ANNEXURE -08	NAFDAC SOP REF. NO.:NAFDAC-QMS-010-00	COMPLAINTS LOG

CONSUMER COMPLAINTS FOR DRUGS – 2021

S/No.	COMPLAINTS NO. (YR/SERIAL NO./DIRECTORATE)	DATE RECEIVED/BY(NAME)	SOURCE	MODE OF COMPLAINTS	ROOT CAUSE INVESTIGATION	CORRECTIVE ACTION	STATUS (OPEN OR CLOSE)	DATE OF CLOSURE	REMARKS
1	2021/CCD/001/PVPMS	02/02/2021 (Director's office)	DD i/c PVPMS	Social media	**NELB Omeprazole CAPS 20mg** Several blisters are empty (did not contain capsules) even though the product has not been tampered with.	The complaint was handled by Ogun State Office. Mystery surveillance was also carried out in several pharmacies in Abuja. The implicated product was not found in stock.	CLOSED	02/02/2021	
2	2021/CCD/002/PVPMS	03/02/2021 (Director's office)	DD i/c PVPMS	Social media	**D-KOFF Expectorant** Product expires FEB 2021 but is still being sold by the facility.	The complaint was handled by Rivers State Office. Mystery surveillance was carried out in several pharmacies in Abuja. The implicated product was not found in stock.	CLOSED	03/02/2021	
	2021/CCD/003/PVPMS	17/05/2021 (Mrs. Yvonne Ikhide)	Walk-in	Written	**AMPICLOX 500mg by GSK** Office pins were discovered in some capsules	Investigation was carried out at the retail outlet (20/05/2021). The implicated batch was not in stock. Investigation was extended to the wholesaler of the complaint product. (20/05/2021). The complaint batch was not found, and records presented by the wholesaler indicated that the wholesaler did not stock the implicated batch. The retailer was invited for a meeting with the DD i/c, PV/PMS to verify the source of the defective product (28/05/2021).	CLOSED	22/07/2021	

- Complaints unresolved due to insufficient information by complainants will be closed after one (1) month, after all efforts to extract such information have failed
- Efforts should be made to conclude all investigations in at most three (3) months from the date when complaint was made

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						The Medical Rep. of GSK was invited for a meeting with the DD i/c, PV/PMS (11/06/2021). The complaint product was submitted to GSK to ascertain if the product is truly theirs. GSK confirmed that the product is theirs, but it had been tampered with. The batch could not be traced to the original source due to fact that both the wholesaler and retailer did not have good distribution practice in place.			
4	2021/CCD/004/PVPMS	10/08/2021 PV/PMS Lagos	PV Email	Email	**TREASURE MAN HERBAL SUSPENSION** Sale of unregistered product with a fake NRN	Complaint was forwarded to PMS for further regulatory action.	Closed	11/08/2021	
5	2021/CCD/005/PVPMS	10/08/2021 Director's Office	Social media	WhatsApp	**KESSINGTON Ciprofloxacin Tablets USP 500mg** MAS issues. - The complainant sent the PIN to the short code and received a message referring to another drug (Kessartem, an ACT) but saying the medicine is 'OK'	The manufacturer was contacted. The Rep stated that the mix-up was from the service provider and both medicines were products of Kessington. He confirmed that the medication is genuine.	Closed	10/08/2021	
6	2021/CCD/006/PVPMS	10/08/2021 Director's Office			**SWIDAR Tablets by Swiss Pharm.** Report of counterfeit Swidar tablets in circulation	The complaint was forwarded to Bayelsa State office for further regulatory action (12/08/21)	Closed	12/08/2021	
7	2021/CCD/007/PVPMS	12/08/2021 Director's Office	Social media	WhatsApp	**Apetamil/ Apetabon** A complaint of products that look alike	An investigation was carried out to verify the information received A 3rd product called **Mamamin** with similar packaging to Apetamil and	Open		Ongoing; awaiting feedback from R&R

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						Apetabon was also discovered during investigation. A request was sent to R&R to ascertain the current registration status of all 3 products, and to verify the approved packaging the products were registered with (19/08/21).			
8	2021/CCD/008/PVPMS	13/08/2021 Director's Office	Social media	WhatsApp	**FERTILAID by Fairhaven** Complaint by the marketer/distributor of the complaint product of parallel importation by someone else	A request was sent to R&R to ascertain if the complainant is the genuine owner of the product (18/08/21). The complaint was forwarded to PMS for further action.	Closed	24/08/2021	
9	2021/CCD/009/PVPMS	11/11/2021 Mrs. Chioma Ebibi	Walk-in	Written	**TORAIN Maxterone 500mg** • The product has two (2) separate packaging on the market – a cardboard paper box and a plastic container. • Both packages have different dosing information on them even though they are both 500mg capsules • The product is an herbal product but its NRN on the packages is not a listed number. • The packages have unverified claims on them.	A memo was written to R&R FCT office to verify the registration status of the complaint product. The online application form for the product shows that while application was made for 60 capsules 250mg in a plastic container, what is obtainable in the market is: 60 capsules 500mg in a cardboard box And 40 capsule 500mg in a plastic container. The manufacturer was invited for a meeting with the DD i/c (PV/PMS) The manufacturer was mandated to supply a list of distributors for	Ongoing		

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						the complaint product, and to initiate a recall of the product. The manufacturer was also directed to apply to the Agency for change in pack size as he had changed pack size without NAFDAC's approval.			

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