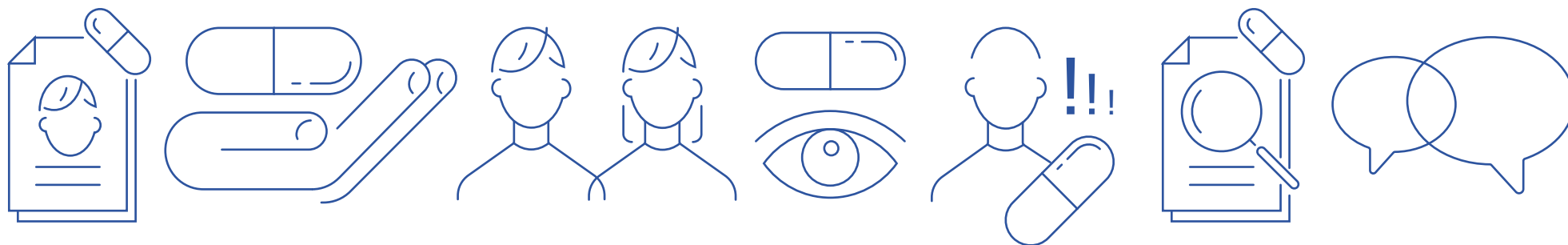




PRAC statistics

November 2021



14 Assessments of safety signals for medicines

- 5 Started
- 9 Ongoing and concluded

63 Periodic safety update reports (PSURs) single assessments

- 42 Recommendations for centrally authorised medicines only
 - 17 Recommendations for nationally authorised medicines only
 - 4 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 14 led to a change in the product information
 - 49 led to no changes

59 Risk management plans (RMPs) for centrally authorised medicines

- 14 RMPs reviewed for new medicines
- 45 RMPs reviewed for authorised medicines

24 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 6 | Protocols for imposed studies reviewed | 2 | Results from imposed studies reviewed |
| 12 | Protocols for non-imposed studies reviewed | 4 | Results from non-imposed studies reviewed |

0 Referrals concluded