



5 Safety signals

- 4 Started
- 1 Ongoing and concluded

109 Periodic safety update reports (PSURs) single assessments

- 65 Recommendations for [centrally authorised](#) medicines only
- 41 Recommendations for [nationally authorised](#) medicines only
- 3 Recommendation for PSURs including both centrally and nationally authorised medicines

67 Risk management plans (RMPs) for centrally authorised medicines

- 13 RMPs reviewed for new medicines
- 54 RMPs reviewed for authorised medicines

30 Post-authorisation safety studies (PASSs)

- 3 Protocols for imposed studies reviewed
- 13 Protocols for non-imposed studies reviewed
- 2 Results from imposed studies reviewed
- 12 Results from non-imposed studies reviewed

1 Referrals

- 0 Started
- 0 Ongoing
- 1 Concluded