Chapter 1
COVID-19 Vaccines: Between Ethics, Health and Economics

1.1 Introduction

From 7 to 13 years of research and development (R&D) and 1.8 million clinical trials to develop a vaccine in the past, we have moved on to 10 months of R&D and tens of thousands of clinical trials to start vaccinating against COVID-19 in 2021.

One cannot talk about vaccines without referring to the Frenchman Louis Pasteur. In 1885, after 8 years of animal research, Pasteur announced the principle of vaccination: 'Inoculate weakened viruses which have the characteristic of never killing, giving a mild disease which preserves from fatal disease ...' (Institut Pasteur, 2021).

On 6 July 1885, a 9-year-old Alsatian boy, Joseph, bitten fourteen times by a rabid dog, gave Louis Pasteur the opportunity to test his treatment on humans. This first vaccination was a success, and the boy became the first human being to be vaccinated (Institut Pasteur, 2021). In 1908, in Lille, France, Albert Calmette began work on a vaccine against tuberculosis. Thirteen years later, the first baby was vaccinated in a Paris hospital. In 1948, the American Jonas Salk focused his research on a polio vaccine. Eight years later, after 1.83 million clinical trials, it was announced that Salk's vaccine was safe and effective in preventing polio (Hammond, 2020).

1.2 Development of the COVID-19 Vaccine

In response to the devastating COVID-19 crisis, the search for a vaccine led to an unprecedented and massive injection of public funds into global R&D. According to the WHO, there are more than 50 vaccine candidates in clinical trials around the world (WHO, 2021a). Laboratories in the US, Europe, Russia, China, Cuba and India have developed and are producing vaccines, several have been licensed and vaccination campaigns have been launched.

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Basically, two types of vaccine technologies are used: the classical ones, based on the use of a whole, inactivated virus, or on the use of a part of the virus; and the so-called 'new' technologies, based on the use of 'pure' nucleic acid (DNA or RNA) (e.g. Moderna and Pfizer-BioNTech) or on the use of a viral vector (e.g., Oxford-AstraZeneca, Johnson & Johnson, Sputnik, CanSinoBIO) (Société de Pathologie infectieuse, 2021). These latter platforms have already been investigated for years in relation to other viruses. They have enabled the rapid identification of a vaccine against COVID-19 as soon as the infectious agent was identified and represent a revolutionary breakthrough.

Historically, large pharmaceutical companies have not been very interested in producing vaccines. Treatment of severe or chronic conditions is more cost-effective than prophylaxis (Bezat, 2021). However, the COVID-19 pandemic has changed this situation. The astronomical sums of public subsidies to private companies have changed their financial prospects and the global epidemic has created a huge potential market. It is a question of vaccinating the entire world's population; it is not known how many times and how often (Bezat, 2021).

1.3 Two Key Issues: Immunity and Contagion

Many questions remain open. The duration of immunity provided by the vaccine is one of them. If it provides immunity for 6 months, it would not be called a vaccine, but a drug. But it will take time to study the duration of vaccine immunity. Unfortunately, this time cannot be 'bought'. Simply injecting money into public health care, as Bill Gates may think, cannot solve everything, such as the necessary reconstruction of healthcare systems that have suffered years of budget cuts.

On the other hand, it is not yet known whether vaccines can block contamination of other people, which is fundamental to the concept of vaccination (Herzberg, 2021). Meanwhile, the emergence of variants complicates the situation, with a possible weaker immune response of some vaccines to certain variants.

At the same time, some vaccines will have a limited global reach due to their characteristics. For example, storing Pfizer's vaccine below –70 °C requires expensive refrigerators – more than 12,000 euros – that are not available in many countries, especially in remote areas, and complex logistics. US researcher William Haseltine also wonders whether 'Pfizer and Moderna have created a Lamborghini when what most countries really need is a Toyota' (Haseltine, 2020).

1.4 Vaccine Nationalism

By the end of March 2021, WHO reported more than 120 million cases and more than two million deaths worldwide . According to the WHO Director-General, as of 18 January 2021, 39 million doses of COVID-19 vaccine had been administered in

49 industrialised countries and only 25 doses in developing countries. 'Not 25 million; not 25 thousand; just 25' doses (WHO, 2021b). In the meantime, the situation has changed, but huge inequalities remain between the industrialised countries and the countries of the Global South.

Some governments, such as those of the United States of America, the United Kingdom and also the European Union, have wanted to buy (monopolise) the entire production of candidate vaccines, or prevent their export outside their borders, to cover their own population first and foremost, an operation known as 'vaccine nationalism'[1] (Santos Rutschman, 2020). The United States, for example, has signed at least six bilateral agreements, totalling more than one billion doses, more than enough to inoculate its entire population (328 million). The European Union (447 million), Britain (67 million) and Canada (37 million) have signed seven bilaterals each, with the potential to cover their populations two, four and six times over, respectively, according to Duke University's Center for Global Health Innovation (Serhan, 2020). Vaccine shortages, linked to production difficulties, have led not only to a fierce market, with uneven distribution, but also to geopolitical leverage games, a 'vaccine diplomacy'. For example, the Chinese vaccine Sinovac has reached Brazil, the Russian vaccine Sputnik has reached Argentina, and the Indian vaccine Covishield (with Oxford-AstraZeneca) has reached several countries in the Global South.

Vaccine nationalism is not new. In 2009, during the influenza A (H1N1) pandemic, similar 'nationalism' also emerged. Access to vaccines and treatments was determined by purchasing power, with high-income countries securing supplies for their populations ahead of the rest of the world.

1.5 The COVAX Mechanism

In June 2020, a global collaboration called the ACT Accelerator defined a financing mechanism for universal access to COVID-19 vaccines (called the COVAX mechanism). This global immunisation plan is co-led by Gavi (the Vaccine Alliance, an international organisation heavily influenced by the Gates Foundation), the Coalition for Epidemic Preparedness Innovation (launched in Davos in 2017) and the WHO (Gavi, 2020).

The announcement of COVAX generated a strong global response, especially from Southern countries concerned about equitable access to future vaccines. Almost a year later, the COVAX mechanism is being challenged because industrialised countries and big pharma have ignored the commitments made. Similarly, it has not been possible to open the debate on compulsory licensing. This World Trade

[1] This expression was used by the WHO Director-General Tedros Adhanom Ghebreyesus during a roundtable discussion on 6 August 2020.

Organization (WTO) legal mechanism would increase access to vaccines in countries but is strongly resisted by industrialised countries and industry.

Compulsory licensing, and even an exception as requested by South Africa and India and supported by many developing countries in 2020 and 2021 at the WTO, are certainly mechanisms to be used in times of a global pandemic threatening the entire planet.

1.6 Compulsory Licensing

The patent holder is free to exploit the invention protected by the patent or to allow someone else to exploit it. However, where justified by the public interest or the need to correct anti-competitive practices, the government may authorise a third party to use the invention, without the consent of the patent holder, under a compulsory license. The patent holder is thus obliged to tolerate the exploitation of his invention by a third party or by the government itself. In such cases, the public interest in ensuring wider access to the patented invention is considered more important than the patentee's private interest in fully exploiting his exclusive rights. Compulsory licenses therefore allow third parties to use an invention without the consent of the patent holder. For example, when certain drugs are protected by a patent and their price makes them unavailable to the local population, local pharmaceutical companies can obtain compulsory licenses to produce generic versions of patented drugs or to import generic versions of drugs from foreign manufacturers. Since 1995, there have been 108 compulsory licensing attempts for 40 pharmaceutical products in 27 countries (Velásquez, 2019).

1.7 Access to Medicines and Vaccines: A New Player

Historically, access to medicines has been in the hands of two actors: the commercial actor (pharmaceutical industry) and the health actor (ministries of health). COVID-19 introduced a new actor: the political actor (governments and opposition to governments). Today, governments buy and decide who should be vaccinated and when. However, they are at the mercy of industry, which makes the 'scientific' announcements about the efficacy of its products, announces timelines, sets expectations, imposes prices and demands immunity from possible negative side effects of its vaccines. Governments have less and less power to regulate and control the vaccine industry, or at least have so far demonstrated their inability to do so. The WHO watches helplessly and lucidly, as its recommendations are voluntary. If the primary objective of the WHO is public health, the industry seeks profit, the national health sector depends on the political actor, and the political actor seeks the votes (support) to stay in or gain power.

Industrialised countries may succeed in vaccinating all or three-quarters of their population by 2021, but they will probably ignore the ethical principles, health logic and economic rationality to which they committed to the COVAX mechanism. The purchase of individual vaccines has been left to the market of supply and demand. The concept of public goods advocated at the World Health Assembly in May 2020 by the UN Secretary-General and many heads of state and government seems to have been sidelined.

Many questions remain to be answered, such as the duration of vaccine coverage, its ability to block transmission and the medium- and long-term side effects. Or to what extent states will accept the industry's demand not to be responsible for possible side effects, to what extent contracts between industry and governments will be transparent, or whether common public goods will be patented. Every day more and more questions arise due to the speed at which the virus advances and solutions are proposed. COVID-19 clearly illustrates the need to use compulsory licensing and, ultimately, the question of how to implement a research and development (R&D) model for vaccines and medicines that ensures equitable access to health for all.

The management of a pandemic cannot be left to commercial companies competing with the primary intention of making money; the public interest needs to be placed well ahead of the commercial interest and knowledge needs to be in the public domain in the service of the progress of science.

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