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I. OVERVIEW

WHAT IS IT? The COVID-19 National Deployment Vaccination Plan Tabletop Exercise (TTX) is a simulation package which uses a progressive scenario together with series of scripted specific injects to provide timely information around development and regulatory approval of COVID-19 related diagnostics, therapeutics and vaccines.

The TTX simulation package is not a test of a plan or other specific measures. Rather, through facilitated group discussion, the exercise aims to assist countries to plan, develop and update their national deployment and vaccination plan (NDVP) for the equitable timely access to COVID-19 vaccines specifically addressing regulatory and safety issues.

The exercise has been developed by the Country Exercises and Reviews Team of the Health Preparedness Department of WHO with the support from technical experts from the COVAX global coordination group. It has been cleared by WHO COVID-19 Publications Review Committee.

OBJECTIVES The specific objectives of the TTX are:

1) **Review** plans for accelerated regulatory frameworks

2) **Review** safety procedures for vaccines, particularly vaccines under accelerated development.

3) **Confirm regulatory procedures** for vaccine approval

4) **Review** systems for monitoring the safety of vaccines.
## II. SIMULATION STRUCTURE

### EXERCISE DESIGN

This exercise is based on the latest WHO guidance for COVID-19 vaccination, including:

- Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines

### ELEMENTS OF THE SCENARIO

The scenario is divided in **four consecutive updates**:

1. **Vaccines are developed and will be soon available to your country** through the COVAX facility.
2. Some countries have approved vaccines for emergency use, but **details remain spare** on which vaccine will be allocated to your country.
3. COVID-19 vaccines **have been approved** by the National Regulatory Authority for use.
4. An **infodemic** threatens to erode confidence in the vaccination programme.

### FLOW OF THE TTX

- The generic simulation package consists of a **series of slides around these four updates**.
- Between each of these updates, there is a slide with a series of **questions (or injects) for the group to discuss and answer**.
- The content of these discussions will be used during the **debriefing** at the end of the simulation exercise and with all the participants to **propose practical ideas to enhance the systems, plans & procedures in your country**.
In order to provide a realistic context for the simulation, the scenario and relevant questions must be adapted to the country specific context, and incorporate some of the following elements:

- Actual names of existing regulation procedures, institutions in your country
- Actual location of services within the country (health care facilities etc)
- Numbers in line with the size of your populations,
- Etc.

In addition, some of the questions may need to be rephrased to align with the current stage of development of your NDVP or new elements related to the vaccines' development.

This adaptation is essential for the success of the exercise; this is what makes the simulation ‘real’ to participants and makes the simulation effort worthwhile.

The facilitators are responsible for adapting the simulation materials beforehand; this should be done in close collaboration with the relevant authorities. WHO and other COVAX partners in country are ready to assist if necessary.

The full TTX simulation package is designed to take place over the course of a full day or be split over two mornings.

Depending on the country situation, a briefing with all relevant stakeholders on current plans, procedures and key planning context can be done before the simulation.

The decision on which model to use will need to be taken by the in-country team in consultation with the Lead Facilitator.
III. TARGET AUDIENCE

PARTICIPANTS

As in most countries the establishment of a COVID-19 vaccine deployment and vaccination mechanism falls with the ministry of health (MoH), this simulation exercise is intended to support them as they develop the regulatory mechanisms related to COVID-19 vaccination plans.

Around 30 people representing all relevant stakeholders should be invited to take part in this simulation exercise: mainly, the national Regulatory Authorities (NRAs), Regional pharmaceutical advisors, Regulatory networks and associated stakeholders.

The participants should be selected carefully as the outputs of the simulation exercise will greatly depend on the skills and knowledge they will bring.
IV. FACILITATORS REQUIREMENTS

FACILITATION TEAM

The simulation exercise is run by a Lead Facilitator, this person will be responsible for the adaptation of the materials to the national context, the delivery of the package and subsequent de-briefing.

The implementation of this package can be supported by the WHO Country Office through the active involvement of the WHO Resident Representative and technical staff.

During the TTX, the designated facilitation members will sit with their relevant functional group and are responsible for taking notes and capturing key points to assist with the debrief sessions.

Trainings on simulation exercise management are available online and some webinars on the use of this specific packages will be organized. Inform the WHO country Office if you want to be contacted for the next webinar.

FACILITATORS’ TASKS

The facilitation team will be responsible for the following tasks:

- **Adapt the materials** to the country specific context, including the participants’ guide.
- **Review in-country physical distancing regulations** and recommendations; and decide on the way to run the simulation exercise accordingly (on-site, online or a mix of both)
- **Complete the practical arrangements** (invite participants, office space, IT set up, lunch, etc.)
- **Run the package**, including the presentation of all injects
- **Facilitate the discussion process** by asking specific leading questions
- **Observe** the group dynamics and **assess** how the group is achieving the objectives of the exercise
- **Prepare for the debriefing** by assessing the substance of the work undertaken during the simulation
- **Draft the exercise report** together with recommendations and follow up actions to be undertaken, with a timeline for completion, and linked these to the NDVP process in the country.
V. ORGANISATIONAL REQUIREMENTS

SUPPORT AND COMMITMENT FROM LEADERSHIP

The full support and commitment of the Minister of Health, WHO WR and partners are critical to the success of the simulation. They will need to be briefed prior to the exercise and may give you valuable input to assist with the adaptation of the simulation material. Moreover, during the briefing the Lead Facilitator should stress the importance of getting the right participants for the simulation exercise. Their support to mobilize high level participation is crucial.

The results of the simulation should enable the Minister of Health to make strategic decisions guiding the development of their National Deployment and Vaccination Plan. The facilitation team should meet leadership also after the exercise to present the outputs of the exercise and the key recommendations that emerged.

TIME COMMITMENT

The implementation of this TTX requires the full commitment of the facilitation team. Nevertheless, this can be done in a relatively short time.

- 1-2 days.. Involvement of the facilitation team in the preparatory work, including the adaptation of the scenario, customization of the participants’ guide and practical arrangements
- 4 hours.... Roll out and facilitation the TTX for the participants
- 4 hours.... Facilitate the debriefing sessions for the participants
- 1 day....... Draft exercise report and compile action plan
- 1 hour ..... Sharing outputs and key recommendations to country leadership
VI. HOW TO RUN THE COVID-19 NDVP TABLETOP EXERCISE

**SETUP**  The decision on how to run the exercise will be based on the *in-country guidelines and recommendations on physical distancing*. Different options can be explored:

- **Face-to-face**: if the group size and the room size allow to comply with physical distancing.

- **On-line**: technology such as Zoom, Teams, Webex, etc. can be used to run the exercise online. By sharing screens, the facilitators cannot only run the presentation, but also capture key discussion points and the debriefing process.

- **A mix approach**: small groups can work face-to-face and feedback to a on-line plenary platform.

**PARTICIPANTS’ GUIDE**  The *participants’ guide* is a short document that needs to be adapted by the facilitation team and sent to all participants prior to the simulation exercise. The guide contains key information for the participants that will help them to prepare themselves for the simulation exercise:

- Objectives and expected outcome of the exercise
- Expected time commitment from the participants (exercise agenda including the debriefing)
- Introduction of reference material that participants should review before the simulation exercise
- Ground rules during the simulation (how to play)
A PowerPoint presentation is the main support material the facilitators will use to run the Tabletop Exercise. The presentation should be adapted by the facilitation team prior to the exercise.

The facilitation of the simulation exercise is split in three main parts:

1. **INTRODUCTION (SLIDES 1 TO 15):**

   Establish a common understanding amongst all participants on:
   - The scope and objectives of the simulation exercise
   - The context (current situation, COVAX, existing guidance, etc.)
   - The rules of the Simulation exercise

2. **SIMULATION (SLIDES 16 TO 29):**

   A succession of scenario updates providing key information that participants will use to collaboratively solve problems and respond to questions (injects)

3. **DEBRIEFING (SLIDE 26 TO 34):**

   The debriefing is the most important part of the exercise. It is during the debriefing that all the participants:
   - Review the strengths and gaps revealed during the simulation;
   - Recommend and prioritize key elements that need to drive the regulatory approval in your country;
   - Develop an action plan with clear responsibility and timeline for the regulatory process.

In the notes' section of the slides, you will find specific facilitation tips and some additional technical background information to assist you during the exercise.