THE EUROPEAN MEDICINES AGENCY: STRUCTURE AND REGULATORY PROCEDURES

Module Jean Monnet: “Regulatory networks and European governance”

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Legal Service - Directorate
OUTLINE

• STRUCTURE / TASKS OF THE EMA
  - DEFINITION OF THE MEDICINAL PRODUCT

• REGULATORY PROCEDURES
  - STANDARD MA PROCEDURE
  - RENEWAL PROCEDURE
  - MAH TRANSFER PROCEDURE
  - REFERRAL PROCEDURES
PHARMACEUTICAL INDUSTRY: A CORE SECTOR FOR EUROPE

~ 635,000 employees, often highly skilled
Limited number of big multinationals and

~ 2,000 biotech companies
~ 145 Billion Euro market value ex factory
~ 205 Billion Euro at retail prices
430 € retail expenditure for each EU citizen
~ 57 Billion Euro invested in marketing and promotional expenditure each year
~ 27 Billion Euro invested in R&D each year

Source: EFPIA
496 million users of medicinal products

30 EU and EEA-EFTA countries

More than 40 national competent authorities

4,300 European experts

6 scientific committees
A EUROPEAN AGENCY

The EMEA is a decentralised body of the European Union

The EMEA has its own legal personality and it is not part of the European Commission

The EMEA issues scientific opinions addressed to the European Commission

The Commission issues decisions concerning marketing authorisations*

Opinions are not binding but Commission has to provide justification if departing from the opinion

* Exception: Decision-making power is assigned to the EMA by Paediatric Regulation with regard to PIPs approval
The EMEA is responsible for the evaluation and supervision of medicinal products for human and veterinary use in the European Union
SCOPE OF THE EMA’s RESPONSIBILITIES

Inter alia:

- Centralised procedure [Reg.(EC)726/2004]
- Referral procedures [Reg.(EC)726/2004 and Dir.2001/83/EC]
- Paediatric medicinal products [Reg.(EC)1901/2006]
- Orphan medicinal products [Reg.(EC)141/2000]
- Advanced therapies medicinal products [Reg.(EC)1394/2007]
45 YEARS OF HARMONISATION

1965 - First Directive set out basic principles
1975 - First pharmaceutical testing Directive
1981 - Specific veterinary legislation adopted
1985 - ‘1992 Single Market’ project launched
1993 - Council Regulation No 2309/93 adopted
1995 - EMEA officially opens and new European system comes into operation
2001 - Commission proposes ‘Review’ package
2004 - Part of new legislation comes into force
2005 - New legislation came fully into force
2006 - New legislation on paediatrics
2007 - New legislation on advanced therapies
2008 - New legislative package
A NETWORKING DECENTRALISED AGENCY

Member States have pooled their sovereignty for authorisation of medicines

EMEA is designed to coordinate the existing scientific resources of Member States

EMEA is not intended to replace national authorities, but to be a partner in the system

A ‘virtual’ agency, providing an interface between all partners

All parties linked by an IT network (EudraNet)
EMA AND EU INSTITUTIONS

EMA is a decentralised agency of the EU, not part of the European Commission.

EMA adopts opinions on basis of scientific criteria, Commission takes decisions based on that opinion.

Commission must fully justify decision when it is not in accordance with EMA opinion.
EMA AND EU INSTITUTIONS

European Commission (mainly DG Enterprise and DG Health and consumer protection)

European Parliament (Environment, public health and food safety committee)

Other EU agencies such as the EMCDDA (narcotics agency), ECDC, EFSA, Translation Centre, etc.
EMA AND NATIONAL AUTHORITIES

EMA hosts CMD (human and vet) meetings and provides secretariat, which meet in parallel to CHMP and CVMP meetings (11/year)

EMA participates at the Heads of Medicines Agencies’ meetings (4/year)

Regular reports between HMA and Management Board (4/year)
EMA AND NATIONAL AUTHORITIES

European experts’ network underpins the work of the scientific committees and working parties

European experts work for EMEA independently of their nominating authority

Scientific competence is guaranteed by their nominating authority, independence and integrity assured through public declaration of interests

Services provided to EMEA on basis of a contract (conditions, quality and payment)
THE EUROPEAN SYSTEM – WHY?

- Complete single EU market for pharmaceuticals
- Protect and promote public and animal health
- Facilitate access by patients to new & better medicines
- Same product information for professionals and for patients
- Benefit European R&D pharmaceutical industry
- Platform for discussion of public health issues at European level
THE EUROPEAN SYSTEM – HOW?

• “One European system: two procedures”
  - Centralised procedure
  - Mutual recognition and decentralised procedures
• EMA is focal point of centralised procedure
• Rapid and EU-wide authorisation
• **1 evaluation, 1 authorisation**
• No price or reimbursement issues
WE (HAVE TO) DIALOGUE WITH ...

- European Commission
- NCAs
- Council of Europe/European Pharmacopeia
- WHO
- FDA
- Other institutional partners (EP, EFSA, EMCDDA, ECDC, etc.)

... regulators
BUT WE (HAVE TO) DIALOGUE
ALSO WITH...

• Industry
• Patients
• Healthcare professionals

... stakeholders
... INCIDENTALLY, THERE COULD BE A SLIGHTLY DIFFERENT APPROACH

Whilst dialogue between regulators is focused on how to ensure better public health interest protection,

... dialogue with industry may be affected by the tendency of pharma companies to seek an equitable balance between general public health interest and corporate financial health interest.
DIALOGUE WITH REGULATORS

EUROPEAN COMMISSION

*our major institutional partner*

- Regular bilateral and *teleconference*
- Two representatives in the Management Board
- Representatives from the Commission in major meetings
- Close EMA/EC Cooperation in implementing legislation
DIALOGUE WITH REGULATORS

NATIONAL COMPETENT AUTHORITIES

- Heads of Medicines Agencies
- One representative each in the Management Board
- NTA meetings
- CMD meetings
- Flow of information concerning PhV issues and, more in general, safety, quality and efficacy of medicinal products
DIALOGUE WITH REGULATORS

COUNCIL OF EUROPE

- EDQM - European Directorate for the Quality of Medicines
- European Pharmacopeia
- Dialogue and cooperation in the field of inspections
- EEA OMCLs network
DIALOGUE WITH REGULATORS

WORLD HEALTH ORGANISATION

• Assistance to non EEA member countries
• Cooperation and consultation provided for by art. 58 of Regulation (EC) 726/2004
• First positive opinions released by CHMP on 17 November 2005
DIALOGUE WITH REGULATORS

FOOD AND DRUG ADMINISTRATION

- Regular bilateral and teleconference
- Meeting FDA/EMA/European Commission
- Provision of parallel scientific advice and exchange of information concerning Q,S & E of medicinal products + regulatory & legal issues
- Confidentiality arrangement
ALREADY IN THE AGENDA/ FUTURE CHALLENGES

• Pre-accession dialogue = PERF, PHARE
• Increase cooperation/interaction with non-EU countries (i.e. Japan, Canada)
• Mutual recognition agreements

... export the network model!

Latin/South America cooperation
DEFINITION OF MEDICINAL PRODUCT

Definition in Article 1(2) of Directive 2001/83/EC allows a substance or combination of substances to become a medicinal product in two ways:

(1) by **presentation**

when the substance/s is presented as having properties for treating or preventing disease in human beings;

or

(2) by **function**

when the substance/s may be used in or administered with a view to restoring, correcting or modifying physical functions by exerting a pharmacological immunological or metabolic action, or to making a medical diagnosis.
DEFINITION: PRESENTATION

Case 319/05 Commission v Federal Republic of Germany

A product is a medicinal product by presentation if it is expressly indicated or recommended as a product for the treatment or prevention of disease; or if the average well informed consumer is likely to think it is intended to prevent or treat disease.

Relevant Factors

- Claims made for product
- Appearance of product (e.g. packaging)
- Form of product (e.g. capsule)
- Method of use
DEFINITION: FUNCTION

Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HL Warenvertriebs GmbH (C-211/03), Orthica BV (C-299/03 and C-316/03) v Germany.

The “Function” definition has potential to (but does not) cover all substances capable of having an effect on the functioning of the body.

Relevant Factors

- Composition of product
- Pharmacological properties
- Manner in which product is used
- Extent of distribution
- Familiarity to consumers
- Risks entailed by its use
It can be difficult to decide whether a product is a medicinal product or some other product such as a

- Food
- Food supplement
- Medical device
- Cosmetic

A product which satisfies the definition of “medicinal product” within the meaning of Directive 2001/83/EC must be held to be a medicinal product and be made subject to the corresponding rules even if it comes within the scope of other, less stringent Community rules.
WHEN IN DOUBT...

Article 2(2) Directive 2001/83/EC

“*In cases of doubt, where, taking into account all its characteristics a product may fall within the definition of a medicinal product and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply*”

**Case - 140/07 Hecht – Pharma GmbH**

Rule of doubt only applies in cases where a product is covered by both the definition of food (supplement), cosmetic product or medical device and the definition of medicinal product.
RULES APPLICABLE TO CENTRALLY AUTHORISED PRODUCTS

Mandatory (since November 2004):

• Biotech plus
  – Medicinal products containing new active substances indicated for the treatment of
    – AIDS
    – Cancer
    – Diabetes
    – Neurodegenerative diseases
  – Orphan designated medicinal products

Mandatory (since May 2008):

» Viral diseases
» Autoimmune diseases and other immune dysfunctions
RULES APPLICABLE TO CENTRALLY AUTHORISED PRODUCTS

• Optional:
  • New active substances
  • Medicinal products with a significant therapeutic benefit, scientific or technical innovation, or answering the interest of patients or animal health at Community level
  • Generics of centralised products
EMA STRUCTURE

The **Executive Director** is the EMA’s legal representative.

The EMA is supervised by a **Management Board** and its scientific activities are largely carried out through its six Committees and their Working Parties.

Management Board, Committees and their Working Parties are supported by the **EMA secretariat**.
THE EXECUTIVE DIRECTOR

Thomas Lönngren

Joined EMEA January 2001
Re-nominated October 2005


Legal representative of EMA

Ultimately responsible for all decisions of the Agency (budgetary, staff and scientific matters)
The Management Board is responsible for the Agency’s budget and work programme

- One representative per Member State
- Two representatives of the European Parliament
- Two representatives of the European Commission
- Two representatives from patients’ organisations
- One representative from doctors’ organisations
- One representative from veterinarians’ organisations
- One observer per EEA-EFTA Member State
MANAGEMENT BOARD

Chairman: Pat O’Mahony

Vice Chairman: Dr Lisette Tiddens-Engwirda
Committee for Medicinal Products for Human Use (CHMP)

The CHMP is responsible for formulating the Agency’s scientific opinions on any aspect regarding medicinal products for human use.

The Committee is composed of one member per Member State. Each Member has an alternate.

The Committee has co-opted five members to provide for additional scientific expertise.

Chairman
Dr Eric Abadie
Committee for Medicinal Products for Veterinary Use (CVMP)

The CVMP is responsible for formulating the Agency’s scientific opinions on any aspect regarding medicinal products for veterinary use.

The Committee is composed of one member per Member State. Each Member has an alternate.

The Committee has co-opted five members to provide for additional scientific expertise.

Chairman
Dr Gerald Moulin
Committee on Orphan Medicinal Products (COMP)

The COMP is responsible for reviewing applications for ‘orphan medicinal product’ designation, submitted by persons or companies (‘sponsors’) intending to develop medicinal products for rare diseases.

The Committee has one member per Member State, three members from patients’ organisations and three members nominated by the EMEA.

Chairman
Dr Kerstin Westermark
Committee on Herbal Medicinal Products (HMPC)

The Committee on Herbal Medicinal Products is responsible for formulating the Agency’s scientific opinions regarding the quality, safety and efficacy of herbal medicinal products.

The Committee has one member per Member State. Each member has an alternate.

The Committee can also co-opt five members.

Chairman
Prof. Konstantin Keller
Paediatric Committee (PDCO)

Regulation (EC) No 1901/2006

The PDCO is responsible for:

• assessing the content of Paediatric Investigation Plans

• formulating the Agency’s scientific opinions on any aspect regarding medicinal products for use in the paediatric population
PDCO Composition

Five members of the CHMP
One member per Member State
not yet represented by CHMP reps
Three members to represent
health professionals
Three members to represent
patient associations
Each Member has an alternate

Chairman
Dr Daniel Brasseur
Committee for Advanced Therapies (CAT)

Regulation (EC) No 1394/2007

Advanced Therapy medicinal products (ATMP)

- Gene therapy products
- Somatic cell therapy products
- Tissue engineered products

CAT prepares a draft opinion on each ATMP application before the CHMP adopt the final opinion

CAT provides scientific advice on classification and other ATMP related queries

Support to SMEs
CAT COMPOSITION

CAT should cover the scientific areas relevant to advanced therapies, including:
- Medical devices [2+2 at least],
- Tissue engineering,
- Gene therapy,
- Cell therapy,
- Biotechnology,
- Surgery,
- Pharmacovigilance,
- Risk management and
- Ethics.

[Recital 9 & Art.21]
EMA BUDGET

About one-third of budget is paid to national agencies for work done at request of EMA (€ 72 million in 2010, € 67.4m in 2009)

Fees represent the major part of total revenue

EU general subsidy is largely stable amount but reducing in proportion of total budget
Budget evolution 1995-2010 (€ million)
A DYNAMIC AND CONSTANTLY CHANGING AGENCY

The Agency new tasks and responsibilities:

- 2001: Orphan medicines (+ new committee)
- 2005 & 2008: Extended mandatory scope
- 2005: ‘Biosimilar’ and generic medicines
- 2005: Herbal medicines (+ new committee)
- 2007: Paediatric medicines (+ new committee)
- 2008/2009: Advanced therapies (+ new committee)
- Soon: pharmacovigilance (+ new committee) and counterfeit medicines legislation
IN THE PIPELINE

The Pharma package:

- Legal proposal on “Counterfeit” medicines
- Legal proposal on Information to patients
- Legal proposal on Pharmacovigilance
PRIORITY AREAS FOR 2010

• Deliver on our core business
• Implement new legislative tasks
• Strengthen the European medicines network
• Continue to improve safety-monitoring of medicines
• International partners and international activities
• Communication, provision of information and increasing transparency
• Contribute to an environment that stimulates innovation and improved availability of medicines
REGULATORY PROCEDURES

- STANDARD MA PROCEDURE
- RENEWAL PROCEDURE
- VARIATION PROCEDURE
- MAH TRANSFER PROCEDURE
- PAEDIATIRC INVESTIGATION PLAN PROCEDURE
- ORPHAN DESIGNATION PROCEDURE
- ADVANCED THERAPIES MEDICINAL PRODUCT PROCEDURE
- REFERRAL PROCEDURES
STANDARD MA PROCEDURE (1)

- applications for the MA shall be submitted to the Agency
- accompanied by fee payable to the Agency for the examination of the application
- **210 days** for giving CHMP opinion counted from the receipt of a valid application in which CHMP:
  - shall verify that the particulars and documents submitted comply with the requirements of the Directive 2001/83/EC
  - may request that an OMCL test the MP/its starting materials/its intermediate products
  - may request that the applicant supplement the particulars accompanying the application within a specific time period (“clock stop”)
STANDARD MA PROCEDURE (2)

- the Agency shall inform the applicant about CHMP opinion
- **15 days** for the applicant to give written notice if intended to re-examine the opinion; within **60 days** after receipt of the opinion obligation to submit detailed grounds for the request
- within 15 days after its adoption the Agency shall send the **final opinion** of the CHMP to the EC/MSs/applicant together with assessment report
- within 15 days after receipt of the opinion the EC shall prepare a draft of the decision; where the draft decision is not in accordance with the opinion of the Agency, the EC shall annex a detailed explanation of the reasons for the differences
- **Standing Committee phase** with MSs observations/comments
- **final EC decision** within 15 days after the end of the procedure
GROUNDS FOR REFUSAL OF MA

*Inter alia:*

- **R-B balance is not considered to be favourable;** or

- therapeutic efficacy is insufficiently substantiated by the applicant; or

- qualitative and quantitative composition of the product is not declared
RENEWAL OF THE MA

- The MA may be renewed after five years on the basis of a re-evaluation by the Agency of the R-B balance.

- Obligation for the MAH to provide the Agency with a consolidated version of the file in respect of Q, S, E incl. all variations at least 6 months before MA ceases to be valid.
VARIATIONS

- Possibility for the MAH to change certain elements of the MA
- “on request” procedure
- Different types of variations: type IA, IB, II

- **Commission Regulation (EC) No 1234/2008** of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
AIM OF NEW VARIATIONS REGULATION

- Simpler, Clearer, More flexible legal framework
- Reduce administrative burden
- Adapt to ICH concepts
- Further harmonise handling of variations in EU

Same level of public and animal health protection
MAIN FEATURES & SCOPE

• Type IA ‘Do and tell’ (annual reporting)
• Type IB by default & Article 5
• Grouping (facilitate review & reduce administrative burden)
• Worksharing (avoid duplication of work)
• CMD referrals (increase cooperation between MSs)
• Implementation of variations by MAH
MAIN FEATURES & SCOPE

- Classification of variations depending on **level of risk** to public or animal health &
- **Impact** on the quality, safety and efficacy of medicinal product concerned

- Applies to:

  Medicinal products authorised via **MRP, DCP**

  Following a **CHMP referral** (full harmonisation)

  Medicinal products authorised via **CP**
MAH TRANSFER PROCEDURE

- “special” variation
- “transfer of a marketing authorization” means the procedure of changing the addressee of the marketing authorization decision
- **30 days procedure**
- The Agency's opinion can only be unfavourable if the documents submitted in support of the application are *incomplete* or if it appears that the person to whom the transfer shall be granted is *not established within the Community*. 
MAH TRANSFER PROCEDURE

• The transfer of the MA shall be authorised from the date of notification of the amendment of the Commission decision

• The date on which the transfer actually takes place shall be set by the EMA by mutual agreement with the holder of the marketing authorization and the person to whom the transfer is to be granted; EMA shall immediately inform the Commission of this date.

• **Commission Regulation (EC) No 2141/96**, of 7 November 1996, concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93
COMMUNITY REFERRALS: RA/LEGAL CONTEXT

Directive 2001/83/EC as amended i.a.:

- Article 30 – “Divergent Decision Referral”
- Article 31 – “Community interest Referral”
- Article 107 – “Pharmacovigilance Urgent Measures”

Reference:
Notice to Applicants, Volume 2A – Chapter 3 Community referrals
SELECTION OF PRODUCTS FOR SPC HARMONISATION

Proactive harmonisation
- CMD(h) lays down list and forwards to Commission
- Commission or MS, in agreement with EMA, taking into account views of IP, may refer the product for arbitration

Criteria for selection of products
- Significant differences in Core parts of the SPC (Sections 4.1 – 4.4)
- Exclusivity/patent expiry dates.
- Extent of the use of the product.
- Number of MS where the product is authorised.

Website: http://www.hma.eu/242.html
### FACTS AND FIGURES

<table>
<thead>
<tr>
<th>Triggering party</th>
<th>No. of procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC</td>
<td>28</td>
</tr>
<tr>
<td>MS</td>
<td>4</td>
</tr>
<tr>
<td>MAH</td>
<td>3</td>
</tr>
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</table>
IMPACT ON PUBLIC HEALTH

• “Old” products are re-examined, streamlined and brought up to date

• Availability of harmonised package leaflets and labelling for widely-use drugs

• Improved patient access and use for both reference and generics
IMPACT ON COMPANIES

- MAHs obtain harmonised and updated PIs, taking into account all variations authorised nationally and all available post-marketing data.
- Indications granted in few MS can be expanded to all EU MS or restricted, depending on the robustness of the scientific data and supporting evidence.
- EC decision leads to MRP status, facilitating subsequent variations and maintenance of the product life-cycle.
- Streamlining of indications is beneficial and avoids “pick and choose” of reference for generics.
- Benefits of harmonised EU position on Safety and Pharmacovigilance aspects
ART. 31 COMMUNITY INTEREST REFERRAL

Interest of Community Public Health related to a medicinal product which is on the market in the EU in the light of Quality, Safety and Efficacy data or new Pharmacovigilance information

Who can trigger?
- Member States
- Commission
- applicant/marketing authorisation holder
## FACTS AND FIGURES

<table>
<thead>
<tr>
<th>Grounds for Referral</th>
<th>No. of procedures</th>
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</thead>
<tbody>
<tr>
<td>Safety/Pharmacovigilance</td>
<td>30</td>
</tr>
<tr>
<td>Efficacy</td>
<td>2</td>
</tr>
<tr>
<td>Safety/Pharmacovigilance + Efficacy</td>
<td>11</td>
</tr>
<tr>
<td>Quality</td>
<td>1</td>
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</tbody>
</table>

![Pie chart showing distribution of grounds for referral](chart.png)
## FACTS AND FIGURES

<table>
<thead>
<tr>
<th>Procedure outcome</th>
<th>No. of procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance/ Variation</td>
<td>32</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4</td>
</tr>
<tr>
<td>Ongoing</td>
<td>8</td>
</tr>
</tbody>
</table>

In case of variation/suspension of MA conditions may apply e.g. CTs, Post-marketing studies, change PSUR cycle.
ART.31–IMPACT ON PUBLIC HEALTH

- Same level of protection to EU patients in relation to specific concerns
- Information widely available through various communication tools
- Update/harmonisation of product information (full or partial)
Article 31 – Impact on MAHs

- EU level assessment → consistency across products including competitors/generics

- In case of revocation → loosing authorisation in all EU Member States

- Only one response/assessment/discussion → better coordination/use of resources

- In case full harmonisation → MRP status (facilitate maintenance life-cycle of the product)
ART.107 - PHARMACOVIGILANCE
URGENT MEASURES

- Where urgent action to protect public health is necessary MS may suspend the MA
- Art 107 triggered automatically and is mandatory; the CHMP shall prepare the opinion
- Possibility to request all MSs where the product is marketed to take temporary measures immediately

MAHs to be heard (written/oral) whenever possible; could be brand leader only!

No legal timeframe – depends on urgency!

No re-examination of Opinion!
# FACTS AND FIGURES

<table>
<thead>
<tr>
<th>Procedure outcome</th>
<th>No. of procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>MA Variation</td>
<td>2</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4</td>
</tr>
<tr>
<td>Suspension</td>
<td>2</td>
</tr>
<tr>
<td>Ongoing</td>
<td>3</td>
</tr>
</tbody>
</table>

![Pie chart showing the distribution of procedures](chart.png)
STEPS COMMON TO ALL REFERRAL PROCEDURES

- Fees
- Letters of Representation
- Legal timeframes (except Art 107!)
- Re-examination (except Art 107!)
- Translations
- Decision-making process
- Published information
FEES AND LETTERS OF REPRESENTATION

No fee if triggered by Member State or EC
Fee of 62 800 € payable for Article 30 and 31 referrals triggered by MAH.

A MAH can group with other MAHs to provide a single answer to CHMP; Letters are used to designate a contact person/grouping
If several MAHs involved possibility to group and provide one single dossier paying a single fee.

Reference: Explanatory note on fees payable to the European Medicines Agency (EMA/649350/2009)
STANDARD TIMETABLES


Notification of referral

Start of procedure

Clock Stop

Evaluation

Opinion

Decision

MS Implement.

D.0  D.1  D.2  D.60*D.127  D.157
RE-EXAMINATION OF CHMP OPINION

Re-examination of the adopted CHMP opinion is possible (except Art 107)

Request for re-examination to be submitted within 15 days of the receipt of the opinion and detailed grounds submitted within 60 days

Possibility of consultation of SAGs or Ad-Hoc Expert Groups

Different Rapporteurs appointed

Based only on scientific data available at initial opinion

FINAL CHMP opinion within 60 days

Ref: Guideline on Procedure for re-examination of CHMP Opinions (EMEA/CHMP/50745/2006)
POST-CHMP OPINION

Translations of CHMP Opinion annexes to all official EU languages (within 5 days).

- Translation of Annex I & III responsibility of MAH/Applicant
- Complex procedure, instructions and translation timetable must be followed, otherwise possible delays!

Start of the European Commission Decision-making Process
**PUBLISHED INFORMATION**

<table>
<thead>
<tr>
<th>EMA website</th>
<th>EC website</th>
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<tbody>
<tr>
<td>Start of procedure</td>
<td>-</td>
</tr>
<tr>
<td>Press release (dedicated for safety referrals)</td>
<td>-</td>
</tr>
<tr>
<td>Opinion</td>
<td>*Special situation: Adoption of temporary measures</td>
</tr>
<tr>
<td>CHMP Monthly report/Press Release</td>
<td>Q&amp;A (All languages)</td>
</tr>
<tr>
<td>CHMP Monthly report</td>
<td>Commission Decision (All languages)</td>
</tr>
<tr>
<td>Q&amp;A (English)</td>
<td>Annexes of Opinion (All languages)</td>
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<td>Annexes of Opinion (All languages)</td>
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THANK YOU!

The views expressed in this presentation are those of the author and do not necessarily reflect and cannot be quoted as the views of the European Medicines Agency.