

# Organisation & Role of European Regulatory Bodies

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# (EMEA/CPMP/Heads of Agencies etc)

## Structure of Presentation

- **Pharmaceutical Legislation in the EU – the basic fabric**
- **Statutory Roles & Responsibilities**
  - National **M**inistries of **H**ealth (MoH) & **H**ealth **A**gencies (HA)
  - H**eads of **A**gencies (HoA) & **M**utual **R**ecognition **F**acilitation **G**roup (MRFG)
  - The EU Commission & Pharmaceutical Committee
  - EMEA/CPMP and their Working Parties
- **Relations to Third Countries: USA, Japan, Central & Eastern Europe, other countries**
- **Relations to Interested Parties**
- **Expected Changes with the Future Medicines Legislation**
- **Summary**

# Pharmaceutical Legislation in the EU – the basic fabric (1)

1957 Treaty of Rome

Public Health – a prerogative of Member States

1965 Directive 65/65 EEC (now 2001/83EC)

Marketing Authorisations based only on **Quality, Safety & Efficacy** criteria

1993 Regulation 2309/93 EC

Established the Centralized Procedure & the European Medicines Evaluation Agency (EMA) in London

2004 Commission Future Medicines Legislation

to amend Regulation 2309/93EC & Directives 2001/82, 2001/83 EC

# Pharmaceutical Legislation in the EU – the basic fabric (2)

- National & Community Legislation Coexist:
  - Primary Legislation: The Treaty of Rome (as amended)
  - Derivative Legislation
    - Decision: directly binding to addressee
    - Regulation: directly binding in all MS
    - Directive: to be incorporated in national laws of MS
  - National Legislations of 15 MS,  
need to be consistent with Community laws,  
National: Legal Status, Distribution, Advertising,  
Pricing/Reimbursement:
  - Not legally binding: Most Guidelines, Notes for Guidance

# Statutory Roles & Responsibilities (1)

- National **M**inistries of **H**ealth (MoH) & **H**ealth **A**gencies (HA)
  - Great Diversity Reflecting the Constitutional & Political Environment: Size, Organisation, Composition, Competence, Financing, Responsibilities,
  - **H**eads of **A**gencies (HoA): informal but important « Joint Venture »  
<http://www.heads.meadagencies.org>
  - **M**utual **R**ecognition **F**acilitation **G**roup (MRFG):  
former informal group nominated by HoA to support Mutual Recognition, now mandatory by new regulation
  - Co-operation, with **E**uropean **M**edicines **E**valuation **A**gency (EMA), **C**ommittee of **H**uman **M**edicinal **P**roducts (CHMP, former CPMP)
  - Consultation case by case with interested parties:  
Trade Associations, Academia, Patient Groups

# Statutory Roles & Responsibilities (2)

- EU Council
  - Political direction, legislation (with EU Parliament)
- EU Commission: [europa.eu.int/comm/dgs](http://europa.eu.int/comm/dgs)
  - DG Enterprise & Information Society (former DGIII)
    - Proposes legislation, monitors implementation of community legislation & free movement of goods services, capital & people, issues decisions
  - DG Health & Consumer protection
    - Food safety, Animal Health & Welfare, Consumer Protection & Rights, Public Health (e.g.. Drug Abuse, Safety of Blood, Antimicrobial Resistance, Alzheimer, Cancer, AIDS)
- EMEA & CHMP
  - The secretariat (EMEA) & scientific body (CHMP)

# Statutory Roles & Responsibilities (3)

- Commission, DG Enterprise, Unit F2  
([pharmacos.eudra.org/F2](http://pharmacos.eudra.org/F2))
  - Proposes Legislation
  - Monitors implementation of community law  
(e.g.: public health, free movement) for pharmaceuticals
  - Supervises international relations and agreements
    - e.g. Mutual Recognition Agreements (MRA), International Conference on Harmonisation (ICH), WHO
  - Provides decisions to approve, refuse, suspend, revoke marketing authorisations and withdraw products from the market
  - Applies the Standing Committee Procedure
  - Supports global competitiveness of the industry

# The Agencies

- National Authorities
  - Responsible for national & MRP
  - Heads of Agencies
  - Mutual Recognition Facilitation Group (MRFG)
    - now mandatory groups
- EMEA: **The** European Regulatory Body



# Statutory Roles & Responsibilities (4)

- European Medicines Evaluation Agency (EMA)

[emea.eu.int/](http://emea.eu.int/)

- Supports administrative review of marketing authorisation application in the centralised procedure
- Monitors centralised products on the European market (pharmaco-vigilance, free movement)
- Organises community referrals:  
arbitration in mutual recognition procedures (art. 29 dir. 2001/83), divergent decisions (art. 30), community interest, i.e. safety issues (art. 31),
- Organisation:
  - Secretariat, Executive Director, Management Board, CHMP, COMP, CVMP\*
  - \*veterinary committee

# Statutory Roles & Responsibilities (5)

- Committee for Human Medicinal Products (CHMP)
  - Evaluates marketing authorisation applications in the CP & community referrals
  - Provides a scientific opinion as the basis for Commission decisions
  - Scientific advice to applicants & guidelines, position papers etc.
  - Maintains the regulatory scientific communication within the EU, with third countries & parties
  - Establishes working parties & ad hoc groups on specific topics:
    - Pharmaco-vigilance, Safety, Efficacy, Quality, Biotechnology, Joint CPMP/ CVMP WP, Scientific Advice Review Group (SciARG), Blood Products
    - Involved actively in ICH-Process

# Statutory Roles & Responsibilities (6)

- Committee on Orphan Medicinal Products (COMP)
- Legal Base:
  - Regulations 141/2000EC & 847/2000EC
  - Directive 2001/83 EC
  - Guideline on format & content of applications for designation ENTR/6283/00, March 2002
- Designation Criteria:
  - Seriousness of condition, no alternatives, rare disease (5/10000) or insufficient return
- Incentive: 10 years exclusivity

# The Registration Process (Timetable)

## Registration of New Medicines

- Role of EMEA & CHMP in a CP (Standard Process)
  - 6 to 4 m : letter of intent to EMEA
  - 3 m : eligibility for CP, appointment of Co/rapporteurs
  - 10 to 0 d : submission and validation
  - *d 1* : start of procedure after validation
  - *d 70* : draft Assessment Reports of to CHMP and applicant
  - *d 120* : CHMP list of questions, request for inspections, clock stop
  - *d 121-180* : Submission of responses, Joint AR, inspections, oral explanation (y/n and 2. Clock stop)
  - *d 181-210* : Final draft SPC, labelling, PL, CHMP opinion
  - *d 230* : Final translations & mock ups to EMEA
  - *d 240* : Transmission of opinion to Commission, MS, Applicant

# The Agencies Responsibility

- Maintenance Activities
  - Pharmaco-vigilance for centrally approved products
  - Referral procedures for national and MRP products
    - Community Interest (Article 31 of Directive 2001/83/EC)
    - Divergent Decisions (Article 30 of Directive 2001/83/EC)
    - Arbitration (MRP: Risk to Public Health; Article 29 of Directive 2001/83/EC)

# Scientific Advice

EMA /CHMP procedures available for providing Scientific Advice

- Any advice given is NOT binding on the EMA or applicant with regards to any future marketing authorisation. However, justification needs to be provided in the Expert Report if advice not followed.
- CHMP will only give scientific advice on questions to address specific scientific issues concerning quality, pre-clinical and clinical aspects.
- National regulatory authorities also provide scientific advice (e.g. Netherlands, Sweden, UK, France, Germany)

# Relations to Third Countries

- EMEA/CHMP/Commission
  - Establish co-operation & information exchange within the EU, with third countries & parties
    - 15 EU MS, European Economic Area (Iceland, Norway, Liechtenstein)
    - Central & Eastern European Countries
    - ICH: Japan, USA
    - WHO
    - In the future: mediteranians

# Relations to Interested Parties

- EMEA/CHMP/Commission
  - Establish co-operation & information exchange within the EU, with third countries & parties
    - Trade Associations: EFPIA, AESGP, EGA
    - Patient & Consumer Groups



# Changes with the New Medicines Legislation

- New names, committees & structures but no real fundamental change
  - CPMP has become CH<sub>uman</sub>MP  
(with changed country representation)
  - New Committee on Herbal Medicines
  - New EMEA Board structure  
( with patients & industry representation)
  - Creation of a Scientific Advisory Board

# Summary

- The EU is not the “United States of Europe”
- 25 MS, 3 EEA MS, 21 languages and different medical cultures
- Complexity of regulatory environment reflected in many Commissions, Committees, Regulatory Bodies (national , European), Working Parties and their interactions
- Regulatory Professionals need experience, negotiation & communication skills and excellent relations for effective navigation through this jungle

**Thank you for you attention !**