Knowledge Ecology International (KEI) comments on the resolution WHA73: "Covid-19 Response" proposed by the European Union (EU)

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Specific comments on the EU resolution

Knowledge Ecology International (KEI) proposes that PP16 be amended to read (additional wording in italics/bold/underline):

> **PP16** Recognising the need to achieve equitable access and availability of appropriate quality protective and other equipment, medical devices *including* ***in vitro medical devices***, medicines, vaccines and other health technologies related to COVID-19 and vaccines by scaling up research and development, clinical trials, and production, engaging early with regulators, as well as addressing market and supply-chain failures;

KEI proposes that operative paragraph 4.2 be amended to read (additional wording in italics/bold/underline):

> **OP4.2** Work collaboratively at international level to develop, test and produce safe, effective, quality diagnostics, medicines and vaccines for the COVID-19 response, and to facilitate the equitable and affordable access of people to them, including through voluntarily pooling their intellectual property for all COVID-19-related medical interventions; ***including where relevant rights in regulatory test data, know-how, cell lines and other biologic resources, copyrights, blueprints and designs for manufacturing diagnostic tests, devices, drugs, or vaccines.***

In relation to operative paragraph 5.17, KEI proposes the addition of a paragraph OP5.17bis:

> **OP5.17bis** *Develop a concise memorandum of understanding with funders of COVID-19 related R&D, on the intent to pool rights, in order to enable provisions in funding contracts to assign rights for use in all WHO member states.*

KEI proposes the following amendment to OP3.8 (additional wording in italics/bold/underline):

> **OP3.8** As far as existing international treaties allow, remove the existing barriers in access quality protective equipment, medical devices ***including in-vitro diagnostics,*** and other technologies, medicines, and vaccines related to COVID-19;

KEI proposes the insertion of a new operative paragraph:

> **OP5.XX** Ensure that the WHO Global Observatory on Health R&D creates a database of R&D activity related to COVID-19, including but not limited to estimates of the costs of relevant clinical trials, and the subsidies provided by governments and charities, to assist countries in identifying funding gaps, designing incentives and evaluating prices and royalties.

KEI proposes the insertion of a new operative paragraph:

> **OP5.XX** Work with governments and other funders of research and development to create an innovation inducement reward fund, to provide for market entry rewards for companies that openly license new drugs or vaccines.

KEI proposes the insertion of a new operative paragraph:

> **OP5.XX** Work with governments to create a fund to buy out global patent rights for essential patents for tests, drugs or vaccines, in the field of use for the detection, prevention, control or treatment of COVID 19.

KEI proposes the insertion of a new operative paragraph:

> **OP5.XX** In order to promote transparency, work with governments to create a global database of prices paid for COVID-19 relevant diagnostic tests, drugs and vaccines, and provide estimates of the manufacturing costs for tests, drugs and vaccines.

KEI proposes the insertion of a new preambular paragraph with the following text:

> **PPXX** *Reaffirming the right to use, to the fullest extent, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provides flexibilities for the protection of public health and promotes access to medicines for all, including compulsory licensing, and the WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all.*

KEI proposes the insertion of a new operative paragraph:

> **OP5.XX** *Cooperate with Member States, at their request, in making full use of the public health safeguards/flexibilities contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including compulsory licensing of other exceptions to rights.*

General comments on the EU resolution

Covid-19 Technology Pool

Knowledge Ecology International(KEI)[1] requests the "World Health Organization and its Member States to support the proposal by Costa Rica for the creation of a global pooling mechanism for rights in the data, knowledge and technologies useful in the prevention, detection and treatment of the coronavirus/COVID-19 pandemic.

A copy of letter from Carlos Alvarado Quesada, Presidente de la República, Costa Rica, and Daniel Salas Peraza, Ministro de Salud, Costa Rica, to Dr. Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, available here).

Costa Rica correctly saw this as a pool with a diverse set of rights, including those relating to patents on inventions and designs, regulatory test data, research data including outcomes, know-how, cell lines, copyrights and blueprints for manufacturing, as these rights relate to equipment, diagnostic tests, devices, medicines, vaccines, and other medical tools. And, Costa Rica also correctly sees this as a pool for global rights, to benefit all WHO member states.

Such a pool would allow for competitive and accelerated production of needed COVID-19 technologies, and expand our capacity to address the need for affordable products for all.

The inputs to such a pool could come from governments that fund research and development or buy innovative products, as well as from universities, research institutes, charities, private companies and individuals who control rights.

The WHO should immediately reach out to Member States that are funding biomedical research relevant to the current pandemic, and engage other rights holders as well.

We recognize that some governments and other entities may be reluctant to openly share technologies globally, such as by open licensing or licensing on reasonable and affordable royalties, when there is uncertainty about whether others will make similar commitments.

To move forward as quickly as possible, and consistent with the Costa Rica proposal, the WHO can put forth an initial phase-one agreement that creates the bare minimum legal basis to permit such assignments/licenses in the future, such as by including options in funding contracts, and create a process for working out the details at a later date, including the ultimate decisions on which technologies to share, and the terms of the authorizations, including possible remuneration. As rights holders work with the WHO and deepen their understanding of the challenges we face in responding to the pandemic, the logic and benefits of cooperation and global pooling will be compelling.

[1] This section under the Covid-19 Technology Pool is taken directly from an open letter published on 27 March 2020 by KEI and supported by dozens of academics and advocacy groups entitled, "Open letter to the World Health Organization (WHO) and its Member States on the proposal by Costa Rica to create a global pool for rights in the data, knowledge and technologies useful in the prevention, detection and treatment of the coronavirus/COVID-19 pandemic".

The most important and needed element today is leadership, to convince those funding R&D or buying innovative products that in this emergency, the broadest sharing of technology could save the most lives. Moreover, and this needs to be addressed in funding agreements, now." (Source: "Open letter to the World Health Organization (WHO) and its Member States on the proposal by Costa Rica to create a global pool for rights in the data, knowledge and technologies useful in the prevention, detection and treatment of the coronavirus/COVID-19 pandemic, 27 March 2020, https://www.keionline.org/32599).

Managing intellectual property rights including the use of non-voluntary licenses

The covid-19 resolution should contain language in the operative section requesting the WHO Director-General to produce a report by June/July/August 2020 on potential intellectual property and regulatory barriers for COVID-19 technologies. This report should cover patents on inventions and designs, regulatory test data, research data including outcomes, know-how, cell lines, copyrights and blueprints for manufacturing, as these rights relate to equipment, diagnostic tests, devices, medicines, vaccines, and other medical tools.

There is an exigent need for countries to have universal access to diagnostic tests, devices, medicines, vaccines, know-how, cell lines, blueprints for manufacturing, and other health technologies in the covid-19 response. As countries struggle with with affordability and financial sustainability issues in the COVID-19 response, they can seek technical assistance from the WHO or other entities in order to use lawful pathways to ensure treatments are affordable and widely available — including through the granting of compulsory licenses and/or through the use of competition law or other means to remedy excessive prices.

As the COVID-19 pandemic rages on, the WHO should be much more active in this regard; rather than waiting passively for countries to approach the WHO for assistance, the WHO could organize a series of virtual workshops to share expertise and best practices on various technical and practical aspects of compulsory licenses, and other related topics including the ability of Member States to implement limitations on remedies for patent infringement.