**Supplementary data**

**Table 1: Defective medicines under class 2, 3 and 4 drug alerts**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Type of defect** | **Number of medications recalled under class 2 alert** | **Number of medications recalled under class 3 alert** | **Number of medications under class 4 alert** | **Company-led recalls** |
| **Substandard medicines** | **Contamination** | 40 | 9 | 7 | 11 |
| **Major packaging defects** | 7 | 5 | 14 | 0 |
| **Minor packaging defects** | 40 | 9 | 22 | 1 |
| **Delivery issues** | 17 | 3 | 4 | 5 |
| **Stability failure** | 11 | 12 | 0 | 0 |
| **Potency issues** | 5 | 0 | 0 | 2 |
| **Issues relating to active pharmaceutical ingredient** | 4 | 1 | 0 | 1 |
| **Other issues** | 33 | 0 | 0 | 2 |
| **Counterfeit medicines** | **Counterfeit medicines** | 4 | 0 | 1 | 0 |
|  | **Total** | 161 | 39 | 48 | 22\* |

\* All company-led recalls were issued by manufacturers in 2011

**Table 2: Substandard parenteral formulations**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Defect Type** | **Intravenous** | **Subcutaneous** | **Intramuscular** | **Intravitreal** | **Total** |
| Contamination | 48 | 6 | 6 | 0 | 60 |
| Minor packaging defect | 16 | 2 | 0 | 0 | 18 |
| Delivery defect | 9 | 4 | 0 | 1 | 14 |
| Major packaging defects | 9 | 0 | 0 | 0 | 9 |
| Stability defect | 2 | 1 | 1 | 0 | 4 |
| Defect in active ingredient | 0 | 1 | 0 | 0 | 1 |
| Potency | 2 | 0 | 3 | 0 | 5 |
| Other defects | 3 | 1 | 2 | 0 | 6 |
| **Total** | **89** | **15** | **12** | **1** | **117** |

**Table 3: Substandard medicines reported by the MHRA, classified according to the organ or system in which they act and according to the therapeutic subgroup they belong (ATC Classification) 2001-2011:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Category** | **No.** | **%** | **Category** | **No.** | **%** |
| **According to organ or system in which the drug acts** | | | **According to subgroup, therapeutic main group** | | |
| **Nervous system** | **45** | **16.1** | **Psychoanaleptics**  **Psycholeptics**  **Analgesics**  **Antiepileptics**  **Anaesthetics** | **12**  **11**  **10**  **10**  **2** | **4.3**  **4.0**  **3.6**  **3.6**  **0.7** |
| **Cardiovascular System** | **41** | **14.6** | **Antihypertensives**  **Cardiac therapy**  **Lipid modifying agents** | **27**  **11**  **3** | **9.6**  **4.0**  **1.1** |
| **Anti-infectives for systemic use** | **35** | **12.5** | **Antibacterials for systemic use**  **Vaccines**  **Antivirals for systemic use**  **Antimycotics for systemic use** | **19**  **9**  **4**  **3** | **6.8**  **3.2**  **1.4**  **1.1** |
| **Blood and blood forming organs** | **30** | **10.7** | **Blood substitutes and perfusion solutions**  **Antithrombotic agents**  **Antianemic preparations** | **18**  **9**  **3** | **6.4**  **3.2**  **1.1** |
| **Alimentary tract and metabolism** | **29** | **10.3** | **Drugs for acid related disorders**  **Drugs for functional gastrointestinal disorders**  **Drugs used in diabetes**  **Vitamins**  **Stomatological preparations** | **10**  **9**  **5**  **4**  **1** | **3.6**  **3.2**  **1.8**  **1.4**  **0.3** |
| [**Antineoplastic**](http://en.wikipedia.org/wiki/Antineoplastic) **and**  [**immunomodulating**](http://en.wikipedia.org/wiki/Immunomodulator)  **agents** | **29** | **10.3** | **Antineoplastic agents**  **Immunostimulants**  **Endocrine therapy**  **Immunosuppressants** | **21**  **5**  **2**  **1** | **7.5**  **1.8**  **0.7**  **0.3** |
| [**Respiratory system**](http://en.wikipedia.org/wiki/Respiratory_system) | **15** | **5.4** | **Drugs for obstructive airway diseases**  **Throat preparations**  **Antihistamines for systemic use**  **Nasal preparations** | **11**  **2**  **1**  **1** | **4.0**  **0.7**  **0.3**  **0.3** |
| [**Genito-urinary system**](http://en.wikipedia.org/wiki/Genito-urinary_system) **and**  [**sex hormones**](http://en.wikipedia.org/wiki/Sex_hormone) | **13** | **4.6** | **Sex hormones and modulators of the genital system**  **Urologicals**  **Gynecological antiinfectives and antiseptics** | **6**  **5**  **2** | **2.2**  **1.8**  **0.7** |
| [**Sensory organs**](http://en.wikipedia.org/wiki/Sensory_organ) | **12** | **4.3** | **Ophthalmologicals**  **Otologicals** | **11**  **1** | **4.0**  **0.3** |
| **Various** | **12** | **4.3** | **All other therapeutic products**  **General nutrients**  **Diagnostic radiopharmaceuticals** | **5**  **4**  **3** | **1.8**  **1.4**  **1.1** |
| [**Musculo-skeletal system**](http://en.wikipedia.org/wiki/Musculo-skeletal_system) | **10** | **3.6** | **Antiinflammatory and antirheumatic products**  **Muscle relaxants** | **8**  **2** | **3.0**  **0.7** |
| **Systemic** [**hormonal**](http://en.wikipedia.org/wiki/Hormonal) **preparations,**  **excluding sex hormones and**  **insulins** | **8** | **2.9** | **Corticosteroids for systemic use**  **Thyroid therapy**  **Pituitary and hypothalamic hormones and analogues**  **Pancreatic hormones** | **4**  **2**  **1**  **1** | **1.4**  **0.7**  **0.3**  **0.3** |
| [**Dermatologicals**](http://en.wikipedia.org/wiki/Dermatological) | **1** | **0.4** | **Corticosteroids, dermatological preparations** | **1** | **0.3** |
| **Total** | **280** | **100** | **Total** | **280** | **100** |

**Table 4: Substandard medicines categorised by manufacturer and type of defects**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** | **Pharmaceutical company** | **Type of defect** | | | | | | | | **Total** | **Area served**  **(Headquarter)** | **Manufacturing facility in the UK (Yes/No)** |
| Stability | Contamination | Minor packaging | Active ingredient | Major packaging | Delivery | Potency | Others |
| **1** | **Baxter Healthcare** | 0 | 14 | 1 | 0 | 0 | 5 | 0 | 0 | 20 | Worldwide (USA) | Yes |
| **2** | **Sanofi Aventis** | 1 | 5 | 3 | 1 | 3 | 0 | 2 | 3 | 15 | Worldwide (France) | Yes |
| **3** | **Pfizer** | 0 | 1 | 10 | 0 | 0 | 2 | 0 | 1 | 14 | Worldwide (USA) | Yes |
| **4** | **Martindale Pharmaceuticals** | 0 | 2 | 1 | 0 | 10 | 1 | 0 | 0 | 14 | UK (UK) | Yes |
| **5** | **Glaxosmithkline** | 1 | 2 | 5 | 2 | 0 | 0 | 0 | 3 | 13 | Worldwide (UK) | Yes |
| **6** | **Novartis** | 1 | 3 | 5 | 0 | 0 | 1 | 0 | 1 | 11 | Worldwide (Switzerland) | Yes |
| **7** | **Merck Sharp & Dohme** | 3 | 1 | 5 | 0 | 2 | 0 | 0 | 0 | 11 | Worldwide (USA) | Yes |
| **8** | **Janssen** | 2 | 4 | 2 | 0 | 0 | 1 | 1 | 0 | 10 | Worldwide (Belgium) | No |
| **9** | **TEVA** | 4 | 1 | 2 | 0 | 1 | 0 | 1 | 1 | 10 | Worldwide (Israel) | Yes |
| **10** | **AstraZeneca** | 1 | 0 | 3 | 0 | 1 | 4 | 0 | 0 | 9 | Worldwide (UK) | Yes |
| **11** | **Sandoz (subsidiary of Novartis)** | 0 | 3 | 0 | 0 | 0 | 2 | 0 | 4 | 9 | Worldwide  ( Switzerland ) | Yes |
| **12** | **Karib Kemi Pharm** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 9 | Europe (UK) | Yes |
| **13** | **Ranbaxy** | 0 | 0 | 7 | 0 | 0 | 0 | 0 | 1 | 8 | Worldwide  ( India ) | No |
| **14** | **Roche** | 0 | 3 | 1 | 0 | 0 | 0 | 1 | 0 | 5 | Worldwide  ( Switzerland ) | No |
| **15** | **FDC limited** | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 5 | Worldwide  ( India ) | No |
|  | | | | | | | | | | 163 |  |  |