24th WHO Regulatory Update on COVID-19

11 December 2020

World Health Organization

Key Messages

In the initial stages of vaccine rollout, with only a small proportion of a country's population immunized, it's vital that governments, communities and individuals continue using proven public health tools.

Highlights and main issues

- Countries are urged to prepare for delivery of vaccine from the COVAX Facility, in particular priming their regulatory processes for national regulatory approvals based on regulatory reliance mechanisms.
- A Reference Panel for anti-SARS CoV-2 antibody preparation and a SARS CoV-2 RNA preparation have been established as WHO International Standards by the Expert Committee on Biological Standardization.
- The 1st anti-SARS-CoV-2 antibody test has received Emergency Use Listing from WHO.
- A public briefing document has been published outlining the efficacy and safety data submitted to the US FDA on the Pfizer-BioNTech BNT162b2 COVID-19 vaccine.
- The UK regulator, the MHRA issued updated guidance to COVID-19 vaccination centres about the management of anaphylaxis, following two reports of anaphylaxis and one report of a possible allergic reaction following immunization.
- Vaccine efficacy results are reported in a peer-reviewed journal of the safety and efficacy against COVID-19 of the Oxford–AstraZeneca chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19 (AZD1222) in adults aged 18 years and older.
- Adoptive transfer experiments, providing evidence supporting the hypothesis that neutralizing antibodies are mechanistic correlates of protection against SARS CoV-2, were reported to both the Animal Models and Assays Working Groups.
- A draft revision of the *International Pharmacopeia* monograph on Oxygen is available for comment.
- WHO guidance on post-market and market surveillance of medical devices including in vitro diagnostics has been published.

24th WHO Regulatory Update on COVID-19

Contents

Update on the ACT-Accelerator

COVAX

COVAX, the vaccines pillar of the ACT-Accelerator, is convened by CEPI, GAVI and WHO, with the ambition of contracting enough volumes to equitably deliver 2 billion doses of safe, effective and quality vaccines by the end of 2021.

Candidates to be included in the COVAX Facility portfolio are being selected from the COVAX R&D portfolio and other clinical candidates. The intention is to select promising candidates across different technologies and geographies. The final COVAX Facility portfolio is expected to have around 10 or more candidates across 4-5 technology platforms, with early doses available in Q1 2021. Countries are urged to prepare for delivery now, in particular priming their regulatory processes for national regulatory approvals based on regulatory reliance mechanisms.

Alignment of approaches by regulators

Oxygen: Draft proposal for revision in The International Pharmacopoeia

It is proposed to revise the *International Pharmacopeia* monograph on Oxygen. A draft for public comment is based on a review of current pharmacopoeial requirements for oxygen. Comments are in particular sought: on the proposal to combine quality requirements of oxygen produced by cryogenic distillation and by pressure/vacuum swing adsorption (PSA/VSA) oxygen generating plants in one monograph; on the suitability of the proposed test methods; and on the need to specify further impurities. In case additional impurities would need to be added to the monograph, the rationale for the inclusion and suggested test methods and limits which could be used are requested.

contact Dr Herbert Schmidt at schmidth@who.int to obtain "Oxygen: Draft proposal for revision"

(**for comments by 26 Feb 2021 –** template for comments**)**

Draft WHO Guidance for comments:

As previously communicated (22nd Regulatory Update), WHO is seeking comments on draft WHO guidance on Good manufacturing practices for investigational pharmaceutical products for clinical trials in humans and Good practices for research and development facilities.

Draft working document: Good manufacturing practices for investigational products

(**for comments by 06 Jan 2021 –** template for comments**)**

Draft working document: Good practices for research and development facilities

(for comments by 06 Jan 2021 - template for comments**)**

In vitro diagnostics

WHO EUL and listing update

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate in vitro diagnostics (IVDs) to detect SARS-CoV-2. The following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

Manufacturers interested in the EUL submission are invited to contact WHO at diagnostics@who.int and schedule a pre-submission call.

WHO EUL submissions

Applicants are asked to submit their applications for assessment based on WHO instructions and requirements for NAT and Ag detection RDTs and IVDs detecting antibodies to SARS-CoV-2 virus.

Manufacturers who are interested in an EUL submission for assays to detect SARS-CoV-2 are invited to contact diagnostics@who.int, to arrange a pre-submission meeting/videoconference/phone conversation.

So far, 27 products have been listed as eligible for WHO procurement among 55 expressions of interest

for NAT assays, 33 for antibody detection assays and 14 for antigen detection RDTs have been received.

The status of each EUL application (09 Dec 2020)

Recently listed IVDs:

- 1st Anti-SARS-CoV-2 antibody test:

  The Elecsys Anti-SARS-CoV-2 test manufactured by Roche Diagnostics GmbH is an electro-chemiluminescence immunoassay "ECLIA" for the in vitro qualitative detection of antibodies (including IgG) to SARS-CoV-2 in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2. The assay runs on cobas e immunoassay analyzers and the total duration of the assay is 18min.

- Veri-Q PCR 316 Coronavirus disease 2019 (COVID-19) Detection System manufactured by MiCo BioMed Co Ltd
- Bio-Speedy SARS-CoV-2 (2019-nCoV) qPCR Detection Kit manufactured by Bioeksen R&D Technologies Ltd

WHO Information Notice for IVD Users related to all PCR for SARS-CoV-2 NAT

WHO has received user feedback on an elevated risk for false SARS-CoV-2 results when testing specimens using RT-PCR reagents on open systems. Healthcare providers are encouraged to take into consideration testing results along with clinical signs and symptoms, confirmed status of any contacts, and other relevant information. Users of RT-PCR reagents should read the information for users carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a positive result.

WHO Information Note for Users

IVDs 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.

The most recent update (23 Nov 2020)

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

WHO Target Product Profiles for COVID-19 Therapeutics in Hospitalized Patients

A new Target Product Profile (TPP) describes the WHO preferred and minimally acceptable profiles for therapeutic agents for COVID-19. It is intended to guide and prioritize the evaluation of repurposed therapeutic agents for COVID-19 or the development of new therapeutic agents. This document is relevant to those groups who wish to obtain WHO policy recommendations for use and WHO prequalification for their products.

All the requirements contained in WHO guidelines for WHO policy recommendation and prequalification

will also apply. The criteria in the document lay out some of the considerations that will be relevant in WHO's case-by-case assessments of COVID-19 therapeutic agents in the future. As new scientific evidence is generated, this TPP may require further review and revision. It was developed through a consultation process with key stakeholders in human and animal health, scientific, funding and manufacturing communities.

COVID-19 Therapeutics Target Product Profile for Hospitalized Patients (30 Nov 2020)

Research mapping of candidate therapeutics

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

the Pfizer-BioNTech BNT162b2 COVID-19 vaccine

As previously reported, the UKs medicine licensing authority, MHRA, has authorized (under Emergency Use Authorization Regulation 174 of the Human Medicine Regulations 2012) specific batches of the Covid-19 vaccine BNT162b2 supplied by Pfizer and BioNTech on 2nd December 2020.

On 4th December, Bahrain's National Health Regulatory Authority (NHRA) reported approval, on 4 December, of the of Pfizer/BioNTech COVID-19 vaccine for use for high-risk groups.

The vaccine was authorized on 9 December by Health Canada under an Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. After a thorough, independent review of the evidence, Health Canada has determined that the Pfizer-BioNTech vaccine meets stringent safety, efficacy and quality requirements for use in Canada. As part of its continued commitment to openness and transparency, Health Canada will publish a number of documents related to this decision, including a high-level summary of the evidence that Health Canada reviewed to support the authorization of the vaccine, a detailed scientific summary and the full clinical trial data package.

Heath Canada authorizes first COVID-19 vaccine (09 Dec 2020)

Health Canada Authorization Information

Guidance to vaccination centres

On 9 December 2020, MHRA issued updated guidance to COVID-19 vaccination centres about the management of anaphylaxis, following two reports of anaphylaxis and one report of a possible allergic reaction following immunization. The guidance is based on an Expert Group, attended by experts in allergy and clinical immunology, that robustly reviewed these reports to consider any possible mitigation on the rare risk of anaphylaxis.

The guidance states that any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose should not be given to anyone who has experienced anaphylaxis following administration of the first dose of this vaccine.

MHRA Press release: Confirmation of guidance to vaccination centres on management allergic reactions following COVID-19 vaccination with the Pfizer and BioNTech (09 Dec 2020)

Safety and efficacy data available to regulators

Prior to the 10 December meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting, the US FDA released a briefing document outlining the efficacy and safety data that will be considered by the Committee. In an analysis of 36,621 participants randomized 1:1 to vaccine or placebo, efficacy in preventing confirmed COVID-19 occurring at least 7 days after the second dose of vaccine was 95.0%, with 8 COVID-19 cases in the vaccine group and 162 COVID-19 cases in the placebo group. Subgroup analyses of the primary efficacy endpoint showed similar efficacy point estimates across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19. Secondary efficacy analyses suggested benefit of the vaccine in preventing severe COVID-19, in preventing COVID-19 following the first dose, and in preventing COVID-19 in individuals with prior SARS-CoV-2infection, although available data for these outcomes did not allow for firm conclusions.

Safety data from approximately 38,000 participants randomized 1:1 to vaccine or placebo with a median of 2 months of follow up after the second dose suggest a favorable safety profile, with no specific safety concerns identified. The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%). Severe adverse reactions were more frequent after dose 2 than after dose 1,and were generally less frequent in participants >55 years of age (<2.8%) as compared to younger participants (>4.6%). The frequency of serious adverse events was low (<0.5%), without meaningful imbalances between study arms.

Among non-serious unsolicited adverse events, there was a numerical imbalance of four cases of Bell's palsy in the vaccine group compared with no cases in the placebo group, though the four cases in the vaccine group do not represent a frequency above that expected in the general population. Otherwise, there were no notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to BNT162b2 vaccine.

With the exception of more frequent, generally mild to moderate reactogenicity in participants <55 years of age, the safety profile of BNT162b2 was generally similar across age groups, genders, ethnic and racial groups, participants with or without medical comorbidities, and participants with or without evidence of prior SARS-CoV-2 infection at enrolment.

VARPAC meeting (recording and event materials)

First efficacy data on COVID-19 vaccine candidates

Based on press releases, first efficacy data are available for COVID-19 vaccine candidates, namely Moderna, AstraZeneca, Gamaleya and Sinopharm.

The Moderna mRNA vaccine candidate has a preliminary point estimate of efficacy of 94.1%, based on a study of >30,000 participants, in which there were 196 COVID-19 cases (11 in vaccine group), with 30 severe cases, all in the placebo group.

The Gamaleya National Center Ad26/Ad5 vectored vaccine prime-boost candidate has a preliminary point estimate of efficacy of 91.4%, based on a study of >40,000 participants, in which there were 39 COVID-19 cases, with no information provided on case severity.

The Sinopharm/BIBP inactivated vaccine candidate has a preliminary point estimate of efficacy of 86%, based on a study of 31,000 participants. The announcement on the Sinopharm vaccine candidate, made

by the United Arab Emirates, did not say how many of those taking part had become ill or give numbers for those given the vaccine or a placebo.

Vaccine efficacy results are reported in a peer-reviewed journal of the safety and efficacy against COVID-19 of the Oxford–AstraZeneca chimpanzee adenovirus vectored vaccine ChAdOx1 nCoV-19 (AZD1222) in adults aged 18 years and older. These are pooled results of an interim analysis of four randomized, controlled trials conducted in the UK, South Africa and Brazil. Preliminary point estimates of vaccine efficacy, derived from analysis of 131 cases, were 62% for subjects who received the intended 2 doses of $5x10^{10}$ viral particles, and 90% for a subset in one trial who inadvertently received a half-dose of the vaccine as a first dose of the vaccine.

> Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK (The Lancet)

Living mapping and living systematic review of COVID-19 studies

Living mapping and living systematic reviews are available based on daily searches of the literature for candidate vaccines against COVID-19.

The tool allows vaccine comparisons where data are available as well as a table with the general characteristics of each trial. For each vaccine comparison, forest plots for all the outcomes of interest are available as well as the Summary of Findings table.

> The mapping tool is available at: https://covid-nma.com/vaccines/mapping/

Landscape of candidate vaccines for SARS-CoV-2

A landscape analysis of candidate SARS-CoV-2 vaccines is regularly published by WHO. Currently, over 200 vaccines are at some stage of development. Of these, **52 vaccine candidates are in human trial**. About 13 are in or entering phase III trials. There are several others currently in phase I/II, which will enter phase III in the coming 2 months. This is a very robust pipeline – the more candidates, the more opportunities for success (typically success rate of candidate vaccines is 10%).

The candidate vaccines are of various types – virus vaccines using live attenuated virus, viral vector vaccines, protein-based vaccines, and nucleic acid or RNA and DNA vaccines, which are completely new platforms.

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

> Landscape of COVID-19 candidate vaccines (08 Dec 2020)

Research protocols, assays and reference standards

Candidate WHO International Standards for SARS CoV-2 antibodies and RNA

Two major international collaborative studies have concluded, respectively, that a Reference panel for anti-SARS CoV-2 antibody preparation and a SARS CoV-2 RNA preparation are both suitable to be established as WHO International Standards. These reagents are intended as global references against which national reference preparations would be calibrated. Calibration of national references against a single global standard will facilitate comparison of results of assays (e.g. of the antibody response to candidate COVID vaccines) conducted in different countries. The development and scientific assessment through collaborative study of these reagents has been completed in record time.

The WHO Expert Committee on Biological Standardization, in its 73rd meeting held on 9-10 December 2020, endorsed the establishment of both preparations as WHO International Standards.

A summary of the meeting will be provided in the next Regulatory Update.

WHO Working Group: Assays and reference preparations

FIND reported on studies to evaluate molecular tests and immunoassays for SARS-CoV-2 to support accurate, affordable and accessible testing in Low- and middle-income countries (LMIC). Updates on evaluation of serological tests were presented at the 2 December meeting. There is no established gold-standard serological assay for SARS CoV-2 therefore criteria were set for inclusion of assays/suppliers in the study. Study samples included plasma or serum from acute and convalescent individuals across different days post symptom onset, and COVID-19 negative samples. The NIBSC reference panels were also included.

The aim of the study was to assess sensitivity and specificity of the serological assays. The conclusions were that there is considerable variability in performance across the assays evaluated; preliminary clinical performance data for serological Rapid Diagnostic Tests (RDTs) demonstrates that the majority will have insufficient accuracy to enable decentralized/point of care detection of prior infection; 8 out of 16 manual ELISAs would meet the proposed minimal performance for a test for prior infection; and, generally, assays targeting total antibody or IgG demonstrated higher performance than IgA or IgM assays.

FIND evaluation update:

SARS-COV-2 Antigen Detecting Tests

SARS-COV-2 Antibody Detection Tests

SARS-COV-2 Molecular Diagnostics

WHO Working Group: Animal Models

03 Dec 2020 meeting:

The failure of imatinib as an antiviral drug against SARS-CoV-2 was reported. Imatinib inhibits different tyrosine kinases essential for SARS-1 and MERS viral replication, and SARs CoV-2 in Vero cells. However, inhibition of SARS CoV-2 was not confirmed in experiments using a human bronchial epithelium differentiated cell line. Furthermore, experiments performed in golden Syrian hamster confirmed that imatinib does not block SARS-CoV-2 replication in-vivo. The researchers suggest that differentiated cell lines, such as human bronchial epithelium differentiated cell lines, are more predictive for testing of SARS CoV-2 antiviral activity of candidate therapeutics than Vero cells.

Topoisomerase 1 inhibition therapy was reported to protect against SARS CoV-2 induced inflammation in animal models. A topoisomerase inhibitor, Topotecan (TPT), was evaluated in golden Syrian hamsters and found to suppress the inflammatory response following SARS CoV-2 infection and protect against death. TPT is essential for chromatin unfolding and consequent gene expression and is in the Essential Medicines List with a cancer indication. Clinical trials are being planned in patients with severe inflammatory response due to SARS-CoV-2 infection.

03 and 09 Dec 2020 meetings:

Evidence supporting the hypothesis that neutralizing antibodies are mechanistic correlates of protection against SARS CoV-2 were presented in the 03 December Animal Models Working Group (WG) and, by the same group, in the 9 December Assays WG meeting. Adoptive transfer experiments were reported with three different doses of purified IgG from convalescent macaques. After allowing time for the IgG to penetrate into tissues (3 days) the animals were challenged with a combined intranasal and intrathecal dose of SARS CoV-2. Sham infected animals became infected but the adoptive transfer of neutralizing IgG protected, in a dose-dependent manner. The neutralizing antibody levels that protected will be

expressed in International Units, after calibration against the WHO International Standard for SARS CoV-2 antibodies. The protective neutralizing antibody level defined from animal experiments then will be compared with correlates which are expected to be derived from statistical analysis of human clinical trials.

Additional studies were reported to investigate if T cells are relevant to protection, especially at a time when antibody levels have waned. Antibody levels were monitored in 10 macaque's convalescent from experimental SARS CoV-2 infection. When antibody levels had declined, some animals were depleted of CD8 cells by treatment with an anti-CD8 monoclonal antibody. All animals were re-challenged with SARS CoV-2. The data showed that CD8 cells protect animals with waning neutralizing antibody titres. The researchers concluded that cellular immune responses contribute to protection against SARS CoV-2 infection when neutralizing antibodies have declined.

Substandard and falsified products

Request for vigilance and reporting by national regulatory authorities

Regulatory authorities should continue to be vigilant for Substandard and Falsified (SF) versions of Covid-19 related therapies, vaccines and in vitro diagnostics and must report these to the WHO Global Surveillance and Monitoring System : rapidalert@who.int. It is essential to report such products early on, regardless if they are only suspected or fully confirmed.

SF medical products are most likely to reach and harm patients when the below three driving forces combine but a single one is sufficient:

- **Constrained access** affects products which are vulnerable to: shortages, scarcity, unmet or excess demand, acceptability, distorted public perception, affordability, etc.
- **Poor governance** affects environments which are vulnerable to: corruption, inefficient procurement and distribution, unethical individual practices, disorganized administrative structures
- **Weak technical capacity** affects systems where resources are overstretched, there is lack of regulatory oversight and/or control, and awareness and readiness levels are low.

Covid19 has diverted attention (and resources) from other health issues and products. As such, vigilance should be extended to all medical products and not just those with a direct link to Covid-19. Particular vigilance is requested for products where the above-described forces come into play and create a market opportunity for SF versions.

Reports of falsified Covid-19 vaccines

The global surveillance and monitoring system of WHO continues to receive reports of falsified Covid-19 vaccines. Some of these products do not imitate existing / registered / authorized products: this includes unlabeled vials or prefilled syringes, or products with very neutral packaging (simply labelled "Covid-19 Vaccine" with no manufacturing information on the labels). The contents of these products are unknown and a source of safety concern. Note that, to date, WHO has not received any report of falsified Covid-19 Vaccine BNT162b2.

Interpol and Europol have both issued generic warnings and public statements regarding the risk of SF vaccines to prevent Covid19 or influenza. These communications were principally targeted at national law enforcement officers, recommending that they take necessary preventive and precautionary measures to identify and prevent supply of falsified vaccines. National medicines regulatory authorities should therefore be aware that local police agencies may organize targeted seizure operations. We encourage close liaison with relevant law enforcement agencies and are fully available for any

questions, clarifications, or required facilitation.

INTERPOL warns of organized crime threat to COVID-19 vaccines (02 Dec 2020)

EUROPOL: early warning notification Vaccine-related crime during the COVID-19 pandemic (December 2020)

Recently issued alerts, notices and warnings

WHO issued a Medical Product Alert on falsified Harvoni (treatment of hepatitis C). This WHO Medical Product Alert relates to one batch of confirmed falsified HARVONI (Ledipasvir/sofosbuvir) identified in Brazil and Turkey. Available information indicates that these falsified medicines were supplied at patient level and are likely still in circulation. Note that the WHO Global Surveillance and Monitoring System database has prior records of other falsified Harvoni batches. Consistent reporting is essential to determine the scope and scale of such falsified products.

Medical Product Alert N°7/2020: Falsified HARVONI (Ledipasvir/sofosbuvir) identified in the WHO regions of the Americas and Europe (08 Dec 2020)

Supply chain

Shortages

See below for updated lists, including a watch list, newly added products and two important shortages that are not related to COVID, but that are impacted by limited access to health services during the pandemic.

Traceability technologies for use with emergency products

Working documents have been released regarding WHO's position on traceability technologies. Countries are encouraged to consider how national systems will be mobilized to benefit from the 2D data matrix codes on secondary vaccine packaging. World Bank, GAVI, UNICEF and WHO are developing recommendations to countries and will circulate a document for feedback in addition to the existing document for manufacturers.

Watch list and active shortages

WHO is still maintaining a watch list on the following products. There are not active reports of shortages, but the watch list remains in force:

- Antibiotics: azithromycin, levofloxacin, metronidazole, amoxiclav, piperacillin, tazobactam
- 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-lumefantrine, artemisinin-based combination therapies, sulfadoxine-pyrimethamine + amodiaquine)
- NCD: Metformin and insulin
- Antipyretics: paracetamol (aka acetaminophen)
- PPE

- Oxygen and related equipment
- Ventilators

Newly added shortages

The following medicines are showing signals of imminent shortage and should be watched carefully. Hording and speculative procurement should be avoided. Care should be used to ensure the best use of available national inventories. At present, the reports are mainly from European countries:

- Influenza vaccines
- Epinephrine
- Adrenaline
- Ceftolozane/tazobactam

The shortages of Epinephrine and Adrenaline are presumed to be from spikes in demand related to preparing for vaccination campaigns and should resolve without significant action. Similarly, the shortage of porcine-derived heparin is some countries is due to increased use in treating COVID-19 patients; however, this is limited to countries that do not have access to other forms of heparin (bovine-derived) or other new generation anti-coagulants. Influenza vaccines are in shortage in some countries due to limited production of the product.

Two additional products have been flagged given their important, but the shortages is not related to COVID-19:

- Erwinase
- Phenelzine-Sulfate

Medical Devices

WHO guidance on post-market and market surveillance of medical devices

Post-market surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. Post-market surveillance is a crucial tool to ensure that medical devices continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the medical device.

This new WHO document pertains to the objectives and processes for post-market surveillance for medical devices conducted by manufacturers with the assistance of their economic operators, as well as market surveillance conducted by regulators, and the role of other stakeholders in these processes. It describes the measures taken to ensure the ongoing compliance of medical devices with the requirements for safety, quality, and performance after they are placed on the market.

> Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics (09 Dec 2020)