Regulation of in vitro diagnostics, therapeutics, and vaccines
WHO Update – 8
Coronavirus disease 2019 (COVID-19)
08 May 2020

World Health Organization

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Key Messages

The US FDA has granted an Emergency Use Authorization for the investigational antiviral drug, remdesivir, for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease.

The approvals were based on data from the US National Institute of Allergy and Infectious Diseases randomized, double-blinded placebo controlled trial of 1063 subjects. Results from this large trial provided reliable and statistically persuasive evidence of benefit for remdesivir. The results from an open-label study conducted in the US by the manufacturer Gilead were consistent with this finding.

The Minister of Health, Labour and Welfare (MHLW), Japan issued a Special Approval for Emergency for remdesivir for COVID-19.

Remdesivir is one of the investigational products in the WHO SOLIDARITY clinical trial. This multiregional clinical trial as well as other national clinical trials for remdesivir are still ongoing.

Highlights and main issues

- Regulators have reiterated that it is crucial to align on common study protocols to ensure that the results meet regulatory requirements to allow the evidence to be used to support the approval of medicines or vaccines. Early inclusion of vulnerable or neglected populations, such as pregnant women, children and elderly people should be considered in COVID-19 studies.
- WHO will promote the inclusion of all interested countries, including low- and middle-income countries from all regions, in the Solidarity clinical trials for therapeutics and vaccines.
- WHO will continue efforts with partners to obtain equitable access to personal protective equipment, diagnostics, and biomedical equipment essential to the pandemic COVID-19 response.
- WHO has published criteria for ethical acceptability of human challenge studies with SARS-CoV-2.
- Manufacturing capacity in India is reported to have increased to up to 70% for export products and 80% for domestic products. Nonetheless, reports of shortages of API and finished pharmaceutical products are continuing, and WHO is working with industry associations to identify particular problems.
- The WHO Prequalification Unit - Inspections Team has published a Q&A document to address numerous questions on regulatory expectations and flexibility during the COVID-19 pandemic.

- A list of priority medical devices for COVID, which describes the medical devices, the purpose of the device and settings where it can be used, is included in the WHO Medical Devices May 2020 Newsletter.

Statement on the 3rd meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19)

The third meeting of the Emergency Committee convened by the WHO Director-General under the International Health Regulations (2005) (IHR) regarding the coronavirus disease (COVID-19), took place on 30 April 2020. The following extracts are from the advice provided by the Committee.

The DG accepted the advice to WHO and issued the Committee's advice to States Parties as Temporary Recommendations under the IHR.

Advice to WHO

- Promote the inclusion of all interested countries, including low- and middle-income countries from all regions, in the Solidarity clinical trials for therapeutics and vaccines.
- Continue efforts with partners to obtain equitable access to personal protective equipment, diagnostics, and biomedical equipment essential to the pandemic COVID-19 response.
- Support countries to address shortages of essential medicines and health products, personal protective equipment, and other medical supplies and to establish sustainable risk management practices to prevent future shortages.
- Clarify the surveillance testing strategy, support countries to increase testing capacity, and aim to provide equitable access to diagnostic tests and supplies in light of market failures and global shortages.

Advice to all State Parties

- Participate in global solidarity efforts to enable access to essential supplies for all.
- Continue to support and conduct COVID-19 research, in line with the WHO Research and Development Blueprint, and the road map for COVID-19 vaccines, diagnostics, and therapeutics.

Alignment of approaches by regulatory groups

Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19

In a high-level meeting on COVID-19 policies, organised by European Medicines Agency (EMA) on 30 April under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), WHO and international regulators from around the world discussed strategic issues and regulatory approaches to ensure a coordinated response to the pandemic. They stressed the need for alignment on pre- and post-authorisation regulatory requirements to facilitate the rapid development, evaluation and availability of medicines for the treatment and prevention of coronavirus disease.

The participants focused on regulatory considerations and challenges related to the development of

medicines and vaccines for the prevention and treatment of COVID-19. They raised concerns about multiple small, rather than large clinical trials and stressed the need for the development of priority criteria for planned trials. In addition, they called for the inclusion of vulnerable or neglected populations, such as pregnant women, children and elderly people in COVID-19 studies. The regulators reiterated that it is crucial to align on common study protocols to ensure that the results meet regulatory requirements and allow the evidence to be used to support the approval of medicines or vaccines.

Regulators also discussed the development, evaluation and use of diagnostic tests in the fight against coronavirus disease. They shared insights into diagnostic accuracy and reliability of serological tests for COVID-19 used in different countries. Meeting participants agreed to make, in collaboration with WHO, an ICMRA inventory of approved tests for COVID-19 to ensure a comparability of the results and to align regulatory approaches.

All participants committed to continue the exchange of information on high-level regulatory flexibilities to enhance the efficiency and effectiveness of regulatory decision-making during the current pandemic.

EMA and FDA are taking it in turns to chair these meetings.

> For information on the 30 April meeting, see https://www.ema.europa.eu/en/news/global-regulators-work-towards-alignment-policy-approaches-regulatory-flexibility-during-covid-19

Regional Regulatory Group Meetings

WHO SEARO office in coordination with the South East Asian Regulatory Network organized a meeting with WHO on 7 May on regulatory updates on the COVID-19 pandemic. The meeting was attended by 63 participants and helped to clarify regulatory positions on a number of issues.

Questions and answers addressed include WHO guidelines on production and quality control of COVID19 vaccines; IVDs listed under EUL procedures; Rapid Diagnostic Tests and laboratory testing strategies; PPEs, including the reuse of masks; favipiravir regarding its inclusion of new candidate therapeutics in the SOLIDARITY trial; the standard treatment protocol for COVID-19 management; and lists of medicines for management of COVID 19.

In vitro diagnostics

WHO EUL for SARS-CoV-2 virus IVDs

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. Applicants submit their applications for assessment based on WHO instructions for NAT and antibody detection rapid tests (RDTs) submissions.

34 submissions for NAT assays have been received so far and 5 more are expected.

The status of each application is presented here.

Five products have been listed as eligible for WHO procurement based on their compliance with WHO EUL requirements:

Date Listed	Product name	Product code(s)	Manufacturer
07 May 2020	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	MFG030010	BGI Europe A/S
24 April 2020	PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay	SY580	SYM-BIO LiveScience Co., Ltd

09 April 2020	Abbott Realtime SARS-CoV-2	09N77-090 and 09N77-080	Abbott Molecular Inc.
07 April 2020	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Z-Path-COVID-19-CE	Primerdesign Ltd.
03 April 2020	cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems	09175431190 and 09175440190	Roche Molecular Systems, Inc.

On 7 May 2020 WHO listed the fifth NAT assay under the emergency use listing procedure. The **Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2 manufactured by BGI Europe A/S** is a qualitative in vitro nucleic acid amplification assay to detect the new (SARS-CoV-2) using Reverse transcription PCR in throat swab and Bronchoalveolar Lavage Fluid (BALF) specimens. The kit is manually operated and is based on in vitro RT-PCR combining fluorescent probing.

The product should be used in combination with the TIANamp Virus RNA extraction Kit (DP315-R) manufactured by TIANGEN or QIAamp Viral RNA Mini Kit (52904) by QIAGEN and the Applied Biosystems™ Real time PCR system 7500; SLAN-96P PCR system.

Antibody detection rapid tests have been eligible for WHO emergency use assessment since 17 April. WHO recently received the first expression of interest for an antibody detection RDT and several pre-submission calls have been held with manufacturers interested in submitting for EUL assessment. WHO is currently working on the development of instructions for submission of antibody detection enzyme immunoassays (EIAs) and antigen detection RDTs. These will be published soon on the WHO website and the EUL eligibility expanded to such products.

COVID-19 in vitro diagnostics listed by National Regulatory Authorities in IMDRF jurisdictions

To help countries, WHO publishes links to emergency lists, together with contact details, on IVDs authorized for use in the International Medical Device Regulators Forum (IMDRF) jurisdictions along with other useful information on policies and guidance.

This information is updated on a weekly basis. The most recent update was published here.

Note: WHO does not endorse any of the lists provided by NRAs. The information is provided exclusively to assist stakeholders with identifying the links to the various lists.

Therapeutics

Remdesivir for COVID-19 treatments

The US FDA granted an Emergency Use Authorization for the investigational antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease on 1st May 2020. While there is limited information known about the safety and effectiveness of using remdesivir to treat people in the hospital with COVID-19, the investigational drug was shown in a clinical trial to shorten the time to recovery in some patients.

The emergency use authorization allows for remdesivir to be distributed in the U.S. and administered intravenously by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. Severe disease is defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

See: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment

On 7th May 2020, the Japanese MHLW granted a Special Approval for Emergency on remdesivir for treatment of COVID-19 with approval conditions to allow the access to the potential treatment of this disease. The Special Approval for Emergency was granted with several conditions such as; written informed consent prior to administration; risk management plan to be implemented; submit the results of additional clinical studies at earliest convenience, at latest within 9 months; surveillance/registry of all patients conducted during the designated period.

See: https://www.pmda.go.jp/english/int-activities/0004.pdf

Research mapping of candidate therapeutics for COVID-19

A living research mapping of candidate COVID-19 therapeutics, displaying studies per country, showing study design, disease severity in study participants, and type of treatment being studied, as well as network maps of these studies, has been made available at: https://www.covid-nma.com/dataviz/

Living synthesis of Covid-19 study results

A list of treatment comparisons, a summary of the evidence for that comparison, and a detailed description of primary studies, including a risk of bias assessment is at: https://covid-nma.com/living_data/index.php

Vaccines

Human challenge trials

Human challenge trials are trials in which participants are intentionally challenged (whether or not they have been vaccinated) with an infectious disease organism. This challenge organism may be close to wild-type and pathogenic, adapted and/or attenuated from wild-type with less or no pathogenicity, or genetically modified in some manner.

Infectious human challenge studies involve deliberate exposure of human volunteers to infectious agents. Human challenge studies have been conducted over hundreds of years and have contributed to vital scientific knowledge that has led to advances in the development of drugs and vaccines. Nevertheless, such research can appear to be in conflict with the guiding principle in medicine to do no harm. It is essential that challenge studies be conducted within an ethical framework in which truly informed consent is given.

General guidance for regulators on human challenge studies, established by the ECBS, is available here: Human challenge trials for vaccine development: regulatory considerations, TRS 1004, Annex 10

Key criteria for the ethical acceptability of COVID-19 human challenge studies

WHO has published criteria for ethical acceptability of human challenge studies but does not advocate a position on this issue. The safety of participants is a key priority in challenge study design – finding this balance is critical through risk minimization; choosing low risk participants, and rigorous consent. The document outlines 8 key criteria – from the scientific justification, risk/benefit assessment, engagement through to site and participant selection, expert review and consent. The document is focused on the need for international cooperation, and focuses on the need for co-ordination, public engagement, careful site selection, and independent review.

The document is available at: https://www.who.int/ethics/publications/key-criteria-ethical-acceptability-of-covid-19-human-challenge/en/

Landscape of candidate vaccines for SARS-CoV-2

A landscape analysis of candidate SARS-CoV-2 vaccines is regularly published by WHO.

The 05 May 2020 version of the landscape analysis is available at: https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines

The vaccine platforms under study are summarized in the tables:

Stage of vaccine development	Type of platform	# of candidates	Comments
Phase 1/2 clinical	Non-replicating viral vector	2	One candidate uses Ad 5 as vector; one candidate uses ChAdOx1 as vector
	LNP-encapsulated mRNA	2	
	Inactivated whole virion	3	2 candidates have no adjuvant; 1 candidate is alum adjuvanted
	DNA	1	Delivered by electroporation

Stage of vaccine development	Type of platform	# of candidates	Comments
Pre-clinical	DNA	9	1 candidate delivered by electroporation
	Inactivated whole virus	4	2 candidates with CpG 1018 adjuvant
	Live attenuated	3	2 candidates are codon deoptimized; 1 candidate is an engineered measles virus (with S, N targets)
	Non-replicating viral vector	13	7 adeno-based vectors;3 vaccinia-based vectors; 1 parainfluenza 5 based vector; 1 deactivated rabies based vector; 1 dendritic cell based vaccine
	Protein subunit	36	Multiple designs
	Replicating viral vector	12	4 influenza vectors; 3 measles vectors; 3 VSV vectors; 1 yellow fever vaccine vector; 1 horsepox vector
	RNA	14	5 LNP-mRNA; 8 mRNA; 1 saRNA
	VLP	6	1 plant-derived
	Unknown	3	
Total pre-clinical		100	

Convalescent plasma

To address requests to WHO on convalescent plasma, WHO Interim Guidance on COVID-19 Blood Supply is being revised to include guidance on collection and preparation of COVID-19 convalescent plasma.

In principle, WHO recommends strongly that COVID-19 convalescent plasma should be used in randomized controlled trials (RCTs) as the most effective and efficient strategy to determine the efficacy and safety of this experimental therapy. In environments where structured clinical studies are not possible, efforts

nevertheless should be made to document patient outcomes and to obtain and archive blood samples from donors and recipients for future scientific study.

WHO continues to liaise with its international partners to obtain and share information on policies and protocols for studies of COVID-19 convalescent plasma that emerge in different countries and regions.

Information relevant to studies of COVID-19 convalescent plasma can be found at an open access website of the International Society of Blood Transfusion at http://isbtweb.org/coronaoutbreak/convalescent-plasma-covid-19-resources/.

> **Note: WHO does not endorse any of the statements or protocols listed at this website. Reference to this information is provided exclusively to assist stakeholders with identifying links to the various statements, guidelines and protocols.**

Enabling research; animal models, clinical trial protocols, assay development, standards

WHO Working Group on Assays and Reference Preparations

A summary of progress made by the Working Group between 18 March and 1 April has been published.

> https://www.who.int/who-documents-detail/summary-of-progress-made-by-the-who-assays-for-vaccines-group-of-experts-(18-march-1-april)

Falsified and substandard products

WHO updated Medical Product Alert n4/2020 relating to falsified chloroquine products to include additional countries in which these products were identified.

Full list of alerts available here: https://www.who.int/medicines/publications/drugalerts/en/

Misinformation regarding "miracle cures", or other approved treatments, as well as scams that attempt to defraud would-be purchasers of medical products in relation to Covid19 continue to proliferate. National health authorities and regulatory agencies are encouraged to liaise with their national law enforcement counterparts (customs, police, judiciary) to ensure that relevant information is shared in a timely manner and to protect the integrity of supply chains.

Supply chain

Supply updates from WHO HQ and Regional Offices

The Global Portal and catalogue of PPEs is now functional and regional offices have had opportunities to participate in training sessions.

Training can be accessed on https://youtu.be/3UACkPbhWXY.

> An excerpt from the announcement of the Portal included the following information and links:
>
> *A catalogue of items that can be requested is available online and is broadly divided into three categories: Personal protective equipment (PPE), Diagnostics and Clinical Management. The Portal is accessed via the COVID-19 Partners Platform.*
>
> *All information is available online, including a guide to requesting and receiving supplies and frequently asked questions.*

Small-Island Developing Countries in Africa (African SIDS) are experiencing shortages of many essential medicines and have requested assistance from WHO. The assistance will move forward in the context of the pooled procurement scheme that is under joint development with WHO and the Secretariat for the African SIDS pooled procurement group.

Many countries are developing quantification plans as a precautionary measure should a second wave of COVID-19 circulate later in the year.

Shipments from UN partners:

Detailed information on UN Shipments are available from the COVID-19 Partners Platform.

Over 105 countries have received shipments of PPE from the UN consortium. Additional products that have been procured include PPE and oxygen concentrators. Procurement of diagnostics is imminent, pending information on production and availability of products. Procurement is implemented across systems of multiple agencies, including WHO, UNICEF and the World Bank.

Shortages:

WHO continues to monitor shortages across regional networks, industry associations and regulatory networks. Shortages of specific products continue. Issues impacting shortages are dynamic and will continue to change as the status of the pandemic and recovery of health systems continues.

Shortages stem from multiple causes, which in this environment continue to have a compounding effect, including:

- Palliative care and some urgent care is shifting to community level facilities, and (where they exist) to long-term care facilities. These facilities may not have been systematically included in forecasting palliative care medicines and an additional demand from these facilities adds to pressures for these products.
- Freight costs continue to be a problem and lack of information regarding flight availability for medicines and health products has become acute, leading to accumulation of goods at ports and docks. This is a critical issue and partners are asked to coordinate information to optimize the use of existing flights.
- The flight availability problem continues to impact supply of API for some medicines as well as finished pharmaceutical products, especially from India.
- Speculative procurement of medicines in clinical trials continues, which continues to skew demand figures.
- Continued high demand for certain ICU medicines, which while has stabilized in some countries, is increasing in others.

A partial list of medicines reported to be in shortage include the following:

- Antibiotics: azithromycin, levofloxacin, metronidazole, amoxiclav, piperacillin, tazobactam
- Renal replacement fluids
- paracetamol
- epinephrine and norepinephrine
- Benzodiazepine sedatives: midazolam and lorazepam
- Nonbenzodiazepine sedatives: propofol
- Antipsychotics: haloperidol
- Neuromuscular relaxants: succinylcholine, atracurium, or vecuronium.

- Opioids: morphine and fentanyl
- Malaria treatments: hydroxychloroquine, chloroquine, Artemether-lumafantrine, Artemisinin-based combination therapies, Sulfadoxine-pyrimethamine + amodiaquine)
- HIV: Lopinavir/ritonavir
- NCD: Metformin
- GI: Nizatidine (use in COVID-19 treatment and a spike in demand due to the recall of ranitidine)

Other products:

- Blood and plasma: In some countries, particularly in areas where clinical trials of convalescent plasma are underway, there are reports of shortages in blood and plasma supply. The shortage is in part due to the unavailability of donors in lockdown measures and also an increase in use.

  WHO guidance: Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19) (20 March)

- Laboratory services for patient samples: in countries where laboratory services are limited, it is normal practice to transport specimens for testing within the country and in some cases to other countries. The lack of transportation is leaving specimens for polio untested. Solutions to use freight flights to move samples to locations that can temporarily be used are under consideration.
- PPE: supplies remain strained.
- Oxygen and ventilators: remain in shortage for a number of countries.

Solutions continue to include:

- alternative supply sources and the regulatory flexibilities to facilitate the implementation
- global labeling to facilitate broader releases to markets
- shifting patients to alternative therapies (relevant to lopinavir/ritonavir)
- allocation models that allow for optimized distribution of medicines within a given country
- allocation models for eventual new medicines, pending outcomes of clinical trials
- special controls on over-the-counter sales, especially through on-line pharmacies (relevant for CQ and paracetamol)
- local production for PPEs and other products where manufacturing capacity can be increased or repurposed

Solutions in limited contexts:

- Some countries report shifting procurement of critical supplies to centralized or federal procurement systems to avoid fragmented demand and to maintain oversite of re-allocation of inventory as needed.
- In countries where medicine supply monopolies/oligopolies exist, anti-trust courts are allowing for direct collaboration and communication about price, supply levels and sources (this would be prohibited under anti-competitive practice laws in some countries to avoid price fixing, etc.)

Transportation

Transportation remains a critical problem and is linked to increasing shortages in some countries. The problem of limited flight availability as well as intra-country transportation have been cited by multiple countries. The lack of information on flight availability has become acute and led to shipments not moving into distribution. Partners are requested to consider means of accessing and using information to optimize use of the available flights. The issue of identifying flight information in advance will also be critical in moving patient samples to testing laboratories as mentioned above.

Manufacturing capacity

While manufacturing capacity in India is reported to have increased to up to 70% for export products and 80% for domestic products. Nonetheless, reports of shortages of API and finished pharmaceutical products are continuing, and WHO is working with industry associations to identify particular problems. The confinement measures in India continue, but have accommodated factory workers and some transportation personnel. Increased access to diagnostics is expected to create another easing of restrictions, but the timing is unknown.

Export restrictions

Export restrictions continue, including restrictions from European countries. This will leave some countries vulnerable to additional shortages and will also limit the potential for any inter-country transfers of inventory (limited to markets with regulatory cooperation).

Procurement of medicines for clinical trials

For countries wishing to access medicines for use in the Solidarity Trials, requests can be made through the Solidarity Trial team. It should be noted that confirmation that medicines are part of sanctioned trials (e.g., approved by an Ethics Review Board, the National Medicines Regulatory Authority and any importation permits) must be available in advance of requesting the medicines.

For the limited number of medicines that are in trials, but that also have existing indications (e.g., hydroxychloroquine and lopinavir-ritonavir), procurement support remains available from UN partners for normal programmatic use outside of clinical trials (i.e., for treatment of malaria, HIV).

Medical Devices

New website on Priority medical devices for COVID prevention, diagnostic and management

In order to protect health care workers, diagnose and treat COVID-19, many medical devices are required.

https://www.who.int/medical_devices/priority/COVID-19/en/

This page will include the 5 subtopics:

- Personal protective equipment
- In vitro diagnostics
- Medical equipment and consumables to manage the patient
- For innovative technologies for COVID
- Global collaboration for medical devices for COVID

Donations of in-kind critical items to WHO

Companies wishing to donate supplies to WHO as part of the COVID-19 emergency response are requested to complete the below form.

WHO is currently only accepting offers of critical items listed in the Emergency Global Supply Chain Catalogue (see below). Minimum requirements are noted within the application form.

Companies are required to submit quality certifications for all items. Prior to the acceptance of any in-kind donation, WHO will review all certifications to ensure they meet WHO minimum technical specifications.

- Access the application form

COVID-19 Biomedical Equipment Inventory Tool

WHO has developed a COVID-19 Biomedical Equipment Inventory Tool (survey) whose aim is to collect facility data on the availability of biomedical equipment (oxygen, accessories and consumables) and ventilators at the country level. These data can serve to inform planning and readiness, at facilities and in-country, as well as to inform WHO's global COVID-19 Supply Chain System of existing capacity so that appropriate equipment is sent to where it can be absorbed, and in an equitable manner.

WHO has a team assembled at HQ to support countries and participants to conduct the survey at facilities in-country, which can be completed electronically via the web or by using a free "app" (SurveyCTO platform), or using a paper survey with an excel spreadsheet "roll-up". We are encouraging countries to complete this survey in order help inform country-level planning, as well as to reduce burden on incredibly stretched global supply chain systems, which are in a current shift towards a WHO-led consortium.

The COVID-19 Biomedical Equipment Inventory Tool can be found at the links below. Of note, WHO is in full support of initiatives already under way to this effect and encourages data sharing to HQ to ensure appropriate allocation.

- WHO Biomedical Equipment Inventory Tool. Quick start guide
- Biomedical Equipment for COVID-19 Case Management Interim guidance Inventory tool for facility readiness and equipment re-allocation (06 May)
- Biomedical Equipment for COVID-19 Case Management (excel, 06 May)

Please contact COVID-MED-DEVICES@who.int for support in implementing the survey, including leveraging existing survey initiatives, as well as if you are willing to participate.

WHO Medical Devices May 2020, Newsletter

The Newsletter provides information on a range of topics, including:

1) the list of priority medical devices for COVID, which describes the medical devices, the purpose of the device and settings where it can be used
2) Emergency supply catalogue
3) the recently launched (01 May) COVID-19 essential supplies forecasting tool
4) rationale for use of personal protective equipment for COVID-19
5) information on WHO and CED hosted COVID19 Critical Topic 1-hour Townhall meetings in May. The townhall meetings planned so far are:

Date: 14:00-15:00 Geneva time	Topic
Tuesday, May 5	Oxygen Systems
Friday, May 8	Masks, Respirators, and Face Shields

Tuesday, May 12	CPAP/BIPAP
Friday, May 15	Pulse oximeters
Tuesday, May 19	Ventilators

The newsletter can be accessed at https://www.who.int/medical_devices/publications/Medical_Devices_Newsletter/en/

Links to critical items https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items

Regulatory Flexibility initiatives

Please see Regulatory Update 7 issued on 01 May for a list of international initiatives. WHO continues to review with a view towards presenting a proposal for best practice principles.

COVID-19 and WHO PQT Inspections - Question & Answers

The WHO Prequalification Unit - Inspections Team has received numerous questions on regulatory expectations and flexibility during the COVID-19 pandemic. To assist Stakeholders, a Question and Answer document has been prepared by Inspections which will be updated periodically to address new questions and to include further information for organizations to the evolution of the pandemic. It will remain valid until further notice.

The document provides basic guidance to manufacturers/laboratories/contract research organizations on regulatory expectations and flexibility during the COVID-19 pandemic in the form of questions and answers. It is underlined that the pandemic is affecting countries at different levels and the progress of the pandemic in each country may be at different stage; hence national measures and guidance should also be considered. The overarching aim is to ensure the quality, safety, efficacy and continuity in the supply of products and services in order to attain a high level of public health.

See: https://extranet.who.int/prequal/sites/default/files/documents/Covid-19_Q-A_May2020.pdf

Access to regulatory updates by WHO staff

All WHO staff have access to the Regulatory Updates at the following location:

P:\PubPersons\RPQ\COVID_Regulatory_Updates