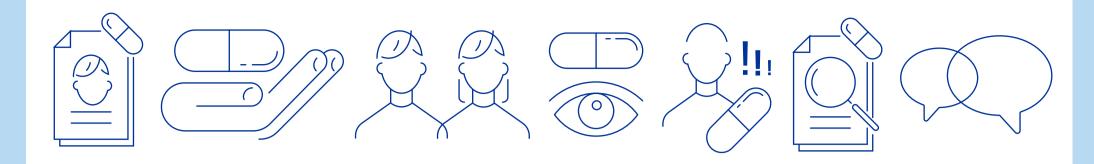
December 2025



5 Safety signals

- 3 Started
- 2 Ongoing and concluded

Periodic safety update reports (PSURs) single assessments

- 47 Recommendations for <u>centrally authorised</u> medicines only
- 15 Recommendations for <u>nationally authorised</u> medicines only
 - 7 Recommendations for PSURs including both centrally and nationally authorised medicines

Risk management plans (RMPs) for centrally authorised medicines

- 15 RMPs reviewed for new medicines
- 47 RMPs reviewed for authorised medicines

11 Post-authorisation safety studies (PASSs)

- 2 Protocols for imposed studies reviewed
- 3 Protocols for non-imposed studies reviewed
- 2 Results from imposed studies reviewed
- 4 Results from non-imposed studies reviewed

1 Referrals

- Started
- 1 Ongoing
- Concluded

