



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reflections on academic path and career opportunities

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An agency of the European Union





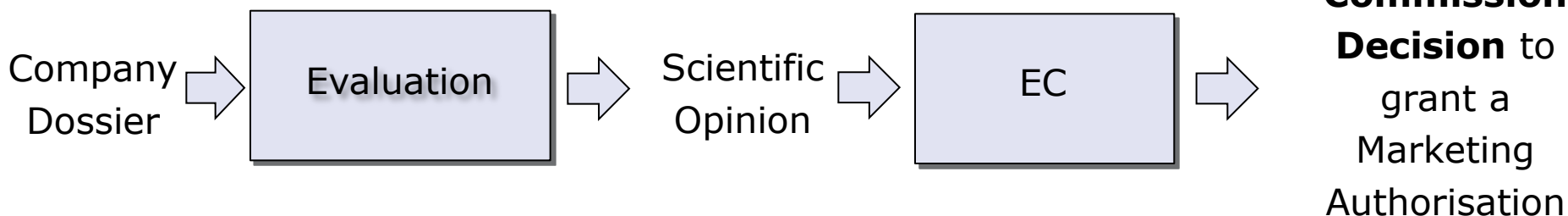
European Medicines Agency (EMA)

- EMA was founded as a 'coordinating body' to manage the centralised procedure
- Decentralised networking administration. It utilises and coordinates the existing scientific resources of Member States
 - Network of 48 Agencies (32 Human and 16 Veterinary)
 - > 4900 experts
- EMA is a service provider for the network
 - *E.g. Network IT and Databases*





Centralised Procedure



Legally binding to all MS

- 1 Invented Name
- **Identical** product information, in all EU languages:
 - **Summary of Product Characteristics (SPC)**
 - **Package Leaflet**
 - **Package Labelling**
- European Public Assessment Report





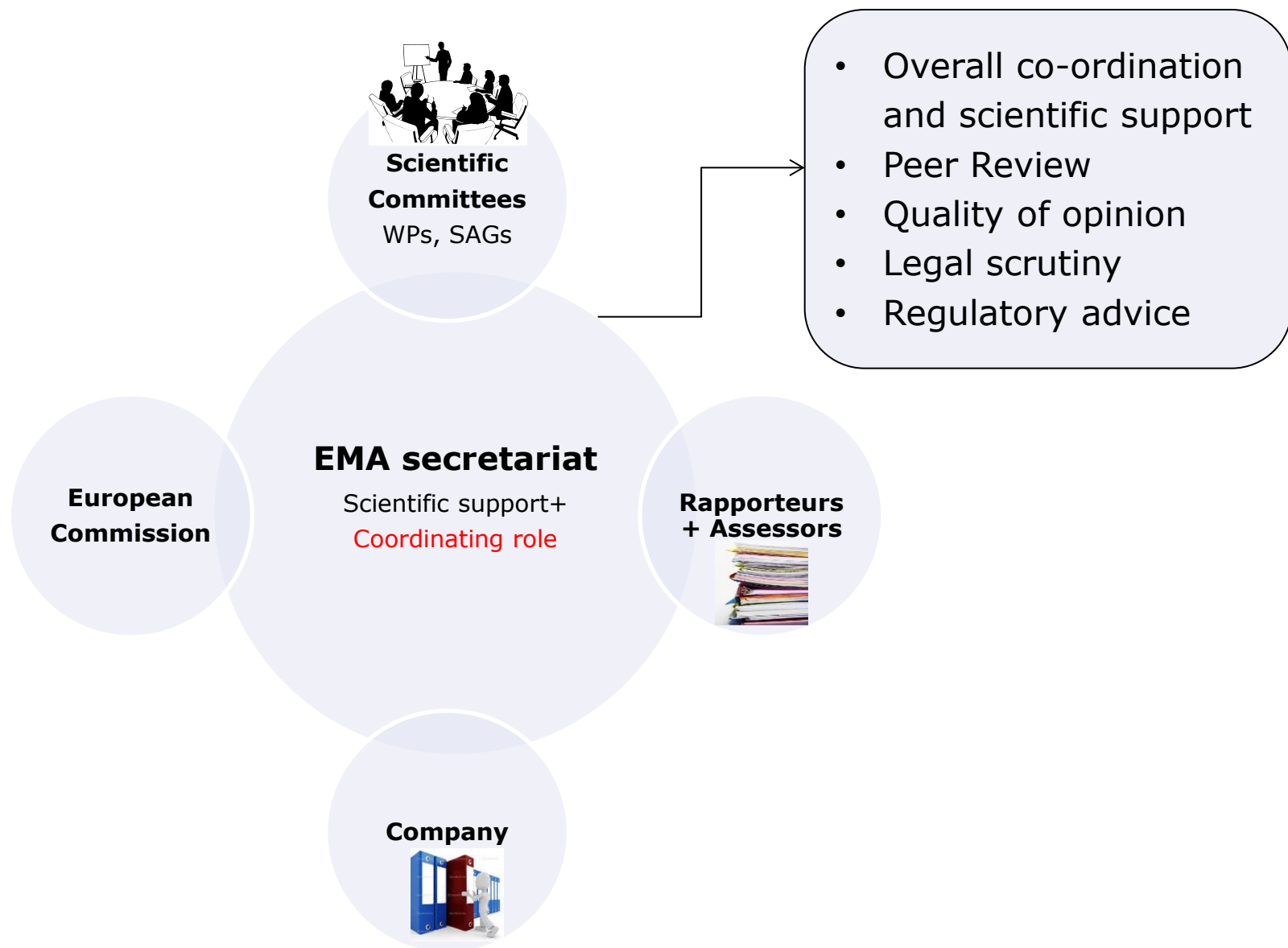
CHMP: Committee for Medicinal products for Human Use

- Appointed for three years (renewable)
- 1 member (and 1 alternate) for each of 28 EU countries
- Norway, Iceland
- Up to 5 co-opted members
- Meets monthly for 4 days

Evaluation assigned to [Rapporteur/Co-Rapporteur](#) teams

- Contract basis
- Typically use resources of national regulatory authorities
- National Experts nominated by Member States

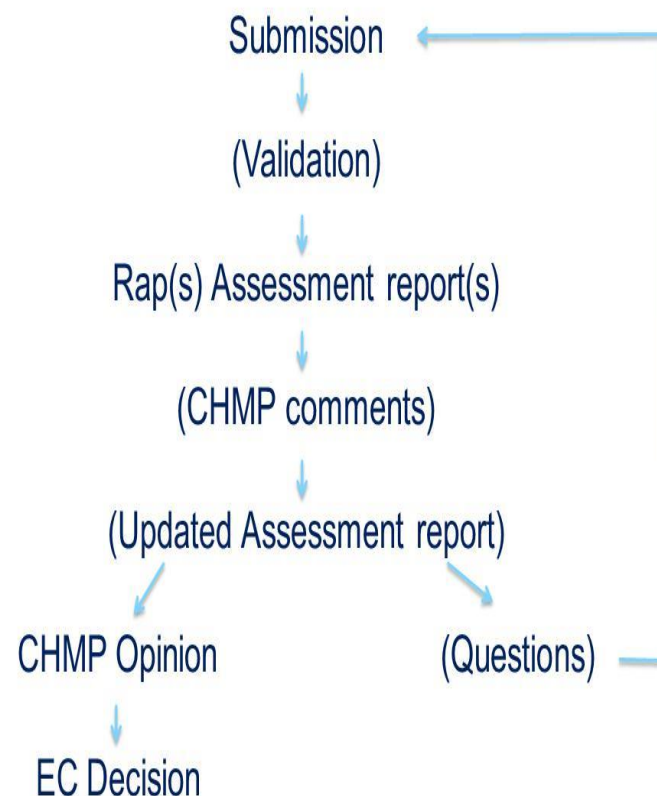






Centralised Evaluation System

- Upon submission of an application
- The CHMP appoints two of its members to act as “**Rapporteurs**” who will do the evaluation .
- The **Rapporteurs’ assessment** is a recommendation to CHMP and forms the basis of the discussion
- The decision to grant an authorisation is taken by **All** CHMP members
- For “complex” cases the CHMP may seek the advise of specialised experts (Working Parties, SAGs)





EMA Product Team





The EMA product team: Role

- Set up for each medicinal product submitted through the centralised procedure.
- Responsible for providing support to the evaluation activities of the EMA scientific committees.
 - The responsibilities are based on the ones already described in Notice to Applicants Volume 2A, Chapter 4 "Centralised procedure", April 2006



EPL/ PM in the context of handling evaluation procedures

Procedure
Manager
(PM)

⇒ **Applicant's primary contact during the course of all evaluation procedures**

- Provision of regulatory procedural guidance
- Ensures adherence to procedural guidelines and timelines
- Regulatory scientific support in simpler procedures
- Maintains process performance metrics

EMA
Product
Lead (EPL)

- Leads the EMA product team
- Accountable for overall product knowledge
- Provides clinical and regulatory science input
- Supports consolidation of a committee position
- Facilitates cross-committee discussions
- Reference for the defined products/ disease area



Role profiles

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Working for the European Medicines Agency

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The European Medicines Agency provides a **multinational work environment** in an **intellectually stimulating** atmosphere.

It is located in London's Canary Wharf, offering staff the opportunity to work and live in a dynamic world-class city.

The Agency's main working language is English.

The Agency is committed to maintaining an environment that enhances the skills and experience of its staff through the creation of learning opportunities and provision of training and development.

Types of contract

Staff at the European Medicines Agency have one of two main contract types.

Temporary Agents

Temporary Agent contracts are offered for **five years** with the possibility of renewal for an indefinite period. Temporary Agent posts are classified according to the nature and importance of the duties:

- ▶ Administrator function group (AD) comprises twelve grades from AD 5 to AD 16 corresponding to technical, administrative, advisory, linguistic and scientific duties;
- ▶ Assistant function group (AGT) comprises eleven grades from AGT 1 to AGT 11

Related information

- ▶ Staff Regulations

Examples of job profiles

- [Example: Standard job profile for a Contract Agent \(Function Group II\) \(01/08/2014\)](#)
- [Example: Specific job profile for a Contract Agent in Programme and Project Management \(Function Group III\) \(01/08/2014\)](#)
- [Example: Specific job profile for a Contract Agent in the Human Medicines Evaluation Division \(Function Group IV\) \(01/08/2014\)](#)
- [Example: Specific job profile for a Contract Agent in the Human Medicines Research and Development Support Division](#)



Competences (examples)

- Qualified experience as an assessor in regulatory authorities or in Research & Development in Industry
- General knowledge of EU institutions including the Agency
- Knowledge of the pharmaceutical legal framework
- Experience in working in a multicultural environment



Skills (Example)

Skills:

- Excellent organisational skills
- Strong ability to follow detailed processes and procedures
- Precision in execution of work with attention to detail
- Initiative, diplomacy and good judgement
- Good written and oral communication skills
- Good interpersonal skills and team spirit
- Tact and discretion in the handling of confidential files and information



EMA trainee programme

The European Medicines Agency operates a trainee programme. The programme gives trainees an understanding of the Agency and its role within the activities of the European Union (EU) and provides professional experience in a working environment.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000321.jsp

UoA Pharmacy
Degree, MSc,
PhD



Industry
experience



Training

Coaching



European
Medicines Agency-
Quality



European
Medicines Agency
Managerial roles



Life-long learning
and
Self-development





Reflections

Enablers

- Pharmacy studies provided a good all around basis for the future career path
- Erasmus studies, MSc and PhD opened up the possibilities for a European career
- Soft skills



Reflections

- Fast changing working environment- Mobility
- Modern workforce takes responsibility for their self-development, i.e. identify areas of development and put in place development plans to address those needs.
- Increased demand and use of online and part-time courses