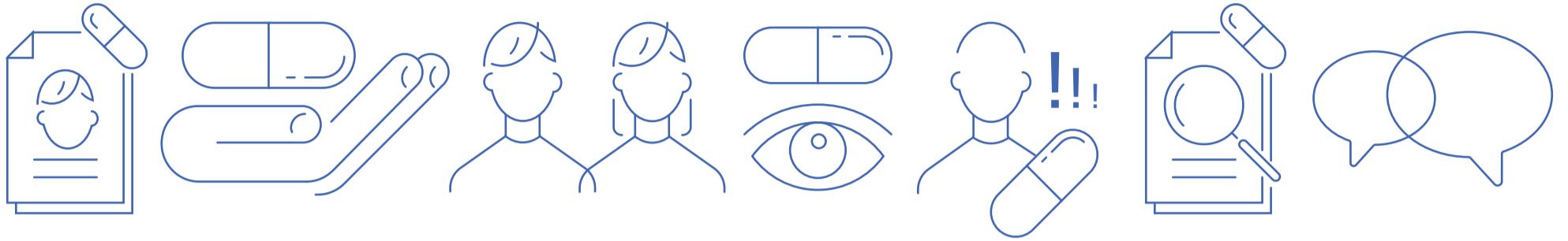




PRAC statistics

September 2021



13 Assessments of safety signals for medicines

- 7 Started
- 6 Ongoing and concluded

106 Periodic safety update reports (PSURs) single assessments

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

71 Risk management plans (RMPs) for centrally authorised medicines

- 15 RMPs reviewed for new medicines
- 56 RMPs reviewed for authorised medicines

43 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 5 | Protocols for imposed studies reviewed | 5 | Result from imposed studies reviewed |
| 22 | Protocols for non-imposed studies reviewed | 11 | Results from non-imposed studies reviewed |

0 Referrals concluded