

Safety signals

- 2 Started
- 5 Ongoing and concluded

81 Periodic safety update reports (PSURs) single assessments

- **50** Recommendations for <u>centrally authorised</u> medicines only
- 28 Recommendations for <u>nationally authorised</u> medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

Risk management plans (RMPs) for centrally authorised medicines

- 6 RMPs reviewed for new medicines
- 48 RMPs reviewed for authorised medicines

Post-authorisation safety studies (PASSs)

- Protocol for imposed studies reviewed
- 5 Protocols for non-imposed studies reviewed
- 1 Result from imposed studies reviewed
- 2 Results from non-imposed studies reviewed

Referrals

- Started
- Ongoing
- Concluded