PRAC statistics

January 2024

13 Safety signals

- Started: 9
- Ongoing and concluded: 4

111 Periodic safety update reports (PSURs) single assessments

- Recommendations for centrally authorised medicines only: 77
- Recommendations for nationally authorised medicines only: 31
- Recommendations for PSURs including both centrally and nationally authorised medicines: 3

42 Risk management plans (RMPs) for centrally authorised medicines

- RMPs reviewed for new medicines: 4
- RMPs reviewed for authorised medicines: 38

40 Post-authorisation safety studies (PASSs)

- Protocols for imposed studies reviewed: 2
- Protocols for non-imposed studies reviewed: 22
- Results from imposed studies reviewed: 2
- Results from non-imposed studies reviewed: 14

1 Referral

- Started: 0
- Ongoing and concluded: 1

Direct healthcare professional communications (DHPCs)
PRAC minutes | PRAC recommendations on safety signals | Outcomes of PSUSAs