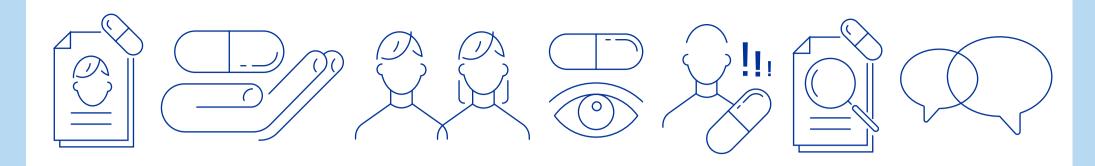
PRAC statistics



11 Safety signals

- 7 Started
- 4 Ongoing and concluded

Periodic safety update reports (PSURs) single assessments

- 45 Recommendations for centrally authorised medicines only
- 13 Recommendations for <u>nationally authorised</u> medicines only
 - 3 Recommendation for PSURs including both centrally and nationally authorised medicines

Risk management plans (RMPs) for centrally authorised medicines

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

Post-authorisation safety studies (PASSs)

- Protocols for imposed studies reviewed
- Protocols for non-imposed studies reviewed
 - 1 Results from imposed studies reviewed
 - 3 Results from non-imposed studies reviewed

