

Restructuring the Global Vaccine Industry

Executive Summary

Felix Lobo



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EXECUTIVE SUMMARY

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RESTRUCTURING THE GLOBAL VACCINE INDUSTRY

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ABSTRACT

The purpose of this report is to analyse the vaccines industry under the focus of Industrial Economics as an input for the design of the pertinent instruments to promote development, manufacturing and distribution of vaccines against SARS-CoV-2 in sufficient amounts to immunize all countries as soon as possible. We also need to be prepared for future emerging infectious diseases with the potential of global expansion.

The report shows that the vaccines industry is – and has been for a long time - far away from the competitive market paradigm with notorious market failures. As a result, the industry is underperforming with shortages and stockouts, exit of firms from the industry, underinvestment in research and development (R&D) and manufacturing, even an “anaemic development pipeline”, all signs of market failure.

After a brief review of policies implemented to tackle these problems we conclude that after the COVID-19 pandemic there is a need to implement a profound overhauling of the industry and to fundamentally reformulate and extend global public policies to stimulate R&D, manufacturing, distribution and access.

L'objectif de ce rapport est d'analyser le secteur des vaccins sous l'angle de l'économie industrielle afin d'une part, de contribuer à la conception d'instruments utiles pour promouvoir le développement, la fabrication et la distribution de vaccins contre le SRAS-CoV-2 en quantité suffisante pour immuniser tous les pays dès que possible et d'autre part, de mieux nous préparer à faire face aux maladies infectieuses émergentes susceptibles de se propager à l'échelle mondiale.

Le rapport montre que le marché des vaccins est, et a été pendant longtemps, très éloigné du paradigme de la concurrence et marqué par de nombreux dysfonctionnements. En conséquence, le secteur, qui est souvent confronté à des pénuries et ruptures de stock, affichent des résultats décevants, qui ont amené certains entreprises à s'en retirer. Il accuse par ailleurs un déficit d'investissement dans la recherche et le développement (R&D) et la fabrication, et son pipeline de développement est inexistant ou presque. Ce sont autant de signes qui montrent que le marché dans ce secteur est défaillant.

Après un bref examen des politiques mises en œuvre pour résoudre ces difficultés, le rapport conclut, après la pandémie de COVID-19, à la nécessité de procéder à une refonte totale du secteur et de reformuler en profondeur les politiques publiques à l'échelle mondiale et de les étendre afin de stimuler la R&D, la fabrication et la distribution de vaccins et d'améliorer leur accès.

El propósito de este informe es analizar la industria de las vacunas bajo el enfoque de la economía industrial como aportación para el diseño de los instrumentos pertinentes que permitan promover el desarrollo, la fabricación y la distribución de vacunas contra el SARS-CoV-2 en cantidades suficientes para inmunizar lo antes posible a la población de todos los países. Además, hemos de prepararnos para enfermedades infecciosas que puedan aparecer en el futuro y que tengan el potencial de expandirse a escala mundial.

En el informe se indica que la industria de las vacunas se ha alejado —y lleva así mucho tiempo— del paradigma de mercado competitivo con infames fallos del mercado. Como resultado, la industria está teniendo un pobre desempeño con escasez de productos y falta de existencias, la salida de empresas del sector, la falta de inversión en investigación y

desarrollo (I+D) y en fabricación, e incluso una “cartera anémica de proyectos de desarrollo”, todos ellos síntomas de fallos del mercado.

Tras un breve examen de las políticas aplicadas para hacer frente a estos problemas, concluimos que, después de la pandemia de COVID-19, existirá la necesidad de efectuar una renovación a fondo de la industria y replantear por completo y ampliar las políticas públicas mundiales con el objeto de estimular la I+D, la fabricación, la distribución y el acceso.

EXECUTIVE SUMMARY¹

Vaccines are our arms of mass salvation to overcome the Coronavirus Disease 2019 (COVID-19) pandemic. There is also a large consensus that globally we will not be safe until we are all safe. Vaccines, now that they are available, have to be manufactured in sufficient amounts and distributed to all countries as soon as possible. We also need to be prepared for future emerging infectious diseases with the potential of global expansion. The purpose of this report is precisely to analyse the vaccines industry under the focus of Industrial Economics as an input for the design of the pertinent instruments to reach these goals. Economics certainly can help in this endeavour.

The vaccines industry is – and has been for a long time - far away from the competitive market paradigm with notorious market failures. As a result, the industry is underperforming. After a brief review of policies implemented to tackle these problems, we conclude that after the COVID-19 pandemic there is a need to implement a profound overhauling of the industry and to fundamentally reformulate and extend global public policies to stimulate research and development (R&D), manufacturing, distribution and access.

1. THE TECHNOLOGY OF VACCINES

We now have vaccines to prevent more than 20 life-threatening diseases, saving 2-3 million deaths every year. Vaccines are biological products made of large, complex molecules more difficult to characterize, with greater variability in production and problems of reproducibility and quality control because of contaminations in comparison with small molecule drugs (chemical pharmaceuticals). As most vaccines are designed for primary prevention and applied to large populations of healthy people, safety requirements must be reinforced. To note, they have a long life-cycle.

Vaccines may be produced by classic biologic methods or, nowadays, also through biotechnology. We can divide vaccines into two broad **types**: “classic or traditional” (Live-attenuated vaccines, Inactivated vaccines and Toxoid vaccines) and “innovative” (Subunit, recombinant protein, polysaccharide, and conjugate vaccines; Virus-like particles and Nucleic acid vaccines). Among the latter, Messenger Ribonucleic Acid (mRNA) vaccines are at present the most important, offering high levels of protection against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and providing in the first half of 2021 a substantial part of supplies. They require shorter developing and manufacturing times and are very safe. But they may be unstable and easy to degrade requiring to be encapsulated into lipid-based nanoparticles and extreme cold temperatures to store.

As of 1st of June 2021, six vaccines against SARS-CoV-2 are already approved by the World Health Organization (WHO), the Food and Drug Administration (FDA) or the European Medicines Agency (EMA). The technology platforms are as follows: two mRNA; two Non-replicating viral vector (adenovirus); two Inactivated virus. As of 7th of May 2021, there were 183 vaccines in pre-clinical and 97 in clinical development, according to WHO.

R&D of vaccines undergoes several **steps**. After the initial discovery research and pre-clinical stages, there are two interrelated streams of innovation: Clinical Development (with the well-known three phases) and Bioprocess Development (more of an industrial nature and with three steps in turn). Finally, regulatory approval by national or regional agencies involves the extensive review of all data to assess safety, efficacy and quality. The total time for development of a vaccine usually amounted to 10 to 15 years. The case of vaccines against SARS-CoV-2

¹ References can be found in the main report.

has been extraordinary. In approximately ten months since sequencing the virus in January 2020, the first vaccine was licensed by FDA and EMA.

In the last fifty years R&D and deployment of vaccines offer impressive **milestones**: the global eradication of smallpox (1980); the reduction of polio cases by 99.5 % since 1988; the first vaccine based on recombinant technology (1986); the first polysaccharide-protein conjugate vaccine (1987); the extension to adolescent vaccines (Human Papillomavirus (HPV) 2009); and, of course, the approval of the first two mRNA vaccines at the end of 2021. mRNA vaccines eliminate some of the difficulties in development, shorten the time needed and can be quickly tailored for new variants or future pandemics.

R&D of vaccines is not only lengthy, it is **risky**. It is estimated that less than 1 in 15 vaccine candidates entering Phase II Clinical development achieves licensure. The average vaccine, taken from the pre-clinical phase, requires a development timeline of 10.71 years and has a market entry probability of 6 %. Nevertheless, vaccine timelines remain significantly shorter when compared to New Chemical Entities development. In sum, R&D of vaccines is a complex, lengthy and risky process.

Vaccine **manufacturing** requires high technological and organizational levels on the part of the manufacturer, substantial investments in plant and equipment and highly trained technical staff. It involves selecting suppliers of key ingredients, setting up manufacturing processes and quality checks, and sourcing primary and secondary packaging. Manufacturing “classic” vaccines is a slow biologic process involving the production of proteins. After inspection, the product is filled into vials, followed by packaging, labeling, and controlled storage. The production of mRNA vaccines - largely chemical and requiring specialized equipment – is less complicated because mRNA molecules are far simpler than proteins and the human body manufactures viral proteins itself.

At least for traditional vaccines, manufacturing processes are therefore **complex**. The lead time to produce a vaccine lot may be as long as three years. Furthermore, to produce proteins involves uncertainty and variability about yields, performance and throughput due to biological variability. There are also contamination incidents. These are some of the reasons why the number of vaccine manufacturers remained low before and upon the explosion of the COVID-19 pandemic and for manufacturing failures and supply shortages.

Manufacturing requires also the organization of a complex **supply chain** of specialized substances. Difficulties in the case of SARS-CoV-2 have been: 1) the supply chain had to be organized from scratch for the new mRNA vaccines; 2) the pressure on global supply chains given the unprecedented scale of vaccines to manufacture.

To cover world demand, **global manufacturing networks** were under deployment in the first half of 2021. Large multinationals and other companies have embarked in agreements with contract development and manufacturing organizations (**CDMOs**). Promoting these arrangements is crucial to increase global capacity and production. The question remains **whether these mainly private market arrangements are enough** to match the entire world population needs and reverse the present highly inequitable distribution of vaccines.

The complexities of manufacturing processes and supply chains for vaccines do not exclude the role of **new actors and increased competition**. Appropriately organized **transfers of technology**, as the hubs initiated by WHO, would be instrumental. **The potential of local production and smaller firms, government research centers and universities** is not to be discarded. The examples of The Serum Institute of India and small/medium innovative firms like BioNTech and Moderna, or the University of Oxford are very clear. Also, consumables can be an area of cost saving given lower prices in low resource countries. **Purely public and**

private/public collaborative internationally driven new projects of manufacturing plants in developed and developing countries are also under serious consideration.

2. A DESCRIPTION OF THE VACCINE INDUSTRY

The **second chapter** describes the vaccine industry. It is a relatively small segment compared to the pharmaceutical industry as a whole. In 2019, it held 3.6 % of the total world market for pharmaceutical products (prescription and over the counter (OTC)) with **sales estimated at 32,500 Million USD worldwide**, being the fifth largest among 14 therapeutic areas.

The sector in the past 20 years has shown **remarkable growth** thanks to innovative vaccines, new target population groups (adolescents) and more aggressive pricing strategies. The COVID-19 pandemic has brought an enormous increase in production and sales to attend the global demand. Therefore, growth is expected to be very high in the next and forthcoming years with estimates between 8.1 and 15 % from 2020 to 2026.

Geographical concentration of production is high. The “vaccine production club”, a small number of nations, concentrates the production and trade of both COVID-19 vaccines and ingredients. This is a consequence of concentration at the firm level, with a small number of multinational companies and plants mostly located in developed countries. Developing economies depend on high-income countries for vaccines. This state of affairs has important policy implications at a time of significant shortages of COVID-19 vaccines. However, East Asia and South Asia are increasingly becoming a source of vaccines for other developing regions. China and Russia have emerged as developers and producers of COVID-19 vaccines.

According to WHO, before the pandemic “about 80% of global vaccine sales come from five large multi-national corporations (MNC)... While maintaining a strong focus on vaccines for industrialized country markets, MNCs also sell their products in developing countries...”. Now, “emerging manufacturers (in India, China, and Brazil), play a critical role in the supply of vaccines of developing countries, particularly basic and some combination vaccines”. It “...has resulted in lower vaccine prices due to increased competition and higher production capacities...”.

There is also vertical **specialisation in R&D** as in other segments of the pharmaceutical business. Large vaccine companies mainly focus in clinical and process development, while smaller biotechnology companies are cantered in the earlier innovative stages.

There are strong **trade interdependencies** in the goods needed to produce, distribute and administer vaccines (access is required to goods produced across a range of countries), in accordance with the concentration of production. Exports of vaccines are significantly concentrated in the European Union (EU) and United States of America (USA). Imports are, in relative terms, less concentrated.

Probably the COVID-19 pandemic is changing the landscape. The rise of capacity in existing firms (“scale-in”) and the unprecedented deployment of agreements and transfers of technology to CDMOs (“scale-out”) and particularly the leading role of innovative new small/medium companies introducing mRNA vaccines are depicting a new reality. More studies are needed to know whether the network of scaling-out agreements will go beyond fill and finish for cost reduction and increasing manufacturing. In the long run the technical capabilities of R&D and manufacturing have to be significantly increased and distributed to meet the global needs and to prevent and respond rapidly to emerging infections and future pandemics in all regions of the world.

3. THE STRUCTURE OF THE VACCINE INDUSTRY

The structure of the vaccine industry is the purpose of chapter three. The first fact is that the **benefit/cost ratio of many vaccines is extremely high**. For every dollar invested the return may rise up to 27. Their performance is outstanding: highly positive health outcomes and reduction of the financial burden on health systems.

The first factor relevant to **demand** is that consumers usually are large, healthy populations. It implies stringent safety standards requiring clinical trials enrolling large groups of subjects. Other factors are that consumption of vaccines is an infrequent event; individual and aggregate demand depends on epidemiological variables, mainly incidence of illness; frequently there are vulnerable subpopulations; and effective treatments may function as a substitute good.

The **market size** for vaccines is not small. For anti-SARS-CoV-2 vaccines of course demand is the whole global population. If we examine vaccines designed for children alone, the number of births per year worldwide (140.1 million in 2019, of which 7.7 million was in Europe and 4.3 million was in North America), though declining in most developed parts of the world, provides a significant target population. Developing countries have a low ability to pay and provide limited sales potential but in the future, their demand will grow because of economic growth and high birth rates. International cooperation has been and will certainly increasingly be a key source of financial support and technical assistance. COVID-19 demand for effective vaccines already available has skyrocketed to 9,000-11,000 million doses for 2021 but it is unlikely it will be fulfilled. The unbalance in supplies and vaccination rates between developed and developing countries is currently the most important global challenge to tackle with the pandemic and recover the international economy. It is also anticipated that COVID-19 will prompt increased demand for new vaccines and therapeutics and shifts in demand for existing therapies.

In the case of vaccines, “**herd immunity**” – a positive externality - occurs when a sufficient portion of a population becomes immune to an infectious disease and the risk of spread from person to person decreases. Those who are not immune are indirectly protected. “Free-riders” may then refuse vaccination expecting others to do so and getting the benefit of herd immunity at no cost. Therefore, the rate of vaccination could fall short of what is needed. This is the first and very important market failure afflicting the vaccine industry. Subsidies, direct provision free of charge, legal requirements to enter schools, work premises, to travel... have to be implemented by the State to overcome free riding.

From the **supply** side there are five points to be highlighted: capital requirements; the production function; product specialization in manufacturing; horizontal concentration and the absence of generic competition.

Information about costs and profits in the pharmaceutical industry at large and in the vaccine segment is scarce, but it seems that the production function involves substantial complexities and high costs in R&D, production, testing, evaluation and distribution.

The vaccine industry is, for technical reasons, a **capital-intensive** business requiring considerable investments in time, manufacturing assets, facilities, and technical staff as was mentioned in chapter 1. This is a barrier to competition from new firms undertaking production. The financial investment in manufacturing plants circa 2017 was in the range of 50 to 700 M USD according to different estimates, countries and types of products. But new methods and technologies are lowering capital costs and time giving room to deploy and switch on small facilities more broadly and quicker.

The **production function** includes different cost items. The high level of **R&D costs** for chemical pharmaceuticals probably is transferable to vaccines. Success rates are better, but

size of clinical trials is larger and a number of unavoidable stages must be passed for vaccine development (mentioned in chapter 1). These high sunk fixed costs are a barrier to new competitors and encourage market concentration (section 3.3.4.). The support of governments, **public funding** and state laboratories to vaccines R&D is very important. Circa 2000, in the USA one third of all funding were provided by the National Institutes of Health (NIH). Operation Warp Speed of the US Federal Government has provided more than 19,000 M USD to seven private pharmaceutical manufacturers including R&D for treatments and the actual purchase of the vaccine doses. Adding up actual purchasing of doses by Member States the total amount of funds mobilized by the EU for vaccines is over €30,000 M.

Risk of batch contamination in manufacturing or distribution is, for technical reasons (section 1.3), a significant entrepreneurial risk, giving rise to significant costs. Current Good Manufacturing Processes (cGMP) have to be followed and enforced.

Given that vaccines are generally administered to healthy individuals, and the risks of adverse effects and contaminations, R&D, production and distribution of vaccines are subject to detailed **regulations** all the life of the product. Regulations include evaluation, licensure and control of the product, the manufacturing plant, the process, the batch, trade operations, adverse events and risk management plans.

Eventual adverse events and contaminations (with or without fault) may give rise to difficulty in insuring **product liability** with very large financial consequences. These risks increase suppliers' costs and diminish incentives to enter the industry and to manufacture and have led firms to discontinue operations and exit the market, as well as to shortages, rising prices and falling number of suppliers. It was one of the main complications in negotiating purchase of anti-COVID-19 vaccines by the EU Commission or India and pharmaceutical companies. Different remedial policies are reviewed in part 5.

In view of these peculiar sources of costs we can conclude that **the production function** is more complicated in the vaccine industry than expected in many industries and goes far beyond the usual components of costs. It is worth noting, nevertheless that manufacturing costs fall once the fixed costs are covered and with higher volumes of production to satisfy larger market demand.

In the vaccine industry plants and equipment are specific for each product. **Product specialization in manufacturing** implies lack of flexibility to adapt to shocks in demand and increased risk of shortages and production dead stops.

High **horizontal market concentration** leads to market power, monopoly or oligopoly and vulnerability of supply chains. The vaccine industry has been depicted as the “vaccine production club”. Concentration has evolved along time as some firms exited the market or as a result of mergers and acquisitions. Top four Western suppliers accounted in 2014 for 85 % of global sales for all vaccines. According to the WHO, nearly one third of vaccines have fewer than four suppliers, while nearly two thirds have two or fewer prequalified products. The negative consequences of concentration are that when key suppliers experience manufacturing problems, supply interruptions and vaccine shortages interrupt immunization schedules, posing risks to vulnerable populations. Nevertheless, emerging manufacturers (in India, China, and Brazil) play a critical role in the supply of classical vaccines for developing countries.

High concentration is rooted in technical reasons, chiefly **economies of scale** (average costs decreasing with increasing levels of production) that may lead to “natural monopoly”, the “natural state” for the industry. Governments and international organizations have to deploy policies to overcome the inefficiencies of monopoly in terms of welfare loss, particularly the risk of shortages and supply breakdowns.

In the case of vaccines, the barriers to entry to the industry cannot be moved away to implement a market for “**generic**” **vaccines** in the same way as for chemical pharmaceuticals. For follow-on vaccine manufacturing, not only the impediment raised by patents has to be removed, but also the know-how to perform the manufacturing processes has to be transferred. Moreover, follow-on versions of existing vaccines are treated as originators by regulation and detailed tests and clinical trials are generally required. In this respect debates are going on in the context of the COVID-19 emergency. It is not known as of today the impact that new technologies such as mRNA may have on this matter.

In sum, in the **structure of the vaccine industry**, demand by large, healthy populations imposes very stringent safety standards and large clinical trials raising upfront costs, and externalities like “herd immunity” compel public intervention to foster vaccination. In turn, the map of supply is demarcated by high capital-intensity, the production and cost function made of high R&D costs, risks of batch contamination, detailed regulations, product liability and product specialization in manufacturing, all barriers to competition. High horizontal market concentration (rooted in technical reasons, chiefly economies of scale leading to “natural monopoly”) ends in market power, monopoly or oligopoly (the “vaccine production club”) and vulnerability of supply chains. Finally, know-how and regulations prevent competition from generics. To overcome all these market failures governments and international organizations must implement a full array of policies to guarantee supply and access to vaccines.

4. INCENTIVES TO INNOVATE AND BOOST PRODUCTION. ECONOMIC CONCENTRATION, EXIT, UNDERINVESTMENT, SHORTAGES AND PROFITABILITY

In previous sections we have extensively documented high levels of market **economic concentration** and provided some data on **industry exit**. Historically **shortages** have been relatively frequent in vaccine supply. We provide clear evidence from the USA and Spain and warnings from experts on repeated mismatch between supply and demand. **Underinvestment in R&D and manufacturing** is a related problem often signalled by experts. The poor performance may be explained by reasons linked to the structure of the industry already considered in this report: demand (externalities) and supply factors (capital requirements; R&D costs; risk of batch contamination; regulation; liability risks; product specialization in manufacturing and concentration). Three more factors have been considered in different studies on profitability of vaccines: heterogeneity of demand, that immunization acts like durable goods (less profitable than non-durable) and public purchasing and tenders driving prices to low levels.

Reduced **profitability** sometimes is signalled as the main cause for exit from the industry, underinvestment, shortages and general underperformance. But this is an empirical question where different analyses, opinions and estimations are flawed because of lack of conclusive data, though some partial evidence and opinions of experts point to high profits. 2002 partial figures provided by Scherer on “price-cost margin” from the US Census of Manufactures showed a margin of 56.4 % for the sector of Vaccines, toxoids and antigens and 62.3 % for Pharmaceuticals vs. 28 % for Manufacturing Industries as a whole.

In conclusion, **two theories would explain** underinvestment, shortages and exit of firms from the market, both highlighting demand and supply factors in the structure of the industry. The first underlines economic concentration, oligopoly and monopoly, all compatible with high profitability, shortages and exit of smaller firms. The second theory directly focuses on lack of profitability, although there are some partial data challenging this assumption. The point is that both theories lead to the same conclusion: market failures are pervasive and prevent the

industry from satisfying effective demand, triggering shortages of products that are essential for public health and economic development.

To overcome all these market failures governments and international organizations must implement a full array of policies to guarantee supply and access to vaccines, breaking concentration and favouring competition and a more dense and even distribution of manufacturing facilities.

5. A BRIEF INVENTORY OF POLICIES TO STIMULATE R&D AND MANUFACTURING

Though the objective of this report is not an in-depth examination of policy options, chapter 5 very briefly summarizes public policies enforced or proposed to solve market failures in the vaccine industry, stimulating R&D and manufacturing.

“Supply push” policies try to stimulate R&D and manufacturing and reduce upfront costs. Patents or more broadly **Intellectual Property exclusivity rights (IP)** are controversial insofar as they create a tension between incentives to innovate and access to medicines, and because the empirical evidence on their actual ability to foster innovation historically is not clear. Proposals to reform IP have been advanced in the last 20 years, but with little success. The fact is that exclusivity rights have been reinforced, with the exception of the so-called flexibilities of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPs flexibilities”).

Other policies to reduce upfront costs are:

- Subsidies to private R&D
- Subsidies to reduce quality control costs
- Government financed or directly implemented basic research and development
- Public-Private partnerships in R&D, quality control and manufacturing

Collaboration among firms to increase capacity and production can be also fostered with government support and stimuli. The issue is extremely important in 2021 for the need to increase production of anti-SARS-CoV-2 vaccines rapidly. **Direct involvement of government in manufacturing** is also a possibility, envisaged for instance in US legislation.

“Demand-pull” policies to expand demand may also contribute to overcome market failures and increasing vaccination of populations:

- Information and education
- Subsidies at the level of the immunization point
- Direct provision by the public sector, vaccination campaigns
- Legal obligation to be vaccinated
- Philanthropic initiatives, voluntary work...

Advance Market Commitments (AMC) are commitments to purchase a specified number of doses at a specified price if a vaccine meeting certain specifications were developed, reducing uncertainties for both parties and ensuring a solvent and reliable demand for the developer. AMC have been extremely successful in stimulating R&D of vaccines against SARS-CoV-2, but once the vaccines are developed and available they have to be redistributed to guarantee access in favor of all populations at risk in the world through international cooperation.

There are also policies influencing **supply and demand** simultaneously. There is evidence of the positive effects of special civil liability regulations for vaccines, like “no tort liability” and limits to compensations. These rules are intended both to guarantee consumers rights and reduce the very important risk for manufacturers of claims for injuries.

International cooperation with developing countries has included up until the pandemic a variety of initiatives by national governments, international organizations and philanthropic institutions, sometimes through private-public collaborations, with important accomplishments. Nowadays the main global international program for vaccines is the COVID-19 Vaccines Global Access (COVAX) facility. But the program needs to be greatly expedited now with determination and political will from partners and in the future in the face of new pandemics and emerging infections much more resolute and overarching strategies have to be deployed.

After the COVID-19 pandemic all these policies – and particularly international actions - will certainly have to be reformulated and extended on the basis of universal cooperation including a profound overhauling of the industry to overcome the market failures afflicting the sector.

CONCLUDING REMARKS

Market failures are pervasive in the vaccine industry, an essential industrial sector that is far away from the competitive market paradigm, both in national and international terms. High levels of market economic concentration limit “the vaccine production club” to a handful of firms and countries. Consequently, performance of the industry is below the needed level, notwithstanding important successes in development of new vaccines and manufacturing before and after the pandemic of COVID-19. But shortages and stockouts in developed and developing countries, exit of firms from the industry, underinvestment in R&D and manufacturing, even an “anaemic development pipeline”, all signs of market failure - and most probably compatible with high profitability (see chapter 4) – are the dimensions of underperformance in the vaccine industry. Furthermore, the non-competitive and concentrated structure of the industry is one of the reasons explaining continuing insufficient access to vaccines in less developed countries, in spite of recent progress powered by national economic development, public health advancements and a number of meritorious actions carried under the auspices of international cooperation. The sharp unbalance in vaccination rates to prevent COVID-19 between developed and developing countries at the middle of 2021 is a clear demonstration. Vaccine deprivation is not only due to deficient health systems, lack of economic development and finance but also to the configuration of the industry.

The COVID-19 pandemic has demonstrated the need to drastically reformulate and extend policies to stimulate R&D, manufacturing, distribution and access to vaccines. The private sector is not enough, though public/private cooperation particularly in industrial endeavours will be the most efficient orientation. There is a need to implement a profound overhauling of the industry with the goal of universal access of all populations to all vaccines. Box 5.1 provides some suggestions for this profound reform. The present and future pandemics and emerging infectious diseases have to be prevented and treated on the basis of universal cooperation and multilateralism for R&D, manufacturing, immunization and distribution, including increased capacity to develop and manufacture new vaccines in all regions, paying particular attention to less developed countries. This is not only mandated by solidarity among human societies but also by the fact that in front of very contagious pathogens in a world of global and fast interrelations no one is safe until everyone in the Earth is safe.

A last remark is the need for reliable, comprehensive and detailed data and statistics as well a whole battery of studies on the Industrial Economics of the vaccine industry. Increasing our knowledge of the vaccine segment of the pharmaceutical industry is essential for planning and achieving the deep reforms to be implemented in the future.



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