## The capture of WHO – and the need to stopp pandemic preparedness and response activities

By Dr. Silvia Behrendt, Director of the Agency for GHR, held at the European Parliament, 19th of April 2023



"Only man has law. Law must be built, do you understand me? You must build the law."

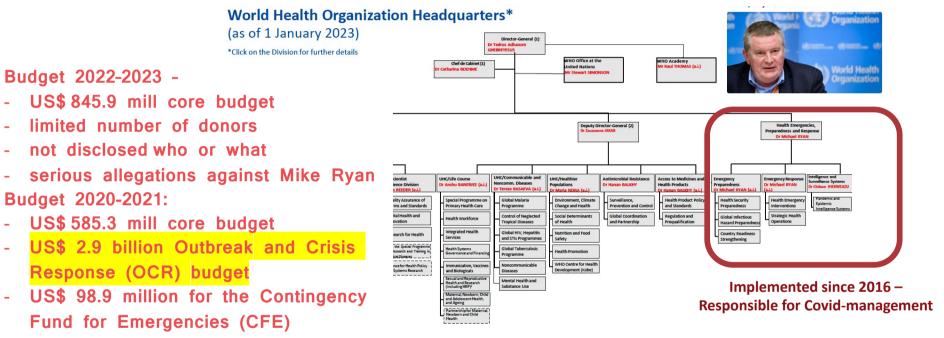
Raphael Lemkin, drafter of the Genocide Convention

#### Vision

We must build an international legal order where human dignity, fundamental freedoms and the inviolable human rights are respected during times of war and peace and any violation by an international organisation or other actor is held to account.

### # stopp Privileges & Immunities

## Structure of HQ



<u>152.EB</u> reads : "The Committee requested the Independent Expert Oversight Advisory Committee to continue its work to finalize the process for handling <u>potential allegations</u> against the Executive Head of the Organization."

GLOBAL HEALTH L. Iro RESPONSIBILITY Global Health Responsibility Agency, Austria Dr. Silvia Behrendt, Director eMail: silvia.behrendt@ghra.ngo  $T_0$ Ministrstvo za zdravje Dr. Vesna Kerstin Petrič Chair of the Executive Board of the World Health Organization Budget 202 1000 Ljubljana eMail: vesna-kerstin.petric@gov.si **US\$ 84**! limited Subject: Allegations - OIS- development of standardized procedures Subject: Allegations - OIS- development of standardized procedures update of anti-corruption & fraud policies & conflict-of-interest declarations not di serio **Budget** Dear Dr. Petrič, US\$ Elsbethen, 28th March 2023 JS in your honorable function as Chair of the Executive Board, I was pleased that you including microlif the in your honorable function as Chair of the Executive Board, I was pleased that you provided representatives of the civil society throughout Europe, including myself, the messihility to meat with you in percon on the 13th of March 2023 in Liuhliana to discuss Provided representatives of the civil society throughout Europe, including myself, the possibility to meet with you in person on the 13th of March 2023 in Ljubljana to discuss several items of concern I narticularly thank you for your accortion that transportance and Possibility to meet with you in person on the 13th of March 2023 in Ljubljana to discuss several items of concern. I particularly thank you for your assertion that transparency and accountability of WHO are principle during your tenure Re severai items or concern. I particularly thank you for your a accountability of WHO are priorities during your tenure. US One of these discussion topics concerned WHO's general approach to fraud and corruntion prevention detection and resonance as covered under the new WHO Policy One of these discussion topics concerned WHO's general approach to fraud and corruption prevention, detection, and response, as covered under the new WHO policy "Preventing" Information Note Fi Corruption prevention, detection, and response, as covered under the new WHO Policy "<u>Preventing, Detecting and Responding to Fraud and Corruption</u>", Information Note Number 12/2022 4th Index 2022 and the current allegations against the Evecutive "Preventing, Detecting and Responding to Fraud and Corruption", Information Note Number 12/2022, 4th July 2022, and the current allegations against the Executive Director, Mike Ryan and notential allegations against the Director of the Office of Internal Number 12/2022, 4<sup>th</sup> July 2022, and the current allegations against the Executive Director, Mike Ryan and potential allegations against the Director of the Office of Internal Ovareight Corvicae Particularly, in the Report of the Programme, Budget and Administration Committee Particularly, in the Report of the Programme, Budget and Administration Committee (PBAC) of the Executive Board, <u>FB142/4, para 11</u>, it was requested for its 37th January committee (FDAC) of the Independent Expert Oversight Advisory Committee (FDAC) shall initiate (PBAC) of the Executive Board, <u>EB142/4</u>, <u>para\_11</u>, it was requested for its 37th January session that the Independent Expert Oversight Advisory Committee (IEOAC) shall initiate work to **develop a standardized anneach and align it with hest practices in the** Session that the Independent Expert Oversight Advisory Committee (IEOAC) shall initiate work to **develop a standardized approach and align it with best practices in the** Inited Nations evetom process for handling protections for both the Work to develop a standardized approach and align it with best practices in the United Nations system process for handling potential allegations for both the Director Office of Internal Oversioht Cervices drawing as appropriate from existing existing the standard United Nations system process for handling potential allegations for both the Director, Office of Internal Oversight Services, drawing as appropriate from existing

We requested more information about the allegations regarding Mike Ryan from the current Chair of the Executive Board of the WHO, Dr. Petric from Slowenia

> vered to the thirty-eighth meeting of ation Committee from Wednesday, 17 May to

Developing a robust standardized process of investigation applicable on the entire leadership management team of WHO, including the Director-General, and across all three management levels of the Organization is an essential ingredient to transform the leadership management team of WHO, including the Director-General, and across all three management levels of the Organization is an essential ingredient to transform the commitment of zero tolerance of fraud and corruption into reality by taking immediate three management levels of the Organization is an essential ingredient to transfor commitment of zero tolerance of fraud and corruption into reality by taking imme disciplinary measures and transparent communication of ongoing allegations. Any commitment of zero tolerance of fraud and corruption into reality by taking immediate disciplinary measures and transparent communication of ongoing allegations. Any new standardized process to be developed has to take this into account. disciplinary measures and transparent communication of ongoing standardized process to be developed has to take this into account. For this purpose, I would like to recommend to the Member States and the IEOAC to draw upon the outlined legal instruments comprised in the OECD-UNODC WB \*Anti-corruption For this purpose, I would like to recommend to the Member States and the IEOAC to draw upon the outlined legal instruments comprised in the OECD-UNODC\_WB <u>Anti-corruption</u> ethics and compliance handbook for husiness". 2013, which includes the United Nations upon the outlined legal instruments comprised in the OECD-UNODC. WB "Anti-correspondence for business". 2013, which includes the United Nations Convention against Corruption, or the UNCAC, and the Convention on Combatine Bribery ethics and compliance handbook for business." 2013, which includes the United Nations Convention against Corruption, or the UNCAC, and the Convention on Combating Bridery of Foreign Public Officials in International Business Transactions as well as regional Convention against Corruption, or the UNCAC, and the Convention on Combating Briber of Foreign Public Officials in International Business Transactions as well as regional instruments like the Inter-American Convention Akainst Corruption, the African Union's of Foreign Public Officials in International Business Transactions as well as regional instruments like the Inter-American Convention Against Corruption, the African Union's Convention on Preventing and Combating Corruption, the Council of Europe's Criminal instruments like the Inter-American Convention Against Corruption, the African Union's Convention on Preventing and Combating Corruption, the Council of Europe's Criminal Law Convention on Corruption and Civil Law Convention on Corruption; the European Convention on Preventing and Combating Corruption, the Council of Europe's Criminal Law Convention on Corruption and Civil Law Convention on Corruption; the Suropean Union's anti-corruption policy, outlined in Article 29 of the Treaty on European Union and Law Convention on Corruption and Civil Law Convention on Corruption: the European Union's anti-corruption policy, outlined in Article 29 of the Treaty on European Union and carried out via two main instruments: the Convention on the Protection of the European Union and Union's anti-corruption policy, outlined in Article 29 of the Treaty on European Union and Carried out via two main instruments: the Convention on the Protection of the European Communities' Financial Interests and the Convention against Corruption Involving Indities' Financial Instruments: the Convention on the Protection of the European nunities' Financial Interests and the Convention against Corruption Involving pean Officials of Member States of the European Union. The document Communities' Financial Interests and the Convention against Corruption Involves European Officials or Officials of Member States of the European Union. The document norwides the essence of existing global laws that have to followed to combat fraud and European Officials or Officials of Member States of the European Union. The document provides the essence of existing global laws that have to followed to combat fraud and corruption within international business corporations, while standards and corruption within international ousiness corpora intergovernmental organizations must be much stricter. e essence of existing global laws that have to followed to combat fraud ar within international business corporations, while standards imental organizations must be much stricter. However, any investigation procedure is only secondary to taking **preventive action** against fraud and corruption, as it cures the disease and not only its symptoms. Generation speaking, decision making by WHO's international officials should serve the action interest and be in line with its Constitution and not hide behind veils of confidentiality or speaking, decision making by WHO's international officials should serve the public interest and be in line with its Constitution and not hide behind veils of confidentiality or Therefore, this is an urgent call upon Member States' awareness and also upon the need to take immediate action for the purpose of transparency and accountability through Therefore, this is an urgent call upon Member States' awareness and also upon the need to take immediate action for the purpose of transparency and accountability the addressing the actual shortcomings of scrutiny at the level of the leadership team. to take immediate action for the purpose of transparency and accountability the addressing the actual shortcomings of scrutiny at the level of the leadership team. In addition to the development of a standardized process, the Member States are under an obligation to introduce appropriate standards for accountable. In addition to the development of a standardized process, the Member States are appropriate standards for accountable framsparency measures towards the WHO headquarters accountable teams, including the Director-General, the Deputy Director for accountable for accountabl transparency measures towards the WHO headquarter teams, including the Director-General, the Deputy Director

It is important to consider that any disciplinary and investigative processes must constitute a deterrent for the staff members and, as a standard-operating-procedure, the

It is important to consider that any disciplinary and investigative processes in the staff members and, as a standard operating processes must staff under investigation is normally suspended during on-going investigations for

constitute a deterrent for the staff members and, as a standard-operating procedure staff under investigation is normally suspended during on-going investigations for the Durpose of due process and avoiding further harm to the Organization. As of vet, no staff under investigation is normally suspended during on going investigations for the purpose of due process and avoiding further harm to the Organization. As of yet, no deterrent and due process disciplinary measures have been applied nor are there any the purpose of due process and avoiding further harm to the Organization. As of yet, no deterrent and due process disciplinary measures have been applied nor are there any regulatory pathways available vet that would set visible lines of conduct for the staff what

deterrent and due process disciplinary measures have been applied nor are there are the statistical of the s regulatory pathways available yet that would set visible lines of conduct for the staff what to expect in case of investigations of if there is a suspicion that WHO's policies and rules are not followed appropriately.

or-4 dha US

Executiv the Progr

Friday, 19 M

ented since 2016 -For Covid-management

mittee requested the Independent Expert mittee to continue its work to finalize ig potential allegations against the Executive ion."

Organization

## WHO's official organs

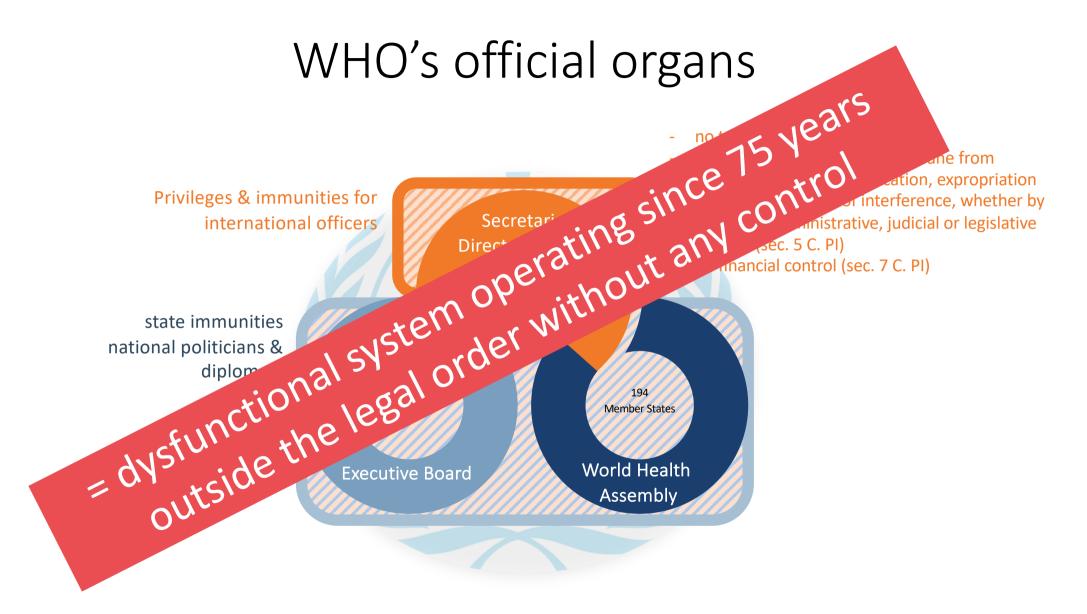


## WHO's official organs



Full immunity protection of the Secretariat, only level of control is Member States

- no taxes
- no domestic legal system immune from search,
  requisition, confiscation,
  expropriation and any
  other form of
  interference, whether by
  executive, administrative,
  judicial or legislative
  action." (sec. 5 C. PI)
- no financial control (sec. 7
   C. PI)



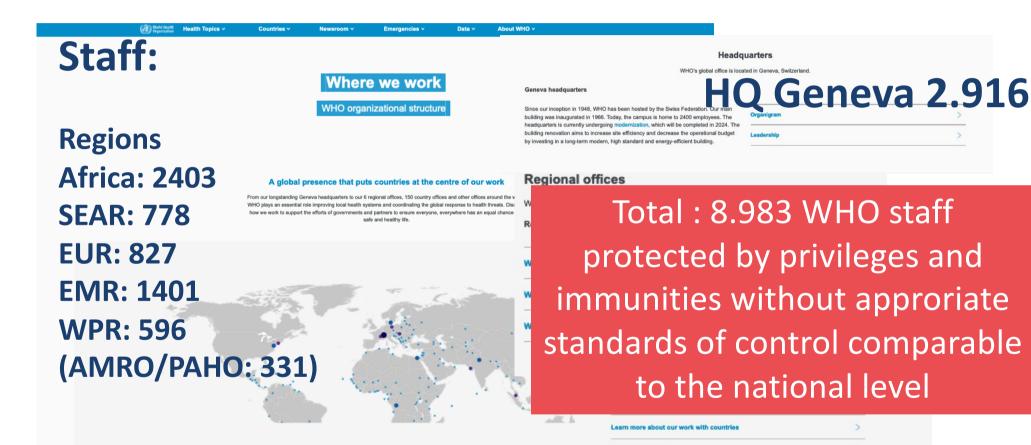
## WHO global expansion



#### WHO global expansion



### WHO staff



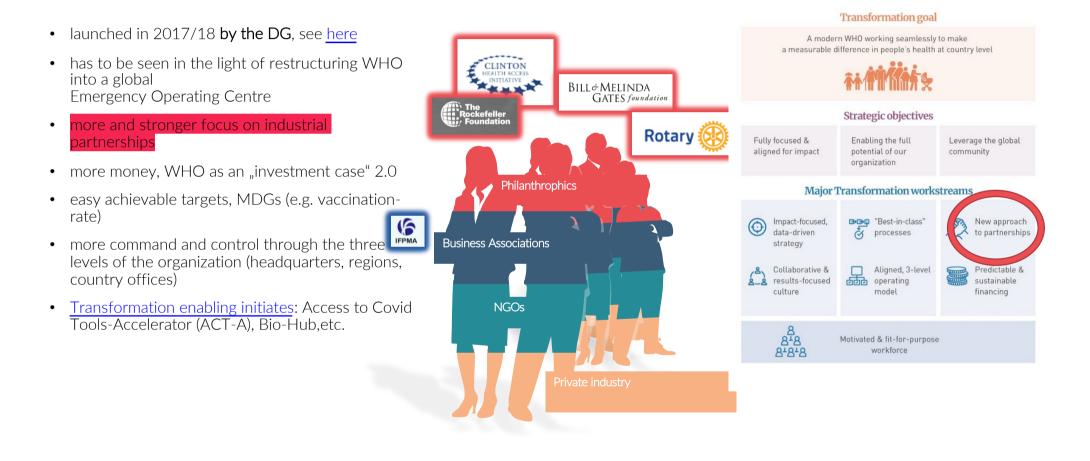
**Country overviews** 

#### # stopp WHO capture by stakeholders

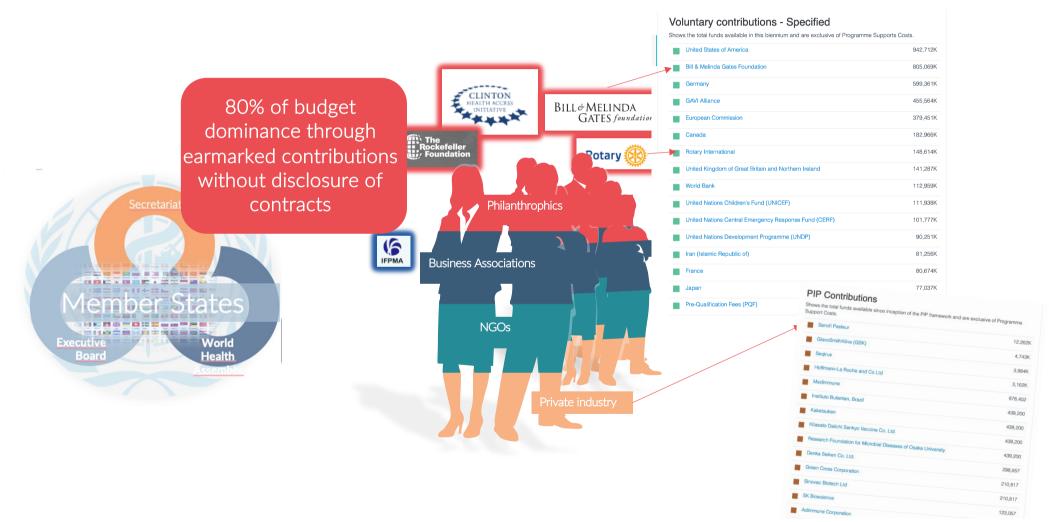
## **Stakeholders Capture of WHO**



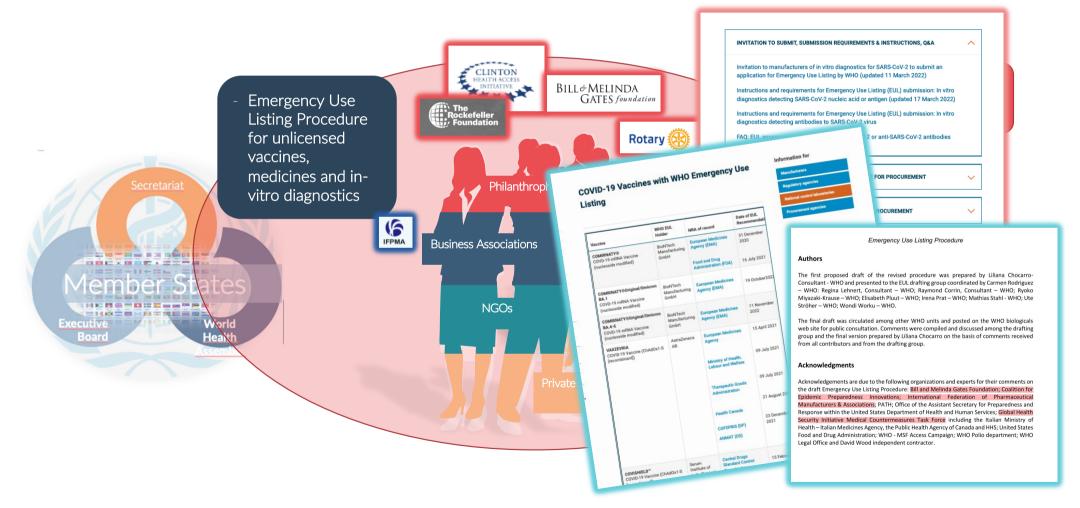
# Stakeholders: Transformation of WHO by DG



# Stakeholder-Budget Capture of WHO



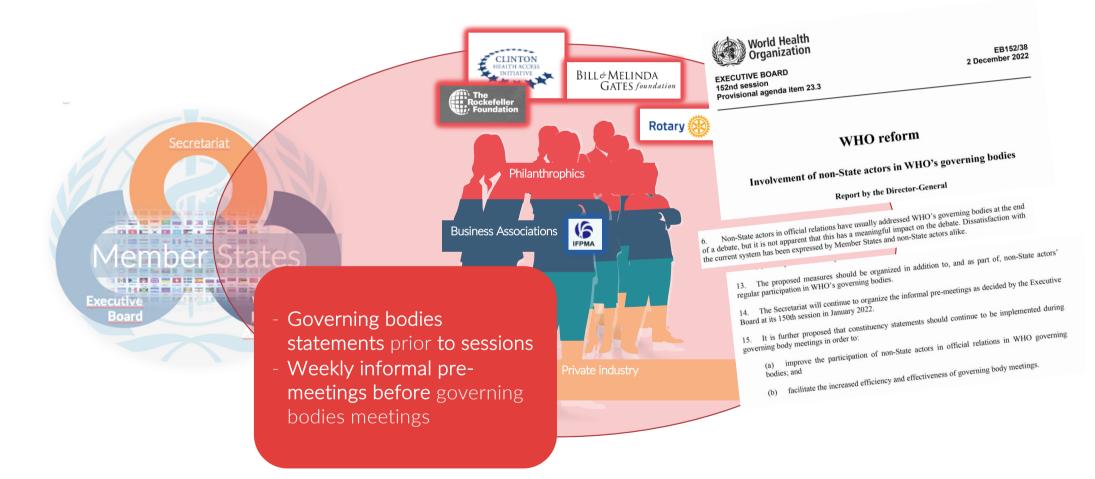
## Stakeholders: Regulatory Capture of WHO



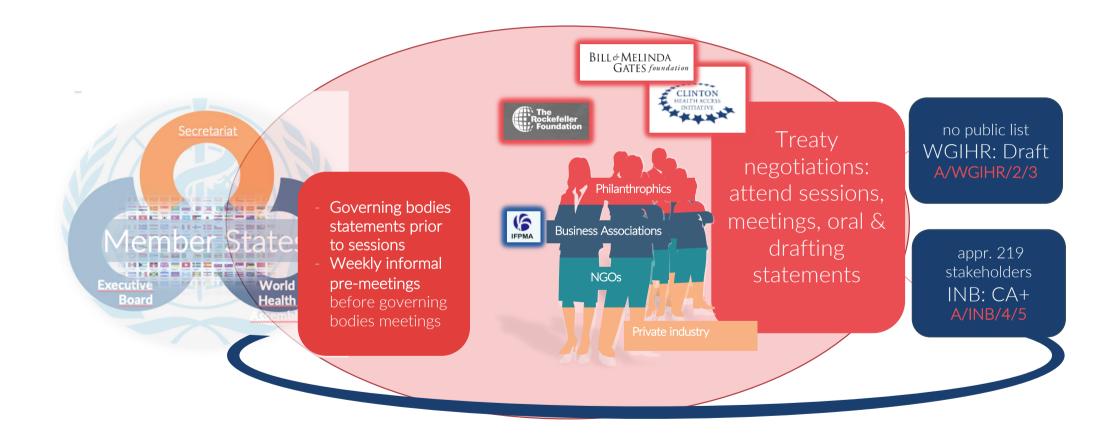
# Stakeholders-Regulatory Capture of WHO



# Stakeholders-Regulatory Capture of WHO



### Stakeholders: Regulatory Capture of WHO



## Stakeholders-Regulatory Capture of WHO

**IFPMA** 



STATEMENT 22 MARCH 2023

#### WHO Intergovernmental Negotiating Body (INB) intersessional briefing o "Access and benefit sharing"

BY IFPMA

Statement J

On 22 March, IFPMA delivered a shortened version of the below statement at the WHO INB intersessional briefing on "Article 10: WHO Pathogen Access and Benefit Sharing System, with the Pandemic Influenza Preparedness Framework as an example" of the WHO convention, agreement, or other international instrument on pandemic prevention, preparedness, and response ("WHO CA+").

> Via the Berlin Declaration, industry has expressed its commitment to early access to reserve an allocation of real-time production of vaccines, treatments, and diagnostics for priority populations in lower-income countries, and to take measures to make them available and affordable

Industry disagrees with the proposed transactional approach to benefit-sharing outlined in Article 10 of the Zero Draft of the CA+ (the "PABS System") and which mimics that of the PIP Framework. Such approaches are more than likely to delay access to pathogens and the timely development of medical countermeasures in the event of a pandemic. Industry's experience with the Nagoya Protocol has shown that a transactional approach is not compatible with rapidly accessing pathogens, particularly when rapid response is needed for epidemics and pandemics. Access to pathogens and their associated information must be fast, easy, and legally certain, and not built on a transactional principle.

Beyond the shortcomings of transactional approaches, due to the specificities of

#### INDA PROTEINENT DOLLAR DOL

#### Sfounda WHO Interdovernmental Neglotiating Body (NR)

ersessional briefing on the "Sustainable and equ stributed production"

WHO Intergovernmental Negotiating Body (INB) intersessional briefing on "Access and benefit sharing" RENT RY: Relevance 🔆

S:

ons

WHO Intergovernmental Negotiating Body (INB) intersessional briefing on the "Transfer of technology and know-how

#### STATEMENT ST MAR SORT WHO Intergovernmental Negotiating Body (INB) intersessional briefing on "One Health and the

Quadrinartite"

#### STATEMENT ST MAR SORT WHO Intergovernmental Negotiating Body ( intersessional briefing on the "Predictable global supply chain and logistics network"

17 March 100464 delivered a shorters

#### ENTEMENT 247

-----

Industry statement at fourth meeting of the Intergovernmental Negotiating Body (INB) for a WHO instrument on pandemic prevention, preparedness an response

Pharma industry contributions to third meeting of the Intergovernmental Negotiating Body (INB)

#### no public list WGIHR: Draft A/WGIHR/2/3

appr. 219 stakeholders INB: CA+ A/INB/4/5

# Excurs: EU - the negotiations mandate

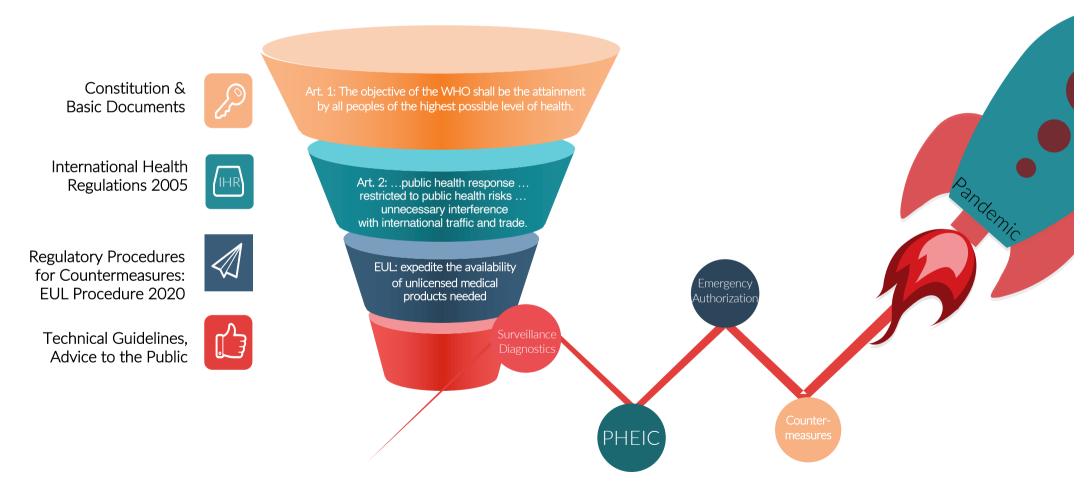
21.3.2022       EN       Official Journal of the European Union       L 92/1         COUNCIL DECISION (EU) 2022/451         of 3 March 2022         authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)	The EU has the accreditation on the same level as Member State sat the WHO under the title "regional economic integration organization" – no limitations
<ul> <li>THE COUNCIL OF THE EUROPEAN UNION,</li> <li>Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) in conjunction with Article 218(3) and (4) thereof,</li> <li>Having regard to the recommendation from the European Commission,</li> <li>Whereas: <ol> <li>On 31 May 2021, by means of its decision WHA74(16), the 74th World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the benefits of developing a World Health Assembly (WTFAT to be convened in order to consider the preserved process to draft and negotiate and protection and Article 168(5) TFEU, in the area of the protection and improvement of combating serious cross-border threats to health, Union action should support, coordinate or supplement of means to be and the resources assigned to them, should be fully respected throughout the negotiate and the allocation of the resources assigned to them, should be fully respected throughout the negotiate are and the allocation of the resources assigned to them, should be fully respected to urge WHO in the allocation of the WHA, which took place from 24 to 29 January 2022, decided to urge WHO potential amendments to the IHR.<!--</td--><td>htereste threete the of human health, and warning of and their health policy and itating process. Invace industry</td></li></ol></li></ul>	htereste threete the of human health, and warning of and their health policy and itating process. Invace industry

# Stakeholders Business Capture of WHO



# # stopp pandemic superpowers

# WHO Legal Architecture

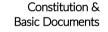


# WHO Governance of Infectious Diseases



WHO's Director-General has unparalleled executive authority without control powers

# WHO Governance of Infectious Diseases



International Health Regulations 2005

Regulatory Procedures for Countermeasures: EUL Procedure 2020

> Technical Guidelines, Advice to the Public



#### Director-General's legal and factual authorities:

Art. 31, 32 Constitution: <u>chief technical and administrative officer</u>, *ex officio* Secretary of the WHA, EB, all commissions, committees, conferences... Financial Regulations In charge of financing /budget/donations/interpretations

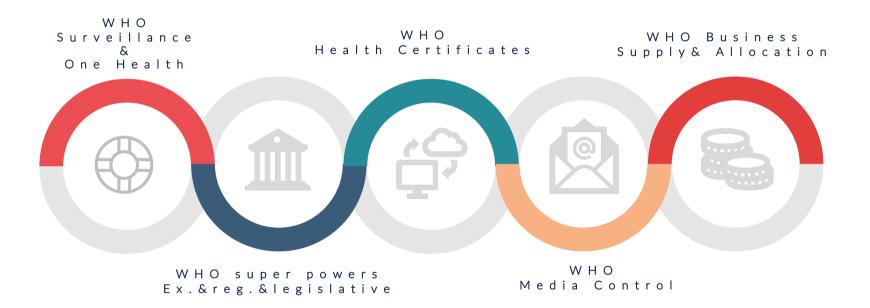
Art. 12: Public Health Emergency of International Concern Art. 15: Temporary Recommendations

Regulation of medical countermeasures 5.2.2. EUL "The recommendation of the TAG-EUL will be used by WHO to decide ...."

advises directly towards the civil society by slogans like "no one is safe until everybody is" – ascertains the safety and efficacy of the Covid-vaccines

### # stopp pandemic treaty & IHR amendments

## Some issues of concern





#### WHO Surveillance & One Health

CA+ Art. 10 WHO Pathogen Access and Benefit-Sharing System (the "PABS System") including 20% (10% donation/10% affordable price) of pandemic related product

IHR: Overlap with rapid sharing with WHO genetic sequence data under Art. 6 Notification

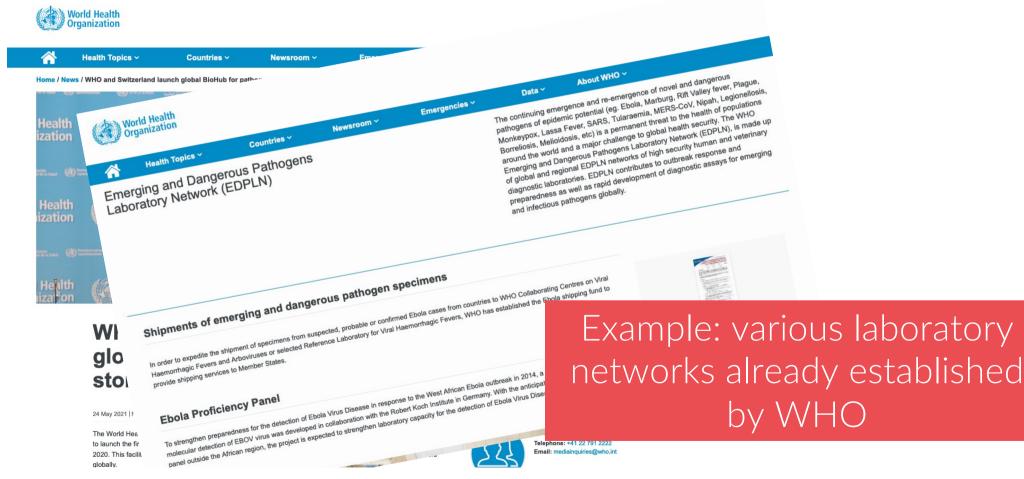


- Gain-of-function
- Prohibition under Biological Weapons Convention dual use function of creating PPP
- IP protection for viruses no further regulatory action to prohibit the patent protection on genetic sequences



- Pandemic influenza Preparedness Framework (PIP)
- R&D fostering by industrial partnerships
- Advanced WHO Laboratory Networks- WHO BioHUB Spiez





#### Pandemic Influenza Preparedness (PIP) Framework

World Health

WH

glob

stora

globally

The PIP Framework brings together Member States, industry, other stal global approach to pandemic influenza preparedness and response. strengthen the sharing of influenza viruses with human pandemic pote developing countries to vaccines and other pandemic related supplies. Member States. It came into effect on 24 May 2011 when it was unanimative World Health Assembly (2011).

Standard Material Transfer Agreements (SMTA2) J Her Banamericana de la salud

What is an SMTA2? work Benefit The SMTA2 is one of the two PIP Frameand the is one of the two for framework centers een WHO and an influenza product manufactury ucument verve and an initiative previous manufacture Biological Materials (PIP BM), such as influenza vin which is part of the Global Influenza Surveillance & or the rate of the entity commits to provide to WHO. to rir bm, the entity contrains to provide to entity to the second to (e.g. vaccines) rechnology license) or respons to test-vacunes concluding SMTA2s now, WHO will have predict conclusing on two town arrow and the product vaccines, antivirals and diagnostics, when they

Who is required to sign a

Non-GISRS recipients of PIP BM must

Indard Material Transfer Agri

Example: PIP already established including access and benefit sharing mechanisms

the United Nations Now, convention or as

ution, or other entity that receives PIP

Shipments of emerging and dangerous pa In order to expedite the shipment of specimens from suspected, probab n oruer to expensive the supprisent of speciments from suspected, probab Haemorrhagic Fevers and Arboviruses or selected Reference Laborator provide shipping services to Member States. 24 May 2021 | News

Ebola Proficiency Panel To strengthen preparedness for the detection of Ebola Virus Disease in re High prevariances on the second of the collaboration with the The World Health C alon, the project is expected to strengthen lab to launch the first W 2020. This facility wi

# **One Health**

CA+ - Art. 18 - identify one health drivers for pandemics (spillovers), capacities and surveillance, national planning, authorize Quadripartite organisations

IHR: Enhanced surveillance draft Annex 1 IHR, expanding wider health system capacities, including One Health



Э

- No commitment that human health is given priority of animals and environment
- No evidence of high zoonotic spill-over rate
- No consideration that spill-overs are taking place in crowd farming and not natural ecosystems
- eventually climate lockdowns to protect the universe



- Quadripartite Alliance established 2022 WHO-UNEP-FAO-OIE
- Integration of one health surveillance in technical guidelines
- One Health High-Level Expert Panel (OHHLEP)

# **One Health**

Related

News

One Health Initiativ

Fact sheets

Health Joint Plan of Actio hed to address health threa

The Quadripartite One Health Joint Plan of Action (OH JPA) at the World One Health Congress 8 November 2022 09:00 – 10:30 SGT | Sands Expo & Convention Centre, Singapore World Organ

#### World Health Organization

for Animal He

The One Health Joint Plan of Action (OH JPA) was developed in response to international requests to prever The One Hearth Joint Plan of Action (UH JPA) was developed in response to international requests to prever pandemics and to promote health sustainably through the One Health approach. It outlines the commitment pandemics and to promote nealth sustainably through the One Health approach. It outlines the commitmen Quadripartite four organizations (FAO, UNEP, WHO and WOAH) to collectively advocate and support the Quadripartite four organizations (FAQ, UNEF, WHQ and WQAH) to collectively advocate and support the implementation of One Health. It builds on, complements, and adds value to existing global and regional Or Imprementation or One Health. It builds on, complements, and adds value to existing global and regional Or and coordination initiatives aimed at strengthening capacity to address complex multidimensional health rid

more resilient health systems at global, regional, and national levels.

Food and Agriculture

 enhancing countries' capacity to strengthen health systems under a One Health approach; The plan includes six action tracks: reducing the risks from emerging or re-emerging zoonatic epidemics and pandemics; requiring are take front enterging or re-enterging zoonouc epidemics and pandemics;
 controlling and eliminating endemic zoonotic, neglected tropical and vector-borne diseases;

- writering and eliminating endernic zoonous, regressed appear and vector-point user
   strengthening the assessment, management and communication of food safety risks; overgenering are assessment, management and communication or
   curbing the silent pandemic of antimicrobial resistance (AMR); and The event will serve as an occasion for the Quadripartite members to present the plan and discuss the
- The event wat serve as an occasion for the customparete memoers to present the plan are onscurs t and challenges with all stakeholders, especially from academia, for its roll-out and implementation.

Session chair: Molecome and introduction of speakers (10 min): the Health and Policy, EcoHealth Alliance

#### One Health High-Level Expert Panel (OHHLEP) . Dr William F





#### Professor Marion Koopmans Director of the WHO Collaborating Centre for emerging infectious diseases at Erasmus Medical Centre, Netherlands

contribution to sustainable development

of Action at all levels and to support co



One Health Joint Plan of Action

and the Quadripartite partners

launched and presented by WHO

Ultimately, this coordination should improve the health of humans, animals, plants, and the environment, while

a plan was launched on 18 October 2022, during a joint event at the World Health Summit in Berlin, hosted by th

Ministry for Economic Cooperation and Development (BMZ), the Deutsche Gesellschaft für Interna nenarbeit (GIZ), the Museum für Naturkunde and the Foundation Healthy Planet-Healthy People.

It use than presented at the hisnnis! World One Health Convress held this year in Singapore. The focus of that

Breaking the silos that exist between sectors and disciplines will require innovative approaches and strengthening of

trative, scientific, economic and political will. Greater investment in applied and multidisciplinan ministrative, scientific, economic and poincal will, oreater investment in applied and memory-tation research, including in social behaviour change across the spectrum from building new knowledge to permentation research, including in social benaviour change across the spectrum internousing new kn lofing and scaling is needed to enable sustainable, locally relevant scientific and evidence-based interve annel scientific inquiry toward positive change.

ntries to establish or further strengthen their One Health systems and

as then preserved at the oriential workd one relation. Congress, here ference was on how One Health could support the COVID-19 reco ctice. The pandemic has spurred many governments to look for gu on is providing them with a framework in which to move forward.

rtite is currently developing an implement

a busy and productive year for WHO's One Health Initiative, together with the other Quadrin 2022 has been a busy and productive year for VMO's one nearin inserve, together with the oner Guasanpartite members, the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), and the World Organization for Animal Health (WOAH), launched the One Health Joint Plan i

ter prevent, predict, detect, and respond to health threats

onalize the One Health Joint Pla



pacitie

\*

The Deve

About Publ

#### Example: Quadripartite One Heath, High-level threats panel



### WHO super powers: executive & regulatory& legislative

# DG executive powers to declare emergencies

CA+ - Art. 3 – Director General shall determine whether the event constitutes a pandemic situation IHR: Art. 1/Art. 12 Director General/Regional Directors shall determine whether the event constitutes a regional emergency or intermediate health alert



- required change of wording "PHEIC" public health problem/event only semantics introduce emergency system
- required stop of uncontrolled powers to declare, unparalleled legal capacities of DG
- no precautions against arbitrariness of procedure without oversight (moneypox)
- global health security doctrine not in accordance with established public health mitigation procedures
- Threshold of everity not included in the drafts



- 7 PHEICs as of now 3 ongoing (polio, m-pox, covid)
- m-pox declared despite advice against by experts
- emergency authorizations through EUL introduced intermediate health alert
- 13th General Programme of Work (until 25') strong on emergencies & PPP

### DG executive powers to declare emergencies

#### All PHEICs & ECs

IHR Emergency Committees

On-going emergency committees

Mpox IHR Emergency Committee

COVID-19 IHR Emergency Con

Poliovirus IHR Emergency Comm

Previous emergency committees

Ebola Virus Disease in the Democratic Republic of the Congo (Equateur) IHR Emergency Com

Ebola Virus Disease in the Democratic Republic of the Congo (Kivu and Ituri) IHR E

Ebola Virus Disease in West Africa (2014-2015) IHR Emergency Co

H1N1 IHR Emergency Committee

MERS-CoV IHR Emergency Com

Yellow fever IHR Emergency Comm

Zika Virus IHR Emergency Committee

#### Second meeting of the **International Health Regulations** (2005) (IHR) Emergency Committee regarding the multicountry outbreak of monkeypox

23 July 2022 Statement Reading time: 21 min (5661 words)

The WHO Director-General is hereby transmitting the Report of the second meeting of the International Health Regulations (2005) (IHR) Emergency Committee regarding the multi-country outbreak of monkeypox, held on Thursday, 21 July 2022, from 12:00 to 19:00 CEST.

The WHO Director-General expresses his sincere gratitude to the Chair, Members, and Advisors for their careful consideration of the issues regarding this outbreak, as well as for providing invaluable input for his consideration. The Committee Members did not reach a consensus regarding their advice on determination of a Public Health Emergency of International Concern (PHEIC) for this event

The WHO Director-General recognizes the complexities and uncertainties associated with this public health event. Having considered the views of Committee Members and Advisors as well as other factors in line with the International Health Regulations, the Director-General has determined that the multi-country outbreak of monkeypox constitutes a Public Health Emergency of International Concern

The WHO Director-General also considered the views of the Committee in issuing the set of Temporary Recommendations presented below.

Example: m-pox PHEIC declaration by DG without consent from experts

### DG executive powers to declare emergencies

#### 5. Phases of the procedure

There are 3 phases of the EUL procedure:

- Pre-emergency phase;
- Emergency phase, and;
- Post-listing phase.

#### 5.1. Pre-emergency phase

Past experiences with emergency situations have shown that a preparedness plan is key to a rapid response when the emergency is declared. The WHO Research & Development (R&D) Blueprint<sup>5</sup> was established based on this principle.

As products in development are added to the pipeline for each priority disease, there are several activities that can be planned and executed during the pre-emergency phase. This strategy is intended to concentrate -as much as possible- on the activities that can be done in advance, thus minimizing the time required for a final decision about possible listing of a product once the lic health emergency is declared.

2. Rationale for the revisience The WHO Informal Consultation on options to improve health emergencies (Geneva, May 2017)1 conclud procedure needed to be reconsidered and revised. The reframed as the Emergency Use Listing (EUL) procedure primarily during a Public Health Emergency of Ini- Director-General may authorize the use of this proce- not meet the criteria of a PHEIC if s/he determines	e regulation ed that he conse ure ; b) th ternation edure for that this	some as insus was ne revised al Conce ra public is in the h	pects of the post of a the post of procedure of procedure procedur	rocess should re should be u ) <sup>2</sup> , although ergency that st of public he	sed the does ealth.	<b>5.1. Pre-emergency pha</b> Past experiences with em- rapid response when the Blueprint <sup>5</sup> was established As products in development activities that can be plan intended to concentrate -a minimizing the time requi
Director-General may according to the according to the according to the criteria of a PHEIC if s/he according to the accordin	Figure 1: Flowchart of the EUL process           PRE-EMERGENCY         Submission		Emergency Use Listing Procedure Public Health Emergency declared Submission LEMERGENCY POST-LISTING		public health emergency is f pre-emergency activities whilst a PHE is in progres ituation, timelines for the The pre-emergency activit	
H1N1 IHR Emergency Committee MERS-CoV IHR Emergency Committee Yellow fever IHR Emergency Committee Zika Virus IHR Emergency Committee	Roster of experts Pre-submission meetings Eligibility Essential data requirements	PEG established List of guidelines Initial review LOQ rounds Report with recommendations to WHO	PEG reviews new data Updated report with updated recommendations to WHO	TAG EUL established Review and deliberations Recommendation Possible intring including post listing requirements	Safety/efficacy data collection PEG and TAG-EUL review new data Listing maintained or product delisted	takeholders involved: Establishment of ar This includes activities that external experts, NRAs res countries. Activities includ necessary expert and advi trategic planning and over UL.
		during PHE				<ul><li>Eligibility and asses</li></ul>

The WHO Informal Consultation on options to improve regulatory preparedness to address public

health emergencies (Geneva, May 2017)<sup>1</sup> concluded that some aspects of the WHO EUAL procedure needed to be reconsidered and revised. The consensus was : a) the process should be

2. Rationale for the revision of the EUAL

Example: there is already a pre-PHEIC established through the EUL procedure

### WHO regulatory powers to authorize pandemic products



CA+ - Art. 8 – regulatory capacities "for timely approval of pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing pandemic-related products for emergency use in a timely manner,"
 Art. 9 "with reference to existing models, a global compensation mechanism for injuries resulting from pandemic vaccines."
 IHR: Art. 13A access to health products (2 versions) obliges WHO to conduct an assessment of availability and affordability of "health products"; to develop an allocation and prioritization plan in the event of shortages in supply; and to direct States Parties to increase and diversify production and distributive functions for health products within individual States



- no liability of producers of pandemic products
- no liability of WHO in the authorization of pandemic products
- Indemnification schemes with a lump sum are a waiver to hold the manufacturers accountable
- no regulations which stop excessive financial gains from health products
- no communication for adverse events/pharmacovigiliance



- · WHO no liability of the EUL products
- global indemnification scheme for vaccine injuries
- used for global allocation of EUL-vaccines

### regulatory powers to authorize pandemic products

#### 2. Rationale for the revision of the EUAL

The WHO Informal Consultation on options to improve regulatory preparedness to address public health emergencies (Geneva, May 2017)<sup>1</sup> concluded that some aspects of the WHO EUAL procedure needed to be reconsidered and revised. The consensus was : a) the process should be reframed as the Emergency Use Listing (EUL) procedure ; b) the revised procedure should be used primarily during a Public Health Emergency of International Concern (PHEIC) <sup>2</sup>, although the Director-General may authorize the use of this procedure for a public health emergency that does not meet the criteria of a PHEIC if s/he determines that this is in the best interest of public health.

#### **Disclaimer to the WHO EUL List Vaccines**

1. Inclusion in this list does not constitute an endorsement of the products listed. WHO explicitly disclaims any warranty of the fitness of any listed unlicensed product for a particular purpose, including in regard to its safety and/or efficacy and/or performance.

2. WHO does not furthermore warrant or represent that:

a. the list is complete or error free; and/or that

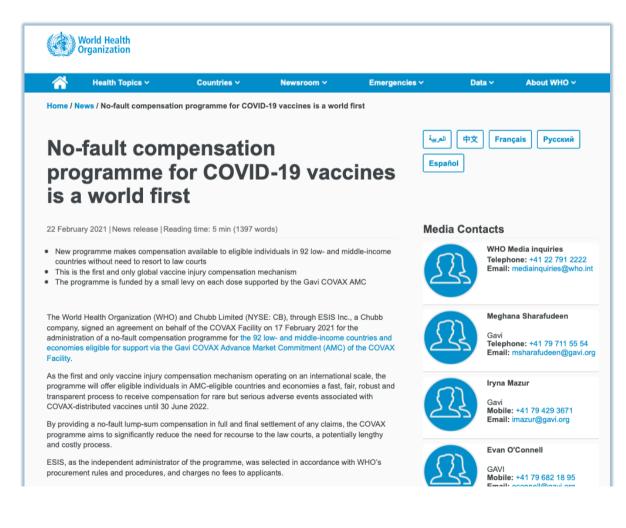
b. the listed unlicensed products which have been found to meet the requirements outlined in the EUL Procedure for use in the context of a PHE will continue to do so; and/or that the unlicensed products listed have obtained emergency use approval for their specified use or any other use in any country of the world, or that their emergency use is otherwise in accordance with the national laws and regulations of any country.

3. In addition, WHO wishes to alert organizations and Members States relying on the EUL list that the improper storage, handling and transportation of medical products may affect their quality, safety, efficacy and performance.

4. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of or in connection with the procurement, distribution and use of any unlicensed product included in the list.

Example: EUL procedure turnes investigational vaccines, in-vitro diagnostica and personal protective equiment into global allocation but has a disclaimer on liability

### regulatory powers to authorize pandemic products



Example: WHO introduced a global no-fault compensation programme for adverse events

### WHO legislative powers to mandate countermeasures

CA+ - EU prop- Chapter III countermeasure expert committee & benefit sharing and equitable access – extensive proposal IHR: Art. 1/13A/15/16 – mandatory temporary recommendations(TR)/countermeasures (other terminology)



If TR under the IHR turn into a mandatory character, the DG would be as strong as the UN Security Council, despite the fact that the temporary recommendations lack the character of a resolution – therefore it could be characterized as legislative powers DG
 RCR: Irrespective of legal coherence, changing temporary and standing recommendations into binding obligations may raise questions of feasibility. At this moment it is still unclear how to assess "compliance" with temporary recommendations issued during PHEICs, since they are defined as non- binding advice. No standing recommendations have ever been issued under the Regulations. To mitigate this feasibility concern, States Parties may wish to adopt the proposed alternate language of "use best endeavours" or maintain the original language "undertake to follow", p. 56.



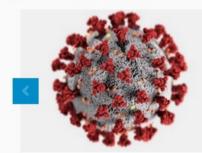
- TR are issued on a quarterly basis on the advice of the EC
- Problematic vaccination rates like 100% for risk groups are advised
- States implemented stronger TR as required by WHO, e.g. lockdowns

### WHO legislative powers to mandate countermeasures

COVID-19 IHR Emergency Committee

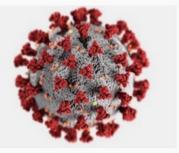
The IHR Emergency Committee for COVID-19 held its first meeting on 22 and 23 January 2020. On 30 January 2020, following its second meeting, the Director-General declared that the outbreak constituted a Public Health Emergency of International Concern, accepted the Committee's advice and issued it as IHR Temporary Recommendations. The Committee continues to meet on a regular basis.

#### Statements



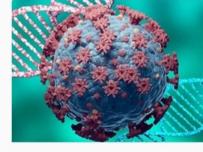
30 January 2023 | Statement

Statement on the fourteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic



18 October 2022 | Statement

Statement on the thirteenth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic



12 July 2022 | Statement

Statement on the twelfth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic 13 April 2022 | St

Statement of the Internat (2005) Eme regarding to (COVID-19) Example: The actual effect of temporary recommendations is tantamount to mandatory



### WHO Health Certificates

# WHO Health Certificates

CA+ - Art. 11 on preparedness and health systems resilience

IHR: Art. 23 para 6 digital health certificates , Art. 31, Art. 35, Annex 6- technical requirements of health documents

- no explicit reference, that everybody has the right to an analog certificate without digital devices
- Purpose of health certificates is incompatible with human rights and fundamental freedoms, against human dignity to demonstrate health status
- no data safety, e.g. EU-Green Certificate disclosed health status to third parties
- RCR concerned that such a requirement may overburden travellers, and may even raise ethical and discrimination-related concerns if used outside PHEICs, p. 61 risk that the health certificate will be used on a permanent basis
- secondary use of individual's health data data mining



Problem

- Digital Documentation of COVID-19 Certificates'
- Developed several standards on global interoperability requirements for health
- Integrated into temporary recommendations

### WHO Health Certificates



Home / Publications / Overview / Digital documentation of COVID-19 certificates: vaccination status: technical specifications and .

Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance, 27 August 2021

27 August 2021 | COVID-19: Vaccines



#### Overview

This is a guidance document for countries and implementing partners on the technical requirements for c digital information systems for issuing standards-based interoperable digital certificates for COVID-19 va status, and considerations for implementation of such systems, for the purposes of continuity of care, an vaccination.

Digital documentation of COVID-19 certificates: vaccination status: web annex A: DDCC:VS core data
 August 2021

 Digital documentation of COVID-19 certificates: vaccination status: technical specifications and imple guidance, web annex B: technical briefing, 27 August 2021

Download (2.1 MB)

iome / News / WHO launches guidance on digitally documenting SARS-CoV-2 test results

#### WHO launches guidance on digitally documenting SARS-CoV-2 test results

31 March 2022 | Departmental news | Reading time: 2 min (605 words)

On 31 March 2022, WHO published Digital Documentation of COVID-19 Certificates: Test Result technical specifications and guidance document for countries and implementing partners on the technical requirements for issuing digital certificates for SARS-CoV-2 diagnostic test result. The full guidance can be found here. This document is the second of two guidance documents on digital documentation of COVID-19 related data of interest: vaccination status and test result.

Similar to the Digital Documentation of COVID-19 Certificates: Vaccination Status Technical Specifications and Implementation Guidance document, this guidance on test results aims to guide countries and technologist in how to develop or adopt digital systems in support of verifiable proof of test results for domestic and cross-border purpose. It provides technical specifications and implementation guidance that details

interoperability standards, facilitated by a common digital architecture, for a digitized test result certificate which can be used as proof of negative test results or proof of previous SARS-CoV-2 infection for international travel, or as a means for protection policies that reduce public health risk in public or private venues – in accordance with individual Member States' public health policy and their risk-based approach to addressing COVID-19. Additional technical details to support the adoption of open standards for interoperability and approaches for intermentional a DDC-CTR

solution can be found in the WHO DDCC Health Level Seven (HL7) Fast Healthcare Interopera (FHIR) implementation guide.

A SARS-CoV-2 diagnostic test result certificate can be purely digital (for example, stored in a sm application) and replace the need for a paper test result certificate; or it can be implemented as augmentation of the traditional paper-based record. A digital certificate should never require a smartphone or computer.

#### Future directions

Digital Documentation of COVID-19 Certificates' (DDCC) specifications (for vaccination status a the foundations for secure personal health records based on the international patient summary records contain the most important health and care information needed to demostrate verifiable and test results. As countries consider adopting personal health records including digital health FHIR international patient summary standard (IPS) is at the foundation of the DDCC; serving as approach that will evolve with the needs of the individual, the public health policies, and the hea specifications are designed using the IPS and architected for future use, such as preparation for concerned.

#### Example: WHO already provided global standards on health certificates



### WHO Media Control

- CA+ -EU prop. extended Art. 17- strengthening pandemic and public health literacy
- IHR, Art. 9: WGIHR might consider how misinformation and disinformation may relate to obligations for WHO to verify information coming from sources other than States Parties.



З

- Infodemic management is a contentious concept which weaponizes information and controls its spread
- censorship techniques in cooperation with Big Social Media
- Social listenening activities in cooperation with Big Media and Big Tech
- who is in charge of
- 40 partnerships through Digital Channels with Big Tech
- WHO Tech Task Force
- Social Listening through EARS
- Infodemic Unit at World Health Emergency Programme constantly rising with Berlin Epidemic Intelligence Hub

#### WHO Tech Task Force and Bay Area Global Health Alliance Joint Meeting

AGENDA:

Strategic

partners

Ad hoc

partners

On February 15, the Alliance hosted a meeting marking the third anniversary of the formation of the **World Health Organization (WHO)** Tech Task Force. Representatives from **Google, Meta**, TikTok, Amazon and other tech companies joined Alliance members for networking and short presentations by Andy Pattison, Team Lead Digital Channels, WHO and his esteemed WHO colleagues, Drs. Ruediger Krech, Director, Health Promotion and Vinayak Prasad, Program Manager.

The presenters provided informative updates on the WHO's work on health promotion, tobacco cessation, humanitarian emergencies, digital communications, and the collaborative work of the WHO Tech Task Force. The Alliance is grateful for the collaborative spirit of the tech companies coming together to advance global health with





Non State Actors

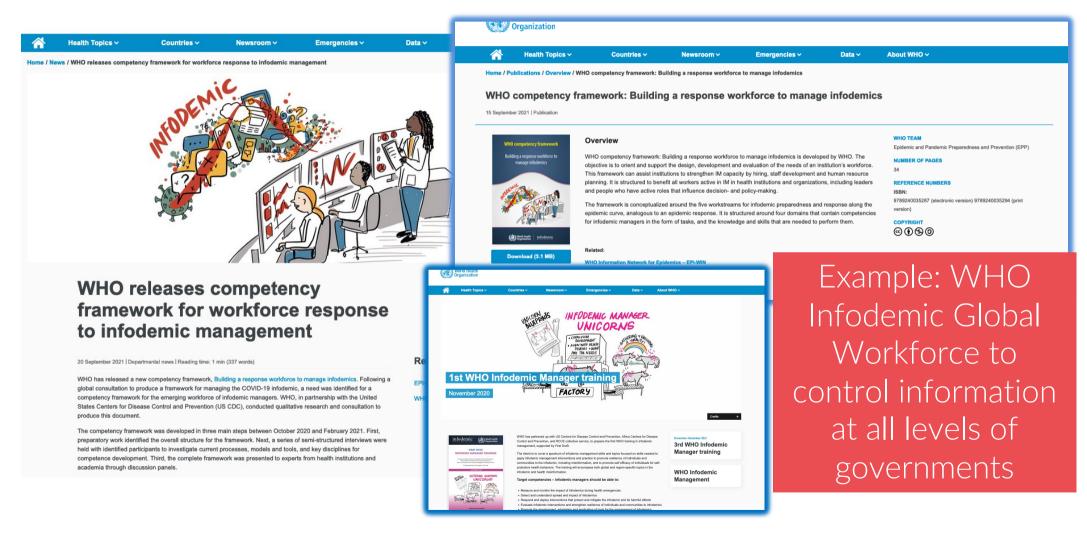
Example: WHO Big Tech Task Force & 40 partnerships with Big Tech

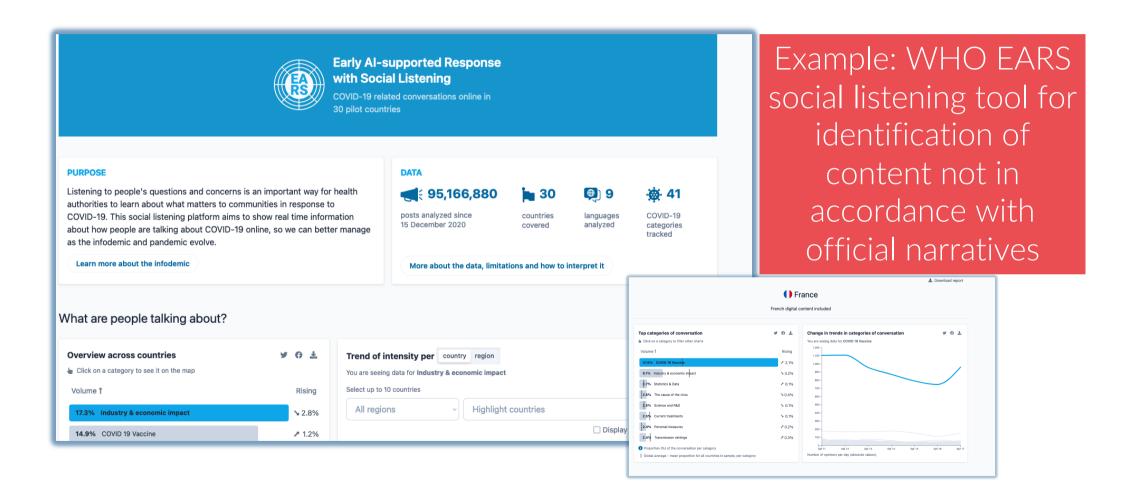


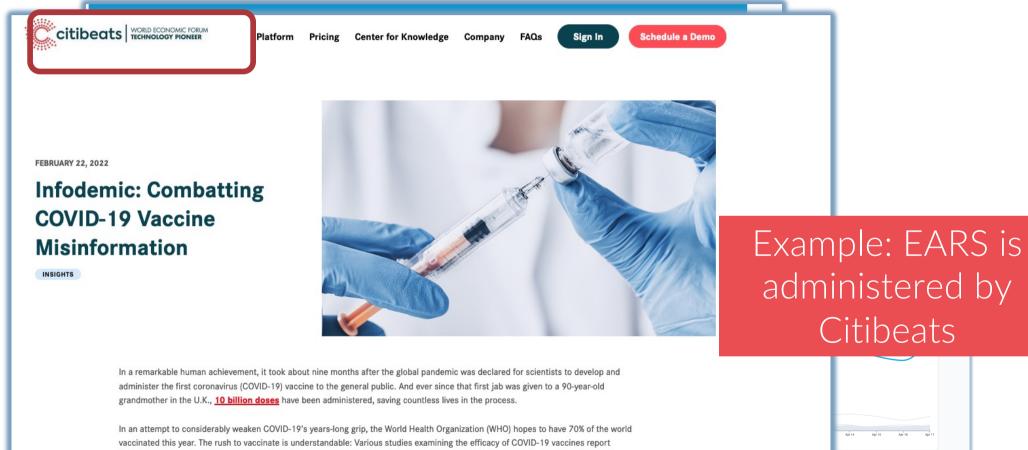
Example: DG lauchned information control strategies in February 2020 at the Munich Security Conference

"We're not just fighting an epidemic; we're fighting an infodemic."

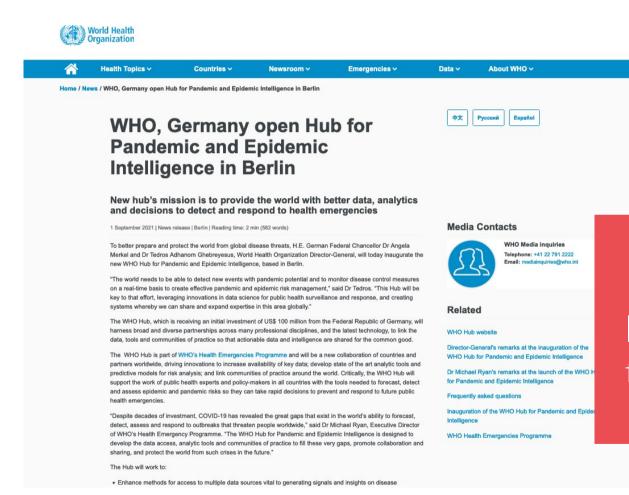
WHO Director-General Tedros Adhanom Ghebreyesus, 15 February 2020







significantly lower death rates for people who are vaccinated.



Example: Infodemic Managment/social listening is located at the Pandemic Hub in Berlin, est. 21'



### WHO Business Supply& Allocation

CA+ -Art. 6 - WHO Global Supply Chain and Logistics network - Parties determine the demand/map delivery - distribution

- IHR, Art. 13A - health products

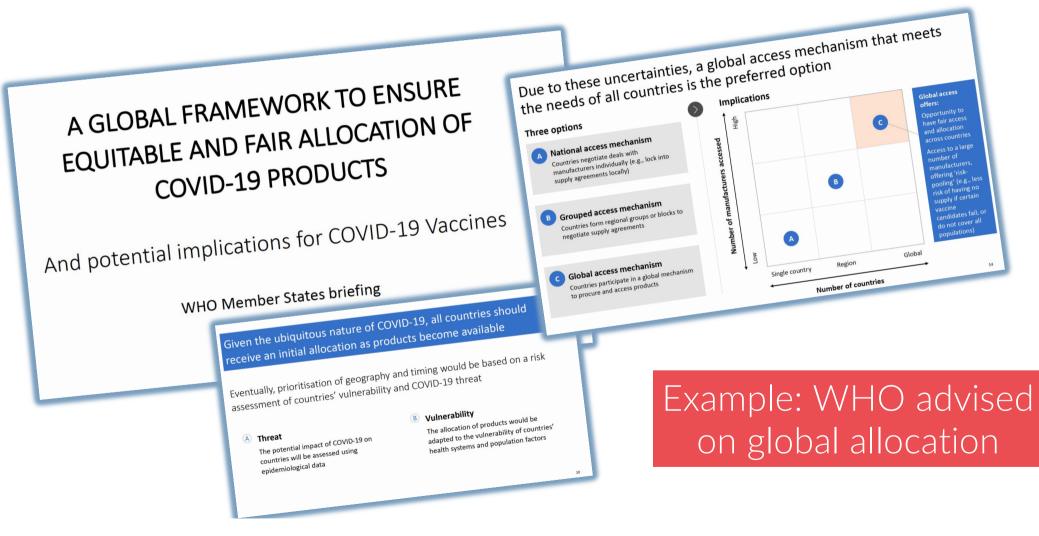


a

- RCR: "A different mode of authority may be required to establish an allocation mechanism.", p. 53
- ACT-Accelerator legislated only critized for not being equitable huge allocation by private sector together with WHO/GAVI/CEPI
- PIP Framework integrated never put to test
- Peak of monopolization of countermeasures without oversight



- PIP Allocation Framework operational
- Global Allocation Plan used during Covid-19
- Logistics and Supply Chain Managment





For most of 2021, COVAX and global vaccine equity efforts were weakened by vaccine nationalism, which WHO's Director-General summarized as a "handful of rich countries gobbling up the anticipated supply as manufacturers sell to the highest bidder, while the rest of the world scrambles for the scraps".

COVAX was also undermined by: a lack of the early funding essential to purchasing the first doses available; supply being directed at surges; and manufacturing and regulatory delays.

As a result, COVAX was unable to get the supply it wanted or at best it was unpredictable, delayed and limited visibility, which hindered rollouts and was a factor in undermining confidence in vaccination and specific products.

With supply constraints lifting, COVAX is moving into Phase 2 of its allocation mechanism. Still focused on equity, Phase 2 will move from a push, supply-driven approach to a pull, demand and absorption capacity-driven approach.

Vaccine allocation decisions made from April 2022 fall into Phase 2, with all previous decisions coming under Phase 1 – see the Independent Allocation of Vaccines Group (IAVG) documents and reports for documents from Phase 1.

#### **Goals and Objectives**

#### Phase 2 goals:

Support all countries' ambitions to control the disease and "reopen society" in 2022.

 Contribute to countries' vaccination coverage goals, in view of the WHO-UN 2022 Global Vaccine Strategy coverage targets, including 70% of the population in every country, and in consideration of supply beyond COVAX. Independent Allocation of Vaccines Group

COVAX

Annex for Phase 2 of COVAX Allocation

Explainer for COVAX Allocation Phase 2

Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility

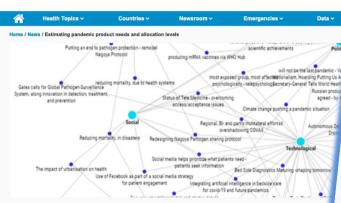
Allocation Mechanism for COVAX Facility

#### COVAX Allocation Round 15 (Ap 2022)

11 April 2022 Report of the Independent Allocation of Vaccines Group on the allocation of COVAX Facility...

#### 11 April 2022

Vaccine Allocation Decision on the allocation of COVAX Facility secured vaccines: 11 April 2022 Example: Covax allocated Covidvaccines globally – mechanism transferred to the negotiations (ACT-Acc is stakeholder at negotiations



#### Estimating pandemic product needs and allocation levels

10 February 2023 Departmental news Reading time: 2 min (428 words

Supported by the PIP Framework Partnership Contribution, in 2022, WHO initiated a project to estimate medical countermeasures (MCMs) needed during a future influenza pandemic

Effective planning for the deployment of pandemic influenza response products including vaccines, antivirals and diagnostics is critical to ensuring the timely delivery of these interventions to populations in need. Fundamental to this is implementing an evidence-based understanding of global product needs in order to inform allocation and prioritization strategies

Using horizon scanning techniques and foresight methodology, this analysis looked at

1. Potential scenarios and the issues that would impact global population needs for MCMs 2. Emerging considerations for the global access, allocation and deployment of pandemic influenza products, and: 3. Potential MCM needs related to public health goals.

This work ultimately aims to support Member States with planning for national influenza vaccine deployment plans.

#### Considering a realistic future scenario

World Health Organization

During the course of the project, interviews with subject-matter experts were conducted, together with desk research



Quantifying future needs

Considering the public health goals and the driving factors (and scenarios) affecting them, several opportunities and threats that may affect the ability to enhance access, allocation and deployment practices were identified – including but not limited to the development of new production facilities, technological advancements in health care provision, and more stakeholders getting involved in deployment activities. These will be reflected in the guidance materials that WHO and partners will produce (e.g. guidance and related supporting materials on developing and implementing a National Deployment and Vaccination Plan, and operational frameworks for global access, allocation and

### Example: Visualizations of future needs under the PIP framework



Dubai forms Vaccine Logistics Alliance to expedite alobal distribution of COVID-19 vaccines through the

#### How WHO is re-imagining and fixing the links in the supply chains during COVID-19

#### 7 May 2020

Getting humanitarian supplies where they need to go is a game of precision and meticulous planning under normal circumstances. Try adding a global, rapidly evolving pandemic to the mix, and you've described the current reality of World Health Organization (WHO) Operations Support & Logistics Chief Paul Molinaro, He is WHO's point man for procuring life-saving COVID-19 equipment and supplies destined for countries hit hardest by the virus.

"There are a lot of pieces of a puzzle that have to be put into place at the same time," Molinaro said.

#### Scaling Up the Orders

In normal times, WHO fulfills country requests by placing orders through long-term contracts with vendors who ship cargo via freight forwarders. The COVID-19 pandemic turned the process upside down. Disruptions in Chinese manufacturing fractured global supply chains, creating shortages in the face of soaring demand. Market competition increased, trade restrictions were implemented, and commercial flights were grounded. These challenges created a whole new level of complexity.

"We're sort of sailing the ship while building it at the same time," Molinaro said. "Right now we have a ship, and there's a lot of holes in it. But we have a ship.

In early April, the United Nations launched the UN COVID-19 Supply Chain Task Force - coordinated by WHO and the World Food Programme (WFP) - to massively scale up the procurement and delivery of personal protective equipment (PPE), testing and diagnostics supplies, and biomedical equipment like ventilators and oxygen concentrators. The Task Force leveraged the capabilities and expertise of each partner into a mega-consortium to identify procurement needs and better negotiate with suppliers. Members include the United Nations Children's Fund (UNICEF), the United Nations Office for Humanitarian Affairs), the World Bank. The Global Fund, the United Nations Office for Project Serves (UNOPS), United Nations Development Programme (UNDP), United Nations Fund for Population Activities (UNFPA), United Nations High Commissioner for Refugees (UNHCR), NGOs, Red Cross and Federation and other WHO health cluster partners. The goal: to make supplies available to everyone, wherever they

#### Related

Watch this video where Paul Molinaro explains the Supply System



Learn more about the supply Chain and other

#### Example: UN Covid-Supply Chain Task force coordinated by WHO

#### COVID-19 Supply Chain System

#### Assessment of the COVID-19 Supply Chain System - NOW AVAILABLE Full report orgunization

PMCID: PMC7941099 PMID: 33716336 Bull World Health Organ, 2021 Mar 1; 99(3): 171-171A. Country snape Coordinating COVID-19 vaccine deployment through the WHO COVID-19 Partners

M Anne Yu,<sup>12a</sup> Angela K Shen,<sup>a</sup> Michael J Ryan,<sup>a</sup> and Linda Lucy Boulanger<sup>a</sup> 20 April 2021 COVID-19 Supply Cha Snapshots Author Information 
 Copyright and License Information <u>Disclaimer</u>

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes the



How to build an international legal order where human dignity, fundamental freedoms and the inviolable human rights are respected during times of war and peace and any violation by an international organisation or other actor is held to account?

### Civil Society has to take action

