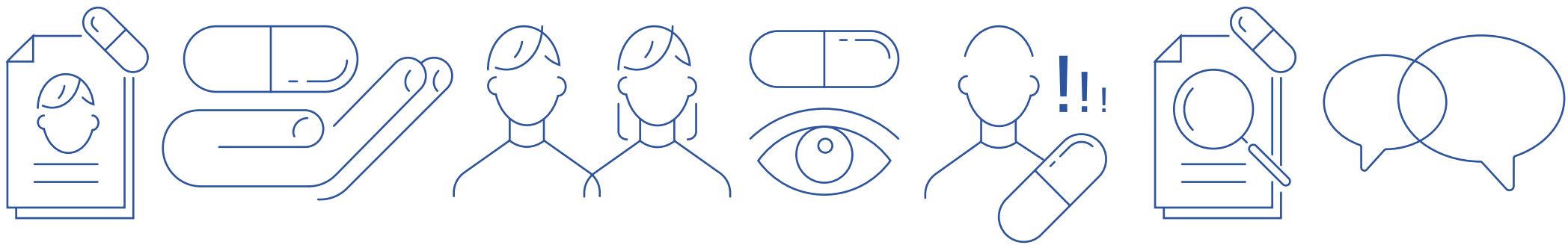




PRAC statistics: June 2019



11 Safety signals

- 3 Started
- 8 Ongoing and concluded

75 Periodic safety update reports (PSURs) single assessments

- 53 Recommendations for centrally authorised medicines only
 - 18 Recommendations for nationally authorised medicines only
 - 4 Recommendations for both centrally and nationally authorised medicines
-
- 15 led to a change in the product information
 - 60 led to no changes

63 Risk management plans (RMPs) for centrally authorised medicines

- 13 RMPs reviewed for new medicines
- 50 RMPs reviewed for authorised medicines

47 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|----|---|
| 7 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 28 | Protocols for non-imposed studies reviewed | 11 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral started for leuprorelin medicines