Ethiopian Food and Drug Authority

Regulatory Preparedness and Mitigation Strategy for Emergency Health Threats

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Table of Contents

Acronyms

AMA	Africa Medicine Agency
ACDC	African Centre for Disease Control and Prevention
EFDA	Ethiopian Food and Drug Authority
EMA	European Medicine Agency
EPHI	Ethiopian Public Health Institute
ESC	Emergency Steering Committee
ETF	Enforcement Task Force
EUA	Emergency Use Authorization
ICH	International Council for Harmonization
IGAD	Intergovernmental Authority on Development
MAH	Market Authorization Holders
MHRA	Medicines & Healthcare products Regulatory Agency
MOH	Ministry of Health
NMRAs	National Medicine Regulatory Authorities
PSUR	Product Safety Update Re port
SEC	Standing Emergency Committee
TA	Technical assistance
TGA	Therapeutics and Goods Administration
USFDA,	U.S. Food and Drug Administration
WHO	World Health Organization

1. Introduction

From the past and current experiences, emergency public health threats including coronavirus (COVID-19) are spreading with alarming rate which affects the stability of the global medical products supply chains. For the purposes of this document, the term "emergency health threat" refers to cross border health threats and national health threats in which the government believed and announced to be an emergency threat for the country and means a hazard of biological, chemical, environmental or unknown origin which is likely to spread across the nation and may cause a potential severe risk to public health necessitating a coordinated action at national level. Public health threat is a true test of the global medical products supply chain, and it is urgent that all players including national health regulatory authorities take appropriate steps to improve access to quality assured medical products and protect the safety of patients and the public.

Today, domestic and global public health preparedness and response benefit from improved products, innovation, responsive manufacturing, and broader surveillance. However, much remains to be done as these critical efforts must be sustained. Scientific progresses in the last decades compel not only to articulate what is possible but also to identify what is needed to truly transform our pandemic preparedness. Research, innovation and new approaches should be considered to augment planning and responses.

During pandemic/epidemic situation, illegal manufacturing, importation and distribution of medical products is a challenge. Various actors might take the opportunity of gaps in product availability and repeated shortages to proliferate illegal practices that could endanger public safety. The public health emergencies might also exacerbate the ongoing problems of substandard and falsified medical products. Moreover, lack of medical products including medical supplies and personal protective equipment might lead to an increased rate of infections and poor control of the pandemics/epidemics.

Under the leadership of Ministry of Health (MoH), the Ethiopian Public Health Institute (EPHI) is responsible for the overall management and coordination of public health emergencies. The Ethiopian Food and Drug Authority (EFDA) is mandated to lead regulatory services which contribute for the success of critical public health decisions taken by the government. In addition,

EFDA plays an important role in streamlining coordination of scientific regulatory matters across the country including expedited approval of research and innovation related to product development, clinical trials, manufacturing and marketing authorization of medical products. Apart from taking measures to facilitate innovation and research, EFDA will also have unique role in mitigating the challenges of shortage of medical products, ensuring safety of patients and protecting public health from falsified and substandard medical products. In addition, creating proper channel for information exchange during emergency situation is important.

Despite uncertainty in future epidemic/pandemic emergency health threats, developing and implementing concerted set of strategies will be critical to ensure prompt and flexible responses. Therefore, this strategy is developed to guide the roles and actions of the authority as part of the overall government efforts in dealing with emergency public health threats.

2. Scope

This strategy focuses on dealing with emerging health threats such as coronavirus, ebola and others that could be caused by biological, chemical, environmental and other unknown triggers. The strategy is meant to provide guidance on regulatory interventions during public health emergencies. This strategy is not intended to health threats triggered by product related defects, which should be handled by product risk management plan that could deal with product specific incidents.

3. Objectives

3.1. General objective

The strategy aims to ensure sustained access to innovative, safe, quality assured and effective medical products through mitigating medical products shortage during public health emergency situations.

3.2. Specific objectives

- Initiate and coordinate scientific research and regulatory innovations involving relevant parties within and outside of Ethiopia during emergency situations.

- Strengthen and coordinate authorization, surveillance and post-authorization follow-up of medicinal products relevant to emergency health response (e.g. vaccines and antivirals), medical devices (e.g. medical masks, shield, mechanical ventilators) and sanitizers (e.g. alcohol based, iodine based).
- Provide special attention towards monitoring and authorization of clinical trials involving conventional and herbal products intended for the emergency situations.
- Expedite the regulatory processes and introduce regulatory flexibilities during public health emergency for Emergency Use Authorization (EUA) so as to alleviate product shortages.
- Detect, prevent and respond to substandard and falsified medical products circulating in the market taking advantage of shortages during public health emergencies.
- Effectively communicate relevant information on timely basis to healthcare professionals, patients, general public and other relevant stakeholders.
- As required, communicate, harmonize and coordinate with international and regional organizations such as WHO, EMA, ICH, AMA, etc and National Medicine Regulatory Agencies (NMRAs) including USFDA, TGA, MHRA, etc. to benefit from and contribute to global and regional efforts in response to public health emergencies; to expedite authorization of new and/or innovative products as part of efforts to improve access to available treatment options to the Ethiopian people during public health emergencies.
- Ensure that EFDA have the appropriate tools and institutional framework for co-coordinated action for management of crises due to emergency public health threat

4. Situational analysis

For the preparation of the emergency public health threat strategy, SWOT analysis was done to properly identify and determine factors that influence the working condition of the authority during public health emergency situation. The SWOT analysis are broadly divided into internal factors (Strengths & Weaknesses) and external factors (Opportunities & Threats) **(Table 1).**

Table 1: SWOT Analysis

Strengths	**Weaknesses**
• Commitment of EFDA top management • Political commitment of the government • Improved flexibility of regulatory requirements and timely responses • Better and improved reporting and data availability • Aavailability of directives and guidelines for Emergency Use Authorization (EUA) • Establishment of national task forces • Integrated inspection and surveillances • Availability of international partners to support the Authority	• Absence of strategic roadmap for preparedness, mitigation and response of public health emergency threat • Inadequate approach on EUA processes of medical products • Limited preparedness to tackle public health emergency • Poor coordination with some government organizations • Lack of robust regulatory system that addresses public health emergency threat • Weak data storage, access to and use of quality information for decision making • Absence of early warning system of shortage of medical products • Lack of technology to detect, prevent and respond adulterated products, substandard and falsified health products
Opportunities	**Threats**
• Presence of scientifically proven and globally accepted health products and technologies • Advancements in technology both globally and locally • Availability of information exchange platforms • High political commitment during health emergencies	• Emergence and re-emergence of disease epidemics/pandemics • Proliferation of and/or weakly controlled illegal activities • Existence of porous borders in the country • Weak regulatory infrastructures both at regions and branch offices such as laboratories and ICT • Political instability hindering regulatory oversight • Limited resources

5. Stakeholders analysis

Stakeholders are key players in the regulatory activities and their analysis is crucial to the success of the implementation of this strategy. Depending on the nature of the public health threat, different organization will be involved in the interventions. It is important to take into account the needs and interests of those who have a 'stake' in the regulatory sector. The stakeholder analysis done for this strategy is presented in **Table 2** below.

Table 2: The stakeholders' analysis

Stakeholders	Behaviours we desire	Their needs	Resistance issues	Institutional response
• Community	• Participation, engagement, Ownership and • Healthy life style	• Access to up-to-date and reliable information, empowerment, • quality and safe medical products	• Dissatisfaction • Opting for unsafe alternatives • Mistrust • Underutilizatio n	• Community mobilization, ensure participation • Ensure sustained access to quality and safe medical products • provide up-to-date, reliable and proper information
• Parliaments, Prime Minister's Office, Council of Ministers, Regional Governments	• Approval of Policies proclamations regulations etc., • Resource allocation • Implementation follow-ups and feedbacks • Leadership support • Political commitment	• Proper implementation of laws, policies etc. • Information exchange • Sustained access to quality and safe products to the public • Quick response to emergencies • Plans & reports	• Administrative measures • Organizational restructuring • Influence on budget allocation • Lack of political commitment	• Put in place strong M&E system and comprehensive capacity building mechanisms • Proper execution of authority and responsibility • Corrective actions based on feedbacks • Provide proper information
• Ministry of Health and its specialized agencies, Regional Health Bureaus	• Leadership support • Integrated regulatory activities • Technical and financial support • Support in enforcement activities • Provide proper information and comply	• Proper plans and reports • Transparency and flexibility of regulatory activities • Efficient approval of import permit and port clearance of medical products	• Fragmentation • Dissatisfaction	• In place regulatory flexibility and efficient approvals • Information exchange • Strong monitoring and evaluation of performance system • Develop regulatory capacity for emergency

Stakeholders	Behaviours we desire	Their needs	Resistance issues	Institutional response
	with requirements for importation of products • Information exchange	• Information exchange		response
• Line Ministries (Trade and industry, Custom, etc.)	• Collaboration and participation • Consider health in all policies and strategies • Information exchange • Enforcement of laws • Control illegal medical products	• Technical support • Up-to-date and reliable information exchange • Collaboration • Integrated operational plan • Access to standards • Evidences	• Fragmentation • Dissatisfaction • Considering medical products regulation as low priority	• Integrated collaboration • Transparency and provision of up-to-date information on regulatory measures • Joint operational work plan on illegal control activities • Advocacy and joint meetings • Use of standards and evidences
• Law enforcement bodies (Justice, Court, Police etc)	• Support and collaboration in enforcing laws • Technical support • Integrated work on illegal trade • Support in preparing legal frameworks and legal advices	• Legal framework • Awareness on medical products laws • Technical support • Clear and concrete evidences • Current and reliable information exchange • Joint operational work plan • Trust	• Fragmentation • Dissatisfaction • Considering medical products regulation as low priority	• Integrated collaboration • Provision of up-to-date information on regulatory activities • Joint operational work plan on illegal control activities • Advocacy and joint meetings • Providing clear and concrete evidences
• Academia	• Technical assistances • Evidence generation	• Collaboration • Engagement and participation • Information exchange	• Mistrust • Fragmentation • Dissatisfaction	• Create transparence and collaboration modalities • Create conducive environment for engagement and participation • Use of evidences generated • Properly utilize their TAs • Provide and take up-to-date information
• Manufactures , Importer and	• Abide with available laws • Participation	• Collaboration • Efficient and timely regulatory services	• Breaching laws • Mistrust • Dissatisfaction	• Ensuring good governance and efficient service delivery

Stakeholders	Behaviours we desire	Their needs	Resistance issues	Institutional response
wholesaler	• avail quality products and services • Information exchange	• Transparency • Fast response • Awareness on legal frameworks • Enabling environment for their engagement • Technical support • Information exchange		• Continuous provision of awareness on laws • Provision of feedback and support • Create transparence and collaboration modalities • Dialogue
• International organizations (WHO, Interpol, AMA, EMA, AMA, etc)	• Technical assistances • Evidence generation • Information exchange • Alert system	• Collaboration • Engagement and participation • Information exchange	• Fragmentation • Dissatisfaction	• Create transparence and collaboration modalities • Properly utilize their TAs • Provide and take up-to-date information
• Development Partners	• Harmonized and aligned • Participation • More financing • Technical support	• Financial system accountable and transparent • Involved in planning, and M&E • Collaboration and engagement	• Fragmentation • Inefficiencies	• Government leadership • Transparency • Efficient resource use • Build financial management capacity • Collaboration and engagement • Provide and take up-to-date information
• NGOs, CSOs, and professional associations	• Harmonization & alignment • Participation, resource & TA • Promote code of conducts • Aware the public and member of the societies	• Involvement and participation • Technical support	• Dissatisfaction • Fragmentation • Scale down • Mistrust	• Collaboration, Transparency, Advocacy • Capacity building • Information exchange • Use of technical support
• Media	• Collaborate on provision of right information to the public about the emergency health threat mitigation and response related activities	• Up-to-date and reliable information • Transparency and participation	• Dissatisfaction • Fragmentation • Mistrust • Dissemination of untruth information	• Provide up-to-date and reliable information • Strengthen collaboration and integrated works • Create transparent and participatory platform for medias

6. Preparedness prior to emergency health threat

The Authority will undertake the following actions as part of the routine preparedness to ensure adequate readiness to deal with an emergency public health threat.

- Regular interactions with vaccine/antimicrobials/antivirals experts and regulatory network with academia, research institutes and relevant stakeholders and partners;
- Regular discussions with local manufacturers and suppliers of medical products.
- Regular interaction with EPHI through early warning and response system set up by EPHI. There should be notification and information sharing of health measures planned or undertaken against serious cross border health threats;
- Regular interactions and information sharing with international organizations such as WHO, EMA, AMA and other national regulatory agencies.
- Regular interactions and information sharing with the African union, African Centre for Disease Control and Prevention (ACDC) & Intergovernmental Authority on Development (IGAD).
- Conduct regular analysis to compare recently imported and locally manufactured products by utilizing trends to forecast imminent shortages and identify alternative solutions.
- Create regulatory flexibility that suits public health emergency mitigation and response
- Prepare and make ready necessary legislative documents that facilitate decisions for emergency use authorization of medical products during emergency situations
- Arrange logistic and supply arrangements including financial and other resources.
- Establish structure within the Authority that deal with emergency and crisis management.
- Harmonize important regulatory requirements with other NMRAs to facilitate speedy access to existing, new and innovative products

7. Triggers and response to health threat

When the Ethiopian government declares an emergency public health threat and needs serious response, the Authority will commence different level of response mechanisms and level of activation of the emergency. In addition, EFDA will establish different task forces in response to the health threat **(Table 3),** which will be translated into coordination of rapid-response teams in the emergency. Those rapid-response teams with members from research institutions, academia, regions, police and professional association should be trained and equipped with appropriate skills and resources. The task forces will be involved in preparations and dissemination of facilitated legislative tools, establishment of systems to mitigate shortages of medical products, combat substandard and falsified medical products, surveillance of market, facilitation and support for innovation and research, and implementation of clear communication mechanisms.

Furthermore, the EFDA technical and administrative directorates will integrate preparedness and response issues in their day-to-day activities as per the recommendations from the emergency taskforces.

T**able 3:** Level of emergency and teams established during the emergency health threat

SN	Level of Emergency	Teams to be Established	Experts to be Involved	Activities
1.	**Level 1** (outbreaks reported)	Emergency Steering Committee (ESC)	Director General (DG), deputy director General (DDG), Directors of technical directorates, Regional Health regulatory bodies, Legal department and communication	Detail roles of committees are explained in section (9) of this strategy
		Standing Emergency Committee (SEC)	Directors of technical directorates, EFDA advisors, representative of academia, association, and research institutions	
		Enforcement Task Force (ETF)	Inspection Directorate, Surveillance Directorate, Inspection department of Regions, Police	
2.	**Level 2** (epidemic/ PHEIC declared)	Emergency Steering Committee (ESC)	As stated in level one emergency	
		Standing Emergency Committee (SEC)	As stated in level one emergency	
		Enforcement Task Force(ETF)	As stated in level one emergency	
3.	**Level 3** (Pandemic declared)	Emergency Steering Committee (ESC)	As stated in level one emergency	
		Standing Emergency Committee (SEC)	As stated in level one emergency	
		Enforcement Task Force (ETF)	As stated in level one emergency	

8. Operational interventions

To mitigate shortages of medical products, contain substandard and falsified medical products, facilitate innovation and research, create flexible regulatory procedures, prompt information exchange and other related regulatory activities during the emergency situation, EFDA will first identify potential problems, develop mitigation strategies and contingency plans to address them. The following sets of interventions will be done by the Authority to respond to public health emergencies.

8.1. Strengthen assessment on shortage of medical products and mitigate shortages

The continued availability of essential medical products, during public health threat such as COVID-19, is of critical concern for the Authority. To help mitigate supply disruptions, EFDA shall setup system that enables the availability of the products. To mitigate this drastic problem, the authority shall consider the following activities.

a. Use data to forecast shortages: EFDA will conduct immediate analysis to compare recently imported and locally manufactured products with historical utilization trends to predict imminent shortages and establish early warning systems to identify imminent shortages. In Addition, it will identify alternative sources for medical products and consumables on shortage or most prone to shortages; and develop guidance for detection and notification of shortages of medical products, and require manufacturers to disclose supply disruptions.
b. Review the risks for supply chain disruption for critically-needed medical products: Consider developing a supply chain vulnerability risk assessment that will model hypothetical situations for future disruptions. This should also be visible to all manufacturers, partners and suppliers in the government.
c. Implement facilitated approach for medical products approval: The Authority will rely on stringent regulatory authorities approved products, and utilize waivers and related instruments to facilitate the availability of critically needed products not yet approved in Ethiopia. In addition, remove non-critical administrative requirements during the emergency situation.
d. Engage compounding pharmacies and small-scale manufacturing institutions: to fill the gaps on the identified products, the Authority will encourage and support the existing compounding pharmacies, hospitals and those who have the potential to compound products

such as sanitizers, alcohols and other necessary products. In addition, small scale manufacturing institutions should come onboard. The Authority will support them to produce the most critical items needed.

e. Lean on local medical equipment manufacturers: EFDA will link hospitals with local manufacturers of personal protective equipment such as gloves, masks and other medical devices such as respirators. In addition, EFDA will design strategies for special support packages to local manufacturers including fast track approval, support in repurposing of manufacturing activities, expediting testing and approval of their products etc.
f. Establish systems and legislations to mitigate future shortages: EFDA will issue temporary directives and guidelines that create flexibility on the existing regulatory requirements. In addition, require manufacturers to submit information on manufacturer location, product details, batch size, current capacity, etc; establish mandatory reporting of shortages by industry, controlled importation of foreign-approved products, and fast-track review for shortage-prone products and develop a categorization system for shortage-prone products. In addition, incentivize manufacturing of shortage-prone medical products.
g. Aware the public and health professionals to conserve the limited medical products and use maximally.

8.2. Protect patients from substandard and falsified medical products

During public health emergencies, illegal manufacturing, importation and distribution of medical products is a challenge. Various actors might take the opportunity of gaps in product availability and repeated shortages to proliferate illegal practices that could endanger public safety. This is double burden to the society and the government as well. Hence, the Authority shall in place special consideration to tackle substandard and falsified medical products circulation. To achieve this, EFDA will perform the following activities or interventions:

a. **Share product quality surveillance information**: Develop systems to share registered products, inspection reports, product quality test results, and other data relevant to medical product quality with other regulatory agencies.
b. **Implement risk-based quality surveillance:** Potential therapeutic options for emerging public health threat e.g. COVID-19 may become a new focus for falsified medicines and substandard manufacturing and should be prioritized for quality surveillance. For

instance, with respect to COVI-19, chloroquine, hydroxychloroquine, azithromycin, lopinavir/ritonavir, ribavirin, and corticosteroids can be considered. In addition, EFDA will monitor the active pharmaceutical ingredients (APIs) and inactive ingredients (excipients) during the situation.

c. Leverage technology to remotely monitor medical product quality: EFDA will use strategies including monitoring and analyzing multiple data points such as social media, announcements though main stream media to report any suspicious activities regarding manufacturing, importation, distribution, usage of health products and technologies claimed for public health emergencies, patient reporting, professional reporting, citizen reporting, WHO data, and imported data. During pandemics, since inspectors may unable to travel, and quality testing may not be conducted on timely manner, remote surveillance capabilities will help protect the public from poor-quality medical products.

8.3. Facilitate to accelerate priority research and innovation

At times of emergency situations, urgent questions and uncertainties may come into front. Every one affected by the incidence seeks countermeasures including diagnostics, vaccines, and therapeutics that could be developed to detect, mitigate and provide appropriate response to the health threat. For example, to stop spreading of COVID-19, improve treatment outcomes; strengthen the ability to detect the virus, increase access to health commodities and control illegal traders and abusers etc are important.

From a regulatory perspective, the Authority needs to facilitate clinical trials approvals and other innovations in the context of an emerging health threats considering the clinical trial and innovation principles. Clinical trial design and innovation may differ substantially depending on the health threat and type of products. EFDA will develop and formalize through relevant administrative approval processes, an expedited ethical review pathway and expedited regulatory review pathways for clinical trials. The Authority should also create and facilitate clear interaction/consultation with Ministry of Health, Ministry of Innovation and Technology, academia and other relevant stakeholders.

Without unnecessarily compromising patient safety and public benefit, maximum shortest realistic priority shall be made to encourage research and innovations. EFDA will support and

accelerate health research, innovation, and knowledge sharing on all matters mandated to regulate including medicines, medical devices and other related procedures and practices. Efficient strategies to expedite review and approval pathways include parallel/simultaneous ethical and regulatory review, close communication between ethical and regulatory groups and non-hesitant decision making. In addition, develop guidance on regulatory preparedness for EUA and ethical principles during emergency health threats. The Authority shall have the regulatory tools to use new health products and technologies during health emergencies.

8.4. Pharmacovigilance aspects

Pharmacovigilance activities in the situation of an emergency health threat should be enhanced, and tools and processes which could be used in these situations shall be in place. There should be proper benefit-risk communication to public and healthcare facilities/personnel of new or existing products used for emergency public health threat. The main elements to be considered during emergency situation are indicated below:

- Activities related to signal detection and management should be enhanced and/or accelerated during emergency or mass use of new products or during mass use of previously authorised products such as campaign vaccinations and mass drug administrations. At this time, Incident Management task force has to be formed and work closely with appropriate emergency public health threat management institutions.
- When the Marketing Authorisation Holder (MAH) becomes aware of an Emerging Safety Issues (ESI) from any source, they should notify it in writing to the authority. Emerging Safety Issues (ESIs) are safety issues considered by a MAH to require urgent attention by the authority because of the potential major impact on the risk-benefit balance of the medicinal product and/or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and healthcare professionals.
- The rapid exchange of information on safety issues between the authority, professionals and relevant stakeholders should take place.

8.5. Develop legal and guidance documents

The Authority should work closely with MoH, other healthcare partners and stakeholders to rapidly identify where flexibilities in the regulation of medical products may be possible. In

response to this, EFDA shall issue legal and guiding documents for EUA that support industries, distributors, researchers and innovators, and other actors engaged in the healthcare products supply chain to provide a wider response to the health threats in Ethiopia.

8.6. Communication and information sharing

EFDA should establish consistent and sustainable communication to the general public (e.g. press releases, interviews, social media, and printing media) in the event of any crisis, and coordination of such communication with partners and stakeholders to ensure coherent and consistent messages to the public. This communication includes elements specific to emergency health threats. In addition, there should be interactions and information exchange with international regulators and international organizations, e.g. USFDA, EMA, WHO. The Authority shall perform the following activities during emergency public health threats.

- Communicate medical product shortages: EFDA should provide periodic communication to citizens on the shortages that have been identified and how they are being mitigated.
- Provide information and alerts to the public, patient, health professionals and other relevant stakeholders on safety and quality of medical products related matters and measures taken.
- Share updates on prevention and treatment options for public health threat like COVID-19. The authority shall communicate to the public the current lack of effective prevention and treatment options for COVID-19, while at the same time informing the public about ongoing vaccine trials, provider/patient agreements to use experimental therapeutic options, and compassionate use of products currently undergoing regulatory review.
- Capture treatment outcomes of any treatment: The Authority will encourage physicians, nurses, and pharmacists and other health professionals to report outcomes on use of any therapeutic products in COVID-19 patients and other future threats. Platform shall be established for health professionals to report to EFDA when encountered such cases.
- Collaborate with existing regulatory networks and regional harmonization initiatives to share both confidential and public information expeditiously for timely decision making.
- Collect, analyze, disseminate and monitor information.

Any form of information including press releases, media brief, interviews, social media, and printing media dissemination to public should be through Public Relation and Communication (PRC) department of the Authority. When higher officials and/or technical persons are needed, the PRC will facilitate the arrangement for its effective implementation of the event.

9. Roles and Responsibilities

The following committees and expert groups will be designated at the time of public health emergency to deal with the health threats/crisis. The committees will have their own rules and regulation, and will also have detail plans. In addition to the roles and responsibilities provided, all actors involved in the implementation of this strategy will be accountable to the activities assigned to them.

9.1. Emergency Steering Committee (ESC)

The Emergency Steering Committee is the highest strategic team for the threat which provides and follows high level consideration to the major scientific, regulatory and communication activities. The following activities will be done by ESC.

- Lead the whole preparedness, mitigation and response to the threat and provide directions
- Assign resources at the beginning of the health threat
- Review and approve the detail plans of SEC and ETF
- Take executive decisions in the interest of the public health
- Coordinate the situation with other stakeholders
- Upon delegation given by the management committee of the Authority, approve legal documents in response to the threat
- Work in close liaison with available committees of the MoH and EPHI
- Keep informed all other teams about high level status reports of the emergency threat
- Ensure that the health threat plan is followed and that the operational activities during the health threat are conducted
- Monitor weekly or daily performances of other committees
- Reports to EFDA management and other committees at MoH and EPHI, when it is required

9.2. Standing Emergency Committee (SEC)

- At the early phase (before formal declaration), act as an initial point of contact for interaction with external stakeholders and coordination within the network for the emergency threat
- Regularly involved in the management of the activities related to the health threat
- Synthesis scientific evidences and provide recommendations to ESC
- Prepare position statements and, Q&A in response to the emergency health threat
- Prepare legal and guidance documents
- Provide advice to domestic manufacturers and innovators on developing medical products against the emergency health threat, e.g. vaccines, sanitizers, therapeutic products, ventilators and other health commodities
- Reports to the emergency steering committee

9.3. Enforcement Task Force (ETF)

- Coordinate with law enforcement bodies
- Survey the market and issue regular enforcement activities
- Monitor internet market and illegal traders
- Perform activities based on the recommendation of the ESC and SEC
- Contribute to product-related assessment and post-authorisation surveillance activities;
- Will deliver assignments given by the higher committees
- Reports to the Standing Emergency Committee

10. Post health threat/crisis assessment

Following closure of the emergency health threat, it is important to take the opportunity to learn from the experience, i.e. to conduct “lessons learned” exercise. This should cover aspects of the health threat or crisis that were not handled well and may need to be changed, but should also describe what was done well and does not need to be changed. A forum to discuss these matters and identify ways of improving the Emergency Health Threat Strategy is to be established. As mentioned, in addition to the revision of the strategy, different improvements to different areas and procedures in particular legislations and internal infrastructures will be addresses.

11.Financial and logistics arrangements

Inventory should be done initially to identify the available logistics and supplies, and financial requirements that help facilitate the preparedness and mitigation activities of the public health threats and available gaps. Mobilization activities should be done to fill identified gaps regarding logistics and supplies, and finance. This should be prepared as early as possible based on the expected number of cases, suspected patients and contacts; and demands for health products and technologies used for the public health emergency.

The source of budget could be from the government budget allocated to normal activities and partners support. To do budget shift from the government allocated budget, procedures provided by the government should be followed. In addition, unless special condition and approval procedure is set, any procurement will be done in accordance with government procurement procedures. However, resource mobilization including financial and technical assistance from partners for such purposes will be sought.

Furthermore, detailed operational plans with budget having detail costing will be developed with global, regional, and country level implementation partners consistent with the overall strategic framework and based on actual needs, gaps, and implementation capacity.

12.Monitoring and Evaluation

Monitoring and evaluation is the key pillar of the preparedness, mitigation and response of Emergency Health Threat Strategy and will be used as a guide to monitor and evaluate the performance of the implementation. The monitoring and evaluation system includes techniques and processes that continuously collect, analyze and interpret data to know the appropriateness of the activities under process, achievements, performance gaps and provide up to date information for responsible body to take necessary corrective actions.

Key performance indicators that monitor the performance of the implementation of the strategic preparedness, mitigation and response will be determined when such health threat has happened.

12.1. Report Plan

Depending on the situation, the committees established will meet on regular basis and report to their respective upper level as per the report template provided by the authority. In addition to the higher management of the authority, the Standing Emergency Committee (SEC) will work in close contact with the committees of the MoH and EPHI. Though could be modified as the situation may be, the following reporting modalities and timelines will be followed **(Table 4).**

Table 4: Reporting modality and timelines

SN	Established committee	Reports to	Timeframe
1.	Emergency Steering Committee (ESC)	EFDA management	15 days
2.	Standing Emergency Committee (SEC)	ESC	Weekly
3.	Enforcement Task Force (ETF)	SEC	Daily[a] and Weekly[b]
4.	Technical Directorates of EFDA	ETF	Daily[a] and Weekly[b]

Note: EFDA will report to MoH on timelines decided by the ministry
[a] Main progress reports of the day and issues that need quick reposes
[b] Summarized reports of activities performed during the week and issues to be resolved, if any

12.2. Data Sources

At a minimum, the following source of data for M&E will be used:

- Routine reports of Emergency Steering Committee (ESC), Standing Emergency Committee (SEC), Enforcement Task Force (ETF),
- Routine reports of relevant directorates such as port of entry & exit, inspection, registration, surveillance and legal directorates.
- Rapid assessments and research related to the emergency
- Data generated from the government, international organizations and other countries

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