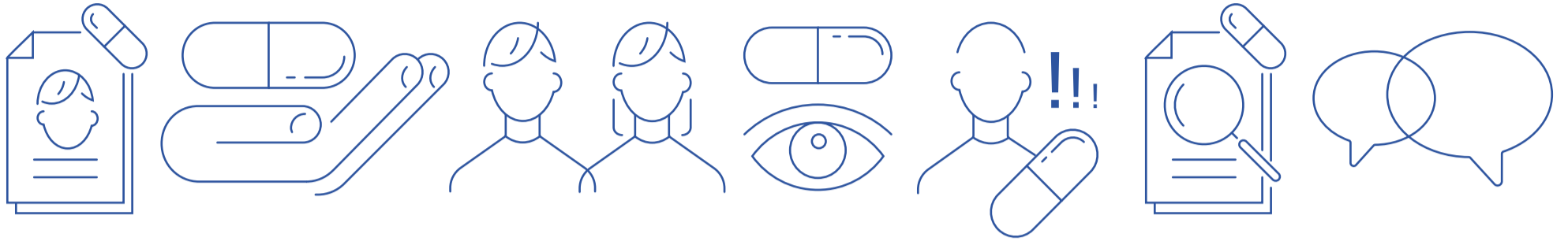




PRAC statistics

May 2020



12 Assessments of safety signals for medicines

- 3 Started
- 9 Ongoing and concluded

65 Periodic safety update reports (PSURs) single assessments

- 37 Recommendations for centrally authorised medicines only
 - 24 Recommendations for nationally authorised medicines only
 - 4 Recommendations for PSURs including both centrally and nationally authorised medicines
-
- 14 led to a change in the product information
 - 51 led to no changes

48 Risk management plans (RMPs) for centrally authorised medicines

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

20 Post-authorisation safety studies (PASSs)

- | | | | |
|----|--|---|---|
| 2 | Protocols for imposed studies reviewed | 2 | Results from imposed studies reviewed |
| 10 | Protocols for non-imposed studies reviewed | 6 | Results from non-imposed studies reviewed |

1 Referral

- 1 Referral concluded for Leuprorelin depot medicines