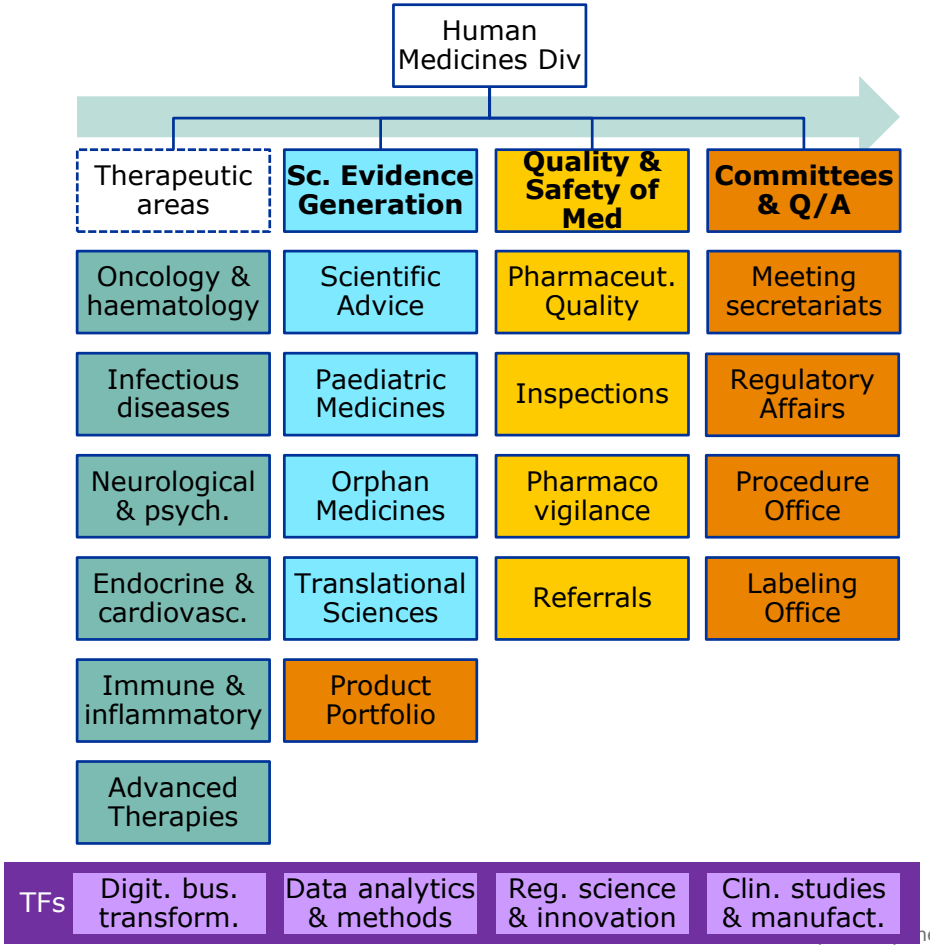
Welcome to the 5th Industry Stakeholder Platform on R&D support

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 request (e.g. connection problems, updated slide deck) please contact esther.cozar@ema.europa.eu.
- Please participate in the discussions- this is meant to be a working environment!

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

***Task Forces** provide services*

Benefits and changes for industry

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 for industry attendance**
- Task Forces provide focused services to **build capabilities** for human medicines (see Task Forces benefits)

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

This will make sure that we have the right expertise on board to assess your MAAs and other procedures

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**