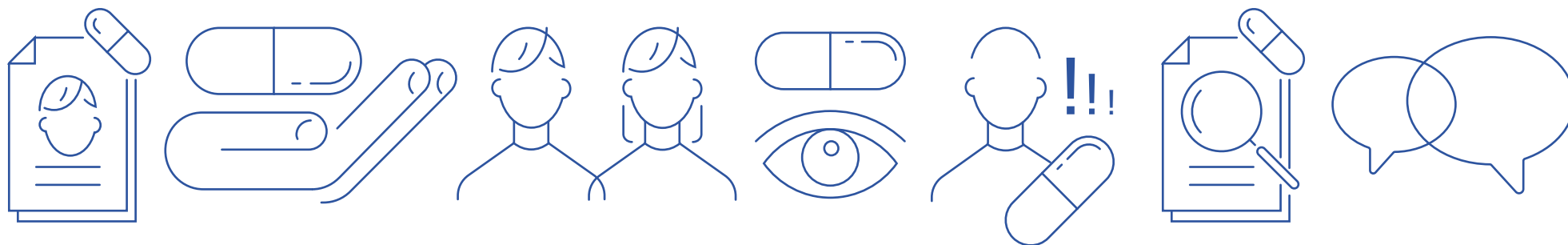




PRAC statistics

March 2020



12 Assessments of safety signals for medicines

- 6 Started
- 6 Ongoing and concluded

55 Periodic safety update reports (PSURs) single assessments

- 43 Recommendations for centrally authorised medicines only
 - 11 Recommendations for nationally authorised medicines only
 - 1 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 7 led to a change in the product information
 - 48 led to no changes

65 Risk management plans (RMPs) for centrally authorised medicines

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

33 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 3 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 16 | Protocols for non-imposed studies reviewed | 13 | Results from non-imposed studies reviewed |

3 Referrals

- 1 Referral started for ifosfamide cancer medicines
- 1 Referral started for ulipristal acetate (Esmya and generic medicines)
- 1 Referral concluded for fluorouracil and fluorouracil related substances