

Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (“INB”)

Informal, focused consultation on Intellectual property, production and transfer of technology and know-how

Concept Note

At its second meeting, the INB decided that the INB Bureau would conduct informal, focused consultations (“IFCs”), open to all Member States¹ and relevant stakeholders, on selected key issues, including with experts, as invited by the Bureau. This Concept Note is for the IFC session on the topic of Intellectual property, local production and transfer of technology and know-how.

Key Information

Date:	7 October 2022
Time:	14:00 – 17:00 (CET)
Location, participation, and webcasting:	<p>The IFC session will be fully virtual, with interpretation in WHO’s official languages.</p> <p>The WHO Secretariat will provide the connection details to all participants in advance of the session.</p> <p>In the interest of transparency, and mindful of the public’s interest in the work of the INB, the IFC session will be publicly broadcast on the WHO website (https://inb.who.int/home/informal-focused-consultations).</p>
Topic details:	<p>This IFC session will address <u>Intellectual property (IP), production and transfer of technology and know-how</u>, including:</p> <ul style="list-style-type: none">• Research and development• Patents and access to technology, including related know-how• The role of TRIPS, compulsory licensing and IP waivers• Production capacity and supply chain considerations• Regulatory approvals during emergencies
Chairs:	<p>Ms Precious Matsoso, INB Bureau Co-Chair Mr Roland Driece, INB Bureau Co-Chair</p>
Moderator:	<p>Ms Emma Ross, Senior Research Fellow, Chatham House, the Royal Institute of International Affairs, London.</p>
Participating experts:	<p>Listed below.</p>
Submission of advance questions	<p>Participants are encouraged to submit their questions in advance of the IFC session, by email to: governanceunit@who.int with the subject line: “written question(s) for INB IFCs session three”. Member States and relevant stakeholders will also be able to submit questions during each IFC, by email to the same address, or through the chat feature of the virtual platform. The submission of advance questions will not preclude participants from taking the floor during the discussions.</p>

¹ And associate members and regional economic integration organizations.

Modalities

The IFC sessions (including this session) will follow the modalities set out in the White Paper on the IFCs from the INB Bureau, which was provided in advance. .

As stated in the White Paper, all IFCs will be moderated and conducted in two parts: 1) an interactive round table among independent experts (listed below), where the moderator will ask questions and stimulate discussion among the experts; and 2) a discussion and reflection session, for Member States and relevant stakeholders, where questions and reflections may be sent through email in advance of the session, or presented during the session, including through the “chat” function.

Reference is also made to the section of the White Paper entitled “*Disclaimer / understanding*” regarding participation in the IFCs, including by WHO Member States.

Run of Show

7 October 2022 (all times CET)

13:30-13:55	<i>Experts join the session and test their connection</i>
14:00-14:10	Welcome remarks by the INB Co-chairs and introduction of the moderator
14:10-15:35	<i>Roundtable Discussion:</i> Moderator introduces experts’ panel and moderates the presentations and experts’ discussion
15:35-15:40	<i>Health break</i>
15:40-16:40	<i>Discussion and reflection session:</i> Moderated discussions and questions, involving audience and panelists
16:40-16:50	Wrap-up by the moderator
16:50-17:00	Outlining of main messages and closing remarks by the INB Co-chair

Roundtable discussion structure

Invited experts will be invited to provide a brief presentation of their topics, as outlined in the table below, from their specific lens of expertise, drawing on the [Working Draft](#), and the mandate of the INB.

WHO Informal, focused consultation 3 – Intellectual property, production and transfer of technology and know-how

Proposed focus areas for expert presentations during the round table component: The topics below aim to elicit from the experts the broadest range of perspectives that can inform Intellectual property, local production and transfer of technology and know-how through a WHO convention or agreement “WHO CA+”². In the interest of coherence and to avoid duplication of contributions, the topics have been grouped and reference has been made to the [Working Draft](#) to ensure that all relevant issues are addressed. In addition, given the complementarity with the IFC on “operationalizing and achieving equity” some topics will be covered in that IFC. More specifically, the topic of access to pandemic response products will be covered in IFC2 in order to focus the discussions in IFC3 to Intellectual property, local production and transfer of technology and know-how.

Topic	Expert(s)	Potential areas for expert focus³
Research and development	Soumya Swaminathan , Chief Scientist, WHO Richard Hatchett , CEO, Coalition for Epidemic Preparedness Innovations (CEPI)	The expert(s) are invited to provide specific input in addressing the following: <ul style="list-style-type: none"> • Mechanisms to incentivize scientific cooperation to accelerate innovative research for developing diagnostics, therapeutics and vaccines for (re)emerging diseases, particularly in developing countries. • Scalable financing to strengthen R&D capacities, as well as scientific and technical cooperation, collaboration and communication.
Patents and access to technology, including related know-how	Carlos Correa , Executive Director of South Centre Padmashree Gehl Sampath , Fellow and Senior Advisor, Global Access in Action Program, Berkman Klein Center, Harvard University and Chair Person, Technical Advisory Group of COVID-19 Technology Access Pool (CTAP).	The expert(s) are invited to provide specific input in addressing the following: <ul style="list-style-type: none"> • Initiatives and multilateral mechanisms that incentivize technology transfer and know-how. • Incentives and innovative approaches to increase and facilitate participation of private-sector entities in technology transfer and know-how.
The role of TRIPS, compulsory licensing and IP waivers	Ellen ‘t Hoen , Director, Medicines Law & Policy / Global Health Law Fellow Law Faculty, University of Groningen, the Netherlands	The expert(s) are invited to provide specific input in addressing the following: <ul style="list-style-type: none"> • Leveraging the commitments and flexibilities under TRIPS to achieve coherence and synergy with the WHO CAII.

² WHO CA+: At its second meeting in July 2022, the INB identified that Article 19 of the WHO Constitution is the comprehensive provision under which the instrument should be adopted, without prejudice to also considering, as work progresses the suitability of Article 21.

³ These sub-areas and topics are proposed for participating experts’ consideration, as they see fit, in the spirit of fostering a robust discussion. They are in no way intended to limit the experts’ presentations or discussions, and the WHO Secretariat is flexible in framing all experts’ contributions in a way that synergizes with their scholarship.

Topic	Expert(s)	Potential areas for expert focus ³
<i>Production capacity and supply chain considerations</i>	Mariângela Simão , WHO Assistant Director-General, Access to Medicines and Health Products	<p>The expert(s) are invited to provide specific input in addressing the following:</p> <ul style="list-style-type: none"> • Development of national, sub-regional and regional approaches to ensure scalability of production capacity that meets surge demand. • Use of stockpiles and pooled purchasing mechanisms to facilitate, coordinate, and equitably allocate supplies. • Approaches to ensure the strength of supply chains that promote equitable, timely and efficient delivery to priority populations in need.
<i>Regulatory approvals during emergencies</i>	<p>Mojisera Adeyeye, Director-General National Agency for Food and Drug Administration and Control in Nigeria (NAFDAC), Nigeria</p> <p>Martin Harvey Allchurch, Head of International Affairs, European Medicines Agency</p>	<p>The expert(s) are invited to provide specific input in addressing the following:</p> <ul style="list-style-type: none"> • Actions to strengthen and harmonize regulatory authority processes (at least at the regional or sub-regional level) to accelerate licensing, approval and/or market authorization of pandemic response products for emergency use in a timely manner. • Strengthening of national regulatory capacities to accelerate emergency approval procedures.

Background

The mandate of the INB was established by the World Health Assembly in decision [WHASS2\(5\)](#), pursuant to which the INB is to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the INB.

Pursuant to that mandate, at its [second meeting](#) the INB “agreed that the instrument should be legally binding and contain both legally binding as well as non-legally binding elements. In that regard, the INB identified that Article 19 of the WHO Constitution is the comprehensive provision under which the instrument should be adopted, without prejudice to also considering, as work progresses, the suitability of Article 21. This identification is made mindful that the decision will be made by the World Health Assembly.”

Further information and documentation regarding the INB, including from past meetings, is available on the WHO website (<https://apps.who.int/gb/inb/>), including the [Working Draft, presented on the basis of progress achieved, for the consideration of the INB at its second meeting](#) and the [paper](#) entitled “Background information related to the identification by the Intergovernmental Negotiating Body of the provision of the WHO Constitution under which the instrument should be adopted”, prepared by the WHO Secretariat for the second meeting of the INB.

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