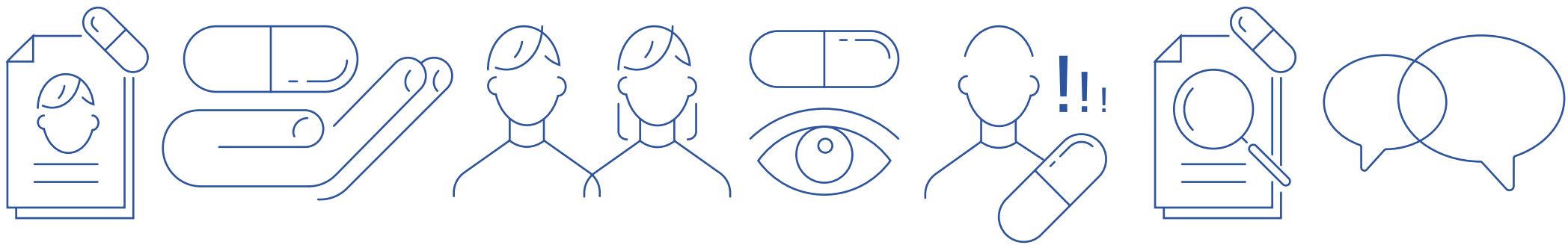




PRAC statistics: July 2019



6 Assessments of safety signals for medicines

- 1 Started
- 5 Ongoing and concluded

84 Periodic Safety Update Reports (PSURs) single assessments

- 53 Recommendations for centrally authorised medicines only
 - 21 Recommendations for nationally authorised medicines only
 - 10 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 23 led to a change in the product information
 - 61 led to no changes

49 Risk management plans (RMPs) for centrally authorised medicines

- 7 RMPs reviewed for new medicines
- 42 RMPs reviewed for authorised medicines

33 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 10 | Protocols for imposed studies reviewed | 0 | Results from imposed studies reviewed |
| 17 | Protocols for non-imposed studies reviewed | 6 | Results from non-imposed studies reviewed |

5 Referrals

- 1 Referral started for cyproterone medicines
- 1 Referral concluded for medicines containing methotrexate
- 3 Ongoing referrals discussed for Lemtrada, for estradiol-containing medicinal products, and for fluorouracil and fluorouracil related substances