#### ORIGINAL ARTICLE

## INTERNATIONAL LAW AND PRACTICE

# The global distribution of COVID-19 vaccines by the public-private partnership COVAX from a public-law perspective

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#### **Abstract**

This article examines COVAX, a public private partnership, from a public law perspective. It asks whether COVAX is a legitimate and appropriate instrument with regard to the goal of distributing COVID-19 vaccines in a globally equitable manner and enabling equal access to vaccination worldwide. By developing public-legal legitimacy standards for this purpose, the article critically distances itself from the outset from considering the use of private actors and forms of action in public functions ('privatization') essentially as a release of market economy rationality, which enables efficiency and effectiveness gains and relieves the public sector. With the public law perspective, the article questions precisely whether private-law, market-based action is appropriate with respect to the global distribution of vaccines in the pandemic.

Keywords: global public health; international co-operation; international public authority; public private partnership; vaccine distribution

### 1. Introduction

By mid-2020, the first vaccines against COVID-19 were nearing approval for release to the market. This raised pressing questions about how vaccines would be procured and distributed. First: Who negotiates with manufacturers on the price, quantity, and delivery deadlines of vaccine doses? Secondly: How are vaccine doses distributed among potential purchasers?

As one possible answer to these questions, collective acquisition and proportional distribution of COVID-19 vaccines among states has emerged: within the European Union, an agreement among member states granted the European Commission the power to activate a centralized procurement mechanism which would negotiate contractual conditions for acquisition of the vaccine on behalf of the participating member states.<sup>1</sup> It was agreed that available vaccine doses would be

<sup>\*</sup>This article is a significantly expanded and updated version of the paper that I presented at my Habilitation colloquium at Giessen University in January 2022 (see (2022) 60 Archiv des Völkerrechts 23; DOI 10.1628/avr-2022-0003). I received many valuable comments by colleagues attending the colloquium and would also like to thank Jürgen Bast, Sigrid Boysen, Tarik Tabbara, and Ingo Venzke, as well as the anonymous reviewers, for their input. The earlier paper was expertly translated from German by Andrew Hammel.

<sup>&</sup>lt;sup>1</sup>European Commission Decision of 18 June 2020 Approving the Agreement with Member States on Procuring Covid-19 Vaccines on behalf of the Member States and Related Procedures, C(2020) 4192 final; the Agreement itself appears in the Annex to the Decision. On the basis of these preliminary contracts, member states could then purchase vaccine doses at the negotiated terms.

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allocated among member states based on population.<sup>2</sup> Centralized negotiation appeared to make economic sense and the distribution scheme seemed appropriate, even fair. In the EU, actors responded to the crisis and distributed vaccines together, collectively. The key benchmark was that populations should have equal access to the vaccine across national borders. The response can be seen as an expression of solidarity within a federal system, where members express mutual recognition between members and (co-)constitute a political community.<sup>3</sup>

This, however, is in stark contrast with what has been happening on the global scene. No publicly administered mechanism to provide equitable access to COVID-19 vaccination worldwide based on centralized procurement does (yet) exist. Instead, what emerged, is an unregulated and unequal competition among countries for scarce vaccine doses. Accusations of 'vaccine nationalism' – in which countries accuse one another of vaccinating their own populations first without regard to international distribution of vaccines – continue to be hotly debated.<sup>4</sup>

This is the context in which the COVAX mechanism was established in 2020 as a tool for the global distribution of COVID-19 vaccines. COVAX is intended to foster global access to COVID-19 vaccination despite significant economic disparities among the world's nations: under COVAX, vaccines are supposed to be procured collectively for all participating countries and, in the process, doses will be (co-)financed for developing countries as a form of development aid. For this purpose, COVAX, managed by the Swiss private foundation Gavi, brings together private and public actors: philanthropic foundations, states, international organizations, representatives of the pharmaceutical industry and civil society, as well as experts in the field of vaccine development, and private donors. The scheme operates through private law contracts both with manufacturers and participating states. COVAX is one of the public-private partnerships which are commonly seen in health policy outside of the purely governmental sphere.<sup>5</sup> It is one dimension of the Access to COVID-19 Tools (ACT) Accelerator, an overarching public-private-initiative aimed at speeding up the development, production, and equitable access not only regarding vaccines against COVID-19 but also regarding tests and treatments.<sup>6</sup> The initiative is based on donations by states and private actors – which, however, have fallen far short of the funding targets and commitments.<sup>7</sup>

COVAX's activities have been the subject of only sporadic legal commentary. This article will examine COVAX from a public-law perspective. This means that the instrumental role that COVAX evidently plays for realizing a public good, namely, the human right to health and public health in the COVID-19 pandemic, is taken seriously. What the public law perspective enables us

<sup>&</sup>lt;sup>24</sup>Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.', Ann. to European Commission Decision C(2020) 4192 final.

<sup>&</sup>lt;sup>3</sup>This discussion follows A. Farahat, *Transnationale Souveränitätskonflikte* (2021), 46, who understands solidarity in terms of a social norm that rationalizes distributive practices and decisions among members of a political community and establishes long-term relations of recognition which are independent of specific political and economic resources.

<sup>&</sup>lt;sup>4</sup>For a discussion on measures criticized as vaccine nationalism see A. von Bogdandy and P. Villarreal, 'The Role of International Law in Vaccinating Against COVID-19: Appraising the COVAX Initiative', MPIL Research Paper Series No. 2020-46; L. Gruszczynski and C. Wu, 'Between the High Ideals and Reality: Managing the Covid-19 Vaccine Nationalism', (2021) 12 European Journal of Risk Regulation 711.

<sup>&</sup>lt;sup>5</sup>See M. Kaltenborn and N. A. Reit-Born, 'Public Private Partnerships als Akteure des globalen Gesundheitsrechts', (2019) 57 Archiv des Völkerrechts 53, at 60, with citations to the common criteria for PPPs: 'Involved partners can thus be, on the public side, states, governmental institutions and/or international organizations, and on the private side, companies, non-governmental organizations, private scientific institutions or private foundations; the only important thing is that both the public and the private side are represented in the partnership arrangement.'

<sup>&</sup>lt;sup>6</sup>See Word Health Organization, 'About ACT-Accelerator', available at www.act-a.org/about.

<sup>&</sup>lt;sup>7</sup>World Health Organization, 'What is the ACT-Accelerator', available at www.who.int/initiatives/act-accelerator/about. The initiative has not been able to reach its funding goals; for the first year (2020–2021), US\$17.8 billion were raised which left a funding gap of US\$15.4 billion, according to data collected by WHO, available at www.who.int/publications/m/item/access-to-covid-19-tools-tracker.

<sup>&</sup>lt;sup>8</sup>See Von Bogdandy and Villarreal, *supra* note 4; from a political science and public health perspective see S. Moon et al., 'Governing the Access to COVID-19 Tools Accelerator: Towards Greater Participation, Transparency, and Accountability', (2022) 399 *The Lancet* 487.

to do is, firstly, measure the extent and categorize the specific form of relying on private actors to deliver (core aspects of) this public good against established criteria and concepts from administrative and public international law. It also highlights that the operation of COVAX is an institutional choice of the international community, and contrasts it with possible alternatives, namely, using institutions and regimes of public international law to address the issue of inequitable access to vaccines. This, then, allows for a more exact normative analysis and critique of the scheme. This is the core of the public law perspective: it asks whether COVAX is a legitimate and appropriate tool to achieve the goal of equitably distributing COVID-19 vaccine globally and providing equal access to vaccination worldwide. Is it convincing to entrust this function to a private law scheme? It is sometimes assumed that using private actors and types of action to accomplish public functions (i.e., 'privatization') unleashes market rationality, securing gains in efficiency and effectiveness, and relieving burdens on the public sector. From the outset, this article will take a critical perspective towards this assumption. There are reasons to be sceptical of COVAX's effectiveness. More than a year after the start of vaccinations against COVID-19 and after the introduction of COVAX, considerable disparity persists in the global distribution of the vaccine and in vaccination rates: on the African continent, an average of 28 percent of the population had been vaccinated against the Coronavirus at least once as of September 2022, but vaccination rates vary widely among African countries. In contrast, about 75 percent of people in Europe had received at least one dose of vaccine at that time. 10 The allocation of vaccine doses is certainly not the only problem of delivering equitable access to the vaccination worldwide. Lacking infrastructures, gaps in technical support, and overburdened health systems may in some contexts be impeding factors as well. But fair distribution of vaccine doses is the first condition for equal access, and COVAX has had to significantly postpone the fulfilment of its delivery goals. 11 At the same time, the workings of COVAX and Gavi, the private foundation administrating it, are not subject to public scrutiny and political accountability in the ways that governmental actors are. All this has given rise to increasing criticism of COVAX.12

Against this backdrop, the public-law perspective of this article will enable it to focus precisely on the question of whether a private-law, market-based approach is suitable for ensuring fair global distribution of vaccines in the pandemic, measuring COVAX against standards of legitimacy under public law. This critical perspective will be developed as follows: first, the challenges and problems of global vaccine distribution in the coronavirus pandemic will be examined (Section 2). Then the structure and functioning of COVAX as a mechanism of global distribution of COVID-19 vaccines will be explained (Section 3). Building on the above, this article will then analyse COVAX through combining a human rights perspective with doctrinal and conceptual insights from (national) administrative law and international public law scholarship (Section 4). It concludes with a normative assessment of the legitimacy and appropriateness of COVAX as a tool for global distribution of coronavirus vaccines (Section 5).

<sup>&</sup>lt;sup>9</sup>These figures are drawn from J. Holder, 'Tracking Coronavirus Vaccinations Around the World', *New York Times*, which is updated continually, available at www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html?name = styln-coronavirus&region = TOP\_BANNER&block = storyline\_menu\_recirc&action = click&pgtype = Interactive&variant = 1\_Show& is\_new = false.

<sup>&</sup>lt;sup>10</sup>EU Figures, available at vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab.

<sup>&</sup>lt;sup>11</sup>See Gavi, 'Joint COVAX Statement on Supply Forecast for 2021 and Early 2022', 8 September 2021, available at www.gavi. org/news/media-room/joint-covax-statement-supply-forecast-2021-and-early-2022; this has strongly been criticized by the WHO Director-General, 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19-8 September 2021', 8 September 2021, available at www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—8-september-2021.

<sup>&</sup>lt;sup>12</sup>See Moon et al., *supra* note 8; E. Banco, A. Furlong and L. Pfahler, 'How Bill Gates and Partners Used Their Clout to Control the Global Covid Response — With Little Oversight', *Politico*, 14 September 2022, available at www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969#.

The central argument is that COVAX, even if acting in private law forms, exercises international public authority which is insufficiently legitimized by the private-law modes of legitimation: global distribution of coronavirus vaccines is a human rights-based public responsibility, and access to vaccines is a public good. Many developing countries, in particular, depend on COVAX for access to vaccines. COVAX, which is based on private-law principles of freedom of contract and voluntary economic redistribution through donations, is not a sufficient and appropriate instrument for global distribution in this context.

# 2. Problems of global access to COVID-19 vaccines

## 2.1 Private determination of access to the scarce resource of vaccines

During the COVID-19 pandemic, states have found themselves competing for vaccines, as production has failed to meet global needs. In the absence of laws to the contrary, vaccines against COVID-19 are generally regarded as commercial goods, and distribution is left to the market: the vaccines are developed and produced by private pharmaceutical companies and consortia (albeit often with public funding) and – after approval by the relevant authorities – sold according to supply and demand, based on the freedom of contract that the pharmaceutical companies enjoy.

The pharmaceutical industry, which mostly conducts the pharmaceutical research and development, holds the patents on the COVID-19 vaccines and sells doses on terms that are separately negotiated with the ordering countries or organizations, such as the EU. As a result, both the states and the organizations which order vaccines negotiate individually and are thus (at least initially) unaware of the contractual terms and conditions in other sales contracts, including matters such as pricing, delivery deadlines, specified production locations, contractual penalties, adjustment clauses, and other aspects of the distribution of risks. The companies insist on confidentiality as to these matters.<sup>13</sup> The fact that contracts with various purchasers are not disclosed makes it easier for vaccine companies to negotiate terms which serve their own interests. The companies are also under no obligation to distribute vaccines according to any standards of equity or fairness.<sup>14</sup> Therefore, even in a pandemic, the pharmaceutical industry can seek to maximize profits, for example by promising priority delivery in exchange for higher prices, or by shifting research and production risks to purchasers.<sup>15</sup>

## 2.2 Unequal global competition for vaccines

Vaccine shortages and the resulting competition for these scarce resources have given rise to the phenomenon of 'vaccine nationalism': states, operating as 'lone wolves', strive to meet their needs by securing as many vaccines as possible without regard for equal participation of all states or for differences in their population sizes.<sup>16</sup> Economically powerful countries can use advanced

<sup>&</sup>lt;sup>13</sup>See the dispute over the accidental posting of the EU's contracts with AstraZeneca and vaccine prices on Twitter, S. Bolseley, 'Belgian Minister Tweets EU's Covid Vaccine Price List to Anger of Manufacturers', *Guardian*, 18 December 2020, available at www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list.

<sup>&</sup>lt;sup>14</sup>See, e.g., the manufacturer Moderna's policies, which sometimes require poorer countries to pay more for the vaccine and wait longer for supplies than rich industrialized nations: R. Robins, 'Moderna, Racing for Profits, Keeps Covid Vaccine Out of Reach of Poor', *New York Times*, 9 November 2021, available at <a href="https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html">www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html</a>.

<sup>&</sup>lt;sup>15</sup>Some vaccine manufacturers, such as AstraZeneca, claim to sell vaccine doses at cost. However, AstraZeneca announced in November 2021 that it would henceforth sell to industrialized nations with a profit margin: T. Espiner, 'AstraZeneca to Take Profits from Covid Vaccine', *BBC News*, 12 November 2021, available at <a href="https://www.bbc.com/news/business-59256223">www.bbc.com/news/business-59256223</a>.

<sup>&</sup>lt;sup>16</sup>See the descriptions in D. P. Fidler, 'Vaccine Nationalism's Politics', (2020) 369 Science (American Association for the Advancement of Science) 749, at 749: 'Countries with the resources to obtain vaccines have not subordinated their needs and capacities to the objective of global, equitable access.', citing Von Bogdandy and Villarreal, supra note 4, at 5: 'Every state has major incentives to use its financial and regulatory capacities to secure as many doses as fast as possible – at the expense of countries that lack comparable means.'

purchase agreements (APAs) to secure priority supply as against other purchasers by offering more attractive purchasing conditions, in particular higher per-dose payments, and by pledging to assume various risks and to support vaccine development.<sup>17</sup> APAs with guaranteed purchases and advance payments safeguard the necessary investments of the pharmaceutical industry (at least in part) and are thus an essential economic inventive for vaccine development and production.

In Europe, the dispute between the EU and AstraZeneca, which even resulted in litigation, can be seen as an outgrowth of market-based competition for the vaccine. The conflict arose when AstraZeneca, starting in January 2021, significantly reduced its deliveries to the EU compared to the contractually agreed volumes, while the UK apparently continued to receive its promised vaccine doses. The issue was that the vaccine produced in EU member states had been exported to the United Kingdom, while the EU, as purchaser, had been given lower priority. The Union responded by basically establishing a licensing requirement for vaccine exports. Other countries have also imposed export bans. Restricting vaccine exports is part of the unregulated competition between states for vaccine access and one manifestation of 'vaccine nationalism'.

The most serious disparities in free-market access to vaccines, however, do not exist among the rich industrialized countries of the Global North. For example, the EU apparently no longer has an imperative need for the vaccine doses which AstraZeneca must deliver in 2022 pursuant to a renegotiated deadline imposed by a court settlement. The EU has since sourced other vaccines and is likely to pass on large portions of AstraZeneca's outstanding shipments to developing countries. The real problem is with financially 'weak' countries: they cannot compete in any way in the global marketplace for vaccines. As early as November 2020, about 50 percent of the doses covered by APAs were reserved for 14 percent of the world's population in rich countries.

Given these conditions, early predictions have come true: in the industrialized countries, there will in principle be enough vaccines to immunize the entire population, and in many of the richest countries enough for even three- to six-fold vaccinations. This goal, however, remains a long way off for the vast majority of developing countries.<sup>24</sup> Controversy about this state of affairs flared up again as rich industrialized countries with sufficient doses for basic immunization of the population started securing booster shots. After the vaccinations necessary for the initial build-up of immunization (generally two doses), booster shots prolong the vaccine's protection. Booster shots tighten available vaccine supply while the vast majority of

<sup>&</sup>lt;sup>17</sup>See Von Bogdandy and Villarreal, ibid., at 5.

<sup>&</sup>lt;sup>18</sup>See Press statement by Commissioner Kyriakides on vaccine deliveries and on the vaccine export transparency scheme, Brussels, 25 January 2021, available at www.ec.europa.eu/commission/presscorner/detail/en/speech\_21\_211.

<sup>&</sup>lt;sup>19</sup>Commission Implementing Regulation (EU) 2021/111 of 29 January 2021, on the introduction of the requirement to hold an export authorization when exporting certain products.

<sup>&</sup>lt;sup>20</sup>See the overview of export restrictions by I. Ibrahim, 'Overview of Export Restrictions on COVID-19 Vaccines and their Components', (2021) 25 (10) ASIL Insights.

<sup>&</sup>lt;sup>21</sup>See J. Deutsch, 'EU and AstraZeneca Settle Court Case over Vaccine Supply', *Politico.eu*, 3 September 2021, available at www.politico.eu/article/eu-and-astrazeneca-settle-court-case-over-vaccine-supply/.

<sup>&</sup>lt;sup>22</sup>For a case study of the 2009 influenza pandemic see M. Turner, 'Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1', (2016) 11 *Global Public Health* 1, at 10, which argues that market-based vaccine procurement disadvantages developing countries and their populations: 'Developing states are least likely to gain timely access to pandemic influenza vaccines on behalf of their populations.'

<sup>&</sup>lt;sup>23</sup>A. D. So and J. Woo, 'Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross Sectional Analysis', (2020) BMJ 371 m4750.

<sup>&</sup>lt;sup>24</sup>Figures of worldwide vaccine distribution are available at www.unicef.org/supply/covid-19-vaccine-market-dashboard (see esp. the heading 'population coverage'); see Holder, *supra* note 9; Gavi, 'Vaccine Availability Forecasts in COVAX at COVAX: The Forecast for Vaccine Supply', 13 September 2021, available at www.gavi.org/vaccineswork/covax-forecast-vaccine-supply.

people living in developing countries, including at-risk groups, have yet to receive any vaccine shots.<sup>25</sup> In the fall of 2021, the Director-General of the WHO called for a moratorium on booster shots until the end of the year and a transfer of vaccines to developing countries so that a vaccination rate of 40 percent of the population could be achieved in all countries.<sup>26</sup>

# 3. COVAX as a tool for global vaccine distribution

## 3.1 Institutional structure of COVAX

#### 3.1.1 Function and basic structure

COVAX was created in April 2020 to procure and distribute COVID vaccines worldwide, particularly to developing countries. COVAX was jointly developed, funded, and managed by private and public stakeholders. COVAX is thus not a separate corporate body, but rather a network of actors which operates in structured workflows. The basic idea of COVAX is a purchasing community: COVAX invests in a range of vaccines at the development stage with a common investment and procurement mechanism for all participating states and purchases approved vaccines. This is known as the 'COVAX Facility'. This early investment in vaccine candidates was expected to provide early access, and large purchase volumes were expected to drive down prices. As a market-based mechanism, many aspects of COVAX follow a model which has been tested within the framework of its umbrella organization Gavi (see Section 3.1.2 below).<sup>27</sup> For example, Gavi is engaging in the procurement and distribution of the vaccine against the human papillomavirus (HPV) in a very similar form.

COVAX was also intended to engage in economic redistribution, mainly through official development-assistance funds: through an integrated financing instrument, the 'COVID-19 Vaccines Advance Market Commitment' or COVAX AMC, government development assistance funds would partially or fully fund vaccine procurement for the benefit of countries in need, generally low-income or lower middle-income countries. The financing scheme also allowed for private donations and loans from development banks.<sup>28</sup> COVAX currently grants access by means of this mechanism to 92 countries which have been selected based on the World Bank data on gross national income which determines eligibility for development assistance.<sup>29</sup>

The EU and some other countries have provided funding or guarantees for the COVAX AMC.<sup>30</sup> In addition, donations have been raised from the private sector, primarily from charitable foundations, but also from companies. As of November 2021, a total of about US\$10 billion has been pledged for vaccine deliveries to developing countries. <sup>31</sup> In addition, a considerable number of states has directly donated their own vaccine doses to the COVAX AMC:

<sup>&</sup>lt;sup>25</sup>WHO, 'Interim Statement on COVID-19 Vaccine Booster Doses', 10 August 2021, available at www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses.

<sup>&</sup>lt;sup>26</sup>J. Keaten, 'WHO Chief Urges Halt to Booster Shots for Rest of the Year', *AP News*, 8 September 2021, available at www.apnews. com/article/business-health-coronavirus-pandemic-united-nations-world-health-organization-6384ff91c399679824311ac26e3c768a.

<sup>&</sup>lt;sup>27</sup>See the description in Kaltenborn and Reit-Born, *supra* note 5, at 72 et seq.; for other programs through which Gavi engages in vaccine support see <a href="https://www.gavi.org/programmes-impact/types-support/vaccine-support">www.gavi.org/programmes-impact/types-support/vaccine-support</a>.

<sup>&</sup>lt;sup>28</sup>See Gavi, 'Vaccine Request Annex A: Covax Facility, Terms And Conditions For The AMC Group Participants', Item 1, available at www.gavi.org/sites/default/files/covid/covax/COVAX-VR-Annex-A-COVAX-Facility-TCs-AMC-group-participants.pdf.

<sup>&</sup>lt;sup>29</sup>For an overview of countries participating in Gavi see www.gavi.org/news/media-room/92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc.

<sup>&</sup>lt;sup>30</sup>For an overview of donors and committed resources see Gavi, 'Key Outcomes One World Protected - COVAX AMC Summit, Assured Resources for the Gavi COVAX AMC', as of November 2021, available at <a href="https://www.gavi.org/sites/default/files/covid/covax/COVAX-AMC-Donors-Table.pdf">www.gavi.org/sites/default/files/covid/covax/COVAX-AMC-Donors-Table.pdf</a>.

<sup>&</sup>lt;sup>31</sup>Ibid., there are no comparative figures for vaccine spending in industrialized nations because prices for vaccine doses are not consistently made public. It should be noted, however, that the EU has contracted for a portfolio of up to 4.6 billion doses for its member states, see <a href="https://www.ec.europa.eu/info/live-work-travel-eu/coronavirus-response/overview-commissions-response\_de">www.ec.europa.eu/info/live-work-travel-eu/coronavirus-response/overview-commissions-response\_de</a>.

by July 2022, more than 600 million doses donated in-kind have been shipped to developing countries, making up for more than half of the total amount of doses that has been delivered at that point.<sup>32</sup> In some cases, stock of vaccine types which the donating country's own population was hesitant to accept was made available to COVAX: for example, Germany announced in 2021 it would donate its remaining AstraZeneca doses to COVAX, after the AstraZeneca vaccine came under suspicion in Germany because of suspected severe side effects.<sup>33</sup> The general aim of COVAX is to grant populations in developing countries vaccine access through free or co-funded doses.

# 3.1.2 Administration of COVAX and the special role of Gavi

The main actors of COVAX are the World Health Organization (WHO) and two private bodies, the 'vaccine alliance', or Gavi, and the 'Coalition for Epidemic Preparedness Innovations', or CEPI. Gavi and CEPI are private-public collaborations which take the legal form of private-law entities. The main impetus for their founding came from the Bill & Melinda Gates Foundation.

Gavi is a foundation under Swiss civil law which is an 'International Institution' under the Swiss Host State Ordinance. One important result of this status is that the Foundation enjoys immunity and tax privileges approximating those enjoyed by intergovernmental international organizations.<sup>34</sup> Gavi was started in 2000 by the Bill & Melinda Gates Foundation and other private donors as a market-based mechanism for vaccine procurement for the developing world.<sup>35</sup> The Gates Foundation continues to be one of its largest private funders.

The Swiss private foundation Gavi serves as the legal administrator of COVAX. As implied by this private administration, COVAX's organization and decision-making and operational structure are also characterized by their private-law form. Gavi acts through the Board of Trustees, which has a total of 28 members. UNICEF, WHO, the World Bank and the Bill & Melinda Gates Foundation have permanent seats.<sup>36</sup> They are joined by the foundation's president and (alternating) representatives of five donor-country governments and developing countries, as well as two representatives of the pharmaceutical industry, one representative of civil society, and nine independent members from the domains of politics, industry, and research.<sup>37</sup>

# 3.1.3 Participants and working methods

The organization of COVAX as an operational structure is as follows: COVAX consists of the interaction of a variety of committees, working groups, and individual actors with decision-making, working, advisory, and supervisory/oversight functions. A guidebook describes how

<sup>&</sup>lt;sup>32</sup>See Gavi, 'COVAX Crosses Milestone of 500 Million Donated Doses Shipped to 105 Countries', 4 February 2022, available at www.gavi.org/news/media-room/covax-crosses-milestone-500-million-donated-doses-shipped-105-countries.

<sup>&</sup>lt;sup>33</sup> Germany to Donate All Remaining AstraZeneca Vaccines', *Reuters*, 7 July 2021, available at www.reuters.com/world/europe/germany-donate-all-remaining-astrazeneca-vaccines-aug-2021-07-07/.

<sup>&</sup>lt;sup>34</sup>Gavi Alliance, STATUTS du 29 octobre 2008 (Modifié pour la dernière fois le 24-25 juin 2020); status as an International Institution was granted in 2009 under the HSO, which is formally known as the Federal Act on the Privileges, Immunities and Facilities and the Financial Subsidies granted by Switzerland as a Host State; see the following press release, available at www. gavi.org/news/media-room/gavi-recognised-international-institution; for a brief description of Gavi see Kaltenborn and Reit-Born, *supra* note 5, at 72.

<sup>&</sup>lt;sup>35</sup>See Gavi's own description of its activities, available at <a href="www.gavi.org/our-alliance/about">www.gavi.org/our-alliance/about</a>: '... the Bill & Melinda Gates Foundation and a group of founding partners brought to life an elegant solution to encourage manufacturers to lower vaccine prices for the poorest countries in return for long-term, high-volume and predictable demand from those countries'.

<sup>&</sup>lt;sup>36</sup>Gavi Alliance, STATUTS du 29 octobre 2008 (Modifié pour la dernière fois le 24-25 juin 2020), Art. 9.

<sup>&</sup>lt;sup>37</sup>Gavi Board Members are listed at www.gavi.org/governance/gavi-board/members.

the actors work together to carry out COVAX's various missions. It also serves as a reference which provides normative guidance and instructions for activities within and by COVAX.<sup>38</sup>

Gavi, as the legal administrator, provides crucial parts of COVAX's governance structure. The Gavi Foundation Board bears ultimate responsibility for decisions made and actions taken by COVAX. Specifically, the Gavi Board of Trustees – through one of its subcommittees, the Market-Sensitive Decisions Committee (MSDC) – reviews the economic and contractual conditions of proposed APAs and decides whether to enter into agreements. The Board of Trustees, through its Audit and Finance Committee, performs supervisory and oversight functions relating to Gavi's activities under COVAX. For day-to-day operations, Gavi has established the Office of the COVAX Facility at its Secretariat in Geneva, which is specifically tasked with managing the operational procurement of COVID-19 vaccines. This includes contract negotiation with industry and management of investments in the vaccine portfolio. The office is advised by specialized committees and working groups, which in turn are located at different working levels.

COVAX's activity is divided into several sub-areas with specific actors and their own work-flows: Development and Manufacturing, Procurement and Delivery at Scale, and Policy and Allocation. Spanning the subsectors is the COVAX Coordination Meeting, which brings together representatives from WHO, UNICEF, Gavi and CEPI, the pharmaceutical industry, and civil society. The committee's role is to promote co-operation across the subdivisions, foster co-ordination at the interfaces, and exercise strategic leadership.<sup>42</sup>

Various committees and groups of stakeholders are involved in the above-mentioned subsectors. They are expected to provide general consulting, especially by recommending investments and contracts for vaccine development and production, providing technical expertise to direct and oversee development projects, providing information across subsectors, and linking the phases of vaccine development, production, procurement, supply, and distribution. As high-ranking representatives of industry, trade associations, research institutions, consulting companies, public health organizations, and politics, individual stakeholders are expected to either provide technical or technical-political expertise in relevant subject areas<sup>43</sup> or mirror the institutional connections and responsibilities within COVAX at the project level and in technical matters (as with representatives of WHO, UNICEF, Gavi, and CEPI). Further, regulatory authorities are involved, in the form of representatives from drug regulatory institutions.<sup>44</sup>

## 3.1.4 Involvement of participating states

States do not wield decision-making authority within COVAX. This is a common, even defining feature of public-private co-operation in the public health sector. There is no intergovernmental decision-making and governing body; states or their representatives exercise only an advisory function. There is a distinction at the institutional level between two categories of states: the first comprises of the so-called self-financing states – developed countries which pay the full COVAX-negotiated price for vaccine doses procured through COVAX. The second are those countries eligible for development assistance under the World Bank criteria, which receive vaccines as a form of development assistance.

<sup>&</sup>lt;sup>38</sup>Gavi, 'COVAX: The Vaccines Pillar of the Access to Covid-19 Tools (ACT) Accelerator, Structures and Principles', 9 November 2020 (updated 17 March 2021), available at www.gavi.org/sites/default/files/covid/covax/COVAX\_the-Vaccines-Pillar-of-the-Access-to-COVID-19-Tools-ACT-Accelerator.pdf.

<sup>&</sup>lt;sup>39</sup>Ibid., at 15.

<sup>&</sup>lt;sup>40</sup>Ibid.

<sup>&</sup>lt;sup>41</sup>Ibid., at 13.

<sup>&</sup>lt;sup>42</sup>Ibid., at 6.

<sup>&</sup>lt;sup>43</sup>See, e.g., the members of the Research and Development and Manufacturing Investment Committee, the Technical Review Group, or the Independent Product Group, according to Gavi, supra note 38, at 7 et seq., 14.

<sup>&</sup>lt;sup>44</sup>This applies, for example, to the Regulatory Advisory Group; see Gavi *supra* note 38, at 10 et seq.

Self-financing states are represented in the COVAX Shareholders Council, which is intended to foster exchange among members and provide strategic guidance and advice to the COVAX Office. Developing countries, for their part, participate exclusively in a separate consultation group, the COVAX Advance Market Commitment Engagement Group. This group handles the development-aid aspect of COVAX and is intended to implement strategic advice and guidance in this area. However, this group does not consist solely of developing countries; it is also open to donor countries, donors, and lenders. 46

# 3.2 Vaccine procurement and distribution by COVAX

# 3.2.1 Use of private law contracts

Gavi, through its Board of Trustees, concludes APAs with pharmaceutical companies within the COVAX framework for vaccines while they are still in development, or after a vaccine has received regulatory approval and manufacturing is able supply (mostly) on time with commitments, 'regular' supply agreements with the producing company. These agreements are considered private-law contracts under English law. In addition, Gavi's relationship with the recipient states is also based on private-law contracts under English law, which are entered into by the foundation's board. Legal relationships arising with states within the Gavi framework are subject to commercial arbitration in accordance with the rules of the United Nations Commission on International Trade Law (UNCITRAL).<sup>47</sup>

In accordance with the two categories of participating states, Gavi generally enters into two types of contracts. The first is a contract with self-financing states for vaccine supplies, known as a Committed or Optional Purchase Arrangement. The second involves fixed eligibility terms for the supply of vaccine doses to developing countries, which fall under the rubric of 'COVAX AMC Vaccine Request, Terms & Conditions and Application Form'. These eligibility conditions govern issues such as transparency and accountability requirements, corruption prevention, money laundering, and support for counter-terrorism. Agreements with developing countries also insulate Gavi and all actors involved in COVAX from liability to the participating state for any damages caused by the vaccines. Participating countries must also indemnify Gavi and all stakeholders with respect to any claims made against them by third parties based on violations of rights caused by the vaccines.

#### 3.2.2 Recommending rules for distribution: The WHO's contribution

The distribution of vaccines available under COVAX is based on WHO recommendations: WHO has developed a 'WHO Concept for Fair and Equitable Distribution of Health Products to Combat COVID-19' (WHO Concept).<sup>51</sup> The WHO Concept was developed by the WHO Secretariat, which states that it derives its power from the general mandate of WHO as well as the specific mandate given by member states in the form of a World Health Assembly resolution on COVID-19.<sup>52</sup> In

<sup>&</sup>lt;sup>45</sup>Ibid., at 13.

<sup>46</sup>Ibid.

<sup>&</sup>lt;sup>47</sup>Gavi Grant Terms and Conditions for COVAX AMC Group Participants, available to download at www.gavi.org/news/document-library/covax-amc-vaccine-request-terms-conditions-and-application-form; Gavi, Committed Purchase Agreement and Optional Purchase Agreement, para. 16, available at www.gavi.org/sites/default/files/covid/covax/COVAX-Self-financing-Participants-Legal-Agreements-and-Explanatory-Note.pdf.

<sup>&</sup>lt;sup>48</sup>Gavi, 'Explanatory Note: Legal Agreements with COVAX Facility Self-Financing Participants', available at www.gavi.org/sites/default/files/covid/covax/COVAX-Self-financing-Participants-Legal-Agreements-and-Explanatory-Note.pdf.

<sup>&</sup>lt;sup>49</sup>See Gavi Grant Terms and Conditions for COVAX AMC Group Participants, *supra* note 47.

<sup>&</sup>lt;sup>51</sup>WHO, 'Concept for Fair Access and Equitable Allocation of COVID-19 Health Products', Final Working Version 9 September 2020, available at www.who.int/docs/default-source/coronaviruse/who-covid19-vaccine-allocation-final-working-version-9sept.pdf.

<sup>&</sup>lt;sup>52</sup>Ibid., at 6; WHO, COVID-19 Response, Seventy-third World Health Assembly, WHO doc. WHA73.1 (2020); in this document, the WHA calls for 'universal, timely and equitable access to, and fair distribution of, all quality, safe, efficacious

addition, a WHO Working Group on Ethics and COVID-19 has developed ethical considerations for a framework for global distribution of vaccines in the pandemic.<sup>53</sup> WHO is also advised by the Strategic Advisory Group of Experts on Immunization on specific recommendations to national policymakers concerning the use of available vaccines.

The WHO Concept is based on the human right to health enshrined in Article 12(2)(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (see Section 4.1.1 below) and in the WHO Constitution as 'the right of every human being to the enjoyment of the highest attainable standard of health without distinction of race, religion, political belief, or economic or social condition'. The Concept states that the availability of affordable, safe, appropriate medicines, vaccines, diagnostics, and other health products for COVID-19 is a prerequisite for the realization of this right. Drawing on these preliminaries, the Concept lists a number of principles which – in conjunction with stated ethical considerations – give rise to principles specifically governing vaccine distribution. The first principle is solidarity, which is joined by transparency and accountability in the context of 'procedural distributive justice', followed by appropriate responses to public health concerns, equity and fairness, affordability, co-operation among global and national actors, and the effectiveness of approval and procurement processes.<sup>55</sup>

The WHO Concept identifies the overarching goal as 'protecting individuals and health systems and minimizing impact on societies and economies'. <sup>56</sup> Under the Concept, the COVID-19 vaccine, which was initially in short supply, would be used to reduce mortality and protect healthcare systems. It would, thus, first be reserved for specific target groups – namely, health workers, people over 65, and people with high-risk pre-existing conditions. <sup>57</sup>

Based on these principles, the WHO has also developed distribution rules for COVAX, namely, the Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility (Allocation mechanism), which is implemented by an algorithm which governs distribution rounds within the COVAX framework. The principles and considerations elaborated in the WHO Concept explicitly serve as the foundation for the Allocation mechanism; the latter is derived from these provisions: the WHO presents the Allocation mechanisms as '[f]ollowing on from the overarching provisions of the global allocation framework for fair and equitable access to COVID-19 health products'. From the viewpoint of WHO, COVAX is thus intended to implement the WHO distribution rules, and serves to implement them in practice.

In practice, vaccine doses are allocated to developing countries in individual distribution rounds based on the quantities of vaccine available.<sup>60</sup> The first phase involves states receiving shipments in proportion to their population size until they have reached the target of vaccinating 20 percent of the population.<sup>61</sup> After this goal is reached, distribution is governed by 'risk and vulnerability criteria'. Actual delivery of vaccine doses is thereby conditioned on availability and on the grant of indemnification to Gavi (see Section 3.2.1, above).<sup>62</sup> The vaccine must also be approved for use at the national or regional level (e.g., by the European Medicines Agency of the European Union).

and affordable essential health technologies and products, including their components and precursors, that are required in the response to the COVID-19 pandemic'.

<sup>&</sup>lt;sup>53</sup>See WHO, supra note 51, at 14 et seq.

<sup>&</sup>lt;sup>54</sup>Ibid., at 7 et seq.

<sup>&</sup>lt;sup>55</sup>See WHO, supra note 51, at 8.

<sup>&</sup>lt;sup>56</sup>Ibid., at 10.

<sup>&</sup>lt;sup>57</sup>Ibid., at 24.

<sup>&</sup>lt;sup>58</sup>Ibid., at 18 et seq.; WHO, 'Allocation Logic and Algorithm to Support Allocation of Vaccines Secured through the COVAX Facility', Explainer Based on Commonly Asked Questions, 15 February 2021.

<sup>&</sup>lt;sup>59</sup>See WHO, supra note 51, at 20, this relation is also visualized at 22, in Fig. 1.

<sup>&</sup>lt;sup>60</sup>Gavi, 'COVAX AMC Application Guidance', at 9, available at www.gavi.org/sites/default/files/covid/covax/covax-amc/COVAX-AMC-APPLICATION-GUIDANCE.pdf.

<sup>&</sup>lt;sup>61</sup>The 2020 COVAX target was to vaccinate approximately 20% of the population of participating developing countries by the end of 2021. See Gavi, ibid., at 11.

<sup>&</sup>lt;sup>62</sup>Ibid., at 10.

#### 3.3 Interim conclusion: COVAX as a private-law organization

COVAX includes private and public actors, in particular philanthropic foundations, states, and international organizations.<sup>63</sup> In addition, the COVAX system uses various methods and strategies: recommendations by international organizations, private contracts between foundations and countries, development aid, and private loans and grants.

The public aspect is thus not the dominant and formative factor in the legal design of the mechanism as a whole. This holds notwithstanding the fact that COVAX involves public actors (namely, the WHO and participating states), and that the rules for distributing vaccines are anchored in the human right to health (see Section 3.2.2, above). Gavi administrates COVAX by means of private-law mechanisms; the Gavi Private Foundation, for its part, is not controlled by public actors. Under COVAX, neither states nor international organizations enjoy control and oversight powers regarding its actual decision-making and use of financial means. The structure of COVAX does not correspond to the classical categories and concepts of actors, sources of law, and forms of action which characterize international and administrative law, such as, for example, international organizations, international treaties, the secondary law of international organizations, or the traditional definitions of agencies, administrative acts and administrative contracts. Nevertheless, there are starting points for a public-law 'reconstruction' of COVAX, as will be shown below. This reconstruction draws on human rights (Section 4.1.1, below), administrative law (Section 4.1.2, below), and global-governance perspectives (Section 4.1.3). It also reflects the choice of private-law measures as a strategic decision (Section 4.2). These perspectives, which productively complement one another, allow us to assess the need for and problems with the legitimation of COVAX (Section 4.3) as a normative matter.

## 4. Aspects of a public law reconstruction of COVAX

# 4.1 Foundations

# 4.1.1 A human-rights perspective: Access to vaccination as a function of public-law guarantees

Vaccination against COVID-19, a potentially life-threatening disease with severe long-term consequences, is currently an essential aspect of preventive health care. This directly implicates the doctrine of healthcare as an individual legal right. COVID-19, however, is not merely an individual health issue. It also affects preventive health care and disease control in the community at large – issues which implicate public health as a common good.

The effects of the Coronavirus on the individual and public dimensions of health care implicate the protection of health as a matter of fundamental and human rights. The right to health is enshrined as a human right in Article 12 of the ICESCR and even more explicitly in the WHO Constitution.<sup>64</sup> Article 12(2)(c) of the ICESCR also explicitly identifies prevention, treatment and control of epidemic diseases as measures to be taken by the state parties to fully realize the right to health. While the European Convention on Human Rights (ECHR) does not explicitly cite a right to health, the European Court of Human Rights has held that the ECHR imposes an obligation on states to take necessary measures to protect the life and health of their populations, including public health measures.<sup>65</sup>

<sup>&</sup>lt;sup>63</sup>The scheme thus takes into account the different orientations of these actors, ensuring a mixture of values from the domains of market rationality, human rights doctrine, medical/ethical distributional theory, philanthropy, and development aid.

<sup>&</sup>lt;sup>64</sup>The provision reads: 'The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'

<sup>&</sup>lt;sup>65</sup>Lopes de Sousa Fernandes v. Portugal, Judgment of 19 December 2017, ECHR Case No. 56080/13, paras. 164–165; Vasileva v. Bulgaria, Judgment of 17 March 2016, ECHR Case No. 23796/10, paras. 63–69. The Court has explicitly cited this principle in a ruling on protective measures in the Corona pandemic: Renaud le Mailloux v. France, Decision of 5 November 2020, ECHR Case No. 18108/20, para. 9.

Even if human rights obligations bind states first and foremost with respect to their own populations, the right to health also has cross-border dimensions. States owe a duty under international law to co-operate with other states and not to interfere with the right to health of populations of other states. In the view of the UN Economic and Social Council's Committee on Economic, Social and Cultural Rights, this duty includes an obligation on the part of richer nations to support developing countries. The Committee considers significant health disparities between developed and developing countries to be an objective shortcoming in the realization of the right to health.

Vaccination against serious infectious diseases is among the essential obligations of state parties under the ICESCR's provisions on right to health, as interpreted by the Committee on Economic, Social and Cultural Rights.<sup>69</sup> Under this principle, vaccinations against COVID-19 are a public good in the sense that all people, without exception, should enjoy access to them. The World Health Assembly has explicitly recognized 'extensive immunization against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end'.<sup>70</sup> In this context, the right to health can be described as a global public good in a politico-economic sense, especially in a pandemic: infectious diseases make it impossible to protect public health in isolation in one country. The COVID-19 pandemic, which spread rapidly across international borders, exemplifies this point.<sup>71</sup> The pandemic affects all countries globally and can only be effectively combated worldwide and in international co-operation. The pandemic thus resembles global warming, another threat which ignores national borders.

The human right to health obligates states to combat the Coronavirus, including by providing vaccinations. States have wide latitude in fulfilling this task. However, this does not mean that they are not bound by legal obligations: there is a positive obligation to act, which, as outlined above, mandates guarantees and co-operation. The duty to co-operate, while also directed at individual states, ultimately requires joint action and thus ultimately addresses states as members of an international community.

As noted above, the WHO distribution Concept also refers to the right to health as a human right which imposes positive obligations to act. By formulating normative standards for vaccine distribution, the Concept is intended to contribute to the practical implementation of existing human rights obligations. The Concept does not impose any obligations on the member states in itself. This is because it is not binding international law, but rather a set of recommendations based on ethical and legal expertise. These can be classified as 'soft-law' recommendations. However, soft-law norms can also become important and have practical effects without being legally binding, particularly when states or other international-law actors regard them as guidelines for their actions and implement them, especially when they do so pursuant to their own implementation mechanisms.<sup>72</sup> COVAX serves as the implementation mechanism of the Concept's distribution model (see Section 3.3.3, above). The question

<sup>&</sup>lt;sup>66</sup>UN Economic and Social Council, Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights), UN Doc. E/C.12/2000/4 (2000), paras. 38, 39, 45.

<sup>&</sup>lt;sup>67</sup>Ibid., para. 45: '... it is particularly incumbent on States parties and other actors in a position to assist, to provide international assistance and cooperation, especially economic and technical ones which enable developing countries to fulfill their ... obligations'.

<sup>&</sup>lt;sup>68</sup>Ibid., para. 38.

<sup>&</sup>lt;sup>69</sup>Ibid., para. 44(b); the Committee assesses this obligation as comparable to the so-called core obligations.

<sup>&</sup>lt;sup>70</sup>See WHO Doc. WHA73.1, supra note 52, para. 6.

<sup>&</sup>lt;sup>71</sup>On the concept of global public good in the Corona pandemic response see G. Brown and D. Susskind, 'International Cooperation During the COVID-19 Pandemic', (2020) 36 Oxford Review of Economic Policy S64, at S64; J. Bäumler and J. Sarno, 'The Immunisation against COVID-19 as a Global Public Good', (2021) 82 Heidelberg Journal of International Law 159

<sup>&</sup>lt;sup>72</sup>On the normative significance of soft law and other so-called 'alternative instruments' of normative action in international law see M. Goldmann, *International Public Power* (2015), at 47 et seq.

arises, however, as to the extent to which COVAX actually achieves the goals set forth in the Concept (see Section 4.3.3, below).

# 4.1.2 Administrative-law aspects: Public-private partnerships as functional privatization

The rise of the involvement of private actors in public functions in the context of the state has made this phenomenon a longstanding and thoroughly researched subject of administrative law scholarship. This scholarship has developed an analytical and argumentative framework that can and should be made fruitful in contexts beyond the state as well, since the core normative-legal issues are the same: how can it be guaranteed that private actors effectively provide the public good in question to the respective population? How to ensure that private actors are accountable toward the public which they are supposed to serve? In what follows, central doctrines on these issues that German administrative law scholarship has elaborated will be introduced and, at a later step, be applied to COVAX (see Section 4.3, below). The basic assumption is this: the mere classification of a task as a 'public' function does not mean that all efforts to fulfil the task must be generally subject to and bound by public law.<sup>73</sup> Only when this argument is accepted is it possible to 'privatize' the fulfilment of public functions beyond the mere use of private-law forms of organization by the public sector: now, fulfilment of public functions can be entrusted to private actors and thus, in principle, exempted from the material and formal-procedural requirements of sovereign action. As regards the concept of privatization, however, it should be noted that involvement of private parties in public functions does not necessarily always entail a transition from public to private action. Such cases are common, and therefore also help to define the administrative-law perspective. However, it is also conceivable that when updating the definition of a specific public function, its fulfilment may be entrusted to private parties (or a private-public co-operation) from the very outset, without there being any public-law 'predecessor' responsible for that function. COVAX is such a case in the context of the public function of global vaccine distribution during the pandemic; there was no 'original' predecessor public entity here. Administrative-law doctrines on privatization can, in many respects, also be fruitfully employed without regard to the 'history' of how a particular public function has been fulfilled. However, the question of how it came to a particular (public-)private approach to the delivery of a public good in the first place is important in itself: this is where the institutional choice among alternative approaches comes into play – a choice that shapes to what extent the public concerned can enforce effectiveness and public accountability (see with regard to COVAX Section 4.2, below).

In principle, it is possible to imagine various levels of privatization. In German administrative law doctrine, the 'public-private partnership' (PPP) is considered a form of action 'between formal-organizational privatization and substantive-material privatization'.<sup>74</sup> The PPP is generally categorized as functional privatization, in which private parties make significant contributions to sovereign action and the fulfilment of a public function.<sup>75</sup> In particular, this means that defined aspects of the administrative process are conferred to private, officially-commissioned third parties, so that private contributions fulfilling the public task are functionally integrated into administrative action.<sup>76</sup>

<sup>&</sup>lt;sup>73</sup>There is, however, an effort to define core state tasks as central regulatory tasks which should be considered 'resistant to privatization'; see H. Schulze-Fielitz, 'Grundmodi der Aufgabenwahrnehmung (Basic forms of task performance)', in W. Hoffmann-Riem, E. Schmidt-Aßmann and A. Voßkuhle (eds.), *Grundlagen des Verwaltungsrechts* (Foundations of Administrative Law) (2012), vol. I, 823, at 868, § 12, marginal no. 95, with additional citations.

<sup>&</sup>lt;sup>74</sup>Ibid., at marginal no. 96; see also marginal nos. 108 et seq., which defines organizational privatization and material/task privatization.

<sup>&</sup>lt;sup>75</sup>See the definition of functional privatization provided by M. Eifert, 'Regulierungsstrategien (Strategies of Regulation)', in Hoffmann-Riem, Schmidt-Aßmann and Voßkuhle, ibid., at 1339 et seq., § 19, marginal nos. 40 et seq.

<sup>&</sup>lt;sup>76</sup>Ibid., at mariginal no. 40.

Within the spectrum of private-party involvement in administrative functions, functional privatization falls short of substantive privatization (of the task as such), which essentially eliminates the public character of the function itself.<sup>77</sup> Within the typology of administrative law, functional privatization does not change the fact that the public entity is responsible for fulfilling the function. 8 Only the fulfilment of the function is not (or is no longer) carried out by the state alone. As the party responsible for carrying out the task, however, it remains ultimately responsible for fulfilment and must ensure that others – i.e., private parties – act effectively to fulfil it. The concept of the 'guaranteeing state' was coined to describe this situation, in which the state initiates, guides and normatively 'encloses' independent fulfilment by private parties.<sup>79</sup> The function of the state is thus transformed into a responsibility to select, regulate, monitor, and observe private actors and their actions, and to deal with any situations they are not equipped for or are unwilling to address. 80 Accordingly, the responsible public entity is assigned wide-ranging responsibility for regulatory action within public-private co-operation. The public entity must ensure that the administrative task is carried out 'correctly' to such an extent that there is no significant difference between the result obtained by the private actor and the one the public entity itself could have achieved. 81 As a substantive matter, the private actor must also respect the 'substantive democratic and constitutional guarantees'82 which are inherent in the bureaucratic rule-enforcement. The choice of the private actor - with emphasis on capacity and reliability - and the contract which defines its responsibilities in carrying out the public function are seen as important levers of the state's 'guarantee' responsibility. 83

## 4.1.3 The global governance perspective: Distributive action as international public authority

Under the catchword 'global governance', scholars of international law and international politics also have acknowledged that private and hybrid actors and approaches which go beyond the classical categories of public law are involved in essential functions of governance beyond the state. Legion companies, associations, private foundations, non-governmental organizations, and scientific groups are often involved in the pursuit of cross-border issues which affect the common good and exercise a regulatory-controlling effect on cross-border activities by means of self-organization and standard-setting. This also posed a challenge to doctrines and theories of international law, which in turn developed various approaches to this issue, such as those of transnational law, global administrative law and the idea of 'international public authority'. The following discussion draws on the concept of international public authority, which Armin von Bogdandy and others have developed as a central category for a legal-doctrinal and normative understanding of global governance. The concept is developed further here – with a view to the distributional function of COVAX – in the context of international distributional action, especially in the form of development aid.

International public authority is understood as any action by international institutions which restricts the freedom of the addressees, including the collective freedom to democratic self-

<sup>&</sup>lt;sup>77</sup>See Schulze-Fielitz, *supra* note 73, at marginal no. 112.

<sup>&</sup>lt;sup>78</sup>See Eifert, *supra* note 75, at marginal no. 41.

<sup>&</sup>lt;sup>79</sup>See A. Voßkuhle, 'Beteiligung Privater an öffentlichen Aufgaben und staatliche Verantwortung', (2002) 62 VVdStRL 266, at 282 et seq, with further references.

<sup>&</sup>lt;sup>80</sup>Ibid., at 285.

<sup>81</sup>See Eifert, supra note 75, at marginal no. 41.

<sup>82</sup>Ibid.

<sup>&</sup>lt;sup>83</sup>Ibid.; see also Voßkuhle, *supra* note 79, at 312 et seq.

<sup>&</sup>lt;sup>84</sup>A. von Bogdandy, P. Dann and M. Goldmann, 'Developing the Publicness of Public International Law: Towards a Legal Framework for Global Governance Activities', in A. Bogdandy et al. (eds.), *The Exercise of Public Authority by International Institutions* (2010), 3, at 7.

<sup>&</sup>lt;sup>85</sup>See the overview in A. von Bogdandy, M. Goldmann and I. Venzke, 'International Public Law: Translating World Public Opinion into International Public Authority', (2017) 28 EJIL 115, at 115.

determination. This also includes actions which do not take traditional legal forms and which are not enforced coercively, but which nevertheless have other normative-controlling effects on the addressees.<sup>86</sup>

Under this definition, the quality of an act as the exercise of official authority is explicitly not dependent on its legal form: rather, it is precisely the point that private-law or hybrid organizations, although not vested with any power to act under public law, can also act in the public interest, i.e., towards achieving the common good instead of narrow private self-interest. The public quality of the overall action consists in the fact that the legal authority for it mandates the pursuit of the public interest and is thus attributable to public law.<sup>87</sup>

This criterion is probably the most controversial aspect of the idea. However, it is precisely this fact – i.e., that the concept of international public authority is based on the legal connection to the common good (and not on the public or private form of action) – which makes the idea useful for the study of the COVAX as a public-private partnership. From a normative perspective, the importance of private actors and private-law forms of action for the pursuit of public interests is increasing. It is therefore inappropriate to regard the legal nature of an action as the decisive criterion of legitimacy under public-law standards. If a legal 'dedication' to the pursuit of public interests is claimed for an action, the action must also be legitimized vis-à-vis the party responsible for ensuring the common good – i.e., the (relevant) public.

For the purposes of a public-law analysis of COVAX, however, the concept of international public authority must be updated: the typical case refers to regulatory action which provides normative guidance, which in turn restricts the freedom of domestic policy and law-making, whether de jure or de facto. With regard to COVAX, however, the issue is international *distributive* action. At first glance, this domain does seem to fall within the definition of international public authority, because it is not primarily aimed at exerting normative influence on the formation of domestic policy priorities.

International distributive action mediates access to goods in which there is a public interest, and encompasses the provision of such things as funding, education, medical products, technology, food, and other tangible or intangible goods or services. Such action (which can be described as *benefit administration* in the context of administrative law) helps to determine the receiving state's level of resources.<sup>89</sup> The study of development aid, in particular, has shown that that distributive action often expands or even establishes the capacity of the recipient state, especially in relation to its own population.

By affecting a country's capacities, aid provided by international institutions affects the effectiveness of the recipient state's power. It is thus generally *also* an instrument of control which affects collective self-determination in the recipient state, especially if aid is linked to conditions. In principle, therefore, distributive action can fall under the concept of force/authority, even if it takes place pursuant to private forms of action and is led by private actors. However, this assumes that donor states claim a public-law legal foundation for their actions. This foundation can be binding or non-binding (international) public law (or to use another typology, 'hard' or 'soft' law). Philanthropy is, thus, not included in this definition.

<sup>&</sup>lt;sup>86</sup>The basic idea is outlined in Von Bogdandy, Dann and Goldmann, *supra* note 84, at 10 et seq.; the most recent contribution is von Bogdandy Goldmann and Venzke, ibid.

<sup>&</sup>lt;sup>87</sup>See Von Bogdandy, Goldmann and Venzke, ibid., at 136 et seq.

<sup>88</sup> Ibid., at 132.

<sup>&</sup>lt;sup>89</sup>P. Dann, The Law of Development Cooperation (2013), 359 et seq., 510 et seq.

<sup>&</sup>lt;sup>90</sup>On aid conditions as a steering and supervisory instrument in development co-operation and the legitimacy issues this raises see Dann, ibid., at 238 et seq.

<sup>&</sup>lt;sup>91</sup>On this qualification see Von Bogdandy, Goldmann and Venzke, supra note 85, at 136 et seq.

<sup>&</sup>lt;sup>92</sup>Ibid., at 139

<sup>&</sup>lt;sup>93</sup>Ibid., at 133 et seq., define the three criteria of the concept of international public authority as international character, publicness, and authoritative quality.

The qualification of distributive action as (international) public authority signals that it is subject to requirements of legitimacy vis-à-vis the public whose common good it affects. <sup>94</sup> It therefore requires legitimation under public-law standards.

When it comes to legitimating global-governance institutions and the public power they exercise, various approaches have been debated. They can be generally classified using German political scientist Fritz W. Scharpf's oft-cited paradigm of 'output' and 'input' legitimation. <sup>95</sup> 'Output', in the sense of performance and effectiveness, is linked to the functionalist idea of technocratic-expertise-based approaches to cross-border problem solving. <sup>96</sup> Michael Zürn attests that institutions of global governance are dominated by technocratic legitimation narratives, if only because beyond the state, conventional legitimation approaches which start with *input* of decisions and actions – such as (in particular) participatory models of involvement of those affected or the addressees – are unlikely to find the necessary functional conditions for effectiveness. <sup>97</sup> Output, defined in terms of effectiveness with respect to cross-border problems, is also seen as a central legitimizing element of international public-private partnerships. <sup>98</sup>

However, questions of legitimate institutional design also arise with regard to the international public authority of private and hybrid actors. This directly implicates the input side of the exercise of international public authority. A number of general benchmarks, or at least influential criteria, have been discussed in this context: the most prominent being state equality; the opening of egalitarian, pluralistic participation opportunities for civil society actors; and the 'publicness' of and justifications for actions taken.<sup>99</sup>

With regard to the institutional design of global distribution and development-aid mechanisms, state equality as a 'form principle' is of particular importance. As Sigrid Boysen has shown, the principle of equal sovereignty and self-determination is a constitutive part of the internal dialectic (of 'ambivalence') of the contemporary international legal order. On the one hand, international law – owing to its colonial genesis and continuing influence – creates and maintains a world order shaped and dominated by the rich countries of the Global North and their distinctive economic logics of growth and 'development'. On the other hand, however, it embraces sovereignty – the fundamental recognition of the countries of the Global South as equals – and thus also contributes to politicization of the traditional relations of order and power. As an institutional form, equality of states requires a formally equal negotiation of distribution issues between donor and recipient countries (that is, industrialized and developing countries) and thus also creates opportunities to politicize and mitigate dominance relations and structural economic inequalities. On the other hand, however, it is industrialized and developing countries and thus also creates opportunities to politicize and mitigate dominance relations and structural economic inequalities.

<sup>94</sup>For a similar argument see Dann, supra note 89, at 510 et seq.

<sup>&</sup>lt;sup>95</sup>For a thorough discussion of the various approaches see M. Zürn, A Theory of Global Governance, Authority, Legitimacy, and Contestation (2018), 62 et seq.

<sup>&</sup>lt;sup>96</sup>Ibid., at 74 f., who presents the technocratic model of legitimation as one of several possible narratives of legitimation: 'This legitimation narrative [the technocratic narrative] builds on non-prejudiced expertise and knowledge of the facts. Expertise is normally derived from the concept of science as an independent search for knowledge with no regard for particular interests, and based on a systematic methodology. Connected with this narrative is the hope for successful goal-oriented policies that especially promote the welfare of the community.'

<sup>&</sup>lt;sup>97</sup>Ibid., at 79.

<sup>&</sup>lt;sup>98</sup>Thus, for example, Kaltenborn and Reit-Born, *supra* note 5, at 81 et seq., discussing PPPs in the field of global health policy, ultimately base their evaluation essentially on the contribution of global health partnerships to the achievement of Sustainable Development Goal 3 ('Ensure healthy lives and promote well-being for all at all ages').

<sup>&</sup>lt;sup>99</sup>Cf. the discussion in R. Forst, 'Justice and Democracy in Transnational Contexts: A Critical Realistic View', (2014) 81 *Social Research* 667, at 676 et seq.

<sup>&</sup>lt;sup>100</sup>S. Boysen, The Postcolonial Constellation (2021), 108.

<sup>&</sup>lt;sup>101</sup>See Dann, *supra* note 89, at 244 et seq., who had earlier also addressed the protection of equal freedom in development co-operation: 'In the context of development cooperation law, the principle [of equality] means that, during bilateral contracting for ODA [Official Development Aid] allocations, both parties are treated formally as equal, even when, in reality, they are immensely unequal. Wealthy donors must, therefore, recognize recipients as equals and negotiate with them as such.'

Ultimately, the question of the institutional structure necessary to legitimate the exercise of international public authority by private or hybrid actors can only be meaningfully addressed by considering the specific institution under review and its function. Yet it must always be asked whether it is legitimate to leave actions addressing a specific public interest to private or hybrid actors – i.e., whether it is *appropriate* to choose a private-law approach to handling a public function. The following section discusses COVAX from the perspective of how public and private approaches are chosen to address public functions.

# 4.2 The choice of the private law form of action as a strategic decision by the community of states

COVAX was not the only imaginable approach to global vaccine distribution. There is the example of the EU's centralized bargaining and pro rata distribution of available vaccine doses among its member states (see Section 1, above). Here, a public institution, the European Commission, was empowered as a means to act collectively and to provide equitable access to COVID-19 vaccination across state borders. This is a different approach to the same issue that COVAX is supposed to address, illustrating that states are exercising institutional choice: Why was the specific institutional form of COVAX - and no other - chosen? States' participation in COVAX is also necessarily a rejection of other possible mechanisms and forums for global distribution of COVID-19 vaccines - in particular, multilateral action under international law. From this perspective, the operation of COVAX, as will be argued below, is the result of a choice - it can be seen as strategic action which states used to limit the extent of their legal commitment and preserve their freedom and autonomy. A comparison with the alternative of using institutions and regimes of international law to address the issue of inequitable access to vaccines also highlights the peculiarities of the public-private partnership approach. The perspective of possible alternatives is not limited to the lever of pharmaceutical procurement and distribution, but should also include other instruments of public international law, such as the much-debated use of waivers under WTO law on intellectual property concerning the protection of patents precluding the production of generica in the Global South. This broad comparison clearly highlights how COVAX's concept of legitimacy differs structurally from that of classical international action within the forms of international law.

COVAX can be understood as a response to the fact that no consensus has been reached for acting within the framework of an international organization to handle global vaccine distribution, or more generally, to enable equitable access to coronavirus vaccines worldwide by means of international law. The balance of power in international relations apparently precluded development of such a consensus. In any event, the WHO, in particular, was not entrusted by member states with authority to procure and distribute vaccines, whether before or during the pandemic. In general, the Coronavirus pandemic graphically illustrated the WHO's limited function and capacities: WHO is not set up to accomplish and enforce the policy co-operation needed to combat the pandemic. States have not granted WHO the necessary authority to regulate, (re)distribute, and ultimately to implement such a policy. The current legal status of the WHO is a result of proactive action by the WHO during the 2004 SARS pandemic which spilled over into state spheres. In response to perceived overreach, states reaffirmed their sovereignty and took pains to ensure the WHO would not receive more political power to combat pandemics, as the analysis by Eyal Benvenisti shows. 102

Dann also discusses the idea of 'procedural reciprocity' as a principle of equal representation and describes problems arising from violations of this principle in the institutional structure of international organizations such as the World Bank.

<sup>&</sup>lt;sup>102</sup>E. Benvenisti, 'The WHO–Destined to Fail?: Political Cooperation and the COVID-19 Pandemic', (2020) 114 American Journal of International Law 588, at 595 et seq.

Responding to criticism of the WHO's lack of leadership in the COVID-19 pandemic, Benvenisti shows that the organization has been designed by member states to disseminate knowledge and up-to-date technical information on diseases and health issues by maintaining networks of medical, technical, and ethical experts and by generating and disseminating technical expertise and providing technical and scientific co-ordination among states on the basis of scientific authority – a process referred to as technical co-ordination. Effective control of cross-border diseases, however, also requires *political co-ordination* between countries: 104

IOs [International Organizations] charged with managing global health must have the tools to overcome the most complex cooperation problems among mutually distrustful sovereigns. They must have independent and impartial global regulators with access to independent sources of information that they can share with all states. They must have norms and systems via which to share the burdens and benefits of global health goods, coupled with mechanisms to ... monitor and enforce compliance with such norms. <sup>105</sup>

The need for political co-operation is particularly clear in the case of vaccine distribution during the COVID-19 pandemic. Indeed, the pandemic can serve as a paradigmatic example of this need: at issue is the distribution of a scarce good, including the question of redistribution between wealthy industrialized countries (which are also home to the pharmaceutical industry) and developing nations, especially countries with low and lowest income.

How does the choice of the PPP approach serve the strategic interests of at least one (majority) of industrialized countries? Although obligations based on the human right to health hover in the background, COVAX does not itself impose legal obligations on states. States participate at their own discretion – they can order vaccines through COVAX and decide on the specific purchase of vaccines on a case-by-case basis, or they may continue to procure vaccines through their own contracts. <sup>106</sup> Use of alternative procurement does not exclude a country from participating in COVAX. Moreover, COVAX does not in itself foster any commitment to solidarity during the pandemic: states are not obliged to fund vaccine doses for the development-aid component of COVAX at a level which would provide approximately equal global access to vaccines. COVAX is thus not a mechanism to legally enforce or otherwise guarantee equal access to vaccination.

There is another aspect to this: COVAX does not remove distribution of vaccines from market mechanisms. This benefits pharmaceutical companies and, indirectly, the states of the Global North which host those companies. Nor does COVAX involve regulatory interventions or other steps which might limit the influence of the market. From a legal standpoint, interventions into the given market dynamics would be quite possible (in various forms) – and are also being discussed as a practical possibility, if, admittedly, without any results in terms of joint action so far. Within the WTO, India and South Africa had already requested a waiver

<sup>&</sup>lt;sup>103</sup>Ibid., at 590 et seq.

<sup>104</sup> Ibid., at 590: 'Health is a coordination game, because actors need to know what the health risks are and the correct ways to treat the disease in question . . . But global health also poses a set of interstate cooperation problems, as states have different capabilities and vulnerabilities that shape their responses to health risks. These differences create externalities . . . scarcity problems plague the attainment of global health goals particularly in times of pandemics as states may hoard medical equipment, profiteer off in-demand resources, and limit their export.'

<sup>&</sup>lt;sup>105</sup>Ibid., at 592.

<sup>&</sup>lt;sup>106</sup>See Committed/Optional Purchase Arrangement, supra note 47; COVAX AMC Vaccine Request, supra note 28.

<sup>&</sup>lt;sup>107</sup>See, for example, the presentation of the legal situation in J. Bäumler and J. P. Terhechte, 'Handelsbeschränkungen und Patentschutz für Impfstoffe – Europa- und völkerrechtliche Aspekte' ('Trade Restrictions and Patent Protection for Vaccines - Aspects of European and International Law'), (2020) *Neue Juristische Wochenschrift* 3481, at 3485 et seq.; H. Grosse Ruse-Khan, 'Access to Covid-19 Treatment and International Intellectual Property Protection – Part I: Patent Protection, Voluntary Access and Compulsory Licensing', *EJIL:Talk!*, 15 April 2020, available at www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-i-patent-protection-voluntary-access-and-compulsory-licensing/.

under the TRIPS Agreement<sup>108</sup> in October 2020 to suspend the enforcement of intellectual property rights in health products and technologies – particularly patents – related to the control, containment, and treatment of COVID-19, which would also include patents regarding vaccines.<sup>109</sup> This would encourage developing countries to build up their own production capacities, which could significantly reduce their dependence on the world market and on imports. It would also provide access to lower-cost generic drugs for countries without their own production facilities, including vaccines.<sup>110</sup>

However, approval would require a basically unanimous decision by the WTO Ministerial Conference pursuant to Article IX paragraphs 3–4 of the WTO Agreement, which is not on the cards at this time. Although a broad coalition of states, including the US, have expressed support for the waiver, Germany, along with the UK and Switzerland, opposes such a decision. The EU, too, has so far favoured the approach of promoting vaccine production through increased licensing (instead of waivers) with priority being given to voluntary licensing and compulsory licensing under WTO law when necessary. The TRIPS Agreement provides for compulsory licensing, under which vaccine can be produced without the consent of the patent holder and exported to countries in need. 113

Countries and pharmaceutical companies opposing waivers and compulsory licenses which would allow developing countries to produce vaccines rely on several arguments. First, they maintain, this approach does not make sense because developing countries lack the capabilities and infrastructure in to produce mRNA vaccines. <sup>114</sup> Second, patent protection is necessary to maintain companies' willingness to innovate and invest in product development. However, this line of reasoning has increasingly been questioned. <sup>115</sup>

Overall, COVAX shows that the balance of power in international relations in the pandemic tends to protect a 'sovereigntist' orientation. This approach favours the interests of richer nations; they retain their freedom of decision and their own autonomy and can continue to pursue their own procurement strategies. It is only at first sight that the fact that COVAX does not provide for intergovernmental oversight seems to contradict this assertion. This is because under COVAX, states avoid any form of multilateral commitment and remain quasi-private autonomous actors, especially with regard to proposals based on notions of solidarity. These wealthier states can

<sup>&</sup>lt;sup>108</sup>1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 UNTS 299.

<sup>&</sup>lt;sup>109</sup>WTO Council for Trade-Related Aspects of Intellectual Property Rights, 'Waiver From Certain Provisions Of The TRIPS Agreement For The Prevention, Containment And Treatment Of Covid-19, Communication From India And South Africa', IP/C/W/669, 2 October 2020; and the revised version, IP/C/W/669/Rev.1, 25 May 2021.

<sup>&</sup>lt;sup>110</sup>See the legal overview in F. Sucker, 'Tripped Up: All You Need to Know about the Covid-19 TRIPS Waiver and What It May Achieve for SA (and What It Won't)', *Daily Maverick*, 11 May 2021, available at www.dailymaverick.co.za/article/2021-05-11-tripped-up-all-you-need-to-know-about-the-covid-19-trips-waiver-and-what-it-may-achieve-for-sa-and-what-it-wont/.

<sup>&</sup>lt;sup>111</sup>Some commentators claim that a majority decision is also possible, cf. I. Venzke, 'Why Germany Should Support Waiving Intellectual Property Rights', *Verfassungsblog*, 31 October 2021, available at verfassungsblog.de/from-charity-to-justice-in-the-pandemic/. For a more general discussion of waivers as instruments see I. Feichtner, *The Law and Politics of WTO Waivers: Stability and Flexibility in Public International Law* (2012).

<sup>112</sup>Communication From The European Union To The WTO General Council, 'Urgent Trade Policy Responses To The Covid-19 Crisis Brussels', 4 June 2021, available at docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?Query=@Symbol=WT/GC/231&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true; Communication From The European Union To The Council For Trips, 'Urgent Trade Policy Responses To The Covid-19 Crisis: Intellectual Property, Brussels', 4 June 2021, available at docs.wto.org/dol2fe/Pages/FE\_Search/FE\_S\_S006.aspx?Query=@Symbol=IP/C/W/680&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true; for a summary, see European Commission, 'EU Proposes a Strong Multilateral Trade Response to the COVID-19 Pandemic', Press Release, 4 June 2021, available at ec.europa.eu/commission/presscorner/detail/en/IP\_21\_2801.

<sup>&</sup>lt;sup>113</sup>For the legal situation see the sources cited in note 108.

<sup>&</sup>lt;sup>114</sup>See Banco et al., supra note 12, Ch. 3.

<sup>&</sup>lt;sup>115</sup>S. Nolen, 'Here's Why Developing Countries Can Make mRNA Covid Vaccines', *New York Times*, 22 October 2021, available at www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html.

continue to secure priority access to vaccines through bilateral agreements. Nor does COVAX in and of itself foster economic redistribution through vaccine financing for developing countries.

# 4.3 COVAX's insufficient legitimation

# 4.3.1 COVAX's distribution scheme as an exercise of international public authority

COVAX has not been granted sovereignty by the international community. It is not based on an international treaty, nor has it been embedded in a decision-making process by the collective of nations and entrusted with the task of distributing vaccines globally. There is, to be sure, a Security Council resolution on the COVID-19 pandemic that classifies it as a potential threat to peace. However, this resolution does not constitute an enabling order, especially under Chapter VII of the UN Charter. Gavi operates as a private-law actor which creates private-law legal agreements with states concerning vaccine distribution.

While COVAX's activities do not invoke a binding international-law mandate, they do refer to the WHO's 'Concept for fair and equitable distribution of health products to combat COVID-19' (see Section 3.2.2, above). This latter can be qualified as soft law which, along with the human right to health, implicates a public interest. In outlining the developmental-aid aspects of the Concept, Gavi emphasizes:

Access to life-saving immunization is a fundamental human right, and the Gavi COVAX AMC was set up to provide safe, effective vaccines to high-risk people in lower-income economies who would have been most likely to miss out on COVID-19 vaccines.<sup>117</sup>

It is thus unambiguously claimed that COVAX is acting in the public interest. Furthermore, from the point of view of WHO, COVAX serves as the practical implementation of the WHO Concept, as the applicable distribution rules for COVAX, the Allocation mechanism, are explicitly derived from the Concept (Section 3.2.2, above). Gavi's public communication about COVAX also repeatedly refers to the Allocation mechanism. This can be understood in the sense that – at least implicitly – the WHO-issued Allocation mechanism and its basis, the WHO Concept, are claimed as a public-interest, public-law legal basis of COVAX. This is not to say that COVAX is represented as a public actor itself, but it takes seriously that Gavi invokes notions of public interest and public law in representing and discursively legitimizing COVAX: it is pictured as an instrument that the international community, via the WHO has dedicated to implement the human right to health in the COVID-19 pandemic.

The extent to which developing countries can safeguard individual and public health against COVID-19 will be determined by how many vaccine doses they receive, whether funded by cash grants or given in-kind. The development-aid component of COVAX is aimed at establishing, or at least promoting, the capacity of states to vaccinate their populations. If COVAX does not fulfil this distributive task, the capacity of needy states will clearly be affected; they will be unable to broadly immunize their populations. The Concept thus helps determine a state's capacity, particularly with regard to whether developing countries can fulfil their obligations to protect individual and public health during the pandemic. As such, COVAX's distributive action qualifies as an exercise of international public authority, although it is carried out in private-law form by a private actor. As an actor exercising international public authority, COVAX requires a level of legitimacy commensurate with its function. Yet achieving this goal is hampered by institutional deficits, as

<sup>&</sup>lt;sup>116</sup>UN Doc. S/RES/2532 (2020); see also A. Peters, 'The Pandemic and International Law', Max Planck Institute for Comparative Public Law & International Law (MPIL) Research Paper No. 2021-03, at 4 (with further citations).

<sup>117</sup>Gavi, 'Protecting Human Rights in the COVAX Roll-Out', available at www.gavi.org/covax-facility/protecting-human-rights.

<sup>118</sup> E.g., ibid.: 'COVAX distributes vaccines equitably according to a Fair Allocation Mechanism'.

outlined in Section 4.3.2, below. Further, there are problems affecting COVAX's performance, as argued in Section 4.4.3.

# 4.3.2 Institutional legitimacy of COVAX

COVAX's approach to legitimacy is private law-contractualist in nature. Although COVAX is not based on a mandate from the international community under international law, the mechanism is legitimized (and empowered) by participating states – namely, through private treaty-based participation. Through private contracting, states have delegated key aspects of marketplace vaccine procurement to COVAX. In addition, they entrust COVAX with distribution – and in doing so, at least implicitly agree to the WHO's distribution Concept. In doing so, however, they remain responsible for protecting individual and public health by providing vaccination against COVID-19. Countries' participation in COVAX can serve to practically operationalize and accomplish its mission. However, COVAX (or respectively Gavi) has not been assigned responsibility for fulfilment. The human right to health (see Section 4.1.1, above), ensures that this is a 'public guarantee function' which cannot be privatized.

In the case of COVAX, the selection of private actors and the contractual design and circumscription of its fulfilment responsibilities as a lever of the state's guarantee responsibility are largely omitted. States cannot choose among various possible private actors to collaborate on vaccine procurement. Their only option is COVAX, because it has a virtual monopoly on global procurement and distribution. However, the problem does not lie primarily in the use of a private actor, the lack of technical and infrastructural capacity, or Gavi's unreliability with respect to vaccine procurement and distribution. Rather, the main problem is that the bilateral agreements with Gavi cannot be used to guide the activity of COVAX as a normative matter. COVAX is a predetermined, pre-formed mechanism whose terms cannot be altered or adapted by means of individual contracts. The contracts that participating states conclude with Gavi specify the terms for vaccine purchase. They do not affect the functioning of COVAX and, in particular, do not subject COVAX to legitimizing requirements of a democratic and constitutional nature. As a result, the institutional design of COVAX does not point to ways in which states can realize their guarantee responsibilities.

In particular, there are no mechanisms which states can use to jointly steer and control decision-making concerning COVAX and its activity in a centralized manner. There is no mechanism by which states can collectively manage or hold Gavi accountable for the global distribution of vaccine doses. Since COVAX has not been jointly mandated by participating states through a formal act of international law, the mechanism is not 'removable' by a joint decision regarding its function. To be sure, that states may individually assert private-law treaty violations. However, individual contracts do not permit claims against COVAX based on overall deficient performance with respect to the established target levels of global distribution, particularly with respect to delivery to developing countries: Gavi simply has no obligation to individual contractors to objectively comply with the WHO principles that concern the criteria for the international distribution of vaccines.

Another problem with the institutional design of COVAX is that donor and developing countries do not participate in the same way. They participate through different bodies. The consortium for self-financed states is not open to developing countries (see Section 3.1.4, above). This unequal and separate institutional involvement is not solely an organizational issue of practical

<sup>&</sup>lt;sup>119</sup>As a regional mechanism for Africa, there is at least AVATT (Africa Vaccine Acquisition Task Team) or AVAT (The African Vaccine Acquisition Trust) under the leadership of the African Union, see <a href="https://www.au.int/en/newsevents/20211026/special-press-briefing-provide-update-africa-vaccine-acquisition-task-team-avatt: 'AVAT' acts as a centralised purchasing agent on behalf of the African Union (AU) Member States, to secure the necessary vaccines and blended financing resources for achieving Africa's COVID-19 vaccination strategy which targets vaccinating a minimum of 60% of Africa's population based on a whole-of-Africa approach.'

participation. It creates a status distinction which does not comply with the principle of the formal equality of states. This distinction thus ultimately signals a disparity in importance, and performatively highlights the fact that dominance and dependency relationships exist in world politics between rich and poor states, and increasingly in the global pandemic.

# 4.3.3 Output legitimacy: The performance of COVAX

COVAX's instrumental importance for the practical implementation of ensuring global access to vaccines (a responsibility imposed by human rights guarantees) points to its output – that is, how successful it is – as an important source of legitimacy. A key aspect of COVAX's legitimacy is, accordingly, whether it ensures equitable global vaccine distribution. From an economic standpoint, COVAX, as noted above, is based on a buyers' consortium. Establishing such a consortium on a global scale was expected to mitigate some of the problems created by the pandemic vaccine market: COVAX aggregates demand, aims to increase buyers' bargaining power, unlock economies of scale, and increase the portfolio of vaccines that purchasers can access. Finally, COVAX was intended to provide developing countries with an escape route from market competition, which would otherwise have denied them equal access to sufficient vaccines to meet their needs. The idea behind COVAX was to replace vaccine nationalism with collective action.

However, this aspiration seems contradicted by practical realities, namely that self-financing states have not used COVAX to date, or at least not exclusively, for vaccine procurement. This reflects a fundamental design problem: the contracts between Gavi and self-funded states do not require the latter to procure vaccines exclusively through COVAX. This is no mere oversight: An exclusivity requirement would likely have deterred richer nations from participating in COVAX. Under current conditions, wealthier countries continue to use their own procurement contracts. For example, according to figures from the UNICEF's COVID-19 Vaccine Market Dashboard, as of March 2023, Germany has used bilateral and multilateral agreements outside COVAX to secure about 500 percent of the demand for (basic) vaccination of its population. The figures are comparable for all European countries. The US has reached about 600 percent; Canada about 870 percent. To reiterate: these figures are for vaccine volumes contracted outside of COVAX.

The solidarity-based idea was that all states would use COVAX as a common procurement tool, abandoning market competition in favour of equal distribution of available vaccines according to *pro rata* principles derived from the WHO Concept. This, however, has not happened in practice. Competition for vaccines and unequal distribution based on ability to pay still exist.

However, it is not just the COVAX collective procurement mechanism which is not performing as well as the WHO Concept mandates. The development-aid dimension also suffers from unmistakable problems: the funding available for the development-aid aspect of COVAX has fallen far short of what is needed. For 2020/2021, for example, donor countries had contributed only *half* of

<sup>120</sup> Gavi, 'COVAX Facility, Terms and Conditions for Self-Financing Participants', at 16, available at www.gavi.org/sites/default/files/covid/covax/COVAX-Self-financing-Participants-Legal-Agreements-and-Explanatory-Note.pdf: "The Facility recognises that some Participants and COVAX AMC Eligible Economies will come to the Facility with bilateral deals. The Facility welcomes these Participants and COVAX AMC Eligible Economies to join recognizing that the Facility, Participants and COVAX AMC Eligible Economies all benefit by having the greatest number of Participants and COVAX AMC Eligible Economies involved. The Facility has a duty to ensure that the founding principles of solidarity and equity remain intact for all Participants and COVAX AMC Eligible Economies so that together, we bring the pandemic under control as quickly as possible.'

<sup>&</sup>lt;sup>121</sup>UNICEF, 'COVID-19 Market Dashboard', Estimated Population Coverage from Bilateral/Multilateral Supply Agreements, Excluding COVAX, available at <a href="https://www.unicef.org/supply/covid-19-vaccine-market-dashboard">www.unicef.org/supply/covid-19-vaccine-market-dashboard</a>.

<sup>&</sup>lt;sup>122</sup>See also Venzke, *supra* note 111; Von Bogdandy and Villarreal, *supra* note 4, at 15, who predict, based on the situation described in the text and on the structure of COVAX, that: '... the populations of richer countries are likely to be better served'.

the funds needed to finance the vaccine needs of developing countries. <sup>123</sup> Only six countries contributed at a level equal to or exceeding their 'fair share'. <sup>124</sup> Direct donations of vaccine doses to COVAX have also so far fallen considerably short of the promised quantities: the promised doses had an estimated value of approximately US\$1.6 billion, but COVAX had received just under one-third of them by the end of November 2021. <sup>125</sup> Vaccines are often donated on short notice and in small quantities, with short remaining shelf lives and without necessary equipment. This complicates the planning and logistics of vaccination campaigns in recipient countries and affects the viability of the donated vaccines. <sup>126</sup>

COVAX's lack of adequate resources also shows in the fact that the September 2021 forecast for vaccine delivery to developing countries was a quarter lower than predicted in June of that year.<sup>127</sup> By the end of 2021, shipments from COVAX were meant to have reached the target of vaccinating 20 percent of the developing world's population. <sup>128</sup> This target was missed by a wide margin – for example, as of January 2022, an average of only about 14 percent of the population in Africa had received a single vaccination, although the range was broad: at the bottom of the scale were Burundi, Congo, Chad, or South Sudan, with vaccination rates below 3 percent. 129 At the time, 72 percent of global immunizations had been administered in high- and middle-income countries, but less than one percent in low-income countries. 130 Still in March 2023, an average of 37 percent of the African population had been vaccinated against the Coronavirus at least once. Worldwide, some of the lowest-income countries, like Haiti, Yemen, or Burundi, still had less than 4 percent of their respective population vaccinated at least once. In contrast, about 75 percent of people in Europe and about 80 percent in North and Latin America as well as in the Asia-Pacific region had received at least one dose of vaccine at that time.<sup>131</sup> The delayed and unequal access to vaccinations of low-income countries has led not only to prolonging the pandemic, but also to slowing down economic recovery and development, and to increasing poverty. 132

## 5. Conclusion

By controlling global distribution of vaccines in the COVID-19 pandemic, COVAX exercises international public authority: the scheme is based on the public-law foundation of the WHO distribution Concept; it is intended to implement the Concept in practice and invokes these provisions of international 'soft law' to justify its function and activity. COVAX serves a public interest, securing the human right to health in the pandemic on a global scale. COVAX

<sup>&</sup>lt;sup>123</sup>WHO, Contributions of public donors as a proportion of their fair share against ACT-A 2020-21 funding need, as of 29 October 2021, available at www.who.int/docs/default-source/coronaviruse/act-accelerator/20211029—act-a-commitment-tracker\_vf.zip?sfvrsn = bbafd89d\_5&download = true.

<sup>&</sup>lt;sup>124</sup>Ibid.

<sup>&</sup>lt;sup>125</sup>WHO, ACT-Accelerator Dose Sharing Through COVAX Tracker, available at www.who.int/docs/default-source/coronaviruse/act-accelerator/20211029—act-a-commitment-tracker\_vf.zip?sfvrsn = bbafd89d\_5&download = true.

<sup>&</sup>lt;sup>126</sup>UNICEF, Joint Statement on Dose Donations of COVID-19 Vaccines to African Countries: A Joint Statement from the African Vaccine Acquisition Trust (AVAT), the Africa Centres for Disease Control and Prevention (Africa CDC) and COVAX,29 November 2021, available at <a href="https://www.unicef.org/supply/press-releases/joint-statement-dose-donations-covid-19-vaccines-african-countries">www.unicef.org/supply/press-releases/joint-statement-dose-donations-covid-19-vaccines-african-countries</a>.

<sup>&</sup>lt;sup>127</sup>Gavi, 'COVAX: The Forecast for Vaccine Supply', 13 September 2021, available at www.gavi.org/vaccineswork/covax-forecast-vaccine-supply.

<sup>&</sup>lt;sup>128</sup>Gavi, 'Joint COVAX Statement on Supply Forecast for 2021 and Early 2022', 8 September 2021, available at www.gavi. org/news/media-room/joint-covax-statement-supply-forecast-2021-and-early-2022.

<sup>&</sup>lt;sup>129</sup>See Holder, supra note 9.

<sup>&</sup>lt;sup>130</sup>Ibid.; see also www.data.undp.org/vaccine-equity/.

<sup>&</sup>lt;sup>131</sup>See Holder, *supra* note 9; EU Figures, available at www.vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab.

<sup>&</sup>lt;sup>132</sup>UN News, 'UN Analysis Shows Link between Lack of Vaccine Equity and Widening Poverty Gap', 28 March 2022, available at www.news.un.org/en/story/2022/03/1114762.

also exercises public authority: COVAX's provision of vaccines determines state capacities, particularly in needy developing countries. They depend on COVAX to fulfil their responsibility – which derives from human rights guarantees – to protect their populations in the pandemic by vaccination.

The human right to health imposes an obligation on states to co-operate and to not hinder other states' attempts to safeguard public health. There is a lively debate on the question of whether human rights create a positive obligation to provide development assistance, known as an 'obligation to fulfil' – and whether this obligation might be invoked to justify an obligation to provide vaccines to developing countries during a pandemic. If so, it is assumed that reservations based on sovereignty and funding would still limit any such positive obligation.<sup>133</sup> The human rights obligation to co-operate, by contrast, is more firmly-grounded: according to Philipp Dann, it is possible to derive a legal principle of development from international law which obliges international organizations and states to co-operate. This principle obliges states to make concrete efforts to enable the delivery of development aid.<sup>134</sup>

COVAX can certainly be interpreted as a form of co-operative action by states; after all, the mechanism is intended to jointly procure vaccines and to enable developing countries to share in access to vaccines through development-aid funds. COVAX indeed has a practical role to play here due to the lack of an international-law framework for vaccine distribution during the pandemic. However, there is also a downside to COVAX's role: COVAX's activities ultimately reflect a lack of international consensus for an effective, co-ordinated global pandemic response under international law, such as within the WHO framework. High hopes were placed in COVAX: 'COVAX could become a vehicle for sustainable solidarity'. 135 A closer analysis of COVAX's design, however, brings disappointment. COVAX has not, in fact, met the need for a mechanism to distribute vaccines in an effective, global, equitable manner. The problem is also one of timing: global access should not be postponed (any longer) but must rather be pressed forward without delay. Developing countries have received some vaccines so far, which is unquestionably better than nothing. However, under current practice, the targets set by the WHO Concept - to say nothing of the vaccination rates which rich countries enjoy - will not be consistently and timely achieved in developing nations. COVAX's performance falls short of specified targets. For the time being, it simply cannot be argued that the COVID-19 vaccines are being equally distributed among the world's population.

There is no centralized mechanism to hold Gavi, the legal administrator of COVAX, accountable for the failure to achieve specified targets. This, however, is consistent with COVAX's dependence on rich countries to voluntarily pledge – and actually contribute – timely assistance. Gavi is, in fact, not primarily responsible for ensuring the effectiveness of COVAX, except in case of administrative failures – but these do not appear to reason for COVAX's ineffectiveness. It is, rather, lack of solidarity on the part of wealthier states which explains why developing countries still lack sufficient access to vaccines.

As an institution, COVAX is characterized by freedom of contract under private law and the voluntary nature of state action; the scheme is built on the assumption of self-determined

<sup>&</sup>lt;sup>133</sup>See Dann, *supra* note 89, at 278 et seq: 'Even from a human rights perspective, the duty to fulfill does not stipulate unlimited obligations but is subject to available resources. The duty also cannot realistically be said to apply to all humans worldwide. Germany's human rights duties also need to be harmonized with its rights under international law. These include sovereignty over its own resources. Provision of aid based on a human rights obligation is therefore contingent on government approval. This does not preclude these rights from turning into a positive duty to provide assistance, e.g., in the extreme case of famine or natural disasters, if the minimum core of rights, such as the right to food, cannot otherwise be protected. But these duties are subject to the availability of funds.'

<sup>&</sup>lt;sup>134</sup>Ibid., at 278 et seq.

<sup>&</sup>lt;sup>135</sup>See Von Bogdandy and Villarreal, *supra* note 4, at 20. The authors, however, qualify this statement with the caveat that some pressing problems would have to be solved for this aspiration to be fulfilled; in particular, financing would have to be secured.

participation in COVAX based on a free decision by participating countries. This contractualist mode of legitimation is, of course, contradicted by the very neediness of the lowest-income states: they have virtually no other procurement options. Gavi thereby contractually dictates the terms of vaccine access, requiring recipients to accept broad liability waivers. As a practical matter, countries are not genuinely free to opt out. Voluntariness is also a problem on the donor side: COVAX preserves the freedom of rich countries to exercise solidarity and allow equal access, or to opt out of procurement and continue vaccine nationalism – all while enjoying 'cover' provided by participation in COVAX. Even the amount they give remains ultimately the free choice of the rich states. The voluntary nature of global (re)distribution of vaccines means that COVID-19 has so far been brought under control through relatively broad vaccination primarily in circumscribed, wealthy regions of the world. Yet the limited nature of vaccine distribution means success is always only temporary. This state of affairs cannot be justified by the argument that each country must first protect its own population. An alternative would have been perfectly conceivable and justifiable: to restrict vaccination initially to risk groups until they had been vaccinated everywhere, and only then to offer vaccination to the whole population.

The scheme suffers from a structural problem which goes beyond the 'output' of COVAX: the principle of donation maintains and performatively reinforces the general pattern of a power imbalance and structural inequality between developed and developing countries. This critique also applies to the institutional design of COVAX. The fact that donor and recipient countries are involved separately and not on an equal footing also makes it difficult to politicize the structural and practical problems which might arise from COVAX's own practice. Furthermore, while states, one the one hand, contribute by far the biggest share of financial means to COVAX (developed states) and, on the other hand, depend on COVAX for access to COVID-19 vaccines (developing states), there are no structures in place by which the community of states can effectively hold Gavi accountable for the administration of COVAX. Overall, there are clear deficiencies in the legitimation and organization of international public authority which COVAX exercises. COVAX thus demonstrates the problems of voluntary co-operation between states organized under private law and the application of market economy principles in the field of international public health.

Action by the international community through COVAX has not yet assured the equitable global access to vaccination required to protect individual and public health protect during the pandemic. In particular, people at special risk in the poorest countries still do not have universal access even more than two years since the first vaccines were licensed – while in richer countries, it has been possible not only to vaccinate the broader population, but even to provide boosters. The continuing steep disparity in immunization access between rich industrialized countries and low-income developing countries highlights the fact that, under COVAX, countries have so far objectively failed to provide developing countries with opportunities for co-operation – and especially the support – which the human right to health requires.

<sup>&</sup>lt;sup>136</sup>See also Venzke, *supra* note 111: 'Donations must however not be mistaken for acts of justice, which would require a transformation of the conditions of dependence and domination.'

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