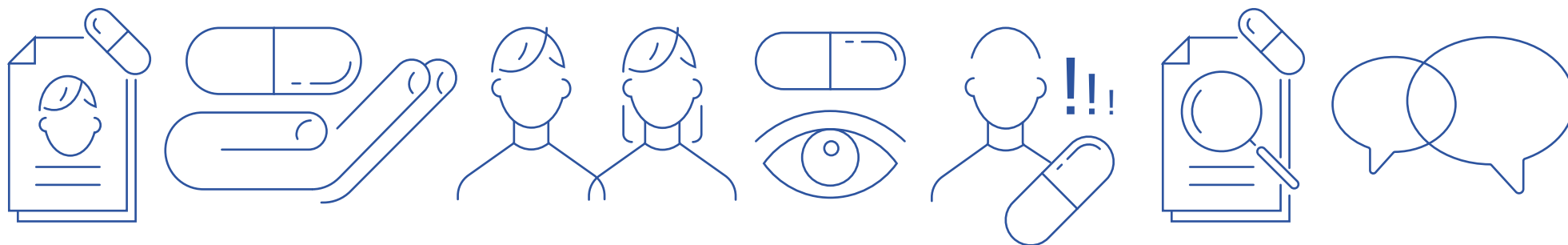




PRAC statistics

November – December 2020



6 Assessments of safety signals for medicines

- 2 Started
- 4 Ongoing and concluded

57 Periodic safety update reports (PSURs) single assessments

- 28 Recommendations for centrally authorised medicines only
 - 22 Recommendations for nationally authorised medicines only
 - 7 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 6 led to a change in the product information
 - 51 led to no changes

57 Risk management plans (RMPs) for centrally authorised medicines

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

31 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 3 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 17 | Protocols for non-imposed studies reviewed | 10 | Results from non-imposed studies reviewed |

0 Referrals

Direct healthcare professional communications (DHPCs)

PRAC minutes | PRAC recommendations on safety signals | Outcomes of PSUSAs