EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Authorisation Procedures

Instrument for Pre-Accession Assistance Programme (IPA)
Introductory Meeting
1-2 February 2010

Presented by: Zaide Frias and Melanie Leivers
Head of Section/Human and Veterinary Regulatory Affairs and Organisational Support

An agency of the European Union

EUROPEAN MEDICINES AGENCY

Background– The history of the EU system

1965: First Pharmaceutical Directive (65/65/EC)

triggered by Thalidomide catastrophe

EU law requires all medicinal products to obtain a Marketing Authorisation (MA) before they can be put on the EU market

EUROPEAN MEDICINES AGENCY

The European Regulatory Environment changed dramatically since 1995 …

1995	2000	2003	2004	2005	2006	2007	2010
EMA Centralised Procedure **Mutual Recognition Procedure**	Orphan Drugs Regulation	Annex I (to Directive 2001/83/EC) Common Technical Document (CTD)	New Legislation Title IV of Reg. 726/04 immediate	New Legislation fully into force DIR & REG **Decentralised Procedure**	Paediatrics Regulation	Advanced Therapy Regulation	Variation Regulation

Enlargement (to 15 MS)

Enlargement (CY, CZ, EE, HU, LT, LV, MT, PL, SI, SK) (to 25 MS)

Enlargement (BG & RO) (to 27 MS)

EUROPEAN MEDICINES AGENCY

European Commission - legislative tools

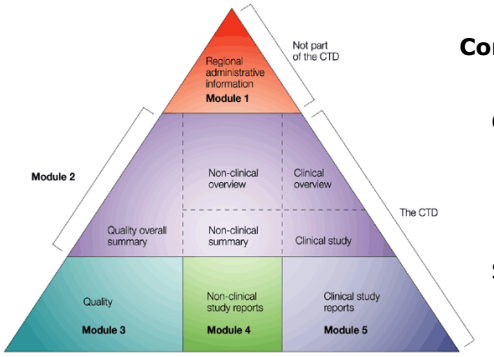
Regulation – binding to all Member State (MS), no national changes allowed e.g. Paediatric Regulation

Directive – result binding but transposition up to MS, local interpretation e.g. Clinical Trials Directive

Guidelines – "Soft Law", recommended but not binding e.g. "Guideline on the readability of the labelling and package leaflet of medicinal products for human use"

EUROPEAN MEDICINES AGENCY

Basis for Marketing Authorisation (MA)



Common Technical Document (CTD)

Companies need to submit data to show that the medicine is Efficient, Safe and of high Quality

Since 2003 CTD structure in EU, harmonised format for applications in EU, Japan & US

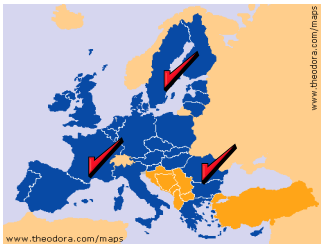
EUROPEAN MEDICINES AGENCY

Post November 2005
Three European Systems

Centralised Procedure (via EMEA)

Mutual Recognition procedure

Decentralised Procedure



EU Procedures

- Medicinal products have to be authorised either at Member State or Community level before they can be placed on the EU market

EU Procedures

Legal Basis of a Marketing Authorisation for a medicinal product for human or for veterinary use

- Human Directive (Directive 2001/83/EC)
- Veterinary Directive (Directive 2001/82/EC)
- Regulation (EC) No 726/2004 (joint Regulation for products for human use and products for veterinary use)

EU Procedures

Routes of authorisation

- National – limited (one Member State)
- Mutual Recognition (Member States) – authorisation granted first in one Member State and then recognised by the others

EU Procedures

Routes of authorisation

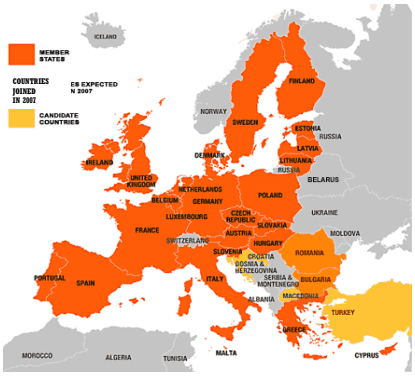
- Decentralised (Member States) – one application submitted in all Member States at the same time
- Centralised via the European Medicines Agency

  Scientific Opinions resulting in a European Commission Decision, applicable throughout the European Union (more about this in a later presentation)

Centralised Procedure

- Managed by single scientific committee (CVMP/CHMP)
- Generate binding scientific opinion
- Max. 210 days to Opinion
- Final Decision
  - 1 MA valid EU
  - 1 (invented) name
  - 1 common Product information
- 22 languages (+IS/NO)
- Transparent system (e.g. EPAR)
- 27 Member States

- Access to potentially 495 million users



EU Procedures

- Member State committee – Co-ordination Group for Mutual Recognition and Decentralised Procedures – vet and human- (CMDv/CMDh)

❖ agreement on running of MR and DC procedures

❖ reach agreement on a product application

EU Procedures

Referrals

- Disagreements between Member States sent ultimately to the European Medicines Agency for evaluation by scientific committee
- Can also be initiated in specific cases where the interests of the Community are involved
- May also concern a range of medicinal products or a therapeutic class

EU Procedures

- Committee for Human/Veterinary Medicinal Products – CHMP/CVMP – for Centralised Procedure and referrals

❖ agreement on running of CP procedures

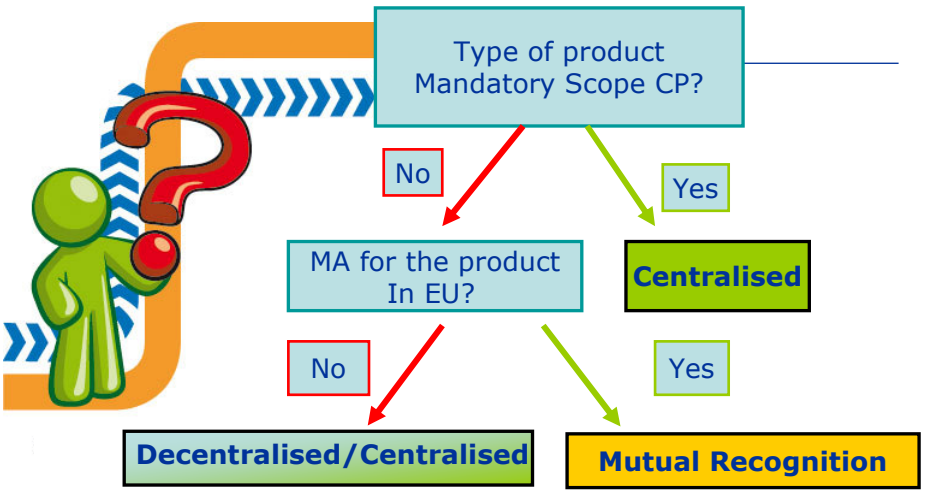
❖ reach agreement on referral procedures

EU Procedures

Other procedures once a product is authorised:

- Extensions e.g. new pharmaceutical form, new food-producing target species
- Variations e.g. change to a product's shelf life
- Renewals – 5 years after authorisation
- Transfers – from one Marketing Authorisation Holder to another

Choice of EU procedure



EUROPEAN MEDICINES AGENCY

Choice of EU procedure

Intended market size?

- National – one market only
- Mutual Recognition/Decentralised – free choice of MS markets within EU
- Centralised – all EU MS markets in one go (incl. enlargement!)

Type of product?

- **CP** mandatory for biotech and advanced therapies products and orphan medicinal products and also for new active substances for: AIDS/HIV, Diabetes, Cancer, Neurodegenerative Disorders, Autoimmune diseases and dysfunctions, viral diseases
- **MRP and DCP** more for older substances and generics but open for all substances (as long as it is not covered by the mandatory CP list)

EUROPEAN MEDICINES AGENCY

Choice of EU procedure

Existing National MA?

- Mutual Recognition – requirement
- Centralised/Decentralised – product needs to be unlicensed

Trade/invented name?

- Single name in CP
- Different names possible in MRP/DCP

Price (fees)?

- CP expensive but includes all MS
- MRP/DCP fees needs to be paid to all involved MS

EUROPEAN MEDICINES AGENCY

Commission Communication
The "Pharma Package" ...

Renewed vision on for the pharmaceutical sector

Legal proposals on:
- "Counterfeit" medicines
- "Information to patients"
- "Pharmacovigilance"

Five legal proposals amending Directive 2001/83/EC and Regulation (EC) No 726/2004

EUROPEAN MEDICINES AGENCY

Future perspectives - "Unity in Diversity"