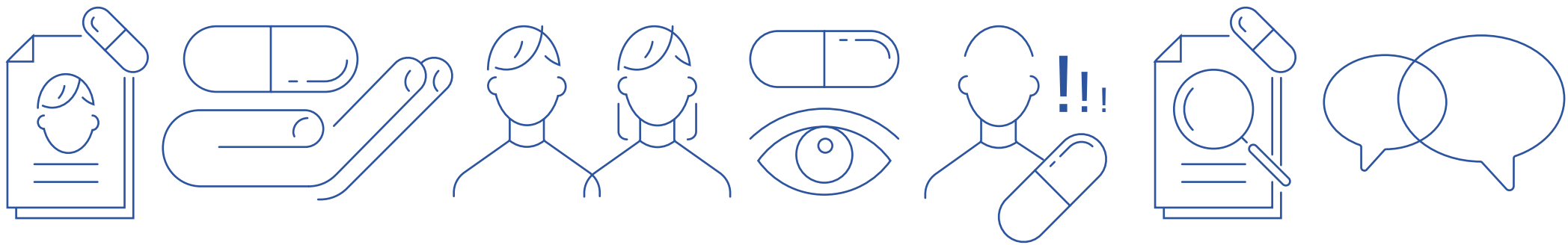




PRAC statistics: November 2019



14 Assessments of safety signals for medicines

- 7 Started
- 7 Ongoing and concluded

59 Periodic safety update reports (PSURs) single assessments

- 40 Recommendations for centrally authorised medicines only
 - 14 Recommendations for nationally authorised medicines only
 - 5 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 8 led to a change in the product information
 - 51 led to no changes

39 Risk management plans (RMPs) for centrally authorised medicines

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

27 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 8 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 11 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

2 Referral

- 1 Referral concluded for Lemtrada (alemtuzumab)
- 1 Referral concluded for Xeljanz (tofacitinib)