

Substandard and falsified antibiotics: neglected drivers of antimicrobial resistance?

Supplementary file 12: Seizures/Recalls/Alerts/Case-reports of substandard and falsified antibiotics

Country	API/combination of APIs	Year	No. Batch/Case	Quality test failure	Report Type	Ref
Cameroon	Metronidazole	Mar-2015	Unstated	Falsified-“Traffic de médicaments: 35 millions FCFA de médicaments contrefaits détruits dans la ville de Bafoussam [...] Entre autres médicaments détruits, l’on a pu dénombrer du Métronidazole intraveineux Metlife 500mg/100ml [...]”	Seizure	[1]
	Amoxicillin, Ampicillin	2016	Unstated	Falsified–no API	Recall/Warning/Alert	[2]
	Phenoxymethylpenicillin (Penicillin V)	Nov-2017	1	Falsified–wrong API (tablet contained paracetamol 50mg)	Recall/Warning/Alert	[3]
	Amoxicillin-Clavulanic acid	Mar-2018	1	Falsified-“[...] packaging appears to be a close imitation of the genuine product but GlaxoSmithKline confirmed they did not manufacture it.”	Recall/Warning/Alert	[4]
Cambodia	Antibiotics-unspecified	Nov-2018	Unstated	SorF-“[...] illegal goods and substandard medication [...] included [...] antibiotics”	Seizure	[5]
Canada	Ampicillin, Doxycycline	Sept-2015	Unstated	Unregistered - seized at “Taste of Ukraine” in Burnaby	Seizure	[6]
	Amoxicillin, Ampicillin	May-2018	Unstated	Unregistered - seized from Gigi’s Market, Ottawa	Seizure	[7]
Costa Rica	Ceftriaxone	Feb-2018	1	Falsified–contains cefazolin and a low concentration of unidentified contaminants.	Recall/Warning/Alert	[8]
Democratic Republic of Congo	Chloramphenicol, Sulfamethoxazole-Trimethoprim	2012	46	Falsified-“cotrimoxazole bought at illicit points of sale is the main etiology of fixed drug eruption”	Case report	[9]
	Amoxicillin, Ampicillin	Oct-2015	1	Falsified–no API	Recall/Warning/Alert	[10]
	Nalidixic acid	Jan-2016	Unstated	Falsified–no API (“30,000 false tablets”)	Recall/Warning/Alert	[11]
	Cefixime	Jan-2018	2	Falsified–one batch contained no API and another batch contain 2.5% cefixime	Recall/Warning/Alert	[12]
Dominican Republic	Antibiotics-unspecified	2014	Unstated	Falsified-“Among the drugs seized there are [...], antibiotics and [...]”	Seizure	[13]
	Amoxicillin, Ampicillin	Oct-2015	3	Falsified-“List of the 22 falsified medicines: [...] Amoxicillin 500mg capsules, Amoxicillin 1000mg capsules, Ampicillin 1000mg capsules [...]”	Recall/Warning/Alert	[14]
El Salvador	Ampicillin, Nitrofurantoin, Sulfamethoxazole-Trimethoprim	Jan-1991	1	Falsified – “[...] Scanprin tablets 400mg + 80mg score narrower and tablet is 1 mm higher than Scanpharm’s; Furinamine s/c tablet 100mg weight approximately 560mg whereas Scanpharm’s tablets weight approximately 460mg, colour brighter blue than Scanpharm’s tablets; Ampiscan capsules 500mg capsule size 00 without snap fit whereas Scanpharm’s capsules are size 0 E with snap fit.”	Recall/Warning/Alert	[15]
France	Amoxicillin-Clavulanic Acid	Jan-2019	4	Substandard-labelling with incorrect administration instruction	Recall/Warning/Alert	[16]

Germany	Gentamicin	Jul-1997	1	Substandard-visible particulates	Recall/Warning/Alert	[17]
Guatemala	Gentamicin	Aug-2013	Unstated	Falsified—"A fake version of Gentamicina MK, injection solution 80mg [...] under the name Gentamicina MIC"	Recall/Warning/Alert	[18]
Haiti	Ciprofloxacin	Apr-2001	1	SorF—"[...] unclear whether the ciprofloxacin he received in Haiti was substandard, his previous prompt response to quinolones alone suggested that it was."	Case report	[19]
India	Ampicillin, Cefalexin	2003	Unstated	Falsified—"[...] two antibiotics have been identified as Amproxin-500 and Sporidex-500."	Seizure	[20]
	Amoxicillin-Clavulanic acid	Apr-2013	Unstated	Falsified—no API	Seizure	[21]
	Amoxicillin-dicloxacillin, ofloxacin	Jul-2014	Unstated	SorF—"Karnataka DC dept seizes 20 out-of-std quality drugs from pharmacies [...] Staph-AC with amoxicillin and dicloxacillin [...] Offmark-Oz containing ofloxacin and ornidazole [...] Dorflox-OR (ofloxacin and ornidazole) [...] Dibaymox which contains amoxicillin with dicloxacillin [...]"	Seizure	[22]
	Ciprofloxacin	Nov-2014	13	SorF-contaminant	Case report	[23]
	Ciprofloxacin	Mar-2015	Unstated	SorF-API contents (not detailed)	Seizure	[24]
	Azithromycin	Jul-2015	1	SorF-visual inspection	Recall/Warning/Alert	[25]
	Cefixime	Jul-2015	1	SorF-API content and identification, dissolution, mass uniformity	Recall/Warning/Alert	[25]
	Erythromycin	Jul-2015	1	SorF-API content and identification, mass uniformity, water content	Recall/Warning/Alert	[25]
	Meropenem	Jul-2015	1	SorF-loss on drying	Recall/Warning/Alert	[25]
	Metronidazole	Jul-2015	1	SorF-dissolution	Recall/Warning/Alert	[25]
	Ceftazidime-Tazobactam	Oct-2015	1	SorF-impurity	Recall/Warning/Alert	[26]
	Clindamycin	May-2016	1	SorF-water content	Recall/Warning/Alert	[27]
	Norfloxacin	May-2016	1	SorF-dissolution	Recall/Warning/Alert	[27]
	Erythromycin	Aug-2016	2	SorF-API content (not detailed)	Seizure	[28]
	Amoxicillin, Cefixime, Ciprofloxacin, Ofloxacin	Dec-2016	Unstated	Falsified—"Koshia told TOI seized drugs included fake amoxicillin, ciprofloxacin, ofloxacin and even high-power antibiotics like cefixime."	Recall/Warning/Alert	[29]
	Gentamicin, Ofloxacin	Jun-2017	Unstated	SorF—"[...] found to be not of standard quality are [...] Gentarid fo rIM/IV use which is gentamycin injection [...] Lifobid-200 which are ofloxacin tablets [...]"	Seizure	[30]
Levofloxacin	Jul-2018	1	Substandard—low API, failed dissolution test	Case reports	[31]	

Amoxicillin-Clavulanic acid	Apr-2019	2	SorF-API content, API identification and particulate matter	Recall/Warning/Alert	[32]
Cefpodoxime	Apr-2019	1	SorF-API content and disintegration	Recall/Warning/Alert	[32]
Ciprofloxacin	Apr-2019	2	SorF-dissolution	Recall/Warning/Alert	[32]
Gentamicin	Apr-2019	1	SorF-particulate matter	Recall/Warning/Alert	[32]
Amikacin	Jun-2019	Unstated	Falsified-“[...] nearly 10,000 fake antibiotic vials of amikacin injection worth Rs 7 lakh were recovered in Agra.”	Seizure	[33]
Ceftriaxone	Nov-2019	1	SorF-dissolution	Recall/Warning/Alert	[34]
Amoxicillin-Clavulanic acid	Dec-2019	1	SorF-API content, content uniformity	Recall/Warning/Alert	[35]
Azithromycin, Cefadroxil, Cefuroxime, Ciprofloxacin, Erythromycin, Norfloxacin	Dec-2019	6	SorF-dissolution	Recall/Warning/Alert	[35]
Azithromycin, Neomycin-Polymyxin, Tobramycin	Dec-2019	3	SorF-API content (not detailed)	Recall/Warning/Alert	[35]
Cefixime	Dec-2019	1	SorF-API content, pH, water content	Recall/Warning/Alert	[35]
Cloxacillin	Dec-2019	1	SorF-description, API identification	Recall/Warning/Alert	[35]
Amoxicillin, Amoxicillin-Clavulanic acid, Clindamycin	Feb-2020	3	SorF-API content (not detailed)	Recall/Warning/Alert	[36]
Erythromycin, Metronidazole	Feb-2020	2	SorF-dissolution	Recall/Warning/Alert	[36]
Oxytetracycline	Feb-2020	1	SorF-water content	Recall/Warning/Alert	[36]
Amoxicillin-Clavulanic acid	Apr-2020	1	Substandard-API content (not detailed)	Recall/Warning/Alert	[37]
Cefotaxime	Apr-2020	1	Substandard-impurity	Recall/Warning/Alert	[37]
Cefuroxime, Ofloxacin	Apr-2020	2	Substandard-API content	Recall/Warning/Alert	[37]
Cefpodoxime, Chloramphenicol, Norfloxacin	Apr-2020	4	Substandard-dissolution	Recall/Warning/Alert	[37]
Cefpodoxime, Ciprofloxacin	May-2020	2	SorF-dissolution	Recall/Warning/Alert	[38]
Ofloxacin	May-2020	1	SorF-API identification	Recall/Warning/Alert	[38]
Amoxicillin-Clavulanic acid	Jun-2020	1	SorF-API content (not detailed)	Recall/Warning/Alert	[39]
Cefotaxime	Jun-2020	1	SorF-“water”	Recall/Warning/Alert	[39]
Doxycycline	Jun-2020	2	SorF-API content, mass uniformity	Recall/Warning/Alert	[39]

	Nitrofurantoin	Jun-2020	1	SorF-dissolution	Recall/Warning/Alert	[39]
	Polymyxin B-Chloramphenicol-Dexamethasone	Jun-2020	1	SorF-API content (not detailed)	Recall/Warning/Alert	[39]
	Ciprofloxacin	Jul-2020	1	SorF-API content, dissolution	Recall/Warning/Alert	[40]
Indonesia	Antibiotics-unspecified	Mar-2009	Unstated	Falsified- "Counterfeit products included antibiotics..."	Seizure	[41]
Ireland	Gentamicin-Prednisolone eyedrops	Oct-2001	Unstated	Substandard-preservative efficacy	Recall/Warning/Alert	[42]
Kenya	Amoxicillin-Clavulanic acid	Aug-2019	1	Falsified-no API	Recall/Warning/Alert	[43]
Lao PDR	Tetracycline	Oct-2004	Unstated	SorF-API content	Case report	[44]
Mali	Amoxicillin	Mar-2014	Unstated	Falsified-"[...] district police of Bamako seized 192 cartons of counterfeit medicines. The boxes consisted [...] amoxicillin."	Seizure	[45]
Nepal	Amoxicillin	Mar-2004	Unstated	Falsified-no API	Seizure	[46]
Niger	Amoxicillin	Oct-2014	1	Falsified-"[...] the following lots have been identified and confirmed as falsified Amoxycillin B.P 250mg [...]"	Recall/Warning/Alert	[47]
	Sulfamethoxazole-Trimethoprim	Feb-1993	Unstated	Falsified-wrong API	Recall/Warning/Alert	[48]
	Ampicillin-Cloxacillin, Lincomycin, Sulfamethoxazole-Trimethoprim	Jun-2010	Unstated	Falsified-"The fake drugs intercepted are [...] lincomycin capsule 500, ampicillin/cloxacillin 500mg, trimethoprim 80mg/sulfamethoxazole 400mg [...]"	Recall/Warning/Alert	[49]
	Ampicillin-Cloxacillin, Chloramphenicol	Oct-2011	Unstated	Falsified-API identification	Recall/Warning/Alert	[50]
	Sulfamethoxazole-Trimethoprim	Oct-2011	Unstated	Unregistered-"Banned product"	Recall/Warning/Alert	[50]
Nigeria	Amoxicillin-Clavulanic acid, Ampicillin-Cloxacillin, Bacitracin-Neomycin, Sulfamethoxazole-Trimethoprim	Jan-2014	Unstated	Falsified-"[...] the seized fake drugs [...] Septrin suspension, Cicatrin powder, Ampiclox suspension, Augmentin syrup [...]"	Seizure	[51]
	Amoxicillin-Clavulanic acid, Cefdinir, Cefuroxime, Clindamycin, Gentamicin	Mar-2015	Unstated	Unregistered	Recall/Warning/Alert	[52]
Republic of the Philippines	Clarithromycin	May-2015	Unstated	Falsified-no API, visual inspections	Recall/Warning/Alert	[53]
	Amoxicillin-Clavulanic acid	Jul-2015	Unstated	Substandard-Low API content	Recall/Warning/Alert	[54]

Tanzania	Amoxicillin, Ampicillin, Betamethasone-Clotrimazole-Gentamicin	Sep-2005	Unstated	Falsified-visible particulates, related substances, no API	Recall/Warning/Alert	[55]
	Betamethasone-Clotrimazole-Gentamicin	Sept-2005	Unstated	Falsified-low API, wrong API	Recall/Warning/Alert	[55]
Uganda	Tetracycline	Nov-2008	Unstated	Falsified-no API, wrong API (soya flour)	Seizure	[56]
	Ceftriaxone	Jan-2016	1	SorF-low API	Case report	[57]
	Amoxicillin-Clavulanic acid	Aug-2019	1	Falsified-no API	Recall/Warning/Alert	[43]
United Kingdom	Amoxicillin	Jul-2004	Unstated	SorF-low API	Recall/Warning/Alert	[58]
	Chloramphenicol eyedrops	Apr-2019	18	Substandard-incorrect PIL and labelling	Recall/Warning/Alert	[59]
United States of America	Tetracycline	Apr-1963	3	SorF-degraded “[...]patients suffering from Fanconi syndrome with suspicions that it was caused by a degradation product of tetracycline[...]”	Case report	[60]
	Clindamycin	Jun-2017	7	Substandard-microbial contamination	Recall/Warning/Alert	[61]
	Ceftriaxone	Jan-2019	42	Substandard-visual particulate in reconstituted vials	Recall/Warning/Alert	[62]
	Piperacillin-Tazobactam	Jul-2018	2	Substandard-presence of particulates identified as glass and silicone material	Recall/Warning/Alert	[63]
	Tetracycline	Apr-2020	8	SorF-dissolution	Recall/Warning/Alert	[64]
	Ceftazidime	May-2020	1	Substandard-stability	Recall/Warning/Alert	[65]
Unknown	Antibiotics-unspecified	Jun-2013	Unstated	Falsified-“[...] fake medicines seize during Pangea VI were antibiotics.”	Seizure	[66]

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