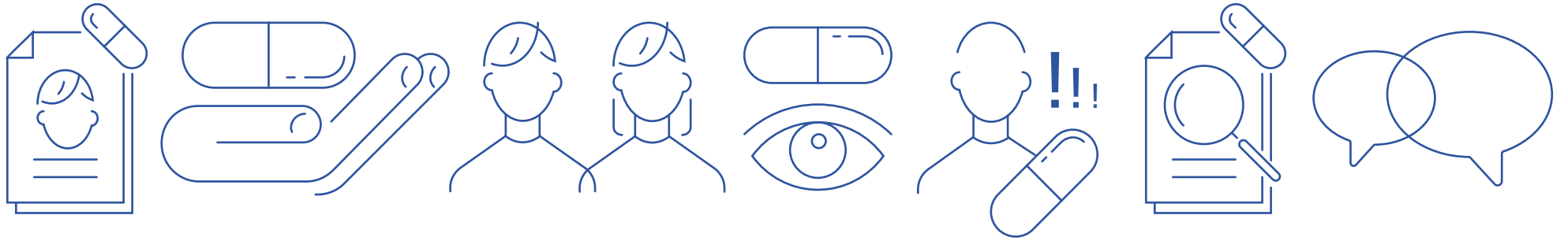




PRAC statistics

July 2021



12 Assessments of safety signals for medicines

- 3 Started
- 9 Ongoing and concluded

57 Periodic safety update reports (PSURs) single assessments

- 39 Recommendations for centrally authorised medicines only
 - 13 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
 - 49 led to no changes

54 Risk management plans (RMPs) for centrally authorised medicines

- 17 RMPs reviewed for new medicines
- 37 RMPs reviewed for authorised medicines

36 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 7 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 18 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

1 Referral concluded