



3

Safety signals

- 2
- Started
- 1
- Ongoing and concluded

57

Periodic safety update reports (PSURs) single assessments

- 37
- Recommendations for
- [centrally authorised](#)
- medicines only
- 19
- Recommendations for
- [nationally authorised](#)
- medicines only
- 1
- Recommendation for PSURs including both centrally and nationally authorised medicines

51

Risk management plans (RMPs) for centrally authorised medicines

- 12
- RMPs reviewed for new medicines
- 39
- RMPs reviewed for authorised medicines

17

Post-authorisation safety studies (PASSs)

- 3
- Protocols for imposed studies reviewed
- 8
- Protocols for non-imposed studies reviewed
- 1
- Result from imposed studies reviewed
- 5
- Results from non-imposed studies reviewed

1

Referrals

- 0
- Started
- 0
- Ongoing
- 1
- Concluded