HEALTH EMERGENCIES PREPAREDNESS AND RISK MANAGEMENT PLAN (HEP&RM)

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Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

1. HISTORY

This is the second edition of these guidelines. Additions in this edition include areas where risk management is applied on a product life-cycle with respect to regulatory preparedness, with particular emphasis on pre-emergency preparedness and emergency response phase. Furthermore, reliance mechanism for Good Manufacturing Practices (GMP) inspections and conduct of clinical trials has also been included.

2. APPLICATION - Guideline for Regulatory Staff

This document is applicable to all the regulatory staff (officers and officials) of DRAP as a guidance document to be prepared and manage the functionality of the Authority in emergency situations.

3. PURPOSE

Drug Regulatory Authority of Pakistan is responsible for coordinating the existing scientific resources for regulation of therapeutic goods. This document is intended to explain the principles upon which the Authority will operate in the event of an emergency situation which poses a threat to human's lives, and describes a high-level process, responsibilities and desired outcomes. It thus relates to human pharmaceutical and biological drugs; however, in case of need, interventions may be extended to cover other therapeutic goods.

The purpose of this document is to provide a coordinated and consistent approach in preparing, preventing, protecting, mitigating, responding and recovering from incidents related to therapeutic products regulated by DRAP.

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4. INTRODUCTION

Public health risk means a likelihood of an event that may affect adversely the health of human population, with an emphasis on one, which may spread at national or international level or may present a serious and direct danger. All countries and communities are at risk of emergencies and disasters including those associated with infectious disease outbreaks, conflicts, and natural, technological, terrorist threats and other hazards. Emergencies and disasters, whether natural or manmade, accidental or intentional, have the potential to cause adverse health and safety effects for large segments of the human and animal populations.

Planning for responding to and communicating on serious health emergencies is an essential component and is complementary for compliance to International Health Regulation (IHR), 2005 developed by World Health Organization. It provides a framework to coordinate preparedness and response planning for strengthening capacities, developing monitoring systems, early warning, assessment and response to health emergencies.

National regulatory authorities (NRAs) play vital role in combating health emergency situations that poses a significant risk to public health and may include, but is not limited to, the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, or other therapeutic goods, that call for immediate actions under the ambit of regulatory authorities.

Drug Regulatory Authority of Pakistan (DRAP) established under the DRAP Act 2012, is mandated to protect and promote public health through regulation of therapeutic goods. The Authority is mandated to ensure that the therapeutic goods available in Pakistan are safe, efficacious and of high quality. The Authority is intended to enhance the accessibility of therapeutic goods for existing and new treatment opportunities. To deal with health emergencies, DRAP intends to prepare an effective and coordinated risk management plan in order to mitigate the consequences and must possess the resources to effectively respond to such emergencies. The coordinated risk management plan will also support federal and provincial governments to combat health emergency crises, as well as also provide assistance to other international counterpart health partner organizations e.g. WHO, UNICEF etc., with common intention to save lives and ensure critical public health and medical needs are met.

5. DEFINITIONS AND ACRONYMS

AE	Adverse events
Crises	An event or series of events representing a critical threat to the health, safety, security, or wellbeing of a community, usually over a wide area. Armed conflicts, epidemics, famine, natural disasters, environmental emergencies, and other major harmful events may involve or lead to a humanitarian crisis.
Disaster	Any occurrence that causes damage, ecological disruption, loss of human life or deterioration of health and health services on a scale sufficient to warrant an extraordinary response from outside the affected community or area.
DRAP	Drug Regulatory Authority of Pakistan
Emergency	A sudden occurrence demanding immediate action that may be due to epidemics, to natural, to technological catastrophes, to strife or to other man-made causes.
Emergency Preparedness	Actions taken in anticipation of an emergency to facilitate rapid, effective and appropriate response to the situation
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practices
Hazard	Any phenomenon that has the potential to cause disruption or damage to people and their environment.
HEP&RM	Health Emergencies Preparedness & Risk Management Plan
ICH	International Conference on Harmonization
MAH	Marketing Authorization Holder
NDMA	National Disaster Management Authority
NRA	National Regulatory Authority
PRAEC	Pharmacovigilance Risk Assessment Expert Committee
PV	Pharmacovigilance

Risk	The probability of harmful consequences, or expected losses (deaths, injuries, property, livelihood, economic activity disrupted or environment damaged) resulting from interactions between natural or human-induced hazards and vulnerabilities.
RMP	Risk Management Plan
SOP	Standard Operating Procedure
Vulnerability	The conditions determined by physical, social, economic and environmental factors or processes, which increase the susceptibility of a community to the impact of hazards or; the degree to which a population or an individual is unable to anticipate, cope with, resist and recover from the impact of a disaster.
WHO	World Health Organization

6. PREPAREDNESS FOR HEALTH EMERGENCIES

6.1. The Authority commences following steps as part of its activities for preparedness to be in a state of readiness for combating health emergencies: -

6.1.1. Collaboration and coordination with National Disaster Management Authority (NDMA) / National Command and Operation Center (NCOC);

6.1.2. Collaboration with Provincial Health Departments through effective coordination for information sharing and taking necessary measures;

6.1.3. Evaluation, review, recall and monitoring the production and import of therapeutic goods;

6.1.4. Interactions with the national and international health experts;

6.1.5. Interactions with therapeutic goods industry;

6.1.6. Interactions with international partners such as WHO, UNICEF and other non-governmental organizations.

7. RISK MANAGEMENT PLAN

The aim of this document is to provide an internal guidance for Authority activities during health emergencies. This plan will be a dynamic and living document and changes and amendments will continue, as and when required, to address the emerging needs. DRAP's preparedness plan is divided into following three stages:

7.1 Pre-Emergency Preparedness

Stage (s)	Risk Management Actions	Emergency Application
Licensing of Premises	Fast-track approvals of licenses for manufacturers & importers	Expedite licensing for manufacturing and import of pharmaceuticals, vaccines, medical devices, nutaceuticals alternative medicnes or disaster-relief medicines.
Regulatory Inspections	a. Remote/virtual inspections where possible b. Prioritization of high-risk facilities	Accelerate GMP inspections or apply exemptions or reliance mechanism for emergency production and import with post-audit checks
Registration	Emergency Use Authorization (EUA) pathways for unregistered drugs/vaccines or other therapeutic goods.	Fast-track review of treatments options.
Quality Control Testing	Prioritize testing of emergency-use products	Rapid batch testing for disaster-relief medicines
Import & Export activities	Prioritize personal use, donation and institutional use NOCs for disaster-relief medicine	a. Conditional release of consignments b. Flexibility in labelling requirements (multilingual inserts) and temporary shelf-life extensions

7.2 Emergency Response Phase

Stage (s)	Risk Management Actions	Emergency Application
Product Quality Surveillance	a. Increased sampling of emergency products b. rapid alerts for substandard/falsified drugs	Monitor disaster struck areas/ camps/ flood-affected areas for degraded medicines
Safety Surveillance (Pharmacovigilance)	Enhanced ADR/ AEFI reporting for EUA products	Detect rare side effects of EUA products
Enforcement	Coordinated activities to identify spurious and counterfeit products	Crackdown on fake drugs during outbreaks/ emergencies through the National Task Force forum
Advertising Monitoring	Prohibit false claims (e.g., "miracle cures" for pandemics).	Ban misleading advertisements for unproven treatments
Drug Shortages	a. Monitor production, import delays, and demand surges via pharmaceutical industry reporting b. Approve alternate manufacturers/importers for high-risk drugs through fast track processes	a. Rapid assessment team to investigate causes (e.g., raw material shortages, factory closures) b. Expedite approvals c. Disseminate information about availability of alternatives

8. PLAN APPLICABILITY

8.1. This plan covers the range of requirements in anticipation of or in response to all health emergency conditions that DRAP manages or participates in, including but not limited to the following:

8.1.1. Natural outbreak of any disease and foodborne illness, epidemics, and pandemics. (e.g. Ebola, Cholera, COVID-19 etc.)

8.1.2. Complaints, adverse events, recalls, or unintentional contamination involving therapeutic goods that present a threat of serious adverse health consequences or death to humans or animals.

8.1.3. Conflict incidents like warfare / terrorist or criminal acts, including the threats or intentional use of chemical, biological, radiological, nuclear, or high-yield explosive weapons against human or animal populations.

9. MAIN OBJECTIVES

9.1. The principle aim of this plan is to achieve the following key objectives. However, depending upon the severity or complexity of situations, some of them may not be immediately applicable: -

9.1.1. Manage and coordinate the availability, market authorization and surveillance of relevant therapeutic goods (e.g. vaccines for respective disease, etc.,) to be used to address the health emergency.

9.1.2. Initiate and coordinate appropriate regulatory activities by involving all relevant divisions / department / organizations within the country (i.e. field force of DRAP, Provincial drug control departments)

9.1.3. Provide appropriate support on any regulatory aspect as needed for coordination and commencement of necessary measures.

9.1.4. Effectively communicate relevant information to healthcare professionals, patients and regulatory partners.

9.1.5. Coordinate with international partners' health organizations for information sharing and support to combat the health emergency.

10. PLANNING AND RESPONSE TEAMS

10.1. Strategic Team

10.1.1. The strategic team will involve from the onset of a health emergency situation and consider the major, scientific, regulatory, planning, and communication aspect of the situation. The strategic team comprises following: -

10.1.1.1. Chief Executive Officer, DRAP

10.1.1.2. Director, Pharmaceutical Evaluation & Registration, DRAP

10.1.1.3. Director, Medical Devices & Medicated Cosmetic, DRAP

10.1.1.4. Director, Biological Drugs, DRAP

10.1.1.5. Director, Health & OTC Products, DRAP

10.1.1.6. Director, Quality Assurance & Lab Testing, DRAP

10.1.2. The Strategic team may include other health experts for any scientific advice. The strategic team might have to take executive decision in the interest of public health, and to support the response team.

10.1.3. The main role of the strategic team is to assign the operational activities during the health emergency e.g. stakeholder liaison, implementing communication strategy, workload management, representing the Authority at external and internal meetings.

10.1.4. In very early phases of any health emergency, e.g. before formal declarations are released by the official bodies, the strategic team shall act as initial point of contact for interaction with external stakeholders and coordination within the DRAP.

10.1.5. The strategic team may also establish public communication through official media coordinator to disseminate key messages as deem appropriate in response to public health countermeasures.

10.2. Response Team

10.2.1. In case of health emergency, Response Team will involve in the management of activities related to health emergency. The response team is composed of the following:

10.2.1.1. Director, Quality Assurance & Lab Testing

10.2.1.2. Additional Director, Pharmaceutical Evaluation & Registration

10.2.1.3. Additional Director, Biologicals Evaluation & Research

10.2.1.4. Additional Director, Medical Devices & Medicated Cosmetics

10.2.1.5. Additional Director, Health & OTC

10.2.1.6. Additional Director / In-charges, Evaluation & Monitoring, DRAP Field offices, Islamabad / Karachi / Lahore / Peshawar / Quetta.

10.2.2. In very early phases of any health emergency, e.g. before formal declarations are released by the official bodies, the Director Quality Assurance & Lab Testing, DRAP shall act as initial point of contact for interaction with external stakeholders and coordination within the DRAP and (s)he may be the only person involved in dealing with the situation prior to activation of the HEP&RM.

10.2.3. Response team will also maintain liaison with provincial and states' drug control organizations (through Chief Drug Controllers / Chief Drug Inspectors) for effective implementation of the directions of strategic team.

10.2.4. Director, Quality Assurance & Lab Testing, DRAP will takes the overall lead coordinating role, ensures that other members of the Responsive Team are kept informed in a timely manner by circulating a brief summary of the situation by email or a status report.

10.2.5. During the health emergency, depending on the need, additional staff members from DRAP may attend the meetings held by the Response Team or may be asked to provide scientific/regulatory support to facilitate the team's operations. The Response Team may also require involvement of other regulatory staff of DRAP in the activities of the HEP&RM as needed.

10.2.6. The main role of the Response Team is to ensure that directions of Strategic Team is complied with in conducting operational activities during the health emergency. The Response Team reports to the Strategic Team as needed. Once operational responsibilities and relative resources are assigned at the beginning of a health emergency, the Response Team meets to resolve issues if they cannot be resolved within one operational entity or if interdisciplinary discussion is needed.

11. KEY STRATEGIES

11.1. Forecasting of Shortages

11.1.1. Division of Quality Assurance & Lab Testing shall activate all field offices for periodic gathering of data for available raw material and finished product of essential drug products. The already constituted Committee on Availability of Life Saving Drugs (CALSD) will conduct immediate analysis to compare recently imported products with historical utilization trends to predict imminent shortages. Identify alternate sources for essential drug products which become short or most prone to shortages.

11.2. Fast track approvals

11.2.1. Statutory bodies, boards and committees will expedite processing of applications related to health emergency products. Divisions will arrange early meetings as and when required for consideration of new application of therapeutic goods required in health emergency.

11.3. Encourage local manufacturers of drug products and medical devices

11.3.1. DRAP will encourage local industry to step-in for manufacturing of products related to health emergency to overcome shortages. Minimum standards of product manufacturing, quality and validation would be utilized.

12. STRENGTHEN SHORTAGE SURVEILLANCE SYSTEMS

12.1. Early warning system for imminent shortage

12.1.1. Develop guidance for detection and notification of shortages of medical products, and require manufacturers to disclose supply disruptions.

12.1.2. Direct the manufacturers to evaluate their entire supply chain, including raw materials, finished dosage forms, and any components that may be impacted in any area of the supply chain due to the outbreak to predict shortages.

12.2. Design strategies for rapid response

12.2.1. Once therapeutic goods in shortage are identified, alternate options are considered, and manufacturers are instructed to increase production of alternative therapeutic goods to meet the demand.

12.2.2. The list of alternative therapeutic goods shall be readily available on an official website for the awareness of general public.

12.2.3. If possible the production of the therapeutic goods in shortage shall be accelerated.

12.3. Develop recommendations for the local pharmaceutical industry

12.3.1. Identify mechanisms which could be adopted to meet the increased demand and avoid shortages e.g., by expediting the regulatory approvals of other manufacturers or encouraging / recommending other manufacturers to produce therapeutic goods in shortage.

12.3.2. Recommend manufacturers to minimize or if necessary stop the export of the therapeutic goods in shortage to meet the local demand first.

13. PROTECT PATIENTS FROM SUBSTANDARD AND FALSIFIED THERAPIES

13.1. Enhance the market surveillance system via the inspectorate including provincial inspectorate to ensure that substandard and falsified medicinal products are not dispensed to the patients.

13.2. If required, the risk based sampling and testing of the medicinal products be carried out to ensure that the quality is not compromised / overlooked in order to meet patient demands.

13.3. There shall be a vigilant system overseeing the market, print and electronic media in order to identify any false claims on registered / unregistered medicines. The system shall also check if a medicinal product is being offered to the public, with a claim of curing the outbreak, without supportive evidence. The manufacturers, quacks or prescribers shall be penalized.

13.4. Once a drug or medicinal product is identified as substandard, falsified or making a false claim, the information shall be published on the official website of DRAP and if deemed necessary in the daily newspapers for awareness of the general public.

14. SHARING OF INFORMATION

14.1. Communicate medicinal product shortages.

14.2. Share updates on prevention and treatment options.

14.3. Rely on existing regulatory networks and regional harmonization initiatives.

15. OPERATIONAL ATTRIBUTES

The following sections provide recommendations to be followed during the health emergency: -

15.1. Facilitation in regulatory approvals

In the context of health emergency caused by e.g. a biological hazard, detailed procedure has been set up for the following: -

15.1.1. Exemption from regulatory procedure

15.1.1.1. Section 36 of the Drugs Act, 1976, empowers the Federal Government, when required in the public interest, to exempt any drug or class of drug from operation of any provision of Drugs Act 1976 and such exemption is notified in the official gazette. The specific provision, conditions and period may also be specified in this regard in the notification.

15.1.2. Permission for import of un-registered drugs / medical devices

15.1.2.1. To facilitate availability of unregistered or short availability drugs, needed to be prepare for and respond to a health emergency, following enabling provision has been provided in the law.

15.1.2.1.1. For unregistered drug products including vaccines and bio-tech products: -

S.R.O. 134(I)/2021 prescribed conditions and procedure for import of unregistered drug products which are essential and lifesaving drugs for use in hospitals and institutions, through exemption from the provisions of sub-clause (vii) of clause (a) of sub-section (1) of section 23 of The Drug Act, 1976.

15.1.2.1.2. For unregistered medical devices:

Rule 24 clause (d) prescribed conditions and procedure for import of unregistered/unlisted medical devices for use in hospitals with prior approval from

Medical Device Board or an officer authorized on its behalf.

15.1.3. **Import of donation medicines**

15.1.3.1. Donation of medicinal products may be imported, for preparation or combat the emergency, through legal provisions defined under the official notification vide S.R.O 135(I)/2021 which provides procedure and conditions for import of donation products. As per this SRO, Federal Government, being of the opinion that the public interest so requires, exempt the drugs imported as donation by any agency in Pakistan from the requirement of routine procedure for registration of drug products (provision of section 23(1)(a)(vii)).

15.1.4. **Expedited pathways for registration / enlistment of therapeutic goods**

15.1.4.1. Priority review and accelerated approval are expedited pathways of registration / market authorization / enlistment which are devised in line with best regulatory practices in the interest of public health. These processed are designed to provide enhance access to vital lifesaving therapeutic goods in public health emergency.

15.1.4.2. Registration Board has devised these mechanisms for expedited registration of pharmaceutical and biological drug products, to ensure faster availability of drugs in market that address the unmet medical needs in special situations including public health emergency. In such cases, application dossier submission is considered for priority review and / or applicants may be granted a conditional registration / marketing authorization for such drug products where the benefits of immediate availability outweigh the risk of less comprehensive data normally required.

15.1.4.3. Medical Devices Board has also devised these mechanisms for expedited registration / enlistment of COVID related medical devices, to ensure faster availability in the market. In such cases,

application dossier submission is considered for priority review by the Division.

15.1.4.4. Following categories of therapeutic goods may be considered for these pathways:

15.1.4.4.1. Orphan medicines for the treatment of rare diseases

15.1.4.4.2. New drug molecule / new indication drug

15.1.4.4.3. Short availability therapeutic goods

15.1.4.4.4. Therapeutic goods for serious condition e.g. outbreak of a disease etc.

15.1.4.4.5. Medical Product aimed at treating, preventing or diagnosing seriously debilitating or life-threatening disease and not registered.

15.2. **Priority review of submission**

15.2.1. Priority review of submission pathways is intended to shorten the assessment timeline. It provides patients and healthcare professional with faster access to new medicinal products and advanced therapies. Priority review is based on full dossier along with substantial evidence of quality, safety and efficacy.

15.3. **Conditional marketing authorization / Emergency use authorization**

15.3.1. For medicinal products intended for use in emergency situations, less comprehensive data may also be accepted by the respective boards.

15.4. **Lot release exemption on biological products**

15.4.1. National Conrol Laboratory for Biologicals (NCLB) has a mechanism for fast track release of the biological products in cases of a public health emergency (earthquakes, floods, natural disasters, pandemics, epidemics and war etc.,) in the larger public interest. In these cases, products may be considered to release out of queue on top priority basis.

15.5. **WHO collaborative registration procedure**

15.5.1. Registration of finished pharmaceutical products (FPPs), having WHO-prequalification or approval by stringent regulatory authorities, can take considerable time for indigenous approval. Therefore, DRAP has signed an

agreement with the WHO for collaborative registration procedure to ensure the early access of treatment that could save their life or improve their state of health. Under this collaborative registration procedure, two pathways are there:

15.5.1.1. Firstly by creating a collaborative procedure to facilitate the assessment and accelerated national registration of WHO-prequalified pharmaceutical FPPs.

15.5.1.2. Secondly by creating a collaborative procedure to accelerate registration of FPPs that have already received approval from a stringent regulatory authority.

15.5.2. The procedure for stringently approved FPPs was developed taking into account the experience gained during development, testing and implementation of the procedure for prequalified FPPs. Thus the procedure for prequalified FPPs is fully operational, whereas the procedure for stringently-approved FPPs is in its pilot phase.

15.6. **Reliance on Good Manufacturing Inspection (GMP) Reports for imported products**

15.6.1 The existing policy for manufacturers abroad, as decided by the Policy Board in its 40th meeting held on 09th March, 2022, covers reliance on the Good Manufacturing Practices inspection conducted by:

i. United States of America, Japan, Australia, Canada, UK, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland, Spain and European Medicines Agency.
ii. Minimum three drug regulatory authorities of former Eastern Europe
iii. GMP certificate (for applied dosage form facility) available on EUDRA-GMDP website.(http://eudragmdp.ema.europa,eu/inspections/gmpc/searchGMPCompliance.do)
iv. WHO prequalified product and manufacturing facility (section) of such product. Any product approved by Pharmaceutical Inspection Co-operation

Scheme (PIC/S) Participating Authority and manufacturing facility (section) of such product. (https://picscheme.org/en/members).

v. Manufacturing site/facilities conformed to the regulatory inspection by any of the PIC/S Participating Authority.

15.6.2 The Policy Board in case of any exigency/ emergency may extend further facilitation with regards to reliance on GMP inspections depending upon the situation.

15.7 Processing of Clinical Trials in Health Emergency/Non-routine procedures for processing of CT applications.

15.7.1 In any health emergency condition as mentioned above (e.g. COVID-19 pandemic etc.) or in the best of public interest, the Chairman Clinical Studies Committee (CSC) may call CSC meeting exercising his power conferred in Rule 13(7) of the Bio-Study Rules 2017, for fast track processing of the application without initial scrutiny and Summary Evaluation Report by the Pharmacy Services Division and the CSC may waive the requirement for auxiliary documents (i.e. non clinical data, details regarding participating countries, sample label of investigational product or undertaking on affidavit), if CSC feels it deems fit.

15.7.2 If an applicant wants to apply a Clinical Research for non-routine/health emergency, he may inform accordingly in the application cover letter, along with reasoning/justification letter for fast-track consideration of application by the CSC.

16. PHARMACOVIGILANCE ACTIVITIES IN HEP&RM

16.1. During the public health emergency, pharmacovigilance activities should be enhanced. Several tools and processes which could be used should be in place. The main elements to be considered are summarized below:

16.1.1. **Accelerated signal management**

16.1.1.1. Activities related to signal management should be enhanced and/or accelerated during emergency or mass use of new products or during mass use of previously authorized products.

16.1.2. **Prompt regulatory actions and safety alerts**

16.1.2.1. Safety issues emerging during a public health emergency, associated with the use of unregistered or already registered or conditionally registered drugs, required to be consider by registration holder and urgently deliberated by the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) because of the potential major impact on the risk-benefit balance of the drug product and / or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and healthcare professionals.

16.1.3. **Rapid Exchange Information**

16.1.3.1. Rapid exchange of information on pharmacovigilance issues between the regional center, national center and Uppsala monitoring center.

17. COMMUNICATION WITH STAKEHOLDERS, INTERNATIONAL PARTNERS AND THE PUBLIC

17.1. The Authority will utilize various communication channels including press release, conference, interviews, meetings etc., for dissemination of relevant information to the general public. The communication will also be maintained with partners organization and stakeholders including pharmaceutical industry, to ensure coherent and consistent messages to the public.

17.2. Similarly, interactions with international regulators and other public health organization, such as WHO, will also be maintained to discuss situation on specific scientific and regulatory aspects of health emergency.

18. REFERENCES

18.1. The DRAP Act, 2012

18.2. The Drugs Act, 1976

18.3. The Drugs (Licensing, Registering and Advertising) Rules, 1976

18.4. The Drugs (Import & Export) Rules, 1976

18.5. Risk Reduction and Emergency preparedness; WHO six-year strategy for the health sector and community capacity developments.

18.6. Risk Management in Regulatory Frameworks: Towards a Better Management of Risks, United Nations, 2012.

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