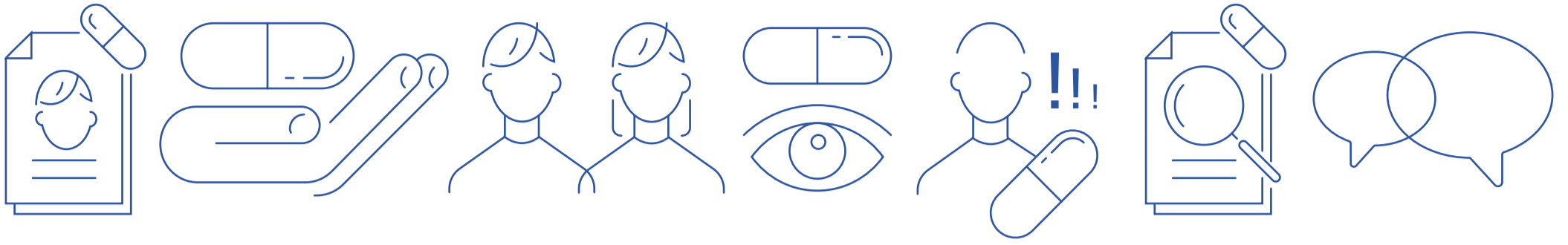




# PRAC statistics: February 2020



## 12 Assessments of safety signals for medicines

- 8 Started
- 4 Ongoing and concluded

## 46 Periodic safety update reports (PSURs) single assessments

- 34 Recommendations for centrally authorised medicines only
  - 11 Recommendations for nationally authorised medicines only
  - 1 Recommendations for PSURs including both centrally and nationally authorised medicines
- 
- 6 led to a change in the product information
  - 40 led to no changes

## 54 Risk management plans (RMPs) for centrally authorised medicines

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

## 28 Post-authorisation safety studies (PASSs)

- |   |  |   |   |
|---|--|---|---|
| 9 | Protocols for imposed studies reviewed     | 2 | Results from imposed studies reviewed     |
| 9 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

## 1 Referral

- 1 Referral concluded for cyproterone containing medicines