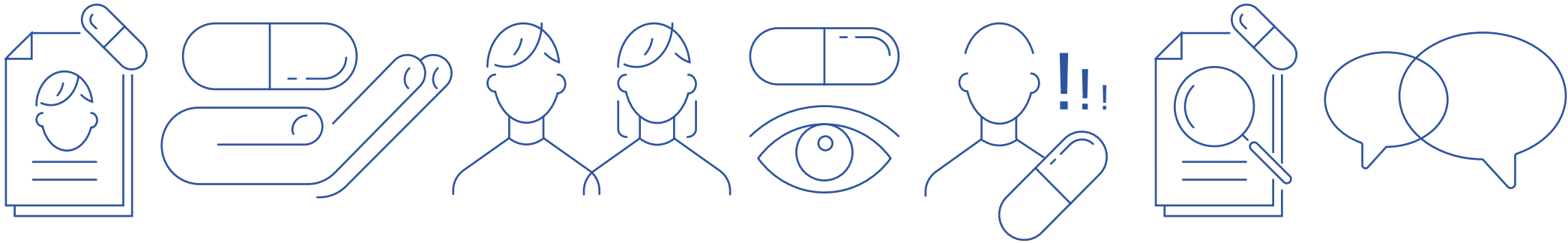




PRAC statistics: December 2019



6 Assessments of safety signals for medicines

- 5 Started
- 1 Ongoing and concluded

58 Periodic safety update reports (PSURs) single assessments

- 39 Recommendations for centrally authorised medicines only
 - 12 Recommendations for nationally authorised medicines only
 - 7 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 9 led to a change in the product information
 - 49 led to no changes

59 Risk management plans (RMPs) for centrally authorised medicines

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

23 Post-authorisation safety studies (PASSs)

- | | | | |
|---|--|---|---|
| 6 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 9 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

1 Referral

- 1 One ongoing referral discussed for fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicines