MEDICAL DEVICE CONTROL STRATEGY 2018-2023

Drug Regulatory Authority

June, 2018

Contents

1.0 Background

The World Health Assembly in the year 2014 adopted a resolution regarding regulatory system strengthening for medical products (WHA 67.20) wherein it states that "effective regulatory systems are an essential component of health system strengthening and contribute to better health outcomes".

As per the WHO Global Model Regulatory Framework, many countries have neither the financial resources nor the technical expertise to transition successfully from an unregulated market to a regulated environment in a single programme. Hence, WHO recommends a progressive, or stepwise, approach to regulating the medical devices such as starting from publication of the law and resourcing the regulatory authority to undertake enforcement actions. It also mentions that regulation of medical devices should be coordinated with regulation of other medical products such as medicines and vaccines. There are certain differences between a medicine and a medical devices such as the former one is based on chemistry, pharmacology the later one is based on engineering.

Recognizing the global need for regulating medical devices to ensure access to safe, effective, and quality medical devices, Bhutan Medicines Board has instructed Drug Regulatory Authority (DRA) to draft medical device regulation. Subsequently, it generated frequent discussions in the Drug Technical Advisory committee (DTAC) meetings and the latest DTAC meeting endorsed the need for a strategic document on Medical Device Control.

1.1 Legal Framework

It was deliberated that Medical devices falls under the scope of Medicines Act of Kingdom of Bhutan 2003, within the definition of "Medicinal Products" and DRA has the mandate to regulate as below:

"(a) All substances intended for internal or external use of human beings or animals and intended to be used in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals; and

(b) Such substances intended to affect the functioning of any structure found in the human and animal body;

(c) Any other substance or device declared by the Board to be a medicinal product or a medicine or a drug and this may belong either to modern (allopathic) or traditional system of medicine"

However, for purpose of clarity, scope and definition of medical devices with responsibilities of DRA will be proposed in the corresponding regulation.

1.2 Rationale

Medical devices are subject to strict controls and procedural regulations in many countries owing to the risks associated with the use to the patients. Currently, in our country, we lack a clear regulatory system for monitoring safety, quality and performance aspects of the products although we import wide range of medical devices. DRA is in receipt of proposals for manufacturing devices (medical syringes) and due to lack of manufacturing standards and policy, there is no clear directives provided to the applicants.

Lack of appropriate policy and regulatory measures such as product recall mechanism compromises on the safety of the patients. The accuracy of the diagnosis of a diseases is depended on the specificity and sensitivity of the testing/measuring equipments and wrong diagnosis leads to exposure of patients to unnecessary medications and treatment. Lack of appropriate qualification and calibration of medical equipments also adds to the wrong results and diagnosis.

There are challenges in identifying quality medical devices through quality inspection carried out by the health professionals and more often than not, it results in accepting substandard medical devices. Eventually, it leads to wastage of resources due to poor accountability of the importers and lack of legal mechanisms for products testing and recall.

Hence, development of regulatory pathways, appropriate use of standards and collaboration among the key stakeholders is key to ensuring the safety and efficacy of the Medical devices placed in the market.

2.0 Purpose and Scope

2.1 Purpose

This document is intended to serve as a guidance document for Drug Regulatory Authority to set up the priorities and details regulatory path for medical devices. This will also be useful for the collaborating agencies to learn the regulatory approach and action plan for the medical devices as it also defines their roles in ensuring the quality and safety of the medical devices in the country. It also describes an operational plan to guide DRA in executing the action plans with the appropriate timeline, the target stakeholders and the budgetary requirements. This document maybe also be referred while revising the Medicines Regulation to incorporate control on Medical Devices.

2.2 Scope

The document is applicable to any devices imported or manufactured for sale and distribution within the following definition of Medical devices;

“Any article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose”. Accordingly, the medical equipment also falls under the scope of this regulatory control provided

that the equipment is utilized directly or indirectly for the above mentioned health purpose.

3.0 Current Situation Analysis

To provide an overview of the DRA's current situation, challenges and opportunities on moving forward with the regulatory reforms, analysis using SWOT has been carried out.

3.1 Current situation

Majority of the medical devices are in the healthcare facilities procured by the government agencies based on the procurement rules and regulation. On the technical front, only few general administrative document such as "letter of Authorization" or dealership certificates from the manufacturers are required to be able to partake in the tendering process of Ministry of Health and no regulatory approvals from DRA are required.

Medical devices such as Oxygen (medical gases) were considered as medicinal products for the purpose of importation was first registered July, 2014. Technical Manufacturing Authorization for Medical Oxygen was also granted in the year 2014 and it has been operational since then. Provisional Authorization to set up the plant for medical oxygen gases are granted to two applicants in 2017 based on the Bhutan Medicines Rules and Regulation 2012.

There are already 56 IEC standards related standards to medical electrical equipment adopted as national standard pioneered by BMED, MoH for basis for monitoring of medical equipment and improved patient safety.

With the implementation of the Blood and Blood Products Regulation of Bhutan 2016, guidelines on registering Transfusion Transmissible Infections (TTIs) was developed and notified for commencement of Registration registration from January 2018.

3.2 SWOT

STRENGTHS	WEAKNESSES
• *Political commitment; Bhutan Medicines Board as the highest policy making body has directed to regulate medical devices.* • *A highly motivated DRA team, with a regulatory experience on medicinal products regulation* • *Same principles of products regulation known to DRA* • *ASEAN network for information sharing and capacity building*	• *Diverse and complex range of medical devices* • *Inadequate knowledge of importers and the Regulators in quality, safety and performance evaluation of the medical devices* • *Little understanding of the medical device dossier information requirement* • *Lack of infrastructure and testing capacity for testing devices in the*

• *Technical support and budget commitment from WHO* • *56 national standards for medical device standards ready for publication which could be made mandatory by DRA*	*national laboratory*
OPPORTUNITIES • *Enhance coordination among the various stakeholders* • *Clear Regulatory system in place to promote safer, quality and effective medical devices* • *Cost savings from reduction is rejects of the medical devices once registered.* • *Cost effective in long run from procuring quality medical devices* • *Increased access to quality medical devices and better health outcomes*	**THREATS** • *Less interested manufacturers to register the devices due to small share of market* • *Price Monopoly for few registered devices* • *Accessibility issues for urgent needs* • *Resistance and poor support from users and importers* • *Increased regulatory burden*

The threat and weaknesses are linked to the Strategies and Risk analysis and management in the sections 4.0 and 5.0 respectively of this document.

4.0 Principles and strategic approach

The main strategies for regulatory control for medical devices are outlined as follows:

i. Clear regulatory framework incorporating the principles, governance and procedural standards, indication of product and service standards.

ii. Gap analysis of existing controls.

iii. Stakeholder consultation and coordination among the relevant agencies.

iv. Categorization of the national medical device list for risk based control.

v. Phase wise Regulatory control with initiation of product registration and surveillance by 2021 for some category of medical devices.

vi. Medical device testing irrespective of their registration status in Bhutan.

vii. Setting standards for Local Manufacturers

viii. Networking with external regulatory Agencies & reliance on Good International Practices system.

ix. Provision of special access to medical devices that have not been registered for special reasons.

x. Human Resource and capacity building both in Govt. and private sector.

xi. Research and development of standards and procedural guidelines.

xii. Monitoring and Surveillance upon institution of regulatory frameworks

xiii. Professional and Industry Associations

xiv. Consumer education and information programs

4.1 Clear Regulatory Framework

For effective regulation on medical devices, it would depend on a clear regulatory framework, hence a sound pragmatic regulation on medical device by June 2019 would be one of the milestone to achieve our goals. As per WHO's recommendation, the regulation should define products, its scope, delineate responsibilities, of the manufacturers, importers, distributors, establish mechanism, accountability, coordination with other external agencies such as justice, police, customs. It should also spell the provision for accommodating a transition phase from basic to expanded regulatory control.

Therefore, DRA will strive to bring out a Medical Device Regulation encompassing the principle requirements from the good international practices not limited to as follows:

4.1.1 Outlining the functions of Drug Regulatory Authority, collaborating agencies and Technical advisory bodies with respect to medical devices.

4.1.2 Governance structure for DRA similar to the existing medicinal product structure.

4.1.3 Definition of medical devices, scope and application of regulatory controls proportionate to risk associated with a medical device.

4.1.4 Consideration of Assessment of Invitro Diagnostics Devices (IVDs) under the medical device regulation assigning with different risk profile.

4.1.5 Basic regulatory controls on premarketing and post marketing and a system of recognizing standards through guidance documents.

4.1.6 Reliance on the functional National Regulatory Agencies and WHO pre-qualification for product licensing or registration.

4.1.7 Grouping of medical into four classes with Class A devices presenting the lowest potential risk (e.g. a thermometer) and Class D devices presenting the greatest potential risk (e.g. pacemakers).

4.1.8 Consideration of the classification of the medical devices made by the national regulatory agencies of the country of origin for imported medical device but with ultimate authority for DRA to rule upon the matters of interpretation for a particular medical device.

4.1.9 System of standardized generic descriptive names or adoption of Global medical device nomenclature (GMDN) system.

4.1.10 Reliance on data from clinical investigations conducted outside the country, provided that the data are adequate and were obtained in accordance with applicable global standards.

4.1.11 Exemption for registration for class A devices with monitoring though Import Authorization and post marketing surveillance.

4.1.12 Control of devices categorized under Class B, C & D through registration, import authorization in addition to post marketing surveillance.

4.1.13 Adoption of Quality System and Products standards recognized by Bhutan Standards Bureau if it is available, or appropriate International ISO standards for the purpose of product dossiers evaluation and inspection.

4.1.14 Arrangement for device testing laboratory and identification of appellate laboratories.

4.1.15 Regulatory procedurals, conditions for obtaining Product registration and Manufacturing Authorization.

4.1.16 Requirement on Quality Management System Standards and Essential Principles of Safety and Performance/declaration of conformity

4.1.17 Exemption of product registration requirements for emergency situations such as during health emergencies, clinical investigations, donations etc.

4.1.18 Criteria and mechanism for determining whether a medicinal product is a medical device

4.1.19 Requirements product labelling, mandatory notification by manufacturer of Field Safety Corrective Action.

4.1.20 A system for vigilance reporting/adverse events associated with the use of medical devices, safety alerts to users and product recall.

4.1.21 Regulatory Procedure for prohibiting deceptive, misleading and false advertising.

4.1.22 Inspection of the premises, offences and penalties.

4.1.23 Requirements on disposal, donation of medical devices.

4.2 Gap analysis of existing controls

A technical working Group (TWG) comprising of the regulators, professional, and legal experts will be formed to evaluate any existing regulatory controls that apply to medical devices allow the both the steps and resources needed to achieve national public health goals and to develop regulatory capacity.

The technical working group will also be responsible to draft the regulation taking into consideration of the current situation and the regulatory principles outlined in the section 4.1 of this document. TWG along with DRA shall also be responsible to consult the stakeholders, propose for the activities during the transition phase in order to avoid disruption in the supply of medical devices during transition period.

4.3 Stakeholders and Collaborating agencies

The regulatory framework and principle requirements shall be discussed among the numerous consultative meeting with the stakeholders such as government's procurement agencies, Biomedical Engineering Division (BMED), Dept. of and Medical Supplies Infrastructure, Essential Medicines Technology Division (EMTD), Dept. of Medical Supplies, MoH & Bhutan Standards Bureau.

The Regulatory Principles on standards, testing protocols, pre-market approval, registration, post-market surveillance, and adverse event reporting shall be consulted with the importers or Market Authorization Holders.

Upon the approval of the Medical Device Regulation, the stakeholders and the collaborating agencies shall be expected to cooperate as below:

Agency	**Type of collaboration required**
Ministry of Health: Procurement Divisions, Royal Centre for Disease(RCDC), Essential Medicines	▪ Ensure compliance to the regulatory requirements in terms of importation and recall. ▪ Appropriate trainings on medical device maintenance and validations.

Technology Division (EMTD), Biomedical Engineering Division (BMED)	▪ Sensitization to the potential importers or Market Authorization Holders ▪ BMED to assist DRA in dossiers evaluation and product inspection and explore third party services for calibration and equipment qualifications, drawing specifications for the National Medical Device List. ▪ EMTD to collaborate in categorization of the medical devices and perform Health Technology Assessment for introduction of any new devices. ▪ RCDC to be equipped with adequate facilities for testing medical devices.
Bhutan Standards Bureau	▪ Assist DRA in certifying to ISO 9001:2015 for Quality Management System of DRA. ▪ Partake as a third party- Conformity Assessment body (CAB) for certifying the QMS (ISO 13485:2016) for local manufacturers. ▪ Development of Product standards for medical devices in consultation with MoH.
Department of Revenue & Customs (DRC), Ministry of Finance	▪ DRC in inspecting for illegal entry of medicinal products
Private clients (Pharmacies license holders/ Pharmaceutical manufacturers,	▪ Consultation and engagement in revision of medicines regulation and while drawing new policies for medical devices and clinical trials.

4.4 Phase wise Regulatory control for imported devices

A stepwise approach to regulating medical devices will considered depending on the readiness of the DRA, stakeholders and the clients. Following approach will be made upon finalization of the medicines regulation for the imported devices.

4.4.1 Categorization of the national medical device list for risk based control

DRA will also take into account of the current standard Medical Device list of Ministry of Health, wherein there are about 3500 + devices along with the accessories listed and review the current system of importation and visual quality inspection system.

Recognizing the broad range of medical devices in use, the national medical devices list will be categorized either into the formal classification of Medical devices (Viz. A, B, C & D) or under intended use category (diagnostics, degree of, and site of, invasiveness into the body invasive or non-invasive, duration of contact of the device with the body etc.) in consultation with relevant programs of Ministry of Health. Any new product for registration non-listed under the national medical device list will also follow the same principle of categorization.

Conformity assessment processes for the devices shall be determined by the class of device it has been classified.

4.4.2 Listing of Medical Devices prior to registration

Medical devices will be listed after referring to certain documents (such as Certificate of Analysis, declaration of conformity) and not subject to full technical dossier evaluation for certain category of products.

Upon categorization of the medical devices, the registration or listing process will be initiated product category wise. Diagnostics devices will be listed in the Initial category for regulatory control since Transfusion Transmissible Infection Test kits are already notified for registration by DRA.

DRA may notify the phase-wise category of products based on the recommendation of the technical advisory body. The post marketing surveillance system will be built for reporting defects and testing of the devices based on the recommendation of the technical advisory body.

The volume of imported devices and common product complaints will also constitute the basis for identifying the products to be regulated in the initial phase of regulatory control.

4.5 Medical device testing

Product Testing is one of means of ensuring the quality of the products as claimed by the manufacturers and hence testing of some devices will be initiated for the products used in Bhutan irrespective of their registration status in Bhutan.

Testing laboratory will be explored from the current contract laboratories of DRA and other suitable laboratories in the region. DRA will also support the capacity building of the national laboratory to reduce the dependency from the external laboratories.

4.6 Manufacturing Standards for Local Manufacturers

The quality, safety and performance of a medical device are determined by systematic controls applied by the manufacturer to its design, development, testing, manufacture and distribution over the device's life cycle through implementation of a Quality Management System (QMS).

Provisional Authorization for manufacture maybe issued upon assessment of the capability of the manufacturer and allocate its medical device to an appropriate risk class. Depending on the medical device risk class, the degree of assessment of the QMS by the regulatory authority or CAB maybe carried out.

For purpose of inspection and certification, identical adoption of international standards such as ISO 13485 for quality management system for both design and manufacturing devices maybe adopted in consultation with Bhutan Standards Bureau.

If there is any application for manufacture of medical devices prior to publication of the Medicines Regulation, DRA shall seek approval from the Bhutan Medicines Board for endorsing the existing international standards developed by Global Harmonization

Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF) as an interim measure.

4.7 Networking with Regulatory Agencies & Reliance

For strengthening of the regulatory system, DRA would continue seeking technical assistance from the experienced NRAs through the platform of the existing regulatory network such as SEARN, ASEAN. DRA will also adopt the system of reliance for the medical devices origination from the functional National Regulatory Agencies.

4.8 Special Access

The Import Authorization will be granted to allow healthcare professional to gain access to medical devices that have not been registered for emergency situations or as the case maybe upon seeking approval from the Bhutan Medicines Board in line with Medicines Act of Kingdom of Bhutan 2003.

4.9 Human Resource and capacity building

In accordance to WHO Global Regulatory Framework, the practice of regulating medical devices effectively and efficiently requires appropriate individual expertise, reinforced by the institutional capacity of the regulatory authority, to act according to good regulatory practices. The general competencies for regulatory professionals include an understanding of public health principles, analytical and communication skills, information handling and skills in effective in intervention and crisis management in addition to the essential knowledge of regulatory system for medical devices, concepts of international standards and harmonization, understanding of a range of different device technologies and applications.

Biomedical engineers trained in regulatory procedures will be considered for the recruitment in DRA. Training such as Quality Management system for medical devices, dossiers evaluation, and oversight of clinical trials will be considered for regulators.

Technical Assistance will be sought (through WHO) to review our Regulation and capacity building of the regulators. Healthcare professional will be trained on incident investigation methodology, risk management, and reporting functions. The Biomedical Engineering personnel in the Ministry of Health will be encouraged for training especially on the maintenance and equipment qualification services.

Training institutions in the country will be encouraged to develop training modules related to medical device technology and provide trainings to the individuals in the private sectors(importers, distributors) etc.

4.10 Research and development of standards and procedural guidelines

Literature review of the Good International Practices (GxP) on regulatory mechanisms will be reviewed to develop procedural guidelines for evaluation on device master file,

plant master file. Research on utilization of the devices, volumes of imports will also be conducted to assign the regulatory control risks and for categorization.

4.11 Monitoring and Surveillance upon institution of regulatory frameworks

In line with the Device Regulation, monitoring and surveillance of the market, Market Authorization holders shall be carried out to ensure compliance to the regulatory requirements.

4.12 Professional and Industry Associations

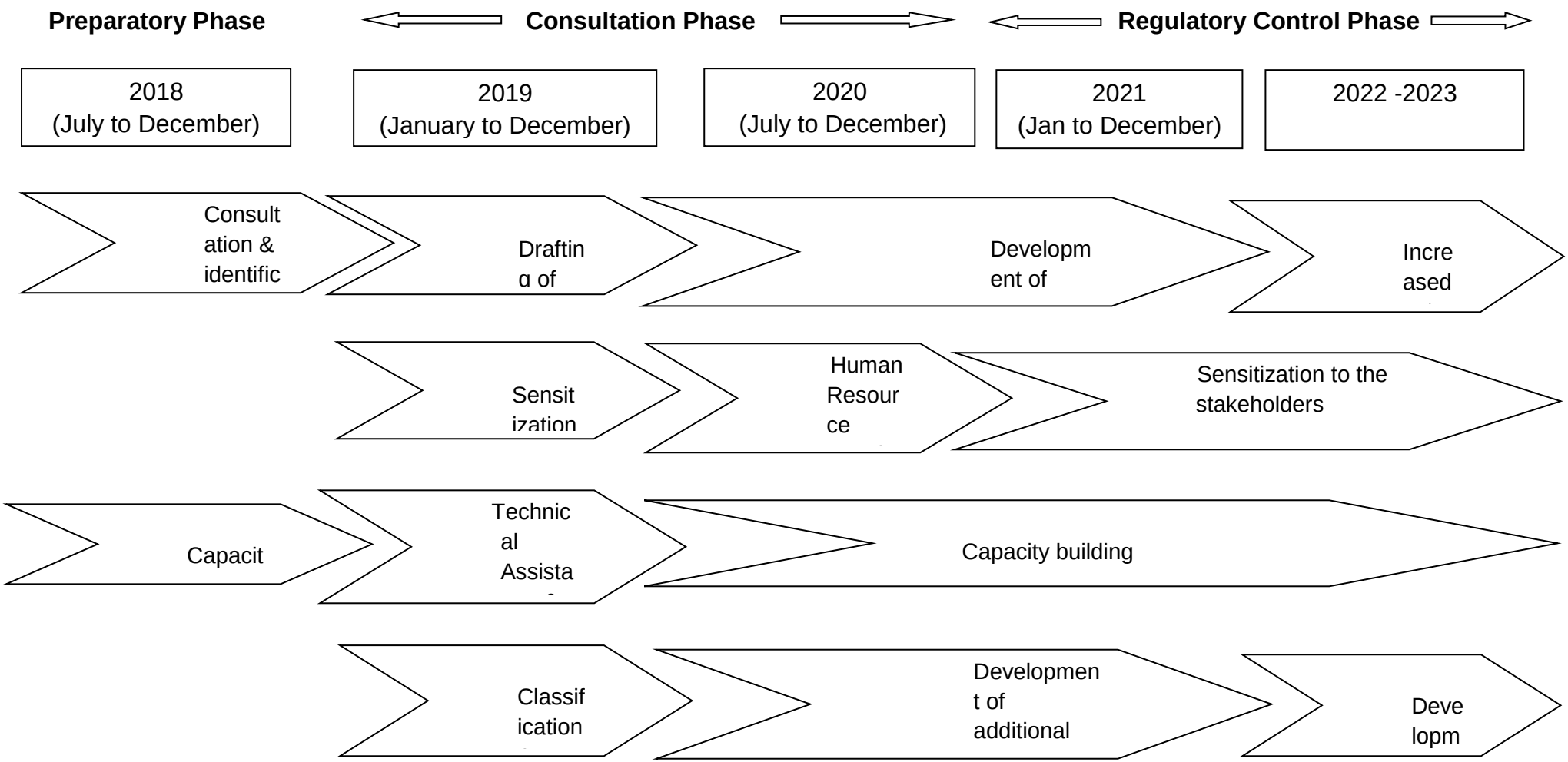
An association of the importers/Market Authorization Holders shall be encouraged to voice concerns on issues directly affecting them and to provide feedback on the regulatory mechanisms. Such professional and industry associations shall also be encouraged to take initiatives to build partnerships with Drug Regulatory Authority and procurement agencies to complement the efforts in ensuring quality, safe and efficacious medical device in the country.

4.13 Consumer education and information programs

Drug Regulatory Authority and relevant agencies should share knowledge experiences, cross sectoral issues and raise awareness, which may be through conferences, seminars, workshops or any other means of interactions.

5.0 Delivery and implementation plan (2018-2023)

5.1 Activity Implementation Timeline



5.2 Action plan

The drafting of medical devices regulation, national standards and consultation meetings forms the core activities for 12 FYP besides initiating the regulatory control on few Medical devices.

Strategies	Activities	Target Group	Deliverables	Time-line
1.Identification of the Gaps and need assessment	i. Visit to nearby NRA for seeking guidance on the Regulatory perspectives.	DRA	Study Tour Report	June 2018
	ii. Review of the current Medical Device list (standard list) and appropriate segregation against the WHO device list.	DRA, EMTD, BMED	National Medical Device list	July-Sept 2018
	iii. Review of the manufacturing standards.	DRA	Draft report on the regulatory requirements	Sept 2018
	iv. Formation of Technical Working Group (TWG) to assess the overall Regulatory gaps and resources.	DRA, EMTD, BMED	Office orders for TWG	July 2018
2.Drafting of Medical Device Regulation	i. Drafting of Principle Regulatory Requirements and Adopting ASEAN/ Indian Medical classification system.	TWG	Draft Regulatory Principles & process	July-Sept 2018
	ii. Discussion and finalization of the scope of the Medical Devices and Regulatory Requirements.	Importers/MAH, Procurement Agencies	Draft Regulatory Framework for regulation	October 2018
	iii. Drafting of the Medical Device Regulation with appropriate schedules.	DRA/ Legal officer	Draft Regulation	September-November 2018
	iv. Review of the Regulation by Technical Expert.	WHO/External Expert	Report with recommendations	November - Dec 2018

	v. Discussion of the draft in the Drug Technical Advisory Committee(DTAC)	DTAC & Co-opt members	Draft Regulatory Framework for regulation	Dec. 2018
	vi. Presentation of the Draft Regulation to Bhutan Medicines Board.	Medicines Board	Regulatory framework ready for legal vetting	January 2019
	vii. Seeking approval from Cabinet/Legal vetting by Office of Attorney General(OAG)	Cabinet/OAG	Approved Regulation	March –May 2019
3. Sensitization of the Regulation on Medical Devices	i. Sensitization Workshop on Regulation of Medical Devices (documentation for registration and Importation).	Importers/MAH, Procurement Agencies	Report of the workshop	July 2019
	ii Sensitization Workshop on Regulation of Medical Devices.	Healthcare professionals	Report of the workshop	August 2019
4. Building Regulatory framework for premarket and post market surveillance	i. Compile the list of Essential medical devices imported to group them under the intended Medical device classification to notify on the level of regulatory control.	DRA, EMTD, BMED	Tentative list of classification of the National Medical devices list	July 2019
	ii. Categorization of the Medical devices for regulation on priority /based on a defined criteria.	DRA	Notified list for priority registration	August 2019
	iii. Development of guidelines and SOP for Pre-market approval for the defined scope of Medical Devices.	DRA	Guidelines and SOP for registration of Notified Medical devices	September 2019
	iv. Explore Testing Laboratory for medical devices.	DRA	Report/Contract Agreement	November 2019
	v. Sensitization on the guidelines for Pre-market approval procedures.	Importers/MAH, Procurement Agencies	Report of the Meeting	December 2019

5. Human Resource, Capacity building & Regulatory networking	i. Workshop on medical device surveillance for all medical professionals and suppliers.	Healthcare professionals and suppliers	Report of the Meeting/List of participants	December 2019
	ii. Participation to SEARN and initiate collaboration activities.	DRA	Meeting Report	April 2019
	iii. Recruitment plan for Biomedical Engineer.	RCSC	Requisition letter	January 2020
	iv. Participation to Medical Expos/Meeting/Workshops.	DRA/BMED/Procurement Agencies		-
	v. Training of the regulators on the specified areas (Medical device- Dossier evaluation, inspection, surveillance, clinical data review).	Regulators	Training certificate/report	March 2020
	vi. In-country workshop for the stakeholders	Custom Officials	Activity Report	July-Aug 2020
	vii. Technical cooperation with Thai FDA New/renewal.	DRA/Thai FDA	Signed Technical Cooperation minutes	2021
6. Device Standards	i. Development of Guidelines for Technical manufacturing for medical devices.	DRA	Guidelines for regulatory requirements	September 2020
	ii. Development of National Standards for Medical devices –quality system.	DRA	National Standards	2022
7. Addition of the category of devices for control	i. Addition of schedules to increase the scope of regulatory control (Invasive devices).	DRA/BMED/EMTD	Schedules to the Regulation	Jan-March 2022
	ii. Notification to the public	MAH/Importers		April 2022
	iii. Development of guidelines and SOP for Pre-market approval for the additional category of devices.	DRA	Guidelines and SOP for registration of Notified Medical devices	July 2022

	iv. Development of guidelines and SOP for Pre-market approval for the defined scope of Medical Devices.	DRA	Revised SOP for registration of medical devices	Oct 2022
	v. Sensitization on the guidelines for Pre-market approval procedures for the identified category of devices.	DRA	Activity Report	January 2023

6.0 Risks Analysis and Management

Risk	Detail	Likelihood	Impact	Mitigation
i. Diverse range of medical devices, DRA may not able to regulate all at once and this could confuse our law enforcement stakeholders	Medical devices are of diverse range and difficult to draw regulatory requirements for all at one time. This could pose confusion to the importers, Custom officials and Healthcare professionals.	*High*	*Medium*	-Thorough consultation with the stakeholders -Categorization of the medical devices and regulatory requirements based on the risk. -Proper procedures in place to guide the importation of medical devices
ii. Manufacturers/ Importers may not come forward for registering Medical devices.	It would be difficult to furnish medical device dossiers due to small share of market size	*Medium*	*High*	Facilitate Market Authorization Holders to register by simplifying the documentation requirement.
iii. Accessibility and price monopoly	DRA maybe blamed for poor accessibility of wide range of medical devices and price monopoly for few registered medical devices	*Medium*	*Medium*	Special Access program for Essential Medical devices
iv. Lack of knowledge on Validation and calibration services	BMED is not equipped for conducting validation services for diverse range of products.	*High*	*High*	Third party outsourcing for such activities, capacity building

v. Increased regulatory burden	Need for additional regulatory officer, testing capacity for testing devices in the national laboratory	*High*	*High*	Recruitment of diverse regulatory officers in DRA, third party outsourcing for such activities, capacity building

7.0 Financial Summary

The budget for regulatory control on Medical devices is projected at Nu. 1370000 (One million and three hundred seventy thousands) including the WHO biennium budget as detailed below:

S/N	Activity	Sources	Budget
1.	Support Regulation and Policy	WHO	*670,000*
2.	Testing & Surveillance	RGoB	*300,000*
3.	National standard and Regulatory procedures consultation & sensitization workshop	RGoB	*40,000*
		Total	*1370,000*

8.0 References

1. WHO Medical Device technical series
2. WHO Medical Device Policy
3. ASEAN Medical Device Directive
4. Medical Device Regulations, Health Canada
5. WHO Global Model Regulatory Framework for Medical Devices including IVD
6. Standard List of Medical devices, Essential Medicines Technology Division, MoH, Bhutan
7. Minutes of the stakeholder meetings (Imported & Procurement agencies) dated 17 April 2018