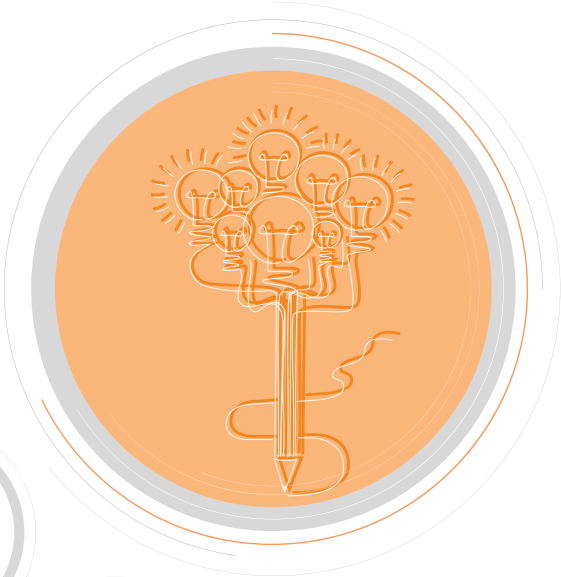
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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



## Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Cesar Hernandez Garcia, HMA on 19 November 2019
Presented by Marco Cavaleri, Anti-infectives & Vaccines, EMA

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# Support innovative approaches to the development, approval 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

# Establish a platform for EU benefit/risk (B/R) monitoring of vaccines post-approval

- The cooperation between regional and national surveillance networks is essential to generate quickly meaningful data on the benefit/risk of prophylactic vaccines. The review of ADVANCE and DRIVE experience may bring important learnings for the creation of a platform to monitor the post-approval benefit/risk of vaccines. Industry should be involved as stakeholder for this topic.
- The incorporation of RWD surveillance efforts into efforts that would provide increases in approaches in post-authorisation monitoring of vaccinations. Large, multi-national systems, such as VigiBase are fundamentally important. Better RWD platforms, potentially linked to electronic health records, would promote this core recommendation.

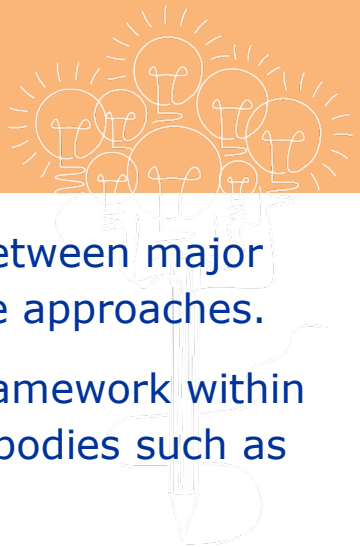
# Communicate proactively with key stakeholders on B/R using evidence-based tools to tackle vaccine hesitancy

- Vaccine hesitancy is significant health risk for EU citizens, it has been driven by insufficient health literacy levels combined with susceptibility to misleading information.
- Special attention should be given to developing local networks and communication tools which can be deployed across a range of channels to rebuild trust in vaccines.

# Examine innovative clinical trial approaches to expedite vaccines development

- Classical development of vaccines is long and costly. Promoting innovative clinical trial design allowing to demonstrate positive benefit/risk with a reduced number of subjects in phase 3 is key to deliver new vaccines quicker to the patients.
- Regulatory acceptance of initial approval based on alternative approaches such as surrogate endpoints or human/animal challenge models combined with post-approval real world data is essential.
- The advancement of methods/tools (e.g. biomarkers) to characterise immune response should facilitate the identification of correlates of protection and surrogate markets and support the development of new approaches (e.g. in vitro methods to identify measurable characteristics of safety, quality and potency).

# Examine innovative clinical trial approaches to expedite vaccines development



- As manufacturers are conducting global developments, cooperation between major regulatory agencies is needed to guarantee global acceptance of these approaches.
- The clinical landscape is changing more quickly than the regulatory framework within the EU; EMA could consider closer engagement with other regulatory bodies such as WHO, national African regulators to adapt.
- Consider early PRIME applications of non-SME companies for vaccines based on proof of principle data. This would allow for regulator input on vaccine innovative clinical trial design early in the development.

# Engage with public health authorities and NITAGs to better inform vaccine decisions

- It is important for vaccine developers to be aware of the positions of recommending bodies/payers in the different Member States on the product profiles they would consider of interest for their country/region.
- The data generated to support the marketing authorisation of a vaccine are not necessarily the same as the data (usually cost-effectiveness data based on local epidemiology and standards of care) that recommending bodies/payers in the different EU Member States want to have available.
- The possibility to involve NITAGs in parallel CHMP/HTA/NITAG scientific advices for prophylactic vaccines should be explored. A pilot took place in 2018, we encourage EMA to continue working with all stakeholders on this topic.

# Advance understanding of the science behind novel technology so to ensure appropriate regulatory oversight and foster ability to exploit value of platform technologies in view of emerging threats

- Novel manufacturing technologies are key enablers for effective and sustainable supply of products. It is crucial to understand the regulatory implications of novel approaches. Gaps in regulatory framework should be identified and strategies established to address them.
- In light of developing technologies e.g. platforms used in vector derived medicines develop guidelines that enable the concept of a “drug master file” type approach to be used across different clinical trial applications for different vaccines using the same vector (e.g. stability data, tox data, safety).

# Harmonise regulatory framework for conduction of vaccines clinical trails including during emergencies

- The landscape across the EU for emergency use of vaccines is rather heterogeneous. In addition, GMO requirements and requirements for challenge material for human challenge studies vary across MSs. A more conducive and predictable environment for vaccines clinical research is warranted.
- Develop guidelines to allow for harmonized GMO assessment across the EU instead of individual national.

# Any questions?

## Further information

RegulatoryScience2025@ema.europa.eu

**Temporary visiting address** Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
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