

Supplementary Table SI. Four grid table of the proportional imbalance methods

| Drug class | Number of reports of the target adverse events | Number of reports of the other adverse events | Total |
|-------------------|---|--|-------------------|
| Cabergoline | a | b | a + b |
| Other drugs | c | d | c + d |
| Total | a + c | b + d | N = a + b + c + d |

Note: a: the number of reports containing both the suspect drug and the suspect adverse events; b: the number of reports containing the suspect drug with other adverse events (except the event of interest); c: the number of reports containing the suspect adverse events with other medications (except the drug of interest); d: the number of reports containing other medications and other adverse events; N: the number of all reports.

Supplementary Table SII. Formulas and thresholds of the four algorithms

| Algorithms | Equation | Criteria |
|------------|--|---|
| ROR | $\text{ROR} = \frac{a/c}{b/d}$ $\text{SE} (\ln\text{ROR}) = \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}$ $95\% \text{CI} = e^{\ln (\text{ROR}) \pm 1.96\text{se}}$ | $a \geq 3$, $\text{ROR} \geq 3$, $95\% \text{CI}$ (low limit) > 1 |
| PRR | $\text{PRR} = \frac{a / (a+b)}{c / (c+d)}$ $\text{SE} (\ln\text{PRR}) = \sqrt{\frac{1}{a} - \frac{1}{a+b} + \frac{1}{c} - \frac{1}{c+d}}$ $95\% \text{CI} = e^{\ln (\text{PRR}) \pm 1.96\text{se}}$ | $A \geq 3$, $\text{PRR} \geq 2$, $95\% \text{CI}$ (low limit) > 1 |
| BCPNN | $\text{IC} = \log_2 \frac{a (a+b+c+d)}{(a+b) (a+c)}$ $\text{E} (\text{IC}) = \log_2 \frac{(a+\gamma+1) (a+b+c+d+a) (a+b+c+d+\beta)}{(a+b+c+d+\gamma) (a+b+a) (a+c+\beta)}$ $\text{V} (\text{IC}) = \frac{1}{(\ln 2)^2} \left[\frac{(a+b+c+d) - a + \gamma - \gamma+1}{(a+\gamma+1) (1+a+b+c+d+\gamma)} + \frac{(a+b+c+d) - (a+b) + a - a}{(a+b+a) (1+a+b+c+d+a)} + \frac{(a+b+c+d+a) - (a+c) + \beta - \beta}{(a+b+\beta) (1+a+b+c+d+\beta)} \right]$ $\gamma = \gamma+1 \frac{(a+b+c+d+a) (a+b+c+d+\beta)}{(a+b+a) (a+c+\beta)}$ $\text{IC} - 2\text{SD} = \text{E} (\text{IC}) - 2 \sqrt{\text{V} (\text{IC})}$ | $\text{IC}_{025} > 0$ |
| EBGM | $\text{EBGM} = \frac{a (a+b+c+d)}{(a+c) (a+b)}$ $\text{SE} (\ln\text{EBGM}) = \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}$ $95\% \text{CI} = e^{\ln (\text{EBGM}) \pm 1.96\text{se}}$ | $\text{EBGM}_{05} > 2$ |

Note: a, the number of reports containing both the suspect drug and the suspect adverse events; b, the number of reports containing the suspect drug with other adverse events (except the event of interest); c, the number of reports containing the suspect adverse events with other medications (except the drug of interest); d, the number of reports containing other medications and other adverse events.

Abbreviations: ROR, Reporting Odds Ratio; PRR, Proportional Reporting Ratio; BCPNN, Bayesian Confidence Propagation Neural Network; EBGM, Empirical Bayes Geometric Mean.

Supplementary Table SIII. The criteria and corresponding scores used to prioritize AEs identified through disproportionality analysis

| Criterion | 2 Points | 1 Point | 0 Points |
|---|-----------------|----------------|-----------------|
| Reporting rate (cases/non-cases) | >10% | 1–10% | 0-1% |
| Signal stability (consistency across disproportionality analyses) | 3 of 3 | 2 of 3 | 1 of 3 |
| Reported case fatality rate (proportion of reports with death as outcome) | >50% | 25–50% | <25% |
| Clinical relevance (serious likely drug-attributable AEs) | DME | IME | None |

Abbreviations: AEs, adverse events, DME, designated medical event, IME, important medical event.

Supplementary Table SIV. Signal strength of AE for cabergoline at the SOC level

| SOC | Cases | ROR (95%CI) | PRR (χ^2) | EBGM | |
|---|-------|----------------------|------------------|---------------|-----------------|
| | | | | (EBGM05) | IC (IC025) |
| General disorders and administration site conditions | 1103 | 0.64 (0.6 - 0.68) | 0.68 (195.64) | 0.68 (0.65) | -0.55 (-0.64) |
| Blood and lymphatic system disorders | 78 | 0.49 (0.39 - 0.61) | 0.49 (41.12) | 0.49 (0.41) | -1.02 (-1.34) |
| Skin and subcutaneous tissue disorders | 158 | 0.31 (0.26 - 0.36) | 0.32 (245.29) | 0.32 (0.28) | -1.66 (-1.89) |
| Cardiac disorders | 1061 | 4.75 (4.45 - 5.06) | 4.32 (2775.29) | 4.31 (4.09) | 2.11 (2.02) |
| Respiratory, thoracic and mediastinal disorders | 603 | 1.39 (1.28 - 1.51) | 1.36 (61.32) | 1.36 (1.27) | 0.45 (0.33) |
| Psychiatric disorders | 1035 | 2.08 (1.95 - 2.22) | 1.96 (514.9) | 1.96 (1.85) | 0.97 (0.87) |
| Pregnancy, puerperium and perinatal conditions | 219 | 5.6 (4.9 - 6.41) | 5.5 (808.03) | 5.49 (4.91) | 2.46 (2.26) |
| Nervous system disorders | 1198 | 1.6 (1.51 - 1.7) | 1.52 (235.88) | 1.52 (1.45) | 0.61 (0.52) |
| Injury, poisoning and procedural complications | 514 | 0.57 (0.52 - 0.62) | 0.59 (157.8) | 0.59 (0.55) | -0.75 (-0.88) |
| Investigations | 597 | 1.04 (0.96 - 1.13) | 1.04 (0.94) | 1.04 (0.97) | 0.06 (-0.07) |
| Eye disorders | 222 | 1.2 (1.05 - 1.37) | 1.2 (7.21) | 1.2 (1.07) | 0.26 (0.06) |
| Vascular disorders | 246 | 1.24 (1.09 - 1.4) | 1.23 (10.77) | 1.23 (1.11) | 0.3 (0.11) |
| Infections and infestations | 200 | 0.4 (0.34 - 0.46) | 0.41 (179.53) | 0.41 (0.36) | -1.29 (-1.49) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 231 | 0.94 (0.82 - 1.07) | 0.94 (0.93) | 0.94 (0.84) | -0.09 (-0.28) |
| Immune system disorders | 54 | 0.52 (0.4 - 0.68) | 0.53 (23.47) | 0.53 (0.42) | -0.93 (-1.32) |
| Musculoskeletal and connective tissue disorders | 225 | 0.45 (0.39 - 0.51) | 0.46 (150.81) | 0.46 (0.41) | -1.12 (-1.32) |
| Surgical and medical procedures | 55 | 0.44 (0.33 - 0.57) | 0.44 (39.93) | 0.44 (0.35) | -1.19 (-1.57) |
| Reproductive system and breast disorders | 206 | 2.74 (2.39 - 3.15) | 2.7 (222.78) | 2.7 (2.41) | 1.43 (1.23) |
| Congenital, familial and genetic disorders | 137 | 4.91 (4.15 - 5.81) | 4.85 (419.6) | 4.85 (4.21) | 2.28 (2.03) |
| Renal and urinary | 63 | 0.36 (0.28 - 0.47) | 0.37 (69.28) | 0.37 (0.3) | -1.44 (-1.8) |

| | | | | | |
|-------------------------|-----|----------------------|-----------------|---------------|-----------------|
| disorders | | | | | |
| Metabolism and | | | | | |
| nutrition disorders | 105 | 0.52 (0.43 - 0.63) | 0.53 (45.44) | 0.53 (0.45) | -0.92 (-1.2) |
| Endocrine disorders | 162 | 7 (5.99 - 8.17) | 6.89 (817.06) | 6.88 (6.04) | 2.78 (2.56) |
| Gastrointestinal | | | | | |
| disorders | 482 | 0.59 (0.54 - 0.64) | 0.61 (132.81) | 0.61 (0.56) | -0.72 (-0.85) |
| Social circumstances | 55 | 1.37 (1.05 - 1.79) | 1.37 (5.5) | 1.37 (1.1) | 0.45 (0.07) |
| Product issues | 63 | 0.43 (0.34 - 0.55) | 0.43 (47.33) | 0.43 (0.35) | -1.21 (-1.57) |
| Ear and labyrinth | | | | | |
| disorders | 57 | 1.43 (1.1 - 1.85) | 1.43 (7.29) | 1.43 (1.15) | 0.51 (0.13) |
| Hepatobiliary disorders | 60 | 0.71 (0.55 - 0.91) | 0.71 (7.26) | 0.71 (0.57) | -0.5 (-0.87) |

Abbreviations: EBGM, Empirical Bayes Geometric Mean; PRR, Proportional Reporting Ratio; ROR, Reporting Odds Ratio; SOC, system organ classes

Supplementary Table SV. Top 30 significant signal strength of AE for cabergoline ranked by ROR at the PT level

| SOC | PT | Cases | ROR(95%CI) | PRR (χ^2) | EBGM | |
|---|--|-------------------|-----------------------------|---------------------|-------------------|---------------|
| | | | | | (EBGM05) | IC (IC025) |
| Cardiac disorders | Mitral valve incompetence | 135 | 78.34 (66.03 - 92.96) | 77.21 (10023.14) | 76.21 (66.04) | 6.25 (6) |
| | Aortic valve incompetence | 125 | 196.61 (164.32 - 235.24) | 193.95 (23217.77) | 187.69 (161.53) | 7.55 (7.29) |
| | Cardiac valve disease | 79 | 88.67 (70.93 - 110.83) | 87.91 (6687.14) | 86.61 (71.86) | 6.44 (6.11) |
| | Tricuspid valve incompetence | 67 | 58.04 (45.59 - 73.89) | 57.62 (3691.59) | 57.06 (46.62) | 5.83 (5.48) |
| | Cardiac failure | 50 | 4.06 (3.07 - 5.36) | 4.04 (114.52) | 4.04 (3.2) | 2.01 (1.61) |
| | Mitral valve disease | 33 | 117.98 (83.53 - 166.63) | 117.56 (3737.94) | 115.24 (86.33) | 6.85 (6.35) |
| | Aortic valve sclerosis | 29 | 252.11 (173.73 - 365.84) | 251.31 (6929.5) | 240.9 (176.41) | 7.91 (7.37) |
| | Pituitary haemorrhage | 35 | 747.74 (525.57 - 1063.82) | 744.9 (23037.19) | 660.09 (491.45) | 9.37 (8.86) |
| | Blindness | 23 | 3.77 (2.51 - 5.68) | 3.77 (46.75) | 3.77 (2.67) | 1.91 (1.32) |
| | General disorders and administration site conditions | Oedema peripheral | 51 | 2.64 (2 - 3.48) | 2.63 (51.59) | 2.63 (2.09) |
| Drug resistance | | 31 | 8.1 (5.69 - 11.52) | 8.07 (191.94) | 8.06 (6) | 3.01 (2.5) |
| Injury, poisoning and procedural complications | Maternal exposure during pregnancy | 73 | 5.87 (4.66 - 7.39) | 5.83 (292.1) | 5.82 (4.8) | 2.54 (2.2) |
| | Pneumocephalus | 33 | 776.2 (539.46 - 1116.84) | 773.42 (22456.62) | 682.38 (503.28) | 9.41 (8.89) |
| | Blood prolactin increased | 88 | 120.81 (97.73 - 149.36) | 119.67 (10146.55) | 117.26 (98.2) | 6.87 (6.56) |
| Investigations | Blood creatine phosphokinase increased | 23 | 4.88 (3.24 - 7.36) | 4.87 (70.82) | 4.87 (3.46) | 2.28 (1.69) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Pituitary tumour | 31 | 137.45 (96.21 - 196.37) | 136.99 (4088.25) | 133.85 (99.3) | 7.06 (6.55) |
| | Neoplasm progression | 30 | 5.31 (3.71 - 7.61) | 5.3 (104.62) | 5.3 (3.92) | 2.4 (1.89) |

| | | | | | | |
|---|-----------------------------|----|----------------------------|--------------------|------------------|---------------|
| Nervous system disorders | Pituitary tumour benign | 26 | 100.82 (68.38 - 148.66) | 100.54 (2518.68) | 98.84 (71.43) | 6.63 (6.07) |
| | Cerebrospinal fluid leakage | 75 | 288.55 (228.63 - 364.17) | 286.2 (20311.8) | 272.77 (224.5) | 8.09 (7.75) |
| | Parkinson's disease | 34 | 12.05 (8.6 - 16.87) | 12 (342.37) | 11.98 (9.04) | 3.58 (3.09) |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous | 62 | 9.94 (7.74 - 12.76) | 9.88 (494.3) | 9.86 (8) | 3.3 (2.94) |
| | Pregnancy | 25 | 7.67 (5.18 - 11.37) | 7.66 (144.52) | 7.65 (5.5) | 2.93 (2.37) |
| Psychiatric disorders | Hallucination | 60 | 5.35 (4.15 - 6.89) | 5.32 (210.53) | 5.32 (4.3) | 2.41 (2.04) |
| | Psychotic disorder | 32 | 7.04 (4.98 - 9.97) | 7.02 (165.13) | 7.01 (5.25) | 2.81 (2.31) |
| | Delusion | 32 | 13.64 (9.63 - 19.3) | 13.59 (372.52) | 13.56 (10.14) | 3.76 (3.26) |
| | Hypersexuality | 28 | 103.62 (71.27 - 150.65) | 103.31 (2787.22) | 101.51 (74.22) | 6.67 (6.12) |
| Respiratory, thoracic and mediastinal disorders | Abnormal behaviour | 25 | 3.9 (2.63 - 5.77) | 3.89 (53.69) | 3.89 (2.8) | 1.96 (1.39) |
| | Pleural effusion | 70 | 7.43 (5.87 - 9.4) | 7.38 (385.83) | 7.37 (6.05) | 2.88 (2.54) |
| | Pulmonary hypertension | 34 | 10.38 (7.41 - 14.54) | 10.35 (286.62) | 10.33 (7.79) | 3.37 (2.88) |
| | Interstitial lung disease | 31 | 4.3 (3.02 - 6.12) | 4.29 (78.13) | 4.28 (3.19) | 2.1 (1.59) |

Abbreviations: EBG, Empirical Bayes Geometric Mean; PRR, Proportional Reporting Ratio; PT, preferred terms; ROR, Reporting Odds Ratio; SOC, system organ classes

Supplementary Table SVI. The clinical priorities and relevant scores of PTs with significant correlation with 4 signal recognition methods

| PTs | Number of cases | Reporting rate (cases/non-cases) | Signal stability | Case fatality rate (%) | Clinical relevance | Clinical priorities (total score) |
|-----------------------------------|------------------------|---|-------------------------|-------------------------------|---------------------------|--|
| Pulmonary fibrosis | 22 | 0.24% | 3 of 3 | 45.45% | DME | Moderate priority (5) |
| Intraventricular haemorrhage | 3 | 0.03% | 3 of 3 | 100.00% | IME | Moderate priority (5) |
| Mitral valve incompetence | 135 | 1.49% | 3 of 3 | 4.44% | IME | Moderate priority (4) |
| Aortic valve incompetence | 125 | 1.38% | 3 of 3 | 1.60% | IME | Moderate priority (4) |
| Pulmonary hypertension | 34 | 0.37% | 3 of 3 | 14.71% | DME | Moderate priority (4) |
| Blindness | 23 | 0.25% | 3 of 3 | 0.00% | DME | Moderate priority (4) |
| Haemolytic anaemia | 10 | 0.11% | 3 of 3 | 0.00% | DME | Moderate priority (4) |
| Cardiomyopathy | 9 | 0.10% | 3 of 3 | 33.33% | IME | Moderate priority (4) |
| Intracranial pressure increased | 7 | 0.08% | 3 of 3 | 28.57% | IME | Moderate priority (4) |
| Foetal growth restriction | 7 | 0.08% | 3 of 3 | 28.57% | IME | Moderate priority (4) |
| Stillbirth | 5 | 0.05% | 3 of 3 | 40.00% | IME | Moderate priority (4) |
| Left ventricular failure | 5 | 0.05% | 3 of 3 | 40.00% | IME | Moderate priority (4) |
| Hydrocephalus | 4 | 0.04% | 3 of 3 | 50.00% | IME | Moderate priority (4) |
| Faecaloma | 4 | 0.04% | 3 of 3 | 25.00% | IME | Moderate priority (4) |
| Multiple congenital abnormalities | 4 | 0.04% | 3 of 3 | 25.00% | IME | Moderate priority (4) |
| Cavernous sinus thrombosis | 4 | 0.04% | 3 of 3 | 25.00% | IME | Moderate priority (4) |
| Ophthalmic vein thrombosis | 4 | 0.04% | 3 of 3 | 25.00% | IME | Moderate priority (4) |
| Foetal death | 4 | 0.04% | 3 of 3 | 50.00% | IME | Moderate priority (4) |
| Cardiac aneurysm | 3 | 0.03% | 3 of 3 | 33.33% | IME | Moderate priority (4) |
| Hypospadias | 3 | 0.03% | 3 of 3 | 33.33% | IME | Moderate priority (4) |
| Cleft palate | 3 | 0.03% | 3 of 3 | 33.33% | IME | Moderate priority (4) |
| Cerebrospinal fluid leakage | 75 | 0.82% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Tricuspid valve incompetence | 67 | 0.73% | 3 of 3 | 4.48% | IME | Moderate priority (3) |
| Abortion spontaneous | 62 | 0.68% | 3 of 3 | 4.84% | IME | Moderate priority (3) |
| Hallucination | 60 | 0.66% | 3 of 3 | 3.33% | IME | Moderate priority (3) |
| Cardiac failure | 50 | 0.55% | 3 of 3 | 12.00% | IME | Moderate priority (3) |
| Pituitary haemorrhage | 35 | 0.38% | 3 of 3 | 20.00% | IME | Moderate priority (3) |
| Parkinson's disease | 34 | 0.37% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Interstitial lung disease | 31 | 0.34% | 3 of 3 | 16.13% | IME | Moderate priority (3) |

| | | | | | | |
|---|----|-------|--------|--------|-----|-----------------------|
| Pituitary tumour | 31 | 0.34% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Delirium | 23 | 0.25% | 3 of 3 | 4.35% | IME | Moderate priority (3) |
| Pericardial effusion | 23 | 0.25% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Angina pectoris | 22 | 0.24% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Acromegaly | 20 | 0.22% | 3 of 3 | 5.00% | IME | Moderate priority (3) |
| Neuroleptic malignant syndrome | 20 | 0.22% | 3 of 3 | 20.00% | IME | Moderate priority (3) |
| Brain herniation | 19 | 0.21% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hallucination, visual | 18 | 0.20% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Coronary artery dissection | 18 | 0.20% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Pneumonia aspiration | 16 | 0.17% | 3 of 3 | 6.25% | IME | Moderate priority (3) |
| Brain neoplasm | 15 | 0.16% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Reversible cerebral vasoconstriction syndrome | 14 | 0.15% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Dystonia | 13 | 0.14% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Ovarian hyperstimulation syndrome | 12 | 0.13% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hemianopia | 11 | 0.12% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Subarachnoid haemorrhage | 11 | 0.12% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Generalised tonic-clonic seizure | 11 | 0.12% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Pericarditis | 11 | 0.12% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hemianopia heteronymous | 11 | 0.12% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Maternal drugs affecting foetus | 11 | 0.12% | 3 of 3 | 9.09% | IME | Moderate priority (3) |
| Hallucination, auditory | 10 | 0.11% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Tricuspid valve disease | 10 | 0.11% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Right ventricular failure | 10 | 0.11% | 3 of 3 | 10.00% | IME | Moderate priority (3) |
| Abortion | 9 | 0.10% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hyperprolactinaemia | 9 | 0.10% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Tumour haemorrhage | 9 | 0.10% | 3 of 3 | 11.11% | IME | Moderate priority (3) |
| Major depression | 9 | 0.10% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Pituitary apoplexy | 9 | 0.10% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Premature separation of placenta | 9 | 0.10% | 3 of 3 | 22.22% | IME | Moderate priority (3) |
| Pulmonary valve incompetence | 8 | 0.09% | 3 of 3 | 12.50% | IME | Moderate priority (3) |
| Posterior reversible encephalopathy | 8 | 0.09% | 3 of 3 | 0.00% | IME | Moderate priority (3) |

syndrome

| | | | | | | |
|---|---|-------|--------|--------|------|-----------------------|
| Sudden onset of sleep | 7 | 0.08% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Ventricular septal defect | 7 | 0.08% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Lung infiltration | 7 | 0.08% | 3 of 3 | 28.57% | None | Moderate priority (3) |
| Bipolar disorder | 7 | 0.08% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Adrenal insufficiency | 7 | 0.08% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Pericarditis constrictive | 7 | 0.08% | 3 of 3 | 14.29% | IME | Moderate priority (3) |
| Acute pulmonary oedema | 7 | 0.08% | 3 of 3 | 14.29% | IME | Moderate priority (3) |
| Colitis ischaemic | 7 | 0.08% | 3 of 3 | 14.29% | IME | Moderate priority (3) |
| Arteriospasm coronary | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Kounis syndrome | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Pituitary tumour recurrent | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Carotid aneurysm rupture | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Ectopic pregnancy | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Psychotic symptom | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Retroperitoneal fibrosis | 6 | 0.07% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Syndactyly | 6 | 0.07% | 3 of 3 | 16.67% | IME | Moderate priority (3) |
| Acute psychosis | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Trisomy 18 | 5 | 0.05% | 3 of 3 | 40.00% | None | Moderate priority (3) |
| Aortic stenosis | 5 | 0.05% | 3 of 3 | 20.00% | IME | Moderate priority (3) |
| Diabetes insipidus | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Cardiac valve sclerosis | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Cardiac failure acute | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Iiird nerve paralysis | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Akinesia | 5 | 0.05% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Aortic dissection | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Uterine haemorrhage | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Endocarditis | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Necrosis | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Encephalocele | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Prolactin-producing pituitary tumour | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Microcephaly | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Mediastinal fibrosis | 4 | 0.04% | 3 of 3 | 50.00% | None | Moderate priority (3) |
| Hepatic infection | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Aortic arteriosclerosis | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Anencephaly | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Autism spectrum disorder | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Alcoholism | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hallucinations, mixed | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |

| | | | | | | |
|--|----|-------|--------|--------|------|-----------------------|
| Cryptorchism | 4 | 0.04% | 3 of 3 | 25.00% | None | Moderate priority (3) |
| Tricuspid valve sclerosis | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Mitral valve stenosis | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Foetal heart rate decreased | 4 | 0.04% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Ventricular hypokinesia | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Breast abscess | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Hypothalamo-pituitary disorder | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Schizoaffective disorder | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Meningitis bacterial | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Cleft lip | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Tourette's disorder | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Growth retardation | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Spina bifida | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Horner's syndrome | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Drug exposure before pregnancy | 3 | 0.03% | 3 of 3 | 33.33% | None | Moderate priority (3) |
| Cardiac procedure complication | 3 | 0.03% | 3 of 3 | 33.33% | None | Moderate priority (3) |
| Holoprosencephaly | 3 | 0.03% | 3 of 3 | 0.00% | IME | Moderate priority (3) |
| Blood prolactin increased | 88 | 0.97% | 3 of 3 | 0.00% | None | Low priority (2) |
| Cardiac valve disease | 79 | 0.87% | 3 of 3 | 7.59% | None | Low priority (2) |
| Maternal exposure during pregnancy | 73 | 0.80% | 3 of 3 | 12.33% | None | Low priority (2) |
| Pleural effusion | 70 | 0.77% | 3 of 3 | 10.00% | None | Low priority (2) |
| Oedema peripheral | 51 | 0.56% | 3 of 3 | 9.80% | None | Low priority (2) |
| Mitral valve disease | 33 | 0.36% | 3 of 3 | 3.03% | None | Low priority (2) |
| Pneumocephalus | 33 | 0.36% | 3 of 3 | 0.00% | None | Low priority (2) |
| Psychotic disorder | 32 | 0.35% | 3 of 3 | 0.00% | None | Low priority (2) |
| Delusion | 32 | 0.35% | 3 of 3 | 0.00% | None | Low priority (2) |
| Drug resistance | 31 | 0.34% | 3 of 3 | 3.23% | None | Low priority (2) |
| Neoplasm progression | 30 | 0.33% | 3 of 3 | 3.33% | None | Low priority (2) |
| Aortic valve sclerosis | 29 | 0.32% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hypersexuality | 28 | 0.31% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pituitary tumour benign | 26 | 0.28% | 3 of 3 | 0.00% | None | Low priority (2) |
| Abnormal behaviour | 25 | 0.27% | 3 of 3 | 4.00% | None | Low priority (2) |
| Pregnancy | 25 | 0.27% | 3 of 3 | 8.00% | None | Low priority (2) |
| Blood creatine phosphokinase increased | 23 | 0.25% | 3 of 3 | 0.00% | None | Low priority (2) |
| Impulse-control | 22 | 0.24% | 3 of 3 | 0.00% | None | Low priority (2) |

| | | | | | | |
|--------------------------------------|----|-------|--------|--------|------|------------------|
| disorder | | | | | | |
| Empty sella syndrome | 22 | 0.24% | 3 of 3 | 0.00% | None | Low priority (2) |
| Caesarean section | 22 | 0.24% | 3 of 3 | 9.09% | None | Low priority (2) |
| Breast pain | 21 | 0.23% | 3 of 3 | 0.00% | None | Low priority (2) |
| Mania | 21 | 0.23% | 3 of 3 | 0.00% | None | Low priority (2) |
| Premature baby | 21 | 0.23% | 3 of 3 | 14.29% | None | Low priority (2) |
| Priapism | 21 | 0.23% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pleurisy | 20 | 0.22% | 3 of 3 | 10.00% | None | Low priority (2) |
| Pleural fibrosis | 19 | 0.21% | 3 of 3 | 10.53% | None | Low priority (2) |
| Visual field defect | 18 | 0.20% | 3 of 3 | 0.00% | None | Low priority (2) |
| Dyspnoea exertional | 18 | 0.20% | 3 of 3 | 0.00% | None | Low priority (2) |
| Insulin-like growth factor increased | 17 | 0.19% | 3 of 3 | 0.00% | None | Low priority (2) |
| Fibrosis | 17 | 0.19% | 3 of 3 | 0.00% | None | Low priority (2) |
| Visual pathway disorder | 17 | 0.19% | 3 of 3 | 0.00% | None | Low priority (2) |
| Obsessive-compulsive disorder | 16 | 0.17% | 3 of 3 | 0.00% | None | Low priority (2) |
| Cardiomegaly | 16 | 0.17% | 3 of 3 | 0.00% | None | Low priority (2) |
| Raynaud's phenomenon | 16 | 0.17% | 3 of 3 | 0.00% | None | Low priority (2) |
| Intracranial hypotension | 16 | 0.17% | 3 of 3 | 0.00% | None | Low priority (2) |
| Mood altered | 15 | 0.16% | 3 of 3 | 0.00% | None | Low priority (2) |
| Sleep apnoea syndrome | 14 | 0.15% | 3 of 3 | 0.00% | None | Low priority (2) |
| Neoplasm | 14 | 0.15% | 3 of 3 | 0.00% | None | Low priority (2) |
| Mastitis | 14 | 0.15% | 3 of 3 | 0.00% | None | Low priority (2) |
| Blood prolactin decreased | 14 | 0.15% | 3 of 3 | 0.00% | None | Low priority (2) |
| Libido increased | 14 | 0.15% | 3 of 3 | 7.14% | None | Low priority (2) |
| Compulsive shopping | 13 | 0.14% | 3 of 3 | 0.00% | None | Low priority (2) |
| Galactorrhoea | 13 | 0.14% | 3 of 3 | 7.69% | None | Low priority (2) |
| Aortic valve disease | 13 | 0.14% | 3 of 3 | 7.69% | None | Low priority (2) |
| Heart valve incompetence | 13 | 0.14% | 3 of 3 | 7.69% | None | Low priority (2) |
| Cardiac murmur | 13 | 0.14% | 3 of 3 | 0.00% | None | Low priority (2) |
| Mitral valve sclerosis | 13 | 0.14% | 3 of 3 | 7.69% | None | Low priority (2) |
| Psychomotor hyperactivity | 12 | 0.13% | 3 of 3 | 0.00% | None | Low priority (2) |
| Blood prolactin abnormal | 12 | 0.13% | 3 of 3 | 0.00% | None | Low priority (2) |
| Muscle rigidity | 12 | 0.13% | 3 of 3 | 0.00% | None | Low priority (2) |
| Gambling disorder | 11 | 0.12% | 3 of 3 | 0.00% | None | Low priority (2) |
| Lactation disorder | 10 | 0.11% | 3 of 3 | 10.00% | None | Low priority (2) |
| Maternal exposure timing unspecified | 10 | 0.11% | 3 of 3 | 20.00% | None | Low priority (2) |
| Dopamine dysregulation | 9 | 0.10% | 3 of 3 | 0.00% | None | Low priority (2) |

| | | | | | | |
|--------------------------------------|---|-------|--------|--------|------|------------------|
| syndrome | | | | | | |
| Persecutory delusion | 9 | 0.10% | 3 of 3 | 0.00% | None | Low priority (2) |
| Blood testosterone decreased | 9 | 0.10% | 3 of 3 | 0.00% | None | Low priority (2) |
| Testotoxicosis | 9 | 0.10% | 3 of 3 | 0.00% | None | Low priority (2) |
| Dilatation ventricular | 8 | 0.09% | 3 of 3 | 12.50% | None | Low priority (2) |
| Suspected counterfeit product | 8 | 0.09% | 3 of 3 | 0.00% | None | Low priority (2) |
| Personality change | 8 | 0.09% | 3 of 3 | 0.00% | None | Low priority (2) |
| Abortion induced | 8 | 0.09% | 3 of 3 | 12.50% | None | Low priority (2) |
| Refusal of treatment by patient | 8 | 0.09% | 3 of 3 | 12.50% | None | Low priority (2) |
| Adenoma benign | 7 | 0.08% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pre-existing condition improved | 7 | 0.08% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hormone level abnormal | 7 | 0.08% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast mass | 7 | 0.08% | 3 of 3 | 0.00% | None | Low priority (2) |
| Mitral valve prolapse | 7 | 0.08% | 3 of 3 | 14.29% | None | Low priority (2) |
| Dilatation atrial | 7 | 0.08% | 3 of 3 | 0.00% | None | Low priority (2) |
| Jealous delusion | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Gambling | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Endometriosis | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Thrombophlebitis | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Poor quality product administered | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast discharge | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Impulsive behaviour | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Neonatal disorder | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Echocardiogram abnormal | 6 | 0.07% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pituitary cyst | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Substance-induced psychotic disorder | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Orthopnoea | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Affective disorder | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hyperventilation | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Torticollis | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Panic reaction | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Insulin-like growth factor decreased | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Arteriovenous fistula | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pre-eclampsia | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |
| Aortic valve stenosis | 5 | 0.05% | 3 of 3 | 0.00% | None | Low priority (2) |

| | | | | | | |
|---------------------------------------|---|-------|--------|-------|------|------------------|
| Somatic delusion | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Aortic valve calcification | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Posture abnormal | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Vasoconstriction | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast enlargement | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Product colour issue | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pituitary enlargement | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hypomania | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Chiasma syndrome | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Sleep attacks | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Vasospasm | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pleural disorder | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Pulmonary arterial pressure increased | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Labyrinthitis | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Ventricular dysfunction | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Middle ear effusion | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast engorgement | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Bundle branch block right | 4 | 0.04% | 3 of 3 | 0.00% | None | Low priority (2) |
| Binge eating | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Weight abnormal | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Heart valve calcification | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Leiomyoma | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast induration | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Lactation puerperal increased | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast disorder | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Malformation venous | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Paramnesia | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Trance | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Disinhibition | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Partner stress | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hypogonadism | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Paradoxical drug reaction | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Benign breast neoplasm | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hypopituitarism | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Breast atrophy | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Hyperplasia | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Facial paresis | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Bradycardia | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Multiple-drug resistance | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |

| | | | | | | |
|-------------------------|---|-------|--------|-------|------|------------------|
| Neuroendocrine tumour | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Polycystic ovaries | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Chorea | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Ventricular hypertrophy | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Psychosexual disorder | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Alveolitis | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Aortic dilatation | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Collagen disorder | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Trisomy 21 | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Marital problem | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |
| Tachyphylaxis | 3 | 0.03% | 3 of 3 | 0.00% | None | Low priority (2) |

Abbreviations: DME, designated medical event; IME, important medical event; PT, preferred terms; SOC, system organ classes