WGPR intersessional meetings on Equity and Leadership/Governance, 18 March 2022: Inputs from TWN, as part of the MMI delegation

To inform its work and in particular the finalization of recommendations to the 75 World Health Assembly, the WHO Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR), convened a series of informal intersessional meetings.

Medicus Mundi International – Network Health for All (MMI) is an NGO in official relations with WHO. MMI invited its members and selected partners to attend the informal meetings of the WGPR and to respond, as adequate and based on their specific expertise, to a set of guiding questions shared by the WHO Secretariat ahead of the meeting.

The inputs below are an edited and extended version of the responses by Nithin Ramakrishnan, Third World Network (TWN), as a member of the MMI Delegation, to the two sub-sessions on 18 March 2022, on Equity and Leadership/Governance. Responses are put in italics, but not all of it could be orally presented in the informal WGPR meeting.

Contact MMI: Thomas Schwarz, schwarz@medicusmundi.org
Contact TWN: Nithin Ramakrishnan, directornithin@gmail.com

TWN/MMI INPUT TO THE SESSION ON EQUITY, 18 MARCH 2022

General remark

The answers to the questions on equity are provided below. These questions limit the discussion on equity to selected areas, without providing a rationale why these questions should herald the discussion.

Member State statements made during EB150, which recognized the importance of WHO ABS mechanism, common but differentiated responsibilities, and the reporting on compliance with IHR obligations on international collaboration and assistance should be recalled in this meeting. These elements are not only critical but also inevitable in realizing equity in health emergency preparedness and response.

Set of questions 1

Recognizing the important role ACT-A plays in the COVID-19 response as well as the COVAX Facility and allocation framework, views are sought on the following in order to develop proposed actions:

Question

Are there lessons learned and good practices to make part of future pandemic preparedness and response (PPR)?

Answers

We still do not have the full picture foo functioning of the ACT-A and its effectiveness in the addressing the availability and accessibility of vaccines, therapeutics and diagnostics. Therefore, a concrete review of the functioning and performance of ACT-A to be carried out in order to address its future role.

At the same, the Covid19 response makes it clear that the allocation framework should be legal binding. It should be developed through a member state led process. Member States or the NSA actors cannot jeopardize such an internationally coordinated allocation framework.

It must be noted that the Articles 13(5), and 15 and 16 of IHR can be used to develop such an allocation framework.

Any mechanism like ACTA should also aim to facilitate diversification of production.

Question

Are there remaining gaps and obstacles, especially for last-mile delivery?

Answers

Unliteral Response measures taken by the States, including advance purchase agreements, travel or trade restrictions, should not affect the allocation the framework. This should be part of the amendments to IHR, especially to Article 42, 43 and 44 of IHR 2005.

Report of the Independent Expert on human rights and international solidarity is very relevant in this regard, where he refers to the legally binding obligations of international collaboration and assistance in IHR 2005. Unfortunately, the recommendations from the rapporteur on solidarity couldn't find its position in WHO Dashboard and survey.

The lack of legal obligation to adhere to the allocation mechanism is a major gap. The lack of effective participation of member State in the priority settings and operation of ACT-A also remains a problem.

Question

Whether/how to make ACT-A into a permanent structure? How can a future ACT-A, if there is to be one, be more inclusive and transparent in its governance and reporting?

Answers

Considering the shortcomings in the governance and reluctance to promote local production, there should not be no reliance on guiding documents, working or structural principles developed as part of ACT-A.

Member States should not endorse ACT-A, but develop a mechanisms and legal commitments to diversify research, manufacture and distribution, rooted in common but differentiated responsibility principle.

What we require is a legal provision to establish a mechanism to address issues of R&D, availability and accessibility of health products required for responding effectively to the health emergencies.

Set of questions 2

Recognizing general agreement on the need to strengthen manufacturing pharmaceutical countermeasures with a focus on regional manufacturing capability/capacity as well as addressing equitable access to all, especially for developing nations:

Question

Are there lessons learned and good practices to make part of future PPR?
e.g. mRNA hub

Answers

mRNA hub is a good initiative to build the technology capacity. However, mRNA hub is more looking at capacity building rather than facilitating local production in the shortest possible time. It is not accelerating the local production the quickest possible time. What we need is a quick mechanism to transfer the technology and start the production.

In the case of mRNA vaccine or Astra Zeneca vaccine contract manufacture could start the production within 4 months of the technology transfer. Therefore, the regional production hub should aim that shortest time period to start the production and not after 3 to 4 years of health emergency outbreak and spread. Damage would have been done by then.

One of the important barriers for technology transfer is IP protection. Therefore during the heath emergencies, countries should have the policy space to temporarily suspend Ip right to facilitate the innovation of new products as well as local production.

Question

Are there remaining gaps and obstacles that could be addressed through WHO mechanisms or other fora?

Answers

Yes. WHO needs to revamp it vaccine marketing approval guideline in the light of COVID 19 vaccines. Currently all vaccine manufactures irrespective originator and non-originator are treated at par and both have to produce safety and efficacy data through clinical trials. This is time consuming and costly.

However, latest evidence suggests that there could be a possibility of biosimilar path way for certain type of vaccines platforms. This could avoid such time and resource intensive clinical trials. Similarly, there could be an for recognizing accelerated pathway for non-originator vaccine producers. Moreover, COVID19 showed us that vaccine regulatory pathway can be cut short. WHO should appoint an expert panel free form conflict of interest to examine the possibilities of non-originator pathway for vaccines with lessened clinical trial burden.

Similarly, we have mRNA vaccine , which is not a biological vaccine . This indicates that a generic pathway is possible. WHO should develop a generic pathway for mRNA vaccines.

Lastly, COVID19 vaccination is a historic vaccine drive in the human history. It generated data. WHO needs to develop Immuno Correlative Protections for COVID19 vaccine, which can help to do away with efficacy trials. Efficacy trial for COVID 19 is getting more and more difficult in the light of large number of infection as well as vaccination.

Question 3

What are the views on the proposal to establish a global coordinating mechanism for R&D? Are there any concrete ideas on it?

Answers

Any global coordinating mechanism for R&D must ensure fair and equitable access to the R&D Outcomes. This should be legally committed.

In terms of R&D capacities, it is important to the build capacities locally at Member States.

This is not the first time WHO discuss this issue. There is a recommendation of Consultative Expert Working Group on Research and Development to establish a such a mechanism including global observatory and an expert committee on R&D. What we ned is the effective implementation of that recommendation. Therefore, this attempt should not fragment by creating additional mechanism focusing only on health emergencies. The WHO Global Observatory on Health R&D is already underfunded.

See:

- *https://www.who.int/observatories/global-observatory-on-health-research-and-development*
- *https://apps.who.int/iris/bitstream/handle/10665/273260/B140_22-en.pdf?sequence=1&isAllowed=y*
- *https://www.graduateinstitute.ch/sites/internet/files/2019-02/3%20Vasee%20Moorthy%20slides%20R&D.pdf*

The same mechanism can enable the coordination and prioritisation of R&D in the area of health emergencies.

CEWG/ Consultative Expert Committee on Research and Development's mandate should be expanded to include the monitoring and prioritisation of R&D in relation to health emergencies.

TWN/MMI INPUT TO THE SESSION ON LEADERSHIP AND GOVERNANCE, 18 MARCH 2022

Sub-topic: IHR Strengthening

Question

Based on the recommendations from the panels/committee and the survey results, IHR strengthening in these areas was identified as a high priority and feasibility item:

- Role and functioning of NFPs;
- Core capacity requirements for preparedness, surveillance and response;
- National notification and alert system;
- Risk assessment and information sharing.

Are there any concrete ideas on how to implement the recommendations either through WHO`s normative work and/or IHR amendment?

Answers

IHR amendment is required to fill the gaps in order to streamline and strengthening the IHR mechanism. While WHO normative work is a good mechanism in this regard but IHR is a legal instrument. Therefore, the best way is to fix the gap through the amendment and then complement with the normative work of WHO. WHO's normative work to strengthen IHR without amendment to IHR provisions would be hollow and will not serve the purpose.

Also, it must be noted that the high priority on core capacity requirements for preparedness, surveillance and response, mentioned in the IHR Annex 1 does not take into consideration the need for resilience of health systems to infectious disease outbreaks and health emergencies. IHR annex core capacities need to revisited.

Question

Some amendments currently before the WHA in May address these high priority areas such as notification and alerts, risk assessments and information sharing. Do those proposed amendments address the gaps raised by the recommendations or can they be improved? Are there other relevant aspects of these high priority areas that should be addressed by WHA75 in some other way?

Answers

150th EB has taken a decision to amend IHR covering the following areas.

- *equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005),*
- *their universal application for the protection of all people of the world from the international spread of disease in an equitable manner*

Based on the decision WGPR should provide an opportunity to all Member States to submit their amendments within a given date. Later all the proposals including the amendments of US should be treated at equal footing. The suggestion to fast tracking of certain amendments goes against the spirit of best practices of international law making and the Vienna Convention on Law of Treaties. Some proposals came before the decision does not mean that it should be taken up early. The mandate of WGPR to deal with IHR amendment came only after 150th EB decision.

Question

Many Member States, both through WGPR statements and survey responses have prioritized in particular for States Parties to share the relevant public health information needed by WHO to assess the public health risk and for WHO to be empowered to respond effectively to outbreaks, while some Member States have expressed caution that such efforts should not compromise national sovereignty. How should we finalize recommendations on this critical area?

Answers

There is already a mandate to shar relevant public information under IHR and it provides an indicative list. However, there is no consensus on the term "relevant public health information". Using this ambiguity certain state parties prosing the sharing of pathogen samples especially genetic sequence data /DSI. This is a far-fetched interpretation. There is no negotiating history to claim such information under the term relevant public health information.

Further, such sharing without any corresponding arrangement for far an equitable benefit sharing violate the international obligations under CBD and Nagoya protocol. There is an urgent need for WHO to establish such a mechanism. The current initiatives of WHO such as Bio Hub and Hub for epidemic intelligence need to work under an ABS mechanism decided through an inter-governmental process. WGPR needs to initiate such a process.

Question

What obstacles need to be addressed and/or support required in order to strengthen national and regional core capacities that could improve IHR (2005) implementation and compliance?

Answers

Access to finance and technological to strengthen surveillance and response capacities including a functioning health system is critical to strengthen national core capacities. Though IHR Article 5,13 and 44 mention about such assistance it is not implemented in a transparent manner. Much of the technical assistance takes place bilaterally and outside the IHR framework. Even during the COVID19 the assistance of WHO took place outside the IHR framework. It is important to bring such assistance within the IHR framework and report periodically. Further, there should be standing agenda item in WHA and EB as well as prosed structure within IHR to oversee such assistance.

It is important to establish a mechanism within IHR to provide finance and assistance like Green Climate Fund.

Sub-topic: Universal Health and Preparedness Review (UHPR) Pilot

Question

After receiving an update on the pilot, what actions do Member States want to recommend related to its continued development?

Answers

Review for Health Emergency Preparedness and Response should not be just "preparedness" focussed. Review should happen on how international community is responding collaboratively to health emergencies as provided in the IHR.

IHR Mechanism for reporting under Article 54 must be read along WHO Constitution and can be developed addressing the specialized requirements for health emergency preparedness and response laws.