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Mail panda@pandata.org
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ANNOTATED SUMMARY OF SIGNIFICANT CLAUSES IN THE IHR AMENDMENTS

By Dr David Bell

Notes: within qualities from IHR draft, *italics* are added for emphasis here.

Acronyms:
DG: Director-General (of WHO)
FENSA: (WHO) Framework for Engagement of Non-State Actors
IHR: International Health Regulations
PHEIC: Public Health Emergency of International Concern
WHA: World Health Assembly
WHO: World Health Organization

'States Parties' in UN parlance (i.e. self-governing countries) is simplified below to 'States' or 'countries'.

See full document at the WHO IHR portal, or annotated at https://www.pandata.org/wp-content/uploads/WGIHR_Compilation-Annotated.pdf

In this section, the implications of the amendments to the Articles of the IHR are highlighted. The section headings draw attention to the process whereby national sovereignty is being replaced by centralised decision-making and control by WHO. The original wording of the Articles is in normal italics, while changes and additions are indicated in bold and underlined. Each extract from the Articles is followed by an explanation of the implications of the changes.

1. Setting the scene: Establishing WHO authority over individuals and national governments in health-related decision-making

Article 1: Definitions

> *'Health technologies and knowhow': Includes '<u>other health technologies</u>', [any of these that solve a health problem and improve 'quality of life' and includes technologies and knowhow involved in the] '<u>development and manufacturing process</u>', and their '<u>application and usage</u>'.*

Note the relevance to the requirement for countries to give these up to other entities as WHO demands. This must be unacceptable to most existing legal systems and corporations.

> *'standing recommendation' means ~~non-binding~~ advice issued by WHO*
> *'temporary recommendation' means ~~non-binding~~ advice issued by WHO*

With respect to 'standing recommendations' and 'temporary recommendations', The removal of the term 'non-binding' is consistent with the requirement (later) for States to consider the 'recommendations' of the DG as obligatory.

Article 2: Scope and purpose of the IHR

> *The purpose and scope of these Regulations are to prevent, protect against, prepare, control and provide a public health response to the international spread of diseases including through health systems readiness and resilience in ways that are commensurate with and restricted to ~~public health risk~~ all risks with a potential to impact public health, and which ...*

The wording changed from "restricted to public health risk" to "restricted to all risks with a potential to impact public health." Public health is an extremely broad term, and potential risks can be any virus, toxin, human behavioural change, article or other information source that could affect anything in this vast field. This is an open slather that would, if operationalised, provide WHO with jurisdiction over anything potentially or vaguely pertaining to some change in health or well-being, as perceived by the DG or delegated staff. Such broad rights to interfere and take control would not normally be allowed to a government department. In this case, there is no direct oversight from a parliament representing the people, and no specific legal jurisdiction to comply with. It allows the WHO DG to insert himself and give recommendations (no longer 'non-binding') to almost anything pertaining to societal life. Remember that health, in WHO's definition, refers to physical, mental and social well-being.

Article 3: Principles

> *The implementation of these Regulations shall be ~~with full respect for the dignity, human rights and fundamental freedoms of persons~~ based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development*

This signals a fundamental change in the UN's human rights approach, including the Universal Declaration on Human Rights (UDHR) that all UN countries have signed up to. The concept of broad, fundamental rights (equally applying to all) is removed, and replaced with vacuous wording: "equity, inclusivity, coherence". Human rights (of the individual) are seen as based on "social and economic development". This implies that the wealthy and the poor have different rights, and there is a hierarchy of 'development' that defines one's rights. This is a return to a feudalist or colonialist view of human rights (in many respects the excuses used to justify slavery) that the post-War WHO and UDHR had sought to move away from.

When implementing these Regulations, Parties and WHO should exercise precaution, in particular when dealing with unknown pathogens.

Again, a clause is added that enables WHO to override human rights previously stated, including for speculative (unknown) threats.

Article 4: Responsible authorities

Each country is required to appoint an '*authorized responsible authority'* with whom WHO will liaise. While seemingly innocuous, this reflects the mindset change within these regulations, with WHO becoming a body that requires compliance, and is no longer 'suggesting' or 'supporting'.

2. Establishing the international pandemic preparedness bureaucracy with WHO at the centre

Article 5: Surveillance

These amendments establish/expand a periodic review mechanism, similar to the UN Human Rights Office. This in itself seems innocuous, but it is a very large resource drain, especially for smaller countries, and requires (as in the human rights compliance case) a large, dedicated, international (WHO) bureaucracy and consultant base. WHO will require regular detailed reports, send assessors, and require changes. This raises questions about both (1) sovereignty in health, and (2) the rational and appropriate use of resources. WHO is not assessing the country's health needs here; it is assessing one small aspect and dictating the resources to be spent on it, irrespective of other health burdens. This is a fundamentally poor and dangerous way to manage public health, and means that resources are unlikely to be spent for maximum overall benefit.

Article 6: Notification

Countries (States Parties) are to make information available to WHO at WHO's request. WHO can make this available to other parties (see later clauses) in a manner yet to be determined by the WHA. This may seem innocuous but, in reality, it removes State sovereignty over data, which had been significant prior to the 2005 IHA amendments. It is unlikely that powerful States will comply, but smaller ones will be left with little choice. China has significantly inhibited the sharing of information and will likely continue to do so. It can be argued that this is appropriate, as such information can have significant economic and social implications.

Article 10: Verification

If the State Party does not accept the offer of collaboration within 48 hours, WHO ~~may~~ shall, when justified by the magnitude of the public health risk, immediately share with other States Parties the information available to it, whilst encouraging the State Party

> *to accept the offer of collaboration by WHO, ~~taking into account the views of the State Party concerned~~.*

WHO gains power to share information from a State or pertaining to a State with other States, without consent. This is remarkable. It is important to understand who WHO is. They are essentially unaccountable beyond the WHA.

Article 11: Exchange of Information (Formerly: Provision of information by WHO)

This article enables WHO to share information, obtained as discussed above, with both UN and non-governmental bodies. The allowed recipients have changed from (formerly) 'relevant intergovernmental' to (now) 'relevant international and regional' organisations, which now includes organisations not related to national governments.

WHO can therefore share a State's information with 'relevant international organisations'. This presumably includes organisations such as CEPI, Gavi and Unitaid, which have private and corporate representation on their boards with direct financial conflicts of interest.

Further:

> *Parties referred to in those provisions, shall ~~not~~ make this information generally available to other States Parties, ~~until such time as~~ when: (a) the event is determined to constitute a public health emergency of international concern, a public health emergency of regional concern, or warrants an intermediate public health alert, in accordance with Article 12; or …*

This widens the criteria determining when WHO can disseminate information from sovereign States from PHEIC to 'health alert', which in practice the DG or subordinates could apply to almost anything. This could occur, as specified later in the Article, when WHO staff decide a sovereign State does not have 'capacity' to handle a problem, or when WHO staff decide (with unspecified criteria) that it is necessary to share information with others to make 'timely' risk assessments. This allows unelected WHO staff, on salaries supported by external conflicted entities, to disseminate information from States that is directly relevant to those entities, based on their own assessment of risk and response, and against undefined criteria.

3. Widening the definition of 'public health emergency' to include any health or pathogen-related event at the DG's discretion, and requiring States' compliance

Article 12: Determination of a public health emergency of international concern, public health emergency of regional concern, or intermediate health alert

This Article both reduces the threshold for the DG to declare an emergency (it can just be a concern about a potential outbreak) and greatly increases the power of WHO to act, by removing the requirement for State agreement.

If the Director-General considers, based on an assessment under these Regulations, that a potential or actual public health emergency of international concern is occurring … determines that the event constitutes a public health emergency of international concern, ~~and the State Party are in agreement regarding this determination,~~ the Director-General shall notify all the States Parties, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (but is not required to follow them)

This removes the requirement for a State to agree to release information pertaining to that State. The DG can declare a PHEIC against the State's wishes and instructions. WHO becomes the dominant party, not the servant of the sovereign State.

An Emergency Committee review is optional for the DG, who can act completely alone in determining a PHEIC - a decision that can have vast health, social and economic implications, and is allowed by the amendments earlier to abrogate basic human rights norms.

~~If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49~~.

This removes the requirement that the DG should seek the agreement of the State before acting.

Regional Director may determine that an event constitutes a public health emergency of regional concern and provide related guidance to States Parties in the region either before or after notification of an event that may constitute a public health emergency of international concern is made to the Director-General, who shall inform all States Parties.

RDs appear to be granted similar powers, though the full implications are unclear.

In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA.

The WHO Framework for Engagement of Non-State Actors (FENSA) allows the DG to "exercise flexibility in the application of the procedures of FENSA" in the case of a health emergency. In the IHR this is broadened, as above, to any concern the DG has regarding potential harm, irrespective of State agreement.

Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and knowhow …

This line is fascinating mainly for its anachronistic (but telling) use of the colonialist-like terms ‘developing’ and ‘developed’ in this formerly egalitarian WHO context.

> *The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.*

WHO is set as the dominant partner. States must comply or provide excuses for not agreeing with WHO's dictates.

> *When requested by WHO, States Parties ~~should~~ shall provide, to the extent possible, support to WHO-coordinated response activities, including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party’s jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams.*

'Should' is changed to 'shall', requiring States to provide resources at WHO’s request for a PHEIC (e.g. monkeypox) or an event the DG considers may pose a potential threat. WHO thus acquires the ability to order States to provide resources, and (later) know-how and IP when ordered by the DG to do so.

NEW Article 13A: WHO-led International Public Health Response

This new Article explicitly lays out the new international public health order, with WHO in charge at the centre, rather than national sovereignty being paramount.

> *States Parties recognize WHO as the guidance and coordinating authority of international public health response during a Public Health Emergency of International Concern and undertake to follow WHO’s recommendations in their international public health response.*

This requires States to follow WHO’s recommendations in a PHEIC. This is declared by an individual (the DG) whose position is determined by non-democratic States and who is open to being influenced by private and corporate money. The criteria for PHEIC are deliberately vague, and at the DG's discretion. This is an amazing reversal of the roles of WHO versus States, and clearly abrogates national sovereignty.

The wild failure of the Covid response and WHO's abrogation of its own guidelines should give pause for thought here. In future, WHO could mandate the abrogation of bodily autonomy by States in relation to medication, vaccination, or testing.

> *Upon request of WHO, States Parties with the production capacities shall undertake measures to scale up production of health products, including through diversification of production,*

technology transfer and capacity building especially in the developing countries.

At the DG's discretion, WHO can require (tell) countries to scale up production of certain products, thus interfering with markets and commerce.

[WHO] shall collaborate with other international organizations, and other stakeholders consistent with the provisions of FENSA, for responding to public health emergency of international concern.

This enables WHO to collaborate with non-State actors (private individuals, foundations, and private corporations, including Pharma and its sponsors). FENSA, which restricts such contacts, can be varied by the DG in a 'health emergency' that the DG declares.

4. WHO requiring countries to provide resources, intellectual property and know-how at their discretion

NEW Article 13A: Access to Health Products, Technologies and Know-How for Public Health Response

States Parties shall cooperate with each other and WHO to comply with such recommendations pursuant to paragraph 1 and shall take measures to ensure timely availability and affordability of required health products such as diagnostics, therapeutics, vaccines, and other medical devices required for the effective response to a public health emergency of international concern.

WHO determines the response within the States' borders, and requires States to provide aid to other countries at WHO's behest.

States Parties shall provide, in their intellectual property laws and related laws and regulations, exemptions and limitations to the exclusive rights of intellectual property holders to facilitate the manufacture, export and import of the required health products, including their materials and components.

States shall change their IP laws to allow, upon the DG's determination of a PHEIC, and at his/her discretion, the sharing of IP with whomever they determine. It is difficult to imagine that a sane State would do this, but it is clearly required here.

States Parties shall use or assign to potential manufacturers, especially from developing countries, on a non-exclusive basis, the rights over health product(s) or technology(-ies).

WHO can require IP to be shared with other States, and thereby IP can be passed to private corporations within those States.

Upon request of a State Party, other States Parties or WHO shall rapidly cooperate and share relevant regulatory dossiers submitted by manufacturers concerning safety and efficacy, and manufacturing and quality control processes, within 30 days.

This requires the release of confidential regulatory dossiers to other States, including to WHO's qualification programme, and to sovereign State regulatory agencies.

> *[WHO shall] establish a database of raw materials and their potential suppliers,*
> *e) establish a repository for cell-lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines …*

WHO holding such materials is unprecedented. Under whose laws and regulatory requirements would this be done? Who would be held responsible for damage and harm?

> *States Parties shall take measures to ensure that the activities of non-State actors, especially the manufacturers and those claiming associated intellectual property rights, do not conflict with the right to the highest attainable standard of health and these Regulations, and are in compliance with measures taken by the WHO and the States Parties under this provision, which includes:*
> *a) to comply with WHO recommended measures including allocation mechanism made pursuant to paragraph 1.*
> *b) to donate a certain percentage of their production at the request of WHO.*
> *c) to publish the pricing policy transparently.*
> *d) to share the technologies, know-how for the diversification of production.*
> *e) to deposit cell-lines or share other details required by WHO repositories or database established pursuant to paragraph 5.*
> *f) to submit regulatory dossiers concerning safety and efficacy, and manufacturing and quality control processes, when called for by the States Parties or WHO.*

The "highest attainable standard of health" is beyond what any State has now. This effectively means, as worded, that WHO can require any State to release almost any confidential product and IP on any product related to the health sector.

This is an amazing list. The DG (WHO), based on their own criteria, can declare an event and then require a State to contribute resources and give up sole rights to the IP of its citizens, and share information to allow others to manufacture their citizens' products in direct competition. WHO also requires States to donate products to WHO or other States on demand by the DG.

To understand the scope of the IP rights to be forfeited to the DG, the definitions (Article 1) describe them as:

> *… health technologies and know-how includes organized set or combination of knowledge, skills, health products, procedures, databases and systems developed to solve a health problem and improve quality of life, including those relating to development or manufacture of health products or their combination, its application or usage …*

5. WHO claiming control of individuals and their rights within States

Article 18: Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

> *Recommendations issued by WHO to States Parties with respect to persons may include the following advice: …*
> - *review proof of medical examination and any laboratory analysis;*
> - *require medical examinations;*
> - *review proof of vaccination or other prophylaxis;*
> - *require vaccination or other prophylaxis;*
> - *place suspect persons under public health observation;*
> - *implement quarantine or other health measures for suspect persons;*
> - *implement isolation and treatment where necessary of affected persons;*
> - *implement tracing of contacts of suspect or affected persons;*
> - *refuse entry of suspect and affected persons;*
> - *refuse entry of unaffected persons to affected areas; and*
> - *implement exit screening and/or restrictions on persons from affected areas.*

Article 18 was already in existence. The new Article 13A, however, now requires States to follow WHO's recommendations. Based on the sole determination of an individual (the DG), and under the influence of non-democratic States and private entities, WHO will now be able to instruct States to incarcerate their citizens, inject them, require identification of medical status, medically examine and isolate them, and restrict their travel.

This is clearly insane.

> *"[Recommendations issued by WHO shall] … ensure mechanisms to develop and apply a traveller's health declaration in international public health emergency of international concern (PHEIC) to provide better information about travel itinerary, possible symptoms that could be manifested, or any prevention measures that have been complied with such as facilitation of contact tracing, if necessary."*

WHO can require the availability of private travel (itinerary) information, and require the provision of medical travel documents. This represents the disclosure of private medical information to WHO.

Article 23: Health measures on arrival and departure

> *Documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form, with paper form as a residual option. Such information should not duplicate the information the traveller already submitted in relation to the same journey, provided the competence authority can have access to it for the purpose of contact tracing*.

The text (which clearly needs further work) is aimed at future requirements for vaccine passports for travel.

6. WHO setting the scene for digital health passports

Article 35: General rule

> *Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.*

This Article further presages digital IDs containing health information that must be available to enable travel (i.e. not at the individual's discretion).

Article 36: Certificates of vaccination or other prophylaxis

> *Such proofs may include test certificates and recovery certificates. These certificates may be designed and approved by the Health Assembly according to the provisions set out for digital vaccination or prophylaxis certificates, and should be deemed as substitutes for, or be complementary to, the digital or paper certificates of vaccination or prophylaxis.*

As noted above, this is preparing the WHO / WHA to set international travel requirements, while the UDHR states that there is a basic right to travel. While vaccination certificates are not new, the PHEIC provisions will expand their use, with their imposition being at the will of the DG. It represents a move from national sovereignty to trans-national control of travel beyond national sovereignty, which is not directly answerable to populations, but heavily funded and influenced by private interests.

> *Health measures taken pursuant to these Regulations, including the recommendations made under Article 15 and 16, shall be initiated and completed without delay by all State Parties.*

All countries are required to comply with these recommendations, and it takes only 50% of the WHA to implement them.

States Parties shall also take measures to ensure Non-State Actors operating in their respective territories comply with such measures.

Private entities and citizens within the State are also required to comply. This will likely necessitate changes to many national laws, and the relationship between governments and the people. This requires a totalitarian approach by the State, subject to a totalitarian approach by a supra-state (but clearly not a meritocratic) entity. Following these IHR revisions, the DG of WHO, at his discretion, has the capacity to order private entities and citizens in any country to comply with his/her directives.

7. WHO being further empowered to order changes within States, including and implementing restrictions on freedom of speech

Article 43: Additional health measures

[Measures implemented by States shall not be more restrictive than] … would ~~achieve~~ attain the ~~appropriate~~ highest achievable level of health protection.

These changes are very significant. "Appropriate" meant taking into account the costs and balancing these against potential gains. It is a sensible approach that takes the needs of the whole of society and population into account (good public health).

The "highest achievable level of protection" means elevating the problem (e.g. an infectious disease or potential disease) above all other health and human or societal concerns. This is stupid, and probably reflects a lack of thought and poor understanding of public health.

WHO ~~may request that~~ shall make recommendations to the State Party concerned ~~reconsider~~ to modify or rescind the application of the additional health measures …

The WHO DG can now require States to remove health interventions, as States have agreed to 'recommendations' being binding (above). As noted elsewhere, WHO is not the instructing party, not the suggesting party. WHO takes sovereignty over former State matters. The following paragraph in the WHO text requires a response in two weeks rather than three months, which was formerly the case.

Article 44: Collaboration and assistance

States Parties shall ~~undertake to~~ collaborate with and assist each other, in particular developing countries States Parties, upon request, ~~to the extent possible~~, in: …

There are changes in the relationship from WHO suggesting or requesting, to WHO requiring.

> *... countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information.*

States undertake to work with WHO to control information and limit free speech.

> *... the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.*

States agree to pass laws to implement restrictions on free speech and the sharing of information.

> *... countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information.*

WHO shall work with countries to control free speech and the flow of information based on their own criteria of what is right and wrong.

8. Nuts and bolts of the verification bureaucracy to ensure that countries follow WHO's requirements

NEW Chapter IV (Article 53 bis-quater): The Compliance Committee
53 bis Terms of Reference and composition

> *The States Parties shall establish a Compliance Committee that shall be responsible for:*
> *(a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;*
> *(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;*
> *(c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and*
> *(d) Submitting an annual report to each Health Assembly describing:*
> *(i) The work of the Compliance Committee during the reporting period;*
> *(ii) The concerns regarding non-compliance during the reporting period; and*
> *(iii) Any conclusions and recommendations of the Committee.*

2. The Compliance Committee shall be authorized to:
(a) Request further information on matters under its consideration;
(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;
(c) Consider any relevant information submitted to it;
(d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and
(e) Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.

This sets up the permanent review mechanism to monitor the compliance of States with WHO's dictates on public health. This is a huge new bureaucracy, both centrally (WHO) and causing a significant resource drain on each State. It reflects the review mechanism of the UN Human Rights Office.

9. More on WHO requiring States to provide taxpayer money to support WHO's work, and restricting freedom of populations to question this work.

ANNEX 1: A. CORE CAPACITY REQUIREMENTS FOR DISEASE DETECTION, SURVEILLANCE AND HEALTH EMERGENCY RESPONSE

Developed Countries States Parties shall provide financial and technological assistance to the Developing Countries States Parties in order to ensure state-of-the-art facilities in developing countries States Parties, including through international financial mechanism …

States shall provide (i.e. divert from other priorities) aid funding to help other States develop capacity. This represents a clear opportunity cost to other disease /societal programmes where funding must accordingly be reduced. However, this will no longer be under the budgetary control of States, but required by an external entity (WHO).

At a global level, WHO shall … Counter misinformation and disinformation.

As above, WHO takes the role of policing and countering free speech and the exchange of information, funded by the taxes of those whose speech they are suppressing.

Useful links

The WHO documents regarding the IHR amendments can be found at:
https://apps.who.int/gb/wgihr/index.html

A summary of the amendments and their implications to international law can be found at: https://www.dinekevankooten.nl/wp-content/uploads/Whotreatyonpandemispreparedness.pdf