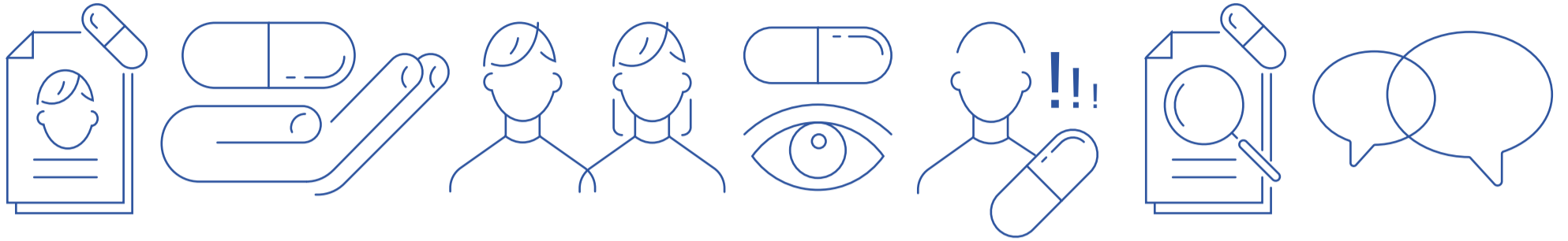




PRAC statistics

September 2020



15 Assessments of safety signals for medicines

- 8 Started
- 7 Ongoing and concluded

87 Periodic safety update reports (PSURs) single assessments

- 60 Recommendations for centrally authorised medicines only
 - 23 Recommendations for nationally authorised medicines only
 - 4 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 14 led to a change in the product information
 - 73 led to no changes

66 Risk management plans (RMPs) for centrally authorised medicines

- 9 RMPs reviewed for new medicines
- 57 RMPs reviewed for authorised medicines

42 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 3 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 27 | Protocols for non-imposed studies reviewed | 12 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral concluded for 5-mg ulipristal acetate medicinal products