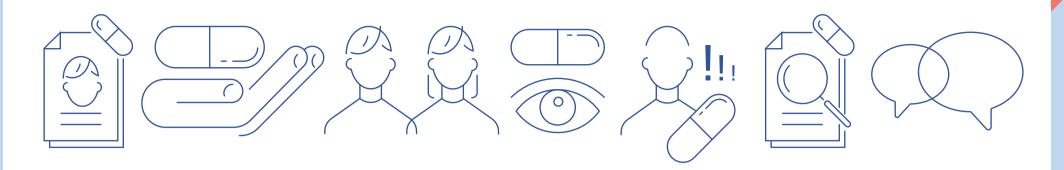




PRAC statistics

October 2022



10 Safety signals

- 5 Started
- 5 Ongoing and concluded

Periodic safety update reports (PSURs) single assessments

- 45 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 4 Recommendations for PSURs including both centrally and nationally authorised medicines

Risk management plans (RMPs) for centrally authorised medicines

- 8 RMPs reviewed for new medicines
- 46 RMPs reviewed for authorised medicines

Post-authorisation safety studies (PASSs)

- 7 Protocols for imposed studies reviewed 4 Results from imposed studies reviewed
- 25 Protocols for non-imposed studies reviewed 5 Results from non-imposed studies reviewed

2 Referrals

- O Started
- 2 Ongoing and concluded