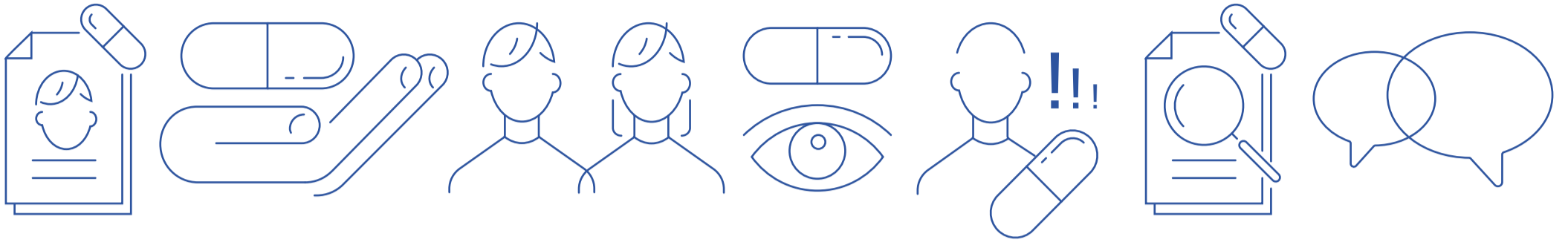




PRAC statistics: May 2019



18 Assessments of safety signals for medicines

- 11 Started
- 7 Ongoing and concluded

83 Periodic safety update reports (PSURs) single assessments

- 55 Recommendations for centrally authorised medicines only
- 21 Recommendations for nationally authorised medicines only
- 7 Recommendations for PSURs including both centrally and nationally authorised medicines

-
- 19 led to a change in the product information
 - 64 led to no changes

64 Risk management plans (RMPs) for centrally authorised medicines

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

18 Post-authorisation safety studies (PASSs)

- | | | | |
|---|--|---|---|
| 1 | Protocol for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 8 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

3 Referrals

- 1 Referral started for Xeljanz (tofacitinib)
- 1 Referral concluded for medicines containing fenspiride
- 1 Ongoing referral discussed for medicines containing methotrexate