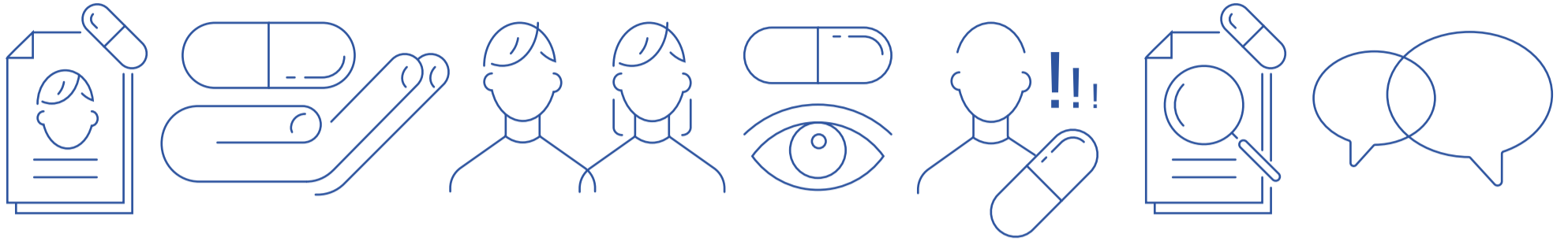




PRAC statistics

October – November 2020



10 Assessments of safety signals for medicines

- 3 Started
- 7 Ongoing and concluded

51 Periodic safety update reports (PSURs) single assessments

- 39 Recommendations for centrally authorised medicines only
 - 9 Recommendations for nationally authorised medicines only
 - 3 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 12 led to a change in the product information
 - 39 led to no changes

37 Risk management plans (RMPs) for centrally authorised medicines

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

22 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 4 | Protocols for imposed studies reviewed | 0 | Result from imposed studies reviewed |
| 10 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral discussed for ifosfamide solutions