An introduction to the European Medicines Agency (EMA)

Committee on the Environment, Public Health and Food Safety
7 November 2019

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What we do

Innovation

• Scientific assessment of all innovative medicines for authorisation throughout the EEA
  One application, one evaluation, one authorisation valid everywhere in Europe
  e.g. for cancer, AIDS, neurodegenerative diseases, all advanced therapies (ATMPs)

• Foster innovation by ensuring best evidence generation through scientific advice

Safety

• EMA monitors the safety of >500,000 medicines on the market

What we don’t do

• Authorise clinical trials

• Make decisions around price and reimbursement of medicines
How we do it

• We are the **hub of the European network** of national medicines agencies

• We pool the **best expertise** to conduct **scientific assessment** of medicines
  • >4,000 experts pre-qualified for conflicts of interest and expertise
  • 7 scientific committees
  • Supported by expert working parties and scientific advisory groups
More on medicines safety

• > 2,000,000 side effect reports have been collected in EMA’s publicly accessible database (EudraVigilance)

• EMA is going beyond passive reporting by:
  o making sure that safety is built-in by design
  o planning for safety at the initial stages of medicines development

• Artificial Intelligence and Real World Evidence will change the way we collect and analyse data for safety and approval

• Patients, healthcare professionals and the general public bring a unique perspective to EMA’s scientific discussions
How we are preparing for the future

• Our ambition, like our **workload, is very high**
• In addition, we are preparing for **new tasks** required by **new legislation**:
  o Clinical Trials Regulation
  o GDPR
  o Medical devices/IVD Regulations
  o New veterinary medicines Regulation
• **We need** the right **expertise** to face the **challenges** ahead
• To best **prepare** for the **future** we need to **adapt** EMA’s organisation
• We need to **resume activities** suspended due to our **move**
What we are doing for crucial public health needs

• Support access to medicines by increasing cooperation with HTA bodies
• Prepare for new generation of innovative therapies
• Work with Member States and the Commission to find solutions for medicines shortages
• Address the challenges posed by the global supply chain
• Strengthen our global response to AMR
• Tackle vaccine hesitancy
Thank you.