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This document is part of a series of discussion notes addressing fundamental questions about the COVID-19 crisis and response strategies. These documents are based on the best scientific information available and may be updated as new information comes to light.]

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With the recent announcements by BioNTech and Pfizer, the global fight against COVID-19 has entered a new phase. Now that the development of one or more vaccines—of varying efficacy and complexity-appears to be reasonably confirmed, the international community is working to establish criteria and ensure the resources needed to facilitate the manufacture and distribution of the vaccine doses needed to implement a global strategy that must provide a comprehensive rather than partial or individual solution and guarantee vaccine coverage in low- and middle-income countries. To inform this strategy, it will be necessary to create population maps and agree on the criteria to be used to prioritise high-risk groups. If the complexity of this task on a national level in each country has few precedents, the challenge of ensuring a production and distribution mechanism that can address the needs of every country in the world is no less daunting.

And doing precisely that is probably be the main purpose of the meeting of the members of the G20 to be held in Rivadh (Saudi Arabia) this coming 21 and 22 November. This international forum—in which Spain has been a permanent guest invitee since 2008—has played a vital role in the effort to reduce the health, economic and social impact of the COVID-19 pandemic. The G20 emerged as an alternative forum for debating and adopting economic decisions during the major recession that followed the 2008 financial crisis. Since then, its role has been consolidated and the scope of the issues addressed has been growing steadily. Since 2017, health ministers from member and guest countries have been meeting at the G20, bringing global health issues and threats to the population's health and well-being into the work agenda.

Last April, the G20 approved an Action Plan in response to the COVID-19 pandemic. The first pillar of this plan is the health response with its focus on "sav-

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ing lives". The primary objective is to strengthen international collaboration to accelerate research and development and support efforts that will lead to the production and equitable global distribution of diagnostics, treatments and vaccines for COVID-19. The end of April saw the creation, with the support of the World Health Organisation (WHO), of the <u>ACT Accelerator</u> initiative, a global collaboration that brings together governments, scientists, manufacturers, businesses, civil society and global health organisations in support of this goal.

To achieve the goals set by the G20, the initiative will need sufficient financial resources and appropriate tools for channelling the support. Several multilateral global health organisations created over the past 20 years have contributed their experience: GAVI, the Vaccine Alliance; the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM); and, more recently, UNITAID and the Coalition for Epidemic Preparedness Innovations (CEPI). Some

of these organisations have, for years, been focused on the task of making available vaccines and treatments for deadly diseases in countries with the least resources where these diseases are endemic. All of the participants play essential roles in this initiative.

ACT Accelerator is organised around three central pillars: vaccines, treatments and diagnostics. These are complemented by a single cross-cutting objective: to strengthen health systems and ensure access to for all those who need it most.

The focus of the present document is COVAX, the vaccine pillar of ACT Accelerator and one of the objectives of the Riyadh summit. Following is an explanation of how COVAX responds to the challenges posed by the need for universal and equitable access to immunisation against COVID-19, which last May was recognised by the WHO as a global public good¹ •

COVAX: the Pillar for Achieving a Globally Accessible and Affordable Vaccine

"The aim of COVAX is to have 2 billion doses of an effective vaccine available by end 2021, the number considered sufficient to end the acute phase of the pandemic."

The challenge facing the international community is to accelerate the development of a number of effective vaccines against COVID-19. Several candidates are already in clinical trials and others will soon reach that stage. Pending the results of these trials, the other challenge is to increase production capacity in order to ensure equitable distribution of the vaccines that receive regulatory approval. The aim of COVAX is to have 2 billion doses of an effective vaccine available by end 2021, the number considered sufficient to end the acute phase of the pandemic.

To achieve this, the initiative must, by the end of 2020, raise sufficient resources to finance this goal.

To respond to these two challenges, the work of COVAX is organised into two areas, as shown in *Figure 1*.

- The first of these is responsible for channelling funds through CEPI to speed up the **development of candidate vaccines**.
- The second is the COVAX Facility, a GAVI-led platform set up to ensure equitable procurement and distribution of the vaccines that receive regulatory

¹ World Health Assembly (2020) 73.1. <u>COVID-19 Response</u>.

approval. COVAX guarantees vaccine manufacturers a volume of demand on a scale that encourages them to immediately take the necessary steps to increase their production capacity and also to start manufacturing effective vaccines as soon as they are approved.

To develop this demand, the COVAX Facility has identified two different **groups** of countries.

• **Self-financing countries**, which can either make a firm commitment or acquire options to purchase the number of doses they wish under the same pre-established conditions for all.

• Lower- and middle-income countries (see *Table 1*), which are eligible for the Advance Market Commitment (AMC) mechanism, a tool that enables Official Development Assistance (ODA) donor countries to fund vaccine access in developing countries once manufacturing begins.

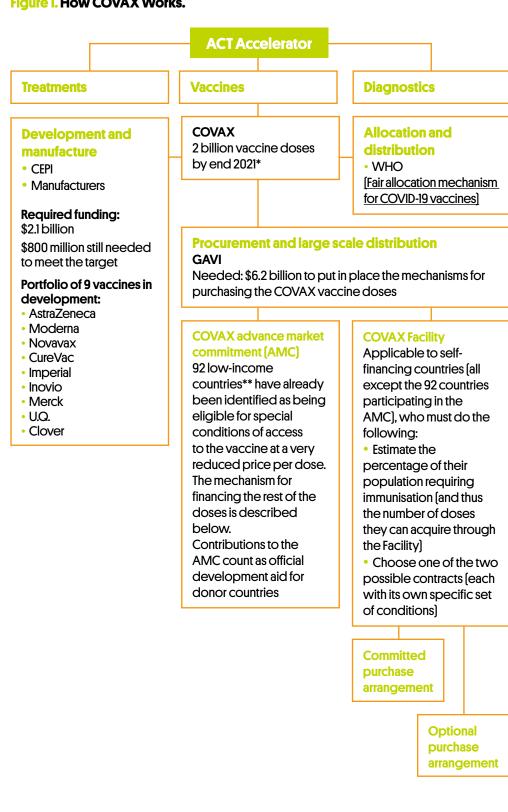
Table 1. Countries Eligible for Advance Market Commitment (AMC).

Low-income Countries	Middle-income Countries	Additional IDA-eligible Countries
Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of Congo, Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, North Korea, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syria, Tajikistan, Tanzania, Togo, Uganda and Yemen.	Algeria, Angola, Bangladesh, Bhutan, Bolivia, Cambodia, Cameroon, Cape Verde, Comoros Islands, Republic of Congo, Côte d'Ivoire, Djibouti, Egypt, El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyzstan, Lesotho, Mauritania, Micronesia Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, West Bank and Gaza, Zambia, Zimbabwe.	Dominican Republic, Fiji, Grenada, Guyana, Kosovo, Maldives, Marshall Islands, Samoa, Saint Lucia, Saint Vincent and the Grenadines, Tonga and Tuvalu.

Unlike bilateral negotiations with manufacturers for the purchase of vaccines (such as those described below being undertaken by the European Union [EU] for its Member States), this global mechanism offers **transparency on the conditions** negotiated for the purchase of the doses for participating countries. It also offers a commitment to the equita-

ble distribution of available vaccine doses among all participant countries, including those with less resources who depend on international aid •

Figure 1. How COVAX Works.



^{*} As of 21 October 2020.

^{**} See countries listed in Table 1.

Committed vs. Optional Purchase.

In both types of agreement, COVAX negotiates with each manufacturer for the advance purchase of a certain number of doses. Upon approval, these will be distributed among the participating countries in accordance with availability and the specific conditions of the agreements undertaken.



Committed purchase arrangement

Estimated cost of a dose: \$10.50 per dose.

- Small upfront payment: \$1.60 per dose
 (15% of the estimated price)
- Financial guarantee for the balance due: \$8.95 per dose acquired

When the vaccine has received regulatory approval and the price has been agreed with the producer:

- 1. If the actual price of the vaccine is more than double the estimated price (over \$21.10 per dose), participants can opt out of the purchase if they have specified this option in their contract.
- 2. If the final price is between \$10.50 and \$21.10 per dose, participants are only obliged to purchase the number of doses covered by the total monetary amount originally specified in the commitment agreement, which, given the higher price, will cover a lower number of doses.
- 3. If the actual price is lower than the estimated price, participants can choose to have the excess financial guarantee returned or they can use the excess to procure additional doses (if available).

This is a committed purchase arrangement and the buyer is obliged to complete the purchase. Buyers cannot select only vaccine candidates with a lower investment risk.



Optional purchase arrangement

- Upfront payment of \$3.10 per dose for an option to purchase, which the countries can later exercise or not for each vaccine that is approved.
- Payment of a risk-sharing guarantee of \$0.40 per dose. The purpose of this guarantee is to help protect the COVAX Facility against the risk that countries decide not to exercise their option to purchase a particular vaccine.

Decision windows for exercising options:

- Before the COVAX Facility enters into an agreement with a manufacturer: if during this window a participant indicates that it is not interested in acquiring a particular vaccine, it will not be issued an option to purchase doses from that deal.
- When the COVAX Facility confirms orders with a manufacturer following approval of the vaccine.
- 1. If a participant chooses to exercise an option, it will receive the doses that have been pre-paid out of its upfront payment and will pay the remainder of its allocation at the price per dose agreed between COVAX and the manufacturer.
- 2. If a participant decides not to exercise its option, it can donate the allocation or trade it with another country. Purchase of the vaccine is not obligatory.

This mechanism does not oblige the participant to purchase, but the investment carries a higher risk.

At the time of writing, 94 self-financing countries are participating in the COVAX Facility. Of these, 27 have opted for committed and 67 for optional purchase. The decision by many participants to choose the optional purchase arrangement has resulted in the availability of more upfront resources than expected; however, it also implies greater financial risk for both the participant countries and the COVAX Facility.

National Interests on the Road to a Multilateral Response

"The case of the European Union perfectly illustrates the tension between the desire for international cooperation and the interest, in this case of a region, in ensuring sufficient supply for a group of countries."

The COVAX initiative is a multilateral and collaborative response to the pandemic, promoted by several international bodies, including the United Nations, WHO, G20 and EU. It has emerged at a time when multilateralism and the international balance of power are being redefined as a result of the multiple crises triggered by the COVID-19 pandemic. Certain key actors in the international system—the United States of America and Russia, for example—have chosen not to participate in this initiative, retreating to positions defined by nationalist messages and policies and focusing their efforts and resources on procuring supplies for their own countries. On the other hand, China recently announced its withdrawal from COVAX.

The case of the EU perfectly illustrates the tension between the desire for international cooperation and the interest, in this case of a region, in ensuring sufficient supply for a group of countries in one of the world's richest regions. One the one hand, the EU has been one of the main drivers of COVAX since its creation; on the other, as a group it has entered into bilateral negotiations with manufacturers for the acquisition of doses for all its Member States.

The EU COVID-19 vaccine strategy authorises the Commission to conduct these negotiations and has made available €.7 billion for this purpose under the Emergency Response Instrument (ESI)².

To date this has resulted in:

- Agreement with AstraZeneca: 300 million doses with an option for a further 100 million
- Agreement with Sanofi-GSK: 300 million doses and a commitment to provide a significant portion of their supply to middle- and lower-income countries through the COVAX Facility
- Agreement with Janssen Pharmaceutica NV (Johnson & Johnson): doses for 200 million people with the possibility of acquiring coverage for a further 200 million.
- Ongoing negotiations with other manufacturers: CureVac, Moderna, BioNTech.

As well as being involved in the effort to set up COVAX, the EU has contributed €00 million³ to the Facility through Team Europe, a programme created to structure the Community's global pandemic response (development cooperation). This contribution is expected to be sufficient to fund the purchase of 88 million doses for use in AMC-eligible countries •

² EU Strategy for COVID-19 Vaccines, page 3.

³ This contribution is the sum of €30 million in cash through a loan from the European Investment Bank and €70 million in financial guarantees from the EU budget.

Box 1. Latin America: No-Man's Land.

The Latin American region illustrates the situation of many **middle-income economies** in the global response to the pandemic. The impact of COVID-19 is exacerbating their inequities and vulnerability⁴, but none of the tools designed to provide universal and equitable access to vaccines offer them a specific response.

Most of the countries in the region are **not eligible for the AMC** (only Haiti, Bolivia, El Salvador, Honduras, Nicaragua, the Dominican Republic, Grenada, Guyana, Saint Lucia and Saint Vincent and the Grenadines). The **only option open to them is to choose one of the two modalities offered by the COVAX Facility to self-financing countries** under the same conditions as economies with greater resources.

Mexico, Argentina, Brazil, Chile, Costa Rica and Suriname have all entered into optional purchase agreements with COVAX. Guatemala, Belize, Panama, Venezuela, Colombia, Ecuador, Peru, Paraguay and Uruguay and many Caribbean countries, including Jamaica, the Dominican Republic and Barbados, have opted for the committed purchase arrangement. Except for Chile, Uruguay and some of the Caribbean nations, the rest of the countries in the region are classified as upper-middle or lower-middle income economies.

The Pan American Health Organisation (PAHO, the WHO regional division for the Americas) recognises **COVAX** as the key option for providing early access to vaccines for most of the countries in the region⁵ and is contributing on behalf of the bloc through the PAHO Revolving Fund for Vaccine Access⁶.

The situation in the Americas highlights a problem that needs to be addressed. On the one hand, for most of the economies in the region, the reliability of COVAX as a global supply mechanism is their only chance to access vaccines once these become available. Hence the strong commitment in the region to the committed purchase arrangement.

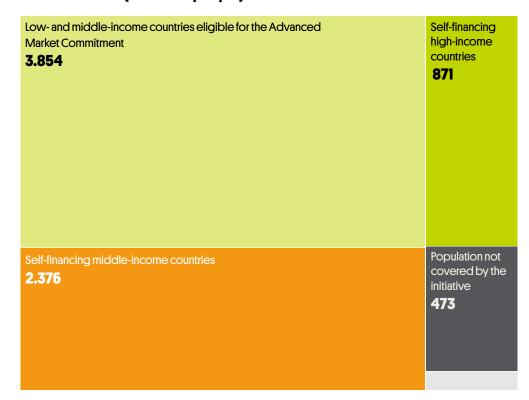
The **paradox** is that they are making this commitment under the same conditions as other countries and regions with much greater resources, which are making an almost symbolic contribution to COVAX through the optional, higher-risk mechanism while negotiating their own bilateral commitments with manufacturers. Moreover, the international aid mechanism for universal access to vaccines has been designed exclusively for low-income countries. Spain has a responsibility to help address and resolve this issue.

⁴ COVID-19 in Latin America: What Does it Take to Go From a Highly-Vulnerable Region to a Pandemic-ready Region? ISGlobal. July 2020.

PAHO urges countries to plan early for COVID-19 vaccinations to reduce deaths. PAHO. September 2020.

Opportunities for PAHO Member States and Territories to engage in the COVAX Facility through PAHO and its Revolving Fund. September 2020

Figure 2. Distribution of the World Population According to Participation in the COVAX Initiative (millions of people).



Source: Own compilation based on data provided by COVAX using income classifications according to World Bank criteria.

The white box corresponds to a population of 73 million people living in countries whose role in the initiative is unknown.

What Role Can Spain Play in this Scheme? Two Recommendations

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The Spanish Government has on numerous occasions expressed a desire to be involved in multilateral initiatives, the effort to achieve the goals of the 2030 Agenda for Sustainable Development, gender equality and human rights. These are the fundamental pillars of its foreign policy. Few actions would be more consistent with this expressed desire than a firm financial and political commitment to COVAX at a time when Spain needs to define its role as a global player. To make good on this commitment, the Government needs to do more than declare its support for the COVAX initiative, it must take steps to procure vaccines using the mechanisms offered by the Facility. Likewise, Spain

should promote this commitment to the initiative within the EU, encouraging it to make its own agreements with the COVAX Facility for vaccine supplies.

Within the EU, Spain should promote the importance of making the COVAX Facility the global vaccine procurement mechanism par excellence.

A very large proportion of the world's population living in lower- and middle-income countries depend on COVAX for early access to COVID-19 vaccines. The mechanism would be **strengthened** and would gain **credibility** if the EU were to commit to procuring a significant part of its supply from the Facility instead of de-

pending exclusively on non-transparent, bilateral agreements with manufacturers who, at the same time, are also entering into agreements with COVAX⁷.

Multilateral bodies, such as the G20 and the UN, actively promote the COVAX Facility and the ACT-Accelerator initiative as a whole. By making a firm commitment, Spain would not only contribute resources to the Facility (something that the G20 has asked international financial institutions and regional development banks to do), but would also garner essential political capital in its negotiations with manufacturers, which would benefit all of the countries participating (in one way or another) in COVAX. Actions of this kind can define the role of the EU as more than the sum of its parts in an international arena which is being becoming the "battlefield" where the fight against the pandemic is being waged.

2. Spain should provide an example of this commitment to COVAX. The following is a concrete proposal on how this can be achieved.

- First, quantify the number of doses Spain can purchase through COVAX to immunise part of the Spanish population, in line with the estimates that indicate that, to end the acute phase of the pandemic, it will be necessary to immunise at least 20% of the population and eventually to reach, if possible, 40% coverage. To achieve this target coverage, the Spanish Government could commit to purchasing through CO-VAX enough doses to immunise 20% of the Spanish population—approximately 9.5 million people. The doses needed to achieve the remaining coverage, up to 40% or 50%, could then be procured through agreements negotiated by the EU with vaccine manufacturers...
- Second, choose one of the two modalities offered by COVAX to self-financing countries: committed or optional purchase. One of the issues that should be evaluated when making this decision is the risk associated with each mechanism: the risk assumed is greater in the case of the optional purchase for both the purchasing country (because it only acquires an option to buy) and the COVAX

Facility. The following table shows the **estimated costs** associated with the immunisation of 20% of the Spanish population with each of the two mechanisms:

Committed Purchase	Optional Purchase
Arrangement	Arrangement
Advance payment:	Upfront payment:
\$30,400,000	\$58,900,000
Financial guarantee:	Shared-risk guarantee:
\$170,050.000	\$7,600,000

Spain's participation in COVAX should also include funding for **Advanced Market Commitment (AMC)**. AMC funding counts as Official Development Assistance from donor countries.

A message that would underscore Spain's commitment to equitable access to vaccines for the whole international community would be to make a contribution corresponding to at least the same number of doses acquired as a self-financing country for its own supply (the immunisation of 9.5 million people) at the price per dose finally established for the AMC mechanism.

Spain must make do its utmost to do this because this mechanism makes possible a more tailored response to the unique situation of middle-income countries, which are currently wholly dependent on their own capacity as self-financing countries under conditions identical to those of economies with much greater resources and capacity to negotiate bilaterally with manufacturers •

This was the position expressed in a statement by Médecins Sans Frontières (MSF) at a hearing before the European Parliament on 22 September this year: https://msfaccess.org/sites/default/files/2020-09/MSF%20AC%20statement%20hearing%20Covid%20vaccines%20EP%20220920.pdf

TO LEARN MORE:

- What Are the Barriers to Achieving Universal Immunisation Against CO-VID-19? ISGlobal. June 2020.
- COVID-19 in Latin America: What Does it Take to Go From a Highly-Vulnerable Region to a Pandemic-ready Region? ISGlobal. July 2020.
- <u>EU Strategy for COVID-19 vaccines</u>. Communication from the European Comission.
- Timeline of EU action. Coronavirus Response. European Comission.
- Latest COVAX news. GAVI.



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