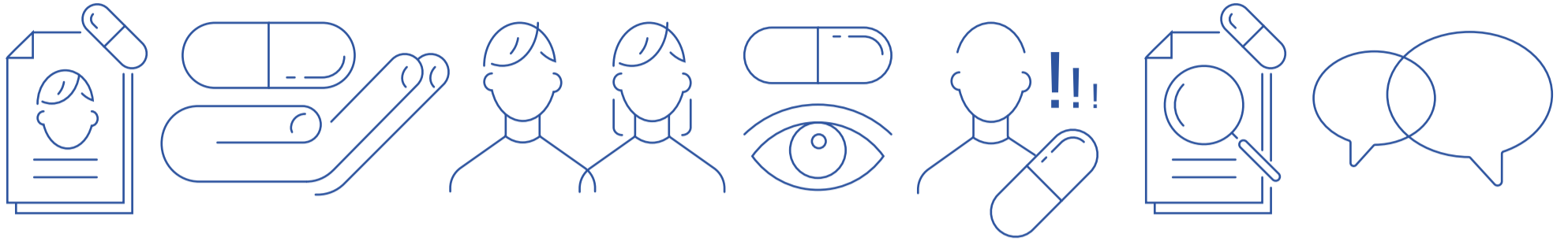




PRAC statistics

February 2021



9 Assessments of safety signals for medicines

- 4 Started
- 5 Ongoing and concluded

69 Periodic safety update reports (PSURs) single assessments

- 43 Recommendations for centrally authorised medicines only
 - 24 Recommendations for nationally authorised medicines only
 - 2 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 11 led to a change in the product information
 - 58 led to no changes

61 Risk management plans (RMPs) for centrally authorised medicines

- 12 RMPs reviewed for new medicines
- 49 RMPs reviewed for authorised medicines

31 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 6 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 15 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

0 Referrals concluded