

UNIVERSAL ACCESS AND AFFORDABLE MEDICINES

WILL PHARMA COMMIT TO DELIVERING AFFORDABLE THERAPEUTICS AGAINST COVID-19?

OPINION

About EPHA

EPHA is a change agent – Europe's leading NGO alliance advocating for better health. We are a dynamic member-led organisation, made up of public health civil society, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe.

About EPHA's Universal Access and Affordable Medicines advocacy

EPHA's Universal Access and Affordable Medicines advocacy promotes transparency, accountability and the public interest in the field of pharmaceuticals in line with the priorities of our members most active in this field. We aim to guarantee better and affordable medicines for Europe by questioning and calling for reforms to the current pharmaceutical business model to ensure better access to medicines for all.

See more at <https://epha.org/universal-access-and-affordable-medicines/>

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Will pharma commit to delivering affordable therapeutics against COVID-19?

By Yannis Natsis

How will pharma price the products against COVID-19, be they anti-viral therapies and/or a vaccine? As the pandemic hits Europe and the U.S., pharma is firmly in the spotlight as society turns to them hoping that some therapeutics will be available sooner rather than later, to fight its spread.

It is safe to say that pharma is one of the few business sectors (along with some in tech) that stands to benefit from this crisis not only financially, but more importantly, reputationally. The pandemic comes at a time when pharmaceutical companies in Europe (and beyond) are under growing pressure to abandon their aggressive pricing and other strategies and respond to calls for more transparency and ensuring affordable access to medicines and vaccines for all.

The international pharma trade association (IFPMA) put together an impressive virtual press conference to outline the sector's multifaceted response against COVID-19. There were some encouraging remarks made by the pharma leaders [interviewed](#), around the affordability of end products, but those were unfortunately not repeated in the subsequent official IFPMA [manifesto](#). The European trade association, EFPIA's, numerous recent publications on SARS-CoV-2 are also short on commitments on behalf of the industry around the accessibility and affordability of the eventual products.

The landscape is not clear yet

There are still many questions over the nature and evolution of this new virus as well as about the fate of the innumerable R&D processes which have been launched. This matters, as different business agendas are attached to these unknowns. It is impossible to fully grasp the consequences of this crisis or how pharmaceutical companies will react depending on their pipeline and portfolios. Pharma is pretty diverse anyhow with a plethora of bigger and smaller fish; with great differences amongst companies in terms of their investors and their expectations, potential products and capacity, the competition landscape - to name but a few of the factors to be considered.

Economic recession looming: Pressure on public pharma expenditure

As governments reflect on exit strategies from lengthy lockdowns and a possible rebound of the pandemic in autumn 2020, a severe economic recession is now expected shortly, which will last well into 2021 and possibly beyond. The road

to recovery will be long but the issue of paralyzing price tags of some medicines will soon monopolise the headlines again. In such an economic context, some in pharma may be tempted to quickly exploit COVID-19 related opportunities looking for short-term profit in the face of projected budget pressure, which will be a major self-defeating strategy as it will negatively reflect on the sector's important role in developing new products that can protect people from the virus.

Monopolies are questioned: Pharma is nervous

In the past few days, there has been a cascade of some pretty astonishing developments in the field of intellectual property (IP) and pharma. Governments do not seem to favour patent-based monopolies these days. In fact, they are growing wary of them. They do not want to have their hands tied and options to tackle the COVID-19 emergency limited by patent barriers and exclusivities.

To this end, **Germany** and **Canada** are just some of the **several** countries reviewing their patent protection laws to facilitate limitations on patents, such as the granting of compulsory licenses (CL), a tool to override patent holders' rights and to promote generic competition. **Israel** went ahead and issued a compulsory license for a drug that could be used against the novel coronavirus. The Financial Times succinctly **summed up** the state of play as "Big drugmakers under pressure to share patents against coronavirus" while its editorial board **published** an unprecedented, straightforward, pro-CL view saying that in light of the present pandemic "the world has an overwhelming interest in ensuring these (drugs and vaccines effective against the virus) will be universally cheaply available. Fortunately, trade rules allow compulsory licensing. If necessary, it must be used."

These developments on behalf of governments could be viewed as warning shots and will surely make the industry nervous. The fact that CL, an instrument traditionally regarded as an extreme, nuclear option loathed by pharmaceutical executives, is today, thanks to COVID-19, normalized and presented as a prudent and reasonable policy choice to be endorsed by even the Financial Times says it all.

In another surprising move, American biotech Gilead whose drug Remdesivir, a medicine previously tested against Ebola, now being tried as a potential coronavirus treatment, applied to the U.S. Food and Drug Administration (FDA) for the orphan drug designation i.e. to classify it as a rare disease treatment, and therefore benefit from longer patent protection and other perks. In a shocking move, the FDA did **grant** the orphan drug status recognizing the coronavirus as a rare disease, just days after the COVID-19 outbreak was declared a pandemic by the World Health Organization. Following public **outcry**, Gilead realized its mistake and asked the FDA to **revoke** the orphan designation it had granted two days ago. The FDA did so.

This mind-blowing move by Gilead offers a glimpse of the intense pricing and marketing deliberations that take place inside companies with promising an-

tiviral candidates these days. Gilead and others are testing the waters trying to anticipate reactions. The FDA should have never granted that designation in the first place as coronavirus is not a rare disease but a pandemic, as many pointed out. It seems Gilead was trying to optimize its monopoly (obtaining rare disease, orphan drug regulatory exclusivities on top of the existing patents on Remdesivir) thinking of the potentially enormous market, but instead dented its reputation by misjudging the public mood.

This latest incident is a stark reminder of how the regulatory environment can trigger this sort of corporate misbehaviours while the FDA and the European Medicines Agency (EMA) become the main channels for IP promotion in medicines.

We have had another recent glimpse into industry calculations. The Chief Medical Officer of Johnson & Johnson **recently set** a 10\$ per unit price tag for a possible J&J vaccine against coronavirus. We are a long way from that as best case scenarios set the approval of an effective vaccine to 12-18 months from now. It is however an interesting -not necessarily affordable- benchmark indeed knowing that vaccines are not a particularly profitable business for pharma.

In the mist of uncertainty, there are nonetheless some opportunities:

Time for collaboration and openness

The urgent race for therapeutic solutions illustrates that the time is ripe for collaboration and openness among pharmaceutical manufacturers and other clinical research actors, not competition and secrecy. Pharma companies are used to working in silos due to the lack of trust and the rivalries among them. The Costa Rican **request** for a WHO tech pool for current Covid-19 research gives companies the chance to revalidate their social contract with patients. In supporting such an initiative, they can show that commercial considerations and profit maximization are not at the top of their priorities right now. In practice, such openness and collaborative spirit will accelerate the drug and vaccines research and development (R&D) processes for the benefit of patients and help tackle future outbreaks. Besides, companies love to talk about partnerships. This is their chance to turn words into actions.

Public research investment to tackle COVID-19: No blank cheques for business

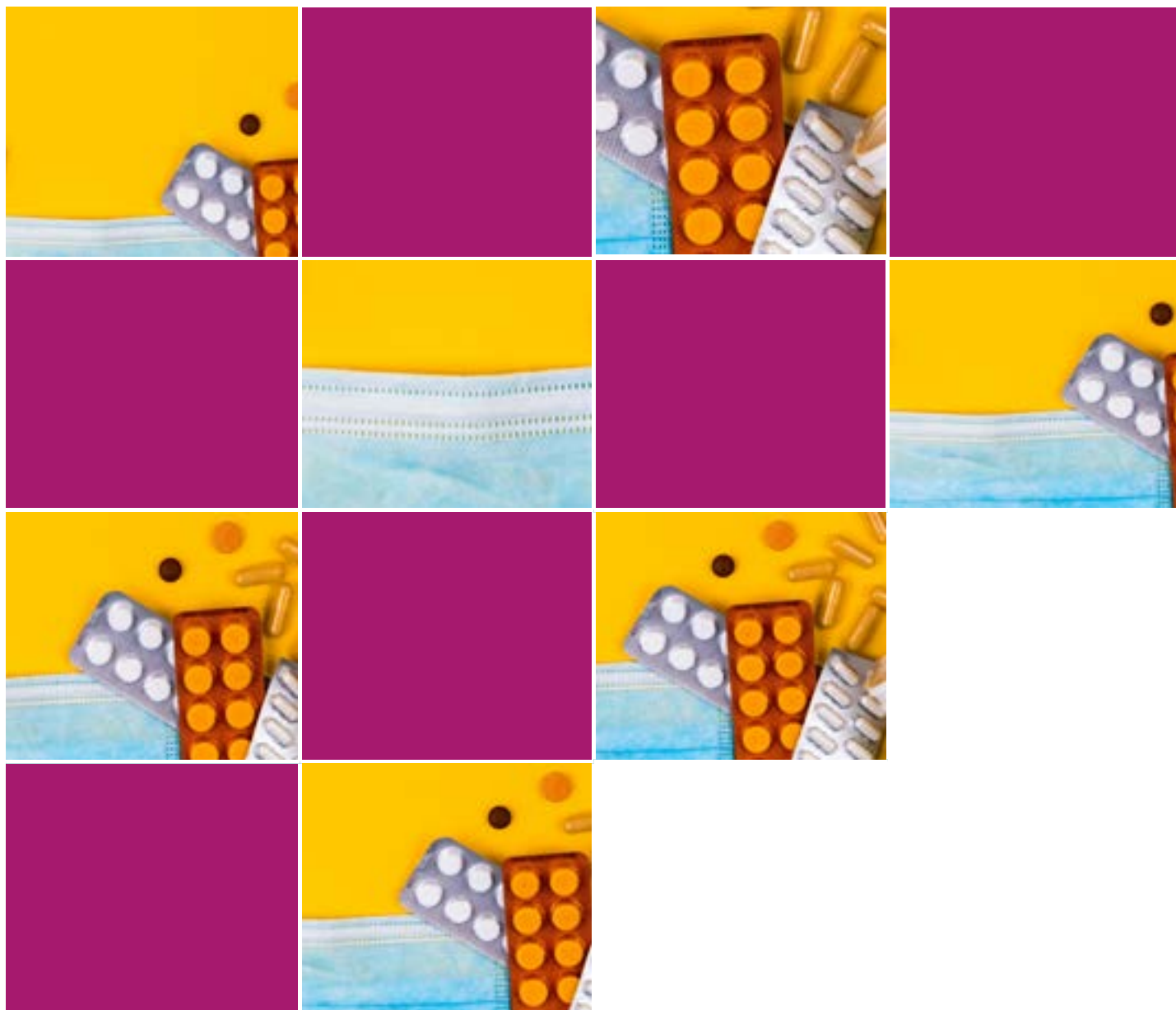
The scale of public investment in COVID-19 related R&D in Europe and worldwide is massive. It is therefore high time we **rewrote** the rules around public funding and public-private partnerships (PPPs) to ensure that the priorities and objectives are not dictated by narrow commercial interests. This is particularly pertinent for EU (Horizon Europe) but also national governments' pledges against the coronavirus. We should not allow these vast amounts of public resources to be simply handed over to corporations with no conditions attached. We need to be careful as COVID-19 is already being exploited by many businesses as a pretext to milk the public cow. PPPs can be of added value only as long as the governance struc-

tures guarantee a fair and balanced representation of public and private interests, especially in the field of biomedical innovation where the public health agenda is not always aligned with corporate priorities.

This is not the time for confrontation. It's the time for positive change.

At this stage, governments are not ready to confront pharmaceutical companies and perhaps this is not the right time to do so. They are preoccupied with other essential concerns. Limitations of resources, planning for future outbreaks, dealing with manufacturing challenges of possible vaccines and antivirals, likely medicines shortages, multiple export bans on medicines and medical equipment disrupting European supply and distribution chains, eventual competition over supply and allocation of covid-19 treatments and vaccines as demand is expected to peak simultaneously across the globe - all while managing a public health crisis which is changing how our societies function - are just some of the headaches decision-makers are having to cope with at the moment. The emphasis right now should be on collaboration, information exchange, Europe-wide coordination and preparedness.

The coronavirus disease offers pharma companies the possibility for public trust in them to be restored. It remains to be seen if they will grasp this chance. More importantly, it offers a real opportunity to reset and improve the way we do things such as biomedical R&D completely. The progress observed today in terms of the massive public support, steps towards **progressive IP reform**, open science alliances, research consortia sharing know-how etc. should not be part of COVID-19 exceptionalism but should become the new normal. This will not only be a significant victory against the latest pandemic but will boost our efforts to tackle other disease areas too.



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