Instrument for Pre-Accession Programme IPA

European Medicines Agency

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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

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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 …

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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 Disease 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**

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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

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- Agencies (e.g. EMA, ECDC, ECHA)

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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

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*List of services and tasks not exhaustive

EU Competence – 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, blood derivatives …

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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**

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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 *(specific)*	directly binding upon those adressed
Recommendations and opinions	no binding force

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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 guidelines	Guidance to industry on inter-pretation & administrative practice

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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

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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
  - Initiative for infringement procedures

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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
2. 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*

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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

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European Parliament

- …..
- 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

…

- 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)

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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
- Specific Working Groups and Working Parties

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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

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