CBG MEB | MEDICINES EVALUATION BOARD

EU ECOSYSTEM FOR MONITORING OF POST-LICENSURE VACCINE BENEFIT AND RISK: FROM ADVANCE TO VAC4EU

Meeting the requirements on quality and timeliness of evidence from heterogeneous existing health data for regulatory decision making

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GOOD MEDICINES USED BETTER

Mandate of the PRAC

All aspects of the riskmanagement of the use of medicinal products including :

- detection , assessment, minimisation and communication of the risk of adverse reactions
- having due regard to the therapeutic effect of the medicinal product
- the design and evaluation of post authorisation safety studies and pharmacovigilance audit

PRAC's composition

Appointed by each Member State:

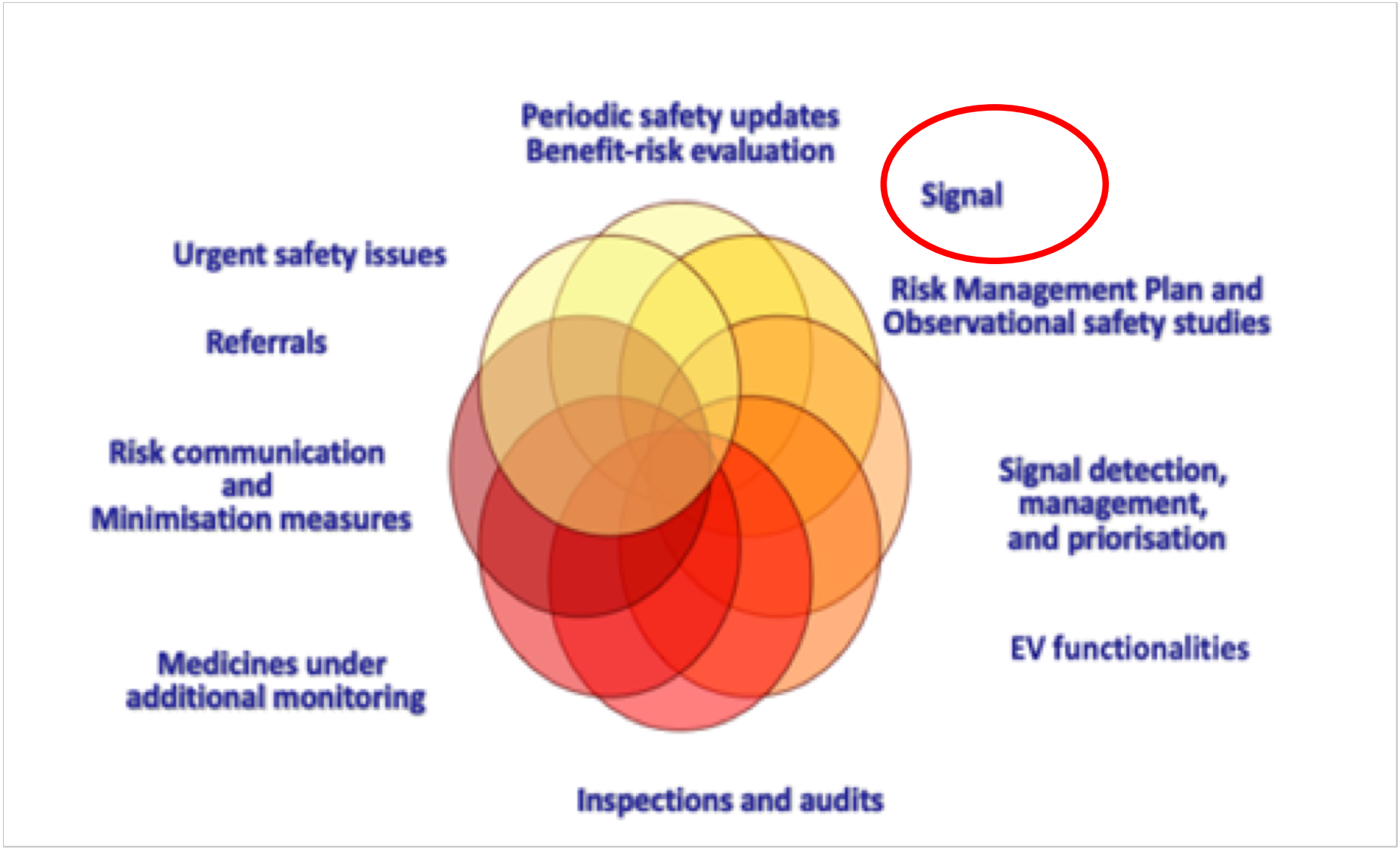
- 1 member + 1 alternate
- 28 + EEA countries non voting members

Appointed by the European Commission following a public call for expressions of interest:

- *1 patient organisations[1] rep + alternate*
- *1 healthcare professionals[1] rep + alternate*
- 6 members to ensure relevant expertise available

[1] *Criteria for involvement in EMA activities*

PRAC's activities



EU signal management process: the full picture

Signal detection (EV) & validation

EMA, NCAs

MAHs

Confirmation

PRAC Rapp / Lead MS

Initial analysis & prioritisation, assessment, recommendation

PRAC (with MAH input)

Validated signal

GVP definition

"A signal where the signal *validation process* of evaluating the *data* supporting the detected signal has *verified* that the available documentation contains ***sufficient evidence*** demonstrating the existence of a *new potentially causal association*, or a *new aspect of a known association*, and therefore ***justifies further analysis*** of the signal."

Signal validation process

[elements of signal validation]

- Clinical relevance
  - Strength of evidence
  - Seriousness and severity
  - Novelty of the reaction
  - Reaction due to possible drug-drug interaction
  - Reactions occurring in special populations

Regulatory Pharmacovigilance Prioritisation System (MHRA)

Four categories and an overall priority

- Strength of evidence for a causal effect
- Potential public health implications
- Public perceptions
- Agency obligations

Strengthening regulatory decisions

Good quality data e.g.

- completeness
- reliability/validity
- consistency

Timeliness

Contextualize risk/concern e.g.

- background on disease/ disease epidemiology
- exposure data /vaccination rate
- baseline rates of ADRs / signal (eg incidence in population seriousness, natural history)
- preventibility

Trust building e.g.

- Consistency
- Transparancy

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