



11 Safety signals

- 9 Started
- 2 Ongoing and concluded

90 Periodic safety update reports (PSURs) single assessments

- 60 Recommendations for centrally authorised medicines only
- 24 Recommendations for nationally authorised medicines only
- 6 Recommendation for PSURs including both centrally and nationally authorised medicines

63 Risk management plans (RMPs) for centrally authorised medicines

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

37 Post-authorisation safety studies (PASSs)

- 1 Protocols for imposed studies reviewed
- 24 Protocols for non-imposed studies reviewed
- 3 Result from imposed studies reviewed
- 9 Results from non-imposed studies reviewed

2 Referrals

- 0 Started
- 2 Ongoing and concluded