



10

Safety signals

- 3 Started
- 7 Ongoing and concluded

77

Periodic safety update reports (PSURs) single assessments

- 54 Recommendations for centrally authorised medicines only
- 13 Recommendations for nationally authorised medicines only
- 10 Recommendation for PSURs including both centrally and nationally authorised medicines

54

Risk management plans (RMPs) for centrally authorised medicines

- 11 RMPs reviewed for new medicines
- 43 RMPs reviewed for authorised medicines

26

Post-authorisation safety studies (PASSs)

- 5 Protocols for imposed studies reviewed
- 14 Protocols for non-imposed studies reviewed
- 1 Results from imposed studies reviewed
- 6 Results from non-imposed studies reviewed

1

Referrals

- 0 Started
- 0 Ongoing
- 1 Concluded