



FINANCING THE PRODUCTION AND SUPPLY OF COVID-19 VACCINES

T. Anev*

Department “Finance and Accounting”, University of Plovdiv Paisii Hilendarski, Plovdiv, Bulgaria

ABSTRACT

This paper presents a summary of two of the world’s biggest programs for securing global access to COVID-19 vaccines. It is narrowed on account of the character of the programs, as well as the diverse modes of financing the vaccine procurement and concludes with the financial scope of the supplementary activities – mechanism of dose donations and strengthening the national cold chain systems.

Key words: COVID-19, Pandemic, ACT-A, COVAX, Vaccine contracting, financing the immunization projects

INTRODUCTION

The response to the COVID-19 crisis had to be addressed with a rapid and integrated approach, coordinating the efforts of many stakeholders. The simplified paradigm could be divided in 5 dimensions – development, production, financing, recipients, and coordination of the distribution. At this point, almost 61% (June

2022) of the world population is vaccinated. A large part of the doses needed for these vaccinations were exported or shared by Europe (1, 2). **Figure 1** shows the distribution according to regions of the percentage of population that received COVID vaccination (3).

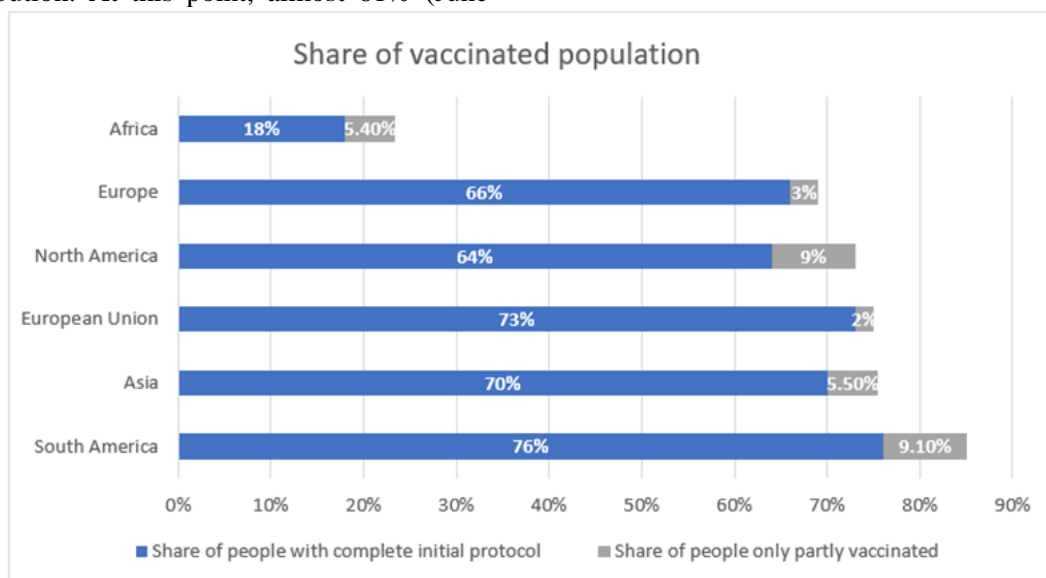


Figure 1. Share of vaccinated population, June 2022

Source: ourworldindata.org (3)

*Correspondence to: Todor Anev, Department “Finance and Accounting”, University of Plovdiv Paisii Hilendarski, Plovdiv 4000, Bulgaria, t.anev@uni-plovdiv.bg

METHODS

This paper consists of 5 parts, explaining in narrative two aggregating mechanisms used to secure availability of COVID-19 vaccines

worldwide – ACT-A and COVAX. This paper uses publicly available data and resources in order to compile an overview of the mentioned programs.

The basic aim is to present a comprehensive summary of the key elements of the financial framework used to shorten the time of development, scale the production and secure wide geographical coverage of the procurement of COVID-19 vaccines.

SUMMARY OF FINDINGS

Description of the mechanism gavi

ACT-A

The ACT-A mechanism stands for “Access to COVID-19 Tools Accelerator”. This is the biggest mechanism that aims to secure equal opportunity and actual access to measures aiming to fight the COVID-19 pandemic. It is composed of three main pillars - vaccines and other immunization supplies, laboratory, and diagnostics (RTDs), therapeutics (monoclonal antibodies – mAbs). The mechanism is based on a piled funding structure designed to scale up development, production and procurement of COVID-19 tools falling into one of its three main pillars. Besides of the financing for the COVID Tools, the ACT-A mechanism provides coverage of the supplemented costs such as transport, logistics and distribution called supply-related expenditures. The initial mechanism aim was to provide access to 500 million tests, 245 million treatment courses and 2 billion doses of vaccines during 2021. (4)

COVAX

COVAX is one of the three pillars of the Access to COVID-19 Tools (ACT-A) Accelerator, which was launched in 2020 as a response to the COVID-19 pandemic (5). The COVAX pillar is focused on the provision of the immunization pillar of the ACT-A program. It is coordinated by Gavi (6), the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, COVAX will achieve this by acting as a platform that is supporting the research, development, and manufacturing of a wide range of COVID-19 vaccine candidates and negotiate their pricing. (7)

Figure 2 shows a schematic representation of the COVAX facility and its overseeing bodies (8). Countries have been invited to participate in the mechanism where together with their application each country is categorized in category I - Advance Market Commitment (AMC) countries – this includes the 92 poorest countries in the world and II : Self-financing Countries (SFC) – in this section are mainly higher low- and mid-income countries. Each of the two sections has equal access to the COVID vaccines and devices and the difference between the categories is in the mode of which the countries are financing the commitment or the purchase of vaccines and devices. The initial aim was to secure 2 billion doses of vaccines in 2021.

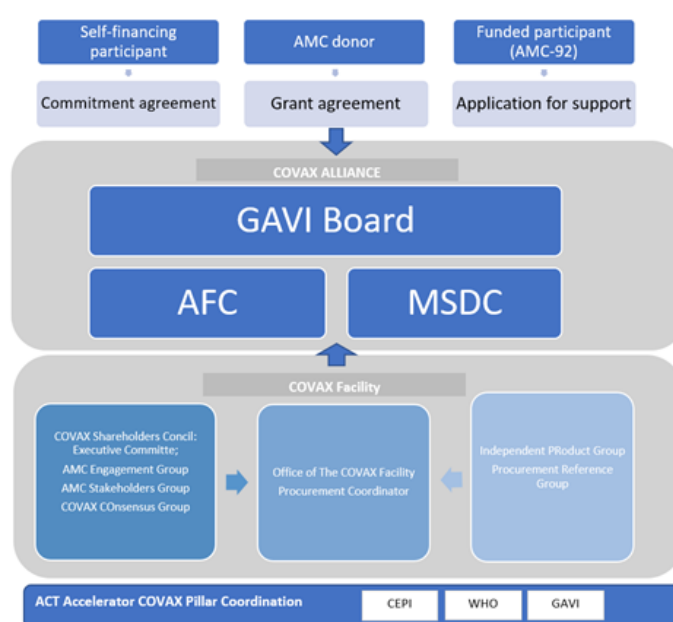


Figure 2. COVAX facility and its overseeing bodies
Source: unicef.org (8)

Mainly the countries in AMC-92 will receive access to financing which will allow them to secure and afford the purchase of COVID-19 vaccines. Through the COVAX facility the more developed countries, which can afford the purchase, but lack bilateral agreements with the manufacturers, have security for doses allocated to them for a specific moment of distribution for up to 20% of their population. Another positive effect is that by aggregating the funding under one mechanism allows COVAX to act on immense scale and fund the development of potential vaccines – this is aiming to increase the chances of final products being launched on the market.

Financing the Mechanisms.

GAVI COVAX.

The process of financing the operations part of the GAVI COVAX mechanism depends in

which group a particular country takes part in – AMC-92 or the SFC group.

AMC-92 Group. Financing for this group is entirely separated from the funds managed on behalf of the SFC group, i.e., it is not possible that self-financing countries are advancing financial resources to the countries part of the AMC-92 group. The fundraising for AMC-92 is done mainly through Official Development Assistance (ODA), which are governmental contributions (of third countries), as well as private contributions. At the 3rd quarter of 2020 the facility has accumulated USD 700 million seed capital where the target was set to achieve USD 2 billion by the end of quarter 4 of 2020 (7). **Figure 3** shows the biggest governmental contributors to the COVAX facility budget, the figures represent pledges per USD 1M of GDP. (9)

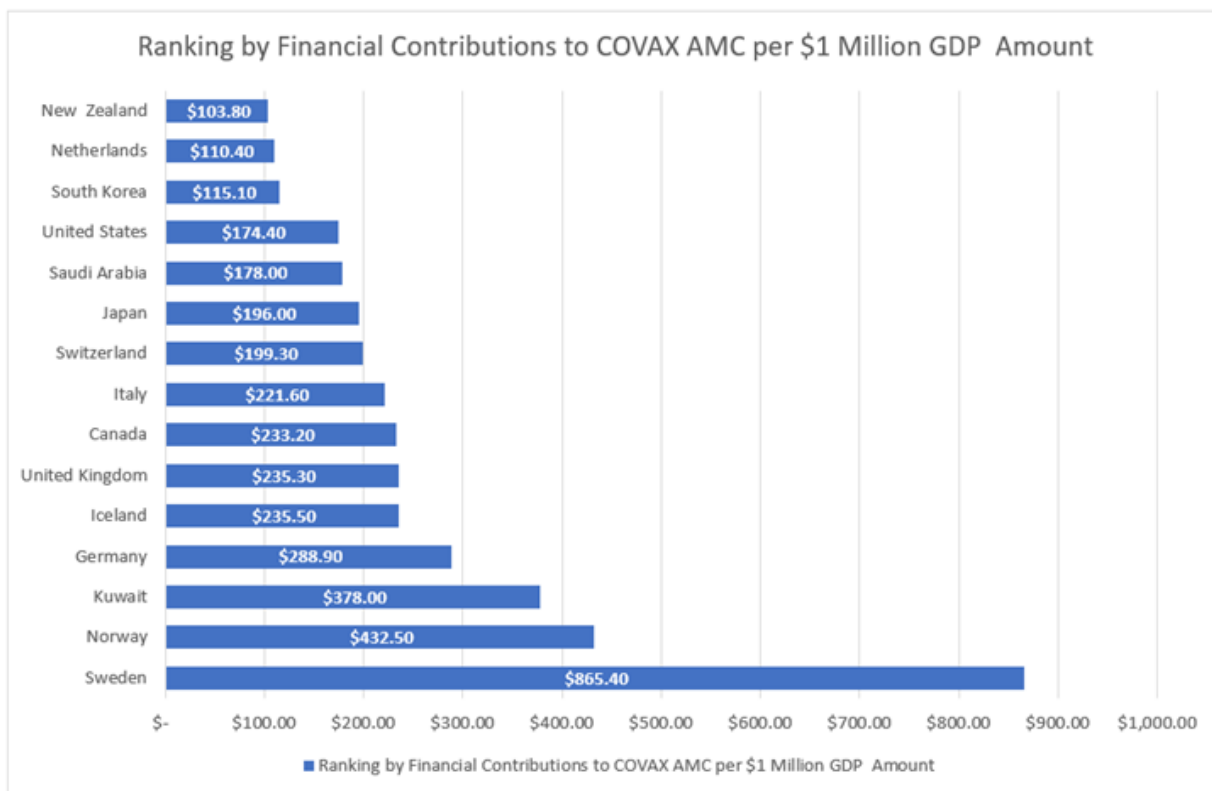


Figure 3. The biggest governmental contributors to the COVAX facility budget
Source: kff.org (9)

Group of SFC (Self-Financing Countries). About 78 higher-income (comparatively) countries and economies have confirmed initial interest in participating the COVAX Facility by the end of 2020 (7). The modality through which the SFC group is participating in the financing of the process of development, production and procurement of vaccines is that

each participating country is committing participation between 10 and 50% of its population. At the time of signing the agreement the schedule of submitting partial pre-payment tranche.

There are two types of purchasing commitment. The Committed purchase agreement is binding to purchase a given number of vaccines – under

this modality the country needs to prepay USD 1.60 per dose (ar. 15% of the price). The other type of commitment is called Optional Purchase Arrangement where the countries could opt out from receiving previously specified quantity and those quantities will be distributed to other countries when they are produced (if not penalty fee is paid). The pre-payment price that is required under this modality is USD 3.10 and additionally a risk sharing guarantee of USD 0.40 is added. The funds are accounted in synthetic account for the country at the GAVI COVAX facility, however, the merged capital is used to advance funding and secure the production line of the vaccines to the selected manufacturers.

There is a specific sub-group part of the general SFC group called Cost Sharing Group (CC). Countries falling in this group, based on their participation agreement in the GAVI COVAX facility, have received loans from big financial institutions such as the World Bank group. The loans are entirely designated to serve for

purchase of COVID-19 vaccines and the tranches are disbursed directly to the COVAX facility.

The ACT-A.

The main fundraising for the ACT-A initiative is done among governments and big financial institutions where the agreed contributions follow signature of contributions agreement. The financing can be directed to one of the three pillars of the ACT-A where the donor might express preferences to either of the three pillars, as well as to a specific geographical region recipient of the aid or even specific countries that might receive their aid. The donors are also able to restrict their donations in time. The initial ACT-A goal is providing low- and middle-income countries with 500 million tests, 245 million treatment courses and 2 billion doses of vaccines during 2021 (4). Whether the figures are achieved is not yet announced, however, **Figure 4** shows the financial gap of fundraising linked to the aimed security as of June 2022 (10).



Figure 4. The financial gap of fundraising linked to the aimed security, June 2022
Source: unicef.org (10)

Financing the development, manufacturing, and dose allotment.

Vaccine development financing.

According to the data published by GAVI in the beginning of the research process there were more than 170 candidate-vaccines in different stages of their development or clinical trials. Based on previous similar development of new vaccines, the cited figures are that there is 7%

chance of success for vaccines in pre-clinical stage and about 20% chance of success for those reaching clinical trials. This low ratio of success is particularly non-motivating for developers and manufacturers to invest vast amount of funds towards scaling up and production preparation until they received an approval of the vaccine. In the situation of ongoing pandemic this approach would cost

valuable time and immense lost for the World Economy (according to GAVI figures it cost USD 375 billion per month).

Instead, the COVAX facility uses the collective purchasing power to advance the needed financial liquidity of the producers so they can have the financial security in investing in future production. Further, the facility uses the scaling up to negotiate fair and more stable pricing for the participants. This is pricing that lacks differentiating per region or income level. As a

pass-through facility, participants pay the amount for the doses that was negotiated by the facility, plus a speed premium invested in accelerating and scale-up of manufacturing, as well as a very small fee for the operation of the facility. Some manufacturers will be providing vaccines at flat prices where others will be tiering the prices based upon income levels (7). **Figure 5** shows visualization of the contracted manufacturers per recipient country or region and the respective secured doses for that country from the given supplier (11).

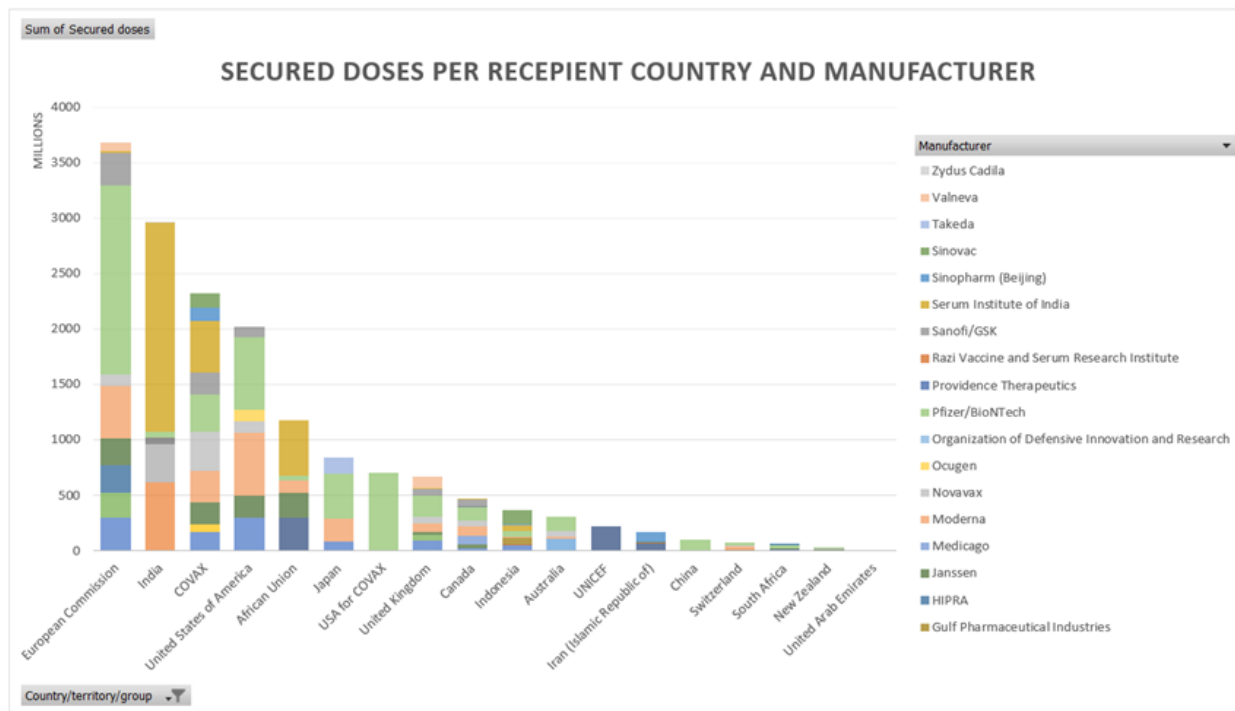


Figure 5. Visualization of the contracted manufacturers per recipient country or region and the respective secured doses for that country from the given supplier
Source: unicef.org (11)

Allotment of doses from the manufactured vaccines

Once any of the COVAX portfolio vaccines have successfully undergone clinical trials and proved themselves to be both safe and effective, and have received regulatory approval, available doses will be allocated to all participating countries at the same rate, proportional to their total population size. A small buffer of about 5% of the total number of available doses will be kept aside to build a stockpile to help with acute outbreaks and to support humanitarian organizations, for example to vaccinate refugees who may not otherwise have access. (7)

Even though self-financing participants can request enough doses to vaccinate between 10-50% of their population, no country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this amount. The only exception is those countries who have opted to receive fewer than 20% (7). The visualized overview of contractual stats is shown in **Figure 6**. The negotiated prices depending on the supplier and recipient are reported to be in the range USD 2- 40. (12)

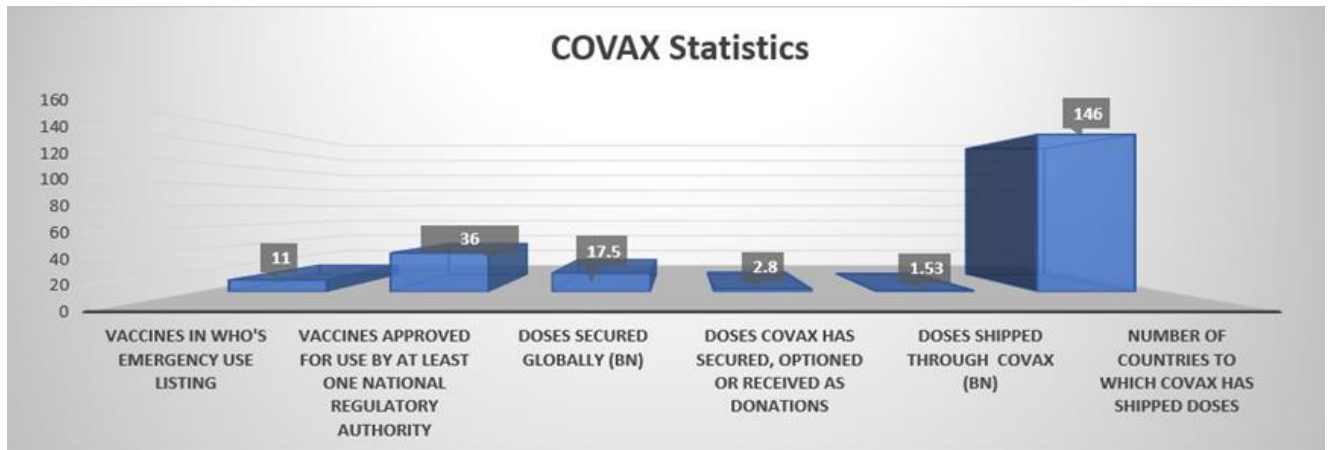


Figure 6. Overview of contractual stats
Source: unicef.org (12)

Figure 7 shows the price range depending on the manufacturer and recipient country/region. Each mark presents the price of a specific producer in a given country/region. For the sake

of a better visualization, only a benchmarking set of countries/regions recipient of the doses is presented. (11)

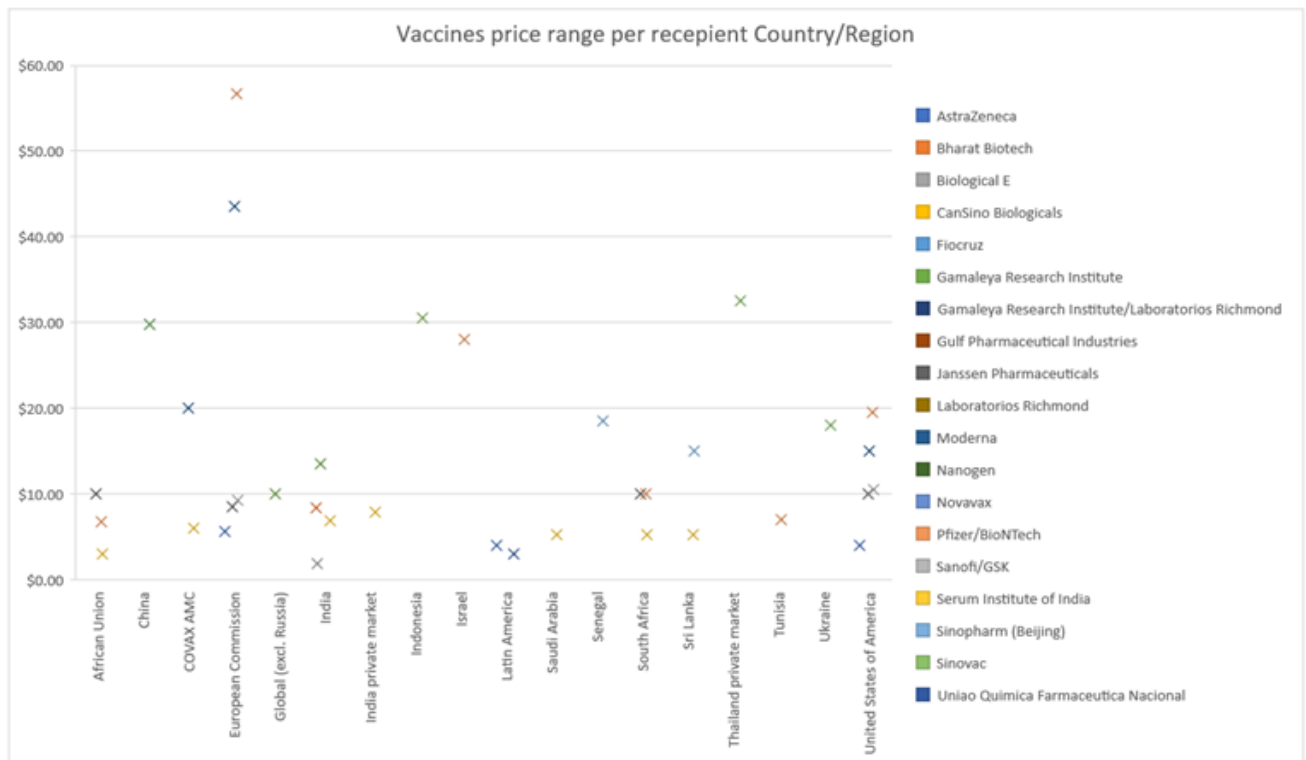


Figure 7. Price range depending on the manufacturer and recipient country/region
Source: unicef.org (11)

NFC – meaning/ operationalization

Although subject to clinical trials, vigorous control and regulations, pharmaceutical products of any kind such as the vaccines can cause, with variable low chance, serious injuries, usually the liability for those serious injuries is covered by the manufacturers with tools such as the product liability insurance, however, in the case of the COVID vaccines, due to the scale of the application, this option is not financially feasible. Therefore, WHO

together with GAVI developed a program called “COVAX No Fault Program” (NFC). The program is aimed to protect both the population receiving the vaccines as well as the manufacturers and the governments of the AMC low-income countries that might not be able to respond to financial indemnity.

This compensation is funded by COVAX from donor contributions and equals USD 0.10 levy per dose for 2 dose vaccines and USD0.20 per

dose for single dose vaccines, delivered by the mechanism. The whole NFP is insured by a licensed insurance company for the risk of compensation payments.

Any individual in an AMC-eligible country who suffered from a serious injury after receiving a COVID-19 vaccine needs to file a claim. The claim is then reviewed from independent panels of nurses and physicians, run by scientific panels of public health experts who consult with recent scientific publications. The NFP aims to ensure transparent and fair process of claims and it provides a universal formula of calculating the compensation in oppose to a court trial where the compensation depends on the legal power of the claim. The formula is presented below.

Compensation Value = GDP (of the AMC residency of claimant) x 12 x HarmFactor

From (1): Harm Factor - it is ranging from 1.5 to 0.1 dependent on the nature of the injury and the level of impairment, as evaluated based on most recent scientific publications of American Medical Association's Guide to the Evaluation of Permanent Impairment. Guides have been developed by medical specialists and are consensus-derived estimates that reflect the severity of the medical condition and the degree to which the impairment decreases an individual's ability to perform common activities of daily living. (13)

For the countries participating in COVAX outside of the AMC group it is either their government that covers the indemnity or they might participate (self-finance) in other similar schemes – such as the one run under the ACT-A initiative.

Dose donation.

Dose donation is a set of mechanisms that aims to re-distribute vaccines that are already purchased but will not be used from the original recipient country until the expiration of their shelf life. One example of such a process is the European vaccine sharing mechanism. The creation of this measure was announced on 19th of January 2021 by the European Commission, when it was underlined that the doses purchased by the Member-States, that will remain unused

will be shared with partner-countries, with special emphasis on the countries of the Western Balkans, Southern and Eastern neighbors to the EU and Africa. (14)

The initial goal was to share 700 million vaccine doses by mid-2022. By February 2022 the 27 EU Member-States have shared 408 million doses with other countries, outside of the EU. The bigger part of those (353 million doses) have been shared via the COVAX mechanism. Another 56 million doses have been delivered via bilateral agreements between the 27 EU Member-States and the recipient countries to the countries of the Western Balkan region. **Figure 8** presents the portion of the donated doses compared to the total number of delivered and announced doses, per donating entity in million doses. (14)

Strengthening the national health systems

As an additional measure to ensure the access to vaccines world-wide as well as to secure the process of vaccination, there are mechanisms aiming to strengthen and prepare national health systems, so they fit the technical requirements, for example, those for distribution, transportation, and storage of the vaccines. Such is the program CCE (Cold Chain Equipment) of COVAX aiming to build or strengthen the Cold Chains or the Ultra Cold chains in a given country. The GAVI board set up USD 150 million for support of the cold chains and ultra-cold chains in the countries participating in the AMC group of COVAX. This measure ensures that the vaccines will reach the distant districts in safe and in usable undamaged condition.

The initial focus was on the 56 poorest countries which needed immediate attention to their CC (2-8C) and UCC (-20C). The package of financing includes delivery of refrigerators, service of installation and the remote monitoring of temperature (RMTDs) and on some occasions - the financing is used for short-period rental of cold chain storage. The remaining 35 AMC countries are also eligible to receive aid based on the funding availability after the initial goal is achieved.

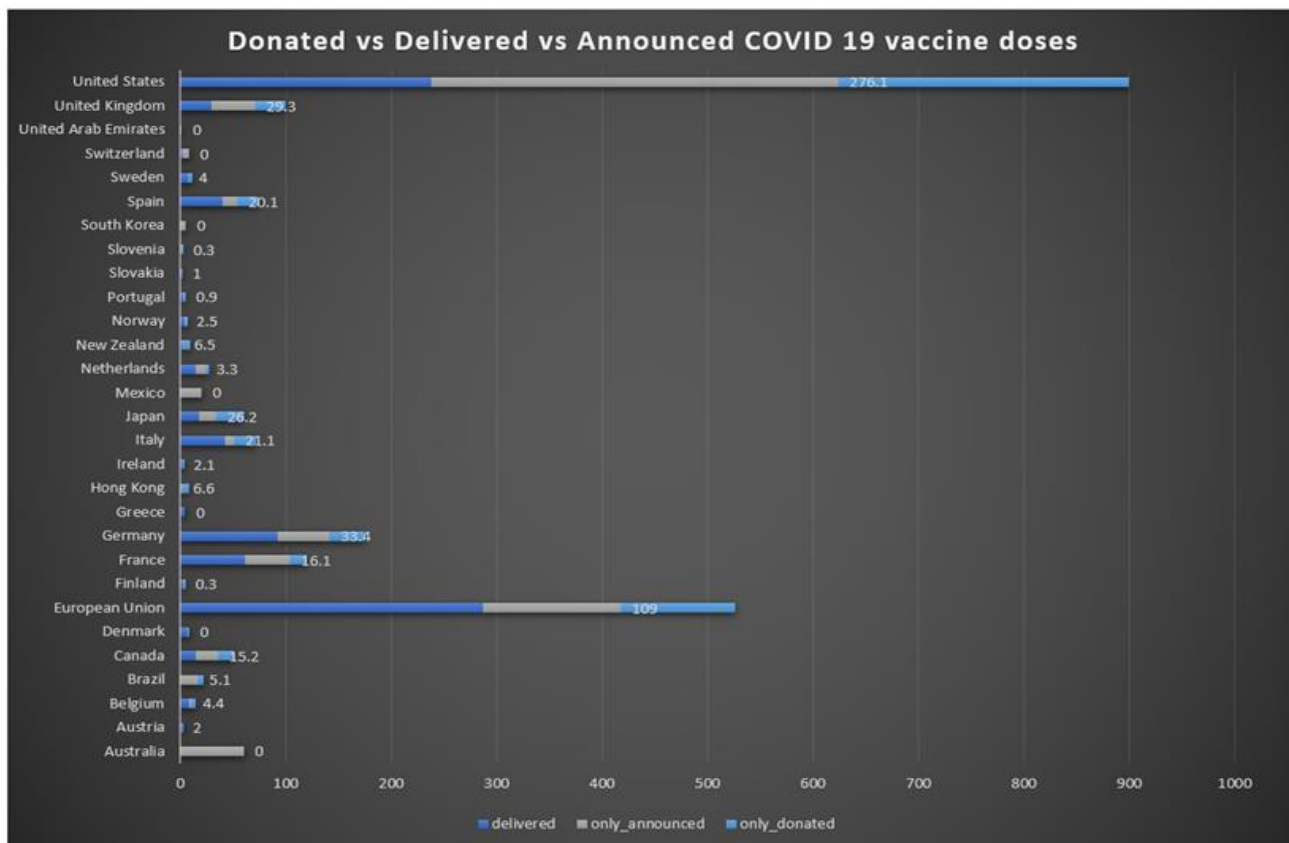


Figure 8. The portion of the donated doses compared to the total number of delivered and announced doses, per donating entity in million doses

Source: ourworldindata.org (14)

COMPARATIVE SUMMARY BETWEEN THE COVAX AND ACT-A MECHANISMS

Table 1 shows the summary of the major comparison factors between the two mechanisms – COVAX and ACT-A. It is evident by the presented data that the major differences between the two mechanisms are in three points.

- The COVAX mechanism is directly involved into the support of the research process of making the vaccines available on the market and ensures initial doses allocation, contracted with each eligible supplier, while ACT-A is rather used as a financial resource to supply the doses

already allocated by other mechanisms (including those from COVAX).

- The mobilized resources at COVAX are managed in a variety of different modalities where with ACT-A the funds are predominantly managed as trust fund accounts.
- COVAX offers a price per dose differentiation depending on the modality in which the recipient country is involved, whereas ACT-A offers a fixed price for each of the supplied type of vaccines, regardless of the recipient country.

Table 1. Summary of the major comparison factors between the two mechanisms – COVAX and ACT-A

Comparison Factor	COVAX	ACT-A
Initial manufacturer contracting for vaccines development	Yes	No
Initial allocation of vaccine doses at the manufacturers	Yes	No
Use of the allocation of doses from other mechanisms	No	Yes (COVAX)
NFC covered	Yes	Yes
Dose donations covered	Yes	Yes
Providing support of 100% of the cost value of the vaccines + additional costs such as shipping and insurance	Yes	Yes
Providing differentiation of the price per dose depending on the modality contracted	Yes	No
Providing participation for self-paying countries	Yes	No
Collective management of the donor funding (funds are co-mingled regardless of their source donor)	Yes	No
Segregation of the funds per donor (the facility acts as a principle, but the funds are segregated per donor/paying country)	Yes	No
Managing the funds as trust funds accounts (the facility acts as an agent)	No	Yes

CONCLUSION

The magnitude and the speed of development of the COVID-19 pandemic as well as the fact that there was no medical treatment or prevention available for this disease have proven that a new innovative and moreover global approach needs to be adopted for achieving massive and immediate impact in resolving the crisis.

The current paper shows a summary of the financial tool engaged in help of the medical research and treatment in order to provide feasible solutions all over the world. The presented programs provide a good example of how the aggregated purchasing power and centralization of the coordination might lead to finding solutions faster and cheaper. The financial tools and economic scaling used in the fight against the COVID-19 pandemic are with no doubt employed and are example models in the global fight against future global health crises/problems.

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