



6

Safety signals

- 4 Started
- 2 Ongoing and concluded

95

Periodic safety update reports (PSURs) single assessments

- 52 Recommendations for centrally authorised medicines only
- 37 Recommendations for nationally authorised medicines only
- 6 Recommendation for PSURs including both centrally and nationally authorised medicines

52

Risk management plans (RMPs) for centrally authorised medicines

- 8 RMPs reviewed for new medicines
- 44 RMPs reviewed for authorised medicines

25

Post-authorisation safety studies (PASSs)

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|----|--|---|---|
| 6 | Protocols for imposed studies reviewed | 0 | Result from imposed studies reviewed |
| 14 | Protocols for non-imposed studies reviewed | 5 | Results from non-imposed studies reviewed |

2

Referrals

- 0 Started
- 2 Ongoing and concluded