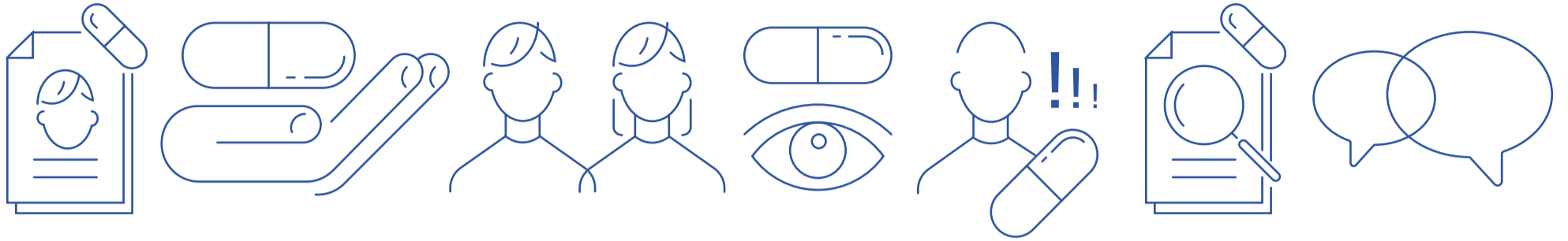




PRAC statistics

April 2023



10 Safety signals

- 5 Started
- 5 Ongoing and concluded

72 Periodic safety update reports (PSURs) single assessments

- 51 Recommendations for centrally authorised medicines only
- 16 Recommendations for nationally authorised medicines only
- 5 Recommendations for PSURs including both centrally and nationally authorised medicines

47 Risk management plans (RMPs) for centrally authorised medicines

- 5 RMPs reviewed for new medicines
- 42 RMPs reviewed for authorised medicines

14 Post-authorisation safety studies (PASSs)

- | | | | |
|---|--|---|---|
| 3 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 9 | Protocols for non-imposed studies reviewed | 2 | Results from non-imposed studies reviewed |

0 Referrals

- 0 Started
- 0 Ongoing and concluded