



12 Safety signals

- 6 Started
- 6 Ongoing and concluded

121 Periodic safety update reports (PSURs) single assessments

- 79 Recommendations for centrally authorised medicines only
- 37 Recommendations for nationally authorised medicines only
- 5 Recommendation for PSURs including both centrally and nationally authorised medicines

49 Risk management plans (RMPs) for centrally authorised medicines

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

28 Post-authorisation safety studies (PASSs)

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| 3 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 15 | Protocols for non-imposed studies reviewed | 9 | Results from non-imposed studies reviewed |

3 Referrals

- 0 Started
- 3 Ongoing