EMA
EUROPEAN MEDICINES AGENCY

Dosage review and adjustment of selected veterinary antibiotics (ADRA)

Regulatory considerations

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Veterinary Regulatory Affairs and Referrals Service (EMA)

Regulatory framework – Regulation (EU) 2019/6

1ST STEP: Scientific assessment Article 141(1)(i) of Regulation (EU) 2019/6

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2ND STEP: Implementation of CVMP scientific advice for individual MAs

CAs

Article 141(1)(i) procedure

Can be triggered by Member States or self-mandated by CVMP

No fee for MAHs involved (Regulation (EU) 2024/568)

No legal timelines

Not directly legally binding (**no EC Decision**)

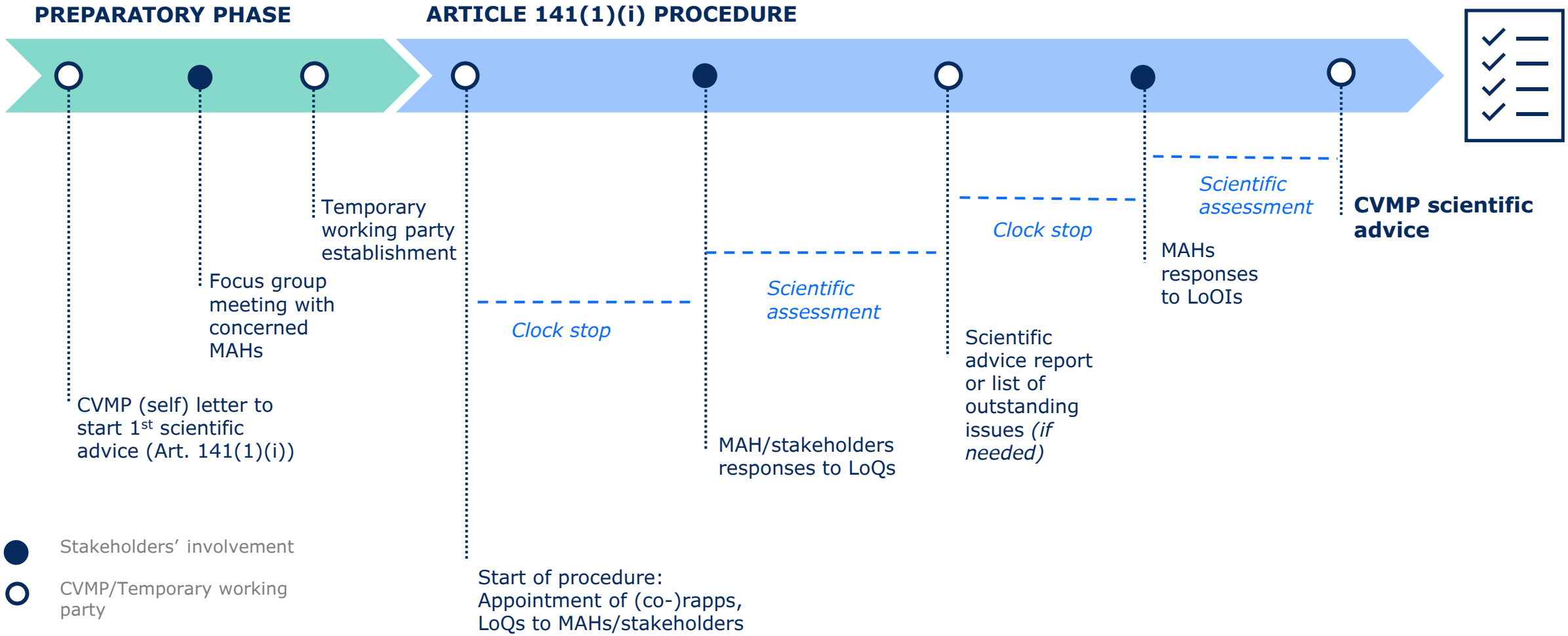
Possible AWP/EWP-V consultation

Stakeholder interaction

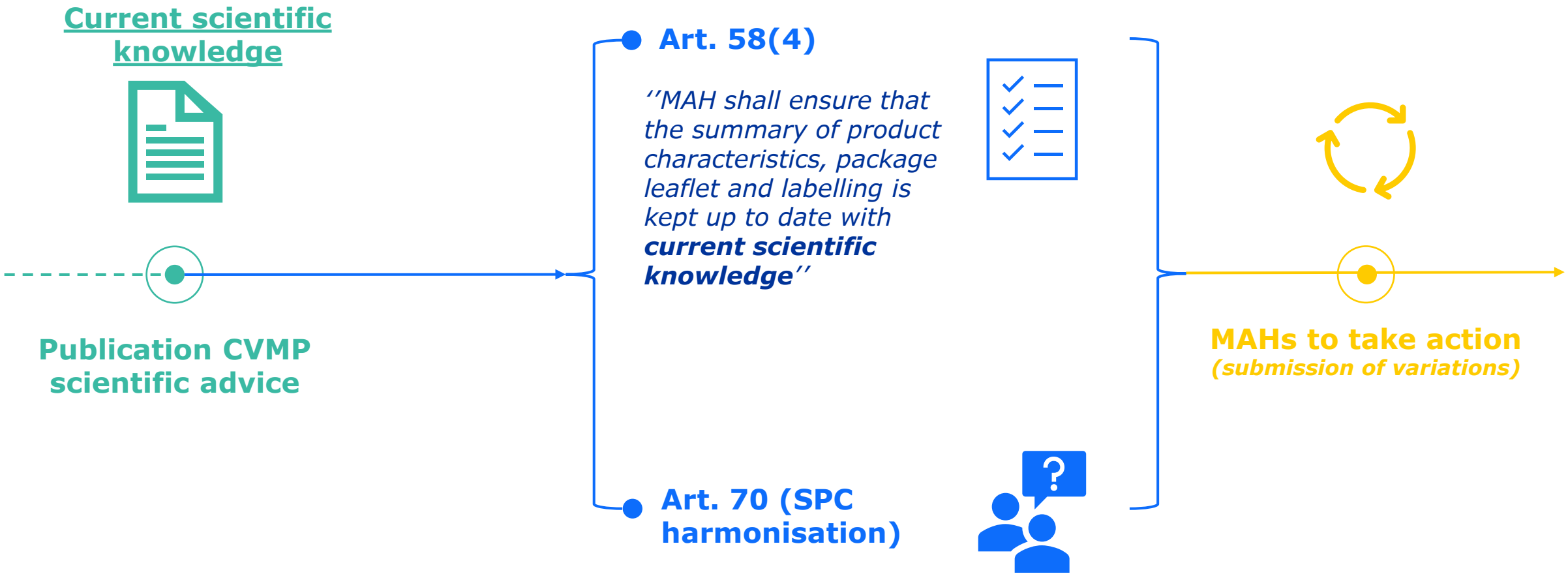
CVMP considers all available data relevant for assessment

Art. 141(1)(i):
''CVMP shall provide scientific advice on the use of antimicrobials and antiparasitics in animals to minimise the occurrence of resistance in the Union, and update that advice when needed''

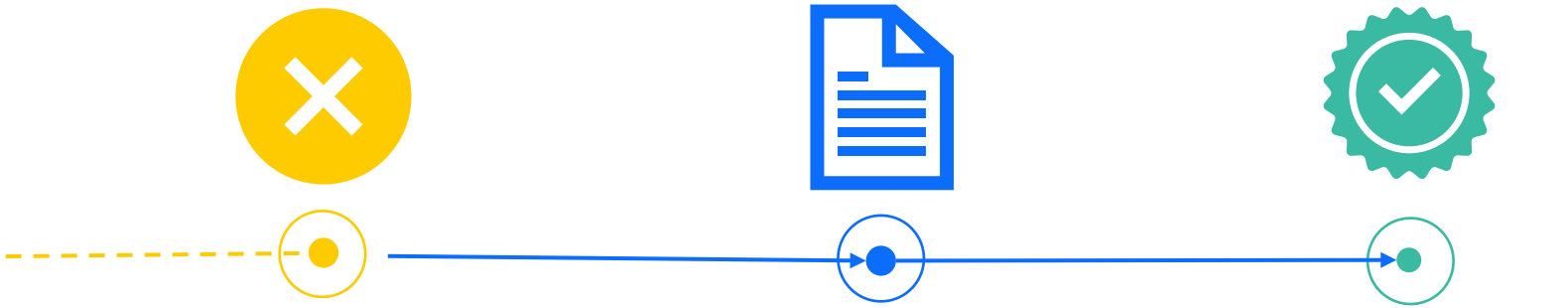
Timelines



CVMP scientific advice implementation



CVMP scientific advice implementation



Submission of variations

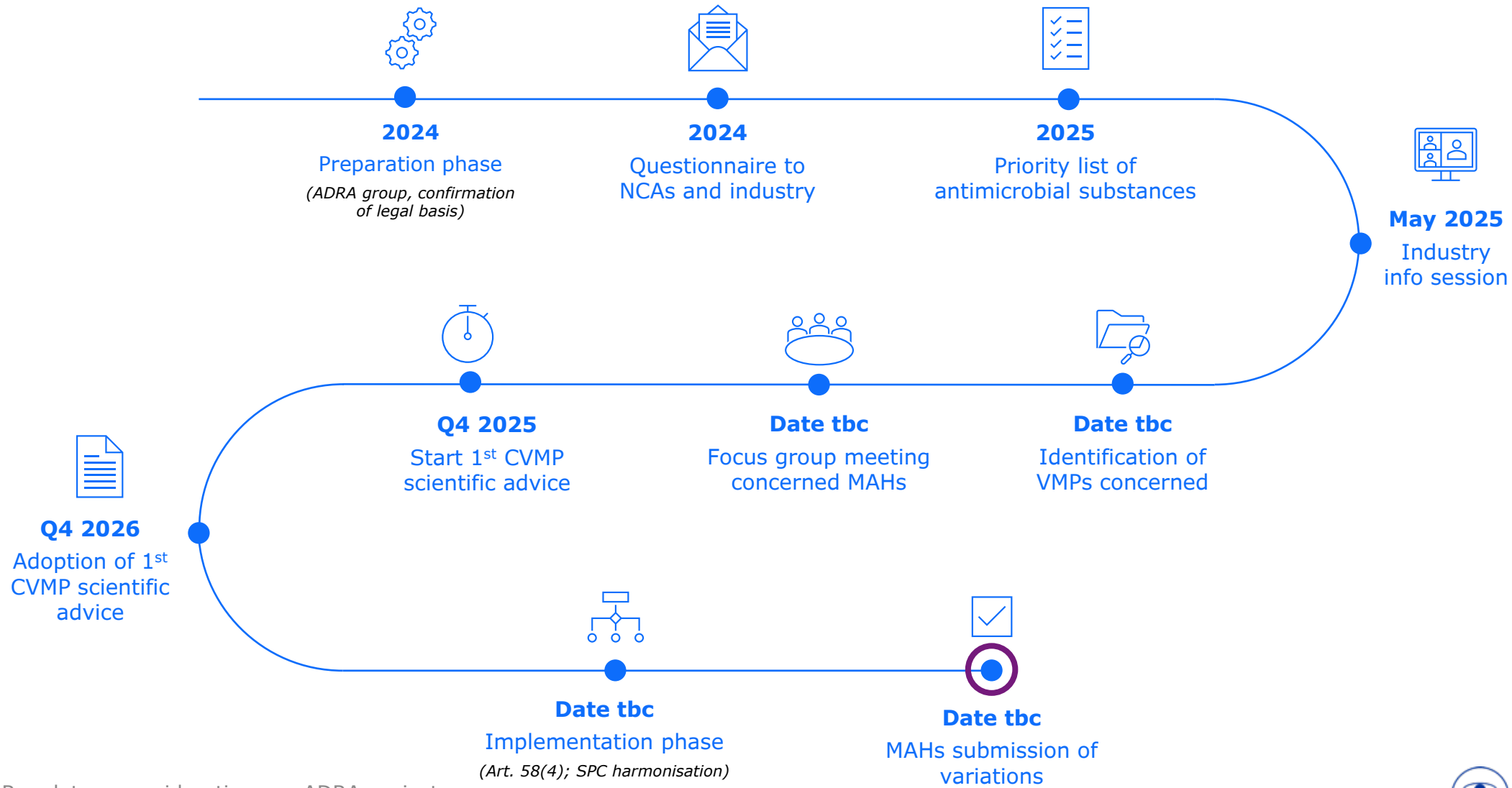
Art. 130(3)(a) Regulation (EU) 2019/6

Scientific advice implemented

Art. 130(3)(a):

"Competent authority/EC may request MAHs to submit a variation to the terms of MA[…] if MAH does not comply with the requirements set out in Article 58".

Timelines ADRA project



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Thank you

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