WHO Medical Devices January 2021 Newsletter

Dear colleagues,

2021, new year, new hopes, but still many challenges ahead.

Please find the following 3 sections:

1. WHO Executive board 19 to 26 February

2. 3rd Essential in vitro diagnostic List

3. Interim guidance, consultations and training material

1. WHO 148 Executive Board 18 to 26 January 2021

34 Member States will convene this week to discuss agenda. They will also define the agenda and topics to be discussed in the World Health Assembly in May 2021.

The other 160 Member States can also make statements. The meeting will be on line and anyone is invited to see the webcast (as it has been the last years).

All documents, including agenda, reports and resolutions by topic; members of the board and webcast can be find here: https://www.who.int/about/governance/executive-board/executive-board-148th-session

A summary of information of the discussions can be found in the annotated agenda. https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_1(annotated)-en.pdf

Please note a draft agenda is planned but some topics might be longer in discussion and thus please review the daily agenda as it can change depending on the discussion by topic.

Topics related to medical devices are the following: (click the hyperlink to see the full document)

EB148/6
Global action on patient safety

See pp 1,17 on assuring the safety of every clinical process

EB148/7
Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases

See pp 2,9,16,36 need for better diagnostics and treatment using medical technologies

EB148/9
Expanding access to effective treatments for cancer and rare and orphan diseases, including medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies and other health technologies; and improving the transparency of markets for medicines, vaccines, and other health products

See pp. 2,10,20,23,25,32 on medical devices including in vitro diagnostics and biomedical engineers

EB148/10
Global strategy and plan of action on public health, innovation and intellectual property

See pp 14 and 19 on medical devices including IVDs and PPEs

EB148/11
Antimicrobial resistance

See pp 28 and 36 on diagnostics

EB148/12
Substandard and falsified medical products

See pp23 on concerns for substandard medical devices found during COVID response.

1.2 on Nomenclature for medical devices

EB148/13
Standardization of medical devices nomenclature

This is a continuation from the 2018 discussion in which many Members requested WHO to develop a classification, coding and nomenclature for medical devices but others requested WHO to analyze the existing nomenclatures, mainly GMDN and avoid the development of more systems. Since then WHO analyzed and cannot use proprietary systems, as these are not public goods, and is working with European Commission to align with the European Medical Devices nomenclature and after a transition period to become the International Nomenclature of Medical Devices managed by WHO as a Global good.

EB148/14
Immunization Agenda 2030

EB148/15
Integrated people-centred eye care, including preventable vision impairment and blindness

See pp 6 and 7 for effective cataract surgery

1.3 on WHO'S COVID-19 response

EB148/16
COVID-19 response

See pp 11 on PPEs, 12 on medical equipment and PPEs procured and delivered to countries based in tech specs developed

EB148/17
Public health emergencies: preparedness and response
WHO's work in health emergencies

See pp10 and 13 on technical specifications for procurement of medical devices including PPEs

EB148/18
WHO's work in health emergencies
Strengthening WHO's global emergency preparedness and response

See pp 7 on need to ensure supply of medical devices

3. Essential in vitro diagnostic list

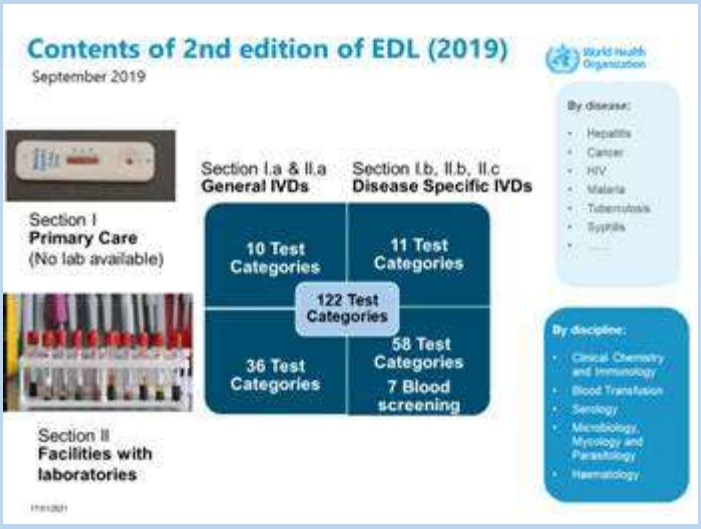
In 2018 WHO convened the Strategic Advisory Group of Experts on In vitro Diagnostics (SAGE IVD) to develop the Essential in vitro Diagnostic List (EDL) in a similar way as the Essential medicines list created 45 years ago by WHO.

Information: https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/

and https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1

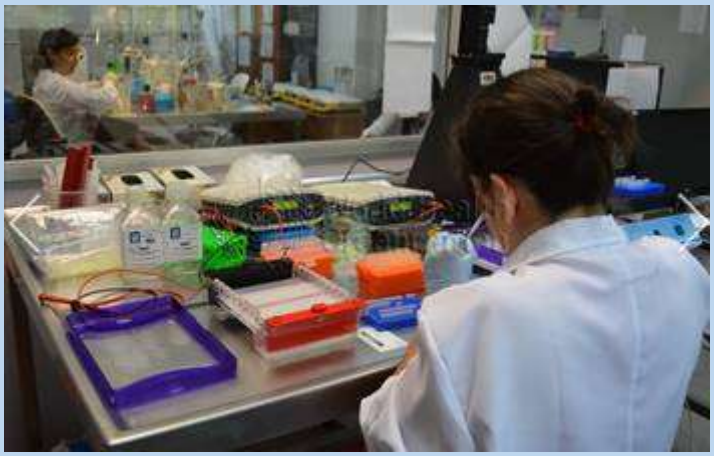
After a year of work, the first meeting was held in March 2018 and the First EDL was published in March 2019.

The Second SAGE IVD hold it's meeting in March to review the submissions and September 2019 the Second Essential in vitro diagnostic list was published.



The 3rd SAGE IVD meeting was planned for March 2020 but needless to explain, that it need to be postponed to be on-line in summer 2020 as many of the member were also tackling the diagnostics work in their countries. It took long.. 20 sessions, 2 hour long, some during June- July- August and then October and November extraordinary meetings to consider COVID-19 tests.

Finally, we cordially invite you to the launch of the 3rd WHO Model List of Essential in vitro Diagnostics in an on-line event 29 of January 14:30 to 16:00 CET.



Agenda will include: Presentation of the 3rd In vitro diagnostic List and panel discussions.

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Learn More | Meeting options

Information : EDLsecretariat <EDLsecretariat@who.int>

3. Interim guidance, publications, consultations and training material for COVID-19

2.1 Interim guidance from November and December 2020

1.On Medical devices:

- **Priority medical devices for COVID-19 and associated technical specifications (20 Nov 2020): https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2**

2.On the Personal protective equipment:

- **Technical Specifications (13 Nov 2020) https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1**

- **Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages (23 December 2020)** https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages
- **Mask use in the context of COVID-19, (1 December 2020)** https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

3. On in-vitro diagnostics,

- Information about emergency use listing, https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open (new website dec 2020)
- Laboratory assessment https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing (23 October 2020)
- Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays (11 September 2020) https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays

4. On the role of imaging diagnostics

- You can find the role of ultrasound, chest X rays and CT scanners, here. https://www.who.int/publications/i/item/use-of-chest-imaging-in-covid-19
- And you can review chapter 8 of the Priority medical devices for COVID for the technical specifications **https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2**

5. **The Emergency Global Supply catalogue. Updated 11 November 2020.**

- https://www.who.int/publications/i/item/emergency-global-supply-chain-system-(covid-19)-catalogue

6. **To support the cold chain and delivery of vaccines, new guidance was recently published** (NEW!)

- https://www.who.int/publications/i/item/background-document-on-mrna-vaccine-bnt162b2-(pfizer-biontech)-against-covid-19

- https://www.who.int/publications/i/item/background-paper-on-covid-19-disease-and-vaccines

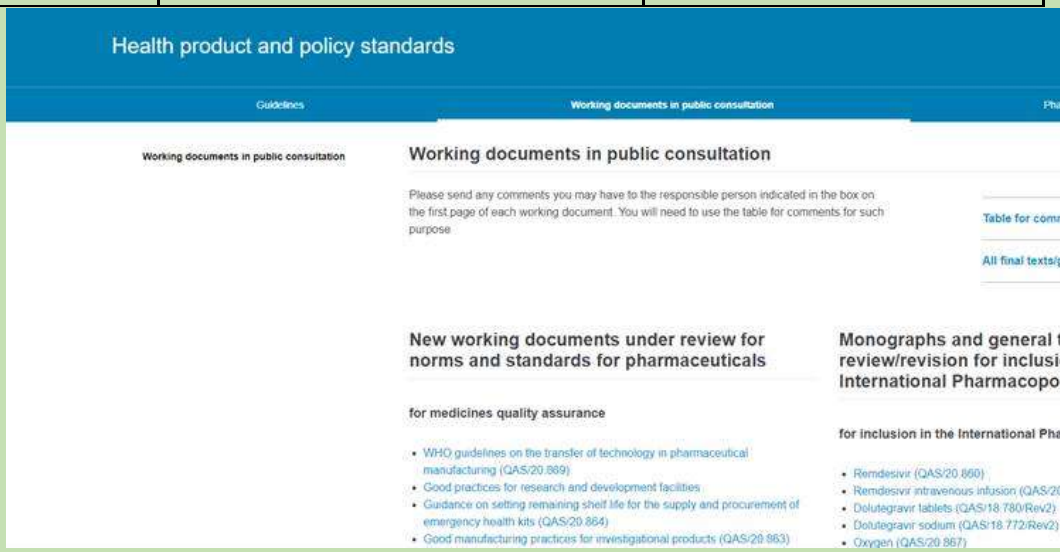
2.2 Consultation

Oxygen is essential medicine and indispensable for COVID-19 management but also for surgeries, trauma, emergencies, other respiratory diseases like Pneumonia

Please review this and comment: "OXYGEN Draft proposal for revision in *The International Pharmacopoeia*"

We invite you to review the following draft working document which will be posted on the WHO Medicines website under "*Monographs and general texts under review/revision for inclusion in The International Pharmacopoeia*":

https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation		
Please use the attached form to provide your comments	**Contact: Herbert Schmidt** (schmidth@who.int);	**Deadline** 26 February 2021



2.3 Training and learning. Check for new courses.

- **https://openwho.org/**

- "OpenWHO is WHO's interactive, web-based, knowledge-transfer platform offering online courses to improve the response to health emergencies.
- OpenWHO enables the Organization and its key partners to transfer life-saving knowledge to large numbers of frontline responders."

- **https://www.who.int/about/who-academy/**
  - "With COVID-19 science now doubling every 20 days and new guidance being published daily by WHO, the WHO Academy continues to improve its COVID - 19 mobile learning app so that health workers can keep up with the constantly evolving knowledge related to this disease."

Still in January, so wishing you a peaceful, healthy, joyful 2021 for all, everywhere.

Sincerely

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