



10 Safety signals

- 6 Started
- 4 Ongoing and concluded

99 Periodic safety update reports (PSURs) single assessments

- 67 Recommendations for centrally authorised medicines only
- 28 Recommendations for nationally authorised medicines only
- 4 Recommendation for PSURs including both centrally and nationally authorised medicines

52 Risk management plans (RMPs) for centrally authorised medicines

- 7 RMPs reviewed for new medicines
- 45 RMPs reviewed for authorised medicines

36 Post-authorisation safety studies (PASSs)

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| 9 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 23 | Protocols for non-imposed studies reviewed | 3 | Results from non-imposed studies reviewed |

1 Referrals

- 0 Started
- 1 Ongoing/concluded