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Review of the ODA coefficients of select health-related organisations on Annex 2 and the Single Table of the Converged Statistical Reporting Directives for the Creditor Reporting System (CRS) and the annual DAC Questionnaire

WP-STAT informal meeting
22-24 November – Hybrid meeting.

This document presents a review of the ODA coefficients of select health-related organisations already on the List of ODA-eligible international organisations (Annex 2 of the Converged Statistical Reporting Directives) or organisations on the Single Table whose mandates may have been affected by COVID-19 activities. It proposes a coefficient for the World Health Organisation's (WHO) Strategic Preparedness and Response Plan (SPRP) for COVID-19. A separate document [DCD/DAC/STAT(2021)30] outlines proposals for the inclusion of organisations on the List.

Members are invited to APPROVE the Secretariat's recommendation on the ODA eligibility of the WHO's SPRP for COVID-19 via written procedure on the WP-STAT community space. If no objections are received by COB 15 December 2021, the proposal will be considered approved and take effect in 2022 reporting on 2021 ODA.

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Review of the ODA coefficients of health-related organisations on Annex 2 and the Single Table of the Converged Statistical Reporting Directives for the Creditor Reporting System (CRS) and the annual DAC Questionnaire

Introduction

1. This paper presents a review of the ODA coefficients of select health-related organisations on Annex 2 and the Single Table of the *Converged Statistical Reporting Directives for the Creditor Reporting System.* The Secretariat carried out this review following the request of the WP-STAT to consider how activities related to the COVID-19 response and recovery may affect the core mandate and function of these organisations, and thereby the concentration of these organisations' activities on the needs of developing countries relative to a global public good (GPG).

2. In advance of an informal meeting of the WP-STAT held in June 2020 [DCD/DAC/STAT(2020)21/REV1], the Secretariat identified four organisations already on Annex 2 that were initially established to respond to diseases primarily affecting developing countries, but which have now extended their activities to respond to COVID-19: the Coalition for Epidemic Preparedness Innovations (CEPI); the International AIDS Vaccine Initiative (IAVI); the International Vaccine Institute (IVI). Additionally, the Secretariat reviewed the eligibility of core contributions to the World Health Organisation (WHO), considering its role as the United Nations (UN) agency that leads global efforts to expand universal health coverage and directs and coordinates the world's response to global health emergencies, and assessed the eligibility of contributions to the WHO's Strategic Preparedness and Response Plan (SPRP) for COVID-19 [DCD/DAC/STAT(2020)43]. The Secretariat considered a review of the eligibility of core contributions to Gavi, the Vaccine Alliance (Gavi), given the role that Gavi has played in the global response to COVID-19, particularly in efforts to allocate and distribute COVID-19 vaccines worldwide. However, after further consideration, it was determined that a review of Gavi would not be necessary: given the strict eligibility criteria to receive support from Gavi, based on a country's Gross National Income per capita[1], all activities would necessarily be implemented in the 73 Gavi-eligible countries that are also ODA-eligible recipients, with developmental benefits accruing exclusively to those countries. Thus, all core support to Gavi is still fully ODA-eligible.

3. Since the COVID-19 pandemic is a global problem, certain COVID-19 related activities [e.g., the research and development (R&D) of a COVID-19 vaccine] could constitute a GPG, benefitting developing and developed countries alike. The Secretariat thus researched the composition, governance, and funding structure of these organisations' COVID-19 related activities to understand the extent to which they were a core priority, insofar as they were funded through core/unearmarked (rather than earmarked) contributions, both presently and in the future. In certain cases, if an assessment had not been carried out in several years, the Secretariat also determined whether an updated coefficient was needed to more accurately and fairly reflect the ODA eligibility of an organisation's core mandate and activities.

4. Table 1 below lists the health-related organisations that were reviewed to reflect possible changes in the work of these organisations in light of the COVID-19 response and recovery. The Secretariat's

[1] https://www.gavi.org/programmes-impact/programmatic-policies/eligibility-and-transitioning-policy

comments and the rationale behind its recommendations are elaborated, by organisation, in sections A through D. Section E summarises the recommended changes.

5. Members are invited to **approve** the Secretariat's recommendation on the ODA eligibility of the WHO's SPRP under written procedure on the WP-STAT community's space[2], on a non-objection basis **by COB 15 December 2021**. Approved changes will be effective for 2022 reporting on 2021 ODA flows.

Table 1. Summary of proposals for changes to Organisations on Annex 2 and the Single Table

Organisation	Specific sub-entity (if applicable)	Current ODA coefficient	Proposal for updated ODA coefficient
A. Coalition for Epidemic Preparedness Innovations (CEPI)	Contributions to CEPI earmarked for COVID-19 related activities in 2021	53% (2020)	88% (2021)
	Core contributions for 2022 reporting on 2021 flows	100%	100%
	Core contributions for CEPI 2.0 (2022-26)	NA	Coefficient will be needed from 2022 onwards
B. The International AIDS Vaccine Initiative (IAVI)	NA	100%	100%
C. The International Vaccine Institute (IVI)	NA	100%	100%
D. World Health Organisation (WHO)	Strategic Preparedness and Response Plan	NA	88%
	Core voluntary contributions account	100%	100%
	Assessed contributions	76%	76%

A - Coalition for Epidemic Preparedness Innovations (CEPI)

6. The Coalition for Epidemics Preparedness Innovations (CEPI) is an innovative partnership between public, private, philanthropic and civil organisations with a mission to stimulate, finance and coordinate cutting-edge vaccine development against known and unknown diseases with epidemic potential, especially in cases where market incentives alone do not achieve this. It was founded in 2016 by the governments of India and Norway, the Bill & Melinda Gates Foundation, Wellcome Trust and the World Economic Forum.

[2] The written procedure will take place on the WP-STAT Collaboration and Knowledge Management Platform (https://community.oecd.org/community/wpstat-collab) so that members can be informed of each other's comments and respond as they see fit. The collaboration platform will thus provide a forum for discussion and ensure full transparency of the review and decision process.

7. The Secretariat was asked to review three components of CEPI's work, elaborated further in this section: (1) the share of contributions earmarked to CEPI for COVID-19 related activities that is reported as ODA in the 2022 reporting on 2021 flows; (2) the ODA coefficient for core contributions to CEPI in 2022; and (3) a preliminary assessment of core contributions to CEPI's forthcoming business plan from 2022 to 2026 ("CEPI 2.0").

Share of contributions earmarked to CEPI for COVID-19 related activities in 2021

8. CEPI is responsible for R&D and manufacturing in the vaccines pillar (COVAX) of the Access to COVID-19 Tools (ACT) Accelerator. The Secretariat earlier assessed that 53% of earmarked contributions to CEPI for COVID-19 activities could be counted as ODA for 2021 reporting on 2020 flows (see FAQ 8 on the DAC website)[3]. In follow-up discussions of the WP-STAT on the eligibility of R&D for a COVID-19 vaccine, it was agreed that this share should be reviewed end 2021. This section recalls the rationale followed by the Secretariat to calculate the 53% share and the elements highlighted in subsequent discussions to take into account in the review, and makes a recommendation for an updated share for 2022 reporting on 2021 data.

Explanation for the 53% share

9. The Secretariat's ODA eligibility assessment of CEPI's R&D and manufacturing work under COVAX was based on the elements listed below[4]:

- The COVID-19 pandemic is a global problem, and a successful vaccine for this disease will be a global public good (GPG), benefitting both developed and developing countries.
- Through its efforts and investments under COVAX, CEPI is a key enabler to secure that developing countries are not left behind in this time of crisis. Therefore, a share of earmarked contributions to CEPI for this work could be counted as ODA.
- The share of contributions to this GPG that could be counted as ODA was calculated based on the number of doses that will be distributed to LICs and LMICs (950 million through the Gavi COVAX AMC + 100 million through an emergency stockpile) out of the total number of expected doses (i.e. taking into account the 950 million doses to be distributed through the COVAX Facility):

Number of doses to be distributed to LICs and LMICs out of the total number of doses =

(950 + 100) / (950 + 100 + 950) = 53%

Review of the share

10. Discussions highlighted two main elements to take into consideration when reviewing the share at end-2021:

- Justification for counting a share of earmarked contributions to CEPI as ODA

[3] As regards members' reporting on 2020 ODA data, to the knowledge of the Secretariat, all members but one applied a 53% coefficient to their earmarked contributions to CEPI for its COVID-19 related activities, in compliance with the Secretariat's guidance. The member concerned firmly believes that all of its contribution to CEPI in 2020 is fully ODA-eligible. The funds were earmarked before the creation of the COVAX facility and were specifically to be used for the development of safe and effective vaccines that would be available to populations most in need, with a primary focus on developing countries.

[4] See DCD/DAC/STAT(2021)6.

1. A workshop was organised in June 2021 with various experts to have a broader discussion on the eligibility of R&D for a COVID-19 vaccine. While some participants were convinced that CEPI's work on R&D should count fully as ODA due to CEPI's focus on equitable access, others were more sceptical given the GPG nature of the vaccines developed and the fact that, in practice, developing countries were still struggling to obtain doses. The conclusion was that, when assessing the ODA-eligible share for 2021, the Secretariat should look into the details of the partnership agreements signed by CEPI with pharmaceutical companies, and the way they ensure that the investments address challenges specific to developing countries, which is the justification for counting a share of these investments in ODA. Moreover, these details should be verifiable and withstand public scrutiny.

- Updated figures on the allocation of vaccine doses to LICs and MICs

2. The formula used by the Secretariat to determine the 53% share was based on the planned allocation of doses to LICs and LMICs at the time of inception of COVAX, but updated vaccine supply forecasts have since become available and the proportion has changed. The new forecasts anticipate that COVAX would distribute a higher share of doses to LICs and LMICs by end 2021. These updated figures should be used to calculate a revised ODA-eligible share of contributions to CEPI for COVID-19 related activities.

Justification for counting a share of earmarked contributions to CEPI as ODA

11. The summary[5] of equitable access provisions in CEPI's COVID-19 vaccine development agreements states CEPI's objective to enable equitable access to the vaccines in which it invests, especially for people living in low- and middle-income countries. The equitable access objective covers several aspects, of which a particular attention can be drawn to the "target product profiles" (to ensure vaccine candidates are suitable for use in developing countries), an affordable and sustainable price, the right of first refusal (all manufacturing output corresponding to the CEPI-funded part of development are to be offered first to the COVAX Facility) and open access to data and materials.

12. Based on the outcome of the consultation conducted in June, the Secretariat consulted with CEPI on the possibility to obtain the details of its partnership agreements. CEPI was able to provide the Secretariat with some details for two contracts out of twelve active agreements – CureVac and Novavax – noting that the information provided for each of them was publicly available6. CEPI confirmed that the same principle of equitable access underlies the other ten contracts7, even if the language on how this principle is implemented may differ based on the stage of the vaccine R&D process at which CEPI becomes involved through its funding and support.

13. The material provided for CureVac and Novavax (see relevant extracts in Box 1 below) illustrates the practical actions that these pharmaceutical companies will take to implement CEPI's equitable access principles. The Secretariat noted that the information is only partially disclosed to the public (due to confidentiality constraints), and that the same kind of information was provided for other contracts in the publicly available summary of equitable access provisions. In its view, this information is sufficient to demonstrate CEPI's focus on equitable access i.e. ensure "a Project Vaccine is available first to populations at risk when and where they are needed at affordable prices", as the contracts indeed provide for manufacturers to supply a share of the vaccine doses to COVAX. Making investments for the purpose

[5] https://cepi.net/wp-content/uploads/2021/09/Enabling-equitable-access-to-COVID19-vaccines-v6-31-August-2021.pdf

[6] See public filings to the United States Securities and Exchange Commission at https://www.sec.gov/Archives/edgar/data/1000694/000110465920092782/nvax-20200630xex10d1.htm and https://www.sec.gov/Archives/edgar/data/1809122/000110465920086354/tm2016252d12_ex10-9.htm

[7] AstraZeneca, Biological E Ltd, Clover Biopharmaceuticals, Dynavax, Gritstone bio, Inovio, Shanghai Zerun Biotechnology Co Ltd, SK bioscience, Univ. Hong Kong, VBI Vaccines Inc.

of securing enough doses at an affordable price for developing countries in turn justifies counting a share of earmarked contributions to CEPI in ODA.

14. In the view of the Secretariat, the rationale for not counting 100% in ODA still holds though, as the investments contribute to the development or scaled-up manufacturing of COVID-19 vaccines, which are a GPG, benefitting developed and developing countries alike. CEPI's involvement in the development of such a vaccine happened in the initial R&D and manufacturing phase, rather than solely in the stage of volume guarantees, procurement, and delivery for LICs and LMICs, where the specific link to developing countries' unique needs becomes clearer. The Participants at the June workshop in particular underlined that despite the focus on developing countries, funds contributed to a system that largely had benefitted developed countries so far, including the pharmaceutical companies and manufacturing sites in developed countries. The COVAX Facility itself benefitted some developed countries.

Box 1. Extracts from partnership agreements of CEPI with CureVac and Novavax related to the equitable access principle

Supply:

- **CureVac**: the agreement stipulates that CureVac will make a proportion of its total capacity available to the COVAX Facility.
  - "For 2021 10%, through participation in the currently ongoing UNICEF/PAHO tender process".
  - "For 2022 and 2023 (if applicable) 15%, through participation in the applicable COVAX process (i.e., Gavi/UNICEF/PAHO, as applicable) with a priority towards Gavi/LICs, and at tiered prices, in both cases as may be agreed in the tender process".
- **Novavax**: "Awardee, will negotiate, in good faith a separate agreement or purchase order to supply Project Vaccine as may be required by the Global Allocation Body in such agreement or purchase order to the Global Allocation Body during the Pandemic Period and after the Pandemic Period for LMICs"; "supply up to [***] of the quantity of the Project Vaccine produced for purchase by the Global Allocation Body pursuant to Clause 14.3 during the Pandemic Period".[8]

Pricing:

- **CureVac**: the price will be tiered based on country income level and "no higher than the lowest price charged by Partner for the sale of CVnCoV vaccines to a third party of a similar volume and to a country of similar income level".
- **Novavax**: "The Parties acknowledge that the price of the Project Vaccine is critical to achieving Equitable Access during the Pandemic Period. Accordingly, Awardee agrees that its pricing shall be reasonable to achieve Equitable Access for populations in need of a Project Vaccine as well as an appropriate return on investment for vaccine manufacturers that make on-going supply commercially sustainable. The Parties acknowledge that the availability of pandemic insurance as described in Clause 17.7 shall be a relevant cost factor in Equitable Access. For clarity, the purchase of Project Vaccine by the Global Allocation Body or by any other purchasing agent(s) designated by CEPI shall be considered to have satisfied the pricing requirements for Equitable Access."

[8] The COVAX Facility had not yet materialised at the time of signing this agreement, and was referred to as the "Global Allocation Body".

Access to data and open publications:

- **CureVac**: CureVac is required to "publish details of any clinical trial under the Project on a publicly accessible clinical trials register as required under law and, as applicable, prior to the commencement of patient recruitment for such clinical trial, and shall provide to CEPI evidence of such publication within [*****] of the same."
- **Novavax**: There are broad-ranging commitments by Novavax regarding the disclosure of project data, including clinical trial data and the sharing of tangible research materials.

In addition, there are specific provisions to ensure that the equitable access requirements are met. For example, Novavax will have to "provide written […] updates … regarding its COGs for Project Vaccines and discuss relevant product development decisions that could affect COGs"[9] and to "provide reasonable information about its COGs, production, supply, pricing and sales of Project Vaccine sufficient to evaluate whether such activities meet the Equitable Access Policy".

Updated figures on the allocation of vaccine doses to LICs and LMICs

15. The latest supply forecast dates from September 2021. It outlines the number of doses that are expected to be available for the COVAX Facility in 2021 and reflects a reduction of doses that COVAX expected to receive in 2021 based on its July 2021 forecast. The reasons for this reduction are export restrictions, scale-up challenges at manufacturing sites, and the timing and likelihood of filing and regulatory approval for candidates produced by different manufacturers. The September 2021 forecast indicates that of the 1.425 billion doses expected in 2021, 1.255 billion doses would be available for COVAX AMC participants, which are 92 low-to-middle-income countries. On this basis, the updated share is 1255 [doses to COVAX AMC]/1425 [total doses] = 88%.

Secretariat's recommendation

16. On the basis of the above, **the Secretariat's guidance to members is that 88% of the contributions earmarked to CEPI for COVID-19 related activities** be reported as ODA for 2022 reporting on 2021 flows. This represents a significant increase from the share of 53% for 2021 reporting on 2020 flows and aligns with the share of 83% indicated in the Secretariat's update in March 2021[10], calculated based on the latest supply forecast available at that time. This ODA share is an estimate of the extent to which the GPG will benefit developing countries through the allocation of and affordable access to vaccines.

ODA coefficient for core contributions to CEPI for 2022 reporting on 2021 flows

17. WP-STAT first reviewed CEPI in 2018 and agreed that any contributions to it in the first years of its operations could be reported as ODA[11], on the basis that the diseases CEPI prioritised mainly affect developing countries, and that vaccines would be made available and affordable to low and middle-income countries. Core contributions to CEPI in 2020 were fully ODA-eligible as all of the core-funded work was still under its first business plan.

[9] COGs stands for cost of goods.

[10] See DCD/DAC/STAT(2021)6, paragraph 5.

[11] CEPI is an innovative partnership between public, private, philanthropic, and civil organisations. Thus, contributions to it are recorded as bilateral ODA under the channel category, "30000 – Public Private Partnership".

18. Following further discussions with CEPI, the Secretariat confirmed that CEPI's core portfolio in 2021 was still under its first business plan, and that CEPI's COVID-related activities were being financed exclusively with earmarked funds under a separate investment portfolio and governance structure. Thus, core contributions to CEPI for 2022 reporting on 2021 flows **are still fully ODA-eligible**.

ODA coefficient for core contributions to CEPI in the 2022-26 period

19. In March 2021, CEPI released its 2022-26 strategy, CEPI 2.0. In line with its previous strategy, CEPI's mission for CEPI 2.0 is "to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need", which CEPI (in its correspondence with the Secretariat) defines as people living in "low-resource settings" or developing countries. To achieve its mission, CEPI has defined three strategic objectives, with a forecasted financial need of USD 3.5-4 billion over five years: (1) prepare for known epidemic and pandemic threats (USD ~1.9 billion, or 55% of the total); (2) transform the response to the next novel threat (USD ~1.3 billion, or 40% of the total); and (3) connect to enhance and expand global co-operation (USD ~0.2 billion, or 5% of the total). The United Kingdom will host the first replenishment event for CEPI 2.0 in March 2022.

20. CEPI's governance structure is expected to evolve with the implementation of its new strategy. For example, CEPI will aim to include more diverse voices and representation in its Scientific Advisory Committee of experts. The Joint Coordination Group, which consists of independent organisations that help steer the development of CEPI's vaccine portfolio with external stakeholders and CEPI's Secretariat, is also expected to evolve to reflect lessons learned from the response to the COVID-19 pandemic, although the details of these shifts have not yet been specified.

21. Activities related to the COVID-19 response and recovery will be a part of the core work of CEPI 2.0. Such activities feature under CEPI's first strategic goal, "prepare for known epidemic and pandemic threats", for which CEPI will: (1) help end the acute phase of the COVID-19 pandemic; (2) systematically eliminate the risk of further coronavirus pandemics; and (3) accelerate the development of vaccines and other biologics against other known high-risk pathogens, such as Lassa, MERS, Nipah, Rift Valley Fever and Chikungunya, especially in low and middle-income countries. In the short-term, activities to accomplish this strategic goal include the development of biologics and prophylactic vaccine-like technologies to assist in rapid response, drive down costs, and make technologies available to all. In the longer-term, CEPI will invest in innovative diagnostic and therapeutic technologies to maximize synergies with the process of developing vaccines.

22. The second strategic goal is to "transform the response to the next novel threat", for which CEPI will: (1) capitalise on existing vaccine development innovations to prepare and reduce vulnerability to unknown but emerging viral threats; (2) invest in and scale research capabilities for vaccine development, particularly in networks of labs with the latest technologies; and (3) build on innovations to make vaccine manufacturing cheaper, faster, and closer to an outbreak, especially in low and middle-income countries' settings.

23. For its third strategic goal to "connect to enhance and expand global co-operation", CEPI aims to build a post-pandemic coalition to develop vaccines and build commitments to preparedness and access. Further examples of activities centred on partnerships include collaboration with other vaccine developers and manufacturers to produce an on-demand vaccine manufacturing network that can help reduce bottlenecks and enable a faster systemic response to outbreaks.

24. As part of its mission to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats to all people in need, CEPI 2.0 will focus on developing partnerships in low and middle-income countries along the following key principles: creating win-win partnerships; engaging with low and middle-income countries through investments, policy, and

advocacy; and ensuring ownership of impact through mutual accountability. Specific areas for further collaboration with low and middle-income countries involve increasing these countries' representation in CEPI's research, projects, and Secretariat, as well as basing more of CEPI's offices in these countries to facilitate knowledge sharing, capacity building, and, where appropriate, transfer of technology and resources for R&D and manufacturing.

Secretariat's recommendation

25. The CEPI 2.0 business strategy features a base case financial envelope that provides more information on expected investments in line with CEPI's strategic priorities[12]. Of the USD 3.5 billion requested, USD 500 million is intended to support vaccine development for diseases that affect developing countries disproportionately, in line with CEPI's first strategy, such as Lassa, Nipah, Chikungunya, MERS, and Rift Valley fever. A further USD 350 million is intended for CEPI's Wave 2 COVID-19 funding, specifically for the development of vaccines with improved characteristics (e.g., single dose, long acting, thermostable, and benefitting vulnerable populations) that would be uniquely suitable to the needs of developing countries.

Table 2. CEPI 2.0 base case financial envelope, million USD

Activity	Amount
Baseline	240
COVID-19	350
Priority pathogen	470
Disease X (2 additional priority pathogen targets; 2 existing viable targets; 1 prototype pathogen approach)	1 720
Outbreak	25
Enabling science	300
Contingency	100
Operational expenditures	260
TOTAL	**3 500**

26. On the other hand, USD 1.7 billion is anticipated for investments in platforms for "Disease X", a pathogen that is currently unknown to cause human disease and may lead to the next epidemic. CEPI's approach to Disease X is to develop vaccine platform technologies that would enable rapid manufacturing of vaccines against different types of diseases. The baseline case highlights three activities under Disease X: (1) the development of a pan coronavirus vaccine and an additional priority pathogen vaccine; (2) the production of vaccines tailored to low and middle-income countries ' needs for diseases such as rabies, fellow fever, or the Japanese encephalitis virus; and (3) the creation of family vaccine libraries for priority pathogens. While the eligibility of the second activity, on the development of vaccines tailored to low and

[12] See Annex 2 of https://cepi.net/wp-content/uploads/2021/03/CEPI-2.0_Strategy-2022-26-Mar21.pdf

middle-income countries ' needs, is relatively more apparent, in the case of the development of a pan coronavirus vaccine for example, it is plausible that CEPI's investment in R&D and at-risk manufacturing would lead to a vaccine that is a GPG as was the case in the early stages of the COVID-19 pandemic, with benefits accruing to the entire world rather than to developing countries uniquely.

27. The examples discussed thus far account for almost three-quarters of CEPI's base case financial envelope (500+350+1700 = 2550). Even though there are examples of activities that address specific and unique challenges faced by developing countries, other activities (particularly in the development of vaccine platforms for Disease X) suggest a scope that may fall outside of the criteria for eligibility as the benefits of these activities accrue to developed and developing countries alike.

28. In its previous assessment of CEPI's eligibility in 2018, the Secretariat noted that CEPI's mandate is global even if low and middle-income countries were CEPI's target group at that time as it prioritised diseases mainly affecting developing countries, and that a coefficient may be warranted in the future. While it is acknowledged that CEPI 2.0's unique value-add is to "complement the market-driven availability of appropriate countermeasures in high-income countries" (ibid.) to enable equitable access to vaccines for all populations, CEPI 2.0 extends the scope of this value-add to diseases beyond those covered in its previous business strategy, such as Lassa, Nipah, Chikungunya, MERS, and Rift Valley fever, which mainly affect developing countries. With investments in vaccine development and preparedness for COVID-19, which is currently affecting developed and developing countries alike, and "Disease X", which may arise from anywhere at any time and thus has the potential to affect the entire world, the focus is no longer exclusively on vaccines for diseases mainly affecting developing countries. This is an important difference between CEPI's first business strategy and CEPI 2.0 that could affect the ODA eligibility of the latter, even when both strategies are addressing market failures that impede the development of vaccines to certain populations.

29. Granular information on the budget and expenditure of CEPI 2.0 is not yet available as it has not yet been fully funded, and it is unclear which aspects of the CEPI 2.0 business strategy will be taken forward after the replenishment event. However, much of CEPI's original core mandate is reflected in CEPI 2.0, and certain activities under each of CEPI's strategic goals are clearly focused on the specific needs of developing countries. Whether that focus extends to the entirety of CEPI 2.0 is as of yet unclear, especially given the analysis presented above. Thus, **the Secretariat anticipates that CEPI will not be fully ODA-eligible in 2022 and beyond, and that a coefficient would be needed for reporting on ODA from 2022 onwards.** The precise coefficient cannot yet be determined in the absence of granular information on the financing, mandate, and activities of CEPI 2.0. The Secretariat will continue discussions with CEPI to obtain as much information as needed to define a precise coefficient in advance of 2023 reporting on 2022 flows.

B - The International AIDS Vaccine Initiative (IAVI)

30. The International AIDS Vaccine Initiative (IAVI) is a non-profit scientific research organisation, founded in 1996, with a mission to develop vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19), and neglected diseases that affect developing countries disproportionately. IAVI's mandate is four-fold: (1) accelerating vaccine research, with a pipeline of novel vaccine approaches and the development of new tools and technologies; (2) strengthening scientific leadership and collaboration for vaccine R&D and future access; (3) working with partners to build momentum towards HIV R&D; and (4) providing benefits for communities most affected by HIV/AIDS. IAVI was previously assessed by the Secretariat in 2003, when its core programme was exclusively on developing vaccine candidates for HIV/AIDS[13].

[13] https://www.iavi.org/phocadownload/IAVI%202003%20Annual%20Report.pdf

31. The Board of Directors of IAVI, consisting of representatives from partner institutions, provide strategic direction to the organisation, while its Secretariat oversees day-to-day operations. With headquarters in New York City and labs and offices in seven countries, including developing countries such as India, Kenya, South Africa, and Uganda, the IAVI collaborates with a diverse network of stakeholders to support the discovery, development, and distribution of vaccines for populations in need. In 2020, the IAVI received USD 103.3 million in funding, with 65% of this revenue from governments, 28% from foundations and private individuals, and 7% from investment income and other sources.

32. At the onset of the COVID-19 pandemic, the IAVI established a COVID-19 vaccine programme to accelerate the process of discovering and developing a candidate. For example, it partnered with Merck for a vaccine candidate that underwent a phase 1 clinical study before being discontinued in early 2021. The Defense Threat Reduction Agency of the United States Department of Defense and the Government of Japan, in partnership with the World Bank, have earmarked funding thus far to support the IAVI's COVID-19 vaccine programme.

Secretariat's recommendation

33. In its correspondence with IAVI, the Secretariat has learned that IAVI's funding structure has changed since it was previously assessed in 2003. At that time, its only programme was to develop vaccine candidates for HIV/AIDS. Members' funding to it was earmarked for this programme, which served as core-like funding to IAVI insofar as it allowed the flexible use of funds to support different initiatives in the core programme. Since 2003, IAVI has expanded its work to other disease programmes, such as for tuberculosis, snakebite, and emerging infectious diseases (e.g. COVID-19). With the exception of funding for operational costs amounting to less than USD 500,000, the majority of members' contributions to IAVI are donor-restricted or designated for specific disease programmes. The Secretariat has confirmed that all of members' contributions to IAVI are reported as earmarked.

34. IAVI's flagship programme, and the top recipient of donor funding, is still on developing vaccine candidates HIV/AIDS. Additionally, since its inception, its work has focused on the research and development of vaccines that are uniquely suited to the needs of developing countries. Therefore, since its core mandate remains unchanged, and funding for its disease programmes (including COVID-19) are restricted/earmarked, the Secretariat recommends that the International Vaccine Institute **remains fully ODA-eligible.** A further review of the eligibility of members' earmarked contributions to IAVI's COVID-19 activities may be warranted in the future.

C - International Vaccine Institute (IVI)

35. The International Vaccine Institute (IVI), a non-profit scientific research organisation founded in 1997 by the United Nations Development Programme (UNDP), has a mission of developing and delivering safe, affordable, and effective vaccines for global public health, with a focus on developing countries and infectious diseases of major global health concern. It has a three-fold approach: (1) R&D for affordable and effective vaccines; (2) partnerships spanning product development, research, and networks; and (3) capacity building in the form of training, technical assistance, and technology transfers. Thus, its work spans each step of the vaccine value chain, from discovery to development, delivery, and capacity building.

36. The IVI focuses on developing vaccines that are needed in resource-limited settings but often overlooked by the market, with initial priorities being vaccines against cholera, typhoid, and dengue. It has since expanded to a range of other diseases that are predominantly found in and affect developing countries disproportionately, such as MERS, schistosomiasis, Chikungunya, and invasive non-typhoidal salmonella, among others. In 2020, the IVI also began partnering with vaccine developers to accelerate the development of COVID-19 vaccines, which included conducting pre-clinical studies as well as early- and late-stage clinical trials for vaccines and therapeutics; establishing vaccine evaluation systems; developing vaccine adjuvants; and undertaking epidemiological studies and other capacity building

activities. All of these activities were supported by earmarked funding from institutions such as CEPI, the Swedish International Development Co-operation Agency, the Bill & Melinda Gates Foundation, and Sanofi Pasteur.

37. IVI's total expenses in 2020 were USD 65.2 million. Projects related to specific diseases are funded by voluntary, earmarked contributions from donor countries and organisations, such as the Bill & Melinda Gates Foundation, CEPI, Wellcome Trust, and others. Such funding is complemented by core contributions from the IVI's four main donor countries – Finland, India, Korea, and Sweden – for management and operational expenses. Such expenses consist of non-project staff personnel costs, administrative costs, and costs associated with the maintenance of the IVI's headquarters and facilities, which include utility costs for the maintenance of its labs in Seoul.

38. Based in Seoul, South Korea, with offices in 24 countries across Asia, Africa, and Latin America, the IVI membership is composed of 36 countries and the WHO. It is governed by a Board of Trustees, composed of representatives from signatory countries, and advised by a Scientific Advisory Group. The Secretariat, led by a Director General and Executive Leadership team, implements day-to-day activities according to the IVI's mandate.

Secretariat's recommendation

39. Following a review of the IVI's financial statements in recent years (2018-20), and correspondence with the IVI Global Affairs and Communications department, the Secretariat has confirmed that the project-related costs of the IVI's COVID-19 activities were funded exclusively using earmarked contributions from various organisations. These activities thus would not affect the IVI's ODA coefficient for core contributions.

40. One potential area of concern initially for the Secretariat was the use of the IVI's labs, the maintenance of which is supported by core contributions, for clinical trials or vaccine development. At first glance, the use of such labs would mean that resources supported by core funding were being used on specific projects or programmes, such as those related to COVID-19. However, the Secretariat confirmed with the IVI that all project-specific costs pertaining to personnel, lab equipment, and other resources were supported through earmarked funding; core funding only supported utilities and general facilities maintenance of the labs. Thus, there is no risk that core resources were used to finance project-specific costs related to COVID-19.

41. Additionally, the focus of the rest of the IVI's work is on diseases that have a high burden on global health and particularly affect countries in Asia and Africa[14]. Thus, **the Secretariat recommends that the International Vaccine Institute remains fully ODA-eligible**.

D - World Health Organisation (WHO)

42. The WHO, founded in 1948, is a United Nations (UN) agency that leads global efforts to expand universal health coverage and directs and coordinates the world's response to global health emergencies. Its core objectives, under its Thirteenth General Programme of Work (GPW) 2019-2023, are "to ensure that a billion more people have universal health coverage, to protect a billion more people from health emergencies, and provide a further billion people with better health and well-being." It is headquartered in Geneva and has 6 regional offices, 150 country offices, and other outposted offices that operate across borders. It is governed by the World Health Assembly, comprised of delegations from all member states and constituting the WHO's supreme decision-making body, and the Executive Board, which implements the decisions and policies of the Health Assembly.

[14] Please see a list of disease areas here: https://www.ivi.int/what-we-do/disease-areas/other/.

43. The WHO, currently in its 2020-21 programme budget amounting to USD 9.2 billion, is funded through member states' assessed contributions and voluntary contributions from member states and other partners. Assessed contributions, which are fully flexible, make up less than 10% of the WHO's approved 2020-21 budget. Voluntary contributions can be subdivided into three categories: the core voluntary contributions account (CVCA), which is fully unearmarked and represents 3% of voluntary contributions; thematic and strategic engagement funds, which are partly flexible and represent 8% of voluntary contributions; and specified voluntary contributions, which are earmarked to specific programmatic areas or geographical locations and represent 88% of voluntary contributions.

44. Given their distinct funding structures and governance, the WHO's assessed contributions (76%) and CVCA (100%) were assigned separate coefficients on the List. They were decided for the first time in 2003 and updated in 2009. Since the coefficients had not been updated since 2009, in addition to assessing whether the WHO's COVID-19 related activities influenced the ODA eligibility of its activities and thereby its coefficients, the Secretariat also considered whether the funding structure of each of these accounts had changed to a significant enough extent to warrant revised coefficients.

45. This section reviews the coefficient for WHO's assessed contributions and CVCA, as well as the WHO's SPRP for COVID-19 in 2021.

ODA coefficient for the WHO's assessed contributions and core voluntary contributions account

46. Following an analysis of the WHO's 2020-21 activity-level budget and expenditures, which included correspondence with the WHO's Department for Planning, Resource Coordination and Performance Monitoring, the Secretariat has confirmed all of the WHO's COVID-19 related activities were funded through specified or thematic voluntary contributions. Additionally, the Secretariat was informed that the WHO does not plan to use core funding to finance COVID-19 related activities in the future, as any such activities would be difficult to plan for or predict and would thus fall outside of the core mandate of the organisation. Correspondence with the WHO also confirmed that the size and composition of the WHO's core funding portfolio has been relatively consistent over time, particularly for its assessed contributions account (the only one of the two to have a coefficient rather than be fully ODA-eligible), which may mitigate the need for updated coefficients.

47. Nevertheless, the Secretariat performed additional due diligence to assess whether the Annex 2 coefficient for both of the WHO's accounts needed to be re-evaluated, given that they were updated previously in 2009. There were three steps in the re-assessment of the overall coefficient for each account. The first step was a calculation of the share of the WHO's support to ODA-eligible country offices, based on which countries and territories were on the DAC List of ODA recipients. The second step was a calculation of the coefficient for the WHO's six regional offices, based on the share of spending in ODA-eligible countries relative to the total spending in each WHO region. The third and last step was a calculation of the coefficient for the WHO's funding to Headquarters (HQ).

48. The WHO's HQ requires a coefficient because it has a partly normative function and provides support to all member countries, some of which are not ODA-eligible. In 2009, the Secretariat proposed a coefficient for HQ by assessing the indicators of each Organisation-wide Expected Result (OWER) to determine whether the OWER had a normative component or not, and if so, whether the normative component was primarily development-oriented. Given that the result structure and hierarchy of the WHO has changed significantly since 2009, with the current GPW organizing the WHO's work according to seven Strategic Objectives (SO) with Outcomes corresponding to each SO, the Secretariat corresponded with the WHO to identify whether the methodology for determining the HQ coefficient needed to be revised.

49. The WHO advised that its expenditures in HQ could be further disaggregated by 'Strategic Shifts', which constitute spending across the following categories for each outcome: (1) leadership in public health;

(2) country support; (3) research; and (4) global public health goods. The Secretariat, in collaboration with the WHO, arrived at a coefficient for HQ by assessing the eligibility of each outcome. If eligible, all funding (using the latest information available from the 2020 Mid-Term Review of WHO) towards that outcome could be counted as ODA; if not, only the 'country support' strategic shift would be counted as it denoted support mainly to ODA-eligible countries. This approach allowed for a more nuanced and precise calculation of the HQ coefficient for each account.

50. Based on the approach proposed above, the Secretariat arrived at coefficients that were very close to the ones calculated in 2009, with the coefficient for the "WHO – CVCA" account remaining at 100%, and the coefficient for the "WHO – Assessed Contributions" account updating to 75% from 76%. Since these numbers are very close, **the Secretariat recommends to keep the current ODA coefficients on the List** so as to minimize disruption in ODA reporting from donors.

ODA coefficient for the WHO's Strategic Preparedness and Response Plan (SPRP) for COVID-19 in 2021

51. In addition to the above assessments, the WP-STAT requested an assessment of the ODA eligibility of the WHO's SPRP for COVID-19. The SPRP (presently in its 2021 edition) is intended to guide coordinated action at national, regional, and global levels to overcome ongoing challenges in the response to COVID-19, address inequalities, and plot a course out of the pandemic. The 2021 SPRP has six strategic objectives: (1) suppress transmission; (2) reduce exposure; (3) counter misinformation; (4) protect the vulnerable; (5) reduce mortality and morbidity from all causes; and (6) accelerate equitable access to new COVID-19 tools, including vaccines, diagnostics, and therapeutics. Funding to the SPRP is fully flexible, which allows the WHO to deploy resources to where they are most needed.

52. For the purposes of national-level planning and coordination, the 2021 SPRP retains the same structure and rationale as the 2020 SPRP. The SPRP outlines eleven operational and technical pillars to inform COVID-19 preparedness and response plans at the national level in over 170 countries, with issues covered in these plans spanning from monitoring and evaluation to risk mitigation and the provision of diagnostics, therapeutics, and vaccines. The SPRP also delineates mechanisms for global and regional coordination across the UN system, led by the WHO.

53. In the Secretariat's review of the 2020 SPRP, there was not sufficient information available on country-level allocations to allow for an accurate determination of its ODA eligibility. Since then, the WHO has published a public dashboard[15] with information on contributions to WHO's SPRP for COVID-19 and detailed country-level SPRP funding. As of 18 October 2021, USD 1.07 billion has been committed to the SPRP, with USD 485 million disbursed.

54. The Secretariat arrived at an overall coefficient for the WHO's 2021 SPRP using the data found in the public dashboard and a methodology similar to the one articulated in paragraphs 46-50 above on the WHO's assessed contributions and CVCA. All activities across the pillars of the 2021 SPRP are ODA-eligible as long as they are carried out in a country or territory that is part of the DAC List of Recipients[16]. For the HQ coefficient, the Secretariat and the WHO assessed the eligibility of HQ-level functions based on whether they contributed to technical, leadership, or administrative activities. The coefficients for

[15] The dashboard may be found here.

[16] The 11 pillars consist of: coordination, planning, financing, and monitoring; risk communication, community engagement, and infodemic management; surveillance, outbreak investigation and calibration of public health and social measures; points of entry, international travel and transport, and mass gatherings; laboratories and diagnostics; infection prevention and control and protecting the health workforce; case management, clinical operations, and therapeutics; operational support and logistics; strengthening essential health services and systems; vaccination; research, innovation, and evidence.

regional offices were calculated based on the share of spending on ODA-eligible countries out of the total number of countries in the WHO region.

55. Based on the available data, the methodology proposed above, and consultations with the WHO, **the Secretariat recommends that 88% of contributions to the WHO's SPRP** can be reportable as ODA for 2022 reporting on 2021 flows.

E. Summary of recommendations

56. Table 2 below summarises the Secretariat's recommendations.

Table 3. Secretariat's recommendations

Name of organisation	Specific sub-entity (if applicable)	Current ODA coefficient	Proposal for updated ODA coefficient
A. Coalition for Epidemic Preparedness Innovations (CEPI)	Core contributions for 2022 reporting on 2021 flows	100%	100%
	Core contributions for CEPI 2.0 (2022-26)	NA	Coefficient will be needed from 2022 onwards
B. The International AIDS Vaccine Initiative (IAVI)	NA	100%	100%
C. The International Vaccine Institute (IVI)	NA	100%	100%
D. World Health Organisation (WHO)	Strategic Preparedness and Response Plan	NA	88%
	Core voluntary contributions account	100%	100%
	Assessed contributions	76%	76%