**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 |  |  |