ACT EU MSP: September 2024

short – medium - long term actions proposed by industry trade associations

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ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

efpia
European Federation of Pharmaceutical Industries and Associations

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EuropaBio
The European Association for Bioindustries

EFSPI
EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

Vaccines Europe

EIPG
European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

Key principles for the discussion on actions

Conduct of Clinical Trials in the EU is critical for bringing novel therapeutic options to EU patients and to ensure its competitiveness. We must join forces to solve the current situation. We are **committed** and want to **continue** running trials in EU.

We believe **timely alignment on priorities** across stakeholders is key (e.g. Collaborate) as well as embracing best practices and proportionate risk-based approaches to ensure rapid implementation

Key pre-requisites to achieving a successful ecosystem:

Resources

- The EMRN needs more resources to do all these actions in a timely manner
- Political commitment is needed
- Risk-based approaches and reliance can help with efficiency and focusing resources in the right place

Simplification and focus

- Focus on key priorities: work with AG for establishing critical priorities and add timelines
- What is key? Where do we simplify? Where do we use our resources?
- Use the tools we have and avoid creating national work-arounds

Trust and Convergence

- NCA-NCA,
- NCA-EC and
- EC-EC
- Convergence in MSs ways of working

Short term action (based on current legal framework)

Review process coordination: NCA-NCA and NCA-EC

- Redefine and strengthen RMS role as a coordinator
  - Clear timetables
  - More resources/support for coordination
  - Main review by RMS, other comment on critical aspects only, decisions by majority
  - Alignment of grounds for non acceptance vs minor issues, clearly labelled, avoid nice-to-know questions
- Requests outside of CTR are not allowed
- Trust and training will be key as well as enforcement and oversight

Efficiency gains and where resources are used

Risk based approaches: some ideas

- centralised IMPD review (and repository)
- cross-reference to already approved documents (IB / IMPD)
- conduct targeted review for applications/documents already assessed (avoid full review). E.g.: for IMPs that are already on the market, trials approved in other key regions, etc.
- Clear separation on review responsibilities between NCA and EC
- Align scope and responsibilities across all countries

Communication and Conditional approvals

- Open more communication streams with sponsors
- Use of conditional approvals:
  - Why are conditions needed?
  - Lack of harmonization
  - Impact on sponsors
  - Can they be avoided with additional communication?
- are a few additional days feasible for clock-stop if open questions?
- Timelines for SM review to address a condition should be accelerated

Medium - long term actions

Medium term:
More advanced changes to CTIS and review process

CTIS

- Ensure single portal brings simplifications
- Achieve more advanced platform

Review process

- Accelerated approval e.g. for vaccines, public health emergencies and unmet medical need.
- Interpretation of CTR (e.g. enable parallel SM)
- Stronger connection to SAWP and PDCO beyond pilots (recognizing efforts done to date)

Long Term:
Re-thinking CTR according to stakeholder priorities

- Changes proposed in short term should be embedded in regulation, mandating simplified review process
- CTR revision is a long term goal, alignment on required improvements and changes needs to start now

Rethinking the system

- molecule based approach (similar to IND) instead of a trial based approach
- true single review in EU and single approval for ultra-rare diseases (in the spirit of x-border trial)
- One entry point with one platform / committee for coordinated review and decision for CTAs, including those with Medical Devices and IVDs (COMBINE and Draghi report)