

#### 8 Safety signals

- 3 Started
- 5 Ongoing and concluded

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

- 49 Recommendations for <u>centrally authorised</u> medicines only
- 19 Recommendations for <u>nationally authorised</u> medicines only
  - 6 Recommendation for PSURs including both centrally and nationally authorised medicines

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

- 9 RMPs reviewed for new medicines
- 43 RMPs reviewed for authorised medicines

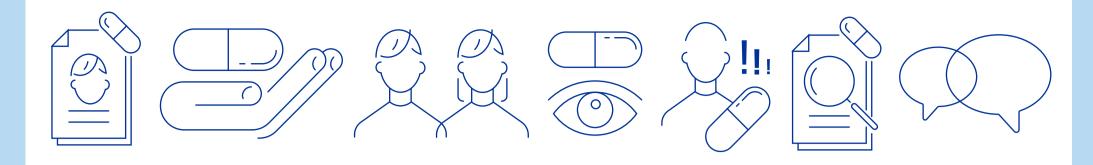
#### Post-authorisation safety studies (PASSs)

- 2 Protocols for imposed studies reviewed
- 9 Protocols for non-imposed studies reviewed
- 2 Results from imposed studies reviewed
- 13 Results from non-imposed studies reviewed

### 0 <u>Referrals</u>

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# PRAC meeting highlights

## December 2024

8 Safety signals

74 Periodic safety update reports single assessments

Risk management plans for centrally authorised medicines

Post-authorisation safety studies

Referral

