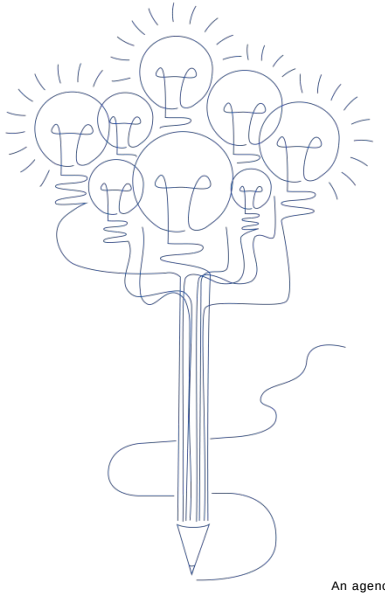
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

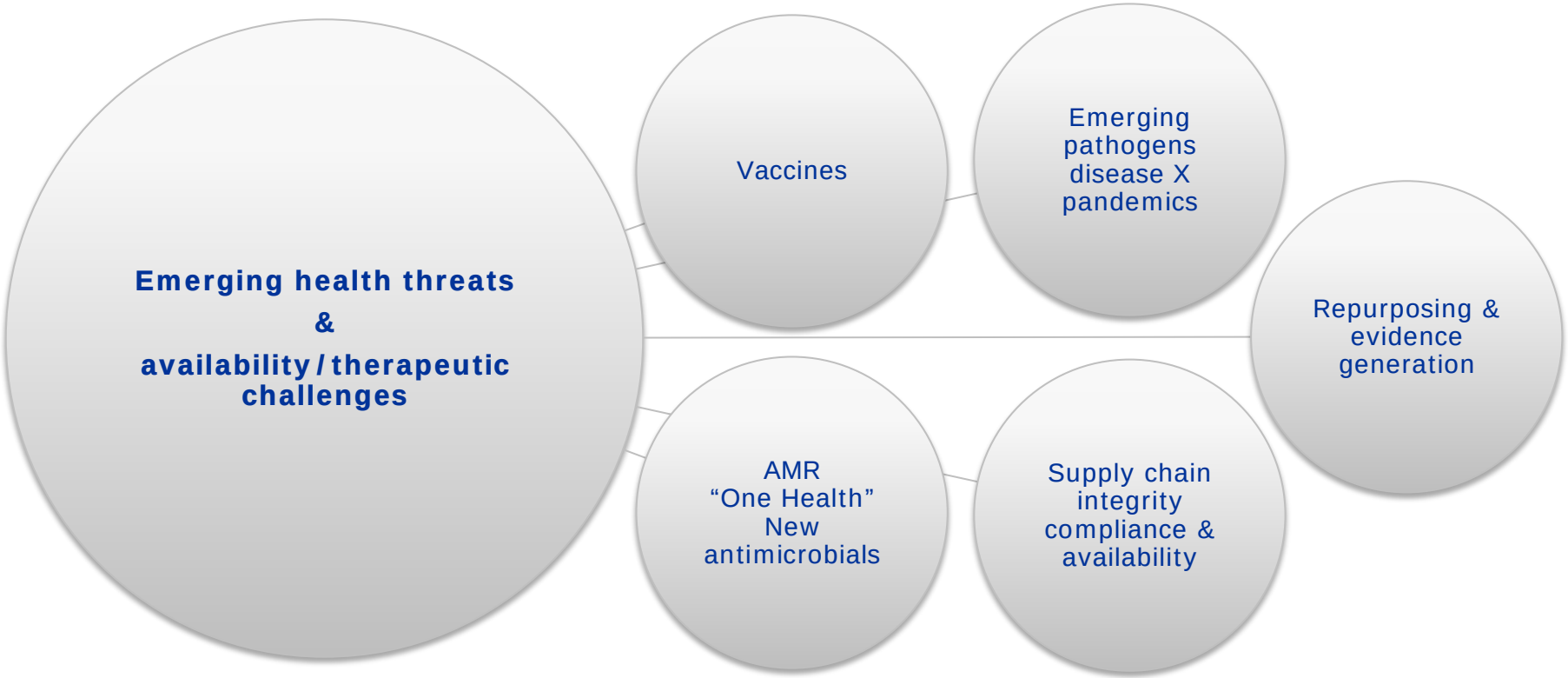
Addressing emerging health threats and availability/therapeutic challenges

EMA's core recommendations

Human Stakeholders Workshop

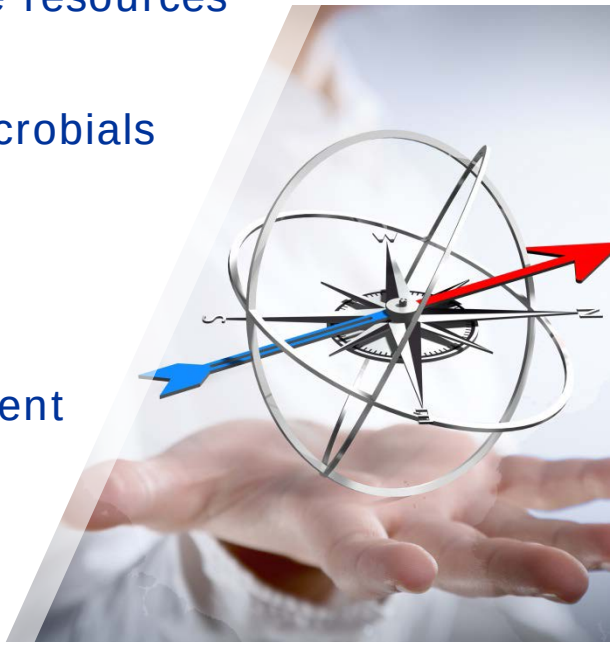


Presented by Marco Cavaleri on 24 October 2018
Head of Anti-infectives and Vaccines


Emerging health threats
&
availability / therapeutic challenges
Vaccines
Emerging pathogens disease X pandemics
Repurposing & evidence generation
AMR "One Health" New antimicrobials
Supply chain integrity compliance & availability

Core recommendations

- Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches
- Continue to support development of new antimicrobials and their alternatives
- Promote global cooperation to anticipate and address supply challenges
- Support innovative approaches to the development and post-authorisation monitoring of vaccines
- Support the development and implementation of a repurposing framework



Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches

- Coordinate scientific and regulatory activities within EMRN
- Evaluate preparedness for emerging pathogens and "disease X"
- Coordinate discussions with EMRN, international partners and stakeholders on the development, authorisation and post-authorisation follow-up of relevant medicinal products
- Effective and timely communication to healthcare professionals, the public and regulatory partners

Continue to support development of new antimicrobials and their alternatives

- Evolve regulatory guidance and support alternative approaches to antimicrobial drug development
- Support initiatives, such as the clinical trials network, to facilitate and accelerate clinical development
- Encourage new business models that provide “pull” incentives beyond the current “funding research” strategy in the EU
- In collaboration with HTAs and payers, define the evidence requirements for new antibacterial medicines
- Support the development and application of rapid diagnostic tools

Promote global cooperation to anticipate and address supply challenges

- Implement the work plan of the HMA/EMA Task Force on availability of authorised medicines
- Explore mechanisms to increase manufacturing capacity in Europe and internationally
- Enhance collaboration with WHO in the area of supply disruptions due to manufacturing quality issues
- Promote greater knowledge exchange with international stakeholders on shortages due to quality/mfg issues
- Develop common definitions and reporting mechanisms for supply shortages

Support innovative approaches to the development and post-authorisation monitoring of vaccines

- Advance methods/tools (e.g., biomarkers) to characterise immune response and to support definition of vaccine quality attributes
- Examine innovative clinical trial approaches to expedite vaccines development
- Engage with public health authorities and NITAGs to better inform vaccine decisions
- Establish a platform for EU benefit/risk (B/R) monitoring of vaccines post-approval
- Communicate proactively with key stakeholders on B/R using evidence-based tools to tackle vaccine hesitancy

Support the development and implementation of a repurposing framework

- Enhance regulatory advice on evidence generation and MAA submission
- Frame suitability of third party data-pooling, relevant RWD and historical non-clinical datasets
- Translate experience with EMA's registry pilot to guide RWD collection
- Explore utility of low-intervention clinical trials for evidence generation

Marie-Pierre Preziosi, WHO

John Rex, F2G Limited

Michel Stoffel, Vaccines Europe

Helene Guillard, AESGP

Julien Veys, Medicines for Europe

Henrik Kim Nielsen, EFPIA