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SCIENCE MEDICINES HEALTH

3.3 EMA/FDA Collaboration in Oncology

Industry Standing Group (ISG) meeting, 23 November 2023

Presented by

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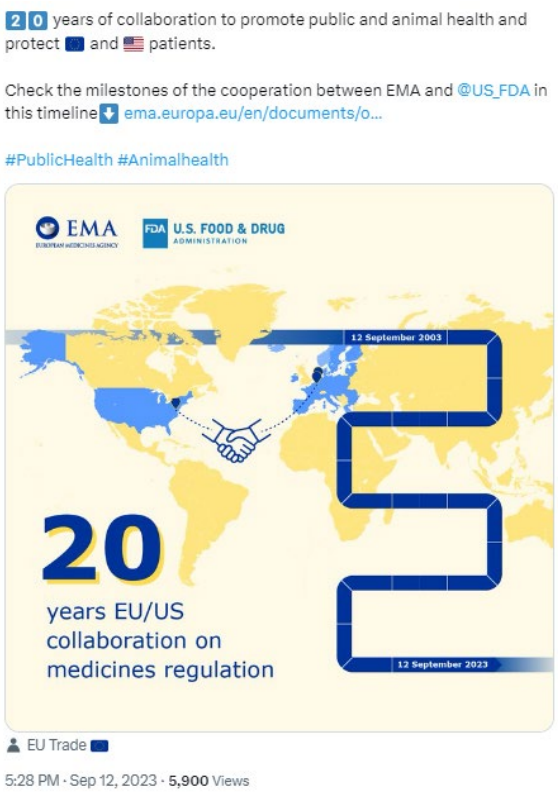
EMA-FDA
20 years of collaboration

https://x.com/FDA_Global/status/1701619337734262963?s=20



EMA/FDA Collaboration in Oncology: the cluster

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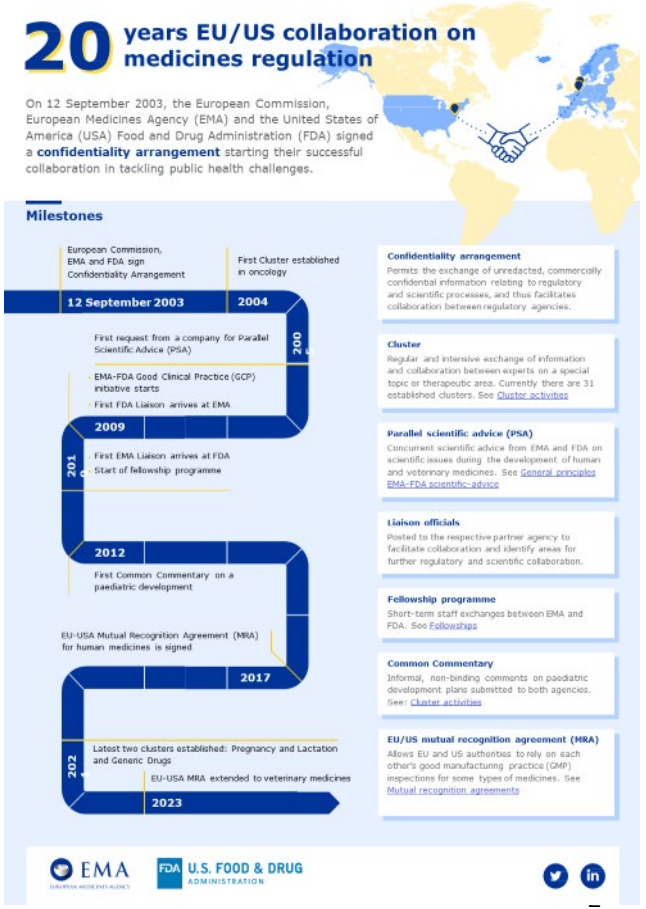
- Started in October 2004 EMA/FDA
- Expanded over the years to include other Regulatory Authorities:
  - Health Canada (HC)
  - Pharmaceuticals and Medical Devices Agency (PMDA)
  - Therapeutic Goods Administration (TGA)
  - Swissmedic
- Monthly meetings
- Discussions mainly focused on ongoing applications
- Limited time for discussion



EMA/FDA Strengthened Collaboration in Oncology

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- Discussions EMA/FDA OCE during 1st half 2023
  - Opportunity for further information sharing to increase awareness and efficiency and opportunity for collaboration on specific activities (e.g. public workshops)
  - Expanded collaboration to include earlier interactions in medicines development e.g. at Scientific Advice with the aim to facilitate potential alignment in key points (endpoints, confirmatory trials, role of SATs)
  - Increased collaboration throughout full life cycle of the medicinal product
  - Working together in outreaching activities
- Some new collaborations already set up and running
- Other areas to be further developed and implemented in near future

EMA/FDA Strengthened Collaboration in Oncology

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- Monthly bilateral meetings with focus on early interactions
  - Mainly products on Scientific Advice
  - Possible also ongoing applications
  - Other topics as relevant
  - During plenary SAWP + participation of CHMP chair/vice-chair + Oncology WP chair/vice-chair + Rapporteurs and assessors (as applicable) + FDA OCE

- Ad-hoc product meetings for ongoing applications

- Possibility to attend each other Agency's meetings:
  - FDA Orientation meetings
  - FDA mid-review meetings
  - CHMP meetings (discussion, oral explanations)

- EMA joining ORBIS as observer

EMA/FDA Strengthened Collaboration in Oncology

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- Collaboration in stakeholder outreaching activities:
  - Conversations on Cancer: 1st EMA/FDA CoC took place on 19 October

    https://www.youtube.com/watch?v=O_-n5fCAqzc

- Other activities:
  - Joint publications
  - Joint workshops
  - Trainings

Conversations on Cancer: Living with Metastatic Breast Cancer

Parallel Scientific Advice

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A mechanism where EMA and FDA concurrently exchange their views on scientific issues with the sponsor

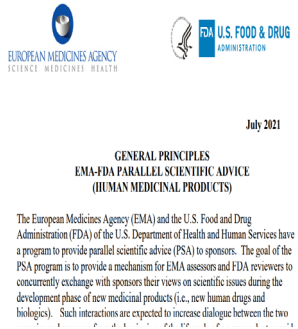
- Increase dialogue early in product lifecycle
- Deepen understanding of regulatory decisions
- Optimize development

Best candidates for PSA

- E.g. medicinal products for unmet medical needs
- indications lacking development guidelines, or significantly different guidelines

Why PSA?

- Opportunity for engagement with both regulatory agencies
- Avoid duplication of work
- Common approach where feasible or better understanding of the reasons for potentially remaining divergences
- Both agencies will strive to provide PSA responses that are convergent' (PSA General Principles)
- Opportunity to simultaneously solicit and receive "official" feedback



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U.S. FOOD & DRUG ADMINISTRATION

July 2021

GENERAL PRINCIPLES
EMA-FDA PARALLEL SCIENTIFIC ADVICE
(HUMAN MEDICINAL PRODUCTS)

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services have a program to provide parallel scientific advice (PSA) to sponsors. The goal of the PSA program is to provide a mechanism for EMA assessors and FDA reviewers to concurrently exchange with sponsors their views on scientific issues during the development phase of new medicinal products (i.e., new human drugs and biologics). Such interactions are expected to increase dialogue between the two

https://www.ema.europa.eu/en/documents/other/general-principles-european-medicines-agency-food-drug-administration-parallel-scientific-advice_en.pdf

Summary

- Strong experience of efficient information sharing on products within the cluster
- Strengthened collaboration
  - Cancer drug development optimisation
  - Stakeholder outreach and engagement
- Discussions ongoing to further broaden collaboration
- Sponsors / Applicants can make use of existing tools

Any questions?

Further information

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