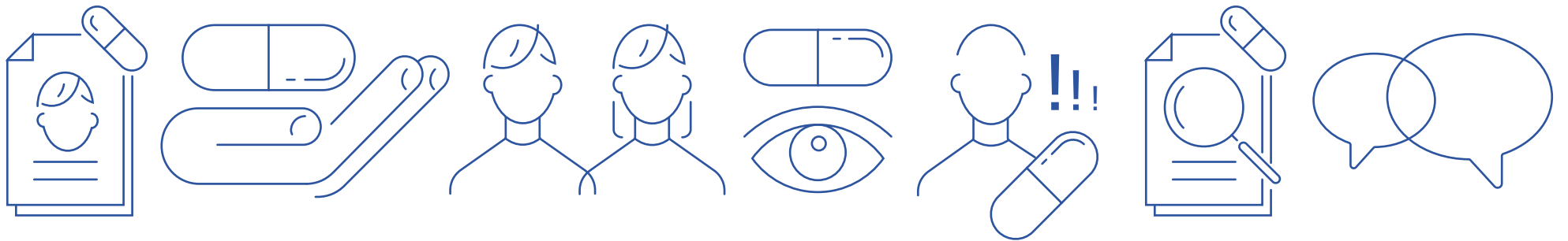




PRAC statistics

April 2020



13 Assessments of safety signals for medicines

- 5 Started
- 8 Ongoing and concluded

76 Periodic safety update reports (PSURs) single assessments

- 56 Recommendations for centrally authorised medicines only
 - 14 Recommendations for nationally authorised medicines only
 - 6 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 9 led to a change in the product information
 - 67 led to no changes

62 Risk management plans (RMPs) for centrally authorised medicines

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

31 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 18 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral concluded for Picato