

10 Safety signals

- 6 Started
- 4 Ongoing and concluded

93 Periodic safety update reports (PSURs) single assessments

- 57 Recommendations for <u>centrally authorised</u> medicines only
- 32 Recommendations for <u>nationally authorised</u> medicines only
- 4 Recommendations for PSURs including both centrally and nationally authorised medicines

49 Risk management plans (RMPs) for centrally authorised medicines

- 12 RMPs reviewed for new medicines
- 37 RMPs reviewed for authorised medicines

Post-authorisation safety studies (PASSs)

- 3 Protocols for imposed studies reviewed
- 23 Protocols for non-imposed studies reviewed
- 2 Results from imposed studies reviewed
- 8 Results from non-imposed studies reviewed

1 Referral

- Started
- 1 Ongoing and concluded

