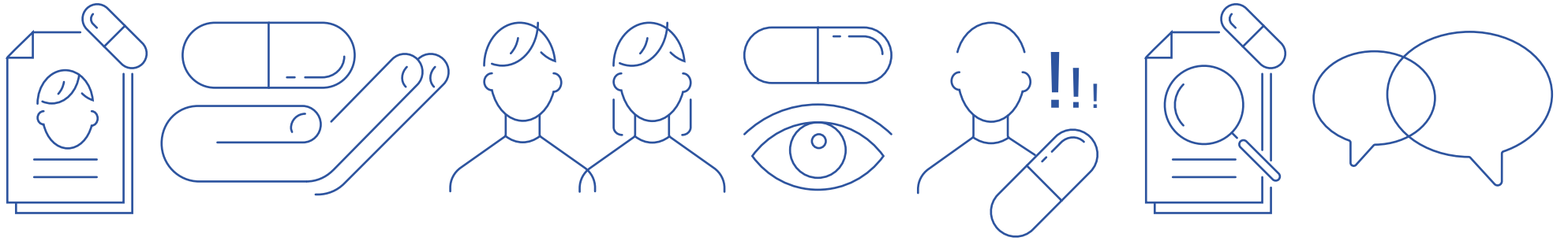




PRAC statistics

May 2021



18 Assessments of safety signals for medicines

- 2 Started
- 16 Ongoing and concluded

42 Periodic safety update reports (PSURs) single assessments

- 28 Recommendations for centrally authorised medicines only
 - 9 Recommendations for nationally authorised medicines only
 - 5 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 8 led to a change in the product information
 - 34 led to no changes

49 Risk management plans (RMPs) for centrally authorised medicines

- 10 RMPs reviewed for new medicines
- 39 RMPs reviewed for authorised medicines

25 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 14 | Protocols for non-imposed studies reviewed | 6 | Results from non-imposed studies reviewed |

0 Referrals concluded