EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CP stakeholder platform - Introduction

5th Industry Stakeholder Platform on the Centralised Procedure

03 December 2020

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Welcome to the 5th Industry Stakeholder Platform on Centralised Procedure

Housekeeping rules for the virtual meeting

- Please make sure your microphone is muted when not speaking.
- Speakers are asked to switch on their camera. Other participants are invited to switch on the camera when they are taking the floor.
- Please use the chat function when you want to take the floor or alternatively raise your hand.
- Please indicate your name and affiliation when taking the floor.
- In case of an urgent technical issue (e.g. connection problems, updated slide deck..etc) please contact Lise.Flaunoe@ema.europa.eu.
- Please participate in the discussions - this is meant to be a working environment!.

Industry Stakeholders Platforms objectives

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- Foster open direct constructive DIALOGUE with Industry Stakeholders
- Enrich the EMA's understanding of issues that are pertinent from the industry perspective
- Increase transparency of stakeholders engaging with the EMA and report on the interaction
- EMA - Medicines life cycle interactions: from R&D, Evaluation to Pharmacovigilance
- Operational implementation: Legislation(new), EMA organisational changes, Centralised process/Surveys, all areas of product-development /evaluation and supervision

Evolution of the industry stakeholder platform on operation of the centralised procedure for human medicinal products

Since its inception, four CP platform meetings were held:

1st CP platform meeting - 24.04.2015

2nd CP platform meeting - 09.11.2015

3rd CP platform meeting - 21.04.2016

4th CP platform meeting - 03.07.2017

(note: the CP platform was paused since 2017 due to business continuity considerations)

Scope: Promoting awareness about the changes introduced in the centralised evaluation procedure, to have an open dialogue and exchanges of views.

Focus: general updates and more focused discussions on specific processes or issues to support continuous improvement

Transparency: Highlight reports and EMA presentations published on the website

Follow-up actions from the last CP platform meeting (1/2)

Outcome of the EMA survey on centralised initial marketing authorisation procedure 2016/2017:

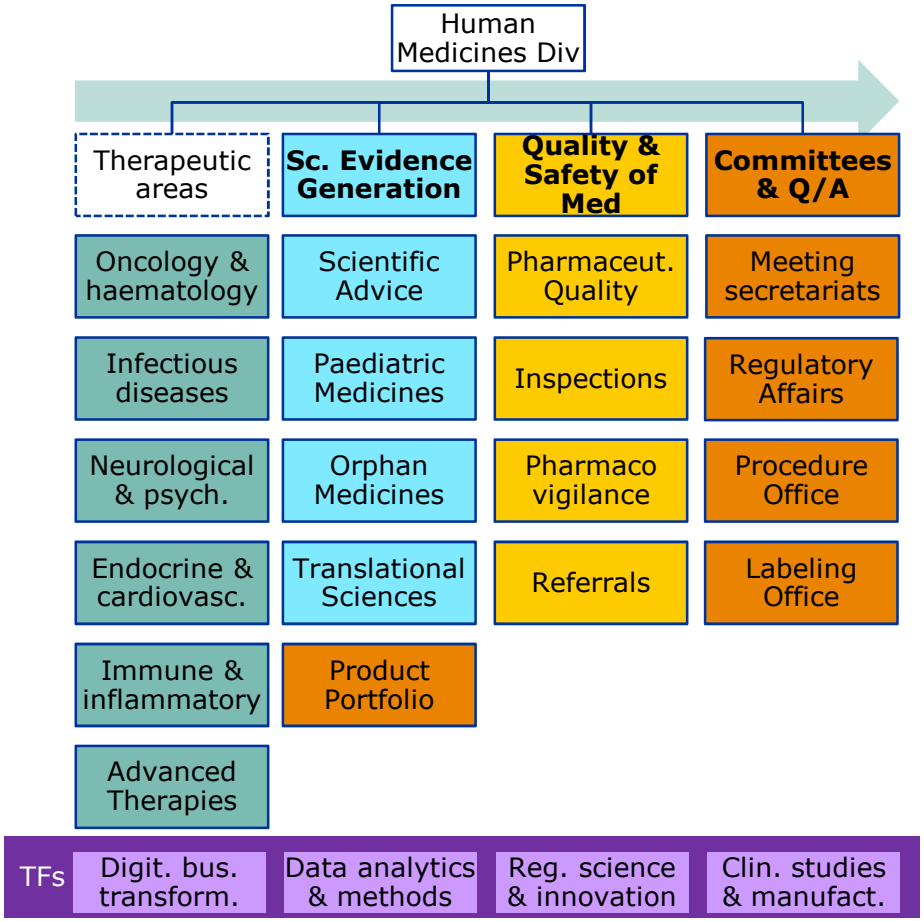
- Across the three phases of the evaluation procedures, the survey results showed a high level of overall satisfaction from all three categories of respondents in term of quality and timeliness of the interaction.

- The survey also identified areas that would benefit from optimisation.

Follow-up actions from the last CP platform meeting (2/2)

Area for improvements	Actions
Increase awareness towards applicants on the validation process	EMA published the validation checklist and update of the most common questions.
Improve circulation timelines for assessment reports & final opinion, and the communication of potential delay to applicants:	Commercially confidential information tick box implemented to speed up AR review time and circulation to applicants.
	Annex A and PI are sent by Friday of CHMP together with the translations timetable so that the Applicant can start translations, in case Opinion not finalised.
	Delays regarding the circulation of AR communicated as early as possible to companies. Use of existing IT tool to better track reports and communicate ongoing.
Optimise timing for the request of the Annex II condition to the marketing authorisation	Annex II has been added to the PI from the start of MAA allowing earlier prompt and assessment on the need for conditions during the MAA.
Clarification regarding who to contact (EPL or PM):	Reorganisation of H Division finalised strengthening EMA support to stakeholders: establishment of TAs and reinforcing the end-to-end responsibility for the product lifecycle for assigned portfolios.

Organisational structure of Human medicines division



[Therapeutic areas]

Office of oncology and haematology (H-ONC).
Office of vaccines and therapies for infectious diseases (H-INF)
O. therapies for neurological and psychiatric disorders (H-NEU)
O. of therapies for endocrine and cardiovascular diseases (H-ECV)
O. of therapies for immune and inflammatory diseases (H-IMM)
Office of advanced therapies (H-ADV)

Scientific Evidence Generation Department (H-EG)

Scientific Advice Office (H-EG-SCA)
Paediatric Medicines Office (H-EG-PME)
Orphan Medicines Office (H-EG-OME)
Translational Sciences Office (H-EG-TRA)
Product Portfolio Office (H-EG-PPO)

Quality and Safety of Medicines Department (H-QS)

Pharmaceutical Quality Office (H-QS-QUA)
Inspections Office (H-QS-ISP)
Pharmacovigilance Office (H-QS-PHV)
Referrals Office (H-QS-REF)

Committees and Quality Assurance Department (H-QA)

Meeting Secretariats Office (H-QA-SEC)
Procedure Office (H-QA-PRO)
Labeling Office (H-QA-LAB)
Regulatory Affairs Office (H-QA-REG)

Task Forces *provide services*

Benefits and changes for industry

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Benefits for Industry

- Increased focus on therapeutic areas will enhance coordination across the product lifecycle, clarifying who is responsible for what at EMA and thereby **improving collaboration with industry**
- **Clarity of points of contact** and responsibilities of each office and department and reduction of reliance on a single product lead for all procedures (product lead maintains overall oversight)
- Integrated scientific evidence generation support is maintained to **support innovation**
- Major variations (type II) for Quality managed by Pharmaceutical Quality Office for an **integrated management of Quality**
- Centralisation of administrative procedures (type I variations, transfers…) in Procedure Office to improve **predictability of service levels**
- Coordination across the product lifecycle supported by the **Product Portfolio Office** (e.g. PRIME...)
- Enhanced cross-Committee and expert group coordination increases process **consistency**
- Task Forces provide focused services to **build capabilities** for human medicines

Changes for Industry

Continuous improvement of our operations will involve incremental adaptation of roles and responsibilities of staff, allowing to optimise the use of existing expertise

In addition, **processes and tools** (e.g. digital transformation) will be reviewed and optimised

We are **digitalising** our processes which impacts the way applications are managed (e.g. IRIS for orphan medicines, parallel distribution, scientific advice); this more digital, approach will be extended to all types of applications

As the Agency proceeds with continuous improvement **you will be informed of any process changes affecting you in due time**

Main topics for today's discussion

- Launch IRIS Market status
- KPIs for the centralised procedure
- EMA experience on eCPPs
- Review of the accelerated assessment tool
- Working Parties Operational Model

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Thank you for your attention

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