EMA
EUROPEAN MEDICINES AGENCY

EMA-FDA Support to Global Development Plans

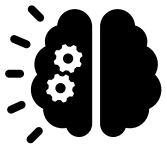
Survey to Industry

Presented by Carlos Aicardo, International Affairs, EMA

16th Industry Stakeholder Platform on Research & Development Support

Parallel EMA-FDA development support

- Regulatory Agencies face calls to support global development of medicinal products by collaborating in providing advice on scientific and regulatory aspects of development plans
- Collaborative tools like PSA have clear benefits, but full potential not used
- Other new mechanisms may support global development plans while existing ones may be adapted



Understand developers' needs, expectations, and practical challenges when engaging with EMA–FDA parallel development support

EMA-FDA Support to Global Development Plans

- Total responses 47; 40% SMEs, 60% large pharma and biotech
- Global presence for large pharma and biotech beyond EU and EU. SMEs presence localised

Positive view towards international collaboration and the different EMA-FDA parallel support mechanisms

Insights

Focus areas

Opportunities

Parallel Scientific Advice

Reasons for PSA

- Innovative technologies
- Divergent EMA/FDA guidelines
- Gaps in development guidance
- Specific populations: paediatrics, orphans
- Acceptability of development programmes

Barriers

- Long procedure timelines
- Different development strategies
- Operational complexity / logistics
- Conservative drift
- Regional pathways for joint questions
- Acceptance / eligibility

Impact

- Opportunity for joint discussions
- Simultaneous advice
- Better understanding of agency positions if no alignment
- Higher-quality advice via expertise
- Stronger global development plans

Focus areas

- Shorter procedure timelines
- Reduced process complexity
- Clearer guidance
- Cross-agency collaboration
- Consolidated feedback in one document
- Opportunities for follow-up meetings

Consultative advice

Insights

- Limited Awareness
- Informal procedure
- Value proposition
- Less resource heavy than other mechanisms
- Possibility of keeping informed the other Agency when parallel advice not possible

Focus areas

- Determine value proposition
- Development of guidance
- Communication

Bilateral interactions

Insights

- Awareness: high for large pharma/bio, low for SME
- Alignment and convergence even if company not present
- Impact on speed of development
- Workload reduction / investment long term

Focus areas

- Extend beyond oncology (e.g. other TAs and orphan)
- Earlier and more coordinated interactions
- Increase applicant involvement and contribution
- Increase transparency
- Common commentary: process, scope

Conclusions, additional insights and next steps

- Parallel support is seen as most relevant for high-uncertainty development area (rare/orphan diseases, paediatrics, novel technologies) but also first-in-class products, innovative endpoints and non-standard development approaches
- EMA scientific advice is shared with other regulators for reliance or information purposes
- Broad interest in deeper global regulatory alignment with possibility of involvement of other regulators
- Calls for PSA expedience, process simplification and consolidated output
- Call for increased transparency in consultative advice and bilateral interactions
- Next steps: further analysis and proposals for process improvement

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Thank you

carlos.aicardo@ema.europa.eu

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