



TRANSPARENCY IN THE RACE FOR A COVID VACCINE

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As the coronavirus crisis continues to have a devastating impact on people's lives and livelihoods, all eyes are on scientists to deliver on a COVID-19 vaccine.

It is widely accepted that a safe and effective vaccine represents our best chance of a permanent escape from this pandemic.

But these vaccines are being developed at an unprecedented pace in even more unprecedented circumstances.

To navigate these uncharted territories while providing a safe vaccine at breakneck speed, regulators and industry are having to innovate to rise to the challenge this presents.

The development of a vaccine under such circumstances has raised a number of concerns, notably over transparency and accountability.

In this Event Report, EURACTIV takes a look at some of the key issues this has thrown up, and how key stakeholders, including the scientific community, regulators, and citizens, can best work together to ensure transparency and safety in this race for a vaccine.



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MEPs call for transparency in race for COVID vaccine amid rising vaccine hesitancy

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By *Natasha Foote* | EURACTIV.com



Green MEP Dr Petra de Sutter stressed that this lack of transparency “undermines public trust” in pharmaceutical companies as a responsible partner

EU lawmakers from across the political spectrum stressed the need for transparency in the COVID-19 vaccine process in a hearing with pharmaceutical industry representatives, emphasising that this is necessary to combat a growing vaccine hesitancy in the EU.

The [hearing](#) was co-hosted by the health (ENVI) and industry (ITRE) committees at the European Parliament on Tuesday (22 September).

It was called to explore the ways to secure access to COVID-19 vaccines for EU citizens after MEPs requested more information about the advanced payment agreements (APA) signed between the European Commission and a growing number of pharmaceutical companies.

These agreements cover part of the upfront costs faced by vaccine producers, allowing investments to be made that might not otherwise have occurred, while also acting as a

down-payment on the vaccines that will actually be purchased by member states.

Most recently, pharmaceutical companies Sanofi and GlaxoSmithKline (GSK) finalised an APA with the Commission for the supply of up to 300 million doses of a COVID-19 vaccine once it is approved.

However, while MEPs welcomed the collaborative efforts made so far to accelerate the development and

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subsequent rollout of a COVID-19 vaccine, questions were raised as to the transparency of these agreements, with a number of lawmakers pointing out that these have not been made publicly available as of yet.

Members lamented that they have had “very little information from the Commission with regards to the content of these contracts,” with MEP Pascal Canfin calling this a “fundamental part of democratic accountability”.

This concern over transparency comes on the back of a recently published joint statement from leading health NGOs calling for more transparency on the governance of the APAs.

“At this crucial stage in the development of one of the main elements of the EU’s response to COVID-19, trust and accountability need to be upheld in order to safeguard and promote public health, the quality of healthcare systems, patient and consumer safety,” the statement said.

In response to MEPs’ concerns, two of the companies leading the charge in the race to find a COVID-19 vaccine, Sanofi and CureVac, agreed to participate in the hearing alongside representatives from academia and specialised medical groups.

TRANSPARENCY VITAL FOR TRUST

Green MEP Petra de Sutter stressed that this lack of transparency “undermines public trust” in pharmaceutical companies as a responsible partner, while the socialist MEP Tiemo Wölken raised

concerns over its contribution to a growing vaccine hesitancy in the EU, saying this is something the EU “cannot afford”.

In response, Thomas Triomphe, executive vice president of Sanofi, stressed that although the exact content of the contract is currently still under confidentiality, the contract was agreed in full accordance with the normal EU process for a call for tender for the development and manufacturing of a vaccine.

Industry representatives stressed their commitments to transparency, with Triomphe outlining Sanofi’s commitment to providing auditable reports to the EU for each step.

Likewise, Jean Stéphane, chairman of the supervisory board of CureVac, emphasised the “joint responsibility for transparency,” offering a commitment that all data will be made publicly available.

‘FRAGILE’ VACCINE CONFIDENCE

Sue Middleton, president of Vaccines Europe, a specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), also emphasised the commitment of the industry to produce a vaccine in line with proper procedural processes, stressing that this is vital to counter vaccine hesitancy.

She highlighted the recent pledge made by nine CEOs of companies developing COVID-19 vaccine candidates to uphold the integrity of the scientific and regulatory process, including a commitment to apply for vaccine approval only once

clinical trials which met regulatory requirements of expert authorities were successfully concluded.

She said the pledge was made for companies to play their role in building confidence in these vaccines, warning that this confidence is “fragile” in many EU countries.

Middleton added that EU authorities must also lay down preparations in the event of adverse effects, either directly or indirectly, as a consequence of the COVID-19 vaccine, which she warned may be likely given the unprecedented scale of this vaccine campaign.

“How we collectively handle this will be key to building or reducing confidence in the COVID vaccine,” she warned, adding that there may well be knock-on effects for vaccine confidence in future.

“One practical approach to building confidence would be to allow any EU citizen who believes they may have been harmed by the vaccine to seek compensation quickly via a no-fault compensation system,” she said.

She added that although this was already in place in 11 member states, not all of these schemes automatically translate to the COVID-19 vaccine.

Health expert: Routine immunisation should not be put on back-burner due to COVID

By Gerardo Fortuna | EURACTIV.com



In France, there have been 57% of postponements or cancellation of routine immunization affecting children during the COVID-19 pandemic. [SHUTTERSTOCK]

A real commitment from all stakeholders and policymakers is needed to support a catch-up immunisation campaign and overcome the difficulties routine vaccination programmes have experienced during the pandemic, according to a key vaccine stakeholder.

In an interview with EURACTIV, the new executive director of Vaccines Europe, Sibilila Quilici, said that while

everyone is rightly focusing on the rollout of COVID-19 vaccination, there is also a concrete risk that other vaccination programmes might end up overlooked.

“Significant healthcare system resources are allocated to COVID-19 vaccination and little, if any, attention is given to routine immunisation to ensure continuity,” she said.

Routine national immunisation

programmes are intended to protect the population against vaccine-preventable diseases such as measles, human papillomavirus-related diseases and cancers, influenza or pneumococcal infections, to name but a few. Such programmes are widely recognised as one of the world’s most successful and cost-effective health interventions.

“Lockdown and social distancing measures created a change in the

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behaviour of the population with regards to access to healthcare in general, including primary prevention such as routine vaccination," Quilici said.

Temporary interruptions of routine immunisation services have been reported as people tended to avoid health services in order not to get infected with COVID-19. In some cases, national governments have even suspended immunisation programmes to prevent such a risk.

According to Quilici, this leads to misleading communication about the importance of vaccination, ending up in a significant reduction in appointments and up-take of routine vaccination.

In France, there have been 57% of postponements or cancellations of routine immunisation affecting children, and 49% for adults.

"We know that population today is not at the level of protection they should have," Quilici stressed.

At the peak of the first wave of the pandemic, the World Health Organisation and UNICEF released a joint statement stating that the COVID-19 pandemic is a "stark reminder that infectious diseases know no borders. All countries are vulnerable, regardless of income levels or the strength of their health care systems."

"The current offer for routine immunisation includes protection at all stages of life, depending on the individual's health status, age, lifestyle and occupation," Quilici said.

"It includes not only kids or the elderly but also adult people such as

young parents, travellers or people with occupation requiring adequate protection against infectious diseases such as military or healthcare professionals," she added.

Complete life-course immunisation programmes are in force all across Europe, with the Italian ones offering one of the most complete protections against 18 infectious diseases.

COVID, A DOUBLE-EDGED SWORD

On the positive side, lockdown measures and protective masks have been an efficient way to avoid an outbreak of influenza and other epidemics this year.

"But what will happen once people are vaccinated for COVID-19 and go out again?" asked Quilici.

The risk of outbreaks for the next season is high as people may not have the right level of protection, she added.

At the same time, people being locked down have had the tendency of not checking whether they are up to date with their vaccination, which affected the overall vaccination coverage.

"And when you have a decrease in vaccine uptake, going back to the protective level of vaccine coverage rates becomes really hard," Quilici said.

The process of catching up might also require time, which is why Quilici calls for a commitment in this sense by all relevant stakeholders and policymakers.

The silver lining of the COVID pandemic is that now people are much more aware of vaccines as they have understood what harm a single virus can do at the global level in terms of social and economic burden.

"Thanks to COVID-19, people start realising the value of vaccines and vaccination," she said.

"However, it is part of the story of vaccines: you have a disease, people want to be protected and like vaccines; once there's no disease anymore, they forget about vaccines and their importance."

She pointed out that Europe is the most vaccine-hesitant continent in the world. "And COVID will not change that."

For her, COVID-19 is going to create artificial vaccine confidence simply because people have grown tired of the lockdowns and travel restrictions.

"They want to have a solution to fix that. And today vaccines is the only solution that is proposed to them," she said.

Quilici did not exclude the possibility that COVID vaccination could become a routine in the likely case that it becomes endemic within Europe.

"We keep updating the influenza vaccines every season with strains that are changing and circulating: something similar could be done for handling COVID-19 too," she concluded.

STAKEHOLDER OPINION

DISCLAIMER: All opinions in this column reflect the views of the author(s), not of EURACTIV Media network.

Progress but the fight against COVID-19 is just beginning

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By Nathalie Moll | EFPIA



[EFPIA]

Over the last few weeks, the European Medicines Agency (EMA) announced they have begun a “rolling review” process on COVID-19 vaccines from AstraZeneca in collaboration with Oxford University, Moderna and from Pfizer in partnership with BioNTech. The announcements are indicative of the industry-wide commitment to finding new diagnostics, treatments and vaccines to stop this pandemic in its tracks.

Nathalie Moll is the Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

As the coronavirus continues to have a devastating impact on people’s lives and livelihoods, this important milestone in the development of three COVID-19 vaccines is positive news.

The rolling review is described by the EMA as “one of the regulatory

tools that EMA uses to speed up the assessment of a promising medicine or vaccine during a public health emergency.

Normally, all data on a medicine’s effectiveness, safety and quality and all required documents must be submitted at the start of the evaluation in a formal application for [marketing authorisation](#).

In the case of a rolling review,

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EMA's human medicines committee ([CHMP](#)) reviews data as they become available from ongoing studies before a formal application is submitted. Once the [CHMP](#) decides that sufficient data are available, the formal application should be submitted by the company. By reviewing the data as they become available, the [CHMP](#) can reach its opinion sooner on whether or not the medicine or vaccine should be authorised."¹

In short, it means reviewing data as it becomes available rather than waiting until the end to begin the review process.

Vaccine developers' top priority is always safety – and that's no different for COVID-19 vaccines. Rigorous clinical studies, with many thousands of participants, in centres around the world are underway to ensure that vaccines are safe and they work.

Any vaccine will only be approved for use when its safety, efficacy and quality are validated by regulatory authorities such as the EMA.² The rolling review process can help this happen faster and importantly, it does not remove any of the steps taken by developers or regulators to establish the safety, efficacy and quality of a vaccine.

There is no doubt that safe and effective vaccines represent our best chance of a permanent route out from under the shadow of the pandemic.

In Europe, there have been more than 3.7 million reported cases and tragically, around 210,000 people have lost their lives.³ The crisis continues to have a profound impact on the

European economy. It is estimated that on average, GDP across Europe will fall by 6.44%⁴. To put that figure in context, according to the OECD, GDP can fall by 1.5% and 2.5% after a recession, and by up to 4.0% after a severe recession.⁵

For vaccines to play the key role in addressing the health and economic emergency caused by COVID-19, requires much more than the critical steps of research, development and regulatory approval.

In the case of COVID-19: it means creating the manufacturing, supply and distribution capacity to supply more than 7 billion doses around the world.

It means ensuring the infrastructure is in place to deliver a vaccination programme on the ground, at an unprecedented scale.

And perhaps most critically, it means ensuring that citizens have confidence in the safety and effectiveness of the vaccines for COVID-19. Experts agree that around 70% of the population must be immune to COVID-19 in order to achieve community immunity (sometimes called "herd protection" by the scientific community).⁶

Reaching that figure requires the scientific community, manufacturers, regulators, health authorities, governments and citizens to work together to make the case for vaccines, to underline the lengths both manufacturers and regulators have gone to in order to ensure the safety of COVID-19 vaccines.

It means making sure the infrastructure is in place to deliver the vaccine on the ground, particularly for vulnerable and hard to reach groups and it means, in the extremely rare event of an individual having an adverse reaction to a vaccine, that citizens know they can access the support they need, when they need it.

As with any drug or vaccine, there could be rare or unexpected cases of adverse events. Side effects related to vaccines are usually mild, and severe side effects are extremely rare, with a rate of only 1-2 per million doses given (a per-person risk of 0.00005%).⁷

People may also mistake normally occurring health problems for vaccine-related side effects. In the case of COVID-19 vaccines, where billions of doses need to be given to people around the world in order to protect them against the virus, it is likely there will be rare or unexpected cases of adverse events – whether actually connected to the vaccination or not.

It is vital that citizens know that if they suffer serious adverse events attributable to the administration of COVID-19 vaccines, no matter how rare this may be, they can access appropriate and timely compensation. The best way to achieve this is to establish compensation systems that work for all, getting the right support to the right people, swiftly and fairly.

Compensation systems that work for all should also include common-sense protections from unwarranted, lengthy and costly litigation for those involved in development and deployment of COVID-19 vaccines – that includes doctors, health systems,

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governments, pharmaceutical companies and others.

These protections only apply if they have acted on the best available science and complied in good faith with all applicable guidelines and regulatory requirements. They would not cover any violations of regulatory requirements or willful misconduct.

Such compensation systems and protections are already established in a number of European countries, avoiding costly and time-consuming litigation, which takes many years, during which time people live with the impact of their injury and the stress of long, complex and expensive litigation with no guarantee of a successful outcome.

Considering the scale of the COVID-19 crisis and the impact that safe and effective vaccines can have on the human and economic costs of the pandemic, it is critical that compensation systems that work for

all are put in place across the whole of Europe.

It was the 31 December 2019 when the World Health Organization (WHO) was formally notified about a cluster of cases of pneumonia in Wuhan City, China. Ten days later, WHO was aware of 282 confirmed cases, of which four were in Japan, South Korea and Thailand. At that stage, few predicted the impact of COVID-19 around the world, and attention quickly turned to the scientific community and particularly the research-based industry to find the tools to fight the virus.

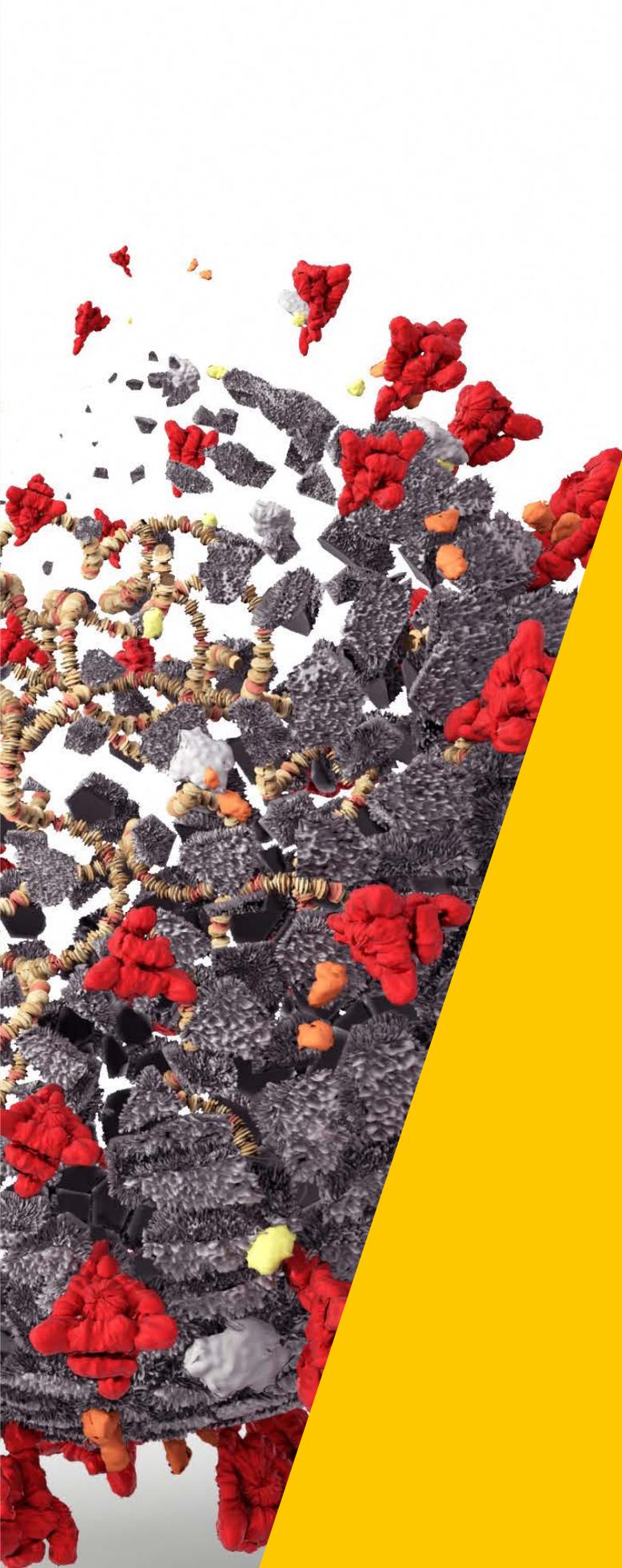
We have witnessed an unprecedented, collaborative research effort involving huge mobilisation of people and resources by our industry and beyond. We are just beginning to see the fruits of that investment but the fight against COVID-19 is really just beginning.

Delivering a successful vaccination programme around the world will continue to require new collaborations, investment, new ways of working and new levels of solidarity.

As an industry #WeWontRest in the fight against COVID-19.

Further Reading

- 1 <https://www.ema.europa.eu/en/news/ema-starts-second-rolling-review-covid-19-vaccine>
- 2 <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid>
- 3 <https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases>
- 4 <https://ec.europa.eu>.
- 5 OECD Working Paper, No. 699
- 6 <https://www.jhsph.edu/covid-19/articles/achieving-herd-immunity-with-covid19.html>
- 7 https://www.vaccines.gov/basics/safety/side_effects



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