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Let Cuba breathe: pneumococcal vaccines between science, sanctions, and economic blockade

Streptococcus pneumoniae continues to be the leading infectious killer of children under five years of age worldwide; each year it is responsible for approximately 200.000-250.000 deaths globally, largely due to invasive pneumonia, meningitis, and sepsis that are preventable through vaccination[1] The geographic distribution of mortality is profoundly uneven and inequitable: the highest pneumonia death rates are recorded in sub-Saharan Africa and South and Southeast Asia, while they are much lower in Europe and North America. In high-mortality regions, the majority of at-risk children are concentrated, reflecting asymmetries in access to pneumococcal conjugate-vaccines. According to World Health Organization data, in 2021 only about 50% of children worldwide at one year of age had received the third dose of pneumococcal vaccine, leaving millions exposed to one of the leading causes of early childhood death. This vaccine inequality reproduces and amplifies the denial of (also) health rights globally: populations most affected by infection and its outcomes are those with the lowest vaccination coverage (and the fewest resources)[2].

Within this inequitable global scenario stands QuimiVio, the heptavalent pneumococcal conjugate-vaccine (now an 11-valent vaccine-candidate) developed by the Instituto Finlay de Vacunas in Cuba, as a scientific and political response to the persistent barriers limiting access to conjugate-vaccines in Cuba and in low-income countries[3]. Vaccines against multiple serotypes of *S. pneumoniae* available on the international market are among the most expensive products in the pediatric immunization schedule. In non-subsidized markets, prices can reach hundreds of US dollars per dose (up to approximately $500-600), levels incompatible and unsustainable for most national health systems and services (especially considering the three doses required for effective coverage). For Cuba, the financial obstacle is inseparable from the economic blockade imposed by the United States since February 1962: Cuba cannot directly purchase commercial vaccines against *S. pneumoniae* nor reliably access indirect supply channels, due to financial sanctions, insurance restrictions, and export controls[4].

The concrete consequences of the economic, financial, and commercial blockade on Cuban biotechnology are deep-rooted and systemic. Extraterritorial "rules," for example, prohibit the sale to Cuba of equipment containing 10% or more US-made components, effectively excluding the country from global suppliers of chromatography systems, spectrometry instrumentation, bioreactors, and filtration systems; numerous critical reagents are subject to denied or revoked export licenses. Furthermore, restrictions on international payments and shipping insurance, along with sanctions against any entity trading with Cuba, further prevent or delay supplies, with cold chains difficult to guarantee and timelines incompatible with the stability of many biological materials. Scientific publications, access to information, peer exchange among professionals, the use of scientific software and updates, as well as maintenance services, both remote and on-site, are also subject to the severe limitations imposed by the blockade, compromising research and the development of biotechnological products essential for public health. Securing commercial partners under these sanctions is extremely complex, including the support of any international bank (itself subject to sanctions) willing to process transactions: all of this constitutes a constant violation of international law.

Actors of philanthro-capitalism such as the Gates Foundation and Gavi, the Vaccine Alliance, have expanded vaccine coverage in many countries, yet they operate within a framework in which the means of producing vaccine innovation are concentrated in a few private actors and prices reflect market

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power relations more than population health needs, configuring a form of (also) health imperialism[5,6]. The recent decision of the Donald Trump administration to suspend all support for these activities has highlighted the limitations faced by poorer countries when dependent on such "alliances." At the same time, Cuba's inclusion on unilateral US lists of "State Sponsors of Terrorism" constitutes an enormous obstacle to dialogue and access to subsidized procurement mechanisms, despite the country's advanced biotechnological capacities and effective public health system.

Developing a conjugate-vaccine against multiple serotypes of *S. pneumoniae* requires a sequence of efficient biotechnological steps: production and purification of capsular polysaccharides from prevalent serotypes, chemical activation and conjugation to carrier proteins, chemical and immunochemical characterization, formulation, and quality control. The transition from 7 to 11 serotypes, calibrated to regional epidemiology, was achieved without regular access to standard supplies, through substitutions, reverse engineering of materials, and adaptation of protocols to the resources available on the island. To date, with QuimiVio7 approximately 40.000 children have been vaccinated during clinical trials and, following authorization in 2024 by the Cuban regulatory authority CECMED, more than 150.000 children have been immunized under the national vaccination schedule, with results comparable to conjugate vaccines authorized in other countries[3,7,8]. With the new QuimiVio11 vaccine candidate, approximately 200 adults and 300 children have been vaccinated in ongoing clinical trials. The impact of QuimiVio among Cuban children has dramatically reduced disease incidence and hospitalizations: in children aged 1-4 years, the incidence rate of meningitis and other invasive respiratory diseases caused by *S. pneumoniae*, previously 3.1-9.1 per 10.000 children, has now been reduced to zero.

Cuba's decision to develop QuimiVio reflects a logic of health sovereignty and equity: removing the production and distribution of the pneumococcal vaccine from dependence on multinational pharmaceutical markets and creating a public technological option for resource-limited settings. In this perspective lies the reflection of Agustín Lage, one of the architects of Cuban biotechnology: "*Knowledge is today the principal productive force*" and in countries of the Global South "*science must be oriented toward social needs, not markets*". The economic blockade "*is not merely a commercial restriction, but a direct obstacle to scientific development*" because it strikes "*the infrastructures of knowledge and technological chains*"[9].

The impossibility of purchasing existing conjugate-vaccines (due to cost, blockade, and sanctions) and the obstacles, constraints, and limitations affecting their production, regarding reagents, equipment, and essential services, define a circuit of exclusion that only sustained public investment can break. An 11-valent pneumococcal vaccine designed, developed, and produced under these increasingly restrictive conditions represents a human, scientific, and public health achievement of the highest significance. QuimiVio and other Cuban vaccines (VAMENGOC-BC, QuimiHib), the Soberana vaccines against SARS-CoV-2, and those developed by Centro de Inmunología Molecular (CIM) and by Centro de Ingeniería Genética y Biotecnología (CIGB) demonstrate that vaccine innovation can emerge outside multinational industrial circuits, even in conditions of prolonged humanitarian emergency. The challenge, in the interest of the common good, is that Cuban vaccines also be made available without political and economic ostracism by a few at the expense of many.

Infections caused by *S. pneumoniae* continue to result in around 200.000 deaths annually among children under five years of age, despite the availability of effective and safe vaccines. Yet access to pneumococcal vaccination in many settings, particularly where need is greatest, is subordinated to international political and market decisions, thereby denying children's right to health worldwide. Likewise,

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the United States' economic blockade against Cuba, which restricts access to vaccines, technologies, and essential resources, constitutes a persistent injury and systemic violation of human rights.

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