Review of the legal developments in World Health Organization (WHO)

- a legal analysis of the draft Pandemic Agreement and the proposed changes in the International Health Regulation

Part 2

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Introduction

This legal report looks at a core aspect of the International Health Regulations (IHR) and the Pandemic Agreement as being negotiated in the WHO under the tight time limits till May 2024.

The International Health Regulations (IHR) concerns rules regarding decisions by the Director-General declaring Public Health Emergency of International Concern. A major methodological challenge of an analysis of the IHR is the complete secrecy about the draft article being negotiated. This means that all the proposals in the IHR are the original ones from states published in December 2022. Many of which are probably not on the table for the negotiations anymore, and more importantly, none of the proposed amendments are available. In April 2024 a draft of the negotiated amendments of the IHR was made available to the public.

The Pandemic Agreement published a draft in November 2023, and then new drafts in March and April 2024. One core methodological challenge for this draft is the lack of expression of disagreement in the draft. Normally, a draft reflects disagreement with alternative text proposals in [] square brackets.

All these features of the two negotiations make analysis of the drafts complicated. This entails a democratic challenge since the timeframe for both these legally binding instruments is May 2024.

Lillehammer May 9th, 2024.

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Abstract

This legal report looks at a core aspect of the International Health Regulations (IHR) and the Pandemic Agreement. Both these legal instruments are being negotiated in the World Health Organization (WHO) with May 27th, 2024, as a deadline. There is an extensive political pressure on the negotiators to finalise the work.

This study looks at the proposed amendments to the WHO instruments. In addition, it seems to illustrate how to assess the degree to which one country is ready of the implementation of recommendations.

Amendments to the International Health Regulations (IHR) have been negotiated in secrecy. The secrecy of the negotiated articles entails a democratic challenge, since the debate about the way forward is absent. IHR concerns rules reacting to the decision of the Director-General declaring Public Health Emergency of International Concern. In the draft IHR, the competence of the Director-General is expanded to declare Pandemic Emergency. The competence to declare Pandemic Emergency is set under the IHR, but the same term is used as trigger point for grating power to the Director-General under the Pandemic Agreement. Already in the IHR version of 2005, the Director-General has comprehensive powers to declare that the world is in a health crisis, and to put forward recommendations to nation-states that they are obliged to initiate and complete without delay in national legal system.

In the procedures for taking decision in the IHR 2005 Article 17, there are no reference to human rights. In the objectives there is a reference to human rights and human dignity. The lack of bringing the human-rights assessments from the mere objective level to the operational article leaves it doubtful whether the Director-General is obliged to assess any potential impact on human rights from each decision taken.

One new aspect in the draft IHR 2024 is that countries shall be obliged to pre-implement acts that make the recommendations by the Direktor-General part of national health law or policy, and to establish an institutional structure to decide on the recommendations by the Director-General. The recommendations given by the Director-General are formally non-binding, according to IHR 2005 Article 1. There are two features that indicate that the recommendations are given a more binding character: The requirement on countries to have laws and institutions ready to implement the recommendations, and IHR Article 42 which requires “Health measures taken pursuant to these Regulations shall be initiated and completed

without delay, and applied in a transparent and non-discriminatory manner." The binding obligation to implement a non-binding recommendation will consequently lead towards it becoming binding. There are four elements promoting the implementation of the recommendation by the Director-General: 1) the states shall have in place one or maximum two institutions that shall implement the IHR, 2) they shall strengthening the legislative and administrative system the implementation of the recommendations, 3) that the counties are obliged to initiate and complete the implementation of without delay, and 4) there is no system for less comprehensive measures.

IHR 2024 also proposes changes the system for certifications regarding vaccines and prophylaxis. This system for certificate is the only one that shall be recognised under WHO. The Director-General is authorised to choose the vaccines that can be registered in the certificate. The choice of vaccines that can be registered in the only recognised certificate for travel grants comprehensive authority to the Director-General and system for selecting vaccines and prophylaxis for the certificate.

The negotiation of the Pandemic Agreement suffers from political disagreements. For several of the core legal concepts as were proposed in the beginning of the negotiation have been changed and been made less detailed and less comprehensive. The three concepts most fare-reaching measures in the draft, One Health, the system for Access and Benefit Sharing of Pathogens and the so-called Infodemic, have all three been watered down during negotiations. For One Health the new concept there is considerable political divergence. The further content is not totally clear from the draft. The system of Access and Benefit Sharing for pathogens is far from ready in the negotiated drafts. This means that considerable negotiations are required before the Pandemic Agreement can set out a functional PABS system. When comparing the drafts regarding the rules regulating the so-called infodemics, they show that there is not political consensus for the hardest regulation of misinformation. The question which is not dealt with but which is of the strongest importance for developing countries, a patent waver for patents to life-saving medicines, is not at all negotiated in the WHO. The absence of the WHO providing a negotiation space for the relationship to the patent system in a situation of a Pandemic Emergency/ PHEIC discloses that the most pressing questions for poor countries has not even been discussed during the last two year as a preparation for a next emergency situation.

The lack democratic participation in the negotiation process is a fundamental challenge with both drafts, in particular the IHR amendments as secrecy has been strictest.

Review of the legal developments in World Health Organization (WHO)

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1 Introduction to the topic and to this analysis

The World Health Organization (WHO) is an organ of the UN directing and coordinating authority for health. The WHO defines its six objectives as

> "It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends."[2]

The World Health Assembly mandated in May 2022 two parallel law-making negotiation processes: the revision of the International Health Regulations (IHR) discussed in a Working Group on Amendments to the IHR (WGIHR),[3] and the Pandemic Accord negotiated in the Intergovernmental Negotiating Body (INB).[4] The two instruments are being negotiated in parallel, and while there are some overlapping topics, they are different in scope and format. A common feature is that both shall be discussed (and adapted) at the 2024 World Health Assembly in May. There is an extensive political pressure on the negotiators to finalise the work: «First, I urge you to deliver the pandemic accord on time, as a generational commitment.» Director-General of the WHO stated on May 22nd, 2023, under WHA.[5]

An updated version of the negotiated text on the WHO Pandemic Agreement was published on October 30th, 2023, and then an update version was made public on March 13th, 2024.[6] The Pandemic Agreement is a completely new international instrument. The published text contains no square brackets signalising a high level of consensus amongst states. However, more realistic drafts have been made available during 2024. The bracketed draft shows a high level of disagreements even short time before the WHA starting on May 27th, 2024. The draft

[2] WHO: World Health Organisation - Office of the Secretary-General's Envoy on Youth (un.org) [12. January 2024].
[3] WHO | Working Group on Amendments to the International Health Regulations (2005)
[4] ***Intergovernmental Negotiating Body*** Intergovernmental Negotiating Body (INB) (who.int)
[5] WHO Director-General's opening remarks at the WHA76 Strategic Roundtable – 22 May 2023 [Sist sett 17. Oktober 2023]
[6] Revised draft of the negotiating text of the WHO Pandemic Agreement

Pandemic Agreement concedes a system for the Conference of the Parties to change the agreement by approval either by consensus, but alternatively by three-quarters majority vote (Draft PA Article 28.3). By signing on to a final version of the Pandemic Agreement, countries subscribe to future amendments, not necessarily adapted by consensus. During the final weeks before the deadline, it looks like, from the draft resolution, that the WHA will be invited to continue negotiating two outstanding topics: One Health and the Pathogen Access and Benefit Sharing (PABS).

The negotiations of modifications to the IHR have been conducted in closed rooms with no renegotiated text having been published since the compilation of proposals from countries at the meeting in November 2022 till April 2024.[7] While the compilation which was published in 2022 was a useful document at the time published to get an overview of the more than 300 proposed amendments, that 2022 document did not reflect the updated situation during negotiations (Compilation document).[8] The WGIHR published a report from the 'Review Committee' on February 6th 2023, document A/WGIHR/2/5,[9] discussing legal challenges regarding the proposals from countries. These are the documents that have been accessible to the public.

The secrecy of the negotiated articles entails a democratic challenge. On October 9th, 2023, a request was sent to the Ministry of Health and Care Service of Norway for access to the latest and updated documents. On November 23rd, 2023, the Ministry refused to grant access to the documents. The criterion for giving access according to section 29 second part of the Freedom of Information Act is as follows: "An administrative agency that receives a request for access shall consider the request on a specific and independent basis. The request shall be decided without undue delay." Leaving a request unanswered for a total of 44 days, is well beyond the legal criterion 'without undue delay'. The justification for excepting the negotiated documents from access is that the organization has shared the information under the condition of secrecy. The preparatory work of the law, highlights in NOU 2003:30, section 12.6.1 that global law-making shall be as publicly available as national law-making. Combined with that argument, the exception concerns pieces of information, not entire documents. The legislative background for this exception was to create transnational trust. Keeping future legislation secret did not form part of the legislative reasoning behind the rule.

[7] ***Working Group on Amendments to the International Health Regulations*** (WGIHR) WGIHR_Compilation-en.pdf (who.int) [12. January 2024]
[8] *WGIHR_Compilation-en.pdf (who.int) IHR 2022.
[9] Report of the Review Committee regarding amendments to the International Health Regulations (2005) (who.int) [sett 11. October 2023]

The Norwegian authorities, Ministry of Health and Care Service, responded that the secrecy was decided by the WHO (in the 'Debatten' October 19th, 2023). We do not know the positions of the member countries regarding openness or secrecy regarding these negotiations. This is problematic from a democratic point of view, as one could question whether the UN organization should decide the public statues of a law-making procedure. Secrecy in law-making is an undemocratic practice. This is the first United Nations negotiation I have followed where the negotiated drafts have been kept so secrete as the IHR under the WHO. It has not been possible to identify whether secrecy was a decision by the member states or by the Secretariate of the WHO.

On April 17th, 2024, some weeks before the 77th WHA, the first negotiated IHR draft text since 2022 was published on the WHO webpage. According to IHR 2005 Article 55 number 2 "The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration." At the meeting in October 2023, the WGIHR concluded that the proposals had already been communicated to the member states. The meeting claimed that procedural requirement according to IHR 2005 Article 55.2 has already been met. If this argument is agreed by member states, the democratic debate regarding the amendments to the IHR can be very short or even completely removed. The public institutions and democracy are the losing interest in a law-making process with poor conditions for an open discussion.

The IHR 2005 are already legally binding treaty-obligations for its member countries. I refer to it as IHR 2005 in this study. I refer to the proposals respectively as 'IHR 2022' and 'IHR April 2024'. It is a methodological challenge to analyze and write about a moving target as is a treaty in the final steps of negotiation. Unlike the Pandemic Agreement, the Working Group on IHR can be more strategic and only put forward to the WHA the draft articles that countries have agreed to. It would not be surprising if the resolution regarding IHR would open for continuing the mandate of the WGIHR negotiating the remaining articles for which no consensus regarding their amendments has been reached.

Adoption of the Pandemic Agreement is subject to the procedures set out in the WHO Constitution Article 19:

> The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

IHR is not formally a treaty. One could ask whether the WHA can adopt the

amendments in the IHR by simple majority, according to WHO Constitution Article 21 and 22. Even if UN agencies are striving toward consensus in their law-making process, both these legally binding treaties can be adopted by voting in the WHA. Consensus is not required. This report will not offer any discussion of the probability of any of these instruments being adopted. In a situation where amendments are adopted, according to IHR Article 59, member countries have a period of 10 months to object to being bound by the amendments, even voting against them at the WHA. This way of binding countries to a treaty is unique (as far as I have managed to find out) in international law. The consequence is that a country can be bound according to the IHR even if the Parliament (or other system of ratification according to the respective national constitution) are not consulted. For conventions and agreements in general for the WHO, WHO Constitution Article 20 sets a rule that countries have a time-limit for ratification (18 months after the adoption of the WHA). For regulations, however, the WHO Constitution Article 21 and 22 sets an even stricter rule "… shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members …" (Article 22). The IHR 2005 sets stricter rules for binding of the member states than the general rule in the WHO Constitution.

This study seeks to discuss and answer two questions: 1) What are the main changes set out in the proposal IHR 2022 and the draft Pandemic Agreement to the current legal situation? 2) Which existing legal norms are potentially in conflict with these proposals?

2 Rules regarding the path from a 'health measure' or recommendation of the Director-General to binding obligations in national law

2.1 Rules regarding 'recommendations'

The system in IHR 2005 is that the Director-General alone decides "… whether an event constitutes a public health emergency of international concern …" (IHR 2005 Article 12.1).

In the draft IHR April 2024 Article 1, an additional situation, the 'pandemic emergency' is suggested:

> **"pandemic emergency" means a public health emergency of international concern that is infectious in nature and:**
>
> **(i) is, or is likely to be, spreading to and within multiple States Parties across WHO Regions; and**
>
> **(ii) is exceeding, or is likely to exceed, the capacity of health systems to respond in those States Parties; and**

> **(iii) is causing, or is likely to cause, social and/or economic and/or political disruption in those States Parties; and**
>
> **(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.**

The IHR April 2024 draft uses the term ‘pandemic emergency’ at least 16 occasions. In the draft Pandemic Agreement, the term “pandemic emergency” is not defined, but it is used at least six times. When the Director-General has declared a “pandemic emergency” as defined in IHR April 2024, legal consequences under the Pandemic Agreement are also triggered. This shows the close connection between the existing IHR 2005 and the draft for å new Pandemic Agreement. The IHR is easier amended than the Pandemic Agreement is agreed to and ratified. Therefore, moving a new controversial article, which is increasing the already vast competence allocated to the Director-General, from the draft Pandemic Agreement to the amendments of the IHR, can prove to be a genius move. If the same trigger-point for competence, declaring “pandemic emergency”, is used in both these legal tools, the declaration concerning a concept under the IHR, will probably also trigger the rules in the Pandemic Agreement.

IHR April 2024 Article 12 proposes a new 4bis:

> **4bis. If the Director-General determines, in accordance with paragraph 4, that an event constitutes a public health emergency of international concern, he or she shall also determine, having considered the matters contained in sub-paragraphs a) through e) of paragraph 4, whether the public health emergency of international concerned also constitutes a pandemic emergency.**

The wording of this proposed paragraph suggests expander of the competence of the Director-General. Thus, the Director-General takes the decisions whether the world is in any of these two situations (public health emergency of international concern or also in a pandemic emergency).

There are procedures that the Director-General must follow when taking his decisions. IHR 2005 Articles 17, 48 and 49 establishes a system for the Director-General to follow on the way to determine temporary and standing recommendations. Nevertheless, the decision rests with the Director-General alone.

When a “public health emergency of international concern” (PHEIC) has been declared by the Director-General, the Director-General gets the competence to “… issue temporary recommendations” (IHR 2005 Article 15) regarding “health measures to be implemented by the State Party” (Article 15.2). The wording “to be implemented” indicates that Members are under certain obligations to follow the recommendations according to the IHR 2005. IHR 2005 Article 18 already gives the Director-General 13 different options of recommendations relevant

to persons. The Director-General can choose between, the following measures, according to IHR 2005 Article 18:

> Recommendations issued by WHO to States Parties with respect to persons may include the following advice:
> – no specific health measures are advised (1);
> – review travel history in affected areas (2);
> – review proof of medical examination and any laboratory analysis (3);
> – require medical examinations (4);
> – review proof of vaccination or other prophylaxis (5);
> – require vaccination or other prophylaxis (6);
> – place suspect persons under public health observation (7);
> – implement quarantine or other health measures for suspect persons (8);
> – implement isolation and treatment where necessary of affected persons (9);
> – implement tracing of contacts of suspect or affected persons (10);
> – refuse entry of suspect and affected persons (11);
> – refuse entry of unaffected persons to affected areas (12); and
> – implement exit screening and/or restrictions on persons from affected areas (13).
>
> (The numbering is added here.)

Several of these types of 'recommendations' are formulated in all-encompassing and unspecified manners. This leaves broad discretion to the Director-General in formulating the further detailed content in each recommendation.

2.2 Process and assessments when applying the competence

IHR 2005 Article 17 sets out criteria and procedures that the Director-General must follow in making the each 'recommendation':

> When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:
>
> (a) the views of the States Parties directly concerned;
>
> (b) the advice of the Emergency Committee or the Review Committee, as the case may be;
>
> (c) scientific principles as well as available scientific evidence and information;
>
> (d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;
>
> **(d bis) availability of, and accessibility to, relevant health products;**
>
> (e) relevant international standards and instruments;
>
> (f) activities undertaken by other relevant intergovernmental organizations and international bodies; and
>
> (g) other appropriate and specific information relevant to the event.
>
> With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.

This list is comprehensive. One observation is that there are committees that shall be

consulted. They however have not the last word or any formal effect on the decision by the Director-General. Several considerations shall be taken. There is however no reference to human rights in IHR 2005 Article 17 nor in the amendments in IHR April 2005. The lack of a clear reference to human rights, human dignity, and fundamental freedoms in the procedural rule, reduces the practical implication of the reference to these three overall considerations in the objectives (IHR 2005 Article 3). The Norwegian Infection Control Act § 1-5 includes three assessment that must be taken for each measure to counter infections.

2.3 The link between the recommendations and human rights

The competence granted the Director-General in IHR 2005 Article 18 is potentially in conflict or overlap with one or more human rights. Almost any potential recommendation on this list might concern values protected by human rights, human dignity or indeed curtail personal freedoms of man. The idea of infection control measures is to steer the behaviour of man. Therefore, recommendations are potentially in conflict with human rights, dignity or fundamental freedoms of man. Whether or not one recommendation is overlapping with each of these three overall principles must be assessed on a concrete basis reading each recommendation.

Since no reference is made to human rights in current IHR 2005 Article 17 or in the IHR April 2024 Article 17 proposal, the principles for implementation of the IHR set out in IHR 2005 Article 3 Paragraph 1 becomes even more important. IHR 2005 Article 3 Paragraph 1 requires that "The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons". In the proposals IHR 2022 the wording regarding these three overall objectives was proposed deleted. In the draft IHR April 2024 the wording in Article 3 Paragraph 1 is maintained and not suggested deleted. The obligation for the WHO to implement the IHR "with full respect for the dignity, human rights and fundamental freedoms of persons" is important.

WHO is as an international organization not party to the conventions on human rights, as for example the European Convention on Human Rights. Thus, without a clear recognition of an obligation for the WHO to implement this legal tool in full respect of human rights, human dignity and fundamental freedoms, the implementation process could be leading away from these overall principles.

To identify the competence of the Director-General one needs to discuss each of these types of potential recommendations according to IHR 2005 Article 18. Each type of

recommendation needs to be discussed in the light of *inter alia* these three overall principles of implementation (human dignity, human rights and fundamental freedom of persons). Potentially, the IHR and human rights are in conflicts.

The potential conflict between recommendations under IHR and existing human rights should be subject to further legal scholar discussions and needs to be taken into account by state parties to the IHR before a new version of the IHR is adapted. This overlap or potential conflict should also be subject to political considerations and discussions by parliaments. This is a strong argument for not adopting the IHR April 2024 proposal in May 2024. WHO should allow time for a thorough democratic discussion and scholar work, so member countries are fully aware of any overlap with and the legality of IHR-rules in respect of "the dignity, human rights and fundamental freedoms of persons".

2.4 Is a 'recommendation' by the Director-General legally binding?

In the discussions about the IHR often the question of the nature of a recommendation is discussed. Is a recommendation binding on state parties? What does binding mean in this context?

The formalistic point of departure is that a 'recommendation' means advice, proposal or suggestion. IHR 2005 Article 1, in the definition of standing and temporary recommendations, the definition reads: "means non-binding advice". The wording itself indicates that there has been no formal transfer of sovereignty or transfer of competence to the WHO to take decisions on behalf of the country.

In the IHR 2022 proposal, the wording "non-binding" was suggested removed from Article 1. Thus, at least one member country suggested to increase the bindingness of the recommendations by the Director-General. The technical committee of the WHO, writes at page 26 in document A/WGIHR/2/5, that this proposed deletion will not change the legal content of the obligations:

> However, given that substantial proposals were made in relation to WHO recommendations in other related articles, the proposed amendments to these definitions could be understood as aiming to change the nature of these recommendations from non-binding to binding, and giving a binding effect to WHO recommendations and requests as proposed in other articles. That change would require a fundamental reconsideration of the nature of recommendations and the process for their adoption and implementation.

It has been claimed that this wording has given rise to discussion that the legal status of

the recommendations according to the IHR will not be changed in the final IHR 2024.[10] In draft IHR April 2024, this proposed deletions of 'non-binding' in the definitions are not upheld.

The degree to which the recommendations binding is not alone decided by the use of the word binding or non-binding in IHR 2005 Article 1.

Other articles in the IHR must be interpreted to paint a more complete picture. IHR April 2024 including the amendments in Article 42 reads as follows:

> Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner. **States Parties shall take all practicable measures, in accordance with national laws, to engage with non-State actors operating in their respective jurisdictions with a view to achieving compliance with, and implementation of, health measures taken pursuant to these Regulations.**

Whereas the core obligation in IHR 2005 Article 42 already establishes a clear and strict obligation on member states: "Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner." States are already under the IHR 2005 Article 42 legally obliged to «initiate […] and complete […] without delay" the health measures taken pursuant to these Regulations. There are especially two terms in the wording that make IHR 2005 Article 42 a strong obligation in public international law: The word "shall" is the strongest word to express an obligation on state parties. Measures "shall be initiated and completed without delay". The wording "without delay" establishes a strict obligation regarding how rapid states must react to the 'recommendations' by the Director-General. The term "without delay" does not open for any margin of appreciation for countries. Often in law, the requirements concerning time frames allow for a reasonable delay or setting an acceptable ground for a lawful delay. Thus, the obligation according to IHR 2005 Article 42 appears as one of the strictest possible in international law.

The wording of IHR Article 42 read in conjunction with all the relevant articles indicates that the recommendations are binding on member countries to the IHR 2005.

2.5 Transfer of competence to a supra-national level?

2.5.1 Obligations leading towards a supra-national decision

There are not many (if any) other examples in international law where countries have undertaken to initiate and complete the content of a decision taken by one person in an

[10] – Usannsynlig at WHO vil få myndighet til å gi bindende pålegg til Norge - Rett24 [sett 11. oktober 2023]

international position. Leaving authority to one individual alone exposes the decisions to challenges of different nature.

After having observed that there is a legally binding obligation for states to "initiate[d] and complete[d]" all recommendations "without delay" the next question is how the decision shall be implemented in the nation state. There is a difference between a binding obligation in international law and that decision having a direct binding character in the national legal system of the nation states. The closer to giving direct effect in national law, more discretion can be said to have been transferred.

The draft IHR April 2024 Article 4 Paragraph 1 imposes another obligation on the member countries to designate either a "**National IHR Authority and** a National IHR Focal Point":

> 1. Each State Party shall designate or establish, **in accordance with its national law and context, one or two entities to serve as National IHR Authority and** a National IHR Focal Point, and **as well as** the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.
>
> **1 bis. National IHR Authorities shall coordinate the implementation of these Regulations within the territory of the State Party.**

Thus, the IHR obliges the member states to establish executive authorities with the legal competence to implement "health measures under these Regulations". A similar obligation follows from Annex 1 number 6 a: "Public health preparedness response. The capacities: (a) Establish **governance structure** to manage a potential or declared Public Health Emergency of International concern." These obligations to establish institutions to implement the 'recommendations' takes the decision system one step closer to rapid implementation of the decisions by the Director-General. Formally, however, the national institution must take decisions in accordance with the recommendation by the Director-General. The obligation to implement laws that are compatible with the obligations at the international level take a step closer direct effect of the decision by the Director-General.

One additional argument is that the IHR 2005 does not treat a situation where a country wants to implement a *less comprehensive* health measure than the recommendation by the Director-General. That option is not foreseen in the IHR 2005. IHR 2005 Article 43 establishes rules for the situation where a state party implements "additional health measures", but not the situation where the country decides to implement less comprehensive measures. This can be interpreted that member countries are meant not to have discretion to implement less comprehensive measures than what follows from the recommendations.

IHR 2004 in combination with proposals IHR April 2024 Article 44 has two references

to the need of countries regarding adopting their regulations for implementation of the Regulations:

> 1. States Parties shall undertake to collaborate with, and assist each other, to the fullest extent possible, in: […] (d) the formulation of laws and other legal and administrative provisions for the implementation of these Regulations; […]
>
> 2. WHO shall collaborate with**, and assist,** States Parties, upon extent possible, in […] **(d) strengthening domestic legislative and administrative arrangements for the implementation of these Regulations; and** […]

Both these two sections indicates that member countries shall "**strengthening domestic legislative and administrative arrangements for the implementation**".

Summing up member there are four elements promoting the implementation of the recommendation by the Director-General: 1) the states shall have in place one or maximum two institutions that shall implement the IHR, 2) they shall strengthening the legislative and administrative system the implementation of the recommendations, 3) that the counties are obliged to initiate and complete the implementation of without delay, and 4) there is no system for less comprehensive measures.

In addition to these obligations on the members, the WHO is discussing to establish a Compliance Committee in a new IHR April 2024 draft Article 54bis:

> **The Implementation and Compliance Committee for the International Health Regulations (2005) (hereinafter the "IHR Implementation and Compliance Committee") is intended to facilitate and oversee the implementation of, and promote compliance with, these Regulations. To this effect, the IHR Implementation and Compliance Committee shall: […]**

The draft IHR 2024 is more focused on the compliance with the Regulations and the decisions taken according to them.

Having looked at all these elements that are surrounding the recommendations we can conclude that the Director-General does not formally take decision with direct legal effect in national law, but the observations presented above established an institutional structure, pre-established national law ready to make national policy and law by the recommendations of the Director-General, the obligations to be rapid in the implementation of them and a compliance system, the IHR April 2024 facilitates as far as possible to make the recommendations binding in national law without formally transferring competence to the Director-General to take decision with direct binding effect in domestic law.

2.5.2 National preparation for rapid implementation of the decision by the Director-General

The other side of this implementation coin is the preparation taken by each country. The scope

of this paper does not allow for investigating the implementation and revision of legislation in all countries. Therefore, a look at Norway is offered here as an example and as to identify which changes in law that needs to be investigated to get a picture of this question.

The Infection Control Act § 1-2 section four, reads: "The provisions of the Act apply with the limitations recognized in international law or resulting from an agreement with a foreign state." Professor Anne Kjersti Befring refers to the IHR in the commentary to this section of the act.[11] She does not discuss the question regarding direct effect of any decision by the Director-General. The wording of section § 1-2.4 does not respond to the question of direct effect of the decisions, but it establishes a subordination of the Norwegian act to international regulations. The wording does refer to "limitations recognized in international law". One question is whether the recommendations can qualify as limitations in the Norwegian act recognized in international law. There is no doubt that the IHR is recognized in international law, and that recommendations from the Director-General also are recognized, although not necessarily binding. Whether the Act § 1-2.4 also covers the recommendations is less clear from the wording, but still an open question.

Until January 2024, the competence of the Directorate of Health, according to the act, should be used after consultations with the Institute of Public Health, according to the wording of § 7-10: "The Directorate of Health must obtain knowledge from the Institute of Public Health and use this knowledge as the basis for its assessments." This sentence was removed from the act with effect from January 1st, 2024. During the last years and the Covid-situation, these two organs have dived the responsibility, seemingly a fruitful division of work and responsibilities. The section of the act now allocates all competence to the Directorate of Health alone. The institutional structure is unified and clarified, as the amended IHR will be requiring.

2.5.3 Similarity between the IHR and the Norwegian Act

The link between the international level and the national state-level is particularly interesting. In Norway an obligation in international law must be implemented in a national act for it to be enforceable amongst citizens. The research question is to what extent the Norwegian Infection Control Act already provides delegated legislative competence to the Directorate of Health to implement administrative regulations in Norway that corresponds with any of the potential 'recommendations' according to IHR 2005 Article 18. The comparison is best explored with a table showing the competence of the Director-General compared to the existing authority delegated to the Directorate of Health in the Act.

[11] XXX

IHR Article 18 regarding humans	Norwegian Infection Control Act
no specific health measures are advised (1);	
review travel history in affected areas (2	Partly § 3-6
review proof of medical examination and any laboratory analysis (3)	
require medical examinations (4);	§ 3-1 and § 3-3, and § 5-2.4
review proof of vaccination or other prophylaxis (5)	The temporary rules on certificates were repealed July 1st 2023.
require vaccination or other prophylaxis (6);	§ 3-8 third to fifth
place suspect persons under public health observation (7);	§ 4-3a and chapter 5
implement quarantine or other health measures for suspect persons (8);	§ 4-3a
implement isolation and treatment where necessary of affected persons (9);	§ 4-3a and chapter 5 (5-2)
implement tracing of contacts of suspect or affected persons (10);	§ 3-6
refuse entry of suspect and affected persons (11);	§ 4-3
refuse entry of unaffected persons to affected areas (12); and	§ 4-3a
implement exit screening and/or restrictions on persons from affected areas (13)	§ 4-3a

From this table, we see that the Norwegian Infection Control Act already establishes competence for the executive power to give legal effect by administrative orders with the effect of an act, to almost any of the recommendations by the Director-General of the WHO. It would be interesting to conduct similar study of all country-members to the WHO. Such a study could provide a more complete picture of the legal structure in place already, to give effect to the recommendations by the Director-General.

In January 2024, the Parliament of Norway, the Storting, passed a new section to the act § 4-3a. This section reads as follows:

> In the event of a serious outbreak of an infectious disease dangerous to the public, cf. § 1-3 nos. 3 and 4, the King may, in order to prevent or counteract the transmission of the disease, issue regulations on
>
> a. isolation for infected persons, cf. § 1-3 no. 2, and
>
> b. the infection quarantine for persons who have an increased risk of being infected by the infectious disease that is dangerous to the general public after close contact with an infected or suspected infected person, or another source of infection.
>
> The King may by regulation determine other restrictions on the freedom of movement for persons covered by the first paragraph, and more detailed requirements for examinations in connection with, or

to compensate for, isolation, quarantine or restrictions on freedom of movement.

By the approval of this section of the act, almost any type of authority that the Director-General has, (according to IHR 2005 Article 18) have a corresponding section in the Norwegian Act. These sections in the Act allocate competence to the Directorate of Health to adopt administrative legislation that could follow almost any 'recommendation'. The Norwegian Infection Control Act does not grant the Director-General direct competence to implement the recommendations in Norwegian law. Decisions by the Directorate of Health is taken by its director. The already existing competence allocated to the Directorate of Health by these sections of the Act allows for implementation without any form of delay. The Directorate of Health will have to take new decisions according to the procedures in Norwegian law.

2.5.4 Relationship to human rights as implemented in national law

The preparatory work of the latest amendments to the Norwegian Infection Control Act only discusses the relationship between the competence to introduce isolation and human rights at a superficial level. Isolation and strict restrictions on freedom of movement creates several complex issues related to human rights. There is a need for exploring this overlap more in details. The extent to which the Norwegian Directorate of Health, will discuss the relationship between each 'recommendation' by the Director-General and the administrative regulation implementing in relation to human rights, dignity, and respect for the freedom of man is an open question.

The Norwegian Constitution establishes guaranties for the core human rights. In the spring of 2024, the Storting – the parliament of Norway, is discussing whether to include a general derogation competence allocated to the executive (government or ministries or directorates). The proposed constitutional amendment will be a new section § 113b.[12] This derogation competence would apply in crisis declared by the executive power from the majority of the human rights set out in the Constitution.

2.5.5 Supranational power?

When discussing transfer of competence or parts of the sovereignty to a supra-national level, from member countries, one needs to interpret relevant sources. Very seldom a treaty will have the heading 'transfer of sovereignty'. Determining whether a certain international rule entails

[12] https://www.stortinget.no/nn/Saker-og-publikasjonar/Saker/Sak/?p=81232

establishing supranational competence depends on an interpretation of the set-up for taking decision at the supranational level in conjunction with the corresponding rules in the relevant national legal system.

The fact that transfer of powers to the supra-national level is less clearly stated in wordings was one topic for the Norwegian Supreme Court. The question of when a legal system entails transfer of sovereignty was discussed in the ACER-case by the Supreme Court in Norway (HR-2023-2030-P, section 144-251). That case concerns the transfer of sovereignty to an EU organ, to which Norway is not a full member. The approach of the Court is interesting beyond the concrete case. None of the discussed articles in the ACER Regulation use the term transfer of competence. Nevertheless, the Supreme Court concludes that one instance entails transfer of discretion. The regulations establish a system where the Norwegian regulatory authority will transfer the decision of the EU organ into Norwegian law. If the Norwegian organ did not itself reach the same conclusion as the EU organ. This system entails a stronger position of the supranational organ, than the wording in IHR 2005. The crucial element for IHR 2005 entailing a situation of transfer of powers is the obligation on states according to IHR 2005 Article 42 in combination with other articles looked at above.

The legal set up in IHR April 2024 is not formally granting direct legal effect to the recommendations by the Director-General in Norwegian law. Formally, this is not a transfer of sovereignty. Technically and practically, two persons together can take decisions regarding all the topics in the table above where there is competence granted the Director of Health in the act. Formally, Director of Health will take the decision for Norway, but under the obligation according to IHR 2005 Article 42, with severe consequences for the country as a whole. None of them are politically elected or eligible for parliamentarian or legal responsibility. Each country will have or have had different process in amending their laws.

2.6 Require vaccination or other prophylaxis (6)

One of the competences of the Director-General according to IHR 2005 Article 18 is to give recommendations to countries to “require vaccination or other prophylaxis”. Recalling that IHR 2005 Article 42 requires that “Regulations shall be initiated and completed without delay”, the Director-General has comprehensive power in recommendations in directing the states to implement obligations on their citizens to undergo vaccination or prophylaxis. From the perspective of the individual, requiring medical treatment is a comprehensive interference in the personal sphere. On this topic it is interesting to explore the national law to identify whether

there are already rules allowing for vaccine mandates.

According to Norwegian law, vaccination or other prophylaxis is as a point of departure voluntary, and medical treatment is mainly a decision by a medical doctor of the patience. To require vaccination or other prophylaxis is an invasive intervention in the private sphere of a person. According to the principle of legality, for a public organ to require vaccination or other prophylaxis, requires a clear legal basis in law. Looking into this for other countries, the question is to explore wither the respective acts have a similar clause grating competence to introduce vaccine mandates.

Norwegian Infection Control Act § 3-8 third to fifth sets competence to the Norwegian authorities to oblige parts of the population to take a vaccine. The obligation establishes a duty to get a vaccine. This duty is combined with a potential reaction according to the Infection Control Act chapter 8 establishing the penalties for not following an obligation set out in an administrative decision. The Infection Control Act § 3-8 also establishes tailor-made reactions for the individuals that are not following a general rule for vaccination. These tailor-made reactions are that the one who refuses to follow the obligation can be required to stay in predetermined areas or be prohibited to participate in organized social activities. Thus, entailing considerable limitations in the human rights and individual freedoms of persons.

These rules in the Norwegian act show the close connection between the competence of recommendations to the Director-General of the WHO and the already granted legal authority to the executive power in Norway.

2.7 Review proof of vaccination or other prophylaxis (5)

IHR 2005 Article 18 number 5, IHR 2005 Part VI (Articles 35 and 36), IHR April 2024 draft for amendments to Articles 35 and 36, IHR April 2024 annex 6 and 7, are all relevant articles regarding requiring proof of vaccination or other prophylaxis. One of the competences of the Director-General, according to IHR 2005Article 18, is to give recommendations regarding the use of "review proof of vaccination or other prophylaxis".

IHR 2005 Article 35 establishes that:

> No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

The article establishes a that WHO/IHR-approved health documents to be the only one that can be required by countries for international travels. There is no mechanism beyond the norms providing for the recommendation according to IHR 2005 Article 18 establishing a system for approval of which vaccines or other prophylaxis that should be included in the health documents approved by the Director-General of the WHO in the IHR April 2024 main document.

IHR April 2024 Annex 6 Article 3 reads: "Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO." This seems to include a competence to the WHO regarding which types of vaccines or other prophylaxis that will be possible to be registered in a global certificate. In Annex 6 there are several references to WHO-approval of "vaccines or prophylaxis".[13]

> Approved by WHO refers to health products evaluated and listed by WHO under the WHO Prequalification (PQ) procedures, applicable to medicines, vaccines, in-vitro diagnostics, vector control products, immunisation devices; and inspection services; and Emergence Use Listing (EUL) procedures, applicable to medicines, vaccines, invitro diagnostics)[14]

This seems to imply that the Director-General, in a recommendation, will have the power to determine which vaccines or other prophylaxis that will be legally included in the travel document.

The power to authorize the inclusion of certain vaccines or other prophylaxis in the global 'digital health document', entails comprehensive power allocated to the Director-General. The decision to include or exclude one vaccine in the certificate system will have effect on the choice of vaccines and other prophylaxis in the health systems of countries. The lack of procedures in the IHR to include other health information in the health documents will narrow the possibility of the person to travel if not being vaccinated with those methods approved by the WHO under IHR.

On June 5th, 2023, the EU and WHO made public that they have concluded an agreement of 'digital health partnership', including making the EU-passport-technology available on a global level for the WHO.[15] The legal basis for the mandatory use of digital passports is partly a technical question and partly a question of law and policy requiring their use. By the collaboration between the EU and the WHO, the technical questions will come closer to being resolved.

[13] Se for a description of this procedure https://extranet.who.int/prequal/about/what-we-do
[14] Footnote to Annex 6, Article 3.
[15] The European Commission and WHO launch landmark digital health initiative to strengthen global health security [last accessed 14. Oktober 2023].

IHR April 2024 Article 35 proposes to be establish more comprehensive rules in the revised IHR regarding the digital health documents:[16]

> **2. Health documents under these Regulations may be issued in non-digital format or digital format, subject to the obligations of any State Party regarding the format of such documents deriving from other international agreements.**
>
> **3. Regardless of the format in which health documents under these Regulations have been issued, said health documents shall conform to the Annexes, referred to in Articles 36 to 39 as applicable, and their authenticity shall be ascertainable.**
>
> **4. WHO, in consultation with States Parties, shall develop and update, as necessary, technical guidance, including specifications or standards related to the issuance and ascertainment of authenticity of health documents, both in digital format and non-digital format. Such specifications or standards shall be in accordance with Article 45 regarding treatment of personal data.**

These proposed rules are detailed. During negotiations from 2022 to present, the rules in IHR 2022 Article 35 was made less binding. Especially two aspects were loosened: The proposal in IHR 2022 was that the certificate must provide a QR code, and they shall be globally harmonised. This reference to the QR code has been removed. The issue of verification is dealt with in IHR April 2024 Annex Article 4*bis*, which includes that for any certificate there may be included "additional elements allowing for the digital ascertainment of their authenticity".

The IHR 2022 proposed to grant competence to the Health Assembly to take decisions, inter alia, regarding technical aspects of the digital passports. Undertaking an obligation in international law where some decisions are left to a certain organ in the future, entails an element of transfer of competence to the WHA. Here the proposed wording said that what is approved by the WHA shall be recognised by all Parties. This competence is now removed

[16] This text has been modified extensively during the negotiations, as the IHR 2022 read like this:
"1. […] Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.
2. Health documents may be produced in digital or paper form, subject to the approval by the Health Assembly of the requirements that documents in digital form have to fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in the health documents. Health documents meeting the conditions approved by the Health Assembly shall be recognized and accepted by all Parties. Specifications and requirements for certificates in digital form shall take into account existing widely used systems established at the international level for the issuance and verification of digital certificates. Parties which are low and lower middle-income countries shall receive assistance in accordance with article 44 for the implementation of this provision."

from the draft IHR April 2024.

In the previous draft, IHR 2022 Article 18 number 2 proposed a new last bullet point:

> […] 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.

That proposed wording goes beyond information about "review proof of vaccination or other prophylaxis" and suggests a standard for travel information in addition to the health documents. A comprehensive rule in IHR 2022 Article 23 number 6 concerned Passenger Locator Data and expanded the proposed certificate with more data about the movement of the person. These proposals did not make it to the current draft IHR April 2024.

The temporary rules of the vaccine passport in chapter 4A in the Norwegian Infection Control Act have not been renewed. Currently, there is no clear regulations about requirement for health documents in Norwegian legislation.

2.8 (8) Implement quarantine or other health measures for suspect persons and (9) Implement isolation and treatment where necessary of affected persons

This merged subsection contains two situations: Where a person is proven to be affected and the situation where a person is suspect affected. Whether a person falls in any of these categories depends on a legal-medical definition. From Covid-19 we remember that at some points of time a person was regarded affected based on non-medical criteria rather than medical symptoms or medical symptoms that are common for different deseases. The definition of a suspect person typically will be a legal-medicinal definition. The term "suspect" is defined in the IHR 2005, as:

> "suspect" means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;

Any definition of "suspect" will be disease-specific and might be changed over time as more medical knowledge is developed. The wording in IHR 2005 Article 1, also leaves part of the definition of "exposed" to the State Party.

Quarantine for a suspect person, isolation for an affected person, mandatory treatment for an affected person and the undefined group of 'other health measures' for suspected persons are all invasive measures for a person.

In deciding how to draft the recommendations there are a number of variables, like whether there is a functional and reliable test, the predicted incubation time, symptoms that can be attributed to that particular disease and manner the disease can be transmitted. All these variables will be relevant to assess when formulating any recommendations for how member countries should implement health measures. The criteria for recommendations set out in IHR 2005 Article 17, along with the very few additions in IHR April 2024 Article 17, are relatively scarce in describing how the medical and scientific reasoning behind a recommendation shall be set up. The lack of such procedures is a challenge for the IHR.

In the Norwegian Infection Control Act § 4-3a and chapter 5 respectively, the health authorities have power to pass general rules concerning isolation, quarantine and other restriction in the movement of persons in and administrative order (§ 4-3a) and individualised decisions for persons assessed by a doctor to be suspect of affected, on a case by case, person by person assessment. The IHR 2005 Article 18 is silent on whether the measures target general rules or individual decisions.

2.9 Human rights that are relevant to consider

For the competences discussed above, different human rights are relevant. Different human right-instruments are also binding for different countries in the membership of the WHO. One relevant question is to identify the manner that each health measure set out in IHR 2005 Article 18 will be overlapping or in conflict with human rights. A core question to explore is how human rights obligations on the member states will conflict with one or more of the obligations in IHR 2024 or the recommendations according to the IHR.

One core question for nations when they implement laws grating competence to the health authority under national law, is to consider the relationship to human rights. The system in The European Convention on Human Rights includes a system for delimiting human rights based on concrete assessment of whether it is necessary in a democratic society, when criteria according to the concrete human right article are fulfilled. Since the recommendation by the Director-General will set out the restrictions on human rights, and since the national health authorities, in many situations, already will have rules granting them discretionary power, the assessment of the overlap with human rights will end up being decided by the health authorities in each country. The human-right idea of requiring law as a legal basis limiting human rights is ideologically funded in the idea of involving the legislative powers when curtailing the rights. The involvement of the legislator is an important part of the justification of grating discretion

to countries to limit human-right protection. By the requirement on State Parties in the IHR to implemented laws ready to respond to the recommendations from the Director-General and emergency situation, there are paragraphs in the act that potentially overlap with human rights. The assessment of the relationship between human rights and any potential restrictions is now being done by the legislator in an abstract manner, and not by a concrete assessment case by case which could include the details of any actual limitation to the human right.

Rather when the parliament has passed an act which grants competence to the executive, then the concrete assessment will be done by the, *in casu*, Health Directorate, which will itself interpret the human right. The Infection Control Act § 1-5 therefore requires the executive to conduct three assessments for every measure implemented:

> Infection control measures according to the law must be based on a **clear medical justification**, be **necessary** for reasons of infection control and **appear useful after an overall assessment**. When implementing infection control measures, emphasis must be placed on voluntary participation from the person or persons to whom the measure applies.

During Covid-19 the executive did not conduct all these three assessments in writing before implementing administrative orders. The Supreme Court of Norway (HR-2022-718-A) did not apply these requirements in a strict manner. The Supreme Court of Norway built on the fact that the executive powers did not consider whether the human rights or the Constitution was infringed by restricting the right to free movement (section 139 in the decision). The Court then concluded that since such an assessment was disclosed during the court process, then Human Rights obligations were met: "[…] nevertheless, there can be no requirement that the authorities have carried out an express assessment of the relationship with the Constitution and the ECHR, if it is made clear in a subsequent judicial review that the conditions for intervention were met". In this case, the Supreme Court sets the threshold low for the requirement to assessments by the health authorities.

To conclude on the discussions regarding the draft modifications in IHR 2005 set out in IHR April 2024: The competence of the Director-General to pass recommendations is comprehensive, wide, and undefined. The States are under strict obligations to have a legal system for implementation of these recommendations. By IHR 2005 States have undertaken to initiate and complete the implementation of the recommendations without delay. What is less clear in IHR 2005 and IHR April 2024 Article 17 and in national law, is how infection control measures shall be assessed and implemented in conformity with human rights and human dignity.

3 Legal Concepts in the Pandemic Agreement

Writing about the Pandemic Agreement now is guaranteed to be describing history. Negotiations will go on till close to the WHA. Therefore, the ambition of this section is to draw some long line concerning the main components of the Pandemic Agreement, with a special focus on the outstanding and difficult political questions.

3.1 One Health

A new concept in law and policy of health has been brought to the global scene as part of the draft Pandemic Agreement. This concept is coined in the term 'One Health'. The 'One Health' concept is introduced in the draft Pandemic Agreement Article 5, whereas other articles in the draft Pandemic Agreement are also relevant to fully understand the concept, for example draft Article 4.

Seemingly, there are political divergencies among countries in the Intergovernmental Negotiating Body to reach consensus on One Health. Especially, obtaining consensus will be difficult, as time is short till the WHA on May 27th, 2024. The latest draft text is much less clear than previous drafts, and the wording is less detailed. One way forward is to agree on the Pandemic Agreement with general references to 'One Health' and negotiate its more detailed content later. This approach is being discussed as part of the final resolution. There are challenges by this approach, as countries are agreeing to a concept with being fully aware of its details.

'One Health' establishes that there is an "interface between human, animal and environment ecosystems" with regards to health.[17] The draft calls for collaboration regarding "emergence and re-emergence of disease at the human-animal-environment interface". 'One Health' entails an expansion of the area of work of the WHO, from being the lead UN organization in human health, to also deal with animal health and ecosystems. Potentially, WHO can end up being in charge of topics beyond human health though the concept of One Health.

One Health is also built on a principle of collaboration among sectors or branches of authority. Draft Pandemic Agreement Article 5.1 reflects this by calling for work to be done "coherent, integrated, coordinated and collaborative among all relevant actors". The concept of

[17] Draft Pandemic Agreement of October 2023 and in the draft of March 17th, 2024, Article 1e).

One Health calls for integrated and coordinated approaches within and between sector authorities within countries and among countries.

The concrete legal content of 'One Health' is not spelled out in details in the current draft. Several articles in the draft Pandemic Agreement concerns collaboration between countries and state obligations on countries to develop domestic law. In the current drafts, there are no links between the concept of One Health and the health measures according to the IHR 2005 or draft IHR April 2024.

In academic theory there has been discussions regarding the usefulness of the concept 'One Health'. The room for its development makes it a highly dynamic concept.

3.2 Exchange of pathogens

The Intergovernmental Negotiating Body has also difficulties to reach agreement on draft Pandemic Agreement Article 12. This draft article proposes to establish a multilateral system for access and benefit sharing.

One core observation regarding ABS systems is that the regulation is made in international law, whereas the obligations in many situations shall apply to private companies, often with branches in many countries. ABS is a complex legal system of rules that takes time to develop. The Access and Benefit-sharing system under the Convention on Biological Diversity also took long time to get in place. When the Nagoya Protocol was supposed to be implemented a new controversy arose around the Digital Sequence Information.

The subject matter is defined in draft Pandemic Agreement Article 1 "(c) 'PABS Material' means the biological material from a pathogen with pandemic potential, as well as sequencing information relevant to the development of pandemic-related health products." This definition circumvents the difficult interpretation of the term "genetic resources" which is the core term for other ABS systems. In an earlier draft another core term was defined in more detailed "(a) "genetic sequences" [which] means the order of nucleotides identified in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus". These draft definitions read in conjunction gives a good impression of what is to be made available in the PABS system. However, the latter definition is not included in the draft of April 22nd, 2024.

The draft published in November 2023 contains an outline for a comprehensive, detailed and specific ABS system, called WHO PABS System. In February the EU commented draft for a Pandemic Agreement became accessible. For most of the article the draft set out major

divergences in the EU position and the clean draft published in November 2023. Regarding PABS (draft Pandemic Agreement Article 12), the EU reserved its position and states that it still was studying the topic. In the draft of April 22nd, 2024, paragraph 1 reads that a "multilateral access and benefit-sharing system for pathogens with pandemic potential" is established. The more detailed rules of such a system are not clear. In the discussion on the resolution for the decision at the WHA, there is a draft for mandating future negotiations on the PABS system.

Diverging views amongst the member states on the establishing of an access system for pathogens has been reported. Experiences from the other international forums that regulates access and benefit sharing is considerable political diverging view on whether and how to establish enforceable rules on the industry.

The Convention on Biological Diversity establishes sovereign rights for countries to genetic material from within their territory, with no exclusions, in principles also not for pathogens. During the negotiation of the Nagoya Protocol, International Chambers of Commerce (ICC) proposed that pathogens should be excluded.[18] This proposal was however rejected by the negotiating parties. The Nagoya Protocol Article 4 (number 2 and 4) opens for specialised instruments for groups of genetic resources.[19] [20] In a previous draft of the Pandemic Agreement it was suggested that the agreement itself shall declare that the PABS is in line with the exception in Nagoya Protocol Article 4. This is problematic since it is the meeting of parties to the CBD and Nagoya Protocol that has the competence to decide if another ABS system is a specialised ABS system. The draft Pandemic Agreement also does not clarify the relationship between PABS and the existing WHO rules under the Pandemic Influenza Preparedness (PIP) Framework.

The draft Pandemic Agreement Article 12 outlines core principles for Access and Benefit Sharing but leaves more of the necessary details out. The draft PABS system is proposed to cover both access to pathogens in a crises situation and in a normal situation. The system is proposed to be based on a Standard Material Transfer Agreement (SMTA), that probably will work as a private law contract. This means that even if the PABS in the Pandemic Agreement reaches a conclusion and is adapted, still a contract must be negotiated or drafted.

[18] Pathogens and IR on ABS 11-09-09 (cbd.int) [Checked: May 8th, 2024.]
[19] Michelle Rourke, The Pandemic Influenza Preparedness Framework as a 'Specialized International Access and Benefit-Sharing Instrument' under the Nagoya Protocol. She is in doubt whether the PIP Framework is sufficient as an article 4 system.
[20] Abbie-Rose Hampton,1 Mark Eccleston-Turner, Michelle Rourke, and Stephanie Switzer. 2023. Equity in the Pandemic Agreement: Access and Benefit Sharing as a Policy Device or a Rhetorical Device? The Journal of Law, Medicine & Ethics, 51 (2023): 217-220.

The draft Pandemic Agreement proposes to establish minimum standards that the SMTA will need to meet in the forthcoming negotiations and in any SMTA (draft Pandemic Agreement April 2024 Article 12.3 (b)). One of the politically difficult legal questions to solve in the negotiations in the INB is how the minimum requirements to the SMTA shall be set out in the binding document in public international law.

Another element of a future PABS-system that is left for later negotiations is the distribution of benefits from the system. The October draft Pandemic Agreement Article 12.6 reads: "The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic-related products, based on public health risks and needs." The term is further defined as: "(f) "pandemic-related products" means products that are needed for pandemic prevention, preparedness, and response, which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;" (October 2023 draft). These products are produced by private companies, thus, to implement an obligation on them to share is not an easy task in legislation.

The text in the version A/INB/7/3, of October 30th ,2023, was comprehensive. The text in the draft of April 22nd, 2024, is much shorter and less detailed.

The draft Pandemic Agreement Article 12 addresses the links to inventions and innovation closely linked to pathogen material or information. It is an open question whether there will be political consensus to regulate these issues in the Pandemic Agreement. The draft also establishes one link to the patent system: Article 12.4.(a) "(iv) Recipients of WHO PABS Material shall not seek to obtain any intellectual rights on WHO PABS Material." The wording does not establish any binding obligations on the actual users of material from the PABS system. Such an obligation must be transformed into the laws of the country to be applicable for private parties. The rule targets the 'Material' from the PABS. The inventions, products and processes, based on research on the Material are outside the scope of the prohibition of patenting.

3.3 Regulation of the link to patent

Draft Pandemic Agreement Article 11 regulates transfer of technology. In particular it foresees the following: "[…] shall strengthen existing, and develop innovative, multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how". The wording of this obligation is softer. What is the detailed legal meaning of strengthening mechanisms that promotes transfer of technology? The

lack of clear wording on how a Pandemic Agreement will establish clear legal rules regarding how the world will deal with patented inventions crucial to combat a pandemic is a challenge.

On May 9th, 2024, there were at least 9,464 patent applications in the WIPO web database containing the search word 'Covid'.[21] These patents have not been investigated in this study, but the high number of applications shows that the patent system is an applicable legal tool in the area of health. The objective behind the patent system is to create incentives to invest time and resources in reseatch and development for solve problems in society.

World Trade Organization (WTO) og World Intellectual Property Organization (WIPO) regulate different aspects of the global patent system. The Agreement on Trade-related Intellectual Property Rights (TRIPS) sets a number of minimum standards for patent protection in national and regional patent systems, *inter alia*, it sets the legal exclusions from patent protection (TRIPS Article 27.3). Member countries to the WTO are all obliged to provide for a patent system with the limited exemptions and exclusions that follows from the TRIPS Agreement.

The WTO with its TRIPS Counsil is more of a law-making organ. The WIPO is both law-making and an executive organisation. WIPO organises the global search for *prior art*, which is the first step in the assessment of whether a patent shall be granted or not. The novelty and inventiveness of an invention depends on whether some else has published a text that is close to the invention described in the patent claims. The patent claims define the patented invention from the rest of the world of applied ideas. The WIPO also secures a global date for priority of the patent application.

The core of a patent right is that the patent owner can set terms and conditions for the use of the invention, including the price of others producing the invention. A combination of a public authority requiring the use of a certain patented health product and a patent to that product will guarantee a high income for the patentholder. This is a combination that will favour the companies that hold patents to the vaccines other prophylaxis that are required for receiving a certificate for travel. A monopoly rights combined with an obligation to use the monopolised product will create a strong position in the market.

During Covid there was a debate in the TRIPS Council regarding establishing limits to the patent protection for core inventions to combat that emergency situation.[22] South Africa and India put forward a proposal for a waiver of patent rights during Covid:

[21] According to the web site Patentscope, https://patentscope.wipo.int/search/en/result.jsf?query=FP%3A%28covid%29&sortBy=-score

[22] directdoc.aspx (wto.org) [Seen 19. Oktober 2023]

> 1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.[23]

The waiver contains five points, but the membership to the TRIPS Council did not agreement to the proposed waiver. Neither the IHR 2022, IHR April 2024, nor the draft Pandemic Agreement contain any patent waiver for health products recommended by the WHO. Rather, in the preamble of the draft Pandemic Agreement states the following about intellectual property rights:

> 10. Recognizing that the protection of intellectual property rights is important for the development of new medical products, and recalling that intellectual property rights do not, and should not, prevent Member States from taking measures to protect public health, and further recognizing concerns about the effects of intellectual property rights on prices.

This wording gives no indication of any waiver of relevant patent rights in an emergency situation. The combination of the experiences in the TRIPS Council under Covid and the lack of any clear waiver of patent rights in an emergency situation indicates that an imbalance in the legal system.

To balance the system and making the combat of a pandemic on equal footing, one could include a general exclusion for patent rights for certain types of products in an emergency situation. The Pandemic Agreement Article 3, paragraph 3 sets equity as one of the objectives. From experiences in the CBD and other international forums, patent issues are seldom allowed negotiated in other forums than WIPO and TRIPS Council.

3.4 Information – infodemics

WHO has increased focus on information and the term infodemics. Both the negotiating forums have proposals regarding information. At a general level, the WHO is already working on infodemic.[24] What was proposed as Article 1 (c) in an early draft, is not the working definition at an informal level, by its use at the website stating that:

> "infodemic" means too much information, false or misleading information, in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviours that can harm health. It also leads to mistrust in health authorities and undermines public health and social measures;

[23] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True [last accessed 7. February 2024]
[24] https://www.who.int/health-topics/infodemic#tab=tab_1

Infodemic is becoming a term and an applied concept before it has been agreed to in a treaty.

In the draft IHR 2022 Article 44 number 1 (h) there was a proposed rule regarding information:

> States shall collaborate as far as possible […] in 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.

This proposal has not been upheld in the draft IHR April 2024.

The wording uses the term "false or unreliable" to characterise information, thus someone must decide what is false and what is not false. The IHR 2022 does not entail proposals for procedures to determine the validity of information or an institutional structure to be applied to determine their validity. In the different versions of the Pandemic Agreement there have been proposed different approaches to information.

One of the first drafts of the Pandemic Agreement included a comprehensive and detailed rules on information:[25]

> 1. The Parties commit to increase science, public health and pandemic literacy in the population, as well as access to information on pandemics and their effects, and tackle false, misleading, misinformation or disinformation, including through promotion of international cooperation. In that regard, each Party is encouraged to:
>
> (a) promote and facilitate, at all appropriate levels, in accordance with national laws and regulations, development and implementation of educational and public awareness programmes on pandemics and their effects, by informing the public, communicating risk and managing infodemics through effective channels, including social media;
>
> (b) conduct regular social listening and analysis to identify the prevalence and profiles of misinformation, which contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust; and
>
> (c) promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and evidence. A/INB/4/3 24
>
> 2. The Parties will contribute to research and inform policies on factors that hinder adherence to public health and social measures, confidence and uptake of vaccines, use of appropriate therapeutics and trust in science and government institutions.
>
> 3. The Parties shall promote science and evidence-informed effective and timely risk assessment, including the uncertainty of data and evidence, when communicating such risk to the public.

[25] A_INB4_3 Draft Article 17

In a later version of the draft Pandemic Agreement, information and disinformation were dealt with in less comprehensive rules on the topic (document A/INB/7/3):

> Article 18. Communication and public awareness
>
> 1. The Parties shall strengthen science, public health and pandemic literacy in the population, as well as access to information on pandemics and their effects and drivers, and combat false, misleading, misinformation or disinformation, including through effective international collaboration and cooperation as referred to in Article 16 herein.
>
> 2. The Parties shall, as appropriate, conduct research and inform policies on factors that hinder adherence to public health and social measures in a pandemic and trust in science and public health institutions.
>
> 3. The Parties shall promote and apply a science- and evidence-informed approach to effective and timely risk assessment and public communication.

The wording establishes clear obligations on member states. The manners and methods for "combat" such information (false, misleading, misinformation or disinformation) are however not specified. This leaves considerable discretion for the future regarding how the law in this area will be guided and how measures will be implemented. The broad manner the wording is formulated will give a lot of flexibility in the concrete measures taken with the objective stated in the wording regarding the combat of "false, misleading, misinformation or disinformation".

The rules regarding information was again shortened and made less detailed in the draft of April 22nd, 2024, which reads as follows:[26]

> Article 18. Communication and public awareness
>
> 1. The Parties shall strengthen science, public health and pandemic literacy in the population, as well as access to transparent, accurate, science- and evidence-informed information on pandemics and their causes, impacts and drivers, particularly through risk communication and effective community-level engagement.
>
> 2. The Parties shall, as appropriate, conduct research to inform policies on factors that hinder or strengthen adherence to public health and social measures in a pandemic and trust in science and public health institutions, authorities and agencies

The wording is not using the terms false information for example. When comparing the text originally proposed and the current draft one observation is the less extensive. The new text is also less focused on the unspecified terms like false information, misinformation and alike. From the existing website of the WHO it seems that infodemics is already established as a concept, with limited legal funding.

[26] https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3Rev1-en.pdf

4 Discussions and Conclusion

4.1 Elements of competence at the supra-national level

One of the political discussions is the extent to which the respective legal tools, the IHR and the Pandemic Agreement are moving competence to the supra-national level.

When a tool of international law transfers competence to an organ beyond the nation-state, the term 'transfer of competence' is rarely in the headline. To assess transfer of competence one needs to interpret the decisions-making system in the legal tool. Transfer of competence can happen for legislative, executive or judicial powers. For transfer of legislative power in international law, typically there will be procedures for amending the treaties or adapting new treaties. For the executive powers, the situation is that decision is taken within the existing treaties, based on any decision-making structure set out in the agreement. Transfer of judicial powers presupposes the establishment of a court or other judicial institution for deciding on single cases. Under the current system of the WHO there are elements of both legislative and executive power at the global level.

4.2 Law-making procedures in the WHO

WHO Constitution establishes the World Health Assembly as the core law-making body of the organization, chapter V, Articles 10-23. According to WHO Constitution Article 19, the WHA can adapt legal binding instruments with a 2/3 majority.[27] 'Regulations' can be adapted according to WHO Constitution Article 21 and 22. It is foreseen that a regulation can according to enter into force more rapidly than an agreement.[28]

A core general principle in international law is that countries must declare themselves bound by a new treaty or amendment to an existing treaty obligation. The legal background for the rule is the principle of sovereignty. A sovereign country is typically not bound unless the country's authorities have followed the country's constitutional rules for binding the country to an international obligation. The Vienna Convention on the Law of Treaties of 1969 sets out rules regarding how a treaty becomes binding under international law.[29] A consequence of this possibility to establish treaty-obligations is that countries can bind themselves to an international system which has competence to create new legally binding obligations.

[27] couv arabe.indd (who.int) [last accessed 16. Oktober 2023]
[28] Eriksen in Kriseregulering argues that a regulation can enter into force when adapted. See professor Eriksens analysis of the IHR: Vil generaldirektøren i WHO få mer myndighet over Norge?. Faktisk. [last accessed 16. Oktober 2023]; professor Eriksen in rett24.no: [last accessed 16. October 2023]
[29] Translated from Part 1.

The WHO Constitution Articles 21 to 22 must be read considering the IHR 2005 Article 59 number 1, which reads:

> The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

The time-limit for countries to reject or reserve themselves from the amendments was shortened by a decision at the WHA in May 2022. It was reduced from 18 months to a period of 10 months. The time-limit for protests to this amendment expired in November 2023 according to the 18 months rule of the IHR 2005 then in force. For the future, the time limit for countries to reject an amendment or refuse to be bound by it is 10 months. It is interesting to observe the strict cut-off clause: "Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect." Members to the IHR 2005 will be bound to amendments if they do not act. In international law, this kind of binding by non-action is not common.

Norway is bound by this system in IHR. The IHR 2005 was not presented by the government for the Norwegian Parliament when it was entering into force. According to professor Eriksen, the government has never presented a case regarding the IHR before the parliament.[30] According to Norwegian Constitution the Parliament must be presented a treaty that the executive power has negotiated and concluded. Normally, a majority in the Parliament is enough for approving the ratification of a new treaty-obligation (Grunnloven, the Norwegian Constitution § 26 second section). In the case of a treaty that confers competence which normally lays with another power, according to the Constitution § 115 the Parliament must approve that treaty by a three fourth majority. One could ask whether the membership to IHR 2005 of Norway is valid as the Parliament has not been presented and voted for the membership.

4.3 Decisions by the Director-General

The second questions regarding transfer of power concerns executive decision. In international law it is rare that competence is allocated to one person like is the case in IHR 2005.

One manner to make rapid implementation of decisions from the supranational level into national law is to require a national decision-making process and institution that matches

[30] Se professor Eriksens uttalelser mot slutten: Vil generaldirektøren i WHO få mer myndighet over Norge?. Faktisk. [sist sett 16. Oktober 2023]; professor Eriksen gav uttrykk for det samme i et intervju i rett24.no: – Usannsynlig at WHO vil få myndighet til å gi bindende pålegg til Norge - Rett24 [siste sett 16. oktober 2023]

the competence of the international body. This is not formally transfer of competence.

From a practical legal point of view, the level of supranational binding will depend on the obligations on the countries in the treaty to follow the supranational decisions. A clear obligation, including an obligation to adapt and implement corresponding legislation together will open for a situation close to transfer of competence.

An important distinction can be drawn regarding transfer of competence, whether the decision is directly applicable as a source of law relevant for the legal situation for legal persons in a country. In such a case, there is a formal transfer of competence. The level of competence transferred is less clear in the situation where the domestic legal system requires a decision according to national procedures for the content to be binding in national law. The degree of discretion for the national authority will be an important argument in clarifying this.

The rule in the Norwegian Act § 1-2 paragraph referring to international law as prior to the rules of the act leaves a significant amount of doubt regarding the legal priority between a decision (recommendation or other) by the Director-General and the rules in the Norwegian act. This rule can be interpreted as that a decision from the WHO has been given a direct effect in Norwegian law. The wording of this rule does not fully answer the question of transfer of discretion.

4.4 Conclusions

Writing an analysis of two drafts that are in negotiation processes under secrecy, is not an easy task. Both drafts are moving targets. It was especially complex to conduct this study in time when their latest drafts were kept secret. Therefore, any of the texts discussed here can already be outdated or dropped. They can also have been modified to a far more comprehensive rule.

Secrecy is not a democratic principle for law-making. Especially, since we have seen in the discussions in section 2 and other parts that the competence concern core parts of the human rights and limitation to core freedoms of persons. From this perspective the pressure on national authorities from an international organization to accept the secrecy can only be challenged politically or legally by requiring access to the drafts on the table. Allowing the organization that is expanding its competence to decide that the negotiations shall be kept secret is particularly problematic in a democratic perspective.

The lack of human-rights perspectives in the negotiations and in the operative articles of the drafts is a challenge for the future of global health law.