EMA in 2020 and beyond: future-proofing EMA

Update to annual PCWP and HCPWP meeting with all eligible organisations
20 November 2019

Presented by Guido Rasi, EMA Executive Director

Why are we future-proofing EMA?

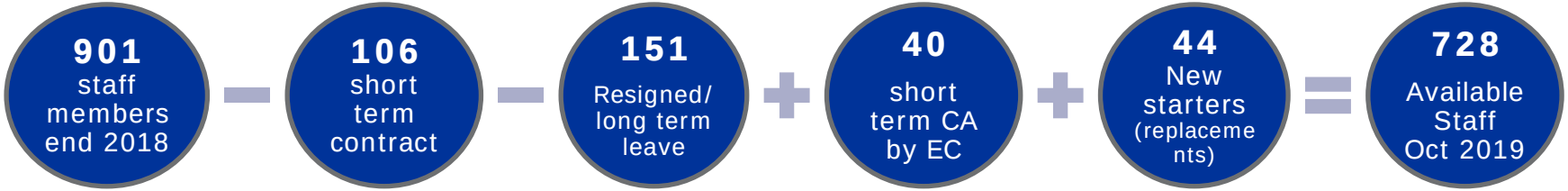
The environment is changing…

- New science (e.g. expected surge in gene and cell therapies, genome editing, ATMPs, personalised medicines)
- New technology (e.g. digitalisation of scientific data, automation)
- New legislation in various stages of drafting, adoption and implementation (challenging regulatory environment)

The EU medicines regulatory network is changing…

Our organisation is changing

- Changes in staff headcount after relocation:



- Restart of activities after BCP
- Other activities:
  - New legislation for Medical Devices
  - New Veterinary Regulation
  - Brexit challenge and shortages
  - Nitrosamines referral

The future-proofing framework

Why now?

- New science
- New technology
- New legislation
- Staff changes
- Re-start of activities

"Future-proofing"

= implementing a framework for continuous improvement

Objectives

1. Focus the Agency's strategy and resources to deliver in high-impact areas
2. Support the quality of scientific output and strengthen support to scientific committees
3. Maximise staff development and grow our skills and expertise

Strategy

1. Establish 4 task forces to deliver mission-critical functions
2. Establish an integrated human medicines division
3. Create opportunities with career paths for managers and staff

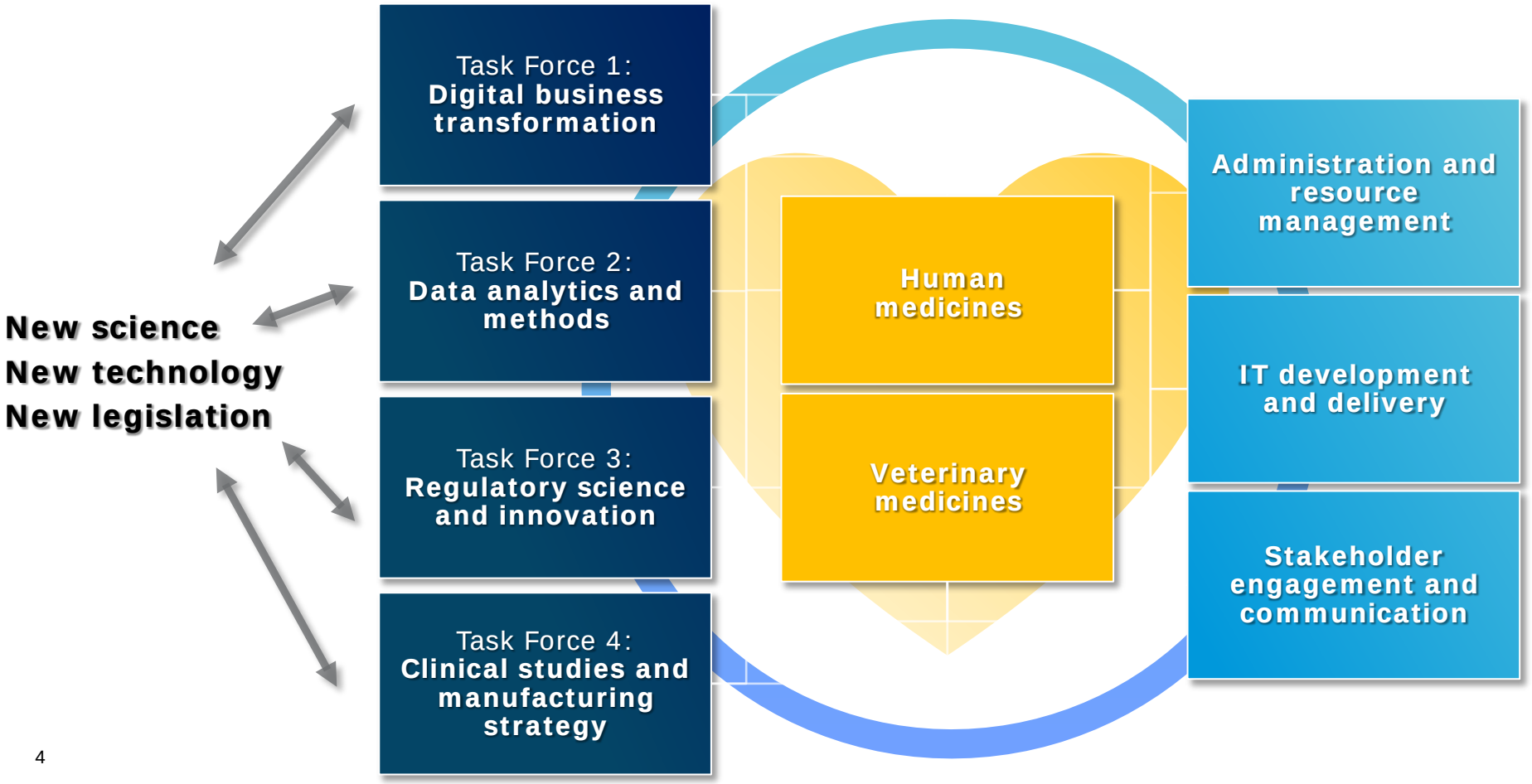
Implementation

Implement changes on all levels:

- Organisational structure and roles
- Skills and knowledge
- Process
- Data
- Technology and tools
- Ways of working and behaviours

Vision

- ✓ Quality of scientific output
- ✓ Continuous improvement
- ➢ Promoting and protecting public and animal health


New science
New technology
New legislation
Task Force 1: Digital business transformation
Task Force 2: Data analytics and methods
Task Force 3: Regulatory science and innovation
Task Force 4: Clinical studies and manufacturing strategy
Human medicines
Veterinary medicines
Administration and resource management
IT development and delivery
Stakeholder engagement and communication

The task forces

Task Force 1: **Digital business transformation**	**The 'transformation engine' of the Agency**, responsible for **driving complex change** initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU Network, its partners and stakeholders.
Task Force 2: **Data analytics and methods**	**The 'service provider' on data analytics and methods**, responsible for transforming the Agency into a modern data driven organisation, delivering robust evidence for benefit risk decision-making (evidence by design) and increasing knowledge of product performance.
Task Force 3: **Regulatory science and innovation**	**The 'observatory'** enabling the continuous future-proofing of the regulatory system by addressing key scientific and technological trends and their translation through the development of regulatory science strategy, planning and governance.
Task Force 4: **Clinical studies and manufacturing strategy**	**The 'touchstone' for clinical studies and manufacturing**, responsible for guiding Agency strategy at EU and global level to support the facilitation of clinical studies and manufacturing, that supports a learning regulatory system as both enabler and gatekeeper.

Our interaction with stakeholders

- ✓ The way we interact with our key stakeholders remains unchanged and solidly based on our frameworks of interaction and collaboration
- ✓ Our Stakeholder and Communication Division will continue to provide support to all internal structures transversally and will work closely with the Regulatory Science and Innovation Task Force in particular
- ✓ PCWP and HCPWP, supported by the wider network of eligible patient and healthcare professional organisations, are unique platforms that will continue to play a critical role

Next steps and how we will inform our stakeholders

- ✓ Scientific committees and PCWP and HCPWP informed of the changes in their November meetings
- ✓ More details to be presented to the Management Board in December
- ✓ Implementation will take place from Q1 2020 onwards once we are in the new building

Any questions?

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