EU-M4all

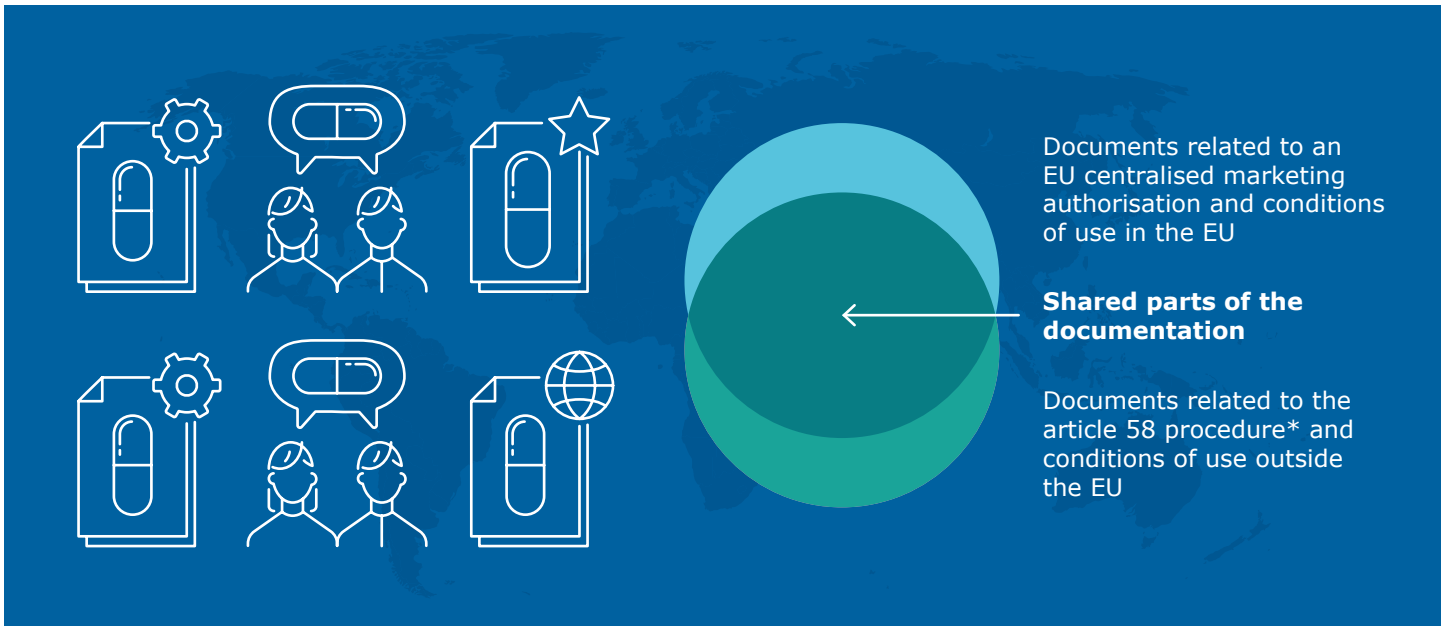
Promoting parallel application for EU-M4all opinion and centralised marketing authorisation procedure

What is it?

- EU-M4all medicines can be evaluated in parallel with a centralised procedure
- Independent outcomes of EU-M4all opinion and centralised marketing authorisation
- Facilitated worldwide access after approval

Eligibility criteria

- Active substances must be identical and indications comparable
- Medicines may have different formulations, forms or routes of administration



Parallel submission process

- Applicant should engage early for EMA scientific advice
- Applicant submits two eligibility requests: for the EU-M4all opinion and for the centralised procedure
- Applicant submits two eCTDs for scientific review
- CHMP carries out the common assessments with WHO, experts and non-EU regulators
- EMA publishes two opinions
- European Commission grants a marketing authorisation for the product evaluated under the centralised procedure and CHMP provides a scientific opinion for the EU-M4all medicine
- The EU-M4all opinion can be used by non-EU regulators for approval
- The respective Risk Management Plans are implemented
- Possible review of the benefit/risk when new data become available

Benefits

- Reduces workload and avoids duplication of efforts
- Same CHMP/PRAC Rapporteur/Co-Rapporteur
- Non-EU regulators see evidence of use of same standards applied for CHMP opinions
- Improves implementation of follow-up measures and pharmacovigilance
- Contributes to making medicines available to children, patients with rare diseases and non-communicable diseases

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* Article 58 of Regulation (EC) No 726/2004