EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Status update of changes to the operations in the centralised procedure

Progress with the implementation programme and upcoming changes

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An agency of the European Union

Overview

- Background of the operational changes
- Progress with the implementation programme
- Recent and upcoming changes
- Other recent initiatives in the centralised procedure

Background: EMA transformation triggers

Triggers for transformation

External Pressures	• Economic pressure • Political pressure • New (upcoming) legislation
Internal Pressures	• Silo-working / duplication of activities across the workflow • Low stakeholder engagement • Lack of horizontal alignment and coordination • Complexity
Agency Objectives	• Focus on core business • Scientific consistency • Existing and new (upcoming) legislation • Network: engaging with our partners (creating a win-win solution) • Communication (internal and external) • Reputation management • Transparency

Internal transformation programme

1. Review EMA organisation
    1. New product team concept
    2. New department to look at Data & Information architecture
    3. New policy and stakeholder department
2. Improve efficiency of core EMA processes
3. Consolidated business requirements for IT enablement

Background: Experience with the product team concept that led to changes to improve the operations

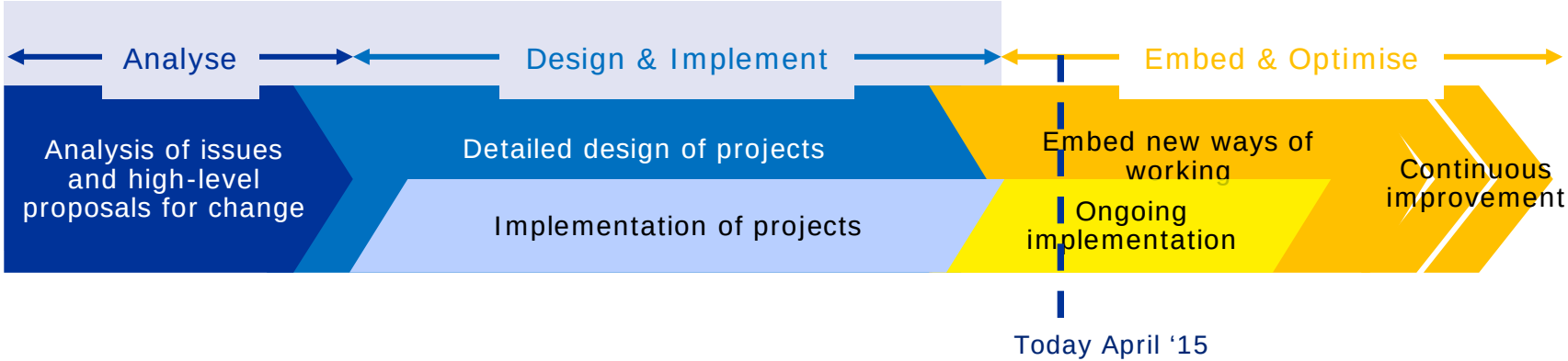
- Previous product team model with a Product Team Leader (PTL) and Product Team Members (PTMs) established in 2003
- Increase in number and complexity of procedures as well as new regulatory science concepts, mainly driven by new/revised legislation

Experience by MAHs:
(EFPIA letter of 25.10.2013)

> "The survey also highlighted the crucial role played by the Agency's PTL. Favourable comments concerning PTL-Applicant interactions were received from numerous companies. However, the responses also noted inconsistent approaches and divergent advice from PTLs."

- Intention to reinforce the consistency and quality of EMA's output and allow development of greater specialities able to respond and support the work of the committees

Background: Overview of the change process



The Agency is now transitioning:

- embedding the new ways of working, and
- continually looking for further improvements.

Stakeholder feedback is important to optimise the operations further, and enable a culture of continuous improvement

Background: Key improvements

Key improvements	***Impact to Applicants / MAHs***
Implementation of the new product team concept	Immediate : Change of contact persons Medium term: Regulatory consistency gains
Processes that use the internal and network expertise depending on content complexity, leading to better utilisation of resources	None
Improved use of Committee plenary time	None
Improvement options to reduce overall procedure time	Medium /long term: Faster regulatory outcomes
Simplification of document management	Immediate: A single assessment report template which is used by the Rapporteur and eventually becomes the CHMP AR for PSURs, Type IIs, Renewals

Implementation update: Overview of key milestones

- March 2014: Applicants/ MAHs were informed of the change through a general press release and individual communication per product and procedure
- April 2014: The new operations were implemented for the first set of application types (variations, PSURs/ PSUSAs, admin. procedures)
- September 2014:The new product team concept was implemented for the rest of procedures with key improvement changes fully implemented by the end of Dec 2014
- Ongoing implementation of remaining improvement proposals for:
  - Initials (accelerated assessment/ generics); Renewals, PASSes, Referrals

Recent and upcoming changes

Recent changes

Additional submission dates for certain Type II variations effective as of 1st of March

Improved interactions in the context of initial Marketing Authorisation Applications

- New Pre-submission meetings guidance published in December 2014
- New Clarification meetings guidance published in January 2015

Improved Guidance for handling of variations

- Guidance on additional pack sizes vs EU numbers published in April2015

Upcoming changes

Revision of the RMP review process during the assessment of initial MAAs

Revision of the Product Information review process

Recent changes: Improved interactions in the context of initial Marketing Authorisation Applications

EMA Pre-submission meetings

New guidance published in November 2014

37. How is a MAA pre-submission meeting conducted at the EMA? Rev. November 2014

Key changes:

- Documentation to be provided for the pre-submission meeting to allow for more substantial discussion
- Optimisation of the application form based on experience
- Possibility for the Rapporteurs or their assessment teams to participate in the pre-submission meeting

➔ for Pre-submission meeting requests as of November 2014

Recent changes: Improved interactions in the context of initial Marketing Authorisation Applications

Clarification meetings

New guidance applicable for CHMP/PRAC/CAT published in January 2015

Objectives of the meeting:

- Clarify scientific rationale behind questions in LoQs/LoOIs/RSIs
- Discuss Applicant's proposed responses' strategy taking into account regulatory context
- Discuss Timeline's implications

To note: **No pre-assessment of the response**

Upcoming changes: Revision of the Product Information review process

Optimised integration of technical / QRD review into the product information review process during the MAA

1st evaluation phase

- Initial EMA PI technical check to be carried out before Rapporteur Day 80 assessment report is produced => allow Rapporteurs to introduce their scientific comments in the same file
  - Focus on SmPC and labelling (compliance and consistency with standards, guideline, and precedents)

2nd evaluation phase

- PI review (ex-D165 QRD comments) by Day 140 => for Rapporteur's to consider for their Day 150 assessment
  - Follow-up on SmPC, labelling
  - Focus on package leaflet (after user testing) and on Annex II (PhVg activities)

Upcoming changes: Revision of the Product Information review process

Expected benefits from applicant's perspective

- Early flagging of PI issues => facilitate discussion of potential issues that can be picked up earlier in the process
- Only one set of comments on PI (encompassing EMA, assessors, committees comments) sent to the applicants at D120 and D180 => No more parallel documents
- Optimised workflow => improved clarity
- Better support to ensure consistency => throughout the evaluation, across therapeutic class, between SmPC and Package Leaflet

To note: **No changes in terms of timelines for the applicant**

Upcoming changes: Revision of the RMP review process during the assessment of initial MAAs

Key aspects:

- Roles and responsibilities of Rapporteurs clarified (CHMP: safety specification; PRAC: prospective risk management planning);
- Timing of detailed PRAC plenary discussion

Practical arrangements (business process and assessment template) currently being put in place, in collaboration with PRAC and CHMP

To note**: No direct impact on applicants**

Other recent initiatives in the centralised procedure

- Implementation of the Effects table for the Benefit/risk assessment: routinely for MAAs/extensions of indications starting since February 2015

- Patient involvement in benefit/risk decision making: pilot project ongoing to integrate patients' unique and critical views into CHMP discussions"

Summary of the journey so far

•Since September 2014 the new operations have been gradually implemented for all types of applications (including e.g. initial MA, renewals)

•The overall objective was to reshape roles and responsibilities, supported by robust, transparent, efficient and connected processes and systems, and appropriately skilled staff

•Applicants / MAHs were guided proactively by product/procedure through any change that directly affected the interface with the Agency

•Procedural guidance has been updated on the Agency's website

•Expect efficiency and consistency gains in terms of procedural management, and better scientific and regulatory support of the assessment work by the committees

Looking ahead

- We aim to learn from experience and continue to improve the service we provide to applicants/ MAHs and the Network
- Stakeholder feedback is important to optimise the operations further, and enable a culture of continuous improvement

Thank you for your attention

Further information

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