



11 Safety signals

- 7 Started
- 4 Ongoing and concluded

140 Periodic safety update reports (PSURs) single assessments

- 78 Recommendations for centrally authorised medicines only
- 57 Recommendations for nationally authorised medicines only
- 5 Recommendations for PSURs including both centrally and nationally authorised medicines

56 Risk management plans (RMPs) for centrally authorised medicines

- 5 RMPs reviewed for new medicines
- 51 RMPs reviewed for authorised medicines

27 Post-authorisation safety studies (PASSs)

- 0 Protocols for imposed studies reviewed
- 18 Protocols for non-imposed studies reviewed
- 1 Result from imposed studies reviewed
- 8 Results from non-imposed studies reviewed

1 Referrals

- 0 Started
- 1 Ongoing
- 0 Concluded