



2 Safety signals

- 2 Started
- 0 Ongoing and concluded

77 Periodic safety update reports (PSURs) single assessments

- 48 Recommendations for centrally authorised medicines only
- 26 Recommendations for nationally authorised medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

49 Risk management plans (RMPs) for centrally authorised medicines

- 9 RMPs reviewed for new medicines
- 40 RMPs reviewed for authorised medicines

26 Post-authorisation safety studies (PASSs)

- 4 Protocols for imposed studies reviewed
- 9 Protocols for non-imposed studies reviewed
- 3 Results from imposed studies reviewed
- 10 Results from non-imposed studies reviewed

0 Referrals

- 0 Started
- 0 Ongoing
- 0 Concluded