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The Committee for Medicinal Products for Human Use

Patrick Salmon
HPRA

CHMP

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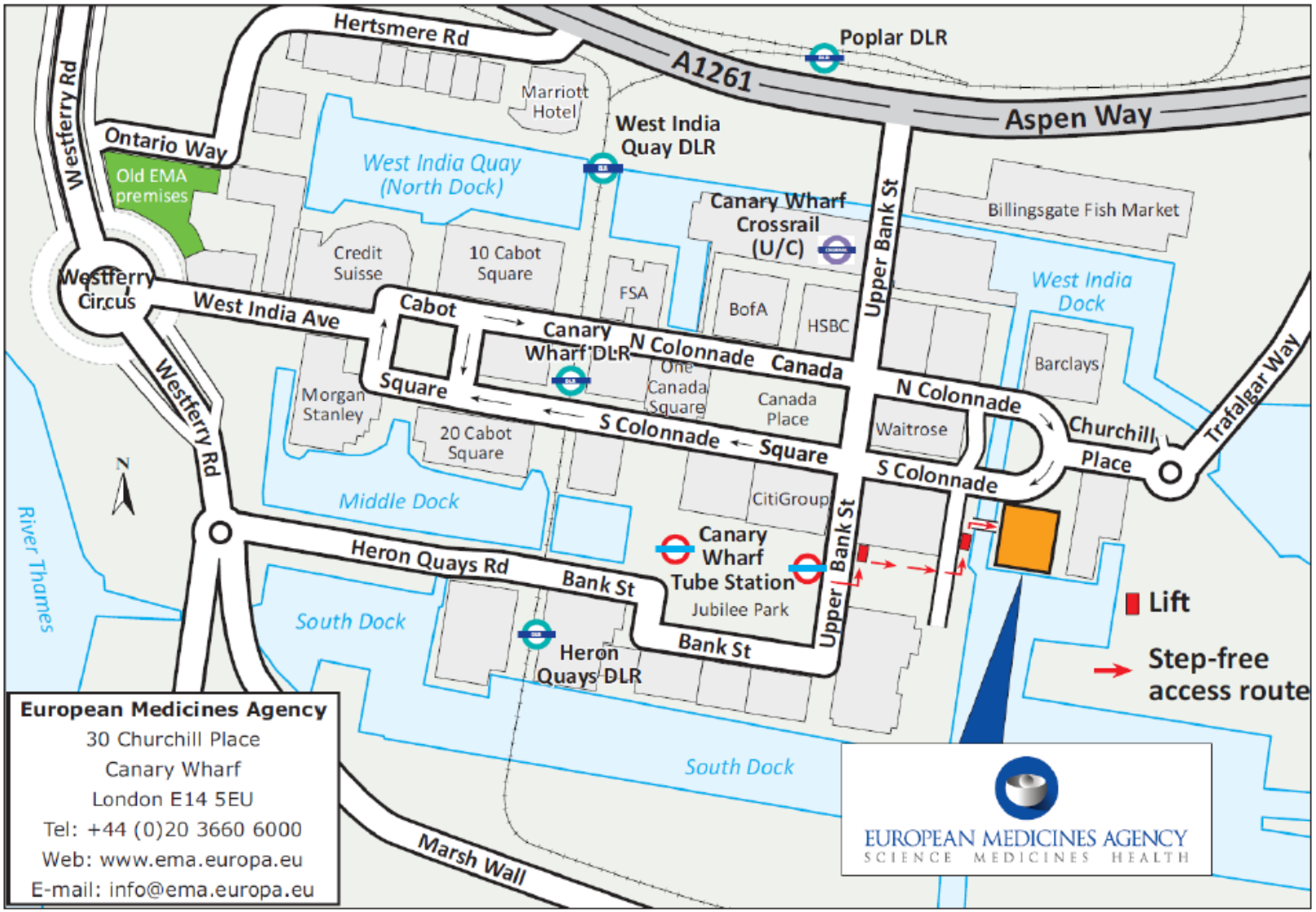
CHMP Move



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The New CHMP

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Where it all happens!

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CHMP..... What is it?

Committee for Medicinal Products for Human Use
Cultural Heritage Management Plan
Committee on Human Medicinal Products *(European Medicines Agency)*
Centrale Humanitaire Médico-Pharmaceutique
Community Hospital of the Monterey Peninsula *(Monterey, CA)*
Certified Hazardous Materials Practitioner *(Institute of Hazardous Materials Managers)*

CHMP

What is it?

The Committee for Medicinal Products for Human Use

CPMP, Committee for Proprietary Medicinal Products

Responsible for delivering scientific opinion

Scientific Committee to provide

- a single assessment in a predetermined time (210 days)
- a single licence and product information throughout the European Union (EU)

Pharmaceutical Legislation

1965.. First European Community Directive

- **national systems covering marketing authorisations**

1975.. CPMP and MRP

- **Community wide procedures and technical standards**

1990.. International Conference on Harmonisation (ICH)

1995.. EMA

- **Centralised procedure**

2000.. Orphan Drug Regulation

2001.. Clinical Trial Directive; Review of legislation

2005/6/7..Implementation of new legislation

2010..Reg 1235/2010 and Dir 2010/84/EU Pharmacovigilance

2012..PRAC

CHMP: The history

Pre-January 1995

- **15 national regulatory agencies**
- **15 parallel national reviews**
- **15 independent marketing authorisations**

- **Poor utilisation of resource**
- **Possible divergent opinions**
- **Different information for patients**

CHMP: The history

January 1995

Creation of the 16th regulatory authority

European Medicines Agency (EMA) London
Centralised procedure
Centralised assessment and opinion

CHMP: The history

Single timely (and predictable) assessment resulting in a harmonised scientific opinion and

A harmonised licence and harmonised information for health care professionals and patients

CHMP Members

The CHMP is composed of:

- one member (and an alternate) nominated by each of the 28 EU Member States; mandate lasting 3 years, renewable
- a chairperson, elected by serving CHMP members;
- one member (and an alternate) nominated by each of the EEA-EFTA states Iceland and Norway;
- up to five co-opted members, chosen among experts nominated by Member States or the EMA and recruited, when necessary, to gain additional expertise in a particular scientific area.

Members act as Rapporteurs for products or procedures

CHMP Members

Co-opted members

- Quality (non biologicals)
- Pharmacovigilance/pharmaco-epidemiology
- Quality and safety (biological), with expertise in advanced therapies (gene, cell and tissue therapies)
- Medical statistics (clinical-trial methodology / epidemiology)

CHMP

EUROPEAN MEDICINES AGENCY

CHMP – Human Medicines

- Chairman (Dr Eric Abadie) & Vice-Chairman (Thomas Salmonson)
- **1** scientific expert **member** nominated by each MS **and 1 alternate**
- **1** scientific expert **member** from NO and IS **and 1 alternate** (observers)
- **5 co-opted members** as appointed by Management Board

5

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CHMP Role

CHMP is responsible for preparing the EMA's opinions on all questions concerning medicinal products for human use:

- The initial assessment of medicinal products for which a Community-wide marketing authorisation is sought
- Several post-authorisation and maintenance activities, including
  - the assessment of any modifications or extensions (‘variations’) to the existing marketing authorisation
- In the ‘mutual-recognition’ and ‘decentralised’ procedures, the CHMP arbitrates in cases where there is a disagreement between Member States concerning the marketing authorisation of a particular medicinal product (‘arbitration procedure’).

- The CHMP also acts in referral cases, initiated when there are concerns relating to the protection of public health or where other Community interests are at stake (‘Community referral procedure’).

CHMP Responsibilities at time of Marketing Authorisation

- **Assessments (in accordance with EU legislation), based on purely scientific criteria (QSE):**

  - Quality (Q)
  - Safety (S) and
  - Efficacy (E) requirements.

  - Positive risk-benefit balance

CHMP Responsibilities Post-Marketing Authorisation

- Monitoring of the safety (pharmacovigilance) of authorised products: PRAC assesses

- The CHMP can make recommendations to the Commission regarding changes to a product's marketing authorisation or the product's suspension/withdrawal from the market.

CHMP Working Parties

CHMP establishes a number of working parties at the beginning of each three-year mandate.

- with expertise in a particular scientific field,
- composed of members selected from the European experts list maintained by the EMA.

The CHMP consults its working parties on:

- scientific issues relating to their particular field of expertise,
- delegates certain tasks to them associated with
  - scientific evaluation of marketing authorisation applications or
  - drafting and revision of scientific guidance documents.

CHMP Working Parties

Supported by over 4 500 experts

Standing

- Biologics Working Party (BWP)
- Patients' and Consumers' Working Party (PCWP)
- Pharmacovigilance Working Party (PhVWP) → PRAC
- Safety Working Party (SWP)
- Quality Working Party (QWP)
- Scientific Advice Working Party (SAWP)
- Healthcare Professionals@ Working Party

CHMP Working Parties: Temporary contd…

- Pharmacogenomics Working Party (PgWP)
- Vaccines Working Party (VWP)
- Blood Products Working Party (BPWP)
- Biostatistics Working Party (GTWP)
- Biosimilar Medicinal Products Working Party (BMWP)
- Pharmacokinetics Working Party
- Cardiovascular Working Party
- Central Nervous System Working Party
- Infectious Diseases Working Party
- Oncology Working Party
- Rheumatology/Immunology Working Party

CHMP Working Parties: Associated contd…

- Invented Name Review Group (NRG)
- Working Group on Quality Review of Documents (QRD)
- Geriatric Expert Group
- Summary of Product Characteristics Advisory Group
- Modelling and Simulation Working Group
- Active Substance Master File Working Group
- Expert Group on the Application of the 3Rs in the Development of Medicinal Groups

- **Co-ordination Group**

  To ensure integrated management of the operation of the scientific committees, working parties and drafting groups.

- **A Guidelines Consistency Group**

  Peer reviews all concept papers, draft guidelines and reflection papers before they are discussed at the CHMP in order to maintain regulatory and scientific consistency.

CHMP: Scientific Advisory Groups (SAG)

Scientific advisory groups are established to provide advice in connection with the evaluation of specific types of medicinal products or treatments.

Consist of European experts selected according to the particular expertise required on the basis of nominations from the CHMP or the EMA.

- Cardiovascular Issues
- Anti-infectives
- Neurology
- Diabetes/Endocrinology
- HIV/Viral Diseases
- Oncology
- Psychiatry
- Diagnostics
- Vaccines

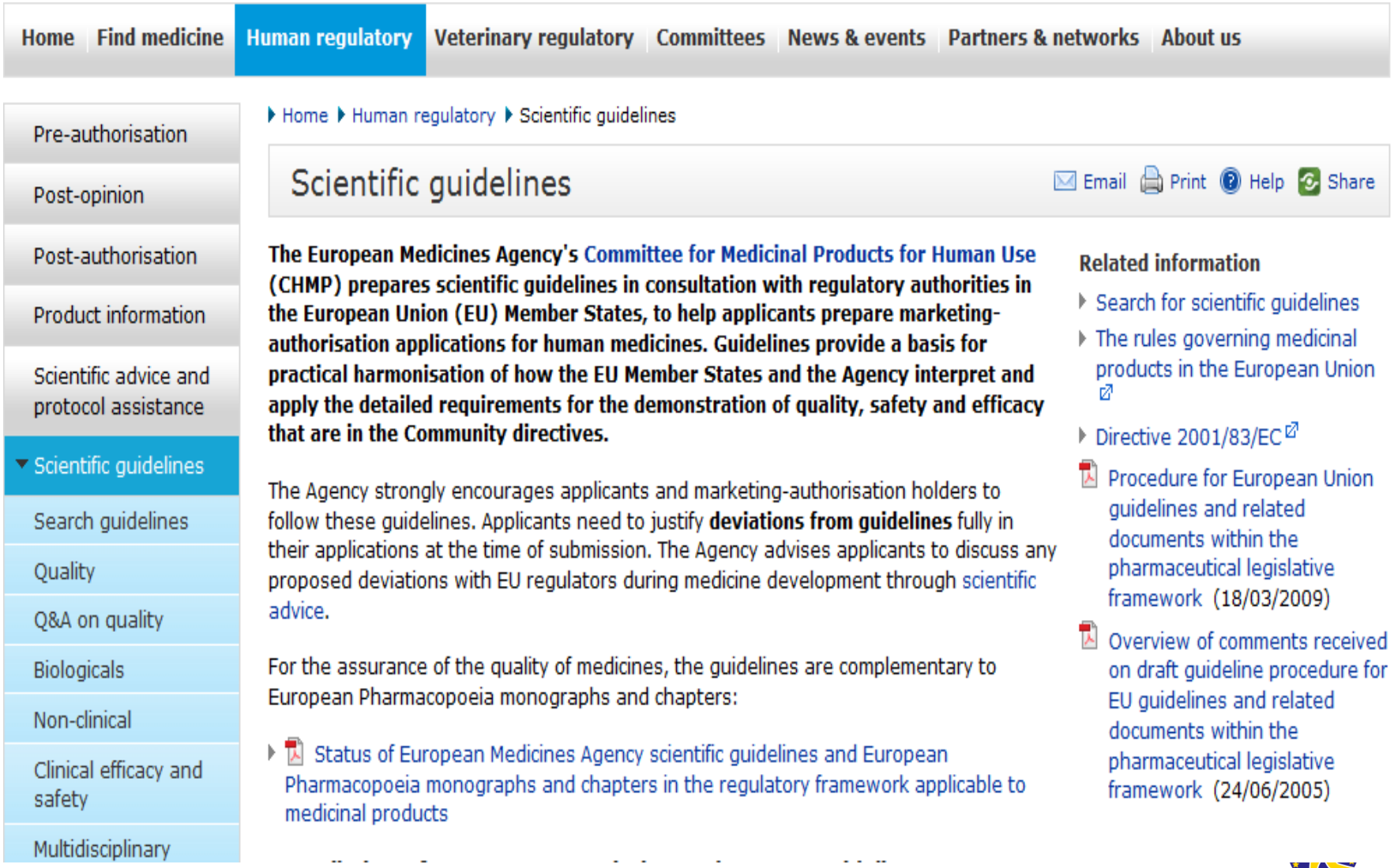
Marketing Authorisation: Decisions

- All based on same premise of Quality, Safety, Efficacy (QSE)
  - i.e. same technical requirements

- Four different procedures: Centralised
  Mutual recognition
  Decentralised
  National

- Irrespective of procedure, underpinned by Good Manufacturing Practise (GMP) requirement for manufacturer, supervised by Member State where manufacturing or importation takes place

Scientific Guidelines



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CHMP Guidance

- Proposal from working party, International Conference on Harmonisation (ICH)
- CHMP circulates proposals for comment
- Influenced by EFPIA, DIA, TOPRA meetings with working parties
- Formal adoption

Facilitates assessment approval and control

Alternative approaches possible.. if justified

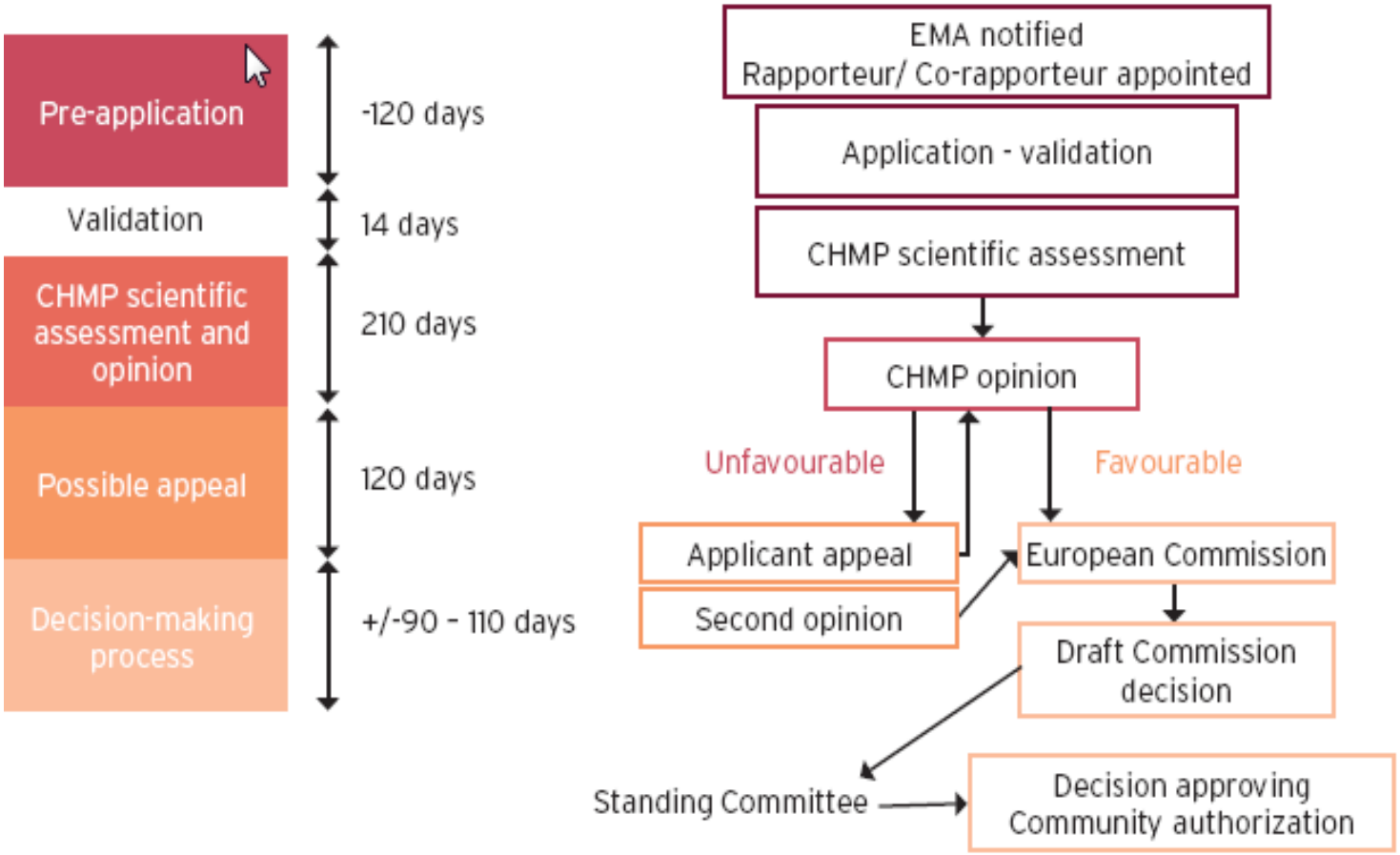
CHMP Guidelines

- Implemented six months after adoption
- Normally prospective
- Exceptions for public health reasons
- Published on EMA web site

Rules Governing Medicinal Products in EU

- Volume 1 Legislation (Human)
- Volume 2 Notice to Applicants
- Volume 3 Quality, Safety and Efficacy (QSE) Guidelines

CHMP Assessment



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CHMP and Patients

Patients' and Consumers' Working Party (PCWP)
(EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations)

Created to provide recommendations to the EMA and its human scientific committees on all matters of direct or indirect interest to patients in relation to medicinal products.

To implement the recommendations for improvement in the following areas:

- Transparency and Dissemination of Information
- Product Information
- Pharmacovigilance
- Interaction between the EMA/Scientific Committees and Patients' Organisations

New initiative to involve patients in CHMP activities

- **To initiate a pilot phase whereby two patient representatives with experience of a disease/condition to be discussed would be invited to participate in product-specific oral explanations with the pharmaceutical company, where it is foreseen that their involvement can bring added value (e.g. likely negative CHMP recommendation or restriction of an indication where a significant impact is expected).**

Press release

26/09/2014

Patients to discuss benefit-risk evaluation of medicines with the Committee for Medicinal Products for Human Use

EMA launches pilot project to integrate patients' unique and critical views into CHMP discussions

The European Medicines Agency (EMA) has launched a pilot project to involve patients in the assessment of the benefits and risks of medicines in its Committee for Medicinal Products for Human Use (CHMP).

Listening to patients enriches the scientific assessment of a medicine with new ways of thinking about benefit and risk from the patient perspective. This pilot project marks the next step in bringing patients' views and values to the assessment of medicines throughout their lifecycle.

Patients and CHMP

When should patients be invited to join CHMP?

- Patients will be invited to participate during product-specific oral explanations where their involvement can bring added value to the benefit/risk discussion.
- The Rapporteurs and EMA team leaders will decide on a case-by-case basis whether a specific oral explanation would benefit from the involvement of patients:

  When the questions refer to benefit/risk aspects;

  - When the CHMP is still undecided on a marketing authorisation application for a new medicinal product in an area where there remains an unmet medical need and would like to assess the impact of their recommendation on the relevant patient population;
  - When the PRAC and/or the CHMP would like to assess the impact of their recommendation, to maintain, suspend, revoke a marketing authorisation, or to restrict the indication of an authorised medicine, on the relevant patient population.

CHMP and Orphans

- **Assessment QSE**
- **Assessment of similarity**
  - Applies if other orphan medicines authorised for same designated condition
  - Need to submit report in module 1.7
    - Molecular structure
    - Mechanism of action
    - Similarity of indication (“significant overlap of populations”?)
  - Assessment by CHMP working party competent
  - Final opinion by CHMP
  - Similarity can be triggered any time before EC decision

CHMP and Orphan

- **Derogations to market exclusivity if product is similar**
- **Assessed based on sponsor's report**
  - Specific timetable (parallel to QSE assessment)
- **Three derogations (Art 8(2))**
  - First MAH's consent (agreement market sharing)
  - Insufficient supply: long term and clinical consequences (presumably)
  - Clinical superiority: better efficacy, better safety or exceptionally major contribution to patient care

CHMP

EMA's scientific committee which produces a single assessment resulting in a harmonised scientific opinion and where appropriate a harmonised licence and harmonised information for health care professionals and patients

- Many tasks and functions
- CONSTANT CHANGE

- CHMP
- PRAC
- CMD(h)

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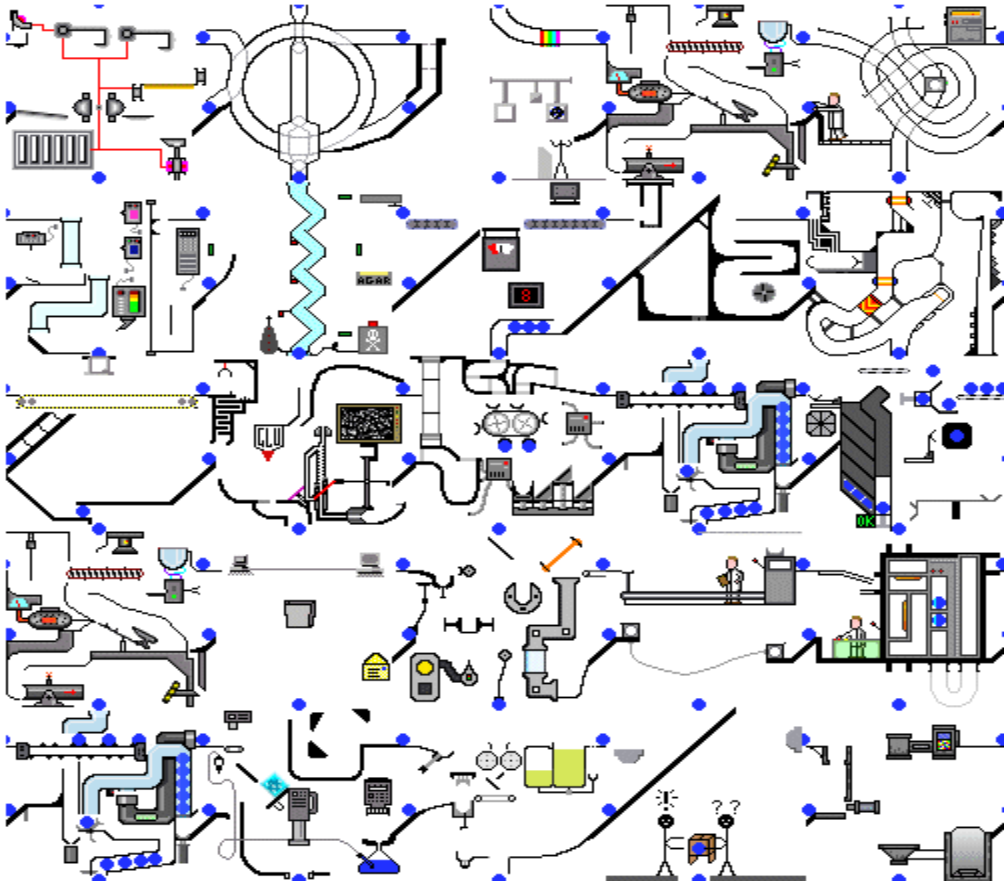
CHMP..... Constant change



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Thank you for your attention

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