## PRAC statistics

### Risk management plans (RMPs) for centrally authorised medicines
- **71** RMPs reviewed for centrally authorised medicines
  - **15** RMPs reviewed for new medicines
  - **56** RMPs reviewed for authorised medicines

### Assessments of safety signals for medicines
- **13** Assessments of safety signals for medicines
  - **7** Started
  - **6** Ongoing and concluded

### Periodic safety update reports (PSURs) single assessments
- **106** PSURs single assessments
  - **57** Recommendations for centrally authorised medicines only
  - **46** Recommendations for nationally authorised medicines only
  - **3** Recommendations for PSURs including both centrally and nationally authorised medicines
  - **19** led to a change in the product information
  - **87** led to no changes

### Post-authorisation safety studies (PASSs)
- **43** PASSs
  - **5** Protocols for imposed studies reviewed
  - **22** Protocols for non-imposed studies reviewed
  - **5** Result from imposed studies reviewed
  - **11** Results from non-imposed studies reviewed

### Referrals concluded
- **0** Referrals concluded

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Direct healthcare professional communications (DHPCs)

PRAC minutes | PRAC recommendations on safety signals | Outcomes of PSUSAs

September 2021