

## 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
<b>Total</b>		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
<b>Total</b>	<b>89</b>	<b>15</b>	<b>12</b>	<b>1</b>	<b>117</b>

**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 and immunomodulating agents	29	10.3	Antineoplastic agents Immunostimulants Endocrine therapy Immunosuppressants	21 5 2 1	7.5 1.8 0.7 0.3
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 and sex hormones	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	12	4.3	Ophthalmologicals Otolologicals	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	10	3.6	Antiinflammatory and antirheumatic products Muscle relaxants	8 2	3.0 0.7
Systemic 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	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
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