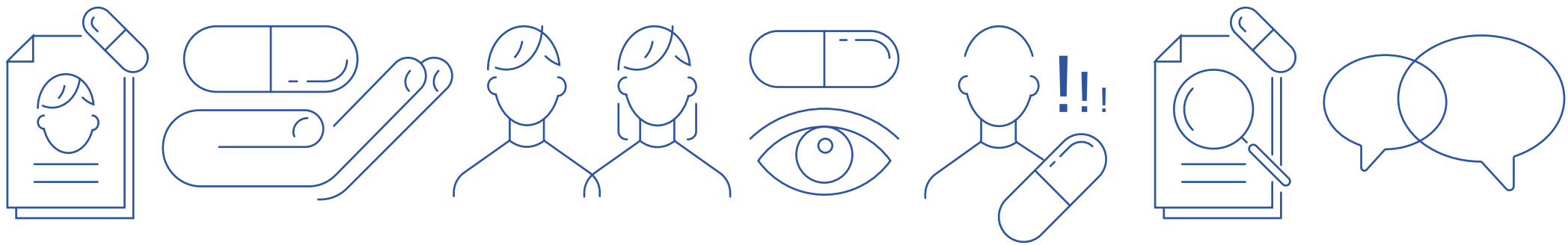




PRAC statistics: October 2019



9 Assessments of safety signals for medicines

- 5 Started
- 4 Ongoing and concluded

68 Periodic safety update reports (PSURs) single assessments

- 46 Recommendations for centrally authorised medicines only
 - 18 Recommendations for nationally authorised medicines only
 - 4 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 11 led to a change in the product information
 - 57 led to no changes

60 Risk management plans (RMPs) for centrally authorised medicines

- 11 RMPs reviewed for new medicines
- 49 RMPs reviewed for authorised medicines

21 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 10 | Protocols for non-imposed studies reviewed | 6 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral concluded for high-strength estradiol creams