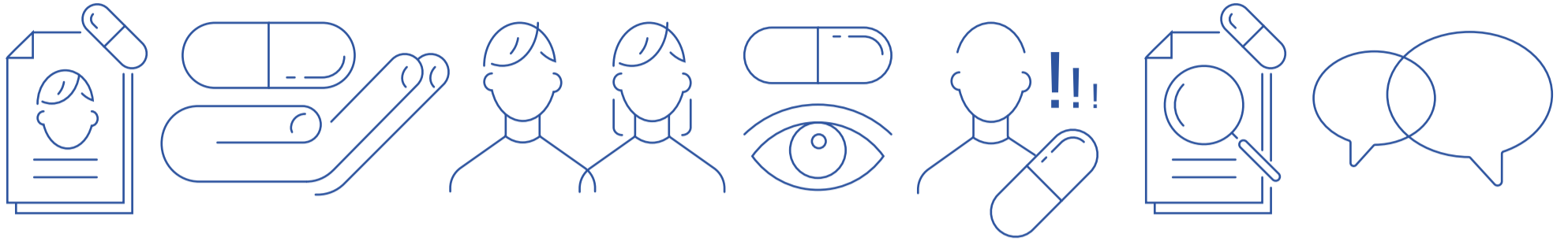




PRAC statistics

October 2020



6 Assessments of safety signals for medicines

- 4 Started
- 2 Ongoing and concluded

101 Periodic safety update reports (PSURs) single assessments

- 59 Recommendations for centrally authorised medicines only
 - 36 Recommendations for nationally authorised medicines only
 - 6 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 7 led to a change in the product information
 - 94 led to no changes

65 Risk management plans (RMPs) for centrally authorised medicines

- 25 RMPs reviewed for new medicines
- 40 RMPs reviewed for authorised medicines

25 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 5 | Protocols for imposed studies reviewed | 2 | Results from imposed studies reviewed |
| 13 | Protocols for non-imposed studies reviewed | 5 | Results from non-imposed studies reviewed |

0 Referrals