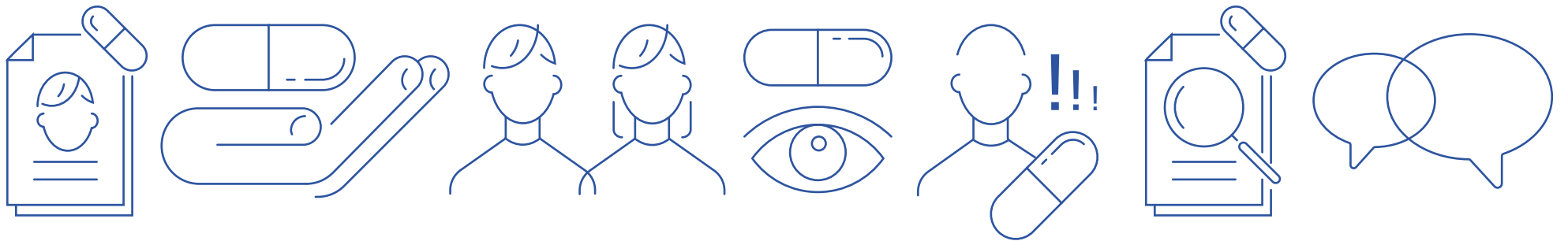




PRAC statistics

June 2020



8 Assessments of safety signals for medicines

- 5 Started
- 3 Ongoing and concluded

59 Periodic safety update reports (PSURs) single assessments

- 43 Recommendations for centrally authorised medicines only
 - 14 Recommendations for nationally authorised medicines only
 - 2 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 8 led to a change in the product information
 - 51 led to no changes

53 Risk management plans (RMPs) for centrally authorised medicines

- 10 RMPs reviewed for new medicines
- 43 RMPs reviewed for authorised medicines

22 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 6 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 12 | Protocols for non-imposed studies reviewed | 4 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral discussed for ulipristal acetate 5mg medicinal products