PRAC statistics

February 2024

8 Safety signals

- 5 Started
- 3 Ongoing and concluded

65 Periodic safety update reports (PSURs) single assessments

- 43 Recommendations for centrally authorised medicines only
- 21 Recommendations for nationally authorised medicines only
- 1 Recommendation for PSURs including both centrally and nationally authorised medicines

46 Risk management plans (RMPs) for centrally authorised medicines

- 10 RMPs reviewed for new medicines
- 36 RMPs reviewed for authorised medicines

21 Post-authorisation safety studies (PASSs)

- 0 Protocols for imposed studies reviewed
- 15 Protocols for non-imposed studies reviewed
- 0 Results from imposed studies reviewed
- 6 Results from non-imposed studies reviewed

1 Referrals

- 0 Started
- 1 Ongoing