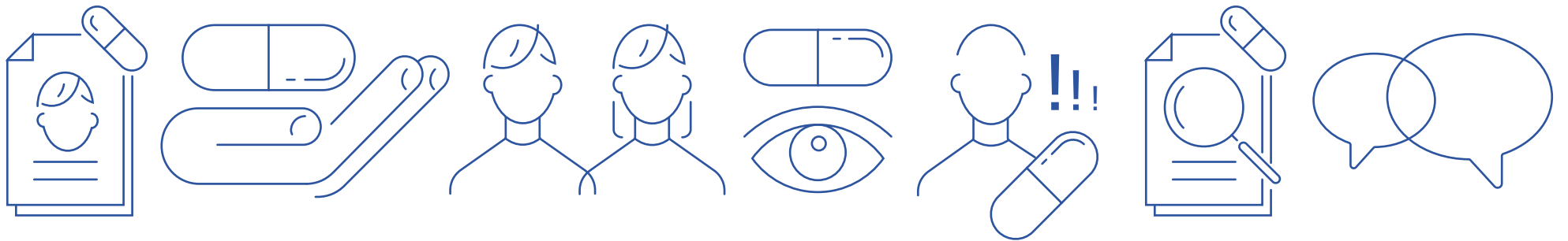




PRAC statistics

April 2021



7 Assessments of safety signals for medicines

- 5 Started
- 2 Ongoing and concluded

66 Periodic safety update reports (PSURs) single assessments

- 47 Recommendations for centrally authorised medicines only
 - 15 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
 - 55 led to no changes

39 Risk management plans (RMPs) for centrally authorised medicines

- 6 RMPs reviewed for new medicines
- 33 RMPs reviewed for authorised medicines

21 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 3 | Results from imposed studies reviewed |
| 10 | Protocols for non-imposed studies reviewed | 4 | Results from non-imposed studies reviewed |

0 Referrals concluded