PERFORMANCE AGREEMENT

BETWEEN

PRIME MINISTER AND DRUG CONTROLLER

DRUG REGULATORY AUTHORITY (DRA)

(July 1, 2017– June 30, 2018)

TABLE OF CONTENTS

Preamble

The Performance Agreement is entered into between the Prime Minister and Drug Controller, Drug Regulatory Authority (DRA).

The objectives of this Performance Agreement are:

a) To establish clarity and consensus about annual priorities for the Drug Regulatory Authority in consistent with the 11th Five Year Plan and Government's other priorities;

b) To make the Drug Regulatory Authority fully responsible for driving implementation and delivering the results against the annual priorities;

c) To provide an objective and fair basis for evaluating the Drug Regulatory Authority's overall performance at the end of the year;

The Performance Agreement represents an important accountability mechanism for inculcating a performance based culture at all levels of government.

THEREFORE, the parties hereto agree as follows:

Section 1: Vision, Mission and Objectives

Vision

The most dynamic, reliable and client-centric model regulatory organization.

Mission

Promoting availability of quality, safe and efficacious medicinal products for consumers.

Objectives

1) To ensure quality, safety and efficacy of medicinal products through registration of products and personnel; technical authorization/clearance and monitoring of premises for manufacture, import, export, sale, storage, distribution and testing.
2) To promote public safety through advocacy and awareness; monitoring of Adverse Drug Reactions (ADR); control of drug advertisement and dissemination of information.
3) To develop/review policies/regulations/guidelines/Standard Operating Procedures (SOPs) through consultative meetings as tools for effective enforcement.
4) To provide efficient and effective operational and direction services.
5) To ensure full utilization of budget

Section 2: Objectives, Success Indicators & Target

Objective	Weight	Action	Success Indicator	Unit	Weight	Excellent [100%]	Very Good [90%]	Good [80%]	Fair [70%]	Poor [60%]
To ensure quality, safety and efficacy of medicinal products through registration of products and personnel; technical authorization/clearance and monitoring of premises for manufacture, import, export, sale, storage, distribution and testing.	50	Assess applications and issue certificates/authorizations for import and registration of premises, products and personnel.	Number of medicinal products registered including renewal.	Number	10	400	360	320	280	<280
			Number of specified services complying with turnaround time (TAT).	Number	5	4	3	2	-	1
			Number of working days taken for issuance of Import Authorizations.	Days	8	2	4	6	8	>8
		Inspection of manufacturing, storage and dispensing premises.	Number of Good Manufacturing Practice (GMP) Inspections conducted.	Number	7	30	25	20	15	<15
			Number of premises for storage and dispensing inspected (Government and Private).	Number	13	200	150	130	100	<100
		Testing of medicinal products including blood and blood products.	Number of medicinal products including blood and blood products tested.	Number	7	203	190	170	150	<150

Objective	Weight	Action	Success Indicator	Unit	Weight	Excellent [100%]	Very Good [90%]	Good [80%]	Fair [70%]	Poor [60%]
To promote public safety through advocacy and awareness; monitoring of Adverse Drug Reactions (ADR); control of drug advertisement and dissemination of information.	20	Capacity building for ADR reporting and conduct data analysis of reports.	Number of sensitization workshop and meetings on Pharmacovigilance and Adverse Drug Reactions (ADR) reporting conducted.	Number	4	3	2	-	-	1
			Percent of ADR reports analysed and uploaded on the VigiFlow within the time frame (15 days for serious and 30 days for non-serious from the date of receipt).	Percent	3	80	70	60	50	<50
			Number of ADR reports analysed and Newsletter published.	Number	5	2	-	-	-	1
		Issue public notifications and alerts on safe use of medicines and monitoring of advertisements.	Number of public notifications served in the media.	Number	2	4	3	2	-	1
		Conduct sensitization and awareness through meetings, workshops and development of animations.	Number of awareness and sensitization workshops and meetings conducted and animations developed.	Number	6	4	3	2	-	1
To develop/review policies/regulations/guidelines /Standard Operating Procedures (SOPs) through consultative meetings as tools for effective enforcement.	15	Develop/Review policies/regulations/guidelines/SOPs and Strategic framework for regulatory assessment.	Number of policies/regulations/guidelines developed or reviewed.	Number	5	2	-	-	-	1
			Number of SOPs developed.	Number	5	4	3	2	-	1
			Number of committee/consultative meetings and workshops conducted.	Number	5	10	7	5	3	<3

Objective	Weight	Action	Success Indicator	Unit	Weight	Excellent [100%]	Very Good [90%]	Good [80%]	Fair [70%]	Poor [60%]
To provide efficient and effective operational and direction services.	10	Strengthen efficient and effective functioning of the office.	Lag-thram for construction of DRA office obtained	Status of Work	3	Lag-thram obtained	Lag-thram under process	Local clearance obtained	Land identified	Land indentification under process
			Percent of Corrective and Preventive Action (CAPA) Plan implemented.	Percent	3	90	80	70	60	60
			Timeline by which the monthly salary is credited in the respective account of the employees.	Date	4	By third week of the month	By fourth week of the month	NA	NA	First week of next month
To ensure full utilization of budget	5	Ensure full budget utilization	Percent of budget utilized	Percent	5	100	-	-	-	<100

Section 3: Trend values of success indicators

Objective	Action	Success Indicator	Unit	Actual Values [FY 2013-14]	Actual Values [FY 2014-15]	Target Values [FY 2015-16]	Projected Values [FY 2016-17]	Projected Values [FY 2017-18]
To ensure quality, safety and efficacy of medicinal products through registration of products and personnel; technical authorization/clearance and monitoring of premises for manufacture, import, export, sale, storage, distribution and testing.	Assess applications and issue certificates/authorizations for import and registration of premises, products and personnel.	Number of medicinal products registered including renewal.	Number	1813	2240	2590	3005	3405
		Number of specified services complying with turnaround time (TAT).	Number	NA	NA	NA	NA	4
		Number of working days taken for issuance of Import Authorizations.	Days	N/A	N/A	N/A	2	2
	Inspection of manufacturing, storage and dispensing premises.	Number of Good Manufacturing Practice (GMP) Inspections conducted.	Number	24	33	38	43	73
		Number of premises for storage and dispensing inspected (Government and Private).	Number	467	564	745	995	1195
	Testing of medicinal products including blood and blood products.	Number of medicinal products including blood and blood products tested.	Number	1580	1657	1717	1797	2000

Objective	Action	Success Indicator	Unit	Actual Values [FY 2013-14]	Actual Values [FY 2014-15]	Target Values [FY 2015-16]	Projected Values [FY 2016-17]	Projected Values [FY 2017-18]
To promote public safety through advocacy and awareness; monitoring of Adverse Drug Reactions (ADR); control of drug advertisement and dissemination of information.	Capacity building for ADR reporting and conduct data analysis of reports.	Percent of ADR reports analysed and uploaded on the VigiFlow within the time frame (15 days for serious and 30 days for non-serious from the date of receipt).	Percent	NA	NA	NA	NA	>80
		Number of sensitization workshop and meetings on Pharmacovigilance and Adverse Drug Reactions (ADR) reporting conducted.	Number	5	10	13	15	18
		Number of ADR reports analysed and Newsletter published.	Number	NA	NA	1	2	4
	Issue public notifications and alerts on safe use of medicines and monitoring of advertisements.	Number of public notifications served in the media.	Number	NA	NA	NA	3	7
	Conduct sensitization and awareness through meetings, workshops and development of animations.	Number of awareness and sensitization workshops and meetings conducted and animations developed.	Number	12	13	15	17	21

Objective	Action	Success Indicator	Unit	Actual Values [FY 2013-14]	Actual Values [FY 2014-15]	Target Values [FY 2015-16]	Projected Values [FY 2016-17]	Projected Values [FY 2017-18]
To develop/review policies/regulations/ guidelines/Standard Operating Procedures (SOPs) through consultative meetings as tools for effective enforcement.	Develop/Review policies/regulations /guidelines/SOPs and Strategic framework for regulatory assessment.	Number of policies/regulations/guidelines developed or reviewed.	Number	1	2	5	7	9
		Number of SOPs developed.	Number	NA	NA	NA	67	71
		Number of committee/consultative meetings and workshops conducted.	Number	12	13	15	17	27
To provide efficient and effective operational and direction services.	Strengthen efficient and effective functioning of the office.	Timeline by which the monthly salary is credited in the respective account of the employees.	Date	NA	NA	NA	By 20th of every month	By third week of the month
		Lag-thram for construction of DRA office obtained	Status of Work	NA	NA	NA	NA	Lag-thram obtained
		Percent of Corrective and Preventive Action (CAPA) Plan implemented.	Percent	NA	NA	NA	NA	90
To ensure full utilization of budget	Ensure full budget utilization	Percent of budget utilized	Percent	-	-	-	-	100

Section 4: Definition of Success Indicators

Success Indicator	Description	Data Collection Methodology	Data Collection Frequency	Data Source
Number of medicinal products registered including renewal.	Total number of registration certificates issued for both new products and for renewal.	Records	Biannually	In house registration software
Number of Good Manufacturing Practice (GMP) Inspections conducted.	Inspection of manufacturing premises including the blood centers both within and outside the country to assess the compliance to regulatory requirements.	Reports	Biannually	In-house Records
Number of medicinal products including blood and blood products tested.	Testing of medicinal products including blood and blood products in the laboratories and using mini lab testing.	Reports	Biannually	In-house Reports
Number of specified services complying with turnaround time (TAT).	Services includes Technical Authorizations, Technical Clearances, Competent Person certifications, Expedited product registration considering the stop clock and 90% compliance to TAT.	Records	Biannually	In-house Records
Number of working days taken for issuance of Import Authorizations.	Import Authorization is issued for the import of medicines.	Records	Biannually	In-house Records
Number of premises for storage and dispensing inspected (Government and Private).	Inspection of hospitals, BHUs, ORCs, veterinary hospitals, retail and wholesale pharmacies, project dispensaries and groceries.	Records	Biannually	In-house Records
Number of sensitization workshop and meetings on Pharmacovigilance and Adverse Drug Reactions (ADR) reporting conducted.	Sensitization of Pharmacist/Pharmacy Technicians on the ADR reporting and monitoring system by the DRA.	Record	Biannually	In-house Records
Percent of ADR reports analysed and uploaded on the VigiFlow within the time frame (15 days for serious and 30 days for non-serious from the date of receipt).	Analyse and upload the ADR reports received	Records	Annually	In-house Records

Success Indicator	Description	Data Collection Methodology	Data Collection Frequency	Data Source
Number of public notifications served in the media.	Issuance of public notifications related to quality, safety and efficacy of medicinal products to the public.	DRA Records	Biannually	In-house Records
Number of ADR reports analysed and Newsletter published.	Analyse the ADR reports and information disseminated.	Reports	Annually	In-house Records
Number of awareness and sensitization workshops and meetings conducted and animations developed.	Sensitization and awareness workshops conducted for relevant stakeholders.	Records	Biannually	In-house Records
Number of policies/regulations/guidelines developed or reviewed.	Develop/review policies/regulations/guidelines for regulation of health supplements and medical devices/cosmetics.	Records	Biannually	In-house Records
Number of SOPs developed.	Development of SOPs for Training evaluation, GMP certification, Crisis/media management, moderation exercise.	Records	Annually	In-house Records
Number of committee/consultative meetings and workshops conducted.	Board/DTAC/BTAC/NPC/wholesaler meetings and other meetings.	Record	Annually	In-house Records
Lag-thram for construction of DRA office obtained	Identify land and obtain lag-thram for construction of DRA office	Reports	Annually	In-house reports
Percent of Corrective and Preventive Action (CAPA) Plan implemented.	Review of CAPA plans and implementation status as per the internal audit report.	Internal Audit Reports	Annually	In-house Records
Timeline by which the monthly salary is credited in the respective account of the employees.	Deposit of monthly salary	Record	Biannually	In-house Record
Percent of budget utilized	This SI measures the variance between revised budget and expenditure of an agency for a fiscal year.	Through analysis of annual budget and expenditure	Annually	MYRB

Section 5: Requirements from other Ministries, Agencies & Dzongkhags

Organisation Name	Relevant Success Indicator	Requirement from the Organisation	Justification for the Requirement	Requirement detail	Impact (If Not Met)
MINISTRY OF HEALTH	Number of specified services complying with turnaround time (TAT).	BMHC Certificate	Depend on the registration of competent person with the BMHC	As and when required	No need to issue certificates
MINISTRY OF AGRICULTURE AND FORESTS	Number of medicinal products registered including renewal.	Release of registration committee members for evaluation of dossiers	Nomination as a registration committee members	As and when required	Evaluation will be hampered
MINISTRY OF HEALTH	Number of medicinal products registered including renewal.	Release of registration committee members for evaluation of dossiers	Nomination as a registration committee members	As and when required	Evaluation will be hampered
MINISTRY OF AGRICULTURE AND FORESTS	Number of premises for storage and dispensing inspected (Government and Private).	Timely compliance and response from Moh/MoAF	All activities are dependent on timely compliance and responses	As and when required	Target may not be achieved fully
MINISTRY OF HEALTH	Number of premises for storage and dispensing inspected (Government and Private).	Timely compliance and response from Moh/MoAF	All activities are dependent on timely compliance and responses	As and when required	Target may not be achieved fully
MINISTRY OF FINANCE	Number of Good Manufacturing Practice (GMP) Inspections conducted.	Financial support	Budget is required to support the GMP inspection	As and when required	GMP inspection cannot be conducted
MINISTRY OF FINANCE	Number of medicinal products including blood and blood products tested.	Budgetary support	To sent samples of medicines for testing	As and when required	Testing of medicines cannot be done
MINISTRY OF HEALTH	Number of sensitization workshop and meetings on Pharmacovigilance and Adverse Drug Reactions (ADR) reporting conducted.	Release of officials	Officials needs to attend the training	As and when required	Meetings may be delayed

Organisation Name	Relevant Success Indicator	Requirement from the Organisation	Justification for the Requirement	Requirement detail	Impact (If Not Met)
BHUTAN INFORMATION COMMUNICATION MEDIA AUTHORITY	Number of public notifications served in the media.	Support for notifications	Public notifications should be done	As and whenrequired	Public notification may be delayed
All Dzongkhags	Number of awareness and sensitization workshops and meetings conducted and animations developed.	Timely release of officials	Every year health officials are targeted for sensitization workshops	As and when required	May not be able to sensitise the targeted Dzongkhags
MINISTRY OF FINANCE	Timeline by which the monthly salary is credited in the respective account of the employees.	Timely release of the budgets	Need to deposit the salaries on time	As and when required	Timely deposit of salaries may be hampered

Whereas,

I, the Drug Controller, Drug Regulatory Authority, commit to the Prime Minister the Government and the people of Bhutan to deliver the results described in this Annual Performance Agreement.

I, the **Prime Minister**, commit to the Drug Controller, Drug Regulatory Authority, on behalf of the Government and the people of Bhutan, to provide the necessary fund and resources for delivery of the results described in this Annual Performance Agreement.

SIGNED:

	8.8.17
Tshering Tobgay Prime Minister of Bhutan	Date
	8/8/17
Mr. Kinga Jamphel Drug Controller, DRA	Date