthcare

European Bodies

- European Council (Heads of States & gov.)
- European Commission
- Council (Member States)
- European Parliament
- European Court of Justice ...
- Committee of the Regions
- Economic and Social Committee
- · Agencies (e.g. EMA, ECDC, ECHA)

European Commission Enterprise and Industry

European Commission Directorates General, e.g.*

- •DG Health and Consumer Policy (SANCO)
 - Health Programmes
 - Safety of food, blood
 - Pharmaceutical legislation
- DG Enterprise and Industry (ENTR)
 - Competitiveness & Biotechnology in the Pharmaceutical Industry
- DG Research (RTD)
 - 7th Framework Programme
 - Innovations Medicines Initiative (IMI)
- DG Development (DEV)
 - Health related programmes with developing countries
- DG Enlargement (ELARG)
- DG Trade (TRADE)
- Leads negotiation on third country agreements

*List of services and tasks not exhaustive

Treaty on the Functioning of the European Union - TFEU

- 1. Approximation of laws (Art. 114 ex Art. 95)
 - Free movement of goods...
- 2. Public Health (Art. 168 ex Art. 152)
 - Programmes to improve public health
 - Intergovernmental cooperaton
 - Combating serious cross-border health threats
 - · High standards of quality and safety
 - for medicinal products and medical devices
 - · Organs & substances of human origin, blood,

European colleged derivatives ...

EU Regulatory Framework relevant for Pharmaceuticals

Harmonised Legislation

- Clinical Trials
- Marketing
- Manufacture
- Import
- Wholesale Distribution
- Blood & Tissue Products
- Inspections
- >MS implement legislation into national laws



Non harmonised legislation (but subject to Treaty)

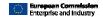
- Pharmacies (incl. Internet)
- Retailers (incl. Internet)
- Health Care Professionals
- Health Insurances, Reimbursement
- MS establish national legislation on basis of regional experiences/ systems

Legal Acts (Art. 288 TFEU, ex Art. 249)	
Regulation (general)	directly binding directly applicable in all MS
Directive (general)	binding framework adressed to MS for implementation in national legislation
Decision	directly binding
(specific)	upon those adressed
Recommendations	no binding force
and European Comment inions Enterprise and Industry	

Legal Acts – Examples - Pharmaceuticals		
Regulation	726/2004	
	Centralised authorisation procedure and EMA	
Directive	2001/83(2)/EC,	
	amended by 2004/27(8)/EC	
	Human (veterinary) medicinal products	
Decision	all marketing authorisations under the centralised procedure	
Specific guild Entries and industry	Guidance to industry on interpretation & administrative practice	

Main Role of the Commission (1)

- to make proposals for harmonised legislation (Art. 17 TEU, Art. 115 TFEU ex Art. 94)
 - e.g. "Pharmaceutical package" incl. legal proposals on
 - Pharmacovigilance
 - · Falsified medicines
 - · Information to patients
- to coordinate intergovernmental cooperation (Art. 168 TFEU – ex Art. 152).
 - e.g. Influenza Pandemic
 - · Health Security Committee
 - · Commission Staff Working Documents:
 - Vaccination strategies
 - Purchase Agreements



Main Role of the Commission (2)

- to issue recommendations to the Council for international treaties and conduct negotiations (Art. 218 TFEU – ex Art. 300)
 - e.g. Mutual Recognition Agreements
 - Agreements for Conformity Assessment (ACAA)
- Preparation for accession of new Member States
 - Assess applicants ability to meet conditions for membership
 - Funds and operates Pre-Accession Programmes
- to ensure that provisions of the Treaty are applied (Art. 258 TFEU – ex Art. 226, Art. 263- ex Art. 230)
 - · "guardian of the Treaty"
 - e.g. transposition & application of EU legislation by MS
 - enterprise and industry

Co-decision procedure Role of the Commission

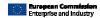
Art. 294 TFEU (ex Art.251)
Principle: 2 readings by Parliament & Council

- 1. submits **legal proposal** based on
 - Consultation of stakeholders
 - Assessment of social, economic, environmental impacts
 - Consultation of all Commission Services
 - Adoption by College of Commissioners
- participates in Council negotiations
- 3. gives a position on common position and changes from European Parliament
- 4. If COM has a negative opinion on changes, Council shall act unanimously

European Commission Enterprise and Industry

Delegated Acts – Implementing Acts

- 1) Delegated Acts (Art. 290 TFEU)
- Powers enferred to the COM
- to adopt non-legislative acts
- To amend certain non-essential elements of legislation
- Commission seeks assistance by MS experts
- Council and EP may decide to revoke delegation.
- 2) Implementing Acts (Art. 291 TFEU)
- Uniform conditions for implementing legally binding acts
- Conclusion: delegated and implementing acts "replace" former comitology procedure



European Parliament

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- Representation of the EU citizens
- Discuss and vote on legal proposals
 - Specific committees (e.g. ENVI)
- Raise questions to the European Commission
- Initiate debates on certain topics
 - e.g. on counterfeit medicines in 2007
- · Adopt resolutions, declarations
 - e.g. resolution on counterfeit medicines
 - e.g. declaration on active substances

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Council

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- Representation of EU Member States
- Involvement in legislative process (Co-decision)
- Committee 207 (Ex 133):
 assists Commission in conducting
 negotiations with third countries or
 international organisations
 (Examples: MRA, ACAA)

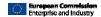
European Commission
Enterprise and Industry

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European Court of Justice

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- Interpretation of Union legislation
- Infringements of Union legislation
- > Establishes "Case law"
- Examples:
 - Parallel trade with pharmaceuticals
 - Doc Morris Case
 - Cases on pharmacies



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Involvement of Member States

1. Governments

Consultation Committees

- Pharmaceutical Committee
- Veterinary Pharmaceutical Committee

2. National Agencies

Heads of (Veterinary) Medicinal Agencies and working groups

3. Technical Experts

Future - tbd

 Involvement of MS experts in preparation of delegated and implementing acts by COM

Committees and Working groups at EMA, e.g.

• CHMP, CVMP

Enterprise an Optimission Commission of Enterprise and Working Parties

Involvement of Stakeholders

1. Consultations via websites

COM

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/index_en.htm

EMA

http://www.ema.europa.eu/

2. Stakeholder/ Interested Parties Meetings



