
ANALYSIS TOOL
**for national integrated delivery of
relevant health products** against
pandemic influenza and other
respiratory viruses of pandemic
potential

DRAFT



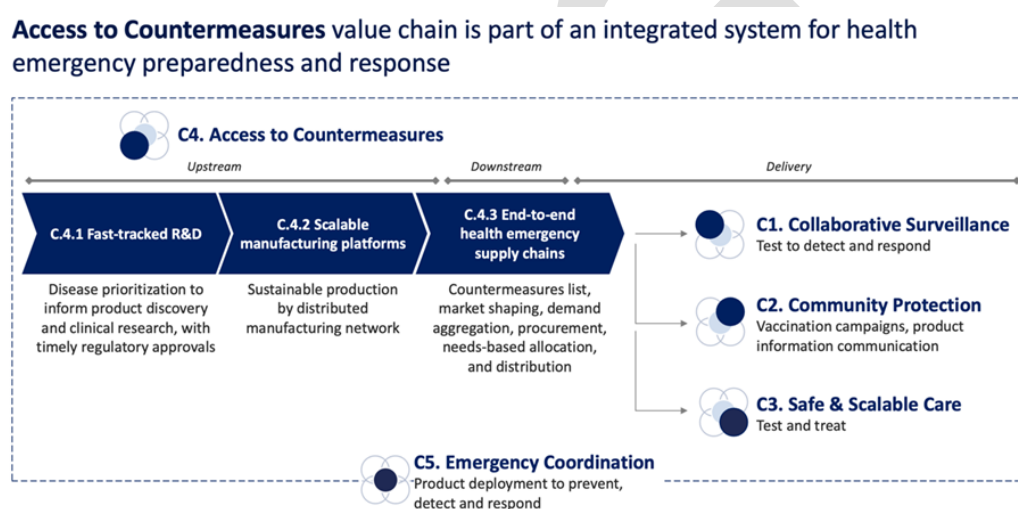
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Introduction

The World Health Organization (WHO) recommends the use of the Health Emergency Preparedness and Response (HEPR) framework for emergency planning and response, emphasizing the five core health emergency components (the five Cs): collaborative surveillance, community protection, safe and scalable care, access to countermeasures, and emergency coordination¹. Planning for interventions supported by medical countermeasures or relevant health products² as they are referred to in the updated International Health Regulations, requires building and maintaining capacities across several of these 'Cs', as exemplified in Figure 1.

Figure 1 MCM interventions pathway along the HEPR 'Cs'



The integrated delivery related planning processes are implemented at national level into relevant national plans, such as a national vaccine deployment and vaccination plan against respiratory viruses of pandemic potential (NDVPs), a similar medical countermeasures specific plan (bringing together interventions using diagnostics, therapeutics and vaccines), a relevant section – (e.g. Access to Countermeasures chapter) from the entire national pandemic plan for respiratory pathogens, or other national plans that deal with national emergency preparedness listing approaches to interventions using relevant health products. For easiness of reference throughout this analysis tool these plans (e.g. NDVPs), or sections of plans (e.g. Access to countermeasures section from the national pandemic preparedness plan) will be referred to as 'national integrated delivery of relevant health products planning' with the understanding that the relevant health products are those against pandemic influenza and other respiratory viruses of pandemic potential.

Aim and objectives of this analysis tool

This analysis tool aims to support the analysis of several critical capabilities which must be in place before the national integrated delivery of relevant health products against pandemic influenza and other respiratory viruses of pandemic potential encompassing planning arrangements on access, allocation, and deployment of such products. It provides concrete technical considerations to support attainment and enhancement of core operational capacities at various levels by listing detailed technical checkpoints.

¹ Strengthening the global architecture for health emergency prevention, preparedness, response and resilience
<https://www.who.int/publications/m/item/strengthening-the-global-architecture-for-health-emergency-prevention--preparedness--response-and-resilience>

² A77/A/CONF./14 Amendments to International Health Regulations (2005) agreed at Seventy-seventh World Health Assembly
https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF14-en.pdf

Therefore, technical people at national level should use the analysis tool:

- To enable a targeted operational assessment of a country's preparedness for national integrated delivery of relevant health products against pandemic influenza and other respiratory viruses of pandemic potential, in accordance with relevant WHO Guidance^{3, 4}
- To use analysis results to develop or update relevant health products-related pandemic preparedness integrated planning.

This analysis tool should also be used in conjunction with the PRET Module 1 and the accompanying *Checklist for respiratory pathogen pandemic preparedness planning*⁵, with the understanding that this relevant health-products analysis tool aims to provide more detailed technical operational checkpoints for key areas listed in the 'Access to countermeasures' segment of the PRET checklist.

Scope

According to the 2024 revised International Health Regulations (2005) "relevant health products" mean those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies.

Under the 2024 revised International Health Regulations (2005) – Annex 1 – Core Capacities, section on core capacities requirements for prevention, surveillance, preparedness and response, it is mentioned that *'each State Party shall develop, strengthen and maintain the core capacities for: (h) access to health services and health products needed for the response'*⁶.

Integrated delivery should consider planning around access, allocation, and deployment of relevant health products in the event of a pandemic influenza, or one caused by a respiratory virus, these typically refer to:

- **Access:** The ability to obtain or produce the relevant health products for timely and equitable national level use⁷. Access also includes overcoming barriers such as costs and ensuring appropriate legal and regulatory preparedness so that products being accessed meet high standards in terms of quality, safety, and efficacy.
- **Allocation:** In a situation of supply scarcity, a prioritization of the use of relevant health products will be necessary. In this case, allocation would involve a national process of distributing available health products fairly and equitably among different groups or regions considering policy recommendations, public health risk, need and strategic national decisions.
- **Deployment:** The actual distribution and delivery of health products to the end-users, ensuring that they reach the targeted key populations or facilities efficiently, their use is monitored, and

³ Guidance on development and implementation of a national deployment and vaccination plan for vaccines against pandemic influenza and other respiratory viruses of pandemic potential <https://www.who.int/publications/i/item/9789240084872>

⁴ Preparedness and Resilience for Emerging Threats Module 1: Planning for respiratory pathogen pandemics Version 1.0:

<https://www.who.int/publications/m/item/preparedness-and-resilience-for-emerging-threats-module-1-planning-for-respiratory-pathogen-pandemics-version-1>

⁵ A checklist for respiratory pathogen pandemic preparedness planning:

<https://iris.who.int/bitstream/handle/10665/374876/9789240084513-eng.pdf?sequence=1>

⁶ A77/A/CONF./14 Amendments to International Health Regulations (2005) agreed at Seventy-seventh World Health Assembly

https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF14-en.pdf

⁷ This could involve several approaches such as national-level mechanisms (e.g., direct national purchase from manufacturers or suppliers using national funds, including advanced purchase agreements (APAs); national production through domestic manufacturing), collaborative and pooled mechanisms (e.g., pooled procurement through joint purchasing by multiple countries or organizations; public-private partnerships (PPPs) consisting of collaborations between government entities and private sector companies), international procurement platforms, donation and assistance-based mechanisms, direct donation, government-to-government agreements (e.g., bilateral or multilateral agreements between governments), licensing agreements.

all activities are conducted mindful of the need to provide accurate information, combating mis- dis - information, addressing public concerns, involving stakeholders, and maintaining transparency and trust during public health emergencies.

Pandemic planning for integrated delivery of relevant health products needs to fully utilize the national health system capabilities, as well as be integrated into the pandemic response coordination structure, ensuring that health products activities align and support the national pandemic response objectives and strategies. Importantly, access, allocation and deployment of health products cannot be considered in isolation from public health and social measures (PHSM) to ensure a robust, comprehensive national pandemic response. Particularly until effective health products are equitably delivered to at-risk and affected populations, targeted, balanced and context specific PHSM should be implemented to reduce the risk and scale of infectious disease transmission.

Target audience

This analysis tool is targeting primarily government and relevant national authorities' technical officers responsible for the planning areas covered by this tool. However, depending on the national planning approaches, international partners, CSOs and NGOs, private sector, academia, and other stakeholders should be involved in this analysis.

Applying the analysis tool

To use the analysis tools effectively, users should be familiar with their country's relevant health products-related pandemic preparedness integrated planning. Users will likely consist of the focal points for each of the planning areas – for example vaccination focal points, clinical managers that would manage the introduction of therapeutics and diagnostics, regulators, logistics specialists, risk communicators and community engagement specialists, infodemic managers, emergency coordinators etc,

While this analysis tool provides an overview of technical areas to be addressed, additions and modifications to fit local context are encouraged.

This analysis tool is available in both paper and electronic version.

Applying the analysis tool

- Tick (✓) the appropriate box for every question that you answer.
- Given the improbability of one individual addressing all items, the analysis tool will require engagement of all focal points across work areas.
- Where there is a 'No' or 'I don't know' response, please provide further details in the section 'comments and priority activities to address gaps'
- The assessment results should be discussed collectively among all focal points and other relevant stakeholders to inform future preparedness activities.
- Countries are encouraged to share the assessment results with WHO.

Country:

Name and title of the person(s) providing the answers/information for this analysis tool:

Name of the institution(s):

Level being checked:

At what level is this analysis tool being applied?	<input type="checkbox"/> National
	<input type="checkbox"/> State
	<input type="checkbox"/> Province
	<input type="checkbox"/> District
	<input type="checkbox"/> Other (specify):

Name of the locality:

☐ Rural ☐ Urban

Today's date DD/MM/YYYY:

Date of last assessment DD/MM/YYYY:

Section 1. Overview of the national integrated delivery of relevant health products planning

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Is the plan containing the national integrated delivery of relevant health products planning (e.g. NDVP or relevant section of the national pandemic plan), available and applicable for influenza and other respiratory disease (if it is only pathogen specific – e.g. COVID-19, please mention this in the comments section)?						
2. Has the plan containing the national integrated delivery of relevant health products planning been endorsed/ approved by relevant Government authorities?						
3. Does the national integrated delivery of relevant health products planning include or describe the necessary actions required to secure access to relevant health products for pandemic response (e.g. vaccines, antivirals, etc.) ⁸ ?						
4. Has there been an evaluation on the latest integrated delivery of relevant health products response? If yes, please comment on whether lessons learned have been introduced into the latest the national integrated delivery of relevant health products planning.						
5. Has a detailed mapping of key stakeholders and partners for the national integrated delivery of relevant health products planning been conducted?						
6. Have relevant implementing partners reviewed the national integrated delivery of relevant health products planning?						
7. Is the national integrated delivery of relevant health products planning ready to be operationalized in the event of a pandemic (e.g. have provisions been endorsed by all relevant organizations and familiar to others who will support its implementation, do all SOPs exist to support operations)?						
8. Referring to the national integrated delivery of relevant health products planning has a budget been prepared and approved for:						

⁸ Please see Footnote 3 for examples of different access mechanisms

*NA- Not Applicable

<p>1) Priority preparedness activities identified as critical for operationalization</p> <p>2) An eventual pandemic response (i.e. a budget envelope that would be available for all the necessary response activities)</p>									
<p>9. Is there a clear pathway/mechanism to address gaps (preparedness activities) identified in the inter-pandemic period for the national integrated delivery of relevant health products planning?</p>									
<p>10. Have the sub-national level officials been oriented on the national integrated delivery of relevant health products planning, with a focus on their roles and responsibilities?</p>									
<p>11. Have simulation exercises been conducted to test the national integrated delivery of relevant health products planning?</p>									

Section 2. Setting strategies, goals and objectives that can be achieved utilizing relevant health products

General questions	Yes	In progress	No	NA *	Don't know	Comments/ Priority activities to address gaps
1. Does the national integrated delivery of relevant health products planning list different strategies, including public health goals and objectives ⁹ , based on pandemic scenarios and assumptions to guide the pandemic response?						
2. Does the national integrated delivery of relevant health products planning detail how relevant health products might be used to attain different public health goals and objectives – one intervention using few products or several interventions using a combination of products, based on different pandemic scenarios?						
3. Are systems in place to calculate and forecast estimated relevant health product needs based on public health goals (using assumptions ¹⁰)?						
4. Are there mechanisms in place to adjust strategies, including goals and objectives based on regular risk assessments, which consider evolving epidemiology and the effectiveness of public health and social measures (PHSMs) and availability of different health products at different times during the response?						

⁹ Examples: reduce mortality, morbidity, maintain critical services, prevent transmission, limit disruption of economic and social functions, protect people in situations of vulnerability/ humanitarian setting etc

¹⁰ Examples can be found in chapter 2 from the Guidance on development and implementation of a national deployment and vaccination plan for vaccines against pandemic influenza and other respiratory viruses of pandemic potential <https://www.who.int/publications/i/item/9789240084872>

Section 3. Legal and regulatory preparedness

General questions – please consider whether the laws and regulations cover all types of relevant health products – make a note in the comments if they don't or are only applicable to some products						In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
						Yes				
1. Have legal requirements for timely introduction of relevant health products ¹¹ (including novel ones) been mapped for the following areas?										
a. Authorize to use/ emergency approval										
b. Timely lot release / exemption of lot release										
c. Imports										
d. Warehousing										
e. Packaging										
f. Shipping										
g. Liability										
h. Administration (e.g. vaccination)										
i. Waste management										
2. Is there clarity on the actions needed to address legal limitations for timely introduction of relevant health products (including novel ones)?										
3. Have barriers or restrictions for issuing an emergency approval for relevant health products been adequately addressed (e.g., by legislation or executive order)?										
4. Have barriers or restrictions for issuing an import permit for relevant health products										

¹¹ Throughout the entire checklist and in particular for this section please consider that relevant health products may include medicines, vaccines, diagnostics, medical devices, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies.

General questions – <i>please consider whether the laws and regulations cover all types of relevant health products – make a note in the comments if they don't or are only applicable to some products</i>						In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
been adequately addressed (e.g., by legislation or executive order)?										
5. Is there legal clarity ¹² to enable accessing relevant health products through various mechanisms, including direct purchasing, donations, pooled procurement, introducing products under clinical trial etc?										
6. What regulatory pathways exist at country level for the rapid introduction of a novel relevant health products?										
a. Independent review of the full dossier										
b. Emergency authorization										
c. Reliance										
d. Recognition										
e. None										
7. Based on the different regulatory pathways, is there clarity (a mapping exists) on the minimum documents/ requirements ¹³ to be submitted to the relevant competent authority?										

¹² Have the legal requirements for each process been identified and there is a legal framework in place at national level.

¹³ please refer to Table 1: Summary of the documentation required for the different pathways available for the authorization of pandemic or other emergency use vaccines: [WHO Expert Committee on Biological Standardization: seventy-eighth report \(WHO Technical Report Series, No. 1054\)](#)

General questions – <i>please consider whether the laws and regulations cover all types of relevant health products – make a note in the comments if they don't or are only applicable to some products</i>		Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
8.	Is there a mechanism in place to facilitate timely clinical trials during a pandemic?						
9.	Is there a mechanism established to fast-track assessments for use of unproven clinical interventions outside clinical trials during public health emergencies (the MEURI framework)?						
10.	Does the country have a mechanism for timely lot release (e.g. exemption of lot release depending on health product source or other approaches)?						
11.	Are mechanisms in place to ensure traceability of relevant health products through market surveillance programme (e.g. unit identification code or 2D bar coding on the secondary packaging)?						
12.	Are systems in place for communication of regulatory decisions and updates on emerging evidence on relevant health products to the public?						
13.	Is there a recent assessment of the National Regulatory Authority (NRA) maturity level using the WHO Global Benchmarking Tool?						

Section 4. Planning and coordination

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Is there a national coordination mechanism/committee for pandemic planning and coordination?						
a. If yes, is this the same mechanism overseeing coordination of relevant health products introduction activities amongst different stakeholders, <i>please make a comment if this delegated to a sub-committee reporting to the pandemic planning coordination committee?</i>						
b. Has the coordination committee reviewed this analysis tool and results from past assessments?						
2. Do mechanisms for enhanced coordination between national and sub national levels exist and are being leveraged for coordination related to health products?						
3. Are functional technical advisory groups for relevant health products , responsible for recommending policy, norms and standards –in place to cover each relevant health product category?						
a. For medicines (e.g. clinical review committees, clinical management guidelines)						
b. For vaccines (e.g. NITAGs)						
c. For diagnostics (<i>please consider that diagnostics may fall under medical devices</i>)						
d. For medical devices						
e. For personal protective equipment						
f. For decontamination products						
g. For assistive products						
h. For other products – e.g. cell- and gene-based therapies, and other health technologies						
4. Are there Terms of References (ToRs) in place for these technical advisory groups which contain provisions related to pandemic response capabilities, roles						

*NA- Not Applicable

and responsibilities?

- a. Has the composition of these technical advisory groups been revised considering pandemic needed expertise?
- b. Are there processes in place for these technical advisory groups to rapidly review and adapt emerging medical recommendations for different relevant health products, to be used within a national context?

5. Have the **functions and focal points related to health products activities** been identified and integrated within the context of: i) pandemic preparedness activities, ii) an eventual pandemic response coordinated through a national Incident Management System?

6. Have international and national partner agencies, civil society organizations and private sector stakeholders been identified for supporting appropriate integrated delivery activity areas?

If yes, has a mechanism for coordination been set up?

Section 5. Allocation of relevant health products including identification of key populations

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Are processes established on how and who will decide on prioritization of key populations/ groups for access to different relevant health products?						
2. Is there a national allocation framework that considers different criteria for the equitable allocation and prioritization , with the understanding that the final decisions on which criteria are best to apply will be made at the time of the pandemic, considering (among others):						
a. Availability of only one or of several types of health products						
b. The interplay between different relevant health products strategies (e.g. testing and treatment strategies)						
c. The need to ensure adjustments of allocation/ prioritization criteria considering emerging evidence and recommendations for use of different relevant health products (e.g. WHO SAGE, WHO clinical recommendations), as well as national supply and demand dynamics						
3. Have reliable sources of data to estimate the size of population groups that may be at risk, based on past experiences and different pandemic scenarios? <i>Please note that populations at highest risk will depend on the particular pathogen and will be determined at the time of the pandemic; however, in the preparedness timeframe, different potential data sources should be investigated to ensure there are systems in place to rapidly capture potential data.</i>						
a. Health and care workers						
b. Older people						
c. Other age-based population segments (children, adolescents, adults less than 65)						
d. Persons with specified underlying health conditions that may be at risk during						

*NA- Not Applicable

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
<p>pandemics caused by respiratory viruses¹⁴</p> <p>e. Persons that are designated to maintain essential services (country-based)</p> <p>f. Vulnerable sociodemographic groups (e.g. low- income migrant workers, refugees, prison inmates, IDPs, asylum seekers, stateless persons, population in conflict, emergency, and humanitarian settings and vulnerable migrants)</p>						
<p>4. To ensure equity in access to relevant pandemic health products, has the allocation framework considered various aspects that may impact access to health products or increase risk for certain populations (e.g. gender, culturally and linguistically diverse groups, populations in situations of vulnerability, etc)?</p>						
<p>a. If yes, have actions been identified to mitigate the issues and ensure equity?</p>						

¹⁴ Noting that a pandemic will be caused by a novel pathogen, there is no possibility to estimate which populations would be at risk in the inter-pandemic period. However when considering past pandemics and risk groups for diseases such as severe seasonal influenza, for planning considerations, noting the previous caveat, the following chronic medical conditions may be noted: those that may affect respiratory system e.g. asthma, cardiovascular system e.g. coronary artery disease, endocrine system e.g. diabetes, hepatic system e.g. liver cirrhosis, renal system e.g. chronic renal failure, neurological/neuromuscular conditions e.g. parkinsonism, any condition compromising respiratory functions e.g. morbid obesity (BMI > 40), physical handicap in children and adults, immunosuppression due to disease or treatment including due to haematological conditions and HIV infection.

Section 6. Delivery strategies

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Are potential delivery strategies of interventions described (e.g. test and treat pathways, vaccination (e.g. venue and modality of delivery)) based on existing systems and lessons learned from past pandemics or health emergency responses?						
2. If applicable, is delivery of relevant health products among special populations in need of humanitarian assistance such as refugees, internally displaced persons or others, described based on lessons learned from past pandemics or health emergency responses?						
3. Have inequities for vulnerable populations ¹⁵ been adequately considered in planning for access to services (delivery strategies are planned to avoid such inequities)?						
4. Have strategies for the timing, location, and method of delivering relevant health products been planned in partnership with the community ?						
5. What mechanisms have been identified for registration of eligible beneficiaries for preventive interventions such as pandemic vaccination? <i>Tick yes if the relevant systems are in place to facilitate their implementation (e.g. there is a software available).</i>						
a. Online advance registration						
b. Manual advance registration (e.g. in person registration at designated locations)						
c. Facilitated registration						
d. Walk in (without prior registration)						

¹⁵ Planning should contain a list of such populations

*NA- Not Applicable

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
6. Do the identified strategies ensure integration with minimal impact on other essential health services , including routine maternal and child health or immunization services, regular testing as part of national programmes, routine clinical care pathways?						
a. Will health staff responsible for essential health services be exempted from also supporting surge pandemic duties?						
b. If regular health staff who are responsible for delivering essential health services are assigned for pandemic services, will these services be planned on days other than the days when essential health services are provided?						
7. Does the plan adequately describe the infection, prevention and control (IPC) measures required at the readiness and response phases to prevent and control the spread of threat pathogens (specifically respiratory illness) during delivery of relevant health products (e.g. vaccination sessions, testing)?						
8. For mass- and rapid specific interventions campaigns (e.g. testing, vaccination), are there clear processes and procedures to rapidly establish microplans and ensure capacity to set up these interventions?						

Section 7. Supply chain and waste management

General questions	Yes	In progress	No	NA *	Don't know	Comments / Priority activities to address gaps
1. Has the mapping and assessment of existing national cold chain infrastructure , including power sources, capacity level and available private sector cold chain facility (in case of need) been conducted in the past 12 months?						
a. +2 to +8 °C						
b. -20 °C						
c. -80 °C						
d. Available private sector cold chain facility (in case of need)						
2. Considering these capacities, are they deemed adequate to maintain routine supply without risking stock out and have enough surge capacity to accommodate, at least, minimum additional supply of pandemic health products (based on assumptions and past experiences)?						
3. To support rapid deployment, has a cold chain hub (s) been identified - this may be used in the initial stages to ensure faster dispatching of products to affected areas?						
4. Is there access to and local production of dry ice ?						
5. Is the dry space availability for storage of logistics adequate at all levels?						
6. Are there adequate numbers of trained staff for cold chain management and relevant health products handling for different deployments (<i>please see previous section on delivery strategies</i>)?						

General questions	Yes	In progress	No	NA *	Don't know	Comments / Priority activities to address gaps
7. Is adequate power backup available for electrical cold chain equipment at all levels?						
8. Is a contingency plan in place to manage health products storage and ensure quality in case of power failure (e.g. a generator may exist but is there funding to ensure availability of fuel)?						
9. Are steps on how to rapidly fill, prior to deployment, any of the gaps identified in the areas below?						
a. Cold chain equipment (for both passive -vaccine carriers and cold boxes for holding session and local delivery, and active cold chain equipment)						
b. Human resources (including training)						
c. Secure distribution and logistics						
10. Is there a clear mechanism to implement reverse logistics ?						
11. Has a budgeted plan for supply chain strengthening been prepared?						
12. Have domestic funds been secured for the pandemic surge requirements for strengthening supply chain or is there an emergency fund that could cover supply chain emergency needs including transportation?						
13. Has the transportation network between different national / regional / local logistics hubs (depots or likely medical facilities) been mapped out?						
a. If yes, have transportation gaps been mapped out at each level?						
b. Have the gaps or the need for surge capacity for transportation been considered in relation to the capacities of other government ministries, the military, the police, civil authorities, and/or						

General questions	Yes	In progress	No	NA *	Don't know	Comments / Priority activities to address gaps
nongovernmental organizations, private sector?						
14. Have sources for the required appropriate PPE and other ancillary supplies needed for relevant health products deployment been identified (either from national or international markets)?						
– If yes, have they been contacted to establish contract mechanisms that ensure a ready supply of the required products when needed?						
15. Are there mechanisms (encompassing methodologies, data gathering systems, analytical capacities, SOPs) in place to:						
a) Calculate quantities/volumes of potentially relevant health products (e.g. vaccine and ancillary items) that must be shipped to each distribution point.						
b) Estimate amount of medical waste generated during deployment that will need to be collected and transported to a disposal site.						
d) Calculate quantities of cold boxes and/or other containers for delivering the vaccines and ancillary items to each site.						
e) List of warehouses/cold storerooms at all levels and their estimated capacities to temporarily store relevant health products						
f) List of distribution sites classified by type of transport to be used.						
g) Have an illustrative schedule of times and dates for the dispatch of consignments, including the required ancillary items.						
h) Estimate <i>surge</i> capacities to support the following activities:						
I. Transportation						
II. Waste management						
III. Storage facilities for large quantities of relevant health products						
IV. Coordination and supervisory activities						

General questions		Yes	In progress	No	NA *	Don't know	Comments / Priority activities to address gaps
	V. Assets to support communication (e.g. phones/ sims with internet access etc)						
	VI. List establishments and the quantities of items to be repacked and forwarded to the next distribution point.						
16.	Has an analysis been done whether to consider national stockpiling for certain products (e.g. those needed for IPC)?						
17.	Is there a national and/or local policy on waste management that includes safe handling, proper segregation and disposal of healthcare wastes?						
18.	Is there a reference guidance on safe disposal of healthcare wastes, including pharmaceutical waste (e.g. biohazard and immunization) and based on this, are SOPs in place?						
19.	Have key partners and stakeholders for supply chain and waste management been mapped, and their roles defined?						
20.	Do the current waste facilities in your area/country have the capacity to process all the waste that will be sent to disposal sites in the event of mass pandemic related interventions (based on past experiences – e.g. COVID-19 vaccination)?						
21.	Have surge capacity plans been made to address the shortage of facilities and/or lack of capacity to process the volumes of medical waste that will be generated in the event of mass interventions (e.g. testing, vaccination) of the population?						
22.	Which of the methods of disposal of contaminated waste, listed below, are used most frequently in your area/country? Tick (√) the method/s used by area. <i>Please make a comment if the method exists but there are no corresponding SOPs.</i>						

General questions		Yes	In progress	No	NA *	Don't know	Comments / Priority activities to address gaps
	Industrial incineration (cement industries)						
	Incineration (private or public)						
	Local or open-pit burning						
	Buried						
	Municipal-waste services						
	Latrine pits						
23.	Are contracts with private medical waste companies in place for the collection and transportation of medical waste from your healthcare service providers?						
24.	Are there resources in place to support maintenance, repair and replacement for supply chain and waste management infrastructure?						
25.	Have mechanisms for safety and security of health and care workers been considered (e.g. ensuring security at intervention delivery sites)?						
26.	Are there security provisions for the safe storage and transportation of relevant health products?						
27.	Have infrastructure and processes been tested for receiving and sending supply-chain related data at all levels (functioning of inventory management systems)?						

Section 8. Human resources and training

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Have human resource surge requirements for supporting pandemic relevant health products delivery been planned out (<i>please comment which specific areas would require surge needs</i>)?						
a. Are there policies and process in place to facilitate timely surge hiring ?						
2. Is there a list of the type of staff (in terms of skills) needed for delivery of relevant health products?						
3. Does the list include terms of reference or job descriptions for each post?						
a. Are processes in place for timely development of job-aids?						
4. Are there processes and procedures in place to facilitate matching the skills of existing staff (i.e. staff available in the health and care system) with the skills that will required by each post during delivery (e.g. HR databases)?						
6. Are HR training and supervision approaches described?						
7. Have training modalities (online, face-to-face, or hybrid) been considered, and has an analysis been performed on when (in which pandemic scenario) these should be implemented?						
8. Have tools been planned for pre and post training assessment to identify the competencies of each category of personnel trained?						

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
9. Has mapping of key stakeholders and partners for HR surge support (a roster of potential additional staff) and training been completed?						
10. Have budgets for HR needs and training been prepared?						
11. Are there plans to ensure the security and wellbeing of staff at the time of the pandemic?						

Section 9. Acceptance and demand of relevant health products

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Is there a comprehensive approach for generating demand for relevant health products (diagnostics to perform rapid testing, uptake of preventive interventions - vaccination, prophylactic treatment) – which includes dedicated strategies for facilitating uptake from health and care workers and general population						
a. If yes, is it incorporated in the integrated delivery of relevant health products planning or is this found in a separate plan?						
2. Do the demand-generation approaches include activities for the periods before, during, and after relevant pandemic health products delivery?						
3. Are protocols in place on how to manage the infodemic , respond to dis- & mis-information or crisis (<i>please consider that this may be part of the wider approach to pandemic response</i>)?						
4. Are there spokespersons, or a group of individuals, responsible for communicating with media and partners for topics related to integrated delivery of relevant health products?						
a) National Level						
b) Regional Level						
c) Local Level						
5. Has collaboration with key community groups and other key stakeholders been established for integrated delivery of relevant health products planning?						

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
6. Is there a recent mapping of communities that are traditionally hesitant about specific interventions (e.g. vaccination) and description of processes on how to engage with them?						
7. Have mechanisms for identification of key community concerns (social listening, media monitoring, Behavioral and Social Drivers of vaccination (BeSD) monitoring) been identified?						
8. Are there capacities to translate the science into context specific communication materials related to integrated delivery of relevant health products?						
9. Do communication approaches on integrated delivery of relevant health products consider:						
a. mass media channels of communication including influencers trusted by the community						
b. social media channels of communication, including by and to health workers trusted by the community						
c. interpersonal channels of communication?						
10. Is there methodology in place to evaluate how campaign(s) influenced the behaviours of the general public and priority target groups towards uptake of relevant health products?						

Section 10. Relevant health products safety surveillance

General questions	In				Don't know	Comments/ Priority activities to address gaps
	Yes	progress	No	NA*		
1. Are there guidelines and procedures for monitoring, management and response to adverse events (including those following immunization).						
a. Are these published and available to all relevant staff at all levels?						
2. Are there specific documents that adequately outline the documented pandemic pharmacovigilance procedures, processes or tools for conducting the following activities below?						
a. Adverse events reporting						
b. Adverse events investigation (including data analysis and obtaining information for action)						
c. Adverse events causality assessment						
d. Risk communication and response to serious adverse events including having spokespersons identified at all levels for crisis communication in response to serious adverse events						
3. Has the composition, expertise that may be needed for a pandemic response (e.g. experience with special populations) and role of relevant national and sub-national committees (NTAGI, AEFI, ADR committees) been reviewed within last 12 months?						
4. Is the country considering setting up a monitoring and reporting system (eg active surveillance) of other safety concerns such as adverse events of special interest (AESI) ?						
5. Does the country have approaches in place to report serious and severe adverse events to WHO through the WHO database (VigiBase)?						
6. Do the marketing authorization (MA) procedures for licensing novel relevant health products include post-deployment safety monitoring (please consider all						

General questions		Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
	types of relevant health products)? <i>Is there an electronic data collection and management system in place for reporting and processing adverse events. If yes, specify in the comments.</i>						
7.	When licensing a novel relevant health product, does the NRA require the MA holder to perform a specific study of safety in the post marketing period?						
8.	Does the NRA require all manufacturers to inform it of any new safety issues or marketing/regulatory decisions taken in other countries with respect to relevant health products?						
9.	Is training mandatory for health workers delivering interventions (e.g. vaccinators) on IPC measures including safe intervention practices and product specific risks and risk management procedures?						
10.	Are mechanisms in place for handling compensation to beneficiaries when appropriate under national law?						
11.	Are there written procedures in place for stopping and recalling a relevant health product should the adverse events or post-deployment surveillance evidence warrant this decision?						

Section 11. Monitoring systems for different relevant health products

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Have sources of data (reported coverages, independent monitoring and coverage surveys) been identified?						
2. Are data mechanisms in place for disaggregation of data by						
a. Product						
b. Geography						
c. Gender						
d. Age groups (<i>every 5 years for those over 60 years old (60-65, 65-70, 70-75, xxxx 95-100)</i>)						
e. Other equity dimensions as applicable						
f. Severity of disease (hospitalization and/ or death)						
g. Intervention results (if applicable) – e.g. test results						
3. Have any dashboards been prepared for visualization and triangulation of relevant health product usage data from multiple sources?						
4. Are there systems in place to support monitoring and reporting of intervention related data to WHO – <i>using existing reporting systems that can integrate this type of data?</i>						
5. What are the impediments for implementation of coordinated monitoring systems (linking the relevant systems to facilitate data analysis/ interoperability)? Tick (√) all that apply:						
Lack of funds						
Lack of known-how						
Lack of trained personnel						
Complexities linked to the management and data privacy of different systems						
Legal complexities						

General questions		Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
Other. Please explain:							
6.	Is there a process to develop or adapt necessary monitoring tools, including vaccination cards/ certificates, facility-based nominal registries and/ or tally sheets, vaccination reports (paper and/or electronic), and analytical tools to monitor progress and coverage among different at-risk categories.						
7.	Are there provisions in place to prevent and respond to a potential hacking attack against all electronic data collection systems?						

Section 12. Pandemic surveillance to aide health products deployment campaigns

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Have key data points from pandemic surveillance systems been identified to inform population prioritization?						
2. Have disease surveillance teams been directed to work in close coordination with teams responsible for introduction of interventions using relevant health products (e.g. immunization)?						
3. Have mechanisms been identified for use of pandemic disease surveillance data to feed into relevant health product effectiveness assessments ?						
4. Have budget implications and source of funding for pandemic disease surveillance been identified considering the need to add new surveillance strategies and capturing data related to monitoring of interventions (testing, vaccination, treatment)?						

Section 13. Termination of pandemic operations for relevant health products

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Does the integrated delivery of relevant health products planning include details on termination of operations ?						
2. If yes, does it clearly articulate how the termination of activities will be triggered in relation to the official declaration of pandemic cessation by WHO, and following instructions from the National Coordination Committee?						
3. Do termination activities include the following:						
a. Scaling down of interventions (e.g. testing, vaccination) and if appropriate make provision on steps towards introducing some interventions as part of national programmes (e.g. national immunization programmes)						
b. Review of stocks of available relevant health products						
c. Recall of excess stocks of relevant health products						
d. Plan for handling these unused or expired relevant health products stocks and other products						
e. Release of surge staff to their parent organization/ department						
f. Completion of disposal of waste						
g. Plan for retaining infrastructure and redistribution of equipment						
4. Are there provisions to develop a termination report for after action review purposes?						

*NA- Not Applicable

Section 14. Monitoring and evaluation of operations for relevant health products

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. What plans are in place for stakeholder coordination and identification of gaps on integrated delivery of relevant health products planning during the inter-pandemic period?						
a. Tabletop simulation exercises ¹⁶						
b. Other simulation exercises ¹⁷						
c. Regional workshops						
d. Other						
2. Is there methodology in place to conduct inter- and after-action reviews (IAR and AAR) related to integrated delivery of relevant health products (<i>methodology should exist in advance, so that IAR and AAR can be performed during the response rapidly</i>)?						
3. What are the impediments for implementation of a monitoring and evaluation system?						
a. Lack of funds						
b. Lack of technical support						
c. Other. Please explain:						

¹⁶ These exercises can be done as part of or separate to full pandemic planning exercises

¹⁷ Ibidem

Section 15. Costs and financing

General questions	Yes	In progress	No	NA*	Don't know	Comments/ Priority activities to address gaps
1. Have costed workplans been prepared at national level for all key activities related to the introducing relevant health products						
2. If yes, are costs for the following included:						
a. Infrastructure improvements, equipment, maintenance/repair including for cold chain capacities						
b. HR related including surge requirements						
c. Supply chain related (transport, reverse logistics, waste management)						
d. Safety and security of staff and relevant health products						
e. Demand generation and community engagement						
f. Monitoring and evaluation						
g. Safety surveillance for relevant health products						
h. Sustaining essential services						
3. Is there a strategy to address the identified budget gaps ¹⁸ ?						
4. Have potential sources of funding been identified (<i>please specify which</i>)?						
5. Is there a mechanism to ensure transparent monitoring of budget implementation (preparedness activities and an eventual response)?						

¹⁸ This may be part of the wider pandemic preparedness plan

*NA- Not Applicable