

WHO – International Health Regulations (IHR) / Internationale Gesundheitsvorschriften (IGV) – Änderungen – Synopsis

In der Synopsis werden die Änderungen in den verschiedenen Fassungen, bezeichnet als IGV-E, einander gegenübergestellt, mit dem Zweck, aufzuzeigen, wann welche Änderungsvorschläge eingebracht worden sind, und inwiefern dadurch die Verfahrensregel von Art. 55 Abs. 2 IGV verletzt worden ist.

IGV-E 2022 (publ. 16.11.1022)	IGV-E 17.4.2024	IGV-E 20.5.2024 (publ. 27.5.2024)	IGV-E 1.6.2024
<p>Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022) https://apps.who.int/gb/wgihr/index.html</p> <p>Legend Strikethrough = delete existing text Underlined and bold = new text proposed (...) = existing text in the IHR for which proposals for amendments were not submitted and thus omitted from this compilation</p> <p>Änderungsvorschläge dieser Fassung, die keinerlei Eingang in die folgenden Fassungen gefunden haben, werden in dieser Synopsis nur soweit aufgeführt und gegebenenfalls farblich unterlegt, als sie allenfalls an einen anderen Ort hin verschoben worden sind (vgl. z. B. Art. 44 Abs. 1 lit. h und Abs. 2 lit. e nach ANNEX 1, A. Ziff. 2 und 3)</p>	<p>Proposed Bureau’s text for Eighth WGIHR Meeting, 22–26 April 2024 https://apps.who.int/gb/wgihr/</p> <p>Neue Texte sind fett hervorgehoben, (teilweise) auch solche, die letztlich keinen Eingang in die folgenden Fassungen bzw. in die Endfassungen gefunden haben, weil sie neue “Wortlaute von Änderungsvorschlägen“ enthalten, welche nicht im Einklang mit Art. 55 Abs. 2 IGV kommuniziert worden sind.</p> <p>Erstmals seit November 2022 erscheinende neue “Wortlaute von Änderungsvorschlägen“ (Art. 55 Abs. 2 IGV werden, soweit sie Eingang in die folgenden Fassungen bzw. in die Endfassung, gefunden haben, hier zudem mit roter Schrift hervorgehoben.</p>	<p>BUREAU’S PROPOSED TEXT https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_9-en.pdf</p> <ul style="list-style-type: none"> – Green: text for which consensus had been achieved ad referendum. – Yellow: text for which the Bureau had presented updated text proposals on 20 May 2024. – Blue and bracketed: the Bureau’s updated proposed text regarding Articles 13(8)(e) and 44(2 ter)(c). – White: text shown on screen at 16:00 Central European Summer Time on 18 May 2024, (excluding highlighted text and attribution of proposals) related to the Bureau’s updated proposed text, presented in text boxes for readability purposes. – Grey: existing text of the International Health Regulations (2005) for which no amendments had been proposed. 	<p>Amendments to International Health Regulations (2005) agreed at Seventy-seventh World Health Assembly https://www.who.int/news/item/01-06-2024-seventy-seventh-world-health-assembly---daily-update--1-june-2024</p> <p>«Im Konsens» verabschiedete Endfassung</p> <p>Neue Texte fett hervorgehoben</p>

<p><i>Article 1 Definitions</i></p>	<p><i>Article 1 Definitions</i></p> <p>“early action alert” means information and non-binding advice issued by the Director-General to States Parties on an event which, at the time of the consideration pursuant to paragraph 4 of Article 12, he or she has determined does not constitute a public health emergency of international concern.</p> <p>“National IHR Authority” means the entity designated or established by the State Party at the national level to coordinate the implementation of these Regulations within the territory of the State Party.</p> <p>“pandemic” means a public health emergency of international concern, that is infectious in nature and:</p> <ul style="list-style-type: none"> (i) has spread and is spreading to and within multiple States Parties across WHO Regions; and (ii) is exceeding the capacity of health systems to respond in those States Parties; and (iii) is causing social and/or economic and/or political disruption in those States Parties; and (iv) requires rapid, equitable and enhanced coordinated international action, with 	<p><i>Article 1 Definitions</i></p> <p>“National IHR Authority” means the entity designated or established by the State Party at the national level to coordinate the implementation of these Regulations within the jurisdiction of the State Party;</p>	<p><i>Article 1 Definitions</i></p> <p>“National IHR Authority” means the entity designated or established by the State Party at the national level to coordinate the implementation of these Regulations within the jurisdiction of the State Party;</p>
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<p><u>“health products” include therapeutics, vaccines, medical devices, personal protective equipment, diagnostics, assistive products, cell- and gene-based therapies, and their components, materials, or parts.”</u> <u>“health products” include medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health</u></p>	<p>whole-of-government and whole-of-society approaches.</p> <p>“pandemic emergency” means a public health emergency of international concern that is infectious in nature and:</p> <p>(i) is, or is likely to be, spreading to and within multiple States Parties across WHO Regions; and</p> <p>(ii) is exceeding, or is likely to exceed, the capacity of health systems to respond in those States Parties; and</p> <p>(iii) is causing, or is likely to cause, social and/or economic and/or political disruption in those States Parties; and</p> <p>(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.</p> <p>“health products” means medicines; vaccines; medical devices including diagnostics; assistive products; vector control products, blood and other products of human origin. They are products used to prevent, protect, diagnose, treat diseases and health conditions.</p>	<p>“pandemic emergency” means a public health emergency of international concern that is caused by a communicable disease and:</p> <p>(i) has, or is at high risk of having, wide geographical spread to and within multiple States; and</p> <p>(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and</p> <p>(iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and</p> <p>(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.</p> <p>“relevant health products” means medicines, vaccines, medical devices including diagnostics, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies, which are needed to respond to public health emergencies of international concern, including pandemic emergencies;</p>	<p>“pandemic emergency” means a public health emergency of international concern that is caused by a communicable disease and:</p> <p>(i) has, or is at high risk of having, wide geographical spread to and within multiple States; and</p> <p>(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and</p> <p>(iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and</p> <p>(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.</p> <p>“relevant health products” means those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-</p>
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<p><u>technologies, but not limited to this course.</u></p>	<p>“product dossier” means a set of documents – organized according to the guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, or other applicable formats, – related to a health product submitted for assessment to either a regulatory authority for marketing authorization or to the World Health Organization for prequalification or emergency use listing;</p>		<p>based therapies, and other health technologies;</p>
<p><i>Article 2 Scope and purpose</i></p> <p>The purpose and scope of these Regulations are to prevent, protect against, prepare, control and provide a public health response to the international spread of diseases <u>including through health systems readiness and resilience</u> in ways that are commensurate with and restricted to public health risk <u>all risks with a potential to impact public health</u>, and which avoid unnecessary interference with international traffic and trade, <u>livelihoods, human rights, and equitable access to health products and health care technologies and know how.</u></p>	<p><i>Article 2 Purpose and scope</i></p> <p>The purpose and scope of these Regulations are to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risk and which avoid unnecessary interference with international traffic and trade.</p>	<p><i>Article 2 Purpose and scope</i></p> <p>The purpose and scope of these Regulations are to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risk and which avoid unnecessary interference with international traffic and trade.</p>	<p><i>Article 2 Purpose and scope</i></p> <p>The purpose and scope of these Regulations are to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risk and which avoid unnecessary interference with international traffic and trade.</p>

<p><i>Article 3 Principles</i></p> <p>1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons <u>based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development.</u></p>	<p><i>Article 3 Principles</i></p> <p>1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and shall promote equity and solidarity among States Parties.</p>	<p>Article 3 Principles</p> <p>1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and shall promote equity and solidarity.</p>	<p><i>Article 3 Principles</i></p> <p>1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and shall promote equity and solidarity.</p>
<p><i>Article 4 Responsible authorities</i></p> <p>1. Each State Party shall designate or establish <u>an entity with the role of</u> National IHR Focal Point and the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations. <u>WHO shall provide technical assistance and collaborate with States Parties in capacity building of the National IHR focal points and authorities upon request of the States Parties.</u></p> <p><u>1bis. In addition, each State Party should inform WHO about the establishment of its National Competent Authority responsible for overall implementation of the IHR that will be recognized and held accountable for the NFP's functionality and the delivery of other IHR obligations.</u></p>	<p><i>Article 4 Responsible authorities</i></p> <p>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.</p> <p>1 bis. National IHR Authorities shall coordinate the implementation of these Regulations within the territory of the State Party.</p>	<p>Article 4 Responsible authorities</p> <p>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.</p> <p>1 bis. The National IHR Authority shall coordinate the implementation of these Regulations within the jurisdiction of the State Party.</p>	<p><i>Article 4 Responsible authorities</i></p> <p>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.</p> <p>1 bis. National IHR Authorities shall coordinate the implementation of these Regulations within the territory of the State Party.</p>

<p><u>NEW (1bis) States Parties shall / ALT may enact or adapt legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and function of then entity with a role of National IHR Focal Point in implementing the obligations under these Regulations.</u></p> <p>(...)</p>	<p>2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:</p> <p>(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and</p> <p>(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.</p> <p>2 bis. States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, by allocating human and financial resources, as well as by adjusting their domestic legislative and administrative arrangements.</p>	<p>2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:</p> <p>(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and</p> <p>(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.</p> <p>2 bis. States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, adjusting their domestic legislative and/or administrative arrangements.</p>	<p>2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:</p> <p>(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and</p> <p>(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.</p> <p>2 bis. States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, by allocating human and financial resources, as well as by adjusting their domestic legislative and administrative arrangements.</p>
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<p>4. States Parties shall provide WHO with contact details of their National IHR Focal Point and National IHR Competent Authority and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Focal Points it receives pursuant to this Article.”</p>	<p>3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.</p> <p>4. States Parties shall provide WHO with contact details of their National IHR Authority and their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Authorities and National IHR Focal Points it receives pursuant to this Article.</p>	<p>3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.</p> <p>4. States Parties shall provide WHO with contact details of their National IHR Authority and their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make the contact details available to all States Parties.</p>	<p>3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.</p> <p>4. States Parties shall provide WHO with contact details of their National IHR Authority and their National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of National IHR Authorities and National IHR Focal Points it receives pursuant to this Article.</p>
<p><i>Article 6 Notification</i></p> <p>1. Each State Party, <u>within 48h after the Focal Point receives information about the event shall assess events occurring within its territory</u> by using the decision instrument in Annex 2, <u>within 48 hours of the National IHR Focal Point receiving the relevant information.</u> Each State Party shall notify WHO, by the most efficient means of</p>	<p><i>Article 6 Notification</i></p> <p>1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a</p>	<p><i>Article 6 Notification</i></p> <p>1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a</p>	<p><i>Article 6 Notification</i></p> <p>1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a</p>

<p>communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA), <u>the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) or other relevant UN entities,</u> WHO shall immediately notify the IAEA, <u>relevant national and UN entities.</u></p>	<p>public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) or other intergovernmental organization or international body pursuant to paragraph 1 of Article 14, WHO shall immediately notify the IAEA or the other intergovernmental organizations and/or international bodies.</p>	<p>public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) or other intergovernmental organization(s), WHO shall, pursuant to paragraph 1 of Article 14, immediately notify the IAEA or, as appropriate, the other competent intergovernmental organization(s).</p>	<p>public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) or other intergovernmental organization(s), WHO shall, pursuant to paragraph 1 of Article 14, immediately notify the IAEA or, as appropriate, the other competent intergovernmental organization(s).</p>
<p><i>Article 8 Consultation</i></p> <p>In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party may nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. <u>However, where available information is insufficient to complete the decision instrument in Annex 2, a State Party shall keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health</u></p>	<p><i>Article 8 Consultation</i></p> <p>In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular including those events for which there is insufficient information available to complete the decision instrument to assess the event within 48 hours in accordance with paragraph 6(a) of Annex 1, a State Party may should nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has</p>	<p><i>Article 8 Consultation</i></p> <p>In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party should nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures in a timely manner. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any</p>	<p><i>Article 8 Consultation</i></p> <p>In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party should nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures in a timely manner. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any</p>

<p><u>measures within 72 hours of the National IHR Focal Point receiving the relevant information.</u> Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.</p>	<p>occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.</p>	<p>epidemiological evidence obtained by that State Party.</p>	<p>epidemiological evidence obtained by that State Party.</p>
<p><i>Article 10 Verification</i></p> <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall, <u>as soon as possible or within a specific time offer within 24 hours</u> to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>4. If the State Party does not accept the offer of collaboration <u>within 48 hours</u>, WHO may shall, when justified by the magnitude of the public health risk, <u>immediately</u> share with other States Parties the information available to it,</p>	<p><i>Article 10 Verification</i></p> <p>3. When WHO receives information of an event that may constitute a public health emergency of international concern, it shall offer as soon as possible to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>4. If the State Party does not accept the offer of collaboration, WHO shall may, when justified by the magnitude of the public health risk, share with other States Parties the information available to it, whilst remaining engaged with and</p>	<p><i>Article 10 Verification</i></p> <p>3. When WHO receives Upon receiving information of an event that may constitute a public health emergency of international concern, WHO shall offer WHO shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>4. If the State Party does not accept the offer of collaboration, and when justified by the magnitude of the public health risk, WHO may should share with other States Parties the information available to it,</p>	<p><i>Article 10 Verification</i></p> <p>3. When WHO receives Upon receiving information of an event that may constitute a public health emergency of international concern, WHO shall offer WHO shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p> <p>4. If the State Party does not accept the offer of collaboration, and when justified by the magnitude of the public health risk, WHO should share with other States Parties the information about the event available to it, whilst encouraging</p>

<p>whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.</p>	<p>encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.</p>	<p>it, whilst remaining engaged with and encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.</p>	<p>the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.</p>
<p><i>Article 11 Provision of information by WHO Exchange of information</i></p> <p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant <u>UN and intergovernmental international and regional</u> organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive <u>or which is available in the public domain, / ALT or which is otherwise available and whose validity is appropriately assessed by WHO</u> and which is necessary to enable States Parties to respond to a public health risk. WHO should <u>shall</u> communicate information to other States Parties that might help them in preventing the occurrence of similar incidents. <u>For this purpose, WHO shall facilitate the exchange of information between States Parties and ensure that the Event Information Site For National IHR Focal Points offers a secure and reliable platform for information exchange among the WHO and States Parties and allows for interoperability with relevant data information systems.</u></p>	<p><i>Article 11 Provision of information by WHO</i></p> <p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations or international bodies, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>	<p><i>Article 11 Provision of information by WHO</i></p> <p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>	<p><i>Article 11 Provision of information by WHO</i></p> <p>1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.</p>

<p>2. WHO shall use information received under Articles 6, and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as <u>when</u>:</p> <p>(a) the event is determined to constitute a public health emergency of international concern, a public health emergency of regional concern, or warrants an intermediate public health alert, in accordance with Article 12; or</p>	<p>2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:</p> <p>(a) the event is determined to constitute a public health emergency of international concern, including a pandemic emergency, in accordance with Article 12; or</p> <p>(a bis) the event warrants the issuance of an early action alert pursuant to Article 12; or</p>	<p>2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:</p> <p>(a) the event is determined to constitute a public health emergency of international concern, including a pandemic emergency, in accordance with Article 12; or</p> <p>(a bis) the event is determined to not constitute a public health emergency of international concern, in accordance with paragraph 4ter of Article 12, and non-binding advice to States Parties is issued;</p>	<p>2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:</p> <p>(a) the event is determined to constitute a public health emergency of international concern, including a pandemic emergency, in accordance with Article 12; or</p>
<p><i>Article 12</i> <i>Determination of a public health emergency of international concern</i> <u>public health emergency of regional concern, or intermediate health alert</u></p> <p>1. The Director-General shall determine, on the basis of the information received, in particular from the State Party within whose territory an event is occurring, whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.</p>	<p><i>Article 12</i> <i>Determination of a public health emergency of international concern,</i> <i>including a pandemic emergency</i></p> <p>1. The Director-General shall determine, on the basis of the information received, in particular from the State(s) Party(ies) within whose territory(ies) an event is occurring, whether an event constitutes a public health emergency of international concern, including, when appropriate, a pandemic emergency, in accordance with the criteria and the procedure set out in these Regulations.</p>	<p><i>Article 12</i> <i>Determination of a public health emergency of international concern,</i> <i>including a pandemic emergency</i></p> <p>1. The Director-General shall determine, on the basis of the information received, in particular from the State(s) Party(ies) within whose territory(ies) an event is occurring, whether an event constitutes a public health emergency of international concern, including, when appropriate, a pandemic emergency, in accordance</p>	<p><i>Article 12</i> <i>Determination of a public health emergency of international concern,</i> <i>including a pandemic emergency</i></p> <p>1. The Director-General shall determine, on the basis of the information received, in particular from the State(s) Party(ies) within whose territory(ies) an event is occurring, whether an event constitutes a public health emergency of international concern, including, when appropriate, a pandemic emergency, in accordance</p>

<p>2. If the Director-General considers, based on an assessment under these Regulations, that a potential or actual public health emergency of international concern is occurring, the Director-General shall notify all States Parties and seek to consult with the State Party in whose territory the event arises regarding this preliminary determination and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”). If the Director-General determines that the event constitutes a public health emergency of international concern, and the State Party are in agreement regarding this determination, the Director-General shall notify all the States Parties, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”) on appropriate temporary recommendations.</p> <p>3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.</p>	<p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State(s) Party(ies) in whose territory(ies) the event is occurring arises regarding this preliminary determination. If the Director- General and the State(s) Party(ies) are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”) on appropriate temporary recommendations.</p> <p>3. If, following the consultation in paragraph 2 above, the Director-General and the State(s) Party(ies) in whose territory(ies) the event is occurring arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern a determination</p>	<p>with the criteria and the procedure set out in these Regulations.</p> <p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State(s) Party(ies) in whose territory(ies) the event is occurring arises regarding this preliminary determination. If the Director- General and the State(s) Party(ies) are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”) on appropriate temporary recommendations.</p> <p>3. If, following the consultation in paragraph 2 above, the Director-General and the State(s) Party(ies) in whose territory(ies) the event is occurring arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination</p>	<p>with the criteria and the procedure set out in these Regulations.</p> <p>2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State(s) Party(ies) in whose territory(ies) the event is occurring arises regarding this preliminary determination. If the Director- General and the State(s) Party(ies) are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the “Emergency Committee”) on appropriate temporary recommendations.</p> <p>3. If, following the consultation in paragraph 2 above, the Director-General and the State(s) Party(ies) in whose territory(ies) the event is occurring arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination</p>
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<p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <p>(a) information provided by the State Party, <u>by other States Parties, available in the public domain, or otherwise available under Articles 5-10;</u></p> <p>(b) the decision instrument contained in Annex 2;</p> <p>(c) the advice of the Emergency Committee;</p> <p>(d) scientific principles as well as the available scientific evidence and other relevant information; and</p> <p>(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.</p> <p><u>4bis. The PHEIC declaration is not designed to mobilise funds in the case of an emergency event. The Director-General should use other mechanisms for this purpose.</u></p>	<p>shall be made in accordance with the procedure set forth in Article 49.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <p>(a) information provided by the State(s) Party(ies);</p> <p>(b) the decision instrument contained in Annex 2;</p> <p>(c) the advice of the Emergency Committee;</p> <p>(d) scientific principles as well as the available scientific evidence and other relevant information; and</p> <p>(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.</p> <p>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</p>	<p>shall be made in accordance with the procedure set forth in Article 49.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider:</p> <p>(a) information provided by the State(s) Party(ies);</p> <p>(b) the decision instrument contained in Annex 2;</p> <p>(c) the advice of the Emergency Committee;</p> <p>(d) scientific principles as well as the available scientific evidence and other relevant information; and</p> <p>(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.</p> <p>4 bis. If the Director-General determines that an event constitutes a public health emergency of international concern, the Director-General shall further determine, having considered the matters contained in paragraph 4, whether the public health emergency of</p>	<p>shall be made in accordance with the procedure set forth in Article 49.</p> <p>4. In determining whether an event constitutes a public health emergency of international concern, including, when appropriate, a pandemic emergency, the Director-General shall consider:</p> <p>(a) information provided by the State(s) Party(ies);</p> <p>(b) the decision instrument contained in Annex 2;</p> <p>(c) the advice of the Emergency Committee;</p> <p>(d) scientific principles as well as the available scientific evidence and other relevant information; and</p> <p>(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.</p> <p>4 bis. If the Director-General determines that an event constitutes a public health emergency of international concern, the Director-General shall further determine, having considered the matters contained in paragraph 4, whether the public health emergency of</p>
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<p>5. If the Director-General, following consultations with the <u>Emergency Committee and relevant States Parties</u> the State Party within whose territory the public health emergency of international concern has occurred, considers that a public health emergency of international concern has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49. <u>If there is still a need for recommendations, he should consider convening the Review Committee to advise on issuing standing recommendations in accordance with Articles 16 and 53.</u></p>	<p>international concerned also constitutes a pandemic emergency.</p> <p>4ter. If the Director-General determines, in accordance with paragraph 4, that an event does not constitute a public health emergency of international concern, the Director-General shall issue an early action alert that includes advice to States Parties on preparing for and responding to the event.</p> <p>5. If the Director-General, having considered the matters contained in sub-paragraphs a), c), d) and e) of paragraph 4, and following consultations with the State(s) Party(ies) within whose territory(ies) the public health emergency of international concern or a pandemic emergency has occurred, considers that a public health emergency of international concern or a pandemic emergency, has ended, because it no longer meets the relevant definition in Article 1, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>	<p>international concern also constitutes a pandemic emergency.</p> <p>4 ter. If the Director-General determines, in accordance with paragraph 4, that an event does not constitute a public health emergency of international concern, the Director-General may issue non-binding advice to States Parties on immediate actions to take to prepare for and respond to the event, including through international support.</p> <p>5. If the Director-General, having considered the matters contained in subparagraphs (a), (c), (d) and (e) of paragraph 4 of this Article, and following consultations with the State(s) Party(ies) within whose territory(ies) the a public health emergency of international concern, including a pandemic emergency, has occurred, considers that a public health emergency of international concern, including a pandemic emergency, has ended, because it no longer meets the relevant definition in Article 1, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>	<p>international concern also constitutes a pandemic emergency.</p> <p>5. If the Director-General, having considered the matters contained in subparagraphs (a), (c), (d) and (e) of paragraph 4 of this Article, and following consultations with the State(s) Party(ies) within whose territory(ies) the a public health emergency of international concern, including a pandemic emergency, has occurred, considers that a public health emergency of international concern, including a pandemic emergency, has ended, because it no longer meets the relevant definition in Article 1, the Director-General shall take a decision in accordance with the procedure set out in Article 49.</p>
<p><i>Article 13 Public health response</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from</p>	<p><i>Article 13 Public health response, including access to health products</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from</p>	<p><i>Article 13 Public health response, including equitable access to relevant health products</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from</p>	<p><i>Article 13 Public health response, including equitable access to relevant health products</i></p> <p>1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from</p>

<p>the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities. <u>Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44.</u></p> <p>(2.)</p> <p>3. At the request of a State Party, WHO shall collaborate <u>articulate clearly defined assistance to a State Party</u> in the response to public health risks and other events by providing technical guidance, <u>health products, technologies, know-how, deployment of civil medical personals</u>, and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary, <u>and if required cooperate with said Member State in seeking support and international financial assistance to facilitate the containment of the risk at source. The State Party shall accept or reject such an offer of assistance within 48 hours and, in the</u></p>	<p>the entry into force of these Regulations for that State Party, the core capacities to prepare for, and respond promptly and effectively to public health risks and public health emergencies of international concern, including a pandemic emergency, as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response core capacities.</p> <p>(2.)</p> <p>3. At the request of a State Party or following its acceptance of an offer by WHO, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.</p>	<p>the entry into force of these Regulations for that State Party, the core capacities to prevent, prepare for, and respond promptly and effectively to public health risks and public health emergencies of international concern, including a pandemic emergency, including in fragile and humanitarian settings, as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response core capacities.</p> <p>(2.)</p> <p>3. At the request of a State Party or following its acceptance of an offer by WHO, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.</p>	<p>the entry into force of these Regulations for that State Party, the core capacities to prevent, prepare for, and respond promptly and effectively to public health risks and public health emergencies of international concern, including a pandemic emergency, including in fragile and humanitarian settings, as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response core capacities.</p> <p>(2.)</p> <p>3. At the request of a State Party or following its acceptance of an offer by WHO, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.</p>
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<p><u>case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. WHO will also share any request for assistance by the affected State party that could not be met by WHO.</u></p> <p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may shall offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. <u>The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which WHO shall share with other States Parties. Regarding on-site assessments, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term; in the event of a denial, it shall provide its rationale for the denial of access.</u></p>	<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern, including a pandemic emergency, is occurring, it may shall offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State(s) Party(ies), to the extent possible, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. The State Party shall make all efforts to reply to such an offer as soon as possible, including the rationale for the reply.</p>	<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern, including a pandemic emergency, is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State(s) Party(ies), including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p>	<p>4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern, including a pandemic emergency, is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State(s) Party(ies), including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.</p>
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<p>5. When requested by WHO, States Parties should shall provide, to the extent possible, support to WHO-coordinated response activities, <u>including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party's jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams. Any State Party unable to fulfil such requests shall inform the reasons for the same to WHO and the Director General shall include the same in the report submitted to WHA under Article 54 of these Regulations.</u> 5</p> <p>(6.)</p> <p><u>New 7. Measures taken by States Parties shall not create barriers to or compromise the abilities of the other States Parties to effectively respond to public health emergency of international concern, unless exceptional circumstance warrant such measures. States Parties whose abilities to respond are affected by the measures taken by other State party shall have the right to enter into consultation with the State Party</u></p>	<p>5. When requested by WHO, States Parties should shall provide, to the fullest extent possible within the means and resources at their disposal, support to WHO-coordinated response activities.</p> <p>6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern, including a pandemic emergency.</p> <p>7. WHO shall support States Parties and coordinate response activities during public health emergencies of international concern, including pandemic emergencies. To facilitate equitable access to health products, this support shall include, as necessary, coordinating with mechanisms and networks that facilitate equitable allocation and distribution of health products, including through technology transfer on mutually</p>	<p>5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.</p> <p>6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern, including a pandemic emergency.</p> <p>7. WHO shall support States Parties and coordinate international response activities during public health emergencies of international concern, including pandemic emergencies, after their determination pursuant to Article 12 of these Regulations.</p>	<p>5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.</p> <p>6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern, including a pandemic emergency.</p> <p>7. WHO shall support States Parties, upon their request or following acceptance of an offer from WHO, and coordinate international response activities during public health emergencies of international concern, including pandemic emergencies, after their determination pursuant to Article 12 of these Regulations.</p>
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<p><u>implementing such measures to find a solution at the earliest considering the country interest.</u></p> <p><u>New 7. In case of any engagement with non-State actors in WHO's public health response to PHEIC situation, WHO shall follow the provisions of Framework for Engagement of Non-State Actors (FENSA). Any departure from FENSA provisions shall be consistent with paragraph 73 of FENSA.</u></p>	<p>agreed terms. The aforesaid mechanisms and networks may include, but are not limited to, regional ones and those established under relevant international agreements.</p> <p>8. After the determination of a public health emergency of international concern, pursuant to Article 12 of these Regulations, the Director-General shall:</p> <p>(a) Conduct, and periodically review and update, an assessment of the availability and affordability of health products needed for the public health response; publish such assessment(s); and consider the assessment(s), when available, in connection to temporary recommendations pursuant to Articles 15, 17, 18, and 49 of these Regulations;</p>	<p>8. WHO shall facilitate and, subject to Article 57, work to remove barriers to timely and equitable access by States Parties to relevant health products after the determination of a public health emergency of international concern, including a pandemic emergency, based on public health risks and needs. To that effect, the Director-General shall:</p> <p>(a) conduct, and periodically review and update, assessments of the public health needs, as well as of the availability and accessibility including affordability of relevant health products for the public health response; publish such assessments; and consider the available assessments while issuing, modifying, extending or terminating recommendations pursuant to Articles 15, 16, 17, 18, and 49 of these Regulations;</p>	<p>8. WHO shall facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products after the determination of and during a public health emergency of international concern, including a pandemic emergency, based on public health risks and needs. To that effect, the Director-General shall:</p> <p>(a) conduct, and periodically review and update, assessments of the public health needs, as well as of the availability and accessibility including affordability of relevant health products for the public health response; publish such assessments; and consider the available assessments while issuing, modifying, extending or terminating recommendations pursuant to Articles 15, 16, 17, 18, and 49 of these Regulations;</p>
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	<p>(b) make use of existing WHO-coordinated allocation mechanism(s) and networks, or facilitate their establishment as needed, to assist States Parties to access relevant health products based on public health risks and needs;</p> <p>(c) support efforts by States Parties to scale-up and diversify, as appropriate, the production of relevant health products;</p> <p>(d) when requested by a State Party, share with the National Regulatory Authority of said State Party the dossier related to a specific health product, as provided to WHO by the manufacturer and where the manufacturer has consented, within 30 days from receiving such request for the purpose of facilitating regulatory authorization by the National Regulatory Authority;</p>	<p>(b) make use of WHO-coordinated mechanisms, or facilitate their establishment, in consultation with States Parties, as necessary, and coordinate, as appropriate, with other allocation and distribution mechanisms and networks that facilitate timely and equitable access to relevant health products based on public health needs;</p> <p>(c) collaborate through relevant WHO coordinated and other networks and mechanisms in the implementation of this aArticle to support States Parties, upon their request, in scaling-up scaling up and geographically diversifying the production of relevant health products, as appropriate, subject to Article 2 of these Regulations, and in accordance with relevant international law;</p> <p>(d) share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party.; and</p>	<p>(b) make use of WHO-coordinated mechanisms, or facilitate, in consultation with States Parties, their establishment as needed, and coordinate, as appropriate, with other allocation and distribution mechanisms and networks that facilitate timely and equitable access to relevant health products based on public health needs;</p> <p>(c) support States Parties, upon their request, in scaling up and geographically diversifying the production of relevant health products, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, subject to Article 2 of these Regulations, and in accordance with relevant international law;</p> <p>(d) share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party.; and</p>
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	<p>(e) support States Parties, upon their request, to strengthen local production; achieve quality assurance through regulatory approval of locally manufactured products; and facilitate research and development and technology transfer on mutually agreed terms.</p> <p>9. Pursuant to paragraph 5 of this Article, and paragraph 1 of Article 44 of these Regulations, States Parties shall, to the fullest extent possible, according to their national law and available resources, and upon request of other States Parties or WHO, undertake to collaborate with each other and to support WHO-coordinated responses activities, including through:</p> <p>(a) supporting WHO in implementing actions outlined in paragraph 8 of this Article,</p> <p>(b) engaging with, and encouraging, relevant non-State actors¹ operating in their respective jurisdictions, to contribute towards equitable access to health products needed to respond to a</p>	<p>[(e) support States Parties, upon their request, and, as appropriate, subject to Article 2 of these Regulations, through relevant WHO-coordinated and other networks and mechanisms, pursuant to subparagraph 8(c) of this paragraph Article, to strengthen local production of quality assured relevant health products; and facilitate the voluntary transfer of technology, know-how and expertise on mutually agreed terms, including for research and development purposes.]</p> <p>9. Pursuant to paragraph 5 of this Article and paragraph 1 of Article 44 of these Regulations, and upon request of other States Parties or WHO, States Parties shall undertake, subject to applicable law and available resources, to collaborate with, and assist each other and to support WHO-coordinated response activities, including through:</p> <p>(a) supporting WHO in implementing actions outlined in this Article;</p> <p>(b) engaging with and encouraging relevant stakeholders operating in their respective jurisdictions, to facilitate equitable access to relevant health products for responding to a public health</p>	<p>(e) support States Parties, upon their request, and, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, pursuant to subparagraph 8(c) of this Article, to promote research and development and strengthen local production of quality, safe and effective relevant health products, and facilitate other measures relevant for the full implementation of this provision.</p> <p>9. Pursuant to paragraph 5 of this Article and paragraph 1 of Article 44 of these Regulations, and upon request of other States Parties or WHO, States Parties shall undertake, subject to applicable law and available resources, to collaborate with, and assist each other and to support WHO-coordinated response activities, including through:</p> <p>(a) supporting WHO in implementing actions outlined in this Article;</p> <p>(b) engaging with and encouraging relevant stakeholders operating in their respective jurisdictions to facilitate equitable access to relevant health products for responding to a public health</p>
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	<p>public health emergency of international concern;</p> <p>(c) publishing relevant terms of government-funded research agreements for health products needed to respond to a public health emergency of international concern, as well as information, where relevant, on pricing policies regarding these products and technologies, in order to support equitable access.</p>	<p>emergency of international concern, including a pandemic emergency; and</p> <p>(c) publishing, as appropriate, relevant terms of their research and development agreements for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency.</p>	<p>emergency of international concern, including a pandemic emergency; and</p> <p>(c) making available, as appropriate, relevant terms of their research and development agreements for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency.</p>
<p><i>Article 15 Temporary recommendations</i></p> <p>1. If it has been determined in accordance with Article 12 that a public health emergency of international concern is occurring, <u>or the event has a potential to become PHEIC,</u> the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.</p> <p>2. <u>Temporary recommendations should be as evidence-based, concise and operational as possible, and refer to existing guidance and international</u></p>	<p><i>Article 15 Temporary recommendations</i></p> <p>1. If it has been determined in accordance with Article 12 that a public health emergency of international concern, including a pandemic emergency, is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern, including a pandemic emergency, has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.</p> <p>2. Temporary recommendations may include health measures to be implemented by the State(s) Party(ies) experiencing the public health emergency</p>	<p><i>Article 15 Temporary recommendations</i></p> <p>1. If it has been determined in accordance with Article 12 that a public health emergency of international concern, including a pandemic emergency, is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern, including a pandemic emergency, has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.</p> <p>2. Temporary recommendations may include health measures to be implemented by the State(s) Party(ies) experiencing the public health emergency</p>	<p><i>Article 15 Temporary recommendations</i></p> <p>1. If it has been determined in accordance with Article 12 that a public health emergency of international concern, including a pandemic emergency, is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern, including a pandemic emergency, has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.</p> <p>2. Temporary recommendations may include health measures to be implemented by the State(s) Party(ies) experiencing the public health emergency</p>

<p><u>technical standards, when appropriate.</u> Temporary recommendations may include <u>the deployment of expert teams, as well as</u> health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic <u>and recommendations on the access and availability of health products, technologies, and know-how, including an allocation mechanism for their fair and equitable access.</u></p> <p><u>New Para 2 bis: Temporary recommendations should be evidence based as per real time risk assessment of a potential or declared PHEIC, and the immediate critical gaps to be addressed for an optimal public health response, that shall be fair and equitable. The recommendations based on these assessments shall include:</u></p> <p><u>(a) support by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite health measures to be implemented by the State Party experiencing the Public Health Emergency of International Concern, or</u></p>	<p>of international concern, including a pandemic emergency, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, including relevant health products, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.</p> <p>2 bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary recommendations, shall provide available information on any WHO-coordinated mechanisms concerning access to, and allocation of, relevant health products.</p>	<p>of international concern, including a pandemic emergency, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, including relevant health products, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.</p> <p>2bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary recommendations, shall provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks.</p>	<p>of international concern, including a pandemic emergency, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, including relevant health products, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.</p> <p>2 bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks.</p>
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<p><u>(b) prohibitive recommendations to avoid unnecessary interference with international traffic and trade.</u></p> <p>(...)</p>	<p>3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern, including a pandemic emergency, to which they relate.</p>	<p>3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern, including a pandemic emergency, to which they relate.</p>	<p>3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern, including a pandemic emergency, to which they relate.</p>
<p><i>Article 16 Standing recommendations</i></p> <p>WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic and recommendations on the access and availability of health products, technologies, and know how, including an allocation mechanism for their fair and equitable access. WHO may, in accordance with Article 53, modify or</p>	<p><i>Article 16 Standing recommendations</i></p> <p>1. WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods, including relevant health products, and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.</p>	<p><i>Article 16 Standing recommendations</i></p> <p>1. WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods including relevant health products, and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.</p>	<p><i>Article 16 Standing recommendations</i></p> <p>1. WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods including relevant health products, and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.</p>

<p>terminate such recommendations, as appropriate.</p>	<p>2. The Director-General, when communicating to States Parties the issuance, modification or extension of standing recommendations, shall provide available information on any WHO-coordinated mechanisms concerning access to, and allocation of, relevant health products.</p>	<p>2. The Director-General, when communicating to States Parties the issuance, modification or extension of standing recommendations, shall provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products as well as on any other allocation and distribution mechanisms and networks.</p>	<p>2. The Director-General, when communicating to States Parties the issuance, modification or extension of standing recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products as well as on any other allocation and distribution mechanisms and networks.</p>
<p><i>Article 17 Criteria for recommendations</i></p> <p>When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:</p> <p>(a) ...</p> <p>(e) ...</p> <p><u>New para (e1): Equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response.</u></p>	<p><i>Article 17 Criteria for recommendations</i></p> <p>When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:</p> <p>(a) ...</p> <p>(d bis) availability of, and accessibility to, relevant health products;</p> <p>(e) ...</p>	<p><i>Article 17 Criteria for recommendations</i></p> <p>When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:</p> <p>(a) ...</p> <p>(d bis) availability of, and accessibility to relevant health products;</p> <p>(e) ...</p>	<p><i>Article 17 Criteria for recommendations</i></p> <p>When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:</p> <p>(a) ...</p> <p>(d bis) availability of, and accessibility to relevant health products;</p> <p>(e) ...</p>
<p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>(1.-2.)</p>	<p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>(1.-2.)</p>	<p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>(1.-2.)</p>	<p><i>Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels</i></p> <p>(1.-2.)</p>

<p><u>New para 3: In developing recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate.</u></p> <p><u>New 3. In Issuing such recommendation: The WHO should consult with other relevant international organization such as ICAO, IMO, WTO to avoid unnecessary interference with international travel and trade, such as the movement of essential health care workers and medical products and supplies.</u></p> <p><u>New 4. In implementing such recommendation: State Parties shall take into consideration their obligations under relevant international law when facilitating essential health care workers movement, ensuring protection of supply chains of essential medical products in PHEIC, and repatriating of travellers.</u></p> <p><u>NEW (3) Where States parties impose trave and/or goods and cargo restrictions, WHO may recommend that these measures not apply to movement of health personnel travelling to the State Party(ies) for a public health response and to the transport of medical immunobiological</u></p>	<p>3. Recommendations issued by WHO to State Parties shall take into account the need to:</p> <p>(a) facilitate international travel, as appropriate, including of health workers and persons in life-threatening or humanitarian situations. This provision is without prejudice to Article 23 of these Regulations; and</p> <p>(b) maintain international supply chains, including for relevant health products and food supplies.</p>	<p>3. Recommendations issued by WHO to State Parties shall, as appropriate, take into account the need to:</p> <p>(a) facilitate international travel, particularly of health and care workers and persons in life-threatening or humanitarian situations. This provision is without prejudice to Article 23 of these Regulations; and</p> <p>(b) maintain international supply chains, including for relevant health products and food supplies.</p>	<p>3. Recommendations issued by WHO to State Parties shall, as appropriate, take into account the need to:</p> <p>(a) facilitate international travel, particularly of health and care workers and persons in life-threatening or humanitarian situations. This provision is without prejudice to Article 23 of these Regulations; and</p> <p>(b) maintain international supply chains, including for relevant health products and food supplies.</p>
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<p><u>products needed for a public health response.</u></p> <p><u>New 3. In developing temporary recommendations, the Director-General shall consult with relevant international agencies such as ICAO, IMO and WTO in order to avoid unnecessary interference with international travel and trade, as appropriate. Additionally, temporary recommendations should allow for the appropriate exemption of essential health care workers and essential medical products and supplies from travel and trade restrictions.</u></p>			
<p><i>Article 19 General obligations</i></p> <p>Each State Party shall, in addition to the other obligations provided for under these Regulations:</p> <p>(a) ensure that the capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;</p> <p>(b) identify the competent authorities at each designated point of entry in its territory; and</p> <p>(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including</p>	<p><i>Article 19 General obligations</i></p> <p>Each State Party shall, in addition to the other obligations provided for under these Regulations:</p> <p>(a) ensure that the core capacities set forth in Annex 1 for designated points of entry are developed within the timeframe provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;</p> <p>(b) identify the competent authorities at each designated point of entry in its territory; and</p> <p>(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or</p>	<p><i>Article 19 General obligations</i></p> <p>Each State Party shall, in addition to the other obligations provided for under these Regulations:</p> <p>(a) ensure that the core capacities set forth in Annex 1 for designated points of entry are developed within the time frame provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;</p> <p>(b) identify the competent authorities at each designated point of entry in its territory; and</p> <p>(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or</p>	<p><i>Article 19 General obligations</i></p> <p>Each State Party shall, in addition to the other obligations provided for under these Regulations:</p> <p>(a) ensure that the core capacities set forth in Annex 1 for designated points of entry are developed within the time frame provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;</p> <p>(b) identify the competent authorities at each designated point of entry in its territory; and</p> <p>(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or</p>

<p>vectors and reservoirs, at its points of entry, which could result in international disease spread.</p> <p><u>New (d): The development of "bi-national" contingency plans with minimum content for the inclusion in plans of action where two countries share a border, for public health emergencies of international concern (PHEIC).</u></p>	<p>contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.</p>	<p>contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.</p>	<p>contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.</p>
	<p><i>Article 20 Airports and ports</i></p> <p>1. States Parties shall designate the airports and ports that shall develop the capacities provided in Annex 1.</p> <p>(2.) ...</p>	<p><i>Article 20 Airports and ports</i></p> <p>1. States Parties shall designate the airports and ports that shall develop the core capacities provided in Annex 1.</p> <p>(2.) ...</p>	<p><i>Article 20 Airports and ports</i></p> <p>1. States Parties shall designate the airports and ports that shall develop the core capacities provided in Annex 1.</p> <p>(2.) ...</p>

		<p><i>Article 21 Ground crossings</i></p> <p>1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the core capacities provided in Annex 1, taking into consideration:</p> <p>(a) ...</p> <p>2. States Parties sharing common borders should consider:</p> <p>(a) ...</p> <p>(b) joint designation of adjacent ground crossings for the core capacities in Annex 1 in accordance with paragraph 1 of this Article.</p>	<p><i>Article 21 Ground crossings</i></p> <p>1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the core capacities provided in Annex 1, taking into consideration:</p> <p>(a) ...</p> <p>2. States Parties sharing common borders should consider:</p> <p>(a) ...</p> <p>(b) joint designation of adjacent ground crossings for the core capacities in Annex 1 in accordance with paragraph 1 of this Article.</p>
<p><i>Article 24 Conveyance operators</i></p> <p>1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:</p> <p>(a) comply with the health measures recommended by WHO and adopted by the State Party;</p> <p>(b) inform travellers of the health measures recommended by WHO</p>	<p><i>Article 24 Conveyance operators</i></p> <p>1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:</p> <p>(a) comply with the health measures, which may include isolation and quarantine as appropriate, recommended by WHO and adopted by the State Party, including for application on board as well as during embarkation and disembarkation;</p> <p>(b) inform travellers of the health measures recommended by WHO</p>	<p><i>Article 24 Conveyance operators</i></p> <p>1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:</p> <p>(a) comply with the health measures recommended by WHO and adopted by the State Party, including for application on board as well as during embarkation and disembarkation;</p> <p>(b) inform travellers of the health measures recommended by WHO</p>	<p><i>Article 24 Conveyance operators</i></p> <p>1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:</p> <p>(a) comply with the health measures recommended by WHO and adopted by the State Party, including for application on board as well as during embarkation and disembarkation;</p> <p>(b) inform travellers of the health measures recommended by WHO</p>

<p>and adopted by the State Party for application on board; and</p> <p>(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.</p> <p><u>(d) implement quarantine promptly on board as necessary.</u></p> <p>(...)</p>	<p>and adopted by the State Party including for application on board as well as during embarkation and disembarkation; and</p> <p>(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.</p> <p>(...)</p>	<p>and adopted by the State Party, including for application on board as well as during embarkation and disembarkation; and</p> <p>(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.</p> <p>(...)</p>	<p>and adopted by the State Party, including for application on board as well as during embarkation and disembarkation; and</p> <p>(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.</p> <p>(...)</p>
<p><i>Article 27 Affected conveyances</i></p> <p>1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:</p> <p>(a) ...</p> <p>The competent authority may implement additional health measures, including isolation of the conveyances, and demand the conveyance operators, the pilot in command of the aircraft or the officer in command of the ship to take practicable measures on the</p>	<p><i>Article 27 Affected conveyances</i></p> <p>1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:</p> <p>(a) ...</p> <p>The competent authority may implement additional health measures, including isolation and quarantine of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.</p>	<p><i>Article 27 Affected conveyances</i></p> <p>1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:</p> <p>(a) ...</p> <p>The competent authority may implement additional health measures, including isolation and quarantine of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.</p>	<p><i>Article 27 Affected conveyances</i></p> <p>1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:</p> <p>(a) ...</p> <p>The competent authority may implement additional health measures, including isolation and quarantine of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.</p>

<p>conveyances as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.</p> <p>(2.) ...</p>	<p>(2.) ...</p>	<p>(2.) ...</p>	<p>(2.) ...</p>
<p><i>Article 35 General rule</i></p> <p>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. <u>Digital health documents must incorporate means to verify their authenticity via retrieval from an official web site, such as a QR code.</u></p> <p><u>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</u></p>	<p><i>Article 35 General rule</i></p> <p>1. 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.</p> <p>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.</p>	<p><i>Article 35 General rule</i></p> <p>1. 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.</p> <p>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.</p>	<p><i>Article 35 General rule</i></p> <p>1. 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.</p> <p>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.</p>

<p><u>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.</u></p>	<p>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.</p> <p>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.</p>	<p>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.</p> <p>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.</p>	<p>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.</p> <p>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.</p>
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	otherwise carry infection or contamination.	otherwise carry infection or contamination.	otherwise carry infection or contamination.
<p><i>Article 42 Implementation of health measures</i></p> <p>Health measures taken pursuant to these Regulations, <u>including the recommendations made under Article 15 and 16,</u> shall be initiated and completed without delay <u>by all State Parties,</u> and applied in a transparent, <u>equitable</u> and non-discriminatory manner. <u>State Parties shall also take measures to ensure Non-State Actors operating in their respective territories comply with such measures.</u></p>	<p><i>Article 42 Implementation of health measures</i></p> <p>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 actors¹ operating in their respective jurisdictions with a view to achieving compliance with, and implementation of, health measures taken pursuant to these Regulations.</p>	<p><i>Article 42 Implementation of health measures</i></p> <p>Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.</p>	<p><i>Article 42 Implementation of health measures</i></p> <p>Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.</p>
<p><i>Article 43 Additional health measures</i></p> <p>1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:</p> <p>(a) ...</p> <p>Such measures <u>shall be based on regular risk assessments, provide a proportionate response to the specific public health risks, be reviewed on a regular basis and</u> shall not be more restrictive of international traffic and not more invasive or intrusive to persons</p>	<p><i>Article 43 Additional health measures</i></p> <p>(1.-6.)</p>	<p><i>Article 43 Additional health measures</i></p> <p>(1.-6.)</p>	<p><i>Article 43 Additional health measures</i></p> <p>(1.-6.)</p>

<p>than reasonably available alternatives that would achieve attain the appropriate highest achievable level of health protection.</p> <p>2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:</p> <p>(a) ...</p> <p>(3.)</p> <p><u>New 3 bis. A State Party implementing additional health measures referred to in paragraph 1 of this Article shall ensure such measures generally do not result in obstruction or cause impediment to the WHO's allocation mechanism or any other State Party's access to health products, technologies and knowhow, required to effectively respond to a public health emergency of international concern. States Parties adopting such exceptional measures shall provide reasons to WHO.</u></p> <p>4. After assessing information <u>and public health rationale</u> provided pursuant to paragraph 3, <u>3bis</u> and 5 of this Article and other relevant information <u>within two weeks</u>, WHO may request that <u>shall make recommendations to</u> the State Party</p>	<p>3 bis. When implementing additional health measures referred to in paragraph 1 of this Article, States Parties shall take all practicable measures to facilitate other States Parties in accessing health products relevant for responding to a public health risk or a public health emergency of international concern.</p>		
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<p>concerned reconsider <u>to modify or rescind</u> the application of the <u>additional health measures in case of finding such measures as disproportionate or excessive. The Director General shall convene an Emergency Committee for the purposes of this paragraph.</u></p> <p>(...)</p> <p>6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure taking into account the advice of WHO and the criteria in paragraph 2 of this Article. <u>Recommendations made pursuant to paragraph 4 of this Article shall be implemented by the State Party concerned within two weeks from the date of recommendation. State Party concerned may approach WHO, within 7 days from the date of recommendations made under paragraph 4 of this Article, to reconsider such recommendations. Emergency Committee shall dispose the request for reconsideration within 7 days and the decision made on the request for reconsideration shall be final. The State Party concerned shall report to the implementation committee established under Article 53A on the implementation of the decision.</u></p> <p>7. Without prejudice to its rights under Article 56, any State Party impacted by a</p>	<p>7. Without prejudice to its rights under Article 56, any State Party that deems</p>	<p>7. Without prejudice to its rights under Article 56, any State Party impacted by a</p>	<p>7. Without prejudice to its rights under Article 56, any State Party impacted by a</p>
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<p>measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution. <u>Parties taking measures pursuant to paragraphs 1 and 2 of this Article shall endeavour to ensure that such measures are compatible with measures taken by other Parties in order to avoid unnecessary interference with international traffic and trade while ensuring the highest achievable level of health protection. To this end, at the request of the Director-General or of any Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article, Parties so requested shall undertake consultations either bilaterally, multilaterally or at the regional level as the case may be. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measures and to find a mutually acceptable solution. The Director-General or WHO Regional Directors on his or her behalf shall:</u></p> <p><u>(a) ...</u></p> <p>(...)</p>	<p>itself impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it, either directly, or through the Director-General, who may also facilitate consultations between the States Parties concerned. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution.</p>	<p>measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it, either directly, or through the Director-General, who may also facilitate consultations between the States Parties concerned. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution. Unless otherwise agreed with the State Parties involved in the consultation, information shared during the consultation must be kept confidential.</p>	<p>measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it, either directly, or through the Director-General, who may also facilitate consultations between the States Parties concerned. The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution. Unless otherwise agreed with the State Parties involved in the consultation, information shared during the consultation must be kept confidential.</p>
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<p><i>Article 44 Collaboration and assistance</i></p> <p>1. States Parties shall undertake to collaborate with and assist each other, <u>in particular developing countries States Parties, upon request, to the extent possible, in:</u></p> <p><u>new (a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;</u></p> <p>(a) the detection and assessment of, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations <u>and in particular as provided in Annex 1;</u></p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and <u>to establish an international financial mechanism for providing financial assistance to developing countries in the development, strengthening and maintenance of core capacities</u></p>	<p><i>Article 44 Collaboration and assistance, including financial assistance</i></p> <p>1. States Parties shall undertake to collaborate with, and assist each other, to the fullest extent possible, in:</p> <p>(a) the detection and assessment of, preparedness for, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health core capacities required under Annex 1 of these Regulations;</p> <p>(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and</p>	<p><i>Article 44 Collaboration and, assistance and financing</i></p> <p>1. States Parties shall undertake to collaborate with each other, to the extent possible, and assist each other, subject to applicable law and available resources, in:</p> <p>(a) the detection and assessment of, preparedness for, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health core capacities required under Annex 1 of these Regulations;</p> <p>(c) the mobilization of financial resources through relevant sources and funding mechanisms to facilitate implementation of their obligations under these Regulations in particular to address the needs of developing countries;</p>	<p><i>Article 44 Collaboration and, assistance and financing</i></p> <p>1. States Parties shall undertake to collaborate with each other, to the extent possible in:</p> <p>(a) the detection and assessment of, preparedness for, and response to, events as provided under these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health core capacities required under Annex 1 of these Regulations;</p> <p>(c) the mobilization of financial resources, including through relevant sources and funding mechanisms to facilitate implementation of their obligations under these Regulations in particular to address the needs of developing countries;</p>
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<p><u>required under these Regulations and functioning health systems resilient to the public health emergencies.</u></p> <p><u>(c-g) ...</u></p> <p>(h) (new) 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</p> <p>(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.</p> <p>(f) (new) facilitating the provision of equitable access to medical countermeasures</p> <p><u>New (e) providing equitable access to health products such as diagnostics, therapeutics, vaccines, PPE equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general population of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans</u></p>	<p>(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.; and</p> <p>(e) the facilitation of access to health products, including through WHO-coordinated mechanisms.</p>	<p>(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations; and</p> <p>(e) the facilitation of access to relevant health products, in accordance with paragraph 9 of Article 13.</p>	<p>(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations; and</p>
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<p>2. WHO shall collaborate with <u>and promptly assist</u> States Parties, <u>in particular developing countries</u> upon request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and</p> <p><u>(c) (New) implementation of the timely, secure and transparent exchange of samples and genetic sequence data of pathogens capable of causing pandemics and epidemics or other high-risk situations, taking into account relevant national and international legal provisions, rules, obligations and principles, including these Regulations, as appropriate, the Convention on Biological Diversity, and the importance of rapid access to information on human pathogens for public health preparedness and response;</u></p> <p><u>(d) (New) application of digital technologies to improve and upgrading communications for health emergency preparedness and response, including through the development of an interoperability mechanism for</u></p>	<p>2. WHO shall collaborate with, and assist, States Parties, upon request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health core capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and</p> <p>(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.;</p> <p>(d) strengthening domestic legislative and administrative arrangements for the implementation of these Regulations; and</p>	<p>2. WHO shall collaborate with, and assist, States Parties, upon their request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health core capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and</p> <p>(c) the mobilization of financial resources to support developing countries in building developing, strengthening and maintaining the core capacities provided for in Annex 1.; and</p> <p>(d) [strengthening] [supporting] [identifying possible ways to strengthen] [legislative] [legal] and administrative [arrangements] [capacities], taking into account national context;</p>	<p>2. WHO shall collaborate with, and assist, States Parties, upon their request, to the extent possible, in:</p> <p>(a) the evaluation and assessment of their public health core capacities in order to facilitate the effective implementation of these Regulations;</p> <p>(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and</p> <p>(c) the mobilization of financial resources to support developing countries in building developing, strengthening and maintaining the core capacities provided for in Annex 1.; and</p>
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<p><u>secure global digital exchange of health information;</u></p> <p>(e) (New) 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;</p> <p>(f) (c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 <u>and Annex 6 through the financial mechanism established under Article 44A and to establish an international financial mechanism for providing financial assistance to developing countries State Parties for the said purpose;</u></p> <p><u>(...)</u></p>	<p>(e) facilitating equitable access to health products through WHO-coordinated mechanisms.</p> <p>2bis. Pursuant to Paragraph 1(c) of this Article, States Parties shall undertake to collaborate to:</p> <p>(a) mobilize financial resources through all relevant sources, including existing and future bilateral, sub-regional, regional and multilateral funding</p>	<p>(d) the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13.</p> <p>2 bis. States Parties, subject to applicable law and available resources, shall maintain or increase domestic funding, as necessary, and collaborate, including through international cooperation and assistance, as appropriate, to strengthen sustainable financing to support the implementation of these Regulations.</p>	<p>(d) the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13.</p> <p>2 bis. States Parties, subject to applicable law and available resources, shall maintain or increase domestic funding, as necessary, and collaborate, including through international cooperation and assistance, as appropriate, to strengthen sustainable financing to support the implementation of these Regulations.</p>
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	<p>mechanisms, to assist each other, in particular developing countries, as necessary and in complementarity to domestic funding as outlined in Paragraph 1bis of Article 13, in the implementation of these Regulations;</p> <p>(b) encourage governance and operating models of existing financing entities and funding mechanisms to be responsive to the needs and national priorities, related to the these Regulations, of developing countries;</p> <p>(c) secure the financial resources necessary to support the implementation of these Regulations through coordination and/or funding mechanisms that may be established in future International Agreement(s) related to pandemic prevention, preparedness and response;</p> <p>(d) review the effectiveness of the provisions in this paragraph two years from their entry into force, and address identified gaps in financing IHR implementation that are not being met by current or future domestic funding, existing and new bilateral, sub-regional, regional and multilateral funding mechanisms, including, if necessary, through the establishment of a dedicated</p>		
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	<p>financing mechanism to provide targeted, supplementary financing, in particular to developing countries, to build, strengthen and maintain the capacities required under these Regulations.</p> <p>2ter. The Director-General shall support the collaboration work in Paragraph 2bis above, as appropriate. The Parties and the Director-General shall report on its outcomes as part of the reporting to the Health Assembly.</p>	<p>2 ter. Pursuant to subparagraph (c) of paragraph 1, States Parties shall undertake to collaborate, to the extent possible, to:</p> <p>(a) encourage governance and operating models of existing financing entities and funding mechanisms to be regionally representative and responsive to the needs and national priorities of developing countries in the implementation of these Regulations;</p> <p>(b) identify and enable access to financial resources, including through coordinating financial mechanism(s), necessary to equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities.</p> <p>2 quater. States Parties shall consider the outcome of the periodic reviews conducted pursuant to paragraph 4 of Article 54, and shall undertake, subject to applicable law and available</p>	<p>2 ter. Pursuant to subparagraph (c) of paragraph 1, States Parties shall undertake to collaborate, to the extent possible, to:</p> <p>(a) encourage governance and operating models of existing financing entities and funding mechanisms to be regionally representative and responsive to the needs and national priorities of developing countries in the implementation of these Regulations;</p> <p>(b) identify and enable access to financial resources, including through the Coordinating Financial Mechanism, established pursuant to Article 44bis, necessary to equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities.</p> <p>2 quater. The Director-General shall support the collaboration work in Paragraph 2 bis above of this Article, as appropriate. The States Parties and the Director-General shall report on its</p>
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<p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies <u>and if undertaken shall be reported to Health Assembly through the report submitted under Article 54.</u></p>	<p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.</p>	<p>resources, to promptly address identified gaps in financing the implementation of these Regulations, in particular with respect to the needs and priorities of developing countries, including, if necessary, through enabling access to additional targeted financing as well as through the establishment of a dedicated coordinating financial mechanism.</p> <p>2 quinquies. The Director-General shall support the collaboration work in Pparagraph 2 bis above of this Article, as appropriate. The States Parties and the Director-General shall report on its outcomes as part of the reporting to the Health Assembly.</p> <p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.</p>	<p>outcomes as part of the reporting to the Health Assembly.</p> <p>3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.</p>
			<p><i>Article 44bis – Coordinating Financial Mechanism</i></p> <p>1. A Coordinating Financial Mechanism (the Mechanism) is hereby established to:</p> <p>(a) promote the provision of timely, predictable, and sustainable financing for the implementation of these Regulations in order to develop, strengthen, and maintain core capacities as set out in</p>

			<p>Annex 1 of these Regulations, including those relevant for pandemic emergencies;</p> <p>(b) seek to maximize the availability of financing for the implementation needs and priorities of States Parties, in particular of developing countries; and</p> <p>(c) work to mobilize new and additional financial resources, and increase the efficient utilization of existing financing instruments, relevant to the effective implementation of these Regulations.</p> <p>2. In support of the objectives set out in Paragraph 1 of this Article, the Mechanism shall, inter alia:</p> <p>(a) use or conduct relevant needs and funding gap analyses;</p> <p>(b) promote harmonization, coherence and coordination of existing financing instruments;</p> <p>(c) identify all sources of financing that are available for implementation support and make this information available to States Parties;</p> <p>(d) provide advice and support, upon request, to States Parties in identifying and applying for financial resources for strengthening core capacities, including those relevant for pandemic emergencies;</p>
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		<p>(e) leverage voluntary monetary contributions for organizations and other entities supporting States Parties to develop, strengthen and maintain their core capacities, including those relevant for pandemic emergencies.</p> <p>3. The Mechanism shall function, in relation to the implementation of these Regulations, under the authority and guidance of the Health Assembly and be accountable to it.</p> <p><i>! Anmerkung: In dieser Schlussfassung ist der gesamte Art. 44bis nicht fett hervorgehoben, was darauf schliessen lassen könnte, es handle sich um eine bereits bestehende Vorschrift der IGV (2005). Dies ist allerdings nicht der Fall, der ganze Art. 44bis ist vollkommen neu. Es sei dahingestellt, ob es sich bei der fehlenden Hervorhebung bloss um ein Redaktionsversehen handelt, welches darauf zurückzuführen ist, dass dieser ganze Artikel – einmal mehr in Missachtung von Art. 55 Abs. 2 IGV – in letzter Minute noch eingefügt worden ist, oder ob es angesichts des völlig die Verfahrensregeln der WHO verletzenden Vorgehens zum Durchpeitschen der IGV-Änderungen um jeden Preis* auf einer bewussten Verschleierungstaktik beruht!</i></p> <p><i>*Nachdem eine Abstimmung über die IGV im vorberatenden Committee A am 30.5.2024 mit 26 JA-Stimmen; 67 NEIN-Stimmen und 9 Enthaltungen bei insgesamt 177 gemeldeten</i></p>
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			<p>Stimmberechtigten, wovon 75 Stimmberechtigte nicht anwesend waren, eine deutliche Ablehnung erfahren hatten, verhandelte die WGIHR hinter verschlossenen Türen gleichwohl weiter, präsentierte am 1.6.2024 um ca. 19:30 Uhr den vorliegenden Entwurf, mit welchem die Länderdelegierten schliesslich nach 21:00 im Plenum überrumpelt wurden.</p>
<p>Article 45 Treatment of personal data</p> <p>(1.)</p> <p>2. Notwithstanding paragraph 1, States Parties may disclose to only internal and relevant personnel and process and disclose personal data where essential for the purposes of assessing and managing a public health risk. In the case where disclosure of personal data is essential for such purposes, State Parties should obtain consent from the State Party which provided the information. When processing and/or disclosing personal data, State Parties, in accordance with national law, and WHO must ensure that the personal data are:</p> <p>(a)</p> <p>(3.)</p> <p><u>New Para 4: WHO receiving personal data, and States Parties receiving personal data from other States</u></p>	<p>Article 45 Treatment of personal data</p> <p>(1.)</p> <p>2. Notwithstanding paragraph 1, States Parties may process and disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:</p> <p>(a) ...</p> <p>In the event that processing or disclosure of personal data pursuant to this paragraph would result in public disclosure of such personal data, the State Party concerned shall inform, if possible prior to such public disclosure, the State Party that provided the data.</p> <p>(3.)</p>	<p>Article 45 Treatment of personal data</p> <p>(1.)</p> <p>2. Notwithstanding paragraph 1, States Parties may process and disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:</p> <p>(a) ...</p> <p>In the event that processing or disclosure of personal data pursuant to this paragraph would result in public disclosure of such personal data, the State Party concerned shall inform, if possible prior to such public disclosure, the State Party that provided the data.</p> <p>(3.)</p>	<p>Article 45 Treatment of personal data</p> <p>(1.)</p> <p>2. Notwithstanding paragraph 1, States Parties may process and disclose and process personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:</p> <p>(a) ...</p> <p>(3.)</p>

<p><u>Parties, shall process the data in a manner such that the data is not duplicated or stored without the permission of the provider States Party.</u></p>			
<p><i>Article 48 Terms of reference and composition</i></p> <p>1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:</p> <p>(a) whether an event constitutes a public health emergency of international concern, <u>based on Articles 1, 2 and 12.4.”;</u></p> <p>(b) the termination of a public health emergency of international concern; and</p> <p>(c) the proposed issuance, modification, extension or termination of temporary recommendations.</p> <p>2. The Emergency Committee shall be composed of experts <u>free from the conflict of interests selected</u> by the</p>	<p><i>Article 48 Terms of reference and composition</i></p> <p>1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:</p> <p>(a) whether an event constitutes a public health emergency of international concern, including one of pandemic emergency nature;</p> <p>(b) the termination of a public health emergency of international concern, including one of pandemic emergency nature; and</p> <p>(c) the proposed issuance, modification, extension or termination of temporary recommendations.</p> <p>1 bis. The Emergency Committee shall be considered an Expert Committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided for in this Article.</p> <p>2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert</p>	<p><i>Article 48 Terms of reference and composition</i></p> <p>1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:</p> <p>(a) whether an event constitutes a public health emergency of international concern, including a pandemic emergency;</p> <p>(b) the termination of a public health emergency of international concern, including a pandemic emergency; and</p> <p>(c) the proposed issuance, modification, extension or termination of temporary recommendations.</p> <p>1 bis. The Emergency Committee shall be considered an Expert Committee expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided for in this Article.</p> <p>2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert</p>	<p><i>Article 48 Terms of reference and composition</i></p> <p>1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:</p> <p>(a) whether an event constitutes a public health emergency of international concern, including a pandemic emergency;</p> <p>(b) the termination of a public health emergency of international concern, including a pandemic emergency; and</p> <p>(c) the proposed issuance, modification, extension or termination of temporary recommendations.</p> <p>1 bis. The Emergency Committee shall be considered an Expert Committee expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided for in this Article.</p> <p>2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert</p>

<p>Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization, <u>as well as Regional Directors from any impacted region</u>. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable <u>age, gender, and geographical representation and gender balance and require training in these Regulations before participation. The WHO, including through the WHO Academy, shall provide them with support as appropriate.</u> At least one member <u>Members</u> of the Emergency Committee should be an <u>include at least one</u> expert nominated by a the State Party within whose territory the event arises, <u>as well as experts nominated by other affected States Parties. For the purposes of Articles 48 and 49, an “affected State Party” refers to a State Party either geographically proximate or otherwise impacted by the event in question.</u></p> <p>3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts <u>free from the conflict of interests</u> to advise the Committee.</p>	<p>Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member <u>Members</u> of the Emergency Committee should <u>include at least one</u> be an expert nominated by a State(s) Party(ies) within whose territory the event arises <u>is occurring.</u></p> <p>3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.</p>	<p>Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member <u>Members</u> of the Emergency Committee should <u>include at least one</u> be an expert nominated by a State(s) Party(ies) within whose territory the event arises <u>is occurring.</u></p> <p>3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.</p>	<p>Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. At least one member <u>Members</u> of the Emergency Committee should <u>include at least one</u> be an expert nominated by a State(s) Party(ies) within whose territory the event arises <u>is occurring.</u></p> <p>3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.</p>
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<p><i>Article 49 Procedure</i></p> <p>(1.)</p> <p>2. The Director-General shall provide the Emergency Committee with the a <u>detailed</u> agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance. <u>The agenda should include a recurrent set of standard items for consideration of the Emergency Committee aimed at ensuring specificity, completeness and coherence of the advice provided.</u></p> <p>(...)</p> <p><u>3 bis If the Emergency Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Emergency Committee's report.</u></p> <p><u>3 ter The composition of the Emergency Committee and its complete reports shall be shared with Member States.</u></p> <p>4. The Director-General shall invite <u>affected States Parties, including</u> the State Party in whose territory the event arises to present its <u>their</u> views to the</p>	<p><i>Article 49 Procedure</i></p> <p>(1.-3.)</p> <p>4. The Director-General shall invite the State(s) Party(ies) in whose territory the event arises <u>is occurring</u> to present its <u>(their)</u> views to the Emergency</p>	<p><u>Article 49 Procedure</u></p> <p><u>(1.-3.)</u></p> <p><u>4. The Director-General shall invite the State(s) Party(ies) in whose territory the event arises is occurring to present its (their) views to the Emergency</u></p>	<p><i>Article 49 Procedure</i></p> <p>(1.-3.)</p> <p>4. The Director-General shall invite the State(s) Party(ies) in whose territory the event arises <u>is occurring</u> to present its <u>(their)</u> views to the Emergency</p>
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<p>Emergency Committee. To that effect, the Director-General shall notify to it States Parties of the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State Party <u>in whose territory the event arises</u> concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>(...)</p> <p>6. The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public <u>including the reasons behind such recommendations.</u></p>	<p>Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State(s) Party(ies) concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>(5.)</p> <p>6. The Director-General shall communicate to all States Parties the issuance of an early action alert, the determination and the termination of a public health emergency of international concern, including a pandemic emergency, any health measure taken by the State(s) Party(ies) concerned, any temporary recommendation, including the supporting evidence, and the modification, extension and termination of such recommendations, together with the composition and views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.</p>	<p>Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State(s) Party(ies) concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>(5.)</p> <p>6. The Director-General shall communicate to all States Parties the determination and the termination of a public health emergency of international concern, including a pandemic emergency, any health measure taken by the State(s) Party(ies) concerned, any temporary recommendations, including the supporting evidence, and the modification, extension and termination of such recommendations, together with the composition and views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.</p>	<p>Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State(s) Party(ies) concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.</p> <p>(5.)</p> <p>6. The Director-General shall communicate to all States Parties the determination and the termination of a public health emergency of international concern, including a pandemic emergency, any health measure taken by the State(s) Party(ies) concerned, any temporary recommendations, including the supporting evidence, and the modification, extension and termination of such recommendations, together with the composition and views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public.</p>
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<p>7. Affected States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p> <p>8. After the declaration of a public health emergency of international concern, the Emergency Committee should present its recommendations to relevant WHO bodies dealing with health emergency prevention, preparedness and response, such as the Standing Committee on Health Emergency Prevention, Preparedness and Response.</p>	<p>7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern, including a pandemic emergency, and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p>	<p>7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern, including a pandemic emergency, and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p>	<p>7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern, including a pandemic emergency, and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.</p>
<p>Article 53A - Establishment of an Implementation Committee</p> <p>The State Parties shall establish an Implementation Committee, comprising of all States Parties meeting annually, that shall be responsible for:</p> <p>(a) Considering information submitted to it by WHO and States Parties relating to their respective obligations under these Regulations, including under Article 54 and through the IHR monitoring and Evaluation framework;</p>	<p>Article 54bis Implementation and Compliance Committee for the International Health Regulations (2005)</p> <p>1. 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:</p>	<p>Article 54 bis States Parties Committee for the Effective Implementation of the International Health Regulations (2005)</p> <p>1. The States Parties Committee for the Effective Implementation of the International Health Regulations (2005) is hereby established to facilitate and oversee the effective implementation of these Regulations, in particular of Article 44, and perform any other functions entrusted to it by the Health Assembly. The Committee shall be facilitative and consultative in nature only, and function in a non-adversarial, non-punitive, assistive and transparent manner, guided by the principles set out in Article 3. To this effect:</p>	<p>Article 54 bis States Parties Committee for the Implementation of the International Health Regulations (2005)</p> <p>1. The States Parties Committee for the Implementation of the International Health Regulations (2005) is hereby established to facilitate the effective implementation of these Regulations, in particular of Article 44 and 44bis. The Committee shall be facilitative and consultative in nature only, and function in a non-adversarial, non-punitive, assistive and transparent manner, guided by the principles set out in Article 3. To this effect:</p>

<p><u>(b) Monitoring, advising on, and/or facilitating provision of technical assistance, logistical support and mobilization of financial resources for matters relating to implementation of the regulations with a view to assisting States Parties to comply with obligations under these Regulations, with regards to</u></p> <p><u>(1) development and maintenance of IHR core capacities;</u></p> <p><u>(2) cooperation with WHO and State Parties in responding to outbreaks or events.</u></p> <p><u>(c) Promote international cooperation and assistance to address concerns raised by WHO and States Parties regarding implementation of, and compliance with, obligations under these Regulations in accordance with Article 44;</u></p> <p><u>(d) Submit an annual report to each Health Assembly.</u></p> <p><u>NEW Chapter IV (Article 53 bis- quater): The Compliance Committee</u></p> <p><u>53 bis Terms of reference and composition</u></p> <p><u>1. The State Parties shall establish a Compliance Committee that shall be responsible for:</u></p> <p><u>(a) Considering information submitted to it by WHO and States Parties relating to compliance with</u></p>	<p>(a) have the aim of promoting and supporting learning, exchange of best practices, actions, and accountability among States Parties, at the national, regional, and global levels;</p> <p>(b) be responsible for monitoring progress with IHR implementation, in order to support effective and equitable provision of technical assistance, logistical support, and mobilization of financial resources, including by tracking collaboration between, and assistance provided by, States Parties for matters relating to implementation of these Regulations, with a view to assisting States Parties to comply with their obligations and strengthen core capacities.</p> <p>2. The IHR Implementation and Compliance Committee shall be comprised of [number] State Party members, [number] from each WHO Region, represented by individuals possessing appropriate qualifications and experience. State Party members shall serve for [number] years.</p> <p>3. States Parties that are not members of the IHR Implementation and Compliance Committee may attend meetings of the IHR Implementation</p>	<p>(a) The Committee shall have the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties;</p> <p>(b) The Committee shall establish a Subcommittee to provide technical advice and report to the Committee.</p> <p>2. The Committee shall be comprised of all States Parties and shall meet at least once every two years. Terms of reference for the Committee, including the way that the Committee conducts its business, and for the Subcommittee shall be adopted at the first meeting of the Committee by consensus.</p> <p>3. The Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party</p>	<p>(a) The Committee shall have the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties for the effective implementation of these Regulations;</p> <p>(b) The Committee shall establish a Subcommittee to provide technical advice and report to the Committee.</p> <p>2. The Committee shall be comprised of all States Parties and shall meet at least once every two years. Terms of reference for the Committee, including the way that the Committee conducts its business, and for the Subcommittee shall be adopted at the first meeting of the Committee by consensus.</p> <p>3. The Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party</p>
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<p><u>obligations under these Regulations;</u></p> <p><u>(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;</u></p> <p><u>(c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and</u></p> <p><u>(d) Submitting an annual report to each Health Assembly describing:</u></p> <p><u>(i) The work of the Compliance Committee during the reporting period;</u></p> <p><u>(ii) The concerns regarding non-compliance during the reporting period; and</u></p> <p><u>(iii) Any conclusions and recommendations of the Committee.</u></p> <p><u>2. The Compliance Committee shall be authorized to:</u></p> <p><u>(a) Request further information on matters under its consideration;</u></p> <p><u>(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;</u></p> <p><u>(c) Consider any relevant information submitted to it;</u></p> <p><u>(d) Seek the services of experts and advisers, including representatives</u></p>	<p>and Compliance Committee and shall have the right to speak after State Party members.</p> <p>4. The IHR Implementation and Compliance Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party members, and shall serve for [number] years.</p> <p>5. The IHR Implementation and Compliance Committee shall meet at least [once] a year in person, virtual or hybrid format, as decided by the Chair and Vice-Chair in consultation with the Director-General.</p> <p>6. The Chair and the Vice-Chair, in consultation with the Director-General, may invite observers, to attend a meeting of the IHR Implementation and Compliance Committee, or parts thereof, without the right to vote if they consider that this would enhance the work of the IHR Implementation and Compliance Committee on a specific item or items on the agenda of the meeting.</p> <p>7. The IHR Implementation and Compliance Committee shall be facilitative in nature and function in a manner that is transparent, non-adversarial and non-punitive. The IHR Implementation and Compliance Committee shall conduct its business on the basis of consensus. In the event</p>	<p>members, who shall serve for two years and rotate on a regional basis.</p>	<p>members, who shall serve for two years and rotate on a regional basis.1.</p>
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<p><u>of NGOs or members of the public, as appropriate; and</u> (e) <u>Make recommendations to a State Party concerned and/or WHO regarding how the State Party may improve compliance and any recommended technical assistance and financial support.</u></p> <p><u>3. The Members of the Compliance Committee shall be appointed by States Parties from each Region, comprising six government experts from each Region. The Compliance Committee shall be appointed for four-year terms and meet three times per year.</u></p> <p><u>53 ter. Conduct of business</u></p> <p><u>1. The Compliance Committee shall strive to make its recommendations on the basis of consensus.</u></p> <p><u>2. The Compliance Committee may request the Director-General to invite representatives of the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions, where appropriate to address a specific issue under consideration. Such representatives, with the consent of the Chairperson, make statements on the subjects under discussion.</u></p>	<p>of inability to reach consensus, the difference in views shall be reported to the Health Assembly.</p> <p>8. The IHR Implementation and Compliance Committee shall report annually and make recommendations, as appropriate while cognizant of respective national circumstances, to the Health Assembly.</p> <p>9. The IHR Implementation and Compliance Committee shall be subject, as far as practicable, to the Rules of Procedure of the Health Assembly, unless otherwise provided in these Regulations.</p>		<p>4. The Committee shall adopt, at its first meeting, by consensus, terms of reference for the Coordinating Financial Mechanism, established in Article 44 bis, and modalities for its operationalization and governance and may adopt necessary working arrangements with relevant international bodies, which may support its operation as appropriate.</p> <p><i>! Anmerkung:</i> <i>In dieser Schlussfassung ist Abs. 4 nicht fett hervorgehoben, was darauf schliessen lassen könnte, es handle sich um eine bereits bestehende Vorschrift der IGV (2005). Dies ist allerdings nicht der Fall, der ganze Art. 54 bis ist vollkommen neu; bei der fehlenden Hervorhebung handelt es sich möglicherweise – möglicherweise allerdings auch nicht, siehe oben</i></p>
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<p><u>53 quater Reports</u></p> <p><u>1. For each session, the Compliance Committee shall prepare a report setting forth the Committee's views and advice. This report shall be approved by the Compliance Committee before the end of the session. Its views and advice shall not commit WHO, States Parties, or other entities and shall be formulated as advice to the relevant State Party.</u></p> <p><u>2. If the Compliance Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.</u></p> <p><u>3. The Compliance Committee's report shall be submitted to all States Parties and to the Director-General, who shall submit reports and advice of the Compliance Committee, to the Health Assembly or the Executive Board, as well as any relevant committees, for consideration, as appropriate.</u></p> <p><u>! Anmerkung:</u> <i>In der – gemäss WHO in Nachachtung von Art. 55 Abs. 2 IGV am 16.11.2022 publizierten – Fassung 2022 wurden das Implementation committee und das Compliance committee noch separat vorgeschlagen. In der nachfolgenden Fassung vom 17.4.2024 wurden die</i></p>			<p><i>Anmerkung zu Art. 44bis – um ein Redaktionsversehen, welches darauf zurückzuführen sein dürfte, dass dieser Absatz – einmal mehr in Missachtung von Art. 55 Abs. 2 IGV – in letzter Minute noch eingefügt worden ist!</i></p>
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<p>beiden Committees in eines zusammengelegt sowie die betreffenden Bestimmungen völlig neu geordnet und formuliert, ebenso wie schliesslich in den Schlussfassungen. Ein weiterer klarer Versoss gegen Art. 55 Abs. 2 IGV!</p>			
<p>Article 44 Collaboration and assistance</p>	<p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE CORE CAPACITIES</p> <p>(1.-3.)</p> <p>4. Pursuant to Article 44, States Parties shall undertake, to the fullest extent possible and in support of WHO, to collaborate and assist each other in developing, strengthening and maintaining core capacities.</p> <p>A. CORE CAPACITIES REQUIREMENTS FOR PREVENTION, SURVEILLANCE, PREPAREDNESS AND RESPONSE</p> <p>52. At the intermediate public health response levels (hereinafter the “Intermediate level”), where applicable, each State Party shall develop, strengthen and maintain the core capacities:</p> <p>(a) ...</p>	<p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE CORE CAPACITIES</p> <p>(1.-3.)</p> <p>4. Pursuant to Article 44, States Parties shall undertake to collaborate with each other, to the extent possible, and assist each other, subject to applicable law and available resources, in developing, strengthening and maintaining core capacities, and support WHO in such activities.</p> <p>A. CORE CAPACITIES REQUIREMENTS FOR PREVENTION, SURVEILLANCE, PREPAREDNESS AND RESPONSE</p> <p>52. At the intermediate public health response levels (hereinafter the “Intermediate level”), where applicable, each State Party shall develop, strengthen and maintain the core capacities:</p> <p>(a) ...</p>	<p>ANNEX 1</p> <p>A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE CORE CAPACITIES</p> <p>(1.-3.)</p> <p>4. Pursuant to Article 44, States Parties shall undertake to collaborate with each other, to the extent possible, in developing, strengthening and maintaining core capacities.</p> <p>A. CORE CAPACITIES REQUIREMENTS FOR PREVENTION, SURVEILLANCE, PREPAREDNESS AND RESPONSE</p> <p>52. At the intermediate public health response levels (hereinafter the “Intermediate level”), where applicable, each State Party shall develop, strengthen and maintain the core capacities:</p> <p>(a) ...</p>

<p>1. States Parties shall undertake to collaborate with <u>and assist</u> each other, <u>in particular developing countries States Parties, upon request</u>, to the extent possible, in:</p> <p>(h) (new) 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</p> <p>2. WHO shall collaborate with <u>and promptly assist</u> States Parties, <u>in particular developing countries</u> upon request, to the extent possible, in:</p>	<p>(c) to coordinate with and support the Local level in preventing, preparing for and responding to public health risks and events, including in relation to:</p> <p>(i) surveillance; (ii) on-site investigations; (iii) laboratory diagnostics, including referral of samples; (iv) implementation of control measures; (v) access to health services and health products;</p> <p>(vi) risk communication, including countering misinformation and disinformation;</p> <p>(vii) logistics.</p> <p>63. At the national level</p> <p><i>Assessment and notification. ...</i></p> <p><i>Public health prevention, preparedness and response. Each State Party shall develop, strengthen and maintain the core capacities for:</i></p> <p>(a) ...</p>	<p>(c) to coordinate with and support the Local level in preventing, preparing for and responding to public health risks and events, including in relation to:</p> <p>(i) surveillance; (ii) on-site investigations; (iii) laboratory diagnostics, including referral of samples; (iv) implementation of control measures; (v) access to health services and health products needed for the response; (vi) risk communication, including addressing misinformation and disinformation; (vii) engaging with relevant stakeholders; and (viii) logistical assistance (e.g. equipment, medical and other relevant supplies and transport); and</p> <p>63. At the national level</p> <p><i>Assessment and notification. ...</i></p> <p><i>Public health prevention, preparedness and response. Each State Party shall develop, strengthen and maintain the core capacities for:</i></p> <p>(a) ...</p>	<p>(c) to coordinate with and support the Local level in preventing, preparing for and responding to public health risks and events, including in relation to:</p> <p>(i) surveillance; (ii) on-site investigations; (iii) laboratory diagnostics, including referral of samples; (iv) implementation of control measures; (v) access to health services and health products needed for the response; (vi) risk communication, including addressing misinformation and disinformation;</p> <p>(vii) logistical assistance (e.g. equipment, medical and other relevant supplies and transport); and</p> <p>63. At the national level</p> <p><i>Assessment and notification. ...</i></p> <p><i>Public health prevention, preparedness and response. Each State Party shall develop, strengthen and maintain the core capacities for:</i></p> <p>(a) ...</p>
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<p>(e) (New) 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</p>	<p>(i) risk communication, including countering misinformation and disinformation;</p>	<p>(i) risk communication, including addressing misinformation and disinformation;</p>	<p>(i) risk communication, including addressing misinformation and disinformation;</p>
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4. Juli 2024

Jürg Vollenweider