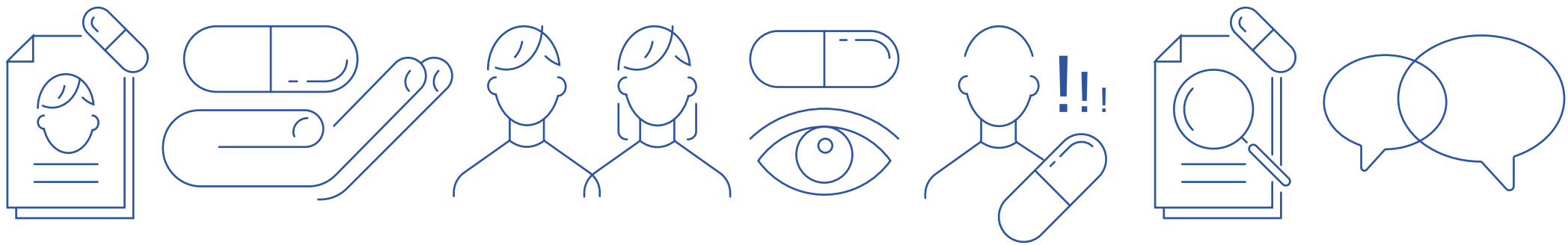




PRAC statistics: September 2019



19 Assessments of safety signals for medicines

- 10 Started
- 9 Ongoing and concluded

105 Periodic safety update reports (PSURs) single assessments

- 73 Recommendations for centrally authorised medicines only
 - 29 Recommendations for nationally authorised medicines only
 - 3 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 20 led to a change in the product information
 - 85 led to no changes

61 Risk management plans (RMPs) for centrally authorised medicines

- 6 RMPs reviewed for new medicines
- 55 RMPs reviewed for authorised medicines

28 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 8 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 15 | Protocols for non-imposed studies reviewed | 5 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral started for Picato