



11

Safety signals

- 6 Started
- 5 Ongoing and concluded

84

Periodic safety update reports (PSURs) single assessments

- 46 Recommendations for centrally authorised medicines only
- 33 Recommendations for nationally authorised medicines only
- 5 Recommendation for PSURs including both centrally and nationally authorised medicines

59

Risk management plans (RMPs) for centrally authorised medicines

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

39

Post-authorisation safety studies (PASSs)

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|----|--|---|---|
| 6 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 24 | Protocols for non-imposed studies reviewed | 8 | Results from non-imposed studies reviewed |

4

Referrals

- 2 Started
- 1 Ongoing and concluded
- 1 Under re-examination