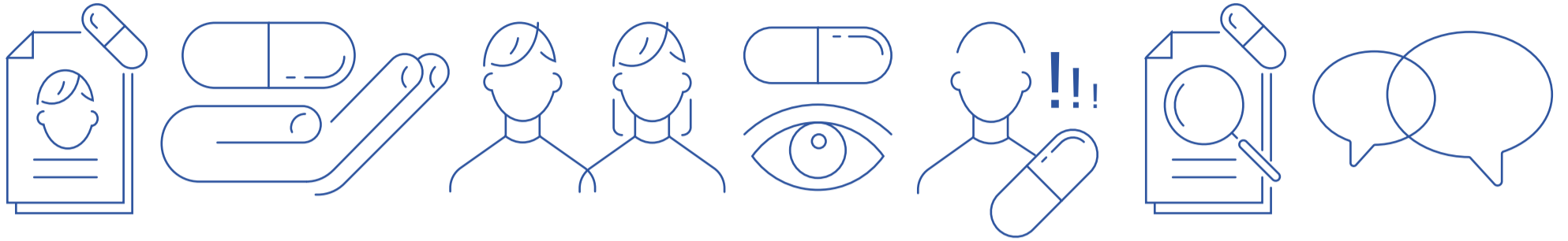




PRAC statistics

March 2021



11 Assessments of safety signals for medicines

- 8 Started
- 3 Ongoing and concluded

75 Periodic safety update reports (PSURs) single assessments

- 44 Recommendations for centrally authorised medicines only
 - 26 Recommendations for nationally authorised medicines only
 - 5 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 13 led to a change in the product information
 - 62 led to no changes

36 Risk management plans (RMPs) for centrally authorised medicines

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

34 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 4 | Protocols for imposed studies reviewed | 2 | Results from imposed studies reviewed |
| 18 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

1 Referral concluded