Federal Office of Consumer Protection and Food Safety

Pilot Signal Management Expert Group (P-SMEG)

EMA - Follow up webinar on signal detection, evaluation and yearly reporting

Pilot Signal Management Expert Group (P-SMEG)

Background

- Provisions of Regulation (EU) 2019/6 for signal management (SM) in the EU are tasking Member States and the Agency with organizing the processes related to SM for veterinary medicinal products authorized in the EU
- HMA and EMA agreed upon a pilot expert group for SM (P-SMEG) for the cooperation in performing the tasks concerning SM
- Pilot is set up for a period of two years
- P-SMEG is established as a subgroup of the Pharmacovigilance Working Party

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Objective

The main objective is to set-up and test new processes through close cooperation of a group of Member States experts with the aim to build an overall sustainable regulatory operational framework to support provisions of Regulation (EU) 2019/6 related to signal management.

Pilot Signal Management Expert Group (P-SMEG)

Main tasks

- To set-up and test new processes regarding signal management
- To identify, prioritize and assess safety issues using all inputs available in the Union pharmacovigilance database (MAH annual submissions, MAH 3-day ESI and 30-day notifications, pharmacovigilance alerts, regular review of the pharmacovigilance data available in the Union pharmacovigilance database .....)
- To support/perform targeted signal management activities
- To transmit for validation to the PhVWP-V, signals detected and proposed regulatory actions
- To contribute to the preparation and the provision of trainings for relevant competent authorities and stakeholders

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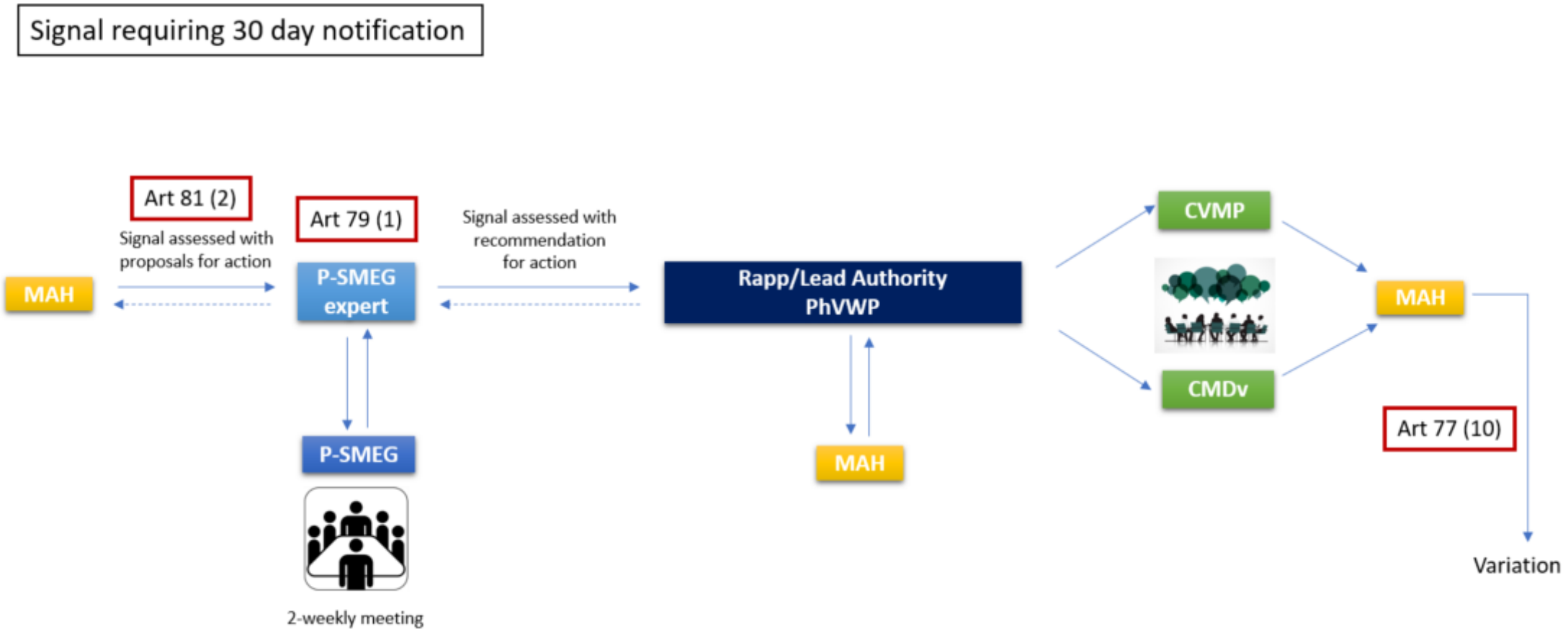
Example process



Any questions?