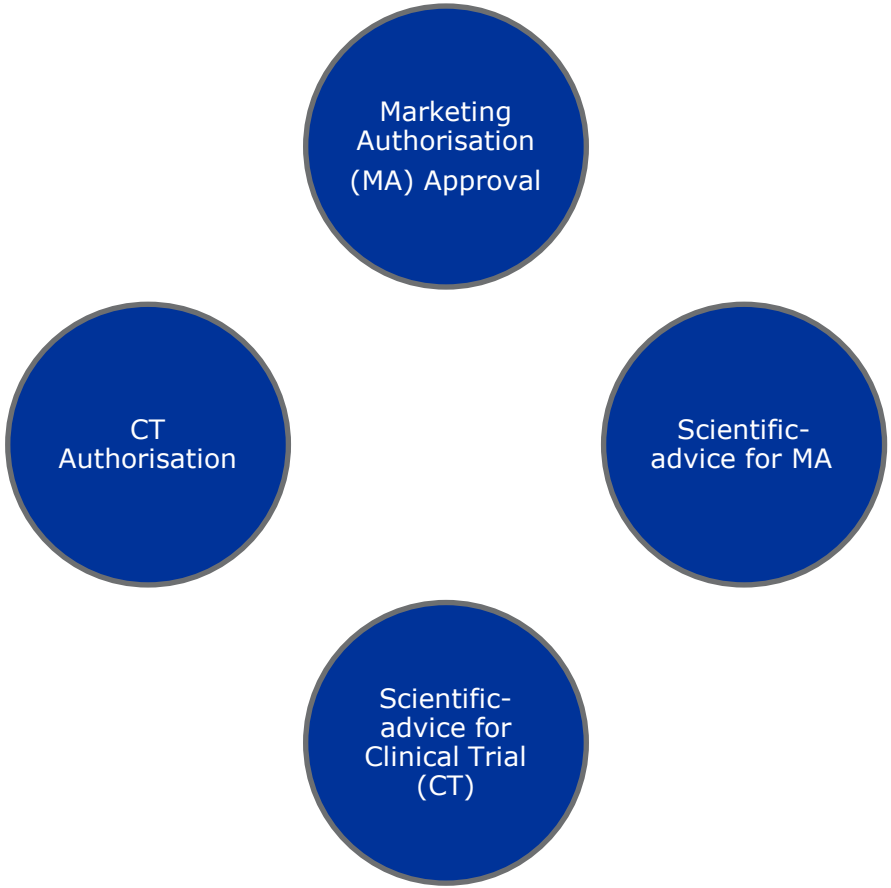
# Multi-stakeholder platform

Scientific Advice coordination

Presented by Jane Moseley on 23 June 2023
Senior Scientific Advice Officer, Scientific Advice Office EMA

# Landscape



# ACT EU goal related to scientific advice

"Heighten the impact of European clinical trials through excellent and coordinated scientific advice as a complement to trial authorisation and to support marketing authorisation and access throughout the medicine lifecycle."

"Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain."

# Workplan for ACT-EU Priority Action 7

Q3 2022 Enhance intra-network information exchange

Q1 2023-Q4 2024 Develop a consolidated scientific advice process

# Information exchange

Established core group for Priority Action 7 Representatives from

- EU-IN (Innovation Task Force and Innovation offices),
- Scientific Advice Working Party (SAWP),
- Clinical Trial Coordination Group,
- Emergency Task Force,
- Simultaneous National Scientific Advice,
- Committee for Medical Products for Human CHMP

Produced comprehensive mapping of Scientific Advice across EU Medicines Regulatory Network

- Published 22/11/2022
- Scientific Advice on medicines for Human use in the EU medicines regulatory network (europa.eu)

# Information Exchange

- How can I get *informal* regulatory and/or scientific advice on my product-specific development programme from medicines regulators in Europe (Medicines for human use)?
- How can I get *voluntary* scientific advice on my product-specific development from medicines regulators in Europe? (Medicines for human use)?
- How can I discuss a new technology or methodology with regulators in Europe? (Medicines for human use)?
  - Published; Options, Provider, Contacts, scope, links to Further information

# *EU informal* regulatory and/or scientific advice medicinal product development Human

| Options | Provider |
|---|---|
| Nationally | National innovation offices |
| Centralised support | Innovation Task Force |
| Centralised support | Small medium enterprise Office |
| Centralised support | CHMP based on Emergency Task Force |
| Centralised support | Paediatric Medicines Office |

informal: process does not lead to an adopted regulatory opinion

# *EU voluntary* scientific advice on medicinal product development Human

| Options | Provider |
|---|---|
| National scientific advice | Scientific advice/clinical trial office in the Member States |
| Simultaneous National Scientific Advice | Innovation office/clinical trial office/Scientific advice office in the Member States |
| Centralised Scientific advice | CHMP based on Scientific Advice Working Party |
| Centralised Scientific advice; medicines for (potential) public health emergency | CHMP based on Emergency Task Force |
| Centralised support PRIME scheme (PRIority MEdicines) | European Medicines Regulatory Network |

# EU regulatory input on a new technology or methodology in context of medicines development Human

| Options | Provider |
|---|---|
| Nationally | National innovation offices |
| Centralised support | Innovation Task Force |
| Centralised Qualification advice | CHMP based on Scientific Advice Working Party |
| Broad centralised scientific advice | CHMP based on Scientific Advice Working Party or the Emergency Task Force |

# Voluntary scientific advice on product-specific development

| | Provider | Scope |
|---|---|---|
|  | Centralised Scientific advice CHMP based on Scientific Advice Working Party | Product- and indication-specific prospective advice on any aspect of medicines development for a marketing authorisation, excludes: advice on a specific clinical trial application (CTA), products addressing public health emergencies.. |
|  | Centralised Scientific advice CHMP based on Emergency Task Force | declared and potential public health emergencies. Includes involvement of Clinical trial Advisory Group (CTCG), Clinical Trial Advisory Group (CTAG) and Member State (MS) …<br>Support to clinical trial sponsors to facilitate CT application and approval and the conduct of large multinational trials. |

# Voluntary scientific advice on product-specific development

| | Provider | Scope |
|---|---|---|
|  | Innovation office, clinical trial office or Scientific advice office in the Member States | SNSA is intended to be used in situations where an applicant wishes to obtain national scientific advice from more than one NCA at the same time<br><br>With ACT-EU, the SNSA pilot will have a specific focus on scientific advice to facilitate clinical trials within the EU |

# Any questions?

## Further information

Jane Moseley@ema.europa.eu

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
**Telephone** +31 (0)88 781 6000
**Send us a question** Go to www.ema.europa.eu/contact

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