Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
16060101-Human Resources motivated and capacited								**7,660,669,047**	
	01-Administrative And Support Services							**7,660,669,047**	
		0101-Administrative And Support Services						**7,660,669,047**	
			1606010101-Rwanda FDA is functional	# of monthly salary Rwanda FDA staff paid on time (No.)	12	Annual: 12, Q1:3, Q2:3, Q3:3, Q4:3	01-prepare and execute the payment of staff	1,999,666,164	GOR
				Institutional support services are efficiently and effectively managed (Qualitative)	available resources well managed	Annual: contract mangement, Q1: procurement plan implementation, Q2: contract mangement, Q3: contract mangement, Q4: contract mangement	02-Support the operation and management of Rwanda FDA	5,230,367,763	
			Total of 1606010101-Rwanda FDA is functional					**7,230,033,927**	
			1606010102-planning and monitoring capacity strengthened	# of Board meeting conducted (No.)	4	Annual: 7, Q1:1, Q2:1, Q3:1, Q4:4	01-Develop Rwanda FDA strategic plan	0	GOR
				# policies and strategic documents initiated or developed (No.)	10	Annual: 28, Q1:5, Q2:8, Q3:9, Q4:6	02-Develop/review manuals, regulations, guidelines, Standard Operating Procedures and forms	95,870,000	
							03-Initiate policies and laws	13,579,620	
							04-Develop QMS Documentation requirements	29,000,000	
							05-Conduct Board Meetings	47,185,500	
							09-Establish governance structure for pharmaceutical traceability implementation	10,000,000	
							10-Development of GS1 and Traceability materials to support capacity building for implementation	48,500,000	
							11-Develop regulations, guidelines, framework and AIDC for implementation of pharmaceutical traceability	14,000,000	
							12-Awareness for news reporters on Rwanda FDA functions and social impact	6,000,000	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
							13-Capacity building in the use of software for data management	6,500,000	
							14-Hiring experts to mentor FDA staff in different technical areas	160,000,000	
			Total of 1606010102-planning and monitoring capacity strengthened					**430,635,120**	
1606EW01-Food and Pharmaceutical products regulated and accessed								**1,006,500,000**	
	EW-Food and Drugs Registration & Inspection							**6,193,281,309**	
		EW01-Food and Drugs Assessment & Registration						**1,006,500,000**	
			1606EW0103-Assessment & Registration of regulated products ensured	% of assessed Medicated cosmetics and households chemicals (%)	8	Annual: 85, Q1:20, Q2:20, Q3:20, Q4:25	04-Participate in the EAC joint dossier assessment for medicines registration	90,000,000	GOR
							07-Assessment of herbal and complemantary medicines	60,000,000	
				% of processed food and food supplements registered (%)	38	Annual: 95, Q1:20, Q2:20, Q3:25, Q4:30	08-Capacity building on health technologies assessment and registration (outside)	40,000,000	
				% of drugs assessed (both vet and Human) (%)	20	Annual: 75, Q1:15, Q2:20, Q3:20, Q4:20	11-Capacity building on processed food, fortified food and food supplements assessment and registration	67,300,000	
				% of Health technologies assessed (%)	5	Annual: 80, Q1:15, Q2:20, Q3:20, Q4:25	14-Capacity building of assessors in human and veterinary dossier assessment and evaluation for market authorisatio	65,000,000	
							15-Stakeholders consultation & Dissemination workshops for technical regulation for registration compliance	0	
							16-Conduct workshop for human and veterinary medicinal products dossier assessment	62,000,000	
							17-Review of Human and veterinary medicinal products dossiers and validation	5,000,000	
							18-Countrywide awareness for Rwanda FDA and Assessment of herbal plant in Rwanda and development of Medicinal plant Rwandan Pharmacopeia.	64,000,000	
							19-Purchase pharmacopeaia for Human and vaccine assessment	10,000,000	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
							20-Conduct workshops for domestic capacity building on assessment of health technologies	62,000,000	
							21-Conduct a workshop for assessment and listing of health technologies	62,000,000	
							22-Capacity building of assesment of cosmetics and households chemicals	55,000,000	
							23-Stakeholders consultation and dissemination workshops for technical regulation of health technologies regulatory compliance	45,000,000	
							24-Conduct workshop for Medicated cosmetics and households chemicals dossier assessment	62,000,000	
							25-Review of Medicated cosmetics and households chemicals dossier and validation	4,000,000	
							28-Acquisition of 140 food standards	3,000,000	
							29-Annual subscription to scientific journals	24,000,000	
							30-Stakeholders consultation and dissemination workshops for technical documents for regulatory compliance for food products	42,000,000	
							31-Countrywide awareness for FDA functions in food sector	62,000,000	
							32-Research and testing of critical food products for registration purpose	27,000,000	
							33-Establishment of a track and trace system for registered food products	10,000,000	
							34-Conduct workshop for dossier assessment for food products	42,600,000	
							35-Conduct workshop for dossier assessment for fortified foods and food supplements	42,600,000	
			Total of 1606EW0103-Assessment & Registration of regulated products ensured					**1,006,500,000**	
	EW-Food and Drugs Registration & Inspection							**6,193,281,309**	
		EW02-Food and Drugs Inspection & Safety Monitoring						**5,186,781,309**	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
			1606EW0202-Food and Drugs Safety Monitoring is ensured	% of Adverse Drugs Reaction(ADR) /Adverse Event Following Immunization (AEFI) reports received and analyzed (%)	60	Annual: 80, Q1:15, Q2:20, Q3:20, Q4:25	12-Conduct Food safety monitoring inspections	30,000,000	GOR
							13-Receive and analyse Adverse Drugs Reaction /Adverse Event Following Immunisation reports	0	
				# of Food safety inspection conducted (No.)	60	Annual: 50, Q1:10, Q2:10, Q3:20, Q4:10	14-Develop and integrate the pharmacovigilance soft ware into Product Regulatory Information Management System(PRIMS)	30,000,000	
				# of samples tested for Post Marketing Surveillance (PMS) (No.)	35	Annual: 100, Q1:40, Q2: 20, Q3:20, Q4:20	15-Capacity building on the use of the developed Pharmacovigilance soft ware	34,000,000	
							16-Capacity building on pharmacovigilance for Drugs Therapeutic Committee (DTC) members in health facilities (public and private)	105,000,000	
							17-Public Awareness campaigns on Pharmacovigilance and rational drug use	210,000,000	
							18-Develop, validate and Disseminate the national Pharmaco-vigilance plan	13,000,000	
							19-Develop Telephone application to report any Adverse Drug Reaction(ADR) /Adverse EentFollowing Immunisation(AEFI) and suspected poor quality	40,000,000	
							20-Payment of subscription fees for Vigiflow at Uppsala Monitoring Centre (UMC)	6,000,000	
							21-Meeting for Pharmaco-vigilance (PV) advisory committee	44,000,000	
							22-Conduct a survey on rational drug use	50,000,000	
							23-Conduct active monitoring on selected drugs for medicines safety	45,000,000	
							24-Conduct supervision and mentoring to improve the Pharmaco-Vigilance reporting system on Adverse Drug Reactions (ADRs), Safety and vigilance of vaccines Adverse Event Following Immunisations (AEFIs) from public and private facilities	50,000,000	
							25-Post marketing surveillance for pharmaceutical products	36,000,000	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
							26-Capacity buidling in food safety suerveillance and Food borne diseases investigations	18,000,000	
							27-Post marketing surveillance for food products	41,000,000	
			Total of 1606EW0202-Food and Drugs Safety Monitoring is ensured					**752,000,000**	
			1606EW0207-Clinical trials regulated	% of clinical trial application reviewed within set timelines (%)	80	Annual: 90, Q1:25, Q2:25, Q3:20, Q4:20	01-Establish systems for clinical trial oversight and evaluation through development of their management database	70,000,000	GOR
				# of Clinical trial site inspected (No.)	3	Annual: 6, Q1:0, Q2:2, Q3:2, Q4:2	02-Regulate clinical and field trial approvals to maximise safety of the regulated products by conducting Clinical Trial Site inspections	36,000,000	
							03-Capacity building on clinical trials	28,000,000	
							04-Reviewing the clinical trial application	0	
							05-Develop guidelines on clinical trial review , GCP inspection and SOPs	60,000,000	
			Total of 1606EW0207-Clinical trials regulated					**194,000,000**	
			1606EW0208-Food and Drugs inspections conducted for compliance	# of food premises inspected (No.)	120	Annual: 300, Q1:60, Q2: 80, Q3:80, Q4:80	01-Conduct inspection for food premises suitability	95,000,000	GOR
				# of pharmaceutical premises inspected (No.)	150	Annual: 250, Q1:50, Q2: 60, Q3:70, Q4:70	02-Conduct GMP inspection of local and foreign food manufacturing facilities	53,500,000	
				% of import and export licenses issued for regulated products and inspections conducted (%)	100	Annual: 100, Q1:100, Q2: 100, Q3:100, Q4:100	03-Prepare and conduct Stakeholders consultation meetings on current procedures	45,000,000	
							04-Inspection of imports at ports of entry and released underseal	35,000,000	
							05-Inspection of goods for exports	15,000,000	
							06-Supervision of inspectors at port of entry	13,000,000	
							07-Capacity building for inspectors	35,000,000	
							08-Conduct Inspections for premise licensing and compliance of pharmaceutical products	190,000,000	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
							09-Conduct GMP inspection of local and foreign pharmaceutical facilities	240,000,000	
							10-Conduct good distribution practice (GDP) among wholesale pharmacies and central medical stores and branches	55,000,000	
							12-Capacity building of GMP, GCP,GLP and GDP Inspectors	175,000,000	
							13-Conduct GMP desk review of facilities located in countries with stringent (listed) regulatory authorities	35,000,000	
							14-Development of regulations, guidelines, SOPs, and forms	150,000,000	
							15-Destruction of impounded drugs and Food products	72,000,000	
							16-Conduct price surveys to inform price and mark ups	25,000,000	
							17-Conduct good laboratory practice (GLP) / Good Clinical Practice (GCP) Inspection	7,500,000	
							18-Public Awareness campaigns on Pharmacovigilance and rational drug use	35,000,000	
							19-Develop Telephone application to report any Adverse Drug Reactions (ADR) /Adverse Event Following Immunisation and suspected poor quality	10,000,000	
							20-Payment of subscription fees for Vigiflow at Uppsala Monitoring Centre (UMC)	3,000,000	
							21-Meeting for PV advisory committee	22,000,000	
							22-Conduct a survey on rational drug use	25,000,000	
							23-Conduct active monitoring on selected drugs for medicines safety	20,000,000	
							24-Conduct supervision and mentoring to improve the Pharmaco-Vigilance reporting system on Adverse Drug Reactions (ADRs), Safety and vigilance of vaccines Adverse Event Following Immunisations (AEFIs) from public and private facilities	25,000,000	

Action Plan for : 2021/2022

1606-RWANDA FOOD AND DRUGS AUTHORITY

Outcom	Prog.	Subpr.	Output	Indicators	Baseline	Targets	Activities to Deliver output	Estimated Budget (RWF)	Stake holders (RWF)
							25-Post marketing surveillance for pharmaceutical products	17,000,000	
							26-Conduct Food safety monitoring inspections	15,000,000	
							27-Post marketing surveillance for food products	20,000,000	
							28-Establish systems for clinical trial oversight and evaluation through development of their management database	35,000,000	
							29-Develop guidelines on clinical trial review , GCP inspection and SOPs	30,000,000	
							30-Regulate clinical and field trial approvals to maximise safety of the regulated products by conducting Clinical Trial Site inspections	18,000,000	
			Total of 1606EW0208-Food and Drugs inspections conducted for compliance					**1,516,000,000**	
			1606EW0209-Testing Laboratory capacity is strengthened	% of Rwanda FDA laboratory performance capacity (%)	Laboratory testing capacity established at 20%	Annual: equipment delivery and lab established at 45%, Q1: Laboratory testing capacity established at 45%, Q2:Technical specifications prepared, Q3:contracts signed, Q4: contract mangement	01-Purchase laboratory equipment	2,359,000,000	GOR
							02-Purchase of laboratory reagents, reference materials and other consumables	200,000,000	
							03-Capacity building of Rwanda FDA staff to use laboratory equipment, ISO 17025 and WHO prequalification	47,237,500	
							04-participate in Proficiency testing and interlaboratory comparisons	20,000,000	
							05-Maintenance and calibration of laboratory equipment	98,543,809	
			Total of 1606EW0209-Testing Laboratory capacity is strengthened					**2,724,781,309**	
								13,853,950,356	