

## Summary Tabulation 15.06.2021

| Active Substance (High Level)        |  | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) |             |       |
|--------------------------------------|--|--|-------------|-------|
| Reaction SOC                         | Reaction PT                            | Serious  | Non Serious | Total |
| Blood and lymphatic system disorders | Anaemia                                | 2  | 1           | 3     |
|                                      | Autoimmune haemolytic anaemia          | 1  | 0           | 1     |
|                                      | Coagulopathy                           | 60   | 26          | 86    |
|                                      | Coombs negative haemolytic anaemia     | 1  | 0           | 1     |
|                                      | Disseminated intravascular coagulation | 1  | 0           | 1     |
|                                      | Immune thrombocytopenia                | 3  | 0           | 3     |
|                                      | Leukocytosis                           | 1  | 0           | 1     |
|                                      | Leukopenia                             | 1  | 0           | 1     |
|                                      | Lymph node pain                        | 1  | 0           | 1     |
|                                      | Lymphadenopathy                        | 6  | 3           | 9     |
|                                      | Lymphopenia                            | 1  | 0           | 1     |
|                                      | Necrotic lymphadenopathy               | 0  | 1           | 1     |
|                                      | Neutropenia                            | 3  | 1           | 4     |
|                                      | Platelet disorder                      | 1  | 0           | 1     |
|                                      | Splenic embolism                       | 1  | 0           | 1     |
|                                      | Splenic infarction                     | 1  | 0           | 1     |
|                                      | Splenic vein thrombosis                | 1  | 0           | 1     |
|                                      | Spontaneous haematoma                  | 1  | 0           | 1     |
|                                      | Thrombocytopenia                       | 28   | 7           | 35    |
|                                      | Cardiac disorders                      | Acute cardiac event                            | 1           | 0     |
| Angina pectoris                      |  | 2  | 0           | 2     |
| Angina unstable                      |  | 1  | 0           | 1     |
| Arrhythmia                           |  | 6  | 2           | 8     |
| Bradycardia                          |  | 1  | 2           | 3     |
| Cardiac arrest                       |  | 2  | 0           | 2     |
| Cardiac failure                      |  | 2  | 0           | 2     |
| Cardiovascular disorder              |  | 45   | 7           | 52    |
| Extrasystoles                        |  | 0  | 1           | 1     |
| Myocardial depression                |  | 1  | 0           | 1     |
| Myocardial infarction                |  | 2  | 0           | 2     |
| Myocarditis                          |  | 2  | 0           | 2     |
| Palpitations                         |  | 40   | 7           | 47    |
| Pericarditis                         |  | 1  | 0           | 1     |
| Pleuropericarditis                   |  | 0  | 1           | 1     |
| Sinus tachycardia                    |  | 2  | 0           | 2     |

|                             |                                    |    |   |    |
|-----------------------------|------------------------------------|----|---|----|
|                             | Tachycardia                        | 36 | 6 | 42 |
| Ear and labyrinth disorders | Deafness                           | 2  | 3 | 5  |
|                             | Deafness unilateral                | 5  | 1 | 6  |
|                             | Ear congestion                     | 0  | 2 | 2  |
|                             | Ear discomfort                     | 4  | 1 | 5  |
|                             | Ear pain                           | 13 | 3 | 16 |
|                             | Hyperacusis                        | 3  | 0 | 3  |
|                             | Hypoacusis                         | 1  | 0 | 1  |
|                             | Meniere's disease                  | 1  | 1 | 2  |
|                             | Sudden hearing loss                | 0  | 1 | 1  |
|                             | Tinnitus                           | 13 | 3 | 16 |
|                             | Vertigo                            | 37 | 5 | 42 |
| Endocrine disorders         | Adrenocortical insufficiency acute | 1  | 0 | 1  |
|                             | Goitre                             | 2  | 0 | 2  |
| Eye disorders               | Amaurosis fugax                    | 1  | 1 | 2  |
|                             | Asthenopia                         | 3  | 0 | 3  |
|                             | Blindness                          | 5  | 1 | 6  |
|                             | Blindness unilateral               | 3  | 0 | 3  |
|                             | Conjunctival haemorrhage           | 1  | 1 | 2  |
|                             | Diplopia                           | 3  | 1 | 4  |
|                             | Eye disorder                       | 1  | 0 | 1  |
|                             | Eye haemorrhage                    | 2  | 3 | 5  |
|                             | Eye irritation                     | 1  | 0 | 1  |
|                             | Eye oedema                         | 1  | 0 | 1  |
|                             | Eye pain                           | 8  | 4 | 12 |
|                             | Eye swelling                       | 2  | 0 | 2  |
|                             | Macular oedema                     | 1  | 0 | 1  |
|                             | Miosis                             | 1  | 0 | 1  |
|                             | Mydriasis                          | 1  | 0 | 1  |
|                             | Ocular discomfort                  | 1  | 1 | 2  |
|                             | Ocular hyperaemia                  | 1  | 1 | 2  |
|                             | Papilloedema                       | 1  | 0 | 1  |
|                             | Periorbital swelling               | 1  | 0 | 1  |
|                             | Photophobia                        | 5  | 1 | 6  |
|                             | Photopsia                          | 1  | 0 | 1  |
|                             | Pupils unequal                     | 1  | 0 | 1  |
|                             | Retinal artery thrombosis          | 3  | 0 | 3  |
|                             | Retinal haemorrhage                | 0  | 1 | 1  |
|                             | Retinal ischaemia                  | 1  | 0 | 1  |
|                             | Retinal oedema                     | 1  | 0 | 1  |
|                             | Retinal vascular thrombosis        | 0  | 1 | 1  |
|                             | Retinal vein occlusion             | 1  | 0 | 1  |
|                             | Retinal vein thrombosis            | 5  | 0 | 5  |
|                             | Swelling of eyelid                 | 0  | 1 | 1  |
|                             | Uveitis                            | 1  | 0 | 1  |
|                             | Vision blurred                     | 20 | 3 | 23 |
|                             | Visual acuity reduced              | 1  | 0 | 1  |
|                             | Visual field defect                | 1  | 0 | 1  |
|                             | Visual impairment                  | 18 | 4 | 22 |
|                             | Visual snow syndrome               | 1  | 0 | 1  |

|                            |  |     |    |     |
|----------------------------|--|-----|----|-----|
| Gastrointestinal disorders | Abdominal discomfort                   | 5   | 1  | 6   |
|                            | Abdominal distension                   | 1   | 0  | 1   |
|                            | Abdominal pain                         | 28  | 9  | 37  |
|                            | Abdominal pain upper                   | 16  | 5  | 21  |
|                            | Abnormal faeces                        | 1   | 0  | 1   |
|                            | Aphthous ulcer                         | 0   | 1  | 1   |
|                            | Colitis ischaemic                      | 2   | 0  | 2   |
|                            | Colitis ulcerative                     | 1   | 0  | 1   |
|                            | Constipation                           | 1   | 0  | 1   |
|                            | Crohn's disease                        | 1   | 0  | 1   |
|                            | Diarrhoea                              | 63  | 9  | 72  |
|                            | Diarrhoea haemorrhagic                 | 1   | 1  | 2   |
|                            | Dry mouth                              | 7   | 0  | 7   |
|                            | Dyspepsia                              | 3   | 0  | 3   |
|                            | Dysphagia                              | 1   | 2  | 3   |
|                            | Eructation                             | 1   | 0  | 1   |
|                            | Faeces discoloured                     | 1   | 0  | 1   |
|                            | Faeces soft                            | 1   | 0  | 1   |
|                            | Flatulence                             | 1   | 0  | 1   |
|                            | Gastrointestinal disorder              | 4   | 0  | 4   |
|                            | Gastrointestinal haemorrhage           | 1   | 0  | 1   |
|                            | Gastrointestinal inflammation          | 1   | 0  | 1   |
|                            | Gastrointestinal pain                  | 1   | 0  | 1   |
|                            | Gastrointestinal vascular malformation | 1   | 0  | 1   |
|                            | Gastrooesophageal reflux disease       | 1   | 0  | 1   |
|                            | Gingival bleeding                      | 2   | 0  | 2   |
|                            | Glossodynia                            | 1   | 1  | 2   |
|                            | Haemoperitoneum                        | 1   | 0  | 1   |
|                            | Haemorrhoidal haemorrhage              | 1   | 0  | 1   |
|                            | Haemorrhoids thrombosed                | 1   | 1  | 2   |
|                            | Hypoesthesia oral                      | 0   | 1  | 1   |
|                            | Intestinal congestion                  | 1   | 0  | 1   |
|                            | Intestinal infarction                  | 1   | 0  | 1   |
|                            | Intestinal ischaemia                   | 3   | 0  | 3   |
|                            | Lip pain                               | 1   | 0  | 1   |
|                            | Lip swelling                           | 0   | 2  | 2   |
|                            | Melaena                                | 1   | 0  | 1   |
|                            | Mesenteric vein thrombosis             | 1   | 0  | 1   |
|                            | Mouth haemorrhage                      | 0   | 1  | 1   |
|                            | Nausea                                 | 796 | 60 | 856 |
|                            | Oesophageal spasm                      | 1   | 0  | 1   |
|                            | Oral discomfort                        | 2   | 0  | 2   |
|                            | Pancreatic enlargement                 | 1   | 0  | 1   |
|                            | Paraesthesia oral                      | 3   | 3  | 6   |
|                            | Plicated tongue                        | 0   | 1  | 1   |
|                            | Rectal haemorrhage                     | 1   | 2  | 3   |
| Regurgitation              | 1                                      | 0   | 1  |     |
| Retching                   | 3                                      | 0   | 3  |     |
| Splanchnic hypoperfusion   | 1                                      | 0   | 1  |     |
| Stomatitis                 | 0                                      | 1   | 1  |     |

|  |                                       |      |     |       |
|--|---------------------------------------|------|-----|-------|
|  | Swollen tongue                        | 1    | 1   | 2     |
|  | Thrombosis mesenteric vessel          | 1    | 0   | 1     |
|  | Tongue discomfort                     | 0    | 1   | 1     |
|  | Tongue disorder                       | 0    | 1   | 1     |
|  | Toothache                             | 0    | 1   | 1     |
|  | Vomiting                              | 82   | 10  | 92    |
| General disorders and administration site conditions | Administration site pain              | 0    | 1   | 1     |
|  | Adverse drug reaction                 | 3    | 0   | 3     |
|  | Adverse event                         | 1    | 0   | 1     |
|  | Application site joint warmth         | 1    | 0   | 1     |
|  | Asthenia                              | 40   | 1   | 41    |
|  | Axillary pain                         | 3    | 2   | 5     |
|  | Brain death                           | 1    | 0   | 1     |
|  | Chest discomfort                      | 12   | 2   | 14    |
|  | Chest pain                            | 26   | 7   | 33    |
|  | Chills                                | 1418 | 102 | 1.520 |
|  | Condition aggravated                  | 3    | 0   | 3     |
|  | Death                                 | 18   | 0   | 18    |
|  | Discomfort                            | 1    | 0   | 1     |
|  | Drug ineffective                      | 0    | 3   | 3     |
|  | Exercise tolerance decreased          | 2    | 0   | 2     |
|  | Extensive swelling of vaccinated limb | 91   | 12  | 103   |
|  | Face oedema                           | 3    | 0   | 3     |
|  | Facial pain                           | 0    | 1   | 1     |
|  | Fatigue                               | 1413 | 118 | 1.531 |
|  | Feeling abnormal                      | 20   | 2   | 22    |
|  | Feeling cold                          | 30   | 5   | 35    |
|  | Feeling drunk                         | 2    | 1   | 3     |
|  | Feeling hot                           | 20   | 5   | 25    |
|  | Feeling of body temperature change    | 15   | 2   | 17    |
|  | Gait disturbance                      | 6    | 1   | 7     |
|  | Gait inability                        | 2    | 0   | 2     |
|  | General physical health deterioration | 5    | 0   | 5     |
|  | Hyperpyrexia                          | 0    | 1   | 1     |
|  | Hyperthermia                          | 2    | 1   | 3     |
|  | Hypothermia                           | 2    | 0   | 2     |
|  | Illness                               | 0    | 1   | 1     |
|  | Induration                            | 2    | 1   | 3     |
|  | Inflammation                          | 1    | 0   | 1     |
|  | Influenza like illness                | 162  | 20  | 182   |
|  | Injected limb mobility decreased      | 1    | 0   | 1     |
|  | Injection site discomfort             | 3    | 0   | 3     |
|  | Injection site erythema               | 15   | 2   | 17    |
|  | Injection site haematoma              | 2    | 0   | 2     |
|  | Injection site haemorrhage            | 1    | 0   | 1     |
|  | Injection site hypoesthesia           | 2    | 0   | 2     |
| Injection site induration                            | 7                                     | 1    | 8   |       |
| Injection site inflammation                          | 1                                     | 0    | 1   |       |
| Injection site movement impairment                   | 2                                     | 0    | 2   |       |
| Injection site necrosis                              | 1                                     | 0    | 1   |       |

|                                      |      |     |       |
|--------------------------------------|------|-----|-------|
| Injection site oedema                | 1    | 0   | 1     |
| Injection site pain                  | 109  | 8   | 117   |
| Injection site paraesthesia          | 1    | 0   | 1     |
| Injection site phlebitis             | 0    | 1   | 1     |
| Injection site pruritus              | 0    | 3   | 3     |
| Injection site rash                  | 1    | 0   | 1     |
| Injection site reaction              | 693  | 50  | 743   |
| Injection site swelling              | 18   | 3   | 21    |
| Injection site warmth                | 10   | 0   | 10    |
| Local reaction                       | 1    | 0   | 1     |
| Localised oedema                     | 1    | 0   | 1     |
| Malaise                              | 806  | 73  | 879   |
| Multiple organ dysfunction syndrome  | 1    | 0   | 1     |
| No adverse event                     | 1    | 0   | 1     |
| Oedema                               | 3    | 0   | 3     |
| Oedema peripheral                    | 3    | 0   | 3     |
| Pain                                 | 23   | 12  | 35    |
| Peripheral swelling                  | 62   | 6   | 68    |
| Puncture site pain                   | 0    | 1   | 1     |
| Pyrexia                              | 1420 | 115 | 1.535 |
| Secretion discharge                  | 1    | 0   | 1     |
| Sensation of foreign body            | 1    | 0   | 1     |
| Sense of oppression                  | 1    | 0   | 1     |
| Sudden death                         | 7    | 0   | 7     |
| Swelling                             | 6    | 3   | 9     |
| Swelling face                        | 1    | 0   | 1     |
| Tenderness                           | 2    | 1   | 3     |
| Thirst                               | 5    | 0   | 5     |
| Tissue infiltration                  | 0    | 1   | 1     |
| Unevaluable event                    | 1    | 1   | 2     |
| Vaccination site discharge           | 0    | 1   | 1     |
| Vaccination site erythema            | 1    | 0   | 1     |
| Vaccination site haematoma           | 1    | 0   | 1     |
| Vaccination site movement impairment | 1    | 0   | 1     |
| Vaccination site pain                | 2    | 3   | 5     |
| Hepatobiliary disorders              |      |     |       |
| Gallbladder necrosis                 | 1    | 0   | 1     |
| Hepatic failure                      | 1    | 0   | 1     |
| Hepatic steatosis                    | 1    | 0   | 1     |
| Hyperbilirubinaemia                  | 1    | 0   | 1     |
| Liver disorder                       | 2    | 0   | 2     |
| Portal vein occlusion                | 1    | 0   | 1     |
| Portal vein thrombosis               | 3    | 0   | 3     |
| Venoocclusive liver disease          | 1    | 0   | 1     |
| Immune system disorders              |      |     |       |
| Anaphylactic reaction                | 8    | 3   | 11    |
| Anaphylactic shock                   | 1    | 0   | 1     |
| Autoimmune disorder                  | 8    | 0   | 8     |
| Hypersensitivity                     | 27   | 11  | 38    |
| Seasonal allergy                     | 1    | 0   | 1     |
| Infections and infestations          |      |     |       |
| Abscess                              | 0    | 1   | 1     |
| Brain abscess                        | 1    | 0   | 1     |

|  |    |    |    |
|--|----|----|----|
| Brain empyema                                  | 1  | 0  | 1  |
| Bronchitis                                     | 1  | 0  | 1  |
| COVID-19                                       | 44 | 6  | 50 |
| COVID-19 pneumonia                             | 1  | 0  | 1  |
| Cavernous sinus thrombosis                     | 1  | 0  | 1  |
| Chronic sinusitis                              | 1  | 0  | 1  |
| Conjunctivitis                                 | 1  | 1  | 2  |
| Conjunctivitis viral                           | 0  | 1  | 1  |
| Cystitis                                       | 1  | 0  | 1  |
| Diverticulitis                                 | 1  | 0  | 1  |
| Encephalitis                                   | 3  | 0  | 3  |
| Erysipelas                                     | 0  | 2  | 2  |
| Eye infection                                  | 1  | 0  | 1  |
| Gastrointestinal infection                     | 0  | 1  | 1  |
| Herpes zoster                                  | 2  | 9  | 11 |
| Influenza                                      | 14 | 11 | 25 |
| Injection site cellulitis                      | 0  | 1  | 1  |
| Laryngitis                                     | 1  | 0  | 1  |
| Lymphangitis                                   | 0  | 1  | 1  |
| Meningitis bacterial                           | 1  | 0  | 1  |
| Nasopharyngitis                                | 16 | 3  | 19 |
| Ophthalmic herpes zoster                       | 0  | 1  | 1  |
| Oral herpes                                    | 1  | 0  | 1  |
| Pharyngitis                                    | 0  | 1  | 1  |
| Pneumonia                                      | 1  | 0  | 1  |
| Pneumonia bacterial                            | 1  | 0  | 1  |
| Pyelonephritis                                 | 1  | 0  | 1  |
| Pyelonephritis acute                           | 1  | 0  | 1  |
| Respiratory tract infection                    | 1  | 0  | 1  |
| Sepsis   | 2  | 0  | 2  |
| Septic shock                                   | 2  | 0  | 2  |
| Sinusitis                                      | 2  | 0  | 2  |
| Streptococcal infection                        | 1  | 0  | 1  |
| Subcutaneous abscess                           | 0  | 1  | 1  |
| Suspected COVID-19                             | 0  | 1  | 1  |
| Sweating fever                                 | 0  | 1  | 1  |
| Tooth abscess                                  | 1  | 0  | 1  |
| Urinary tract infection                        | 2  | 1  | 3  |
| Vestibular neuronitis                          | 1  | 0  | 1  |
| Viral myocarditis                              | 1  | 0  | 1  |
| Injury, poisoning and procedural complications |    |    |    |
| Contusion                                      | 7  | 7  | 14 |
| Epicondylitis                                  | 1  | 0  | 1  |
| Exposure during pregnancy                      | 0  | 2  | 2  |
| Fall   | 7  | 1  | 8  |
| Head injury                                    | 1  | 0  | 1  |
| Incorrect route of product administration      | 1  | 2  | 3  |
| Intentional dose omission                      | 1  | 0  | 1  |
| Kidney rupture                                 | 1  | 0  | 1  |
| Maternal exposure during breast feeding        | 2  | 2  | 4  |
| Medication error                               | 1  | 3  | 4  |

|                |  |    |   |    |
|----------------|--|----|---|----|
|                | Off label use                                  | 1  | 2 | 3  |
|                | Product administered at inappropriate site     | 0  | 1 | 1  |
|                | Vascular injury                                | 1  | 0 | 1  |
|                | Vasoplegia syndrome                            | 1  | 0 | 1  |
|                | Venous injury                                  | 0  | 1 | 1  |
|                | Wrong product administered                     | 0  | 1 | 1  |
| Investigations | Anti-platelet antibody                         | 1  | 0 | 1  |
|                | Antibody test negative                         | 0  | 1 | 1  |
|                | Babinski reflex test                           | 1  | 0 | 1  |
|                | Blood albumin decreased                        | 1  | 0 | 1  |
|                | Blood bilirubin increased                      | 1  | 0 | 1  |
|                | Blood fibrinogen decreased                     | 2  | 0 | 2  |
|                | Blood fibrinogen increased                     | 1  | 0 | 1  |
|                | Blood glucose abnormal                         | 1  | 0 | 1  |
|                | Blood glucose increased                        | 1  | 0 | 1  |
|                | Blood pressure decreased                       | 12 | 1 | 13 |
|                | Blood pressure increased                       | 9  | 2 | 11 |
|                | Body temperature decreased                     | 2  | 1 | 3  |
|                | Body temperature increased                     | 5  | 3 | 8  |
|                | C-reactive protein increased                   | 12 | 0 | 12 |
|                | Capillary nail refill test abnormal            | 1  | 0 | 1  |
|                | Ejection fraction decreased                    | 1  | 0 | 1  |
|                | Fibrin D dimer decreased                       | 0  | 1 | 1  |
|                | Fibrin D dimer increased                       | 18 | 2 | 20 |
|                | General physical condition abnormal            | 2  | 0 | 2  |
|                | Haematocrit decreased                          | 1  | 0 | 1  |
|                | Haematocrit increased                          | 1  | 0 | 1  |
|                | Haemoglobin decreased                          | 1  | 0 | 1  |
|                | Heart rate abnormal                            | 0  | 1 | 1  |
|                | Heart rate decreased                           | 1  | 0 | 1  |
|                | Heart rate increased                           | 24 | 6 | 30 |
|                | Heart rate irregular                           | 0  | 1 | 1  |
|                | Heart rate normal                              | 1  | 0 | 1  |
|                | Heparin-induced thrombocytopenia test positive | 4  | 0 | 4  |
|                | Homans' sign negative                          | 0  | 1 | 1  |
|                | Interleukin level increased                    | 1  | 0 | 1  |
|                | International normalised ratio increased       | 1  | 0 | 1  |
|                | Intestinal transit time abnormal               | 0  | 1 | 1  |
|                | Liver function test abnormal                   | 2  | 0 | 2  |
|                | Lymphocyte count decreased                     | 0  | 1 | 1  |
|                | Oxygen saturation decreased                    | 3  | 0 | 3  |
|                | Platelet count decreased                       | 5  | 0 | 5  |
|                | Platelet count increased                       | 1  | 0 | 1  |
|                | Procalcitonin increased                        | 1  | 0 | 1  |
|                | Red blood cell count decreased                 | 1  | 0 | 1  |
|                | Red blood cell count increased                 | 0  | 1 | 1  |
|                | Red blood cell sedimentation rate increased    | 1  | 0 | 1  |
|                | Respiratory rate decreased                     | 0  | 1 | 1  |
|                | SARS-CoV-2 antibody test negative              | 0  | 3 | 3  |
|                | SARS-CoV-2 test negative                       | 0  | 1 | 1  |

|   |                                  |      |     |       |
|---|----------------------------------|------|-----|-------|
|   | SARS-CoV-2 test positive         | 0    | 1   | 1     |
|   | Troponin T increased             | 1    | 0   | 1     |
|   | Troponin increased               | 2    | 0   | 2     |
|   | Venous pressure increased        | 1    | 0   | 1     |
|   | Weight decreased                 | 5    | 0   | 5     |
|   | White blood cell count decreased | 0    | 1   | 1     |
| Metabolism and nutrition disorders                                  | Decreased appetite               | 67   | 7   | 74    |
|   | Dehydration                      | 2    | 0   | 2     |
|   | Feeding disorder                 | 1    | 0   | 1     |
|   | Fluid retention                  | 1    | 1   | 2     |
|   | Gout                             | 1    | 0   | 1     |
|   | Hyperkalaemia                    | 1    | 0   | 1     |
|   | Hypoglycaemia                    | 1    | 0   | 1     |
|   | Hypovolaemia                     | 1    | 0   | 1     |
|   | Lactic acidosis                  | 2    | 0   | 2     |
|   | Oligodipsia                      | 1    | 0   | 1     |
| Musculoskeletal and connective tissue disorders                     | Arthralgia                       | 637  | 53  | 690   |
|   | Arthritis                        | 4    | 0   | 4     |
|   | Back pain                        | 29   | 6   | 35    |
|   | Bone pain                        | 2    | 0   | 2     |
|   | Connective tissue disorder       | 0    | 1   | 1     |
|   | Fibromyalgia                     | 1    | 0   | 1     |
|   | Jaw disorder                     | 0    | 1   | 1     |
|   | Joint stiffness                  | 0    | 1   | 1     |
|   | Joint swelling                   | 0    | 1   | 1     |
|   | Limb discomfort                  | 14   | 3   | 17    |
|   | Mobility decreased               | 0    | 1   | 1     |
|   | Muscle contracture               | 1    | 0   | 1     |
|   | Muscle discomfort                | 1    | 0   | 1     |
|   | Muscle spasms                    | 14   | 1   | 15    |
|   | Muscle swelling                  | 1    | 0   | 1     |
|   | Muscle twitching                 | 2    | 0   | 2     |
|   | Muscular weakness                | 15   | 6   | 21    |
|   | Musculoskeletal pain             | 0    | 1   | 1     |
|   | Musculoskeletal stiffness        | 63   | 3   | 66    |
|   | Myalgia                          | 1206 | 105 | 1.311 |
|   | Myosclerosis                     | 1    | 0   | 1     |
|   | Neck pain                        | 20   | 3   | 23    |
|   | Osteoarthritis                   | 2    | 1   | 3     |
|   | Pain in extremity                | 75   | 21  | 96    |
|   | Spinal deformity                 | 0    | 1   | 1     |
|   | Spinal pain                      | 0    | 1   | 1     |
|   | Still's disease                  | 1    | 0   | 1     |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Neoplasm malignant               | 1    | 0   | 1     |
| Nervous system disorders  | Ageusia                          | 4    | 0   | 4     |
|   | Altered state of consciousness   | 4    | 1   | 5     |
|   | Amnesia                          | 6    | 0   | 6     |
|   | Anosmia                          | 3    | 0   | 3     |
|   | Aphasia                          | 7    | 0   | 7     |
|   | Areflexia                        | 1    | 0   | 1     |



|                                  |      |     |       |
|----------------------------------|------|-----|-------|
| Balance disorder                 | 9    | 2   | 11    |
| Bell's palsy                     | 1    | 0   | 1     |
| Brain oedema                     | 3    | 0   | 3     |
| Burning sensation                | 3    | 0   | 3     |
| Carotid artery thrombosis        | 1    | 0   | 1     |
| Cerebellar stroke                | 1    | 0   | 1     |
| Cerebral haemorrhage             | 10   | 0   | 10    |
| Cerebral infarction              | 3    | 0   | 3     |
| Cerebral ischaemia               | 2    | 0   | 2     |
| Cerebral mass effect             | 1    | 0   | 1     |
| Cerebral thrombosis              | 4    | 0   | 4     |
| Cerebral venous sinus thrombosis | 1    | 0   | 1     |
| Cerebrovascular accident         | 9    | 0   | 9     |
| Cervical radiculopathy           | 0    | 1   | 1     |
| Coma                             | 2    | 0   | 2     |
| Dementia Alzheimer's type        | 1    | 0   | 1     |
| Depressed level of consciousness | 4    | 0   | 4     |
| Diplegia                         | 1    | 0   | 1     |
| Disturbance in attention         | 8    | 2   | 10    |
| Dizziness                        | 53   | 11  | 64    |
| Dizziness postural               | 1    | 0   | 1     |
| Dysarthria                       | 5    | 0   | 5     |
| Dysgeusia                        | 6    | 1   | 7     |
| Dyskinesia                       | 2    | 0   | 2     |
| Dysstasia                        | 0    | 1   | 1     |
| Electric shock sensation         | 1    | 0   | 1     |
| Epilepsy                         | 3    | 0   | 3     |
| Facial nerve disorder            | 1    | 0   | 1     |
| Facial paralysis                 | 9    | 1   | 10    |
| Formication                      | 0    | 1   | 1     |
| Guillain-Barre syndrome          | 5    | 0   | 5     |
| Head discomfort                  | 6    | 3   | 9     |
| Headache                         | 1476 | 134 | 1.610 |
| Hemianopia                       | 1    | 0   | 1     |
| Hemiparaesthesia                 | 0    | 1   | 1     |
| Hemiparesis                      | 2    | 1   | 3     |
| Hemiplegia                       | 5    | 0   | 5     |
| Hyperaesthesia                   | 4    | 0   | 4     |
| Hyperreflexia                    | 1    | 0   | 1     |
| Hypoaesthesia                    | 15   | 7   | 22    |
| Hypokinesia                      | 1    | 0   | 1     |
| Intracranial pressure increased  | 1    | 0   | 1     |
| Ischaemic cerebral infarction    | 1    | 0   | 1     |
| Ischaemic stroke                 | 3    | 0   | 3     |
| Leukoencephalopathy              | 1    | 0   | 1     |
| Loss of consciousness            | 9    | 2   | 11    |
| Memory impairment                | 3    | 0   | 3     |
| Meningism                        | 0    | 1   | 1     |
| Migraine                         | 25   | 0   | 25    |
| Migraine with aura               | 1    | 0   | 1     |

|  |  |    |   |    |
|--|--|----|---|----|
|  | Monoplegia                             | 3  | 0 | 3  |
|  | Motor dysfunction                      | 1  | 0 | 1  |
|  | Muscle contractions involuntary        | 1  | 0 | 1  |
|  | Muscle tone disorder                   | 1  | 0 | 1  |
|  | Nervous system disorder                | 45 | 9 | 54 |
|  | Neuralgia                              | 3  | 0 | 3  |
|  | Neuropathy peripheral                  | 1  | 0 | 1  |
|  | Nystagmus                              | 1  | 0 | 1  |
|  | Pachymeningitis                        | 1  | 0 | 1  |
|  | Paraesthesia                           | 19 | 8 | 27 |
|  | Paraparesis                            | 1  | 0 | 1  |
|  | Paraplegia                             | 1  | 0 | 1  |
|  | Paresis                                | 1  | 0 | 1  |
|  | Petit mal epilepsy                     | 1  | 0 | 1  |
|  | Presyncope                             | 1  | 1 | 2  |
|  | Restless legs syndrome                 | 3  | 0 | 3  |
|  | Retrograde amnesia                     | 1  | 0 | 1  |
|  | Sedation                               | 1  | 0 | 1  |
|  | Seizure                                | 17 | 6 | 23 |
|  | Sensory loss                           | 2  | 1 | 3  |
|  | Somnolence                             | 11 | 2 | 13 |
|  | Speech disorder                        | 4  | 1 | 5  |
|  | Spinal cord infarction                 | 1  | 0 | 1  |
|  | Spinal cord ischaemia                  | 1  | 0 | 1  |
|  | Superior sagittal sinus thrombosis     | 1  | 0 | 1  |
|  | Syncope                                | 16 | 7 | 23 |
|  | Taste disorder                         | 2  | 2 | 4  |
|  | Transient ischaemic attack             | 3  | 0 | 3  |
|  | Transverse sinus thrombosis            | 2  | 0 | 2  |
|  | Tremor                                 | 22 | 5 | 27 |
|  | Unresponsive to stimuli                | 5  | 0 | 5  |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous                   | 2  | 0 | 2  |
|  | Foetal death                           | 1  | 0 | 1  |
|  | Preterm premature rupture of membranes | 1  | 0 | 1  |
| Product issues                                 | Oversensing                            | 2  | 0 | 2  |
| Psychiatric disorders                          | Agitation                              | 5  | 0 | 5  |
|  | Anxiety                                | 3  | 1 | 4  |
|  | Apathy                                 | 2  | 0 | 2  |
|  | Confusional state                      | 19 | 0 | 19 |
|  | Daydreaming                            | 2  | 0 | 2  |
|  | Delirium                               | 2  | 0 | 2  |
|  | Delusion                               | 0  | 1 | 1  |
|  | Depressed mood                         | 0  | 2 | 2  |
|  | Depression                             | 1  | 0 | 1  |
|  | Disorientation                         | 2  | 0 | 2  |
|  | Dissociation                           | 0  | 1 | 1  |
|  | Eating disorder                        | 1  | 0 | 1  |
|  | Emotional poverty                      | 1  | 0 | 1  |
|  | Fear of death                          | 1  | 0 | 1  |
|  | Feeling of despair                     | 1  | 0 | 1  |

|   |                                 |    |   |    |
|---|---------------------------------|----|---|----|
|   | Hallucination                   | 1  | 1 | 2  |
|   | Hallucination, visual           | 1  | 0 | 1  |
|   | Initial insomnia                | 1  | 0 | 1  |
|   | Insomnia                        | 32 | 2 | 34 |
|   | Nervousness                     | 1  | 0 | 1  |
|   | Nightmare                       | 1  | 1 | 2  |
|   | Panic attack                    | 1  | 0 | 1  |
|   | Phonophobia                     | 1  | 0 | 1  |
|   | Psychomotor retardation         | 1  | 0 | 1  |
|   | Restlessness                    | 3  | 0 | 3  |
|   | Sleep disorder                  | 1  | 0 | 1  |
|   | Stress                          | 1  | 0 | 1  |
| Renal and urinary disorders                     | Acute kidney injury             | 3  | 0 | 3  |
|   | Bladder dysfunction             | 1  | 0 | 1  |
|   | Calculus urinary                | 1  | 0 | 1  |
|   | Chromaturia                     | 1  | 0 | 1  |
|   | Dysuria                         | 1  | 0 | 1  |
|   | Haematuria                      | 1  | 1 | 2  |
|   | Hydronephrosis                  | 1  | 0 | 1  |
|   | Incontinence                    | 1  | 0 | 1  |
|   | Neurogenic bladder              | 1  | 0 | 1  |
|   | Pollakiuria                     | 1  | 0 | 1  |
|   | Polyuria                        | 1  | 0 | 1  |
|   | Renal colic                     | 2  | 0 | 2  |
|   | Renal disorder                  | 8  | 0 | 8  |
|   | Renal failure                   | 1  | 0 | 1  |
|   | Renal pain                      | 4  | 0 | 4  |
|   | Renal tubular disorder          | 1  | 0 | 1  |
|   | Renal vascular thrombosis       | 1  | 0 | 1  |
|   | Urge incontinence               | 1  | 0 | 1  |
|   | Urinary incontinence            | 4  | 0 | 4  |
|   | Urinary retention               | 2  | 0 | 2  |
| Reproductive system and breast disorders        | Amenorrhoea                     | 1  | 0 | 1  |
|   | Breast cyst                     | 1  | 0 | 1  |
|   | Breast inflammation             | 1  | 0 | 1  |
|   | Breast pain                     | 2  | 2 | 4  |
|   | Breast swelling                 | 0  | 1 | 1  |
|   | Dysmenorrhoea                   | 2  | 0 | 2  |
|   | Ejaculation disorder            | 0  | 1 | 1  |
|   | Erectile dysfunction            | 1  | 0 | 1  |
|   | Heavy menstrual bleeding        | 2  | 1 | 3  |
|   | Menstrual disorder              | 5  | 1 | 6  |
|   | Menstruation irregular          | 1  | 0 | 1  |
|   | Polymenorrhoea                  | 1  | 0 | 1  |
|   | Postmenopausal haemorrhage      | 0  | 1 | 1  |
|   | Vaginal haemorrhage             | 2  | 1 | 3  |
|   | Varicose veins pelvic           | 1  | 0 | 1  |
|   | Vulval haematoma                | 0  | 1 | 1  |
| Respiratory, thoracic and mediastinal disorders | Acute pulmonary oedema          | 1  | 0 | 1  |
|   | Apparent life threatening event | 1  | 0 | 1  |

|  |    |    |     |
|--|----|----|-----|
| Asthma                                 | 6  | 2  | 8   |
| Choking sensation                      | 1  | 0  | 1   |
| Chronic obstructive pulmonary disease  | 1  | 0  | 1   |
| Cough                                  | 29 | 1  | 30  |
| Dysphonia                              | 2  | 0  | 2   |
| Dyspnoea                               | 67 | 5  | 72  |
| Dyspnoea exertional                    | 5  | 0  | 5   |
| Epistaxis                              | 15 | 4  | 19  |
| Hyperventilation                       | 6  | 0  | 6   |
| Lung disorder                          | 2  | 0  | 2   |
| Nasal congestion                       | 3  | 0  | 3   |
| Oropharyngeal pain                     | 14 | 2  | 16  |
| Painful respiration                    | 2  | 0  | 2   |
| Pharyngeal paraesthesia                | 0  | 1  | 1   |
| Pharyngeal swelling                    | 1  | 2  | 3   |
| Pleural effusion                       | 2  | 0  | 2   |
| Pleurisy                               | 1  | 0  | 1   |
| Productive cough                       | 1  | 0  | 1   |
| Pulmonary embolism                     | 31 | 1  | 32  |
| Pulmonary hypertension                 | 1  | 0  | 1   |
| Pulmonary microemboli                  | 1  | 0  | 1   |
| Pulmonary oedema                       | 2  | 0  | 2   |
| Pulmonary pain                         | 1  | 1  | 2   |
| Rales                                  | 1  | 0  | 1   |
| Respiration abnormal                   | 1  | 0  | 1   |
| Respiratory depression                 | 1  | 0  | 1   |
| Respiratory disorder                   | 94 | 13 | 107 |
| Respiratory distress                   | 3  | 0  | 3   |
| Rhinorrhoea                            | 3  | 2  | 5   |
| Sneezing                               | 1  | 0  | 1   |
| Snoring                                | 1  | 0  | 1   |
| Stridor                                | 1  | 0  | 1   |
| Tachypnoea                             | 1  | 0  | 1   |
| Throat irritation                      | 1  | 1  | 2   |
| Tonsillar erythema                     | 0  | 1  | 1   |
| Wheezing                               | 2  | 0  | 2   |
| Skin and subcutaneous tissue disorders |    |    |     |
| Angioedema                             | 4  | 2  | 6   |
| Blister                                | 2  | 0  | 2   |
| Cold sweat                             | 2  | 1  | 3   |
| Dermatitis allergic                    | 1  | 0  | 1   |
| Ecchymosis                             | 2  | 0  | 2   |
| Eczema                                 | 1  | 1  | 2   |
| Erythema                               | 14 | 4  | 18  |
| Erythema multiforme                    | 0  | 1  | 1   |
| Hyperhidrosis                          | 72 | 4  | 76  |
| Macule                                 | 0  | 1  | 1   |
| Miliaria                               | 2  | 0  | 2   |
| Night sweats                           | 1  | 2  | 3   |
| Pain of skin                           | 10 | 0  | 10  |
| Pemphigoid                             | 1  | 0  | 1   |

|                                 |                                 |    |    |     |
|---------------------------------|---------------------------------|----|----|-----|
|                                 | Petechiae                       | 7  | 3  | 10  |
|                                 | Photosensitivity reaction       | 3  | 0  | 3   |
|                                 | Pruritus                        | 13 | 4  | 17  |
|                                 | Pseudofolliculitis              | 0  | 1  | 1   |
|                                 | Psoriasis                       | 1  | 0  | 1   |
|                                 | Purpura                         | 1  | 1  | 2   |
|                                 | Rash                            | 4  | 1  | 5   |
|                                 | Rash erythematous               | 4  | 0  | 4   |
|                                 | Rash macular                    | 2  | 1  | 3   |
|                                 | Rash papular                    | 0  | 1  | 1   |
|                                 | Rash pruritic                   | 1  | 1  | 2   |
|                                 | Sensitive skin                  | 3  | 0  | 3   |
|                                 | Skin discolouration             | 1  | 2  | 3   |
|                                 | Skin disorder                   | 74 | 30 | 104 |
|                                 | Skin lesion                     | 0  | 1  | 1   |
|                                 | Skin lesion inflammation        | 1  | 0  | 1   |
|                                 | Skin mass                       | 1  | 0  | 1   |
|                                 | Skin odour abnormal             | 1  | 0  | 1   |
|                                 | Urticaria                       | 7  | 4  | 11  |
| Social circumstances            | Bedridden                       | 0  | 1  | 1   |
|                                 | Disability                      | 0  | 1  | 1   |
|                                 | Impaired work ability           | 1  | 1  | 2   |
|                                 | Sitting disability              | 1  | 0  | 1   |
|                                 | Walking disability              | 1  | 0  | 1   |
| Surgical and medical procedures | Bed rest                        | 1  | 0  | 1   |
|                                 | Chemotherapy                    | 1  | 0  | 1   |
|                                 | Dialysis                        | 1  | 0  | 1   |
|                                 | Explorative laparotomy          | 1  | 0  | 1   |
|                                 | Eye laser surgery               | 1  | 0  | 1   |
|                                 | Hospitalisation                 | 1  | 1  | 2   |
|                                 | Interchange of vaccine products | 1  | 1  | 2   |
|                                 | Thrombectomy                    | 1  | 0  | 1   |
|                                 | Thromboembolectomy              | 1  | 0  | 1   |
| Vascular disorders              | Arteriosclerosis                | 0  | 1  | 1   |
|                                 | Axillary vein thrombosis        | 1  | 0  | 1   |
|                                 | Blood pressure fluctuation      | 1  | 0  | 1   |
|                                 | Bloody discharge                | 1  | 0  | 1   |
|                                 | Capillary leak syndrome         | 1  | 0  | 1   |
|                                 | Cyanosis                        | 2  | 3  | 5   |
|                                 | Deep vein thrombosis            | 18 | 6  | 24  |
|                                 | Flushing                        | 1  | 0  | 1   |
|                                 | Giant cell arteritis            | 1  | 0  | 1   |
|                                 | Haematoma                       | 5  | 7  | 12  |
|                                 | Haemodynamic instability        | 1  | 0  | 1   |
|                                 | Haemorrhage                     | 1  | 2  | 3   |
|                                 | Hot flush                       | 13 | 0  | 13  |
|                                 | Hypertension                    | 30 | 5  | 35  |
|                                 | Hypertensive crisis             | 2  | 0  | 2   |
|                                 | Hypotension                     | 21 | 5  | 26  |
|                                 | Hypovolaemic shock              | 2  | 0  | 2   |

|                              |              |             |               |
|------------------------------|--------------|-------------|---------------|
| Infarction                   | 1            | 0           | 1             |
| Ischaemia                    | 1            | 0           | 1             |
| Jugular vein thrombosis      | 3            | 0           | 3             |
| Lymphoedema                  | 1            | 0           | 1             |
| Pallor                       | 1            | 0           | 1             |
| Pelvic venous thrombosis     | 0            | 1           | 1             |
| Peripheral coldness          | 5            | 2           | 7             |
| Peripheral ischaemia         | 1            | 0           | 1             |
| Peripheral vascular disorder | 1            | 0           | 1             |
| Peripheral venous disease    | 1            | 1           | 2             |
| Periphlebitis                | 0            | 1           | 1             |
| Phlebitis                    | 2            | 3           | 5             |
| Phlebitis superficial        | 0            | 1           | 1             |
| Subclavian artery thrombosis | 1            | 0           | 1             |
| Subclavian vein thrombosis   | 1            | 0           | 1             |
| Thrombophlebitis             | 2            | 0           | 2             |
| Thrombophlebitis superficial | 5            | 4           | 9             |
| Thrombosis                   | 18           | 5           | 23            |
| Varicose vein                | 1            | 1           | 2             |
| Vascular pain                | 1            | 1           | 2             |
| Vascular rupture             | 1            | 0           | 1             |
| Vasodilatation               | 2            | 1           | 3             |
| Vein disorder                | 1            | 0           | 1             |
| Vein rupture                 | 1            | 1           | 2             |
| Venous aneurysm              | 0            | 1           | 1             |
| Venous occlusion             | 0            | 1           | 1             |
| Venous thrombosis            | 3            | 1           | 4             |
| Venous thrombosis limb       | 1            | 1           | 2             |
| <b>Total</b>                 | <b>13261</b> | <b>1518</b> | <b>14.779</b> |