EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA product team and applicant / MAH interaction

Composition, roles and practical aspects

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An agency of the European Union

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

The EMA product team: Composition

- Established during the pre-submission phase of the initial marketing authorisation application and in place throughout post-authorisation.
- Composition of the team is adapted over time depending on the complexity of the product and procedure as well as the type of issues raised during the product's lifecycle.
- Oversight of all elements of product knowledge is ensured through the complementary contributions of the various team members.

From an applicant's perspective in the context of handling evaluation procedures

Procedure Manager (PM)

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

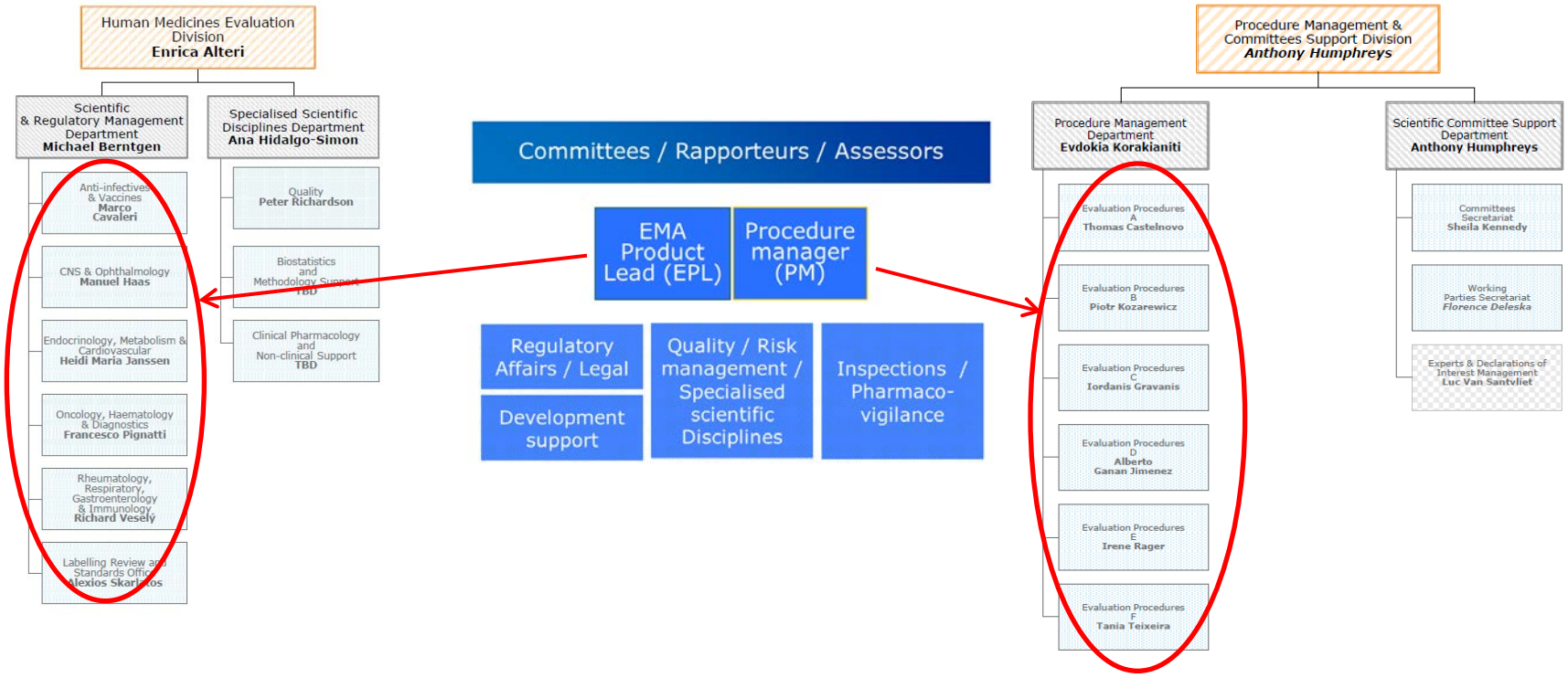
- Provision of regulatory procedural guidance
- Ensures adherence to procedural guidelines and timelines
- Regulatory scientific support in simpler procedures
- Maintains process performance metrics

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

The applicant / MAH will be notified of the appointed PM and the EPL, as well as any subsequent changes.

Allocation of EPL and PM in the organisation



The organisational design supports the intended role purpose to provide therapeutic area oversight and procedural expertise.

Practical aspects of applicant contacts during the MAA evaluation (1/2)

Procedure manager	EMA Product Lead
The applicant should contact the **PM** for all questions regarding the evaluation procedure, including •Requests for guidance in the pre-submission phase, such as the pre-submission meeting; •Any type of procedural questions during the evaluation, such as availability of assessment reports and Opinion documents; •Discussion on timetables including requests for extension of clock-stops etc.	At certain milestones the **EPL** and the applicant will be in direct contact to facilitate the discussion on the scientific evaluation, e.g.: •Clarification meetings; •Immediate feedback from committee plenary discussions; •Oral Explanation expectations; •Discussion of required post-authorisation measures; •Late-stage revisions of the product information before adoption of the final Opinion.

Practical aspects of applicant contacts during the MAA evaluation (2/2)

- The first point of call for the applicant during the MAA evaluation is the PM.
- Questions concerning the validation of the MAA, once submitted, will be dealt with by an assigned Validation Officer
- Occasionally other members from the EMA Product team may contact the applicant directly to facilitate the discussion on specific aspects (e.g. quality, risk management, mock-up review).
- Where the applicant is in direct contact with the EPL (or another member of the EMA Product Team) the PM should always be copied on the correspondence.

Practical aspects of applicant contacts during post-authorisation evaluation procedures (1/2)

Procedure manager	EMA Product Lead
• A PM will be allocated for each post-authorisation procedure (all types of variations, extension applications, renewals, annual-reassessments, PSURs/PSUSAs, PASS protocols, referrals, post-authorisation measures as well as administrative procedures. • The PM oversees all aspects of the management of the specific procedure. The MAH should contact the **PM** for all questions regarding the evaluation procedure.	• May be directly involved during the evaluation depending on the scope and the complexity of the particular application other members of the product team, as needed. • In particular, for extensions of indications the **EPL** will at certain milestones during the evaluation procedure (akin to those for the initial MAA) be in direct contact with the MAH to facilitate the discussion on the scientific aspects of the evaluation.

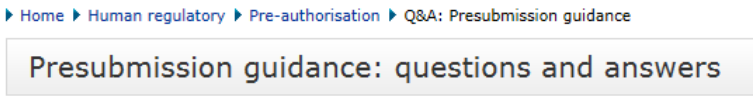
Practical aspects of applicant contacts during post-authorisation evaluation procedures (2/2)

- The first point of call for the applicant during the evaluation of post-authorisation procedures is the PM.
- Where an MAH requires regulatory procedural guidance or has questions prior to submission of the application, the **Pre-submission Queries Services (PQS)** can be contacted.
- For products with a high number of upcoming post-authorisation procedures, which may require a detailed planning discussion, the PQS should be your first point of contact. The PQS colleagues will liaise with the relevant members of the product team to provide you with a consolidated responses. If needed follow up discussion can take place.

Practical aspects of applicant contacts in the post-authorisation phase outside procedures

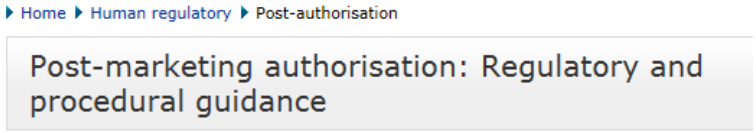
- Where any other issue in relation to the product arises during the post-authorisation phase, which is not related to a specific evaluation procedure listed above, the MAH should contact the assigned **EPL**.
- Such situations refer to a variety of topics and do include, where applicable, upcoming shortages in supply of the medicinal product, information about emerging safety issues, provision of important late breaking information that potentially impacts the product profile or the marketing authorisation, as well as withdrawal of the MA.
- Communication through the EPL is supplementary to, not replacing, the formal reporting requirements and established reporting channels where they exist, e.g. for pharmacovigilance reporting.

Q&A's to be published on the EMA website to better guide applicants/MAHs



New Q&A's:

- What is the role of the EMA Product Team?
- Who is my contact at the European Medicines Agency during a marketing authorisation application (MAA) evaluation procedure?



New Q&A's:

- Who is my contact at the European Medicines Agency during post-authorisation procedures?
- Who is my contact at the European Medicines Agency during an application procedure for extension of indication?
- Who is my contact at the European Medicines Agency during the post-authorisation phase outside any evaluation procedures?

Maintaining oversight of the product activities during the life-cycle

- Oversight of the product knowledge ensures best support to scientific evaluation during an assessment, across committees, over the life-cycle

➔Product knowledge in the context of the **therapeutic area** / disease-specific armamentarium

- Product team members provide regulatory and scientific input → complementary contribution
- Structures and tools in place to support such oversight

One year on: experience with the new operational model

Achievements	Continuous improvement
• Applicants / MAHs have adapted to the new operational model ➔ Fewer queries from Industry • Fine-tuning of roles has continued based on practical experience • Stabilisation in the appointment of EPLs and PMs for products ➔ Supporting oversight activities • Improved framework to better support the scientific evaluation	• Optimisation in PM allocation post-authorisation • Framework for planning of post-authorisation submissions • Continuous improvement in the role refinement ➔ Experience from day-to-day practice • Review with the scientific committees of their experience