

Onscreen version as at 13:44 CET on Saturday 23 March 2024



**NINTH MEETING OF THE INTERGOVERNMENTAL
NEGOTIATING BODY TO DRAFT AND NEGOTIATE
A WHO CONVENTION, AGREEMENT OR OTHER
INTERNATIONAL INSTRUMENT ON PANDEMIC
PREVENTION, PREPAREDNESS AND RESPONSE
Provisional agenda item 2**

**A/INB/9/3
13 March 2024**

Revised draft of the negotiating text of the WHO Pandemic Agreement

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DEL Para 3 (EU)]

[4. The WHO Secretariat shall provide technical assistance, upon request, to the manufacturing facilities under subparagraph 2(a) for its effective functioning (BGD, PSE, CHN, SYR, ZAF, IRN, IDN, FJI)]

Article 11. Transfer of technology and know-how

1. In order to enable sufficient, sustainable and geographically-diversified production of pandemic -related products each Party, taking into account its national circumstances, shall:

In order to [enable (~~DEL AF GROUP + EGY, PSE, SYR, IRN~~)] [in order to ensure (AF GROUP + EGY, PSE, SYR, IRN)] sufficient, sustainable and geographically-diversified production of pandemic -related [health (EU, JPN, TUR, UK)] products each Party [for the attainment of the objectives of this instrument (COL, BRA, GTM, SLV, MEX, PSE, CRI, DOM, IDN, FJI, SYR, NGA, PRY, BOL)] [taking into account its national circumstances (~~DEL COL, BRA, GTM, SLV, ARG, MEX, CRI, DOM, IDN, FJI~~)], shall [enhance cooperation through facilitating the following measures on voluntary and mutually agreed terms (JPN, CHE, ISR, CAN) (~~DEL PAK, IDN, NAM, BGD, SYR, ZAF, FJI, MYS, IRN, NGA, AF GROUP + EGY~~)]:

(a) promote and otherwise facilitate or incentivize the transfer of technology and know-how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development;

promote [and otherwise facilitate or incentivize (~~DEL EU~~) (**RETAIN KEN**)] the [voluntary (EU, CHE) (~~DEL NGA, IRN~~)] transfer of technology and know-how for [both (~~DEL USA, CAN, ROK, AUS~~)] pandemic-related [[and routine (~~DEL USA, CAN, ROK, QAT, AUS, ISR, IND, JPN~~)] health products], [on voluntary and mutually agreed terms, (USA, CAN, ROK, AUS, UK, ISR, JPN, CHE, EU) (~~DEL NGA, IRN, FJI, SYR~~)] including through the use of [worldwide, transparent and non-exclusive (COL, BRA, GTM, SLV, MEX, CRI, FJI, CHN, PHL, IDN, HON)] licensing and collaboration with regional or global technology transfer partnerships and initiatives [including those coordinated by the WHO (MYS, COL)], and in particular for the benefit of developing countries [at all times (PSE, TUN, NGA, SYR)] and for technologies that have received public funding for their [research and (COL, BRA, GTM, SLV, MEX, CRI, CHN, FJI, HON)] development;

(b) promote the timely publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related products, in accordance with national laws;

promote the [timely (**DEL** EU) (**RETAIN** NGA, IRN)] publication by [public or (COL, BRA, GTM, SLV, MEX, CRI)] private rights holders of the terms of [voluntary (EU, CHE) (**DEL** NGA, IRN)] licensing agreements and/or technology transfer agreements for pandemic-related [health (USA, EU, TUR, QAT, UK, ISR)] products, in accordance with [national (**DEL** EU)] [domestic (EU)] laws [and policy (EU)];

(c) make available licenses, on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries, for government-owned pandemic-related products, and shall publish the terms of these licenses at the earliest reasonable opportunity and in accordance with national laws; and

[pandemic emergencies, (USA, NZL, ISR) (**DEL** NGA, IRN)] [make available licenses (**DEL** EU, CHE, UK)] [promote the voluntary licensing (EU, CHE, UK, ISR, CHE) (**DEL** NGA, IRN, FJI)], on a [non-exclusive, [worldwide (**DEL** EU, UK) (**RETAIN** NGA, IRN)] and transparent (**DEL** UK) (**RETAIN** NGA, IRN)] basis [and for the benefit [of manufacturers and (BGD, PSE, NGA, SYR)] of developing countries (**DEL** USA)], [for (**DEL** EU, UK)] [where the party is the owner of all the rights in (a) (EU, UK)] [government-owned (**DEL** EU, UK)] pandemic-related [products (**DEL** USA, JPN, NZL)] [pandemic related technologies for which licenses could be made available (PAK, PSE)] [technologies (USA, JPN, NZL, ISR)], and [[shall (**DEL** USA, NZL, ISR)] publish (**DEL** EU, UK)] [the publication of (EU)] the terms of these licenses at the earliest reasonable opportunity and in accordance with [national (**DEL** EU, UK)] [domestic (EU, UK)] laws [and policies (EU, UK)]; and

(d) provide, within its capabilities, support for capacity-building for the transfer of technology and know-how for pandemic-related products.

provide, within its capabilities [and subject to available resources and applicable law (USA, ISR)], support for capacity-building for the [voluntary (EU, CHE)] transfer [on mutually agreed terms (EU)] of technology and know-how for pandemic-related [health (USA, TUR, QAT, ISR)] products [particularly to developing countries (COL, BRA, GTM, SLV, TUN, MEX, CRI, NGA, PHL, SYR, MYS)] [on voluntary and mutually agreed terms (USA, CAN, EU, AUS, ISR, CHE) (**DEL** NGA, IRN, FJI, SYR)].

[(e) Make available the regulatory dossiers of the government-funded pandemic-related products to WHO for further sharing of the same with regulatory agencies and production facilities mentioned under subparagraph 2(a) of Article 10 (BGD, PSE, NAM, FJI, MYS)]

[**SUPPORT** Bureau text for Para 1: IND]

2. The Parties shall develop and strengthen, as appropriate, mechanisms coordinated by WHO with the participation of other relevant technology transfer mechanisms as well as other relevant organizations, to promote and facilitate the transfer of technology and know-how for pandemic-related products to geographically diverse research and development institutes and manufacturers, particularly

in developing countries, through the pooling of knowledge, intellectual property, know-how and data to all developing countries.

The Parties [hereby establish and (BGD, MEX, PSE, MYS)] shall develop and strengthen, as appropriate, mechanisms [that facilitate the transfer of technology and know-how for pandemic related health products on voluntary and mutually agreed terms. Such mechanisms may be (USA, QAT, JPN)] coordinated by WHO [and partnerships with other United Nations entities and relevant international organizations to promote synergies, complementarities, and coherencies, (PSE, TUN, IRN, SYR)] [in conjunction (USA, QAT)] with [the participation of (~~USA, QAT~~)] other relevant technology transfer mechanisms [and (USA, QAT)] [as well as (~~USA, QAT~~)] [with the participation of (USA)] other relevant organizations, [to promote and facilitate [voluntary (UK, CHE, CAN, QAT)] the transfer of technology and know-how [on mutually agreed terms (UK, JPN, CHE, CAN, QAT)] for pandemic-related products to geographically diverse research and development institutes and manufacturers, particularly in developing countries, [including through transfer hubs and technology pools (CAN, BRA)] [[referred to under Art 10.2a (BGD, PSE)] through (~~USA, QAT~~) (**RETAIN TUN**)] [and may include (USA, QAT, JPN)] the pooling of knowledge, [on a non-exclusive worldwide and transparent licensing of (COL, BRA, TUN, GTM, SLV, MEX, CHN, IRN, IDN, PHL, CHL, BGD, PSE, SYR, MYS, CUB, FJI, QAT, ECU, VEN), HND] intellectual property, know-how and data [to all [especially to (COL, BRA, TUN, GTM, SLV, MEX, PHL, MWI, IRN, CHL, PSE, SYR, CHN, CUB, FJI, BGD, QAT, ECU, VEN, HND)] developing countries [(~~USA~~) (**RETAIN BRA, CUB, NIC**)] [at all times (PSE, SYR, TUN, CUB, NIC)]] (~~CAN~~).

[*Alt 2:* The Parties shall develop and strengthen as appropriate, mechanisms for the voluntary pooling of knowledge, intellectual property, know-how and data aimed to promote the voluntary transfer of technology and on mutually agreed terms of technology and know-how for pandemic-related health products to geographically diverse research and development institutes and manufacturers, particularly in developing countries (EU).]

RETAIN Bureau's text: MYS, AG + EGY, IND, FJI

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:

During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:

(a) encourage holders of relevant patents regarding pandemic-related products, in particular those who received public funding, to forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products; and

encourage holders of relevant patents [regarding (~~EU~~) (for (EU))] pandemic-related [health (USA, EU)] products, in [particular (~~EU~~) (including EU)] those who received public funding, to [, on voluntary and mutually agreed terms, (USA, JPN, AUS)] [forgo [royalties (EU)] or otherwise (~~JPN, CAN~~)] [charge (~~EU~~) (licensed any relevant patent EU)] reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related [health (USA, EU)] products [;with the aim to

increase the availability and affordability of such products to Parties in need; (EU)] [and (DEL EU)]

(b) consider supporting, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic related- products to the extent necessary to increase the availability and adequacy of affordable pandemic related- products.

[[in the case that the intellectual property rights are deemed a barrier to access, take appropriate measures to support (BRA, COL, GTM, SLV, FJI AG + EGY, TUN, IDN, NIC, MYS, IRN)] [[consider (DEL CHN, BGD, AG + EGY, IDN, IRN, VEN)] supporting (DEL BRA, FJI, AG + EGY, IDN, TUN, IRN)], within the framework of relevant institutions, [time-bound waivers of (DEL ROK) (RETAIN BGD)] [compulsory licensing of TRIPS Agreement (ROK)] intellectual property rights [, technology transfer and know-how to the manufacturers with technology capability and capacity (CHN, BGD, AG + EGY, IDN, TUN, CUB, SYR, IRN, VEN)] to accelerate or scale up the manufacturing of pandemic -related products to the extent necessary to increase the availability and adequacy of affordable pandemic -related products. (DEL USA, EU, CHE, CAN, UK, JPN)]

[c. compel manufacturers within its jurisdictions to share undisclosed information, as defined in art 39.2 of the TRIPS agreement, with qualified third-party manufacturers where such information prevents or hinders urgent manufacture by such qualified third parties of a pharmaceutical product that is necessary to respond to a pandemic. (COL, BRA, SLV, GTM, AG + EGY, NIC, IDN, VEN, ARG) (DEL EU, JPN, UK, AUS, USA)]

RETAIN Bureau's text: AG + EGY, IND

4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.

The Parties [who are members of the (PSE, SYR, TUN)] [that are (DEL PSE, SYR, TUN)] WTO Members [reaffirm (BGD, BRA, NIC, PAK, SYR, AG + EGY, COL, SLV, GTM, MYS, FJI, NGA, JPN) [recognize (DEL BGD, BRA, NIC, NAM, PAK, SYR, AG + EGY, FJI, NGA, JPN)] that they have the right to use to the full[-est extent (MYS, BGD)], the [[flexibilities [inherent (DEL CAN)] in the (RETAIN MYS, BGD)] (DEL USA, NZL, JPN) [WTO (USA, NZL, JPN)] TRIPS Agreement [including those (MYS, BGD)] [as [reiterated (DEL BGD, NIC, NAM, IDN, FJI) reaffirmed (BGD, NIC, NAM, IDN, FJI)] (DEL BRA, COL, GTM, SLV, TUN, FJI)] in (DEL USA, NZL, JPN) [and (USA, NZL, JPN)] the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to [take measures to (PAK, SYR)] protect public health including in future pandemics, [and shall fully respect the use thereof by others (DEL USA, EU, UK, QAT, CHE, NZL)].

[4bis. The Parties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO Members to use TRIPS flexibilities at any multilateral,

regional, bilateral, judicial or diplomatic forum. (BRA, COL, GTM, SLV, NIC, TUN, ARG, AG + EGY, BGD, FJI, PHL, PAK, IDN) (~~DEL~~ EU, JPN, USA, UK, NZL, ROK, CAN, CHE)]

[*4alt.* Nothing in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and public health of 2001 and subsequent relevant decisions, which provide flexibility to protect public health including in future pandemics, shall be construed as preventing the WTO Members from taking measures to protect public health and to promote equitable and universal access to health products under this Agreement. (IRN, SYR, PSE, TUN, CHN, BLR, FJI, PAK) (~~DEL~~ EU, USA, CAN, CHE)]

RETAIN Bureau's text: RUS, IND

5. Each Party shall, as necessary and appropriate, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 4 of this Article in a timely and effective manner.

[Each Party [that is a Member of the WTO (PSE, IRN)] [shall (~~DEL~~ CHE, AUS) may (CHE)] [will endeavor to (AUS)], [review and consider amending (USA)] as necessary and appropriate, [review [and update (~~DEL~~ USA)] (~~DEL~~ EU, CHE)] its [national (~~DEL~~ EU) domestic (EU)] legislation [in order (~~DEL~~ USA)] to [ensure (~~DEL~~ EU, CHE) enable (EU, CHE)] [it is able to implement (USA)] [the implementation of such flexibilities [for the protection of public health (MYS, BGD, TUN)] referred to in paragraph 4 of (~~DEL~~ USA) (**RETAIN** TUN)] this Article in a timely and effective manner [including ensuring adequate exceptions and limitations in their intellectual property laws and regulations to facilitate the manufacture, export and import of the health products needed during health emergencies (BGD, TUN, SYR)] (~~DEL~~ CAN)].

RETAIN Bureau's text: RUS, BRA, NIC, IND, FJI, TUR

6. The WHO Secretariat shall work towards the improvement of access to pandemic-related products, especially during pandemic emergencies, through transfer of technology and know-how, including through cooperation with relevant international organizations.

The [WHO (~~DEL~~ EU)] Secretariat [, in cooperation with relevant international and regional organizations and other stakeholders, (EU)] shall work towards [supporting (EU)] the [implementation of the provisions of this article (EU)] [improvement of access to pandemic-related products, especially during pandemic [emergencies (~~DEL~~ AG + EGY)], [and humanitarian emergencies settings (PSE, IRN)] through [mechanisms for the (COL, FJI, BRA, GTM, SLV, IRN)] [promoting the (JPN)] transfer of technology and know-how [on voluntary and mutually agreed terms (JPN, CAN, CHE)], [at all times (PSE, SYR, IRN)] including [in (COL, FJI, BRA, GTM, SLV, IRN)] [through (~~DEL~~ COL, FJI, BRA, GTM, SLV, IRN)] cooperation with relevant international organizations (~~DEL~~ EU)]. [In this regard, the WHO Secretariat shall:

- a) maintain a database of pandemic related products containing information on their specifications, manufacturing process, design etc and provide access to manufacturing facilities under Article 10.2(a) as well as other manufacturers on the condition of supplying at affordable price.

b) establish a biobank to create a repository of relevant biomaterials required for the production of pandemic related products. (BGD, PSE) (~~USA~~)

[*alt.* The WHO Secretariat, in collaboration with relevant international organizations, including the WTO and the WIPO, shall work to address issues related to improving access to pandemic related health products during pandemic emergencies (USA, UK, AUS, CHE, NZL, CAN).]

RETAIN Bureau's text for para 6: TUN, RUS, IND

[7. A transfer of technology committee is hereby established. The Committee shall develop and adopt guidelines on the identification of technologies and know-how necessary to attain the objectives of this Agreement. (COL, BRA, GTM, SLV, PER)]

Article 12. Access and benefit sharing

1. The Parties hereby establish a multilateral system for access and benefit sharing for pathogens with pandemic potential: the WHO Pathogen Access and Benefit-Sharing System (PABS System).

1. [Without prejudice to their biological safety and to their economies (RUS)] The Parties[, recognizing Member States' sovereign rights over their biological materials and resources (CHN, IDN, SYR, MYS, AF GROUP + EGY, IRN, BGD, MCO, PHL, PAK, UAE, BOL, QAT)] [hereby (~~UK, CAN~~)] [agree to (UK, CAN)] [recognize the need to agree upon and (RUS)] establish [as part of a separate negotiation process (RUS)] a [transparent and equitable (MYS, SYR, BGD)] multilateral system for access and benefit sharing for [pathogens with pandemic potential: (**RESERVE** USA)] the WHO Pathogen Access and Benefit-Sharing System (PABS System).

[**SUPPORT** Bureau's text: BRA, FJI, AF GROUP + EGY, COL, IDN, GTM, IND, BGD, URY, MYS]

2. The PABS System aims to ensure rapid, systematic and timely access to biological materials of pathogens with pandemic potential and the genetic sequence data (GSD) for such pathogens, which contributes to strengthened global surveillance and risk assessment, and facilitates research, innovation and development of health products; and on an equal footing, equitable, fair and rapid sharing of monetary and non-monetary benefits, including timely, effective and predictable access to relevant diagnostics, therapeutics or vaccines, based on public health risks, needs and demand, contributing to the rapid and timely control of public health emergencies of international concern and pandemics.

2. The PABS System aims to ensure rapid, systematic and timely access to [pandemic preparedness (RUS)] biological materials of [pathogens with pandemic potential (**RESERVE** USA, EU)] and the [related (RUS)] genetic sequence data (GSD) for such pathogens [, as appropriate (AF GROUP + EGY, BD, SYR)], [which [contributes to (~~USA~~)] [yields inherent benefits such as (USA)] strengthened global surveillance and risk assessment, and [facilitates (~~USA~~)] research, innovation and development of health products [it also provides for strict compliance with applicable national and international export control requirements for pathogens with pandemic potential to ensure the safe international distribution such materials (RUS)]; [and on an equal footing, equitable, [and (USA)] fair [and rapid (~~USA~~)] sharing of monetary and non-monetary benefits [, that arise from the utilization of such biological materials and genetic sequence data, (AF GROUP + EGY,