Toolkit for the Establishment of a Medical Products Regulatory System in Small States

VOLUME 2

Establishing a Legal Framework to Support a National Regulatory System

In partnership with Canada

PAHO Pan American Health Organization

World Health Organization Americas Region

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Abbreviations and Acronyms

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunization
GBT	Global Benchmarking Tool
NRA	National Regulatory Authority
GxP	Good Practices
SF	Substandard or Falsified
WHO	World Health Organization
MA	Registration and Marketing Authorization
LI	Licensing Establishments
LT	Laboratory Testing
MC	Market surveillance and Control
RI	Regulatory Inspection
VL	Vigilance

Introduction and Background

A country's National Regulatory System provides the framework that supports the World Health Organization (WHO) recommended essential regulatory functions. A sustainable, well-functioning regulatory system will ensure that there is independent and competent oversight of medical products. A strong legal framework, with a core set of essential laws and regulations is the foundation of a national regulatory system. It provides the basis to introduce a legal requirement that all medical products used in the country are registered by the National Regulatory Authority (NRA) and that all establishments used in manufacturing, importing, and distributing are licensed by the NRA. Comprehensive laws and regulations governing medical products are essential to the protection of public health.

A well-defined effective legal framework for the regulation of medical product must:

- Define the structure, responsibility, and powers of the NRA.
- Define the scope and type of products to be regulated.
- Provide for a mandatory system of licensing of:
  - all medicinal products, whether locally manufactured or imported.
  - all local manufacturers, importing and exporting agents, and distributors, and
  - all premises and facilities used locally to manufacture, store, distribute or retail
- Establish systems for market surveillance and control, and pharmacovigilance.
- Define the actions to be taken for unauthorized, unsafe, substandard, and/or falsified products, and non-compliant facilities, including suspension of licensure, recall, suspension, withdrawal and/or destruction.
- Assign accountability for safety, efficacy and quality to manufacturers.
- Empower an official quality control laboratory to test products independently based on a risk-based approach.
- Establish deterrent sanctions when the law or regulations are violated and should include mechanisms for NRA staff accountability.

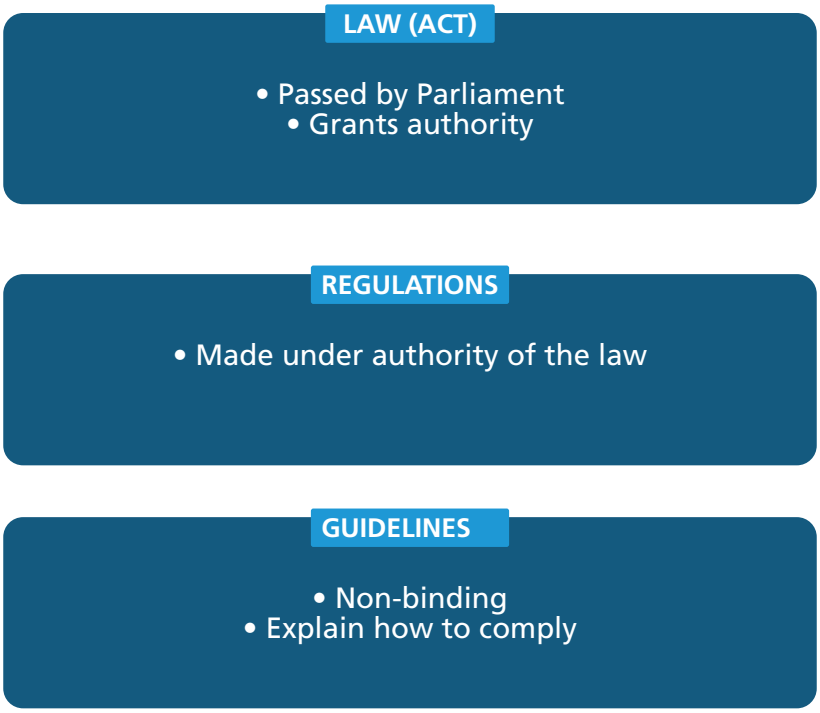
Establishing a regulatory system without a legally empowered authority is not possible. As defined by WHO's Good Regulatory Practices (Annex 11) and the Global Benchmarking Tool (GBT), every essential function—registration, licensing, inspection, vigilance, and others—must be grounded in national law. In countries, where some functions may currently fall under older pharmacy acts or are delegated without explicit legal empowerment, a formal review and reform of legislation is essential to enable the full implementation of a regulatory system aligned with GBT maturity level 1 or higher

What are Laws and Regulations?

Laws, sometimes referred to as Ordinances or Acts, are the most formal expression of the will of the State and must be made by Parliament or government processes through a process often referred to as enactment.

FIGURE 1

Illustration of the relationship between laws, regulations, and guidelines within a medical product regulatory framework



The purposes of a law or Act may either be of a general, public nature or private, conferring powers or special rights or exemptions on individuals or groups. They are written in general terms so that they are flexible enough to meet present day needs as well as those of the future, reducing the need for changes to be made over the years. Laws should set out at a high level the roles and responsibilities of the NRA, define the products, persons and activities that are to be regulated and state what is permitted and what is not. Laws also authorize the creation of lower level (or subordinate) regulations. Regulations usually state the conditions to be met and detail the requirements defined in the laws. For instance, a law may require that a medicinal product be registered, before it can be sold or distributed, but the regulations would set out the conditions for obtaining a registration. A third type of instrument, Guidelines, is used to provide details on the operational processes to be used to enforce the respective laws and

regulations. (Figure 1). Within a regulatory framework for medical products, guidelines are generally more detailed and technical in nature, making them appropriate for describing approaches used to satisfy regulatory requirements but unsuitable to be embedded into legislation as they reflect current scientific knowledge and likely to evolve or change in the future.

To draft a set of laws that meet the necessary requirements stated above, it is important to look at models from other countries, both small countries with similar size populations and challenges, and larger countries with well-established regulatory systems, such as the European Union, USA, Canada, and Australia. This will promote harmonization with respect to definitions of product types, which will be of benefit to both the NRA and the pharmaceutical industry as it will facilitate reliance. Also, as laws are written in general terms, common language can be observed across many countries' legislation and can hence be used in drafting. Within the PAHO region, there are many good examples of medical product legislation in small states, including the Food and Drugs Act of Jamaica, Food and Drug Ordinance 2016 of the Turks and Caicos Islands and the Food and Drugs Act of Trinidad and Tobago.

Some laws have power on their own. Many examples of medical products laws or Acts contain prohibitions, or statements that forbid certain activities. For example, a law prohibiting the manufacturing, importation, distribution or retail of an unsafe, adulterated or unsanitary product can give an NRA broad power that can be wielded to address many regulatory challenges. Other laws, such as those requiring products to be labelled appropriately, will require subordinate regulations detailing the labelling requirements to bring them into effect. While laws and their corresponding regulations are often drafted together, the drafting of laws can proceed on its own, with the drafting of regulations following in stages as required and based on what the priority issues to be addressed are.

An example of how laws, regulations and guidelines work together in a regulatory scheme can be seen in the following example:

The law may have a statement like the following:

No person shall sell or advertise any drug unless they are the holder of a market authorization for that drug, issued by the Minister (or Board or Authority).

It would likely also state:

The Minister may make regulations respecting the of issuance market authorizations referred to in section XX and the amendment, suspension and revocation of those authorizations.

This establishes the requirement for a drug to have a market authorization and provides the necessary authority to make regulations for a market authorization scheme and process.

The regulations will state something like:

No person shall sell or advertise a drug unless:

a. the manufacturer of the drug has filed with the Minister a submission (or market authorization request), relating to the drug that is satisfactory to the Minister.

b. the Minister has issued a market authorization notice (or whatever term is to be applied) to the manufacturer of the drug in respect of the submission; and

c. the market authorization in respect of the submission has not been suspended.

Another regulation may state something like:

A drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

a. detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended.

b. evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended.

The regulation however should not specify what type of tests or evidence will meet the requirements and be deemed sufficient or satisfactory. It is near impossible to include the specifics of this information in regulations as it will differ from product type to product type and will also depend on the state of science and medicine at times and therefore be subject to change. For example, the amount of clinical evidence to demonstrate effectiveness for a vaccine to be used in large scale vaccination of children will differ dramatically from that required for a drug for a rare, life-threatening disease. Guidelines, or other non-legal documents are instead used to detail the technical and process requirements of how a regulation is to be met. They serve as the regulator's interpretation of the type and amount of data needed to comply with a regulation. Since guidelines are not legal provisions, there are usually easier than laws or regulations to modify and update.

While guidelines about administrative processes will need to be written by the regulatory authority as they will be country specific, those about technical and clinical data requirements may not need to be created. Referencing international guidelines, such as those of the International Conference on Harmonization of Technical Requirements for Pharmaceuticals (ICH) or the Pan American Network for Drug Regulatory Harmonization (PANDRH), will save valuable resources and promote harmonization with other authorities.

Establishing a Regulatory Framework: The Steps

Establishing a national regulatory system is a complex process requiring an investment of time and resources. Furthermore, strong, and sustained support at the highest political and government levels, as reflected in long-term national government policies on regulatory systems, must be secured for the effective implementation of regional regulatory mechanisms and to pave the way for the national regulatory authority to operate and coordinate efforts with the regional regulatory authority.

Small states wishing to establish a national regulatory system for medical products are recommended to follow this stepwise approach:

STEP 1

Preliminary

In approaching the establishment of a national regulatory system, drafting of laws and regulations, the self-benchmarking against the WHO Global Benchmarking Tool (GBT) can be an essential information tool. The process for conducting a self-benchmarking is described in Volume 1 of this Toolkit. Using the information from the self-benchmarking, it is helpful to consider the following questions, prior to proceeding with the drafting of any laws or regulations:

Has Ministerial support and commitment been obtained?

This is critical as the drafting of laws and regulations must follow established government and parliamentary procedures. Once is place, there must be support and the allocation of resources sufficient to enact and enforce the system.

Have key policy decisions on the scope of products and the activities to be regulated been made?

These decisions must be made in advance and in consideration of the likely availability of resources and the extent of the use of reliance on the work of other NRAs in decision-making.

What pertinent laws and regulations already exist?

Even if there are no laws specific to medical products, there may be other laws that impact on medical products, such as public health laws, import control laws, emergency preparedness, laws, practice of medicine and pharmacy laws. It is important to determine to what extent existing laws will contribute to the desired state of a national regulatory system for medical products. It is also important to ensure that newly crafted laws and regulations do not conflict with those already in existence.

What is needed to fulfill the prioritized functions?

Existing laws may need to be amended, moved, or repealed and replaced with new laws, if they are extremely outdated or overly rigid. Are there laws which could be used effectively but require regulations to bring them into force? Are there regulations that lack clarity and require guidelines to interpret them to make them effective? These questions are essential to the development of a drafting plan.

STEP 2

Conducting a Legislative Review

A strong legal framework, with a core set of essential laws and regulations is the foundation of a national regulatory system. It provides the basis to introduce a legal requirement that all medical products used in the country must be registered by the NRA and that all establishments used in manufacturing, importing, and distributing must be licensed by the NRA. Compliance with the WHO GBT requires that for each essential function, legislation or regulations exist granting the NRA the authority to perform that function.

The first step in building a strong legal framework is a legislative review to examine what authorities currently exist and to look for gaps that must be filled. Completion of a self-benchmarking exercise against the WHO GBT will serve to complete such a review as many of the GBT indicators and sub indicators pertain to the existence of laws (referred to in the GBT as legal provisions) and regulations for specific activities. However, a legislative review can be conducted independently or as a preliminary step to aid in the completion of the self-benchmarking.

The following questions can be used to guide the conduct of a legislative review by an NRA. However, it is important to remember that the extent to which a State will need to meet each of these requirements will depend upon the scope of products to be regulated, whether they are manufactured domestically or imported and to what extent reliance will be used in application of the regulatory framework.

General

- Do you have laws and/or regulations that define the types of medical products that should be regulated?

- Do you have laws and/or regulations that define the institutions that are involved as part of the regulatory system, as well as their mandates, functions, roles, responsibilities, and enforcement powers?

- Do you have laws that provide for adequate and proportional sanctions and penalties.

Registration and Market Authorization

• Do you have laws and/or regulations to define regulatory framework for registration and marketing authorization, including those:

– Requiring the receipt of a registration or marketing authorization before placing the product on the market?

– Requiring demonstration of the product quality, safety and efficacy?

– Mandating specific product labelling, including the placement of a product's unique identification number on its outer packaging?

– Allowing the NRA to recognize and/or rely on relevant decisions, reports or information from other NRAs or regional and international bodies?

– Allowing for the acceleration of the standard registration and marketing authorization process in the event of a health emergency?

– Allows for the suspension, withdrawal or cancellation of a registered product if there are concerns on its quality, safety or efficacy?

Licensing and Inspection

• Do you have laws and/or regulations to define a framework for licensing activities, inspection, and enforcement, including those:

– For the licensing of facilities throughout the supply chain and based on Good Practices (GxPs) compliance?

– Empowering the NRA to issue, suspend or revoke licenses for establishments.

– Requiring that the NRA to be informed, for the purpose of notification or approval, in case post-licensure changes or variations are made?

– Providing a mandate to inspect the establishments of marketing authorization holders, manufacturers, importers, exporters, and distributors for compliance with national standards and GxP guidelines?

– Allowing inspectors to enter facilities throughout the supply chain and collect relevant evidence, including samples, during inspections?

– Allowing the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well- defined criteria?

Vigilance

• Do you have laws and/or regulations that define the scope and extent of the vigilance system, including the requirement for the NRA to:

– Establish a national Pharmacovigilance Programme to monitor and report on the safety of medical products?

– To establish a reporting system for Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFIs)?

– To allow recognition and/or reliance on vigilance-related decisions, reports, or information from other countries or regional or international bodies?

– Provide the authority for the responsible entity to take actions if needed?

Market Surveillance and Control

• Do you have laws and/or regulations providing for a framework of market surveillance and control activities, including those:

– With respect to import activities including regulatory intervention at entry and exit ports where medical products are being moved?

– Addressing the role of NRA in dealing with substandard or falsified (SF) medical products?

– For the control of promotion, marketing, and advertising of medical products to avoid communication of false or misleading information?

– To take actions on recall, suspension, withdrawal and/or destruction of SF medical products?

Laboratory Testing

• Do you have laws and/or regulations that define a regulatory framework for laboratory testing activities, and which provide the necessary mandate to implement all activities related to this regulatory function, including:

– Authorizing the NRA to sub-contract the required testing services?

– Allowing the NRA to recognize and use laboratory testing-related decisions? reports, or information from other NRAs or regional and international bodies?

Lot Release

• Do you have laws and/or regulations to conduct and enforce a lot release programme? for all vaccines, and other biologics, including the authority to accept test results from a National or Regional Control Laboratory that is not part of the NRA

It is important to note that while some of these requirements may seem onerous or not necessary, a state pursuing local production should have a regulatory framework and system in place that will meet both current and future needs as well as the requirements of the WHO GBT. Furthermore, if clinical trials are performed or may be performed within the state, appropriate laws, and regulations for the conduct of clinical trials will be necessary. The WHO GBT provides an excellent summary of the legislative needs for clinical trials.

STEP 3

Examine laws of other countries

Look for consistency in definitions and included provisions to observe common models of legislation. Harmonizing product definitions with those used by other NRAs can be important in facilitating trade and overcoming barriers to other markets for locally produced products and can help avoid disputes or challenges about product classifications. While it may be feasible to simply copy the law of another country and doing so may save significant time and resource, it is imperative to ensure that the needs of your state will be adequately met by the legislation, and that sufficient resources are available for enforcement. Adaptation to local traditions and practices may be necessary to help ensure that the law will serve the desired objectives.

Discussions with regulatory staff in countries with existing laws can allow for the sharing of valuable experience and lessons learned in the drafting and enforcement of laws.

STEP 4

Drafting Laws and Regulations

Drafting Laws

The making of laws, also referred to as acts or bills, is one of the most important activities of government. It is of the utmost importance that any government department setting out to make or amend laws, plan and manage the process in accordance with the required and established requirements of their government or Parliamentary system. Laws and the subordinate regulations must be drafted in a way so that they are viewed as products of a continuous process of law. A law

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- Analyzing the matter to be addressed and its alternative solutions.

- Determining that government intervention is justified and that the subject is within the purview of the Government's legislative power. It is important to note any limits on the exercise of legislative powers.

- Consulting with those who have an interest in the matter, including other departments that may be affected by the issue and proposed solution.

- Analyzing the impact of the proposed solution and the resources that the proposed solution would require, including those needed to implement or enforce it. All government have limited resources and cannot deal with every situation

- What, if any, monitoring or enforcement measures will be needed, such as penalties, inspections and court action

While laws can have power on their own, most legislative schemes depend on subordinate regulations to make them work. Therefore, an Act to introduce new laws must include the necessary powers to make regulations, and a regulation must strictly conform to the limits established by the Act that authorizes it. When possible, an Act and its regulations are developed together as it will make the legislative scheme easier to understand for those parties which must comply with it. When regulations are developed under an existing Act, it is important to ensure that they fall within the authority granted by that Act.

When the decision to draft an Act has been made, a project team of legal and health experts familiar with the subject should be established. A senior member of the team is named as the instructing officer. The drafting process will be most effective if the instructing officer:

- Is a senior departmental official with direct access to the Minister's office

- Has the authority to make or obtain decisions quickly

- Was directly involved in decision-making of the legislative proposal and has a good knowledge of the subject matter.

During the drafting process, the instructing officer will be responsible for reading any draft versions of the proposed legislation critically to:

- Check the draft legislation against the instructions to ensure that nothing is missing.
- Check the draft legislation for internal consistencies and readability.
- Confirm that the draft legislation meets the policy intentions of the department, and,
- Answer any questions that legislative counsel has raised

If possible, the members of the team should be dedicated to the project and relieved of other responsibilities. The project team needs to establish reasonable time targets to produce **drafting instructions.** Thinking through the detail of drafting instructions will raise new policy issues that need to be addressed and resolved. Good drafting instructions will avoid delays in drafting the Act because of unresolved policy questions. It is also important for the project team to ascertain whether the Government or the Minister made any public commitments, either generally or about the specific legislative proposal, that could affect its contents or timing.

The project team should also include a legal advisor to examine the legal issues around the Act, including identifying any conflicting legislation or any other proposed bills that may overlap. the legislation or any of its elements.

Act Content

A comprehensive Act for the regulation of medical products includes:

- What should be regulated
  - Scope of products
  - Premises, persons and practices involved in the manufacture, importation, distribution, procurement, supply and sale of products, as well as the promotion and advertising
- Who regulates
  - Governments have primary responsibility, but public and private professional associations also have a role to play.

- General provisions
- Title or name of the law
- Date of entry into operation of the entire law or certain parts, sections and articles.
- Area of operation (geographical) and application (state, private and public sector)
- Purposes and objective.
    - What are the main objectives of the proposal?
- Relationship to other existing laws
- Definitions of selected terms and concepts, exclusions
- Statutory powers, duties and responsibilities of the regulatory authority, its organization, resources and staff
- Licensing and registration system (products, companies and individuals in the contexts of manufacture, import, export, transit, procurement, distribution, prescribing, dispensing, storage, use)
- Labelling, advertising and promotion
- Enforcement procedures (seizures), and penalties.
    - Sanctions, administrative measures.
    - Legal sanctions (warnings, fines, withdrawal of licences, imprisonment).
- Special issues (patents, pricing, clinical trials), if applicable
- Surveillance
- Regulation-making scope and power

They should also include a general instruction to make consequential amendments to other provisions.

Drafting Regulations

Like Acts, regulations are a form of law and have binding legal effect. Regulations deal with matters of a legal (as opposed to administrative) nature that are subordinate to the main principles of the corresponding Act. This includes:

- Procedural matters, for example, how to apply for a licence.
- Matters that are likely to need adjusting often.
- Technical matters involving scientific or other expertise.
- Applicable fees for services.

The authority to make regulations must be expressly delegated by an Act. The Act will generally set out the framework of a regulatory scheme and delegates the authority to develop the details and express them in regulations.

In some cases, it may not be necessary to write regulations, if another document exists that can be referred to in lieu of detailing requirements. Incorporation by Reference is a technique whereby other regulations, international guidelines or industry standards for example can simply be referred to rather than restating them. This avoids duplication of the incorporated rules and can be a way of harmonizing the laws of several jurisdictions if they each incorporate the same set of rules. However, this technique may be subject to legal considerations, particularly if a state has more than one official language that laws must be written in.

Preparing Drafting Instructions

In the preparation of drafting instructions, a balance must be struck between providing too much or too little detail. Drafting instructions should be general enough to allow flexibility for minor policy questions to be worked out in the drafting process but should not provide overly broad authority to draft legislation for vaguely defined policy objectives, without any indication of how the objectives are to be achieved. It is important to find a balance between sufficient information to provides an understanding of the most important issues and a degree of flexibility that allows for unforeseen questions to be addressed. It is also important to consider the appropriate use of the following words:

- "may" empowers the regulatory authority or regulated party to do something, without obliging it to do so
  Example: "An inspector may take photographs of premises and equipment"

- "shall" indicates an obligation or prohibition
  Example: "The label applied to a medicine shall carry….", "No person shall advertise a drug…."

Drafting instructions should be written in clear, straightforward, and as far as the subject matters allows, non-technical language with topic headings. Flow charts, diagrams and tables may also be helpful to include with the instructions to illustrate a proposed process or to indicate a relationship between concepts. It is generally not advisable to write instructions in the form of a draft law or regulation or what it is envisioned the law or regulation will look like in the end.

Checklists are often helpful when writing drafting instructions, to help ensure that all relevant questions are addressed. An example of such a checklist can be found in Appendix A.

Good Examples of Legislation

There are many excellent examples of comprehensive medical products legislative schemes in PAHO member states, and small states looking to establish a system should look to these models. Two useful references to consult are:

WHO Expert Committee on Specifications for Pharmaceutical Preparations 35th Report Annex 8 National Drug Regulatory Legislation: Guiding Principles for Small Drug Regulatory Authorities.

Management Sciences for Health, Chapter 6 Pharmaceutical Legislation and Regulations, 2013.

Regulatory Consultations

The development of an effective legislative or regulatory proposal necessitates that consultations with the parties who will be affected by the proposal are conducted. The extent to which stakeholders are involved in a consultation process will vary from simply providing them with information to engaging them in a partnership on the decision making. A good consultation process will assist in the development of quality laws and regulations and enhance compliance once implemented since sooner manufacturers and importers are aware of the new requirements, the sooner they can start preparations to comply. Involving key stakeholders and the public in consultations during the drafting process will also serve to build confidence and transparency in the regulatory system under development, and the NRA.

There is no one-size-fits-all approach to regulatory consultations as the size and scope of the consultative process depend on the proposed laws or regulations and the number of people or groups affected by them. The process, therefore, may be broad (e.g. many stakeholders, across several regions) or more targeted (e.g. specific stakeholders, specific regions). In certain states, the need to consult when drafting new laws or regulations may be mandated in the legislative process that must be followed. Regardless, it is an important part of the process of developing laws and regulations.

Identify Your Stakeholders

Broadly defined, stakeholders are individuals, groups, or organizations likely to be affected by proposed changes. Examples of stakeholders include members of the public, and community groups and industry groups, non-governmental organizations, internal regional bodies, municipalities, foreign governments and health care professionals and associations. The following principles should apply to the interactions with stakeholders during the consultation process:

Meaningfulness

- Be open to stakeholders' views and opinions and as much as possible take these into account in preparing the proposed regulations.

Openness and balance

- Identify the "most affected stakeholders" but provide all stakeholders, whether directly or indirectly affected, with an opportunity to contribute their views.

Transparency

- Be clear about any aspects of the proposal that are not subject to change
- Communicate how stakeholder input will be used

Accountability

- Document how the views of stakeholders were considered during the development of the laws and
- Outline reasons why input is not reflected in the final proposal
- Conduct consultations over a reasonable period, so that participants have sufficient time to submit their views.

Develop a Consultation Plan

A clear and comprehensive consultation plan will help facilitate a smooth consultative process. The consultation plan should frame the boundaries of the consultation process, the objectives of the process, the issues under review, any environmental analysis, key participants, timelines, and a mechanism for reporting consultation results. However, consultation plans do not need to be complicated or overly detailed. A simple consultation plan should include the following:

Statement of purpose and objectives

- A clear statement of the objectives of the consultations (to maintain focus during the consultation process and to deflect distractions that are outside the consultations' parameters).
- It should be broad enough and flexible enough to accommodate stakeholders' views, but precise enough to keep the discussion centred on the issue at hand.

Timelines

- Identify realistic timelines that for reach activity and set milestones for all aspects of the consultative process. The amount of time required for a consultation will depend on the complexity of the issue and the consultation methods selected.
- Ensure timelines are flexible enough to allow for unforeseen circumstances

Identify necessary Internal and interdepartmental coordination

- Ensure that all relevant departments and agencies have an opportunity to participate and that differences are resolved before outside stakeholders are engaged.
- Allow adequate time for other departments to review the proposed consultations and regulatory proposals and provide meaningful input.

Select the consultation tools

- Include an assessment of the most appropriate consultation tool based on the size and scope of the proposal, regional considerations, and the types of stakeholders.
- Consultation tools may include interviews, toll-free hotlines, questionnaires/surveys, open house / public meetings, conferences/workshops, bilateral meetings, focus groups, advisory boards / committees, requests for written submissions, websites/forums, video conferencing
- Research previous consultations to determine the methods usually used for consulting on this issue and with these stakeholders
- Assess the advantages and disadvantages of using various consultation tools

Select the participants

- Define the range of stakeholder involvement Identify which regions of the country should be represented
- Develop criteria for selecting participants
- Consideration should be given to how the public will be consulted.

Establish a budget

- The degree of financial, personnel, and time investment should be commensurate with the size and scope of the regulatory proposal.
- Budgeting may need to cover communications, technical information, logistical and travel arrangements, third-party support (e.g. facilitators), participant funding, and translation (i.e. written and simultaneous translation).
- Determine the funding available

Documentation

- Determine how input will be tracked, evaluated and communicated
- Include options for providing feedback

Pre-Publication

Pre-publication is the critical consultation period, when a first draft or version of the new Act or Regulations is made available for comment. A posting on a government website or in a government released publication is the most comment pre-publication tool and ensures that the draft version is available to everyone.

When draft regulations are pre-published, interested and affected parties are allowed a specified period to express their views. The pre-publication comment period may also be determined by international agreements, such as World Trade Organization agreements if there is a potential impact on international trade.

Comments received during the pre-publication period should be given careful consideration to determine whether changes to the drafted laws or regulations are needed. A tracking document to monitor and categorize the comments received is a helpful tool and it can be referred to later to explain how stakeholder concerns were addressed or why it might not have been possible to do so. An example of a tracking form is provided in Appendix B.

It is important that regulatory consultations be managed in an open and transparent manner. Stakeholders must feel that their input is warranted and valued. There should be clear communication regarding the nature of comments received, which were accepted or rejected, and the rationale for rejecting any comments.

Why Legal Frameworks are Essential for Meeting GBT Maturity Level 1

The GBT requires that each essential regulatory function be grounded in law for it to be considered implemented—even at the most basic level (Maturity Level 1). Policies, guidelines, or informal practices are insufficient without a corresponding legal provision.

In small states where regulatory functions are sometimes embedded in pharmacy councils or dispersed across health ministries, this presents a critical challenge: functions must be legally mandated and clearly assigned to the National Regulatory Authority (NRA) or equivalent body.

TABLE 1

Examples of GBT Legal Subindicators

Function	GBT Subindicators	Legal Provision Required
Registration and Marketing Authorization	MA01.01	Law requieres marketing authorization prior to product distribution
Licensing Establishments	LI01.01	NRA has legal mandate to license manufacturers, importers, and distributors
Regulatory Inspection	RI01.01	Inspectors are legally empowered to access facilities and collect samples.
Vigilance	VL01.01	Legal basis exists for pharmacovigilance and ADR/AEFI reporting.
Market Surveillance and Control	MC01.01	Law authorizes action on substandar/falsified productos, including recalls.
Laboratory Testing	LT01.01	NRA has legal authority to conduct or subcontract product quality testing

In short, no regulatory function can be implemented without an enabling legal base. A full legislative review against the GBT's legal sub-indicators is a critical first step in any effort to establish or strengthen a regulatory system. By reviewing and strengthening legislation with these requirements in mind, countries can ensure that their regulatory systems meet the minimum legal thresholds established by the GBT—a prerequisite for any further progress in system strengthening.

Summary

A strong legal framework, with comprehensive laws and regulations is the foundation of a national regulatory system. It provides the basis to introduce a legal requirement that all medical products used in the country are registered by the NRA and that all establishments used in manufacturing, importing, and distributing are licensed by the NRA.

While the process of drafting effective laws, regulations and guidelines can be complicated and laborious, if done properly, the foundations of a strong and sustainable regulatory system will have been laid.

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APPENDIX A: Drafting Checklist

A. GETTING STARTED

- Identify the instructing officer
- Estimate (in consultation with legislative counsel) the time needed for drafting

B. GENERAL MATTERS

- Describe and explain the principal objectives
- Decide how to implement the objectives
- Assess the legal content

C. LEGISLATIVE ELEMENTS

- Consider the key legislative design questions
- Who? - Who is subject to the rule?
- What? - What is the basic rule? That is, what is it that the subject
- Where? - Is there a geographical component to the rule?
- When? - Is there a time component to the rule?
- Why? - What is the purpose of the rule?
- How? - Is there a means/method aspect to the rule?
- How much? - Is there a cost/charge aspect to the rule?
- If? - Are there limits to when the rule will apply?
- If not? - Are there sanctions (fines, administrative penalties, something else) if the rule is not followed?
- But? - Are there exceptions to the rule?

D. LEGISLATIVE STRUCTURE

- Consider whether the proposal belongs in an Act, in regulations under an Act, in administrative instruments or some combination
- Consider where to place specific provisions

E. POWERS AND DUTIES

- Decide who powers and duties should be given to
- Consider whether to allow powers or duties under the legislation to be delegated, and if so to whom

F. EXTRAORDINARY PROVISIONS

- Identify any extraordinary provisions that require specific approval
- Determine whether regulations to be made under the Act will include extraordinary provisions

G. SPECIFIC ISSUES

- Decide on a proposed title for the legislation
- Consider whether the legislation's application needs to be expanded or limited in any way
- Plan for any required regulations
- Provide for any special procedural requirements

• Establish authority for the making of any needed appointments (to boards, tribunals or other senior positions), and clarify who will make the appointments
• Provide full details as to any new public body
• Provide for the collection or disposition of public money, if required
• Consider the need for special rules in relation to access to or disclosure of information
• Decide if enforcement mechanisms are required, and what those should be
• Decide whether to include a review process for any decisions under the legislation that affect people's rights
• Decide whether a special dispute-resolution mechanism is needed

H. ANCILLARY MATTERS

• Provide for any necessary repeals of Acts or regulations
• Assess the need for consequential amendments
• Decide whether transitional provisions are needed
• Determine when the legislation should come into force

I.REVIEWS AND CONSULTATIONS

• Internal consultation: consider whether other Ministers, departments or Government agencies need to be consulted
• Joint drafting or review: decide whether other departments or government agencies should participate in the drafting process or review the draft legislation
• External consultation: consider whether the views of other governments, nongovernmental bodies or the public are needed

J. FINAL CONSIDERATIONS

• Identify outstanding policy issues
• Recommend an implementation schedule
• Other consideration

Appendix B: Pre-Publication Results Tracking Document

Proposal - Title

Provision	Stalkeholder	Commets	Disposal
Indicate the section of the regulatory proposal that was commented on	Name of individual or organization providing the comments	Nature of the issues	Proposed response identify how the response will be conveyed to the stalkeholder