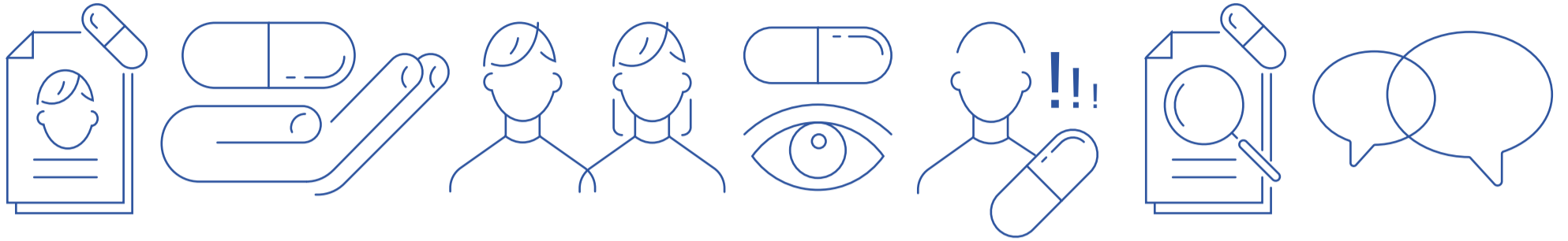




PRAC statistics

January 2021



16 Assessments of safety signals for medicines

- 13 Started
- 3 Ongoing and concluded

126 Periodic safety update reports (PSURs) single assessments

- 76 Recommendations for centrally authorised medicines only
 - 45 Recommendations for nationally authorised medicines only
 - 5 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 21 led to a change in the product information
 - 105 led to no changes

45 Risk management plans (RMPs) for centrally authorised medicines

- 11 RMPs reviewed for new medicines
- 34 RMPs reviewed for authorised medicines

22 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 0 | Result from imposed studies reviewed |
| 12 | Protocols for non-imposed studies reviewed | 6 | Results from non-imposed studies reviewed |

0 Referrals