



9 Safety signals

- 4 Started
- 5 Ongoing and concluded

64 Periodic safety update reports (PSURs) single assessments

- 39 Recommendations for centrally authorised medicines only
- 24 Recommendations for nationally authorised medicines only
- 1 Recommendation for PSURs including both centrally and nationally authorised medicines

42 Risk management plans (RMPs) for centrally authorised medicines

- 12 RMPs reviewed for new medicines
- 30 RMPs reviewed for authorised medicines

27 Post-authorisation safety studies (PASSs)

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| 4 | Protocols for imposed studies reviewed | 2 | Result from imposed studies reviewed |
| 17 | Protocols for non-imposed studies reviewed | 4 | Results from non-imposed studies reviewed |

2 Referrals

- 1 Concluded
- 1 Re-examination concluded