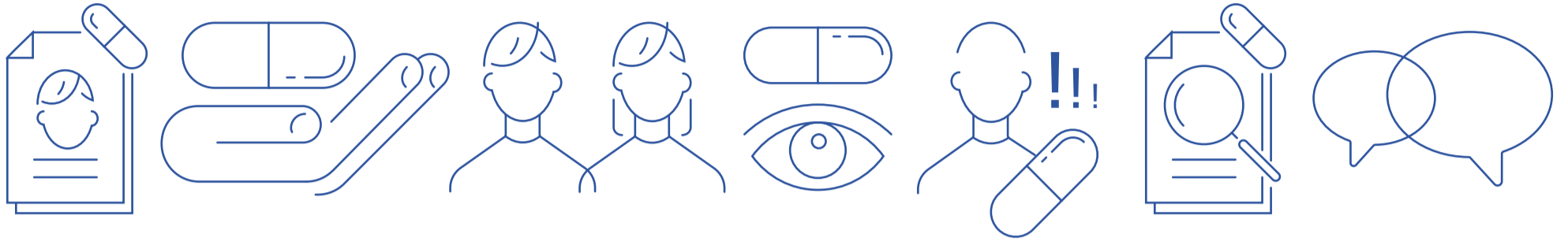




PRAC statistics

December 2021



11 Assessments of safety signals for medicines

- 8 Started
- 3 Ongoing and concluded

108 Periodic safety update reports (PSURs) single assessments

- 59 Recommendations for centrally authorised medicines only
 - 43 Recommendations for nationally authorised medicines only
 - 6 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 24 led to a change in the product information
 - 84 led to no changes

60 Risk management plans (RMPs) for centrally authorised medicines

- 13 RMPs reviewed for new medicines
- 47 RMPs reviewed for authorised medicines

37 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 2 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 25 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

0 Referrals concluded