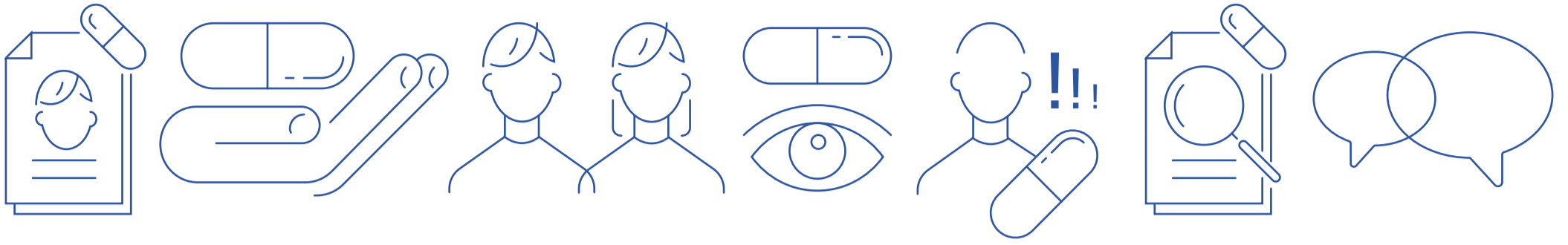




PRAC statistics: January 2020



17 Assessments of safety signals for medicines

- 8 Started
- 9 Ongoing and concluded

88 Periodic safety update reports (PSURs) single assessments

- 59 Recommendations for centrally authorised medicines only
 - 26 Recommendations for nationally authorised medicines only
 - 3 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 14 led to a change in the product information
 - 74 led to no changes

55 Risk management plans (RMPs) for centrally authorised medicines

- 8 RMPs reviewed for new medicines
- 47 RMPs reviewed for authorised medicines

24 Post-authorisation safety studies (PASSs)

- | | | | |
|---|--|----|---|
| 5 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 8 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

2 Referrals

- 1 Referral discussed and provisional suspension of Picato (ingenol mebutate) agreed
- 1 Re-examination concluded for high-strength estradiol creams