



18

Safety signals

- 11 Started
- 7 Ongoing and concluded

76

Periodic safety update reports (PSURs) single assessments

- 48 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 3 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

18

Post-authorisation safety studies (PASSs)

- 3 Protocols for imposed studies reviewed
- 10 Protocols for non-imposed studies reviewed
- 0 Results from imposed studies reviewed
- 5 Results from non-imposed studies reviewed

1

Referrals

- 0 Started
- 1 Ongoing
- 0 Concluded