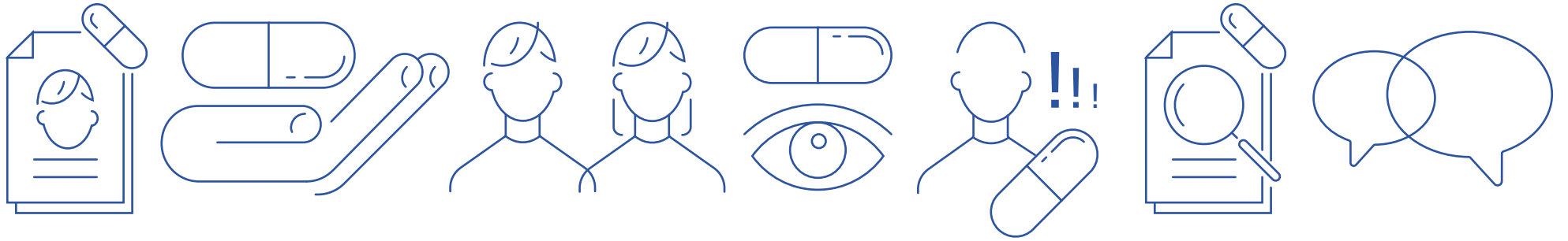




# PRAC statistics

July 2023



## 7 Safety signals

- 6 Started
- 1 Ongoing/concluded

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

- 50 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 3 Recommendations for PSURs including both centrally and nationally authorised medicines

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

- 8 RMPs reviewed for new medicines
- 48 RMPs reviewed for authorised medicines

## 30 Post-authorisation safety studies (PASSs)

- |    |  |   |   |
|----|--|---|---|
| 3  | Protocols for imposed studies reviewed     | 2 | Results from imposed studies reviewed     |
| 16 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

## 0 Referrals

- 0 Started
- 0 Ongoing/concluded