

QUESTIONNAIRE ON NATIONAL/REGIONAL OR GLOBAL INCENTIVES TO FACILITATE SCALE UP AND ACCESS TO COVID-19 HEALTH TECHNOLOGIES, INCLUDING VACCINES, DIAGNOSTICS, AND THERAPEUTICS

Objective

- The WHO COVID-19 COVID-19 Technology Access Pool (C-TAP) provides a platform for developers of COVID-19 therapeutics, diagnostics, vaccines and other health products to voluntarily share their intellectual property, knowledge, and data, with multiple quality-assured manufacturers. This enables manufacturers that currently have untapped capacity to produce COVID-19 health products by giving them the legal rights to manufacture and sell the products; the technological know-how required to develop assured-quality products effectively and efficiently; and access to clinical data needed to obtain regulatory approval for their products.
- National or regional incentives may help motivate technology holders, particularly biopharmaceutical companies, but also including universities and public and philanthropically funded researchers, to share their intellectual property, knowledge, and data and/or facilitate technology transfer to scale up manufacturing capacity through C-TAP and respond to the pandemic.
- A broad commitment by Member States to share the information about the R&D funding and the incentives they are already providing or would additionally consider offering would signal a spirit of collaboration with technology holders in order to promote their engagement through the WHO C-TAP initiative and the principles of the Solidarity Call to Action.
- Support by Member States, including the co-sponsors of the Solidarity Call to Action, would encourage technology holders to participate in discussions on the kind of incentives they consider necessary to voluntarily share their IP and knowledge, and data through the C-TAP initiative.
- Incentives could come in different forms; for example, in terms of facilitating administrative procedures, fast-track approvals to facilitate market access, innovation and financial incentives, etc.
- This questionnaire is intended to guide Member States in identifying relevant laws, regulations, guidelines and procedures that could be modified or introduced to facilitate the sharing of technologies through C-TAP for rapid scale up in such an unprecedented pandemic.
- The responses to this questionnaire will be compiled in aggregated form and analyzed by the WHO C-TAP Secretariat to be presented to the C-TAP Steering Committee and Member States to support the engagement with COVID-19 technology holders in voluntary pooling of knowledge, IP and data.

Questionnaire

For each type of incentive, please circle the most accurate response. You are also encouraged to provide details and explanations in the text box:

- Already implemented in your country or region
- Your country or region would not be able to implement
- Not implemented but would consider

There are 17 questions in this survey.

Incentives

1. Funding health R&D: Is your country/region providing funding/incentives for COVID-19 R&D for health technologies?

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

2. Simplification of administrative procedures: Simplify administrative procedures or requirements, for example, related to importation, regulatory approval (see also below), and other government processes in order to reduce time and cost of submitting and processing applications.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

3. Importation duties and tariffs: Measures related to the reduction or suspension of duties and tariffs on COVID-19 health products or all products for a defined period. For example, could be considered cost reduction from a company to market a product in the country or region.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

4. Customs processes: Measures to speed review of imports; or provide for pre-certification; or other related measures to accelerate market availability and reduce costs.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

5. Taxes on income, sales, wages, and property (national, regional, and local): Provide a tax credit or exempt some revenues from taxation. For example, tax reductions go directly to a company's bottom line profit, and could be substantial. Tax credits or exemptions have the benefit of being tied to activity in the country.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

6. Administrative fees or other fees (national, regional, and local): Suspend or reduce fees, e.g., for filing documents, licenses, or doing business.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

7. Regulatory incentives: (i) Administrative simplification: Reduce/streamline/simplify requirements and procedures for product approval and other regulatory process that maintains the integrity of the system.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

8. Regulatory incentives: (ii) Good Regulatory Practices: Measures that support 'smart regulation' and the most effective use of resources through harmonization and convergence of requirements based on international standards, work-sharing and reliance (see reference¹)

¹ WHO guidelines on good regulatory practices and good reliance practices, published as annexes to the Technical Report Series in March 2021.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider (please provide rationale)

Please enter your comment here:

9. Regulatory incentives: (iii) Regulatory timelines: Implement and publish internationally competitive timelines for market review and authorization and other regulatory processes.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider (please provide rationale)

Please enter your comment here:

10. [Regulatory incentives](#): (iv) Local clinical studies: Waive mandatory requirement for clinical studies in the local population (when there are no efficacy and safety concerns) to provide for at least conditional approval.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider (please provide rationale)

Please enter your comment here:

11. [Regulatory incentives](#): (v) Other regulatory measures: Please describe other regulatory measures that could be adopted to encourage private sector engagement in C-TAP such as measures to increase transparency, promote clear regulatory requirements and enhance engagement with industry.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

12. [Financial/innovation incentives](#): Implement financial incentives that de-link R&D costs from prices and sales of the products, for example in the form of prize funds or other mechanisms to promote further development of health products in exchange of sharing of IP or know-how through C-TAP. It may be possible to promote financial incentives in exchange of sharing of IP or knowledge by one country or a group of countries.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

13. [Engage with technology owners at national or regional level](#): Meet with companies, associations, universities and other relevant technology holders to explore potential incentives, including receiving feedback on which incentives would motivate them to voluntarily share knowledge or IP through C-TAP initiative. Engaging the technology holders at national/regional level would signal a desire to understand their potential concerns and explore mutual collaboration.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

14. Market Access: Price: Grant free pricing on launch of a product (with reasonable limits, e.g., not more than the lowest price in the highest-priced developed markets) for a defined period of time.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

15. Market Access: Market Segmentation (e.g. Exclusive supply for the public market): Confer an exclusive supply agreement for the public market on the company for a defined, limited period.

- ☐ Already implemented in your country or region
- ☐ Your country or region would not be able to implement
- ☐ Not implemented but would consider

Please enter your comment here:

16. Please identify any other market access regulations and opportunities that might be modified to incentivize technology holder's participation in C-TAP.

17. Please indicate any other existing or potential national/regional or global incentives that may encourage technology owner's participation in C-TAP.