

## JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

# WHO Inspection Services Business Continuity during the Pandemic

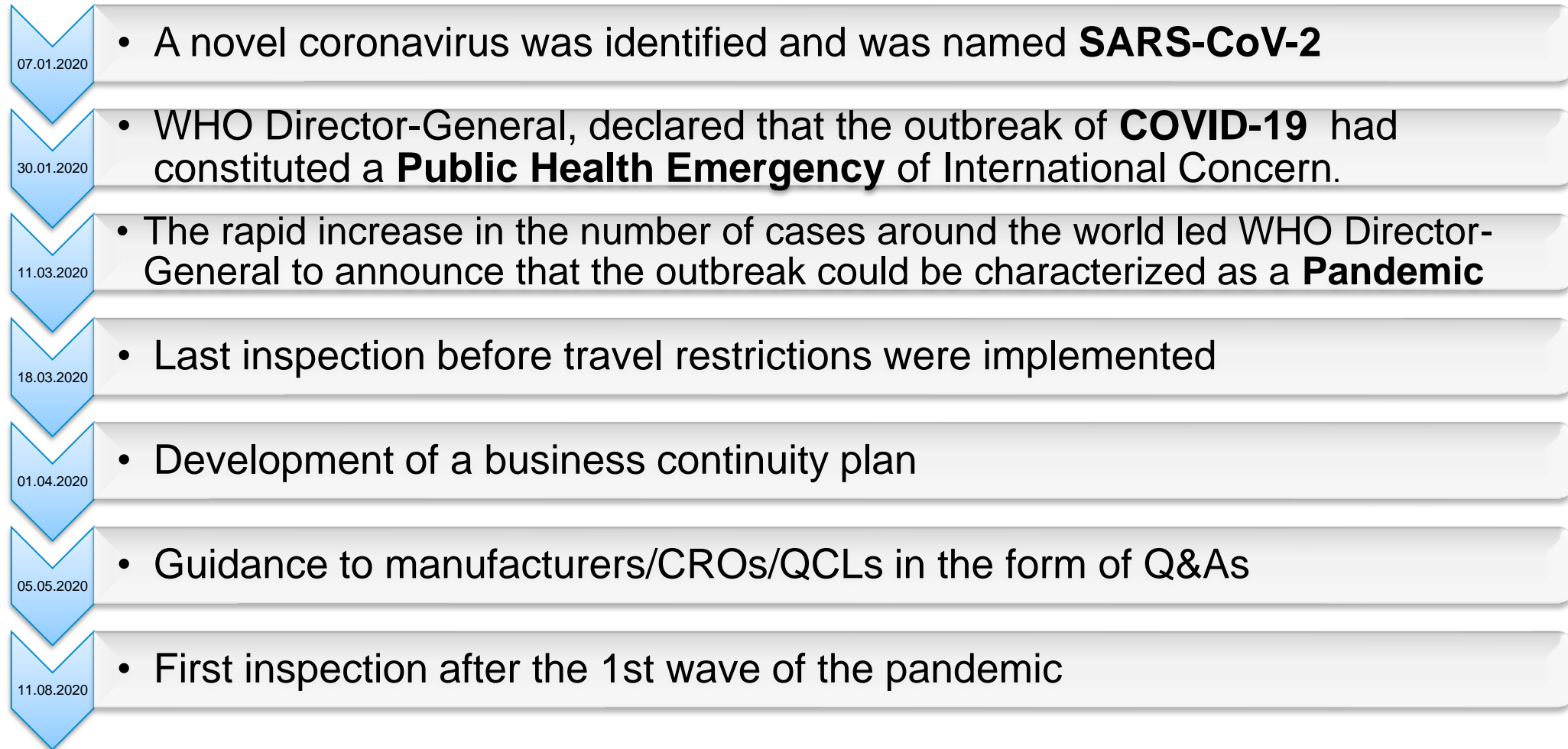
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World Health Organization



# Outline

- ❖ Inspection Services Response to COVID-19
- ❖ Challenges
- ❖ Business Continuity
- ❖ Regulatory Expectations

# Timeline: Inspection Services COVID-19 Response



# Challenges during the Outbreak of the Pandemic

- Travel restrictions leading to problems in repatriation of inspectors
- Cancellation or postponement of already planned inspections
- Limitations for consultants and NRAs to contribute to WHO Prequalification inspections
- Delays in submission of CAPA plans for inspections carried out during Q1
- Delays in submission of supportive documentation for desk assessments
- Limitations in conducting desk assessments or remote assessments

# Inspection Services - Business Continuity Plan (1)

- Continue to identify manufacturers/CROs/QCLs for inspection based on risk.
- Priority to be given to companies/ products related to COVID-19
- Continue to conduct inspections of manufacturers/CROs/ QCLs located in areas that are less affected by the pandemic
- Agree in advance of the inspection precautionary measures to protect company's personnel and inspectors
- Desk assessments to be carried out in lieu of on-site inspections where restrictions due to the pandemic are in place and relevant documentation is available

# Inspection Services - Business Continuity Plan (2)

- Develop guidance in the form of Q&As to assist manufacturers/CROs/QCLs facing constraints during the pandemic  
<https://extranet.who.int/pqweb/news/update-question-answer-covid-19-and-who-pqt-inspections>
- Develop and implement a procedure on conducting remote assessments i.e. conducting a distant evaluation of a company using IT applications and software such as video-conference and file sharing.
- Exchange information with NRAs and participate in international fora and initiatives with an aim to facilitate regulatory oversight and provide guidance to industry

# Regulatory Expectations for Industry during the Pandemic (1)

- Business continuity and disaster plans should be deployed, where applicable.
- QRM principles should be applied in order to maintain a functional QMS, production and/or quality control and any other supportive operations.
- Any major deviations or changes in QMS and key procedures/operations due to the pandemic should be risk-assessed, documented, and communicated to PQ Inspection Services, where necessary. Documentation and implementation related to these changes and deviations will be verified during the next routine inspection



# Regulatory Expectations for Industry during the Pandemic (2)

- Top/senior management is responsible for identifying key operations to be maintained during the pandemic and personnel to work on/off-site based on risk management principles
- A plan for transition back to the normal state should also be established based on risk management principles and national guidance
- The definitive aim should be to ensure the quality, safety, efficacy and continuity in the supply of products and services to meet a high level of public health and protect human lives.



THANK  
YOU

Dimitrios Catsoulacos JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS 30 November -3 December 2020