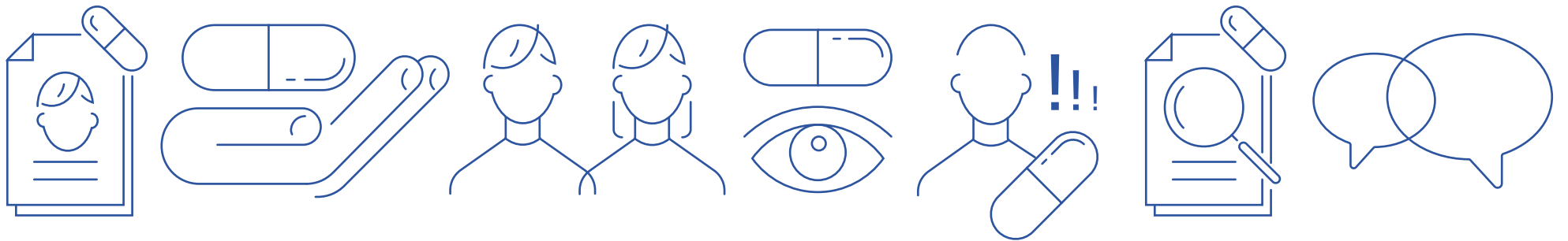




PRAC statistics

July 2020



9 Assessments of safety signals for medicines

- 4 Started
- 5 Ongoing and concluded

72 Periodic safety update reports (PSURs) single assessments

- 45 Recommendations for centrally authorised medicines only
 - 19 Recommendations for nationally authorised medicines only
 - 8 Recommendation for PSURs including both centrally and nationally authorised medicines
-
- 12 led to a change in the product information
 - 60 led to no changes

46 Risk management plans (RMPs) for centrally authorised medicines

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

32 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 4 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 12 | Protocols for non-imposed studies reviewed | 15 | Results from non-imposed studies reviewed |

2 Referrals

- 1 Referral discussed for ulipristal acetate 5mg medicinal products
- 1 Referral discussed for Ifosfamide solutions