



10 Safety signals

- 5 Started
- 5 Ongoing and concluded

77 Periodic safety update reports (PSURs) single assessments

- 46 Recommendations for centrally authorised medicines only
- 25 Recommendations for nationally authorised medicines only
- 6 Recommendation for PSURs including both centrally and nationally authorised medicines

58 Risk management plans (RMPs) for centrally authorised medicines

- 10 RMPs reviewed for new medicines
- 48 RMPs reviewed for authorised medicines

22 Post-authorisation safety studies (PASSs)

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| 3 | Protocols for imposed studies reviewed | 1 | Result from imposed studies reviewed |
| 13 | Protocols for non-imposed studies reviewed | 5 | Results from non-imposed studies reviewed |

1 Referrals

- 0 Started
- 1 Ongoing