



## **PHARMACOVIGILANCE & POST-MARKET SURVEILLANCE (PV/PMS)**

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### **LIST OF SAFETY ALERT PUBLISHED AND DISTRIBUTED IN 2016 - 2018**

<b>S/N</b>	<b>NAME OF DRUGS</b>	<b>MANUFACTURER/ SOURCE</b>	<b>BATCH NUMBER</b>	<b>REASON FOR REGULATORY ACTION</b>	<b>REGULATORY ACTION TAKEN</b>
1.	5% Dextrose Injection	B. Braun Medical Inc.	J5J706	Presence of particulate matter identified to be microbial growth within the solution	Dear HealthCare provide letter issued to Healthcare professionals by NAFDAC. Product recalled by the manufacturer.
2.	Quinine Sulphate 300mg	Novadina Pharmaceuticals Ltd, London United Kingdom	10H05	Falsified Quinine Sulphate (in Cameroon and Congo)	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC.
3.	i) Metronidazole Injection USP 500mg/100ml  ii) 0.9% Sodium Chloride Injection 100ml	Singaporean Health Science Authority (HAS)  Singaporean Health Science Authority (HAS)	P339135  P337857	Due to leakages and particulate issues	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC.

4.	i) Spotchem II Basic Panel -1 Reagent Test Strip ii) Spotchem II Glucose Reagent Test Strip	Arkay Pharmaceutical, India	PN5C26 EA4M78	Inaccurate blood sugar reading.	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC.
5.	Clindamycin Injection USP Vials	Hospira Inc Lake Forest, Illinois USA. For Alvogen Pharmaceuticals	68-104-EV 68-105-EV 68-106-EV 73-154-EV 73-155-EV 73-156-EV 73-157-EV	Microbial growth detected during routine stimulation of Manufacturing Process.	Dear HealthCare provider letter issued to Healthcare professional by NAFDAC.  The product was recalled by the manufacturer.
6.	Riomet (Metformin Hydrochloride Oral Solution) in 118ml, 473ml, bottles	Sun Pharmaceutical Industries	A160031A A160031B	Contaminated with Scopulariopsis Brevicaulis.	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC'  Product was recalled by the manufacturer.
7.	0.9% Sodium Chloride Injection USP	Fresenius Medical Care, 45 Staples Avenue, Suite 110 Richmond Hill, Canada	16EU05011 16EU05012 16EU05013	Leakages in the solution bags	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC.  Product was recalled by the manufacturer
8.	i) Fleming Tablet 1g ii) Fleming for oral suspension 457mg/5ml iii) Fleming for suspension 228.5mg /5ml	Medreich Pharmaceutical Franchise, Hong-Kong.	HK -52242 HK -56072 HK- 56069	Misinformation on the Package label Instruction which did not match the registered version.	Dear HealthCare provider letter issued to Healthcare professionals by NAFDAC.
9.	Fentanyl Citrate injection 50mcg/mL		59277EV 60028EV	Confirmed ampoules with broken tips.	Dear HealthCare provide letter issued to Healthcare professionals by NAFDAC

10.	Paliperidone Extended Release Tablet, 3mg	Teva Pharmaceuticals USA, Inc.	1160682A	Failed Test result due to dissolution.	Dear HealthCare provider issued to Healthcare professional
11.	Valsartan 40mg, 80mg, 160mg capsules.	Dexcel Pharm Limited	PL 14017/0192 PL 14017/0193 PL 14017/0194	Contamination of active pharmaceutical ingredient.	Public Alert Notice was issued by NAFDAC.  Products were recalled by the manufacturer.
12.	Valsartan 40mg, 80mg, 160mg, 320mg film-coated tablets	Actavis Group PTC EHF	PL 30306/0109 PL 30306/0110 PL 30306/0111 PL 30306/0405	Contamination of active pharmaceutical ingredient.	Public Alert Notice was issued by NAFDAC.  Products were recalled by the manufacturer.
13.	Highly Purified Human Chorionic Gonadotrophin) powder for injection HP-hCG 1500, 5000, 1500, 1500, 1500, 5000 MX, 1500,	Ferring GmbH, Wittland 11 24109 Kiel, Germany.	M11450, M11453, M14238, N11461, N12932, N15061, P11497	Glass breakage at the vial inlet during filling operations causing contamination	Public Alert Notice was issued by NAFDAC.  Product was recalled by the manufacturer.
14.	i) AMLODIPINE 5mg Tablets  ii) AMLODIPINE 10mg Tablets	Ecomed Pharma Ltd.  Plot 32, Lynson Chemical Avenue, Km 38, Lagos-Abeokuta	7J006001 8A006001 8A006002   7L007001 7M007002	False and misleading labelling.	Public Alert Notice was issued by NAFDAC.  Products were recalled by the manufacturer

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15.	<ul style="list-style-type: none"> <li>i. Costrim Tablet</li> <li>ii. Metronidazole Tablet</li> <li>iii. Catrim Tablet</li> <li>iv. Cemtrim 480 Tablet</li> </ul>	Mr. Emeka Madu (Alias Cabara)	<ul style="list-style-type: none"> <li>i. CST 530</li> <li>ii. 009</li> <li>iii. CPC 104</li> <li>iv. 542</li> </ul>	Falsely labelled with the names of different manufacturers. Falsified NAFDAC Registration Numbers. Falsified medical products	<p>Products were confiscated.</p> <p>Mr. Emeka Madu was arrested and the illegal manufacturing outfit sealed up.</p>
16.	Malco (Vitamin B Complex) injection 10ml	Shreechem Pharmaceuticals PVT Limited, India.	All batches	Observed particulate materials (possible microbial growth) in bottles of the product.	<p>Public Alert Notice was issued by NAFDAC.</p> <p>Product was recalled by the manufacturer</p>