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Cuban Anti-COVID-19 Vaccines Pharmaceutical Autonomy in Favor of the Population

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Abstract

The emergence of COVID-19 made it even more visible that the center of pharmaceutical and therapeutic treatment was the development of a medication for the disease since therapies focus attention on monitoring the disease in each patient. As part of its strategy to confront this pandemic, Cuba assumed the design of its own vaccines as a health policy. This article reveals the importance of vaccines produced by the nation within the Cuban strategy to confront COVID-19. In addition, it makes the main results visible through the review of reliable sources of information, both international and nationally produced. It is concluded that the mass vaccination of the population, as a significant part of the aforementioned strategy, has led to the successful achievement of the national biopharmaceutical sector that, together with Cuban medicine and science, show favorable results in the management, prevention and treatment of the pandemic.

Keywords: Cuban Vaccines; COVID-19; Pharmaceutical Autonomy; Pharmacology; Mass Vaccination; Confronting COVID-19

Abbreviations: SCTI: Science, Technology and Innovation; UNIDO: United Nations for Industrial Development; CECMED: Control of Medicines Equipment and Medical Devices

Introduction

Since the emergence of Covid-19, the specialized literature on pharmaceutical products, especially focused on vaccines and antibiotics, has grown exponentially, but it is still far from an explanation of the discovery of the drug that is robust enough to generate consensus between which of the therapies have been the most effective. On the contrary, the concentration of professional efforts on manipulating and combating microbes has done nothing other than multiply dissimilar and antagonistic approaches. An area of particular disagreement is located in the questioning of the effectiveness of the main therapeutic medications, as well as in specifying the core of the contribution of the biomedical sector. The emergence of Covid-19 made it even more visible that the center of pharmaceutical and therapeutic treatment was the development of a medication for the disease, taking the patient's characteristics to the background, since individualized treatment is not prioritized, but instead Therapies focus attention on monitoring the disease in each patient. The magnitude of the pandemic, as the immediate cause of the deepest crisis in modern society [1-3], consolidates the need for the socialization of access to medicines and pharmaceutical products for the patient, which deepens the reduction of role of the doctor. The need for industrial production of vaccines is reinforced on a global scale and the market as a means of access is becoming globalized in an asymmetrical manner. The role of the doctor as a mediator between the pharmaceutical industry and the patient is strengthened.

Among the nations that assumed, as a health policy to confront the COVID 19 pandemic, the design of vaccines and thus reduce the incidence, severity and mortality from such disease is Cuba. In the Cuban case, the creation of vaccines has a history of more than 30 years [4], which makes it a comparative advantage to face such a pandemic, as an essential tool within the structured national

public health system. By 2020, Cuba's biotechnology industry, made up of more than 30 research institutes and manufacturing companies of the state conglomerate BioCubaFarma, had 2,438 patents registered outside this nation, and its products included vaccines, medications and medical equipment that were registered and they were sold in more than 50 countries [5], everything that constituted a national strength to face COVID 19. This article reveals the importance of vaccines produced by the nation within the Cuban strategy to confront COVID-19. In addition, it makes the main results visible through the review of reliable sources of information, both international and nationally produced. Given the epistemic richness of the topic, the approach is done through an approximation; concluding that the implementation of mass vaccination of the population, as a significant part of the aforementioned strategy, has led to the successful achievement of the national biopharmaceutical sector who, together with Cuban medicine and science, show favorable results in the management, prevention and treatment of the pandemic.

Approach to Cuban anti-COVID-19 vaccine studies

The emergency of COVID-19 in the Cuban scenario demanded a coordinated response through integrated state action, led from the highest levels of the State and the government together with the Cuban System of Science, Technology and Innovation (SCTI), the multiple actors of the public health sector, the medical-pharmaceutical biotechnology industry and other sectors of society. Which generated new experiences in the robust health system, as well as new technological developments, innovative processes and new approaches to intersectorality in terms of prevention, treatment and immunization in the face of large-scale health disasters, as well as the place of vaccines in them. For Cuba, one of its strengths in managing the pandemic was having its own well-developed biotechnology-medical-pharmaceutical industry [6,7], which began to take off in the 1980s and since 2012 has been grouped in the state business organization BioCubaFarma. The centers that comprise it carry out scientific research, technological development, and production and export activities. Hence, far from being an overnight success, this nation's ability to develop a vaccine is the result of decades of investment in its biopharmaceutical industry, which in its early stages of development had the support of the Organization of the United Nations for Industrial Development (UNIDO). To achieve its vaccines, Cuba formed a heterogeneous team around the Data Monitoring Committee (CMD), also called the independent, external or safety committee. It was necessary to lay the foundations to encourage the systematic use of CMDs in this nation, in clinical trials related to the prevention and treatment of COVID-19, which guaranteed the safety of the participating subjects, the validity and integrity of the data and the reliability of the results; which facilitates the early introduction of the new product into normal medical-pharmaceutical practice. In coherence with the standards of good clinical practices of Cuba, the Americas and the International Conference on Harmonization [8-10] as responsibilities of the sponsor, establishing an independent data monitoring committee in clinical trials can or should be considered. to advise you, at intervals, on the progress of the research and, based on its considerations, recommend whether you should continue, modify or stop the study.

The use of CMDs in clinical trials offers guarantees about the quality of the research and provides a healthy component of independence and objectivity to unplanned decisions in the study. Furthermore, it confers additional value due to the role of external monitoring, under the principles of confidentiality, responsibility and non-existence of conflicts of interest, which contributes to progressive recognition of its scientific value worldwide [11,12]. The clinical trial of the first Cuban vaccine against COVID-19 is registered in the public registry of clinical trials of Cuba (RPCEC 00000332). The CMD was appointed by the sponsor during the planning of the study and was made up of a multidisciplinary group of experts with training and experience in good clinical practices, biostatistics, and bioethics and in the disease being studied. In addition, members demonstrate the ability to work as a team, autonomy, good judgment and training in the functioning of the committee. Along with the search for vaccine candidates, pharmacological treatments classified into different therapeutic protocols, depending on the person's situation, covered 22 Cuban products. New biotechnological drugs are used such as Jusvinza®, others already known such as recombinant interferon alfa 2b and interferon gamma, erythropoietin, Surfacen®, hyperimmune plasma, oseltamivir and azithromycin [13,14]. In this scenario, the Center for State Control of Medicines, Equipment and Medical Devices (CECMED) was integrated into the national response against the pandemic, evaluating and agreeing on a series of measures to guarantee agility and adaptability in the analysis of authorizations and medication modifications for use in patients and the community.

The regulatory authority in this period has focused on the promotion of work methodologies that simplify, accelerate, and facilitate administrative procedures to respond to emerging needs, maintaining established standards of quality, safety and effectiveness [15]. The entire effort has taken place in a very difficult economic environment, accentuated by the strong economic, financial and commercial blockade and the permanent political harassment of the leading economic and military power on the planet. Without a doubt, it is much more difficult for Cuba than other countries to acquire essential resources to confront the pandemic. The situation encouraged a strategy aimed at creating its own capabilities. For this, the background explained above was available, which is summarized in the existence of qualified human potential, a robust industry, a developed health system and a higher education system with the possibility of supporting this effort. Of all this there was much more than financial resources and facilities to acquire medicines, equipment, vaccines and other essential supplies in the international market [16]. The Caribbean nation proposed to inoculate its entire population

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against COVID-19 with a vaccine of its own production, for which the country was betting on the development of clinical trials with the Cuban vaccine candidates Soberana 02, Abdala and Soberana Plus (for convalescents) which was approved by CECMED and implemented in voluntary subjects from selected territories in March 2021. The participants in this clinical trial were: volunteer subjects selected by the researchers in the territories of Havana, Santiago, Granma and Guantánamo. The total number of doses administered during these clinical trials was 266,466, excluding from this figure the doses of placebos administered during these trials (Table 1). Also starting in March 2021, an intervention study will begin, as part of the research associated with the Cuban vaccine candidates Soberana 02 and Abdala, aimed at subjects in risk groups and who could provide relevant data. The participants were: health workers, BioCubaFarma workers and other risk groups in the territories of Havana, Santiago de Cuba, Granma and Guantánamo. During this Study, a total of 454,064 doses are administered (Table 2).

Table 1: Dose behavior in the clinical trial.

Total Doses Administerd	1st Dose	2nd Dose	3rd Dose	Complete Schedule
266 466*	92 675	88 504	85 287	85 887

*Placebo doses administered during clinical trials are excluded from this figure.

Source: Ministry of Public Health of the Republic of Cuba (2023) Update of the strategy for the development of Cuban vaccines.

Table 2: Results of the Intervention Study.

Total doses administered	1st Dose	2nd Dose	3rd Dose	Complete Schedule
168 461	150 928	134 675	134 675	147 222

Source: Ministry of Public Health of the Republic of Cuba (2023) Update of the strategy for the development of Cuban vaccines.

Later, in May 2021, the Minister of Public Health, supported by article 64 of Law 41 "Public Health Law", of July 13, 1983, approved a health intervention with the Cuban vaccine candidates Abdala and Soberana 02 in risk groups and territories. Participants on this occasion were: health workers, BioCubaFarma, students of Medical Sciences and other risk groups; whose population was determined in risk territories selected in stages. The total number of doses administered during this health intervention was: 9,618,831 (Table 3). In November 2021, following the approval of the Booster Dose Strategy, the Clinical Study with vaccine candidates was approved: SOBERANA 01 and Mambisa. As well as, the start of vaccination with a fourth dose, starting with health workers and risk groups. These booster doses are added to the cumulative number of doses applied in the country. The participants were: health workers, population of selected territories and other risk groups. During the Study: 325,775 doses were administered. It is significant to note that, in Phase I/II clinical studies with 792 volunteers, ABDALA generated a high level of seroconversion of anti-RBD antibodies in more than 90% of vaccinated individuals, aged between 19 and 80 years of age, only 14 days after the last immunization. Furthermore, the functionality of the induced antibodies is evident, with a positive correlation in assays of inhibition of binding to the SARS-CoV-2 virus receptor and in viral neutralization studies. In the Phase III clinical study of vaccine efficacy with 48,290 volunteers (multicenter, randomized, double-blind, placebo-controlled), ABDALA demonstrated an efficacy of 92.28% in reducing the risk of suffering from symptomatic disease due to COVID-19, in comparison with the placebo group, with a 95% confidence interval of 85.74% to 95.82% [17]; From all these results it is evident that ABDALA constitutes an effective vaccine that meets the requirements demanded by the World Health Organization for these vaccines.

Table 3: Results of the Health Intervention.

Total doses administered	1st Dose	2nd Dose	3rd Dose	Complete Schedule
9 618 831	3 305 344	3 213 645	3 099 842	3 099 842

Source: Ministry of Public Health of the Republic of Cuba (2023) Update of the strategy for the development of Cuban vaccines.

With the development of these clinical trials, intervention studies, health intervention, clinical study and their results, the context was prepared to ensure equitable access of the Cuban population to national vaccines. The control infrastructure in the development of safe and effective drugs against COVID-19, something essential for the complete and safe restoration of the economy and social activity, was guaranteed by the CECMED and the CMDs formed. From a public health point of view, ensuring that all inhabitants had prompt access to the COVID-19 vaccine was essential to keep the pandemic under control and guarantee the safeguarding of life. Once vaccines begin to obtain approval from regulatory agencies and the image that emerges is not that of

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a centralized or multilateral system governed by the logic of public health or ethics, but of a hodgepodge of agreements conditioned by geopolitical, industrial, financial or biological factors [18] in Cuba everything was giving signs to move towards large-scale vaccination, which the following pages will discuss.

Application of Cuban anti-COVID-19 vaccines. Results in favor of the population

Currently, there is a consensus that among public health interventions, immunization is one of the greatest successes of medicine, since it allows two to three million deaths to be avoided each year due to infectious diseases, thus becoming one of the actions more cost effective and successful. Therefore, to end the COVID-19 pandemic, a large part of Cuba's inhabitants had to be immune to the virus; the safest way to achieve this was with vaccines. Several national research teams accepted the challenge of developing vaccines that protect against SARS-CoV-2 to minimize the effects of the disease and reduce the loss of human life [19]. Before moving directly to the application of vaccines and their effectiveness against COVID-19, it is necessary to draw up some guidelines regarding the scenario that should be transformed with the immunization of the majority of the population, given the impact of such a pandemic. The introduction of the disease occurs after the appearance of the first imported cases in March 2020, in the province of Sancti Spíritus, from then on the epidemiological scenario would be changing, largely determined by the reopening of borders and the introduction of the Delta strain in November 2020 and July 2021 respectively, which caused the maximum peak of cases in August of the aforementioned year with a rate of 586.7 per 100,000. All provinces and municipalities, including the special municipality Isla de la Juventud have reported cases in all age groups [20]. The application of Cuban vaccines becomes an example of how it is possible that policies driven by social objectives, that is, solving important health problems for the population can produce high-level science and radical innovations with broad and favorable social impact. Cuba considered accessing a vaccine through its own efforts; it was clear from the beginning that a strategy had to be sought that made production costs compatible with the resources available for public health policy. The Cuban effort has led to having a complete schedule and booster doses for the majority of its population, including the majority of pediatric age, see Figure 1.

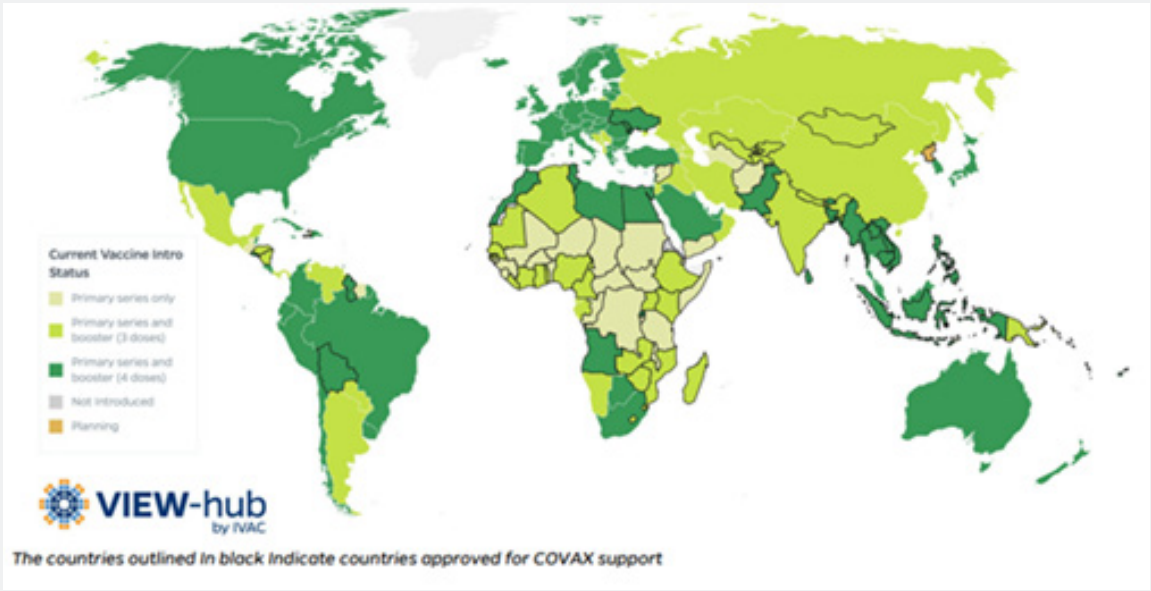

Figure 1: Spatial distribution of vaccines and doses supplied.

At the end of November 24, 45,781,756 doses administered with the Cuban vaccines SOBERANA 02, SOBERANA Plus and ABDALA have accumulated in the country. To date, 10,781,806 people have received at least one dose of one of the Cuban vaccines SOBERANA 02, SOBERANA Plus and ABDALA. Of them, 9,486,167 people already have a second dose and 9,177,784 third doses. 10,039,565 people have a complete vaccination schedule, which represents 90.9% of the Cuban population; It is specified that the first dose includes those vaccinated with SOBERANA Plus as a single dose. A total of 8,780,227 people have received booster doses, of them 325,775 as part of the Clinical Study and 8,454,452 as part of the booster vaccination that is being applied to the population of selected territories and risk groups. Mass vaccination began on July 29, 2021; participants were the population over 19 years of age from territories with epidemiological risk and risk groups at the level of all provinces.

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In addition, the pediatric population from 2 to 18 years old from across the country also participated. A total of 35,116,620 doses are administered during this vaccination. Previously, a phase I/II clinical trial was carried out with the pediatric population with the Soberana 02 vaccine candidate. The approval of said trial was based on the existing epidemiological context, characterized by a considerable increase in positive cases in the pediatric population, and It was applied, in the ages between 3 and 18 years, divided into two groups: adolescents from 12 to 18 years and children from 3 to 11 years, in two stages, and in that order based on the results of safety and immunogenicity that the vaccine candidates showed: Soberana 02 and Soberana Plus, as part of the phase I and phase II clinical trials [21]. Both candidates, already applied to thousands of people, had shown to be safe and well tolerated in adults, both in clinical trials and in the intervention study, which allowed phase III to be carried out. To observe the doses administered in mass vaccination See Table 4. To make visible the effectiveness of Cuban vaccines, it is necessary to establish a comparison between the % lethality of that nation and the rest of the world, which gives a measure of the effectiveness of said self-produced drugs. For an appreciation of this matter, it is recommended to observe Table 5.

Table 4: Doses administered during Mass Vaccination.

Total doses administered	1st Dose	2nd Dose	3rd Dose	Complete Schedule	Booster Dose
35 146 980	7 218 262	6 035 637	5 859 804	6 708 444	8 445 625

Source: Ministry of Public Health of the Republic of Cuba (2023) Update of the strategy for the development of Cuban vaccines.

Table 5: World level comparison until 6:59 CET on December 6, 2023/Cuba until December 8.

Area	Confirmed cases	Deaths notified to WHO	% fatality
World	772.138.818	6.985.964	0,90
Cuba	1.115.171	8.53	0,76

Sources: World Health Organization. WHO Coronavirus (COVID-19) Dashboard | WHO Coronavirus (COVID-19) Dashboard with Vaccination Data.

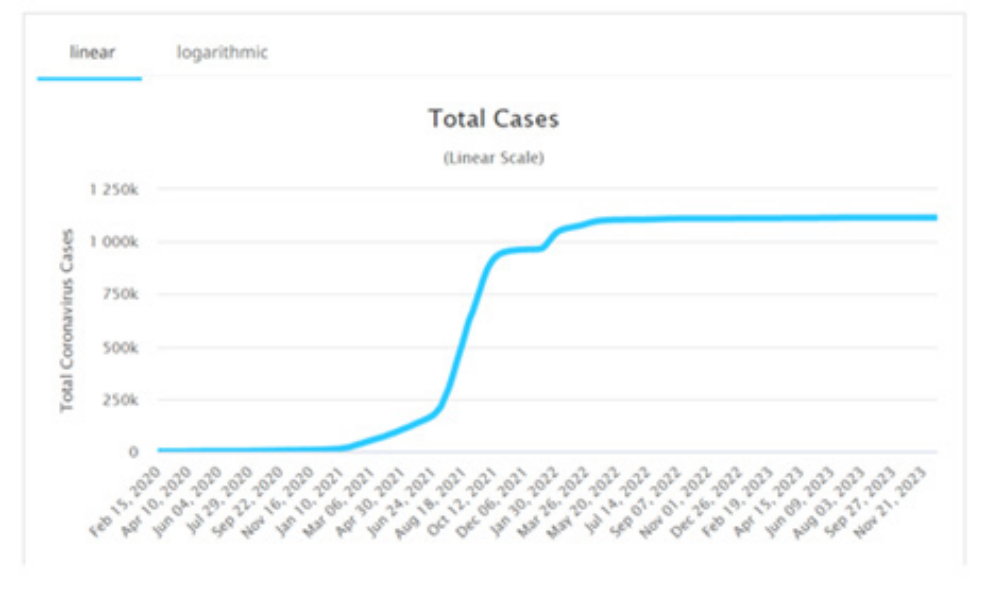

Figure 2: Total Coronavirus Cases in Cuba.

Although monitoring the results of vaccinations is essential to understand the effectiveness, together with the possible decrease in the immune response over time and the possible adverse effects, it is undeniable that due to prevention and control measures of both a social nature and implemented by the National Health System, among which mass vaccination of the population stands out, including pediatric vaccination, led to the beginning of the decrease in incidence and fatality in the first half

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of October 2021 [20]. As can be seen in Figure 2, 2021 was the most epidemiologically complex for Cuba as the presence of the pandemic was sustained throughout this year. From January to March, there is a gradual increase in the most negative indicators of the disease in the country; The appearance, on the national scene, of two new variants that were identified in this first quarter had a lot to do with this increase: Alpha and Beta, fundamentally in the province of Havana with high dispersion in the rest of the national territory. Then, starting in the second quarter, the numbers skyrocketed with the appearance of the Delta variant in the month of April, much more contagious and deadly than the other variants of SARS-Cov2, which spread to the entire nation and reached its peak highest in the months of July and August of the same year. Consistent with the progress of the mass vaccination process, which began on July 29, 2021, stability in the control of COVID-19 is observed in the country. However, with the emergence of the new variants of Omicron from the beginning of December until April 2022, an increase in patients is evident.

Figure 3 shows the indicator of new cases that occur daily, where a behavior similar to what was explained above can be seen; to a large extent, the increases were caused by the influence of the SARS-Cov2 variants, while the decrease in cases was influenced by the impact of the effects of the vaccination campaign. Very negative aspects to highlight are the reports of pediatric cases and pregnant women positive for the disease, which skyrocketed during 2021. In the case of the first, more than 2 thousand cases were reported in one day. In total, 952,946 confirmed cases of Covid-19 were diagnosed that year. Another indicator that reflects the relationship, directly proportional, between the decrease in the impact of the pandemic and the immunization of the population through national vaccines is reflected in Figure 4, which denotes the decrease in the incidence of active cases in the nation globally. in the face of the high dispersion and contagiousness of the disease in almost the entire national territory prevailing before the advance of mass vaccination. However, in 2021 there were 8,175 deaths for a fatality rate of 0.9%. On average, around 23 people died daily, reaching the highest number on August 3 and 14 with 98 deaths from the Covid-19 disease on both days. This indicator was marked by the loss of pediatric cases and pregnant women that manifested itself throughout the year after the appearance of the Delta variant, mainly. Although with the advance of vaccination it is possible to control this fatal and sad indicator, as shown in Figure 5.

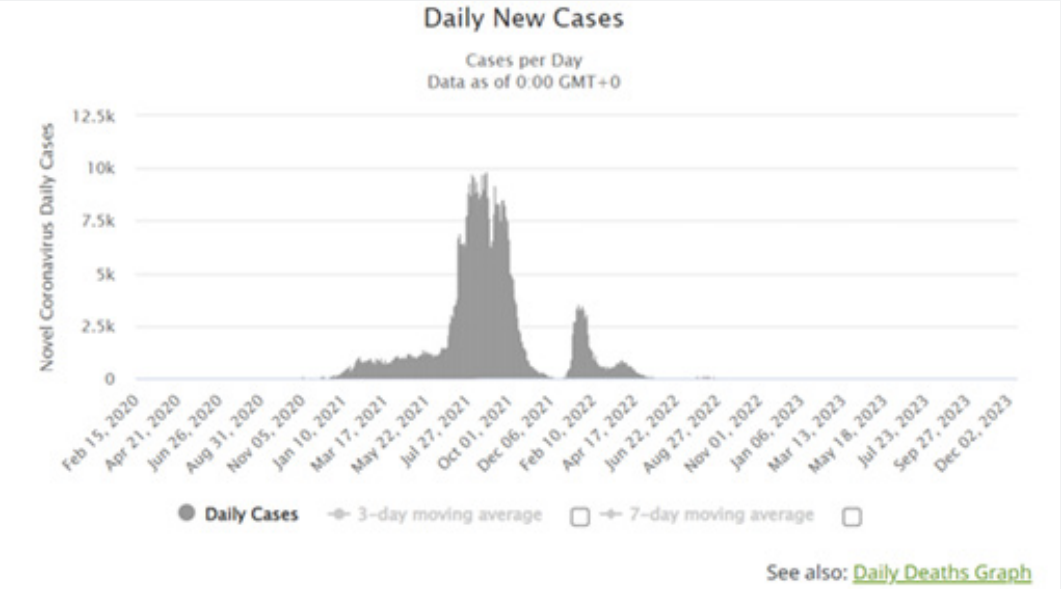

Figure 3: Daily New Cases in Cuba.

Cuba, at the end of the week from December 2 to 8, reported that 13 patients were admitted; all of them suspected and confirmed active 0. For the surveillance of COVID-19 in Cuba, 476 samples were carried out, resulting in 0 positive. The country on that date, it accumulates 14 million 395 thousand 533 samples carried out and 1 million 115 thousand 171 positive ones. Of the 1,115,171 patients diagnosed with the disease, none are actively admitted. There are 8,530 deaths accumulated (none in the week). No serious or confirmed critical patients are reported in the country's Intensive Care Units [22]. Figure 6 shows the behavior of new deaths, which is important because it expresses the increase or not of them. As of December 8, in Cuba, 45 812 116 doses had been administered; 10 041 395 people have a complete vaccination schedule, which represents 90.9% of the

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Cuban population. According to the Ministry of Public Health, a total of 8 781 400 people have received booster doses, of which 325 775 are part of the Clinical Study and 8 455 625 are part of the booster vaccination that is being applied to the population of selected territories and groups risk [23,24]. This tour has served to reveal the importance that the mass vaccination campaign has had for the nation to record the lowest figures since the rebound in 2022, especially in deaths (Figure 7).

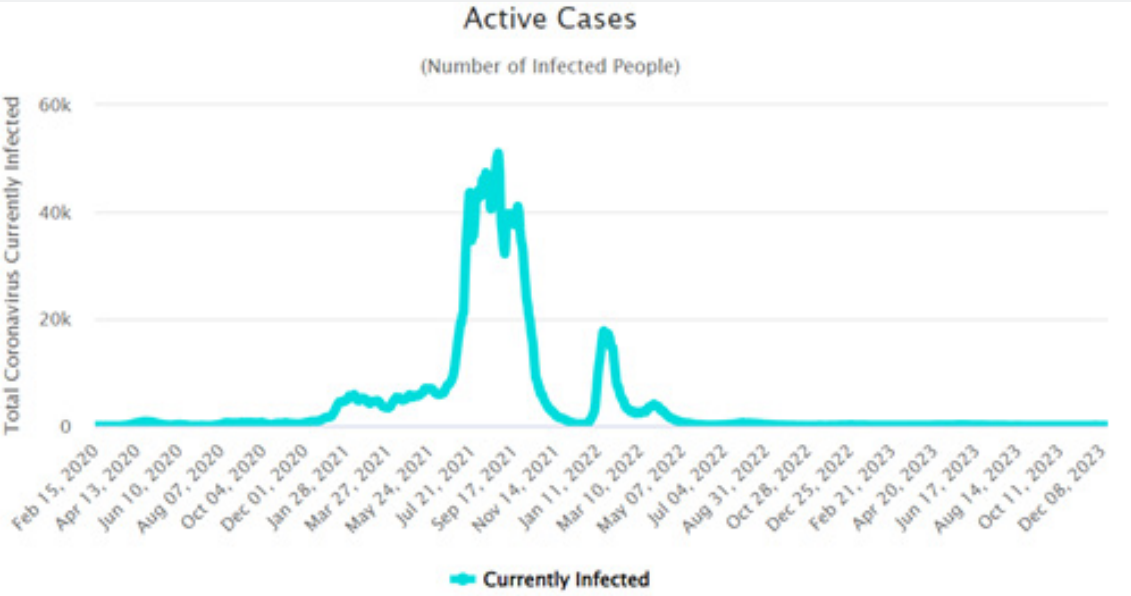

Figure 4: Active Cases in Cuba.

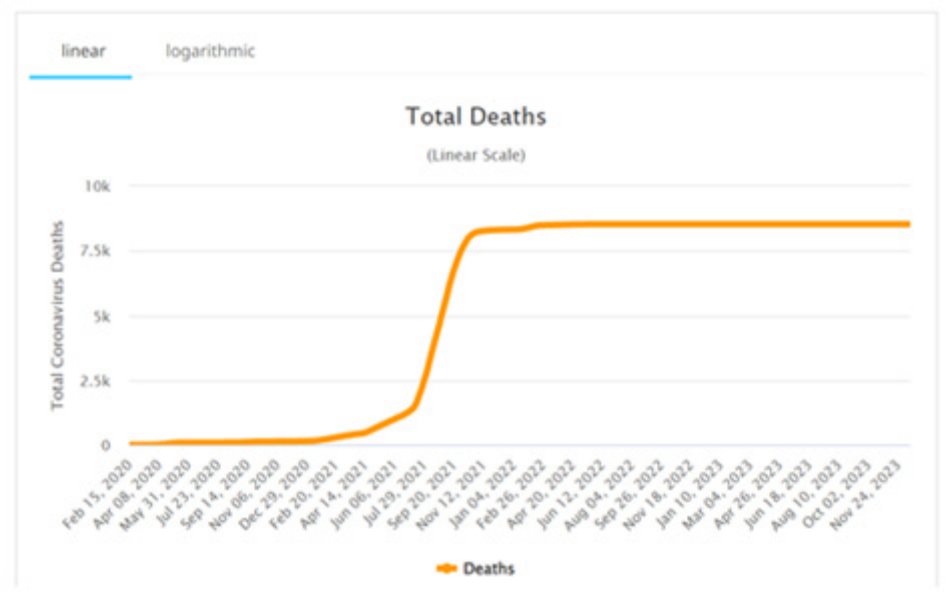

Figure 5: Total Coronavirus Deaths in Cuba.

Conclusions

Within the Cuban strategy against COVID-19, the mass vaccination program with its own vaccines plays a determining role among the drugs applied to prevent and achieve the levels of immunization necessary to avoid the transmission of the disease. To reduce the risk of this pandemic, the goal is to reach

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as many vaccinated individuals as possible. The implementation of mass vaccination of the population, as a significant part of the aforementioned strategy, has led to the successful achievement of the national biopharmaceutical sector that, together with Cuban medicine and science, show favorable results in the management, prevention and treatment of the pandemic. In the face of COVID-19, Cuba has bet on the inestimable value of mass vaccination of the population using its own vaccines, a way of doing science that, according to international debates, corresponds approximately to the concept of sustainability science and is clearly divergent from capitalism dominant cognitive in the global medical-pharmaceutical industry. The Cuban case is an exalting and heartbreaking experience at the same time, as it consolidates the best practices and values of national science and multiplies its social function in the face of the post-COVID-19 period, where science, and especially, the production of drugs becomes even more important.

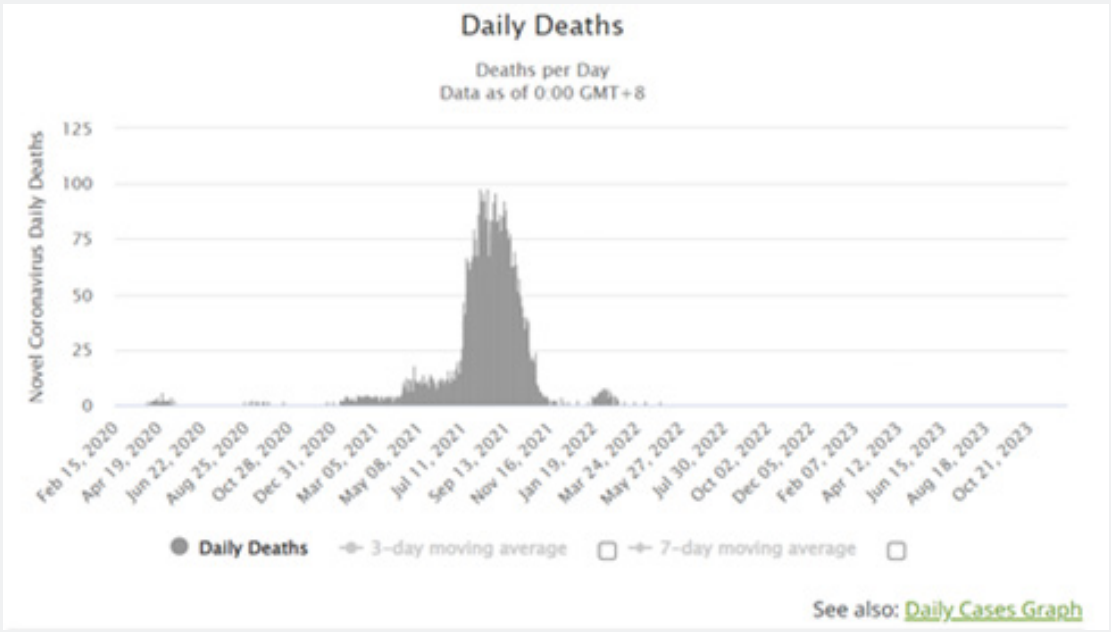

Figure 6: Daily New Deaths in Cuba.

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