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SCIENCE MEDICINES HEALTH

Perspectives of EMA on VAC4EU

EU Ecosystem for monitoring of post-licensure vaccine benefit and risk: from ADVANCE to VAC4EU

Brussels, March 6, 2019

Xavier Kurz MD, MSc, PhD, Head of Surveillance & Epidemiology service
Pharmacovigilance & Epidemiology Department

An agency of the European Union

In this presentation:

What is the place of VAC4EU in the landscape of post-authorisation studies performed, commissioned or required by EMA?

Premise

VAC4EU fully implements the best practice solutions developed by ADVANCE (see previous presentation)

Need for RWE in vaccine life-cycle

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- Understanding medical needs
- Natural course of disease/disease burden
- External comparator group
- Definition of target population
- Background rates of adverse events of special interest
- Planning of post-authorisation activities
- Monitoring of vaccine and immunisation programme vaccine safety and effectiveness
- Vaccination coverage
- Investigation of safety concern (post-authorisation safety study)
- Post-authorisation efficacy study
- Evaluation of effectiveness of risk minimisation measures
- Economic analysis to inform immunisation recommendations

(...)

Need for RWE in vaccine life-cycle

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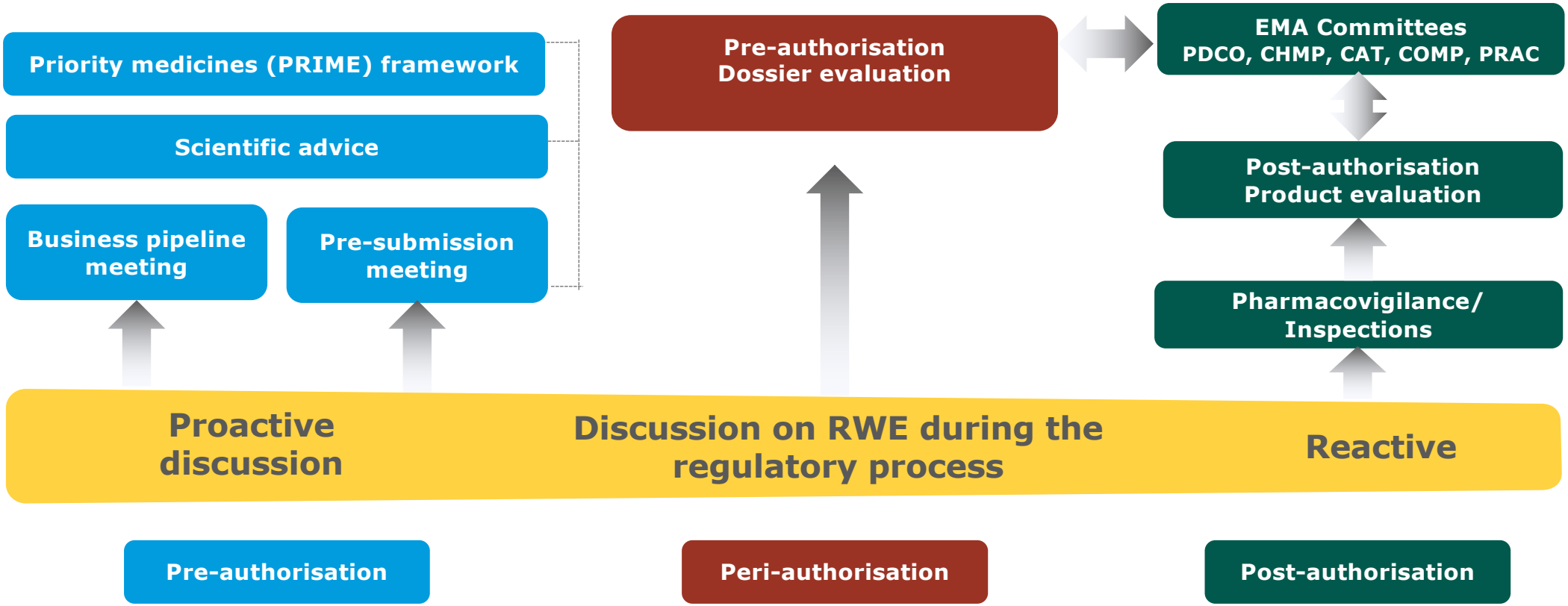

Discussion of need for RWE during the authorisation process

RWE: Real-world evidence; CAT: Committee for Advanced Therapies; CHMP: Committee for Medical Products for Human Use; COMP: Committee for Orphan Medicinal Products; PDCO: Paediatric Committee; PRAC: Pharmacovigilance Risk Assessment Committee.

Need for RWE in vaccine life-cycle

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- <1% of medicinal products with marketing authorisation in the EU are vaccines
- 5.5% of spontaneous case reports of suspected adverse drug reactions (ADRs) received for all medicines in the EudraVigilance post-marketing module are related to vaccines
- 12 safety issues for 6 vaccines were discussed by the PRAC since September 2012
- 4% of studies registered in the EU PAS register concern vaccines

Relatively few regulatory procedures at EU levels for safety concerns on vaccines…

… but need for quick and complete investigation in cases of crises

e.g. Guillain-Barre syndrome, narcolepsy, anaphylactic shock, CRPS, POTS, (lack of) effectiveness

EMA options for generating RWE

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Requests to vaccine manufacturers

- Scientific Advice and protocol assistance for method and product development
- Post-authorisation safety (PASS) or efficacy (PAES) study imposed as legal obligation
- Specific obligation in the framework of a marketing authorisation granted under exceptional circumstances
- Requirement in the risk management plan (RMP) to investigate a safety concern or to evaluate the effectiveness of risk minimisation activities
- Requests for data in the course of safety signal assessment

PASS/PAES:

- data source cannot be imposed to vaccine manufacturer
- protocol and study report to be endorsed by PRAC/CHMP for imposed studies
- may concern class of vaccines rather than single product
  - joint study strongly encouraged

EMA options for generating RWE

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EMA in-house studies

- In-house RWD studies to support Committees (mainly PRAC)
  - two databases selected through procurement procedure: THIN (UK), IMS (FR and DE)
  - 2013-2017: 46 THIN studies – 29 IMS studies

EMA funded studies

- External studies funded to support EMA Committees – 21 studies launched in 2013-2018 – 1 on vaccine (H1N1 pandemic vaccine)
- Topics related to substance or class of products
- 9 framework contractors selected though procurement procedure (2018-2021)
- Re-opening of competition for specific study
- Sub-contracting is possible

EU Regulatory network study

- Joint study of national authorities with access to electronic health records/claims data

A changing environment

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COUNCIL RECOMMENDATION
of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases
(2018/C 466/01)

the Council welcomes the Commission's intention to take the following actions, in close cooperation with the Member States:
(…)
10. With the support of the European Medicines Agency and in cooperation with the ECDC, continuously monitor the benefits and risks of vaccines and vaccinations, at EU level, including through post-marketing surveillance studies

Added value of VAC4EU for regulators

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METHODS

- Increased power and statistical validity of study results
- Common methodology, improved standardisation of reporting and comparability of results
- Dashboard providing rapid visualisation of key indicators
- Culture of methodological development

CONTENT

- Large population and geographical area
- Potentially, wide range of outcomes and vaccines used in the EU
- Comparison of vaccine safety and effectiveness across different populations, regions, immunisation schedules
- Improved timeliness of results for new vaccines or safety concerns arise
- Possibility to quickly address media concerns and counter vaccine hesitancy

Providing confidence in data quality: EMA Qualification ?

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EMA Qualification

- Scientific advice on acceptability of a specific method in the context of research and development of pharmaceuticals
- Given by the Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party (SAWP).
- Based on assessment of data submitted by applicant
- Public consultation before final adoption of opinion

Providing confidence in data quality: EMA Qualification ?

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Procedure No.: EMEA/H/SAB/080/1/QA/2017
EMA/CHMP/SAWP/802259/2017
Product Development and Scientific Support Department

Qualification Opinion

The European Cystic Fibrosis Society Patient Registry (ECFSPR)

EMA/CHMP/SAWP/423488/2018
Committee for Medicinal Products for Human Use (CHMP)

Draft qualification opinion on Cellular therapy module of the European Society for Blood & Marrow Transplantation (EBMT) Registry

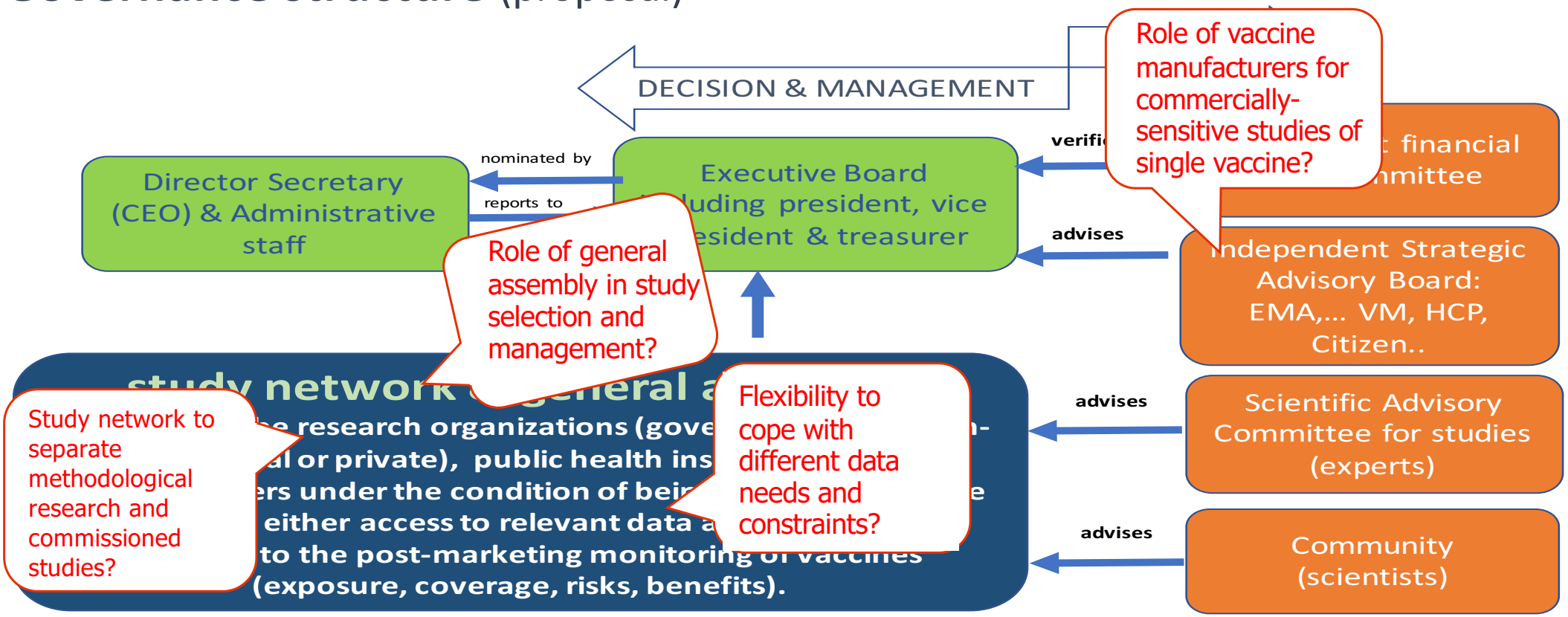
"The current status of ECFSPR (coverage, core dataset, governance, quality assurance approaches and completeness of core variables) may allow its use for:

- **Drug utilisation studies** for total recorded population and subgroups
- **Drug efficacy/effectiveness studies**
  - Concurrent assessment of effectiveness, in specific circumstances
  - Source of historical control data for comparative purposes in the context of RCTs (i.e. when this would be the only reasonable option)
- **Drug safety evaluation**
  - Safety data with focus on important identified and potential risk: incidence, comparative risk assessment studies "

Outstanding questions

VAC4EU
VAccine monitoring Collaboration for Europe

Governance structure (proposal)



Role of EMA?

VAC4EU
VAccine monitoring Collaboration for Europe

Governance structure (proposal)

Conclusions

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- VAC4EU study network well placed to meet the needs of an European infrastructure for studies on vaccine benefits and risks
- High potential as source of RWE for regulatory activities on vaccines
- Solid foundation based on ADVANCE deliverables
- EMA Qualification should be considered
- Core of the infrastructure should be the study network
- Other structures should facilitate activities of the study network

Thank you for your attention

Further information

Contact us at Xavier.kurz@ema.europa.eu

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