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EMA public stakeholder meeting on COVID-19: how safe and effective vaccines are developed and authorised in the EU

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Patients/Carers

Bine Haase, FSHD Europe, DGM e. V., Germany

As a person with a progressive muscle disease (FSHD), but also as a patient representative for people with this and other muscle diseases in Germany and Europe, I have the following questions and would be pleased if these could be considered and of course answered. Also with Covid-19 it is difficult to impossible to get answers as someone with a rare disease.

1. Do all patients with a muscle disease, genetically and autoimmune, belong to the risk group? Or only under certain conditions?
2. Can patients with autoimmune diseases be vaccinated?
3. Can patients receiving immunosuppressive drugs be vaccinated?
4. Does the vaccine have the same subcutaneous effect as intramuscularly or would there be less or no protection?
5. Does the vaccine contain aluminium?

Christopher Kamper, Austria

a) Please vaccinate medical professionals and caregivers first, and then the risk groups. In my personal opinion this would have the greatest impact.

b) Please adjust measures after vaccinations have started "fluently" and dynamically, don't keep us in lockdowns / social distancing / masks for longer than necessary

c) I think vector vaccines and mRNA vaccines are great and safe, but please be VERY careful with DNA vaccines

d) When the vaccine is available for everybody, please consider advertising it to socially active groups especially, maybe similar to HIV campaigns - with the tone of "social life is great and healthy, but please get vaccinated"

e) Adding to "d)": please consider relaxing any remaining measures a lot for people who are immunized (either by disease or the vaccine) - like them not having to wear masks, being allowed to attend large gatherings, etc...

François Houÿez, European Organisation for Rare Diseases (EURORDIS), France

1. Among people living with a rare disease, the perception of health threat due to COVID-19 is high or very high for 71% of people (RareBarometer survey April-May 2020, 6,945 people)

EURORDIS trust the high-quality evaluation of vaccines against SARS-Cov-2 by this agency and the regulatory network. Over the years we've learned, observed, witnessed how you work. Vaccines will be key to protect the most vulnerable populations. Otherwise, a complete locked down is the only way we can protect ourselves.

We hope to be back to our "normal" life as soon as possible, even though life is never completely normal when you live with a severe disease. Normality is when you can visit your hospital again with no fear of getting the virus.

2. EURORDIS believes EU citizens are better placed:
 - a. There is a stringent evaluation by the EMA
 - b. Probably no mandatory vaccination but the freedom to choose between 2, 3 or more vaccines, discussing with our doctors
 - c. European Commission and Member States already ordered 1.5 billion doses of several vaccines
 - d. Lower prices were negotiated, and vaccines should be covered or reimbursed in the EU, with a call for vaccines to be affordable in third countries
 - e. No political interference compared to other regions, e.g. USA, Russia, United Kingdom, or even Hungary
3. The evaluation of vaccines should be science-driven. EURORDIS condemns attempts made by some governments to influence the evaluation process.
4. The technologies used to develop these vaccines (mRNA) were launched in 2013 with MERS and SARS-coV-1, research did not just start in December 2019.
5. EURORDIS believes people living with a chronic and/or rare disease should be among the first beneficiaries

Certainly healthcare professionals and the elderly should be prioritised. Among elderly, this virus is as deadly as the Ebola virus. When the benefit/risks will evolve, with more data coming in and longer-term follow up, lower risk people will have more information to make their decisions.

6. And we are getting prepared
 - Information on efficacy and safety of the vaccines, measured in large phase III trials with 24,000 volunteers or more, is not fully complete yet for all people
 - Our organisations engaged with their centres of expertise and their European Reference Networks
 - E.g. Rett syndrome , with clinicians explaining that the risks of experiencing an adverse reaction to a COVID vaccine are far less than the risks of being infected by the coronavirus without the vaccine
 - Even if the safety profiles of the candidate vaccines seem to be Ok, there might be some specific questions which might differ the moment when all PLWRD can decide to get vaccinated:
 - Rare epilepsies: fever as a side-effect can trigger seizures.
 - Dravet syndrome: possible interactions between vaccines using the mRNA technology with antisense therapies based on mRNA technology as well
 - Hereditary Haemorrhagic Telangiectasia, rare cancers, immune deficiencies: blood transfusions and immuno-suppressant recipients. Need for a wash-out period?
 - Auto-inflammatory diseases: need to stop anti-inflammatory treatment? How long before? When to start again?

To conclude:

Our organisations should engage with their clinical centres, vaccine developers and regulators to organise real time surveillance, for example using mobile apps for reporting any feedback.

Patients should express their concerns now, there is still time. For example, if you are in a clinical trial for a treatment for your disease, ask your doctor now if the study protocol authorises the use of that vaccine.

Engaging and listening is an essential component of transparency and trust, and today is an excellent opportunity. Eurordis is confident the EMA and national authorities will continue to listen and respond to all questions the public might have

Jose Drabwell, International Patient Organisation for Primary Immunodeficiencies (IPOPI), United Kingdom

I will define more at a later stage but as a patient with a primary immunodeficiency, representing patients with this disease on a worldwide basis, I know that people with an impaired immune system have to be cautious about vaccine ensuring that the vaccine are dead or attenuated, but also that these patients are in a group of extremely vulnerable patients and therefore should be considered as one of the first sections of society to receive this vaccine. It is therefore incredibly important to be able to weigh up the variations in each vaccines, which have been declared so far as a viable option. We need to know if there are any side effects, if this vaccine prevents or lessens the virus and many more. Reading about these vaccines it appears as though 2 out of 3 have positive results for the over 60 year plus group, but there are many young patients with an immune problem and how will these vaccines be suitable for younger people.

Kathi Apostolidis, European Cancer Patient Organisation (ECPC), Greece

Cancer Patients, covid-19 and vaccines

Marguerite Friconneau, France

I would like to know how people with special needs such as rare diseases or previous immune or autoimmune diseases, will be taken into account; These needs have to be precisely described for each disease and clinical trials must include these people; vaccines must be riskless for everybody; we experience the most challenging and dangerous situations at the moment and need the vaccines but we do not want to jeopardize our lives.

Marieke Van Meel, Netherlands

I would like to know if simulations have been done for patients with rare diseases as eg Nephrotic Syndrome patients which have unknown immunerelated backgrounds? Is there evidence what doses various age groups should receive? Furthermore I would like to know how after vaccination care for rare disease patients will be given? Is there a safety vaccine available in case of emergency of allergic reactions?

Marilena Vrana, European Heart Network (EHN), Belgium

Fragile groups of the population have been tremendously affected by COVID-19. For example, people living with pre-existing cardiovascular diseases are at higher risk of contracting COVID-19 and have a worse prognosis.

According to the Robert Koch Institute (RKI), about 81 percent of COVID-19 infections are mild, about 14 percent severe and 5 percent critical. People with chronic conditions have often weaker immune systems and are at increased risk of severe courses of the disease. These include cardiovascular diseases such as cardiac insufficiency, high blood pressure, coronary heart disease as well as persons with high CVD risk factors, e.g. smokers, overweight, diabetes.

A disease of the lungs, such as that triggered by SARS-CoV-2, is usually associated with an additional burden on the heart. The vital organ has to perform immense extra work to maintain the body's oxygen supply and compensate for the weak lung function. If cardiovascular disease is present, the heart weakened by heart disease is at risk of overloading. In addition, the heart itself can be attacked by corona viruses.

- Does the EMA have any results on the effect of the vaccine on people with underlying conditions, like cardiovascular patients?
- Based on the current data, will candidate vaccines prevent COVID-19 infection or will they prevent the onset of the disease (i.e. people will be infected but not get ill)?
- Will the new vaccine have a lower success rate in elderly people (comparable to influenza vaccination)?

Peggy Maguire, European Institute of Women's Health (EIWH), Ireland

The COVID-19 crisis has highlighted and exacerbated sex and gender and age inequities in society across Europe and the need for clearly defined response mechanisms. The sustainability of health systems has become an urgent issue and with-it universal access to prevention, treatment, and care for all EU citizens.

Older adults and those with serious chronic medical conditions have increased vulnerability to the coronavirus. Ethnic minorities are also being hit particularly hard by the pandemic. Refugees, migrants, people with disabilities and Roma populations also find themselves in vulnerable situations regarding the pandemic. These susceptibilities are influenced by sex and gender. Therefore, COVID-19 responses incorporating sex and gender considerations from the outset are important.

It has also become apparent that many physiological and pathological functions are influenced by sex-based differences in biology. Recent research on cardiovascular disease, osteoporosis, and depression has identified significant differences among women and men with respect to the distribution of certain diseases. Women and men have different sex- and gender-related risks for developing certain conditions and may respond to treatment differently. For example: biological differences between males and females can affect how a medicine works in the body. Additionally, patterns of gene expression differ between males and females. This has important implications for health and healthcare.

The coronavirus has implications for the treatment and care of women who are pregnant. According to European Centre for Disease Prevention and Control (ECDC), clinical manifestations in pregnant women can range from asymptomatic to mild; however, there have been reports of critical cases in countries like Sweden. At the moment, there is very little data and information on the role that COVID-19 plays in pregnancy. Studies of other diseases, such as SARS and influenza, have shown that pregnant women have higher rates of infection and have more severe outcomes when compared to women of the same age groups.

Women are generally under-represented in clinical trials. Ever since the Thalidomide tragedy in the late 1950s there has been a reluctance to include women of childbearing age in clinical trials. "The general

assumption prevailed that women did not differ from men except where their reproductive organs were concerned, and data obtained from clinical research involving men could simply be extrapolated to women"

Attention to sex and gender in biomedical, health and clinical research is an important quality and safety issue. Medicinal products are safer and more effective for everyone when clinical research includes diverse population groups

The new EU Clinical Trial Regulation aims to create an environment that is favourable to conducting clinical trials in the EU with the highest standards of ethical and safety protection for participants. The Regulation requires more transparency of clinical trials data, including the population groups for whom the medicines are intended. "Unless otherwise justified in the protocol, the subjects participating in a clinical trial should represent the population groups, for example gender and age groups, that are likely to use the medicinal product investigated in the clinical trial" and "non-inclusion has to be justified.

- Q: In line with the new Clinical Trials Regulation (536/2014) will EMA in the evaluation of the current vaccines consider an age and gender balance in the current vaccine clinical trials as well as consideration of vulnerable groups such as, pregnant women, chronic disease patients, ethnic minorities, and older people?
- Q: Following the approval and launch of vaccine(s), will post marketing surveillance collect data on the safety and effectiveness of COVID-19 vaccines disaggregated by age and sex/gender?

Peter Lakwijk, Thyroid Federation International, Sweden

In clinical trials patients with comorbidities are usually excluded from the trials. Now everything all of a sudden goes so quick, that I wonder whether all safety and security is taken along the way.

1. Are comorbidities tested for the new vaccines and for which diseases?

Only for lung diseases or also autoimmune diseases like thyroid diseases (hypothyroidism and hyperthyroidism) and patients with elevated heart rate due to hyperthyroidism.

2. How great is the risk that in the real world unexpected diseases arise, like narcolepsy with the H1N1 vaccine?

Normally it can take a long time before drugs that are approved by the EMA, are evaluated and verified by the healthcare authorities of the different countries.

3. How long will it take for individual countries to verify the new vaccines in their health system?

Isn't this an example why an European healthcare system is necessary?

Richard Ballerand, France

I would like an update on how the EMA will be coordinating COVID19 vaccine regulation with external bodies

- notably the FDA, the Australia-Canada-Singapore-Switzerland (ACSS) Consortium, including the now sovereign MHRA?

As a lay advisor whose family straddles countries both in and out of the EU I do have a personal interest.

I should mention that I have been involved with European, North American, and British regulatory entities for several years now.

We have seen a great deal of collaboration at speed to date. How will the EMA ensure that we retain any expedited and improved practices as we emerge from the pandemic?

Robert Kroess, Austria

Attenuated vaccines are forbidden for me to receive.

My questions are:

1. Were immune suppressed people part of the vaccine studies so far?
2. If so: Are there results available, if they a) work and b) are safe to be received by an immune suppressed person?

Roberto Martín Santos, Hipertension Pulmonar ORG, Spain

I would inform my organization.

Viorica Cursaru, Myeloma Euronet Romania, Romania

These are questions to be addressed to the panel of specialists:

1. Are there any known side effects for the blood cancer patients
2. For effectiveness, how many times do people have to be vaccinated and at which intervals
3. Will vaccines be free of charge
4. Would the quota allocations be distributed evenly and at the same time (according to population number) to all EU member states.
5. In case of major problems, who is to be held accountable.
6. Who is responsible for the monitoring of the vaccine administration at the national level (EU or national authorities).

Consumers/citizens

Ana-Maria Vişenoiu, Romania

Should we expect some serious changes in our long-term health system? Does the fact that it wasn't tested a long time on subjects should raise some kind of awareness?

Anca Pantelimon, Romania

Is this vaccine compatible to all genetic profiles? From which countries come the volunteers who have taken part in the process of the development of the vaccine, what age groups and blood group do they have? Is the blood group relevant for the vaccine's efficiency?

Ancel-la Santos, The European Consumer Organisation (BEUC), Belgium

BEUC welcomes EMA's initiative to organise a public event about the EU regulatory process for approving COVID-19 vaccines. Because the pandemic requires making vaccines available faster than usual, addressing questions from citizens on vaccine development and approval is key to safeguard

public confidence in the system. There are three other aspects we consider important to build public trust around any approved COVID-19 vaccine:

1. Clinical trial data must be public. This is necessary to enable better understanding of regulatory decisions and quality of health care. Therefore, we welcome EMA's decision to publish the clinical study reports of COVID-19 treatments and vaccines, in addition to other documents such as risk management plans.
2. Consumers must have easy access to information about vaccines' safe use, any contraindications and potential side effects. Electronic product information is an interesting tool, but not equally useful to everyone e.g. the elderly. It is necessary that package leaflets or printouts are available in the national language(s).
3. Communication materials must speak to laypersons. To ensure this, consumer representatives and, as much as possible laypersons, must be engaged in the revision of product information. BEUC will be happy to contribute, as we do regularly upon EMA's request. It is also important to involve consumer and patient groups in the development and dissemination of public communication campaigns. Proactive communication is essential to counteract dis- and misinformation.

We would like to conclude by stressing that, like with any other medicine, COVID-19 vaccines must be approved based on strong safety and efficacy data. It will also be crucial to have a solid plan to continue gathering evidence after vaccine approval and enable easy consumer reporting of any suspected adverse drug reaction. This will contribute as well to uphold public trust in the regulatory system.

We look forward to continuing the dialogue, thank you.

Andreea Marculescu, Romania

I am interested in any safety concerns regarding this new type of vaccine, using ARN

Anyoleth Pérez, El Salvador

Buen día, he leído que el mecanismo de la vacuna consiste básicamente en que cuando una persona recibe la vacuna, sus células leerán las instrucciones genéticas y producirán la proteína de pico, quisiera saber si este cambio en las células es permanente o si esto pueda causar cambios en la genética de los individuos a corto o largo plazo y si la vacuna es segura para embarazadas, o si puede causar cambios o daños en el feto. [**Google translation:** Good morning, I have read that the mechanism of the vaccine is basically that when a person receives the vaccine, their cells will read the genetic instructions and produce the peak protein, I would like to know if this change in the cells is permanent or if this can cause changes in the genetics of individuals in the short or long term and if the vaccine is safe for pregnant women, or if it can cause changes or damage to the fetus.]

Bogdan Radulescu, Romania

I am mainly interested in gathering more information regarding the vaccine and perhaps have a professional opinion about big questions such as "What were the shortcomings in the past that did not allow the development of mRNA vaccines and what changed with the Covid-19 vaccine?".

Bogdan Secheli, Romania

I would like to know more about:

- this vaccine addresses to immunity against infection to COVID-19, against spreading the disease in case you are infected or it will help you have minor symptoms in case of infection?
- how long does the protection will last: a few months or years?
- why does it need to be contained at -70 degrees Celsius?
- what side effects are known by now? Having 95% efficiency, what side effects the remaining 5% have?
- what contraindications it has? There are certain people for whom this vaccine is not recommended (e.g. heart conditions, diabetes, cancer, cardiovascular diseases etc.)?

Brittany Gordon, France

Could you please discuss the timelines associated with the marketing authorization review and the ability for Member States to access the vaccine prior to the issuance of an official marketing authorization under compassionate use.

The currently listed timeframes of Expedited marketing authorization review are 70 days and under 150 days, compared to the average of 210 days. The US FDA by contrast has stated its review for emergency use authorization will be about 3 weeks. So will the EMA take 70-150 days to approve the vaccine or will there be a mechanism for emergency or compassionate use where Member States can access the vaccine quicker?

Does the EMA use or share information with the FDA so that an approval from the FDA could be used by either the EMA or Member States to shorten the review process?

Buchir Costel Ovidiu, Romania

I want to know more informations about vaccines.

Eoin Byrne, Ireland

In relation to when the vaccines are rolled out.

If I am vaccinated, will I still need to get tested and self isolate if I am alerted that I have been in close contact with another person who has tested positive?

Would I be contagious if I am Vaccinated?

Héctor Duarte, Argentina

To get knowledge about the timelines.

Irina Puscasu, Romania

I really don't know what to think about the vaccine, the time of the release was too short... It is safe??

Jim Madden, Ireland

Get an understanding of the vaccine and its potential effectiveness.

Michele Rivasi, Member of European Parliament, France

"WE NEED TRANSPARENCY AND ACCESS TO DATA TO BUILD CONFIDENCE"

TRANSPARENCY AS THE FIRST REMEDY TO RESTORE CONFIDENCE

The issue of vaccines is of extreme importance given the global health challenges we face. As a member of the European Parliament, I would like to stress the importance of transparency in the development and authorisation of vaccines. Ensuring confidence in vaccines requires "total transparency" for both producers and regulators.

It is not media hype or corporate communication that will restore the confidence of European citizens in the vaccine system. But it is the transmission of safe and reliable information.

The acceptance of these vaccines developed so rapidly and by the new technologies requires a high degree of confidence in the manufacturers and especially in the approval authorities.

TRANSPARENCY AS A GUARANTEE OF HEALTH SECURITY

By playing the transparency card, you allow confidence in both processes and decisions, while increasing the level of protection of the population. The provision of the content of clinical studies must in particular make it possible to detect any statistical errors, to verify and contextualize the information relayed in the media. This collective effectiveness requires that this information be accessible to civil society, independent experts and health authorities.

We also know that often the results of biological or health studies provided by the industry tend to be found in the best interests of the industry. The article by Peter Doshi in the British Medical Journal published in October 2020, the errors in dosing of the AstraZeneca vaccine corrected by the University of Oxford, or the fraudulent article unpublished by the Lancet last May are recent and concrete examples of errors which could distort scientific studies and which required independent verifications to be detected.

All clinical trial data, protocols (trial objectives, methods, populations concerned, etc.), results, and raw data, must be freely accessible to the public. This data access must relate to all clinical trials of treatments and vaccines that are currently being evaluated and submitted for the authorization.

Access to clinical trial data should take place before the authorization, not immediately afterwards as the EMA now offers for the COVID treatments and vaccines. Making clinical data available prior to authorization allows civil society, stakeholders, journalists and experts to conduct their own, industry-independent checks.

Moreover, it is important to note that transparency is essential for two reasons: because it is the only way to guarantee the validity and credibility of decisions, but also because this research is financed by the public money.

ENSURE THE POSSIBILITY OF COMPARING PRODUCTS TO ENABLE STATES TO IMPLEMENT THE BEST POSSIBLE HEALTH POLICIES - AND AVOID SUBSTANDARDS

Several vaccines are currently in phase 3, more will be there in the coming months. For fear of running out of vaccines, member states are tempted to buy a variety of different vaccines. We must have the means to compare them with each other. To compare their positive effects, negative effects, composition (in particular the presence and effects of the adjuvants), the effects on the different types of populations, and the duration of these effects.

The EMA has a responsibility to ensure that these comparisons are made, according to the necessary scientific rules, i.e. randomized compared trials.

THE NEED OF TRULY COMPLETE DATA TO GUARANTEE RELIABLE AND OBJECTIVE EVALUATIONS

We must at all costs avoid making authorization decisions based on incomplete, preliminary or partial data.

The announcements made in recent weeks by pharmaceutical companies, through press releases and statements, without publication of studies, for example, were based on the intermediate results. These first results, statistically insignificant, have been put forward as evidence of the efficacy of vaccines during the Phase 3.

We must avoid making hasty authorization decisions under political or media pressure. The European Parliament supports the EMA, which says it wants to wait to receive all the clinical data, to have the necessary time to analyse it and decide afterwards.

We must be clear on the parameters on which we judge these vaccines. What is their action: do they have an effect on the development of the disease and its severity, on mortality, on infection, on contagion? Do they have different effects on different populations? How long do these effects last?

We must ensure that we comply with all stages of the existing regulations, including carrying out impact studies that are required to be done in advance. The health of our populations is at stake.

To assess different vaccine candidates, it is extremely important to have all the data on safety, efficacy and quality. Swiss medical regulator, Swissmedic says it does not have the necessary information to approve the three anti-Covid vaccines by Pfizer / Biontech, Moderna and AstraZeneca. Swissmedic is particularly interested in obtaining data on subgroups and on pre-existing diseases of the people who participated in these clinical studies.

Is the EMA satisfied with the data it receives from the companies, is there any data you don't have yet?

DO NOT REPEAT LACKS OF EVALUATION OF THE TAMIFLU OR REMDESIVIR

In the case of Remdesivir, the gray areas need to be clarified; the EMA still has to decide on the conditional authorization for the European marketing of this drug. Beyond the lack of efficacy of Remdesivir, demonstrated in several studies - in particular by the results of the WHO "Solidarity" clinical trial - the risks of drug poisoning, particularly in the kidneys, are known.

The conclusion of the joint procurement framework agreement by the European Commission for 500,000 treatment courses with Remdesivir, carried out without knowledge of the results of the WHO "Solidarity" clinical study, is surrounded by uncertainties and inconsistencies.

Ten years ago, the health and financial fiasco of the Tamiflu. Today, the health and financial fiasco of the Remdesivir.

Can we avoid repeating these scenarios with vaccines?

PHARMACOVIGILANCE: AN AMBITIOUS, RESPONSIBLE AND IMMEDIATE EMERGENCY PLAN

Pharmacovigilance resources must be ensured urgently. We should not be satisfied that only around 10% of problems caused by the drugs or by adverse effects of vaccines are reported, thus distorting public decision-making.

It is necessary to strengthen pharmacovigilance by immediately releasing the necessary funds for the implementation of the databases and online tools provided for by European legislation.

The European Parliament is your best ally in asking for adequate funding to enable the EMA to meet all these challenges.

Norbert Oberndorfer, Austria

I am a journalist working at a regional newspaper in Lower Austria. As individual, I sense that many citizens have serious concerns about Covid-19-vaccines. People are especially troubled by the mRNA-vaccines, the speedy development and research, and the lack of knowledge on possible long-term and delayed effects. In Austria one third of the population attended so far recent public health antigen-testings organized by the government. Recent media polls stress that people demand more information on vaccines. For now, only one in five Austrians would go for a vaccination.

A lack of information, no space for respectful and serious debate (Social Medias are definitely not a space for that) and badly or not answered questions provide plenty of ground and fruitful soil for growing conspiracy theories – not only since the tragic event of 9/11. According to the Swiss psychiatrist Carl Jung conspiracy theories also represent psychological shadows of ourselves and therefore of our society. I think, that we need to take them seriously and therefore stay open for dialogue and debate. Bubble-building, whether scientifically or politically driven, can lead to deep divisions in our society. On the other hand, there are as well certain groups and individuals who push mistrust and therefore misuse the current situation and the anxiety of people.

If the European Union, scientists, politicians and us journalists do not manage to explain and deliver easy-to-understand but nevertheless full-scope explanations on how, why, who and who profits around the vaccines development, trust among the people might further erode. From my neighbourhood I hear from academic professionals, teachers, craftsmen to farmers that even solid facts and explanations provided would leave many sceptical and uncertain on the vaccines and their development. A basic mistrust in politics and certain global players might be one of many reasons behind this.

The influence, interdependency and interests of politics, global pharmacy enterprises and certain global foundations - as well the individuals behind - will be very important to make public and transparent to all citizens. It will be as well crucial to stress the obvious risks and dangers of the vaccines besides their positive effects to prevent or to alleviate the effects of Covid-19 illness. So-called half-truths are not helping to build confidence, quite the contrary. They are not contributing to a constructive dialogue between authorities and citizens. People are searching the truth – especially in global and crisis times like these. If they don't find it, they create their own.

I see my mission and my professional role as journalist to foster a free and open dialogue, to report the last possible version of the truth and not to pre-frame or defame individuals or groups as „conspiracy theorists“. I try to follow the principle „audiatur et altera pars“: „let the other side be heard as well“.

Phanos Anastasiou, Netherlands

It is enormously exciting that through vaccines we are finally seeing a light at the end of the tunnel and a way out of this global pandemic. With cautious optimism it's important for society to work together during this process.

It is vital that the EMA acknowledges that the public has reasonable concerns around the speed of the regulatory approval process. It is also important to avoid polarization and ensure that the public does not split into two separate pro-vaccine and anti-vaccine camps. It is only natural for people to be worried about optimism bias and even residual uncertainty in the results.

The EMA should actually encourage cautious interrogation and ease vaccine concerns through a fully transparent approach to communication and an honest assessment of the benefits and remaining uncertainties of approved vaccines.

It is also important for the public to frame concerns as constructive criticism and to engage with the EMA and governments. The EMA again has a strong role as an enabler for such a process through events like today's but also complete and transparent FAQs and more local engagement plans.

It is important to also acknowledge what we still do not know. Honesty will build trust with the public and communication should not feel like a sales pitch but rather more interactive.

Key questions that hopefully the EMA's stakeholder session will have already addressed:

1. How is the likelihood of long-term side effects evaluated during the regulatory approval stage?
 - a. Sharing the track record of other vaccines in terms of long-term side-effects would help here.
2. Let's acknowledge we don't know what we don't know. For example, are there additional risks presented by vaccines that utilise new technologies never used before for human vaccines such as mRNA?
3. It is difficult to evaluate the duration of provided immunity evaluated during the regulatory approval stage. What are the implications of this residual uncertainty on vaccine approval/selection. Does short-term immunity still contribute significantly to suppressing the pandemic
4. Do we have data on whether vaccines prevent contagiousness or just disease severity?
5. Are there any risks identified from giving the vaccine to people who have already had the disease?
6. How quickly can we learn from a country that is ahead in schedule? Specifically, lessons learned should be extracted from the UK being ahead in terms of timeline and already kicking off the vaccination process. Similarly, with examples outside Europe such as Russia and China.
7. The analysis and differences across different age groups or ethnic groups should be clearly presented. Vaccines are sometimes less effective in the elderly so a clear risk/benefit analysis for different age groups is important.

Sandra Fenkart, Austria

Has the vaccination been tested on people with chronic cardiovascular disease (eg pulmonary Hypertension)? If so, what were the side effects?

Sinead Hewson, Netherlands

My question is in three parts:

1. How do you ensure that data is evaluated objectively and reduce the risk of political, consumer, social and economic pressure to approve no matter what.

(For example: maintaining EMA standards even when a vaccine is already approved in another market, or when commercial organisations communicate publicly early research findings of, 90, 95% efficacy)?
2. Are vaccine developers required to present disaggregated data to the EMA so that the impact / benefit or risk to covid-19 risk groups is understood (e.g. by age, gender, ethnicity)?
3. Will EMA specifically request that vaccine developers systemically examine the safety of the vaccines in the medium to long term? (child/ teenager into adulthood, cross generational

(pregnancy health of babies after a mother has been vaccinated, integrity of the immune system which the new generation of vaccines, compare side effects with long-term Covid-19 symptoms)

Thanks for the opportunity to ask a question

Tania Martina Gligorea, Romania

I would like to know what long term side effects are known, whether we are rushing this vaccines or not. How are we going to make sure that the less fortunate people have access to a vaccine and that they won't be marginalized in any way. Strong point is south eastern Europe. Where corruption is blooming. I would like to emphasize and make sure that our corrupt politicians won't take advantage of this vaccine and of the less fortunate.

Thiel Michael, Germany

In my opinion the approval of vaccines against SARS-CoV-2 should be rejected by the EMA at least at this early state of testing. No other decision is justifiable. Vaccination against a pathogen that on the one side doesn't cause very much harm in comparison with other diseases and on the other side is changing rapidly by mutation doesn't make much sense anyway. Most people are suffering from so called collateral damage of lock downs and most of the other political decisions of our governments - should we really add even more suffering by causing probably severe side effects by vaccinating, such as expected autoimmune diseases and cancer?!

In this regard it is especially important to warn against the new mRNA-based vaccines!

Apparently the pharmaceutical companies involved were successful in excluding claims for damages in their deals with the EU, they surely know the reason for. And our governments know very well, why they claim their treaties with the vaccine manufacturers top secret.

By the way meanwhile there is a bunch of quite effective therapeutic measures in case of severe Covid-19, such as heparin, dexamethasone or hyperimmune serum, also legitimate hope for other drugs as fluoxetine.

If vaccination would be such essential for our survival or health (it is not!) - why didn't we accept Russia's offer to produce it in the EU under license? Of course, profit would be much lesser for Pfizer and Co...

Industry

Alberto Catapano, Italy

In 2009, due to the H1N1 pandemic virus, from a regulatory point of view, EU Applicants used the "core pandemic procedure" to speed up the regulatory process and get the approval. The core pandemic procedure was drawn up as a lesson learned from the H5N1 virus. The authorization of 'mock-up' vaccines was particularly useful as it proved to be the fastest route for the authorization of H1N1 vaccines in the EU.

For the current pandemic situation, the core pandemic procedure cannot be used due to the nature of COVID19. I was wondering if we could use the same regulatory platform and process in the future and if this platform could be used to develop effective vaccines against other coronaviruses.

I mean: which could be the lesson learned from a regulatory point of view for COVID19?

Dario Sannino, Italy

Personally I'm in favour of vaccines development and is amazing the global effort of pharmaceutical companies, universities and government. I'm actively helping people to trust in science and the regulated steps that are behind the development of drugs. From this side the most common question that I faced is the following one:

In the EMA website is written "Vaccine development for COVID-19 vaccines is being fast-tracked globally. Development is compressed in time, applying the extensive knowledge on vaccine production gained with existing vaccines" but mRNA is a quite new technology or at least not globally well known. How can EMA ensure that mRNA vaccine, for which long term impact are not known, is safe as inactivated virus vaccine technology?

Each government is hardly working on information encouraging the population to trust on this vaccine race. Unfortunately in each country a lot of people don't trust in politicians even if they are moved by sincere and good intentions. EMA is often perceived as an independent authority that is not influenced by politics. How EMA is planning a massive information campaign that reaches individual European citizens with facts?

George Kargiolakis, Greece

I am working in the pharmaceutical industry as a Pharmacovigilance Manager and I believe that it would be great for EMA to emphasize on the safety profile of the vaccines and maybe start a campaign addressed to the general public regarding drug safety in order to increase PV awareness and educate people on clinical trials processes and how EMA with the pharma industry is monitoring the safety of such products.

Jennifer Spiegeler, Netherlands

What is expected from the authorities for emergency supply manufacturing in relation to:

- 1) Traditional Process Validation
- 2) Continuous Process Verification
- 3) Not having sufficient QbD experiments and hence only preliminary CPPs and CMQs

Katerina Arsova Manchevska, North Macedonia

I would like to know, which registration procedure will be used for obtaining MA in the nonEU countries (like my country)?

I have concern about efficacy and safety of the vaccine.

Marco Antonio Gonzalez, Spain

Regarding the Health impact: Report in a simple and direct way. Without masking and without options for denialist political interpretations. Early diagnosis and control of the diagnosis. Severity of the pandemic, the pathologies and long-term effects it causes. Message that is understood by the European population (most of it is not a professional healthcare technician), this is the key. About the Vaccine / s: - Report in a simple and direct way. The protection that the vaccine gives and the benefit it produces. The need for immediate vaccination, staggered by risk groups and age and mandatory. The mandatory form is a concept that has not been discussed so far, and it is necessary since group

immunity must be acquired by vaccination, not by infection. The death of many people must be avoided and it will only be achieved by vaccination. (2) On the Regulatory Process, Approval of vaccines and the role of the European Regulatory Agency: Inform simply and directly. Protection role for the population of the Regulatory Agency. Role of guarantor and notary for the safety of citizens against the economic interest of pharmaceutical laboratories. The pharmaceutical industry has codes of ethics and deontology whose mission is to research, design and produce drugs and vaccines to save lives. The Regulatory Agency will not allow a phase jump and time savings in the safety of the vaccine and will implement all controls exhaustively and relentlessly. (3) Regarding the Social and Economic impact: Simply and directly inform that there is the axiom health versus economy. Without health there is no economy. For the economy to exist, there must first be general public health. General public health will only be achieved with vaccination. Recovering the economy as it was before the Pandemic is only possible with the control of early diagnosis, with vaccination and control of population movements. In the end, a health passport will have to be issued to recover the economy.

Martina Schild, Germany

I have no concerns about the regulatory process, just a general interest what is communicated to the public.

Monika Ruge-Lindroth, UCB Pharma GmbH, Germany

How long does the vaccination last, is to be vaccinated each year?

Pahlen Bettina, Germany

Please provide following information in detail:

Information about details of study set up (BioNTech/Pfizer, Moderna as applicable).

Information about efficacy of this Phase III clinical study as of 02 Nov 2020 (95% efficacy based on 94 individuals from active/placebo groups out of 40,000 patients in total??).

Status of data evaluation and results.

Side effects known / recorded?

Priscille De Lajarte, Thermofisher, France

Overview of the covid treatment / availability / flexibility regarding procedures and where we are today.

Ral Ogbah, United Kingdom

I only wish to participate as a silent observer and get information from the EMA.

Raveanu Marius-Octavian, Romania

I have a simple question and a technical question who is linked with first one. Why the mRNA vaccine was not a solution for other infectious disease until now? We know about some studies with mRNA vaccines, some of them have been rewarded by European Commission, but we haven't yet an approved mRNA vaccine. Some disease are killing millions of people every year (tuberculosis is one example) for decades.

Because is a new method, with new production facilities for a huge batch size, how can be approved in such a sort time a product with a new technique of production? They have been validated 3 batches? They have accelerated stability studies? How many risk assessments have been done in this moment in all steps who are link with mRNA vaccines?

Renée Gallo-Daniel, ÖVIH - Austrian Vaccine Manufacturer Association, Austria

The Value of Vaccines is demonstrated through a lot of examples in the past (MMR, Polio..). Although the current Covid-19 pandemic is a threat and costs lives and bring morbidity, vaccine hesitancy regarding COVID - 19 Vaccine is high in our country.

In my lecturer I would like to motivate people to take a vaccine. As health psychologist working in the vaccine industry, it's my role to explain WHY we all (Industry and authorities) worked very closed together in making vaccination against COVID-19 possible for European citizens!

Awareness for COVID-19 Vaccines and willingness to vaccinate against COVID-19 will be given if people understand the WHY!

Following the spirit of our Austrian vaccine manufacturer association 'Impfen heißt Verantwortung tragen für Eden Einzelnen und für die Gesellschaft' / 'Vaccinate means, having responsibility for yourself and for the society' I would be happy and would honour to get the chance to have a short lecture during that great meeting.

Sue Middleton, Vaccines Europe, Belgium

[Vaccines Europe is a specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA) representing major global innovative and research-based vaccine companies, as well as small and medium-sized enterprises.]

COVID-19 is a public health challenge of unprecedented scale, which requires all stakeholders to work together in a concerted effort. Vaccines Europe represents companies who research, develop or manufacture vaccines in Europe. In response to this devastating pandemic, our members have been working around the clock in search of a vaccine, or to be more precise, in search of several vaccines that can then be manufactured at scale. Vaccine companies are working in collaboration with each other, academic institutions, governments and regulators in this endeavour.

We now have three vaccines which have proven efficacy in the clinical trials. This is giving the world cause for hope. These positive results are being evaluated by regulators around the world. Whilst these vaccines have been developed at unprecedented speed, it is vitally important that we – the industry, regulators, and health professional and others – build confidence that COVID-19 vaccines, just like all vaccines, are subject to rigorous testing on safety and efficacy.

As I am sure all of you at this stakeholder meeting know, the safety requirements for COVID-19 vaccines are the same as for any other vaccine in the EU and have not been lowered in the context of the pandemic. The positive results seen to date are based on very large well-defined trials recruiting tens of thousands of volunteers. Many other vaccines are still in development and we hope that these will also prove successful in the near future. COVID vaccines will only be approved based on objective scientific review of data from large-scale, high quality, randomised and observer-blinded clinical trials.

And we wouldn't have it any other way. In a joint statement earlier this year, the CEOs of nine leading European and US vaccine developers have made this clear. These vaccine industry leaders committed

to apply for regulatory approval only after demonstrating safety and efficacy through phase 3 studies designed and conducted to meet the requirements of expert regulatory authorities.

If regulators approve COVID-19 vaccines for use in a broad population, this will not be the end of the process. The safety and effectiveness of the vaccines will continue to be monitored during the roll-out.

We appreciate the flexibility granted by the European Commission and the Member States for labelling/packaging requirements and I would like to remind that it is critical to have a single pack for all Member States in order to meet the demand as quickly as possible across Europe.

It is worth finishing by reflecting on the fact that approval of these vaccines is just the start. Our members started manufacturing these vaccines months ago, before they knew they would be successful. Still, vaccines will not be available in sufficient numbers to vaccinate everyone at the start of the roll-out and it is good to see Member States making clear recommendations on which groups to vaccinate first. Companies will continue to work closely with Member States and European Authorities to ensure the roll-out of these vaccines is as smooth as possible, reaching people in Europe and around the world as quickly as possible in order to let us all get back to normal.

Tal Zaks, Moderna Biotech Spain, S.L (a subsidiary of Moderna, Inc.), Spain

My name is Dr. Tal Zaks, and I am requesting 5 minutes to speak at the Public Stakeholder Meeting. I will be speaking as the Chief Medical Officer for Moderna, Inc. My testimony will provide my perspective on the mRNA technology platform and mRNA-1273, Moderna's investigational vaccine candidate against COVID-19. I will also provide a high level overview of the clinical development plan including pediatrics and the manufacturing plans and supply for the EU. I would describe also at a high level the emerging safety and efficacy results from our Phase 3 study and provide a perspective on the consideration to follow study participants after a Conditional Marketing Authorisation for safety and efficacy within their randomised groups for at least one year after completing vaccination.

Tatiana Reimer, Germany

I am helping pro bono to develop treatment for COVID-19 in moderate and severe patients and would like to learn updates on vaccine development with the Authority perspective.

Vincenzo Ferraro, Italy

I would like to understand if any rna integration have been evaluated in the long term considered Endogenous retrovirus and virus genome contained in human dna.

Furthermore, I would like to understand if there is a possible linkage between rna therapies and CRISPR/casp9

Healthcare professionals

Alexander Marakhovsky, Ukraine

I am concerned of the industry originated bacteria role in COVID-19 Pandemic. Uncontrolled, widest, continuously long (30+y.) usage of bacteria and their ingredients as probiotics, create a specific human Microbiome, when such bacteria colonized human gut and other mucosa covered organs, acting as dominant strains, instead of native microorganisms. This change human innate immunity and individual's response to many inflectional diseases. Some diseases getting down, as flu. COVID-19 raise in 2020 become possible due to readiness of human immunity to accept and promote SARSCoV-2 infectivity and pathogenicity. November 14th 2020 I published my concept. Here is a Statement: Exogenous industry generated Bifidobacterium animalis subspecies lactis underlie the predisposition of individuals to high infectivity and severe COVID-19. COVID-19 pandemic become possible due to long, more than a decade wide usage of Bifidobacterium animalis subspecies lactis strain in commercial dairy products, industrial food and agriculture processes, including swine meat production. Regular consumption of products enriched by this bacteria, or contaminated meat, lead enormous colonization of human individuals by this (or metabolic similar another one) industry originated bacteria, following a dysbiotic gut environment. Angiotensin-converting enzyme 2, a cell surface protein that plays a key role in innate immunity is the target of SARS-CoV-2. SARS-CoV-2 gains entry into host cells via an interaction between its Spike protein and the host cell angiotensin- converting enzyme 2. Bifidobacterium animalis subspecies lactis produce metabolites that boosts the SARS-CoV-2 ability to enter mammalian cells via ACE2 protein(receptor), increasing of susceptibility to SARS-CoV-2 and providing severe clinical disease course via deregulation of host innate immune response, excessive cytokine production. One more industry originated Bacterial genera or sp.(as Lactobacillus acidophilus).

Anca Hnatiuc, Romania

It is safe to vaccinate the people who already has the Infection Covid 19?

Angeliki Ladia, Private Geriatric clinic Evagelistri, Greece

It's without doubt, that older people and those with pre-existing medical conditions (such as diabetes, high blood pressure, heart disease, lung disease, or cancer) appear to develop serious illness from covid-19 more often than others. In our clinic that patients suffer from severe chronic diseases and geriatric syndromes, this danger is higher.

According to ECDC' and greek ministry of health guidelines visits have been banned since March. Consequently, geriatrics' relatives or carers have not seen or touched their beloved ones for months. The technology, safety and efficacy of covid-19 vaccines and vaccines in general, are scientific aspects unfamiliar to the public. So, it is important for me that EMA should take into consideration how to convince them (relatives and carers) to vaccinate their geriatrics patients despite the widely spread controversial opinions about the vaccine.

I would also like to talk about a more practical aspect. EMA should take into special consideration the procedure that geriatric population is going to be vaccinated since this frail population in majority cannot walk or even move. In my opinion, maybe the clinics' or/and hospitals' healthcare personnel would help by participating in the procedure.

Antonella Romanini, Associazione Contro il Melanoma, Italy

Will the vaccine be tested in specific subpopulation like cancer patients during their treatment with chemotherapy or immunotherapy, before it is released? Which test will be done to ensure that the vaccine is safe in cancer patients under specific treatments?

Christophe Bonneton, Spain

I would like to ask several questions regarding efficacy, who will be responsible in case of adverse events and pricing.

On behalf the healthcare association I represent, many Spanish citizens organizations are concerned regarding those points.

Claudio Torbinio, Italy

How coronavirus is affecting trauma systems in Italy

The trauma program at Ospedali Riuniti in Ancona treats nearly 1,200 major trauma patients per year. But according to trauma medical director Dr. Mario Giusti, the volume of injured patients has fallen by half in recent weeks.

The most evident effect is a significant decrease in the number of trauma cases.

Compared to the same period last year, we are estimating a 50% reduction in hospitalized patients. This corresponds to an overall reduction in emergencies, especially the lower codes.

the recent fall-off is directly related to local quarantines and self-isolation.

Our major traumas are typically caused by car crashes and work accidents. Now, people cannot move, they cannot go to work, they aren't playing sports — so we are seeing much fewer injured patients in the hospital. It's a paradox, but as a trauma program we are working less now.

I must say, however, that injured patients who come to our hospital are worse now.

Previously, we received a lot of situational major trauma [trauma patients without compromised vital signs], but now these patients are very few. Now, the major trauma patients coming to the hospital are all clinical major trauma. This is probably due to the overtriage done in the last few years.

The lockdown imposed by civil authorities in Italy led to a shift in the spectrum of trauma cases. On the one hand, citizens stayed at home much more, which led to a big reduction in trauma due to road accidents or accidents at work. On the other hand, we have detected increases in several other injury types:

Domestic accidents have increased approximately 500%

Trauma caused by family violence has gone up roughly 100%

Accidents on owned farmland have risen by about 50%

Attempted suicides have increased approximately 300%

Elena Petelos, European Public Health Association (EUPHA), Netherlands

We welcome the JS of HMA and EMA on vaccine approval highlighting the need to ensure robust scientific opinions given short timeframes and the explicit mention of SA to advise on quality, safety and efficacy. EUPHA-IDC and EUPHA-HTA would like to highlight:

Vaccine efficacy and safety

Establishment of relevant endpoints and utilisation of the SA mechanism would safeguard sound decision-making; a sound approach in terms of minimum efficacy would contribute to disease control and to avoiding a false sense of security adversely impacting other control measures. Emergency use renders continuous data collection imperative throughout development phases & beyond licensure.

Sound B/R communication, incl. procedures to update it as data emerges in a thorough, transparent manner, and in terms of implication for individuals, different population groups, etc. This can only be effective if context-specific and culturally appropriate. Lack of such communication may lead to apprehension/fear of vaccines and vaccination; need to demonstrate accelerated development does not imply compromises on safety.

Before and after approval, research and reporting aspects necessitating head-to-head comparisons need to be considered, i.e., relative efficacy across population groups, technology differences, dosage, protection against disease & duration thereof, concomitant administration, need to vaccinate seropositive individuals, MoD, and mass vaccination challenges, incl. logistics (e.g., cold chain). These need to be examined in an interdisciplinary manner (incl. for HTA) and via cross-sectoral collaboration given magnitude and complexity. RWD collection via interoperable mechanisms across EU to allow for robust evidence-synthesis and evidence-informed decision-making.

European public health/global health

Related decisions impact access to and affordability of a safe and effective vaccine having wider implications for the safety and wellbeing of people and for societal cohesion.

Gunce Bayram Severoglu, Turkey

Question: Are asymptomatic individuals evaluated in Phase III clinical trials of vaccines, or are records of infected persons based on symptomatic ones? Is it possible for healthcare professionals to know if a given vaccine prevents infection or illness? If a vaccine does not prevent infection but prevents symptomatic disease, this means that a successfully vaccinated individual can still unknowingly transmit the disease to vulnerable people. In this case, healthcare professionals should know this fact and inform their patients by telling them "while this vaccination protects you, it does not protect your immediate family members if they are not vaccinated as well". The answer to this question is also directly related to the public health plans that countries may be making, in terms of prioritization.

Herbert Weltler, Healthcare professional, Austria

1. safety
2. protection of transmission
3. side effects including autoimmune diseases
4. rollout

5. logistic details

Jonas Alexa, Belgium

Concern vaccin using viral vector adenovirus:

All humans may be exposed to natural AAV infections and could mount an immune response against the virus. Consequently, there can be a high prevalence of pre-existing anti-AAV immunity. Could this presents a potential limitation for AAV-based vaccination? due to the potential for AAV-specific antibodies to reduce the efficacy of the vaccination?

Could the use of vaccination with viral vector AAV produce anti-AAV imunity next to anti-covid 19 immunity?

Viral vector-based gene therapies (GTx) have received significant attention in the recent years and the number of ongoing GTx clinical trials is increasing. Could the presence of anti-AAV immunity post vaccination present a potential limitation for AAV-based gene therapy?

Therefore should the vaccination based on AAV vector be prescribed to the older population?

Krüger Mahire, Germany

Health and democracy are important values. They have to be saved and not misused as a business.

Merve Turan, Turkey

I wonder about what is happening about new covid 19 treatment.

Mounir Rizovsky, Belgium

Interest in evaluation and pharmacovigilance process.

Ole Weis Bjerrum, European Hematology Association (EHA), Denmark

Patients with blood disorders may receive immuno-suppressants including chemotherapy, for a malignant or benign disorder, in temporary or life-long treatments. These patients are considered as high-risk in a COVID setting, and precautions to avoid infection have been very important to comply with in the standard of care. To inform the patient, relatives, routines at wards etc, including the potential risk for staff. Expectations are that the clinical trials and authorisation of drugs to treat COVID-19 may continue and progress, supported by the EMA expertise, awaiting the COVID-vaccines. Development of drugs against COVID-19 are of vital importance (also) for high-risk patients and personnel at risk, including the potential use of effective plasma-products containing antibodies from healthy subjects. Vaccination of immuno-compromised persons is a well-known issue, and information may be provided by EMA in the Product Information on the COVID.vaccines, if any aspects have to be taken into account using different products, and a guidance for interpretation of antibody-response as biomarkers, considering a need for re-vaccination. EHA has established fora for disease-specific studies in COVID, and developed educational material for the dissemination of knowledge, which is public available at the EHA website (EHAweb.org) and conveyed via scientific working groups. This also includes information received from EMA, of interest for patients (-organisations) and physicians, why transparency is important in the process going forward, introducing novel drugs to treat and prevent COVID-19 infection. EHA looks forward to work with other specialties in the EMA collaboration.

Olumuyiwa Ariyo, Ekiti State Ministry of Health and Human Service. Ekiti State, Nigeria

SAFETY AND EFFECTIVENESS OF COVID-19 VACCINES AMONG AFRICANS

The available clinical trials have demonstrated that COVID-19 vaccines that are well advanced in development are safe and effective. However, all the studies except for Oxford/AstraZeneca was conducted outside of Africa. Therefore, it is yet to be determined if these vaccines will be as effective and safe as demonstrated so far. Little COVID-19 vaccine development is taking place in Africa, Egypt and Nigeria are examples, but they are mostly at the preclinical stage. There is a palpable apprehension that the vaccine may not be as effective as in Africa due to the obvious genetic variations and diversity seen on the continent and the strains of the SARS-CoV-2 that were used to develop the vaccines. Studies may need to be accelerated to evaluate this but there may be challenges of acceptability of the vaccine's trials considering the misconception and myths about the pandemic across a large part of Africa. These are however not insurmountable.

Philip McMillan, United Kingdom

Highlighting the importance of patient selection with the use of a vaccine.

Most people with infection have mild symptoms or asymptomatic.

COVID-19 is being shown to be characterised by immune dysregulation as the primary cause of severe disease.

Research is now strongly suggestive that severe COVID-19 is a viral mediated autoimmune disease triggered by SARS-COV2 virus. The severe immune response tends to occur in males, obesity, those with cardiovascular and kidney disease and tends to spare children, young adults and older people on immunosuppressive medication.

The pathophysiology will be shown to be connected to individuals with elevated levels of serum ACE-2 (males, obesity, hypertension, heart disease and kidney disease) which combine with SARS-COV2 to trigger an autoimmune response.

In considering who should get the vaccine, it should include measurement of serum ACE-2 for potential recipients and accompanied by short course of aspirin to minimise the risk of an immune over reaction.

Razvan Vintilescu, Romania

As a GP and father of three children I am interested in how were the vaccines tested on children in such a short time and from what age is the vaccine recommended in kids. Also, how come that no evidence based medical study on the efficiency of natural immunity to Sars-Cov2 on past subjects of the disease has been published prior to the announcement of these vaccines, that claim to give this immunity. Neither EMA, FDA, WHO have said until now what is the relation between SarsCov2 antibodies(IgG) and a safe period of time for those that have been sick. What changed and what is that relation?

We know by now, that Covid-19 comes with serious side effects for a long period of time. Bergamo based studies have shown up to 6 months for this side effects to take place. Isn't it safe to wait for 6 months or a similar time from the moment of the last trials to see what happens?

Renate Schoorlemmer, Netherlands

As a general practitioner, I'd like to be able to ask questions or make critical remarks.

Sandra Alexiu, Bucharest Association for Family Doctors, Romania

As expected, most of today's statements are probably about Covid 19 vaccine safety and patient safety.

In my opinion, it is important that medicines regulatory authorities should also have in mind to review the following:

1. Transplacental transfer of post-vaccine antibodies and the degree of protection given to the newborn. Will pregnant women be vaccinated as with TdAp? Or will there be a recommendation for preconception vaccination?
2. Given the process of immunosenescence (or aging), the vaccination of the elderly (the most targeted risk category) will require a particular schedule, with more doses, or the succession of two different types of vaccines (as stated in pneumococcal vaccination)?
3. In our activity we use safety guidelines, communication guidelines and general guidelines to build national schedules, catchup schedules. In the case of covid19 vaccines, the general principles of vaccination should be maintained, otherwise trust will be seriously shaken.
4. The effectiveness of the vaccine conditioned by previous exposure to virus - an issue? If testing before vaccination is necessary, then regulations concerning the types of tests and timing should be specified.

Teodora Ivanova, Germany

The first COVID-19 vaccines to receive a marketing authorisation are not classic but based on a very new technology. Very little clinical experience exists for gene-based vaccines. Except for two new vector-based vaccines, there are no mRNA or DNA vaccines approved for use in humans, although they have been researched for decades.

The EMA has accelerated the approval process for any medicinal products related to COVID-19. Despite all efforts, however, it remains practically impossible to observe and prove or exclude long-term effects (effectiveness and most importantly safety) within such a short time period. This is highly relevant for vaccines in general as they are to be applied on healthy humans, but particularly important for novel vaccine types.

Mild to severe adverse effects have been observed during the clinical trials of gene-based COVID-19 vaccines, including transient haematological changes. There are very few findings for risk groups as mostly young and/or healthy participants have been included for all trials. As mentioned above, data regarding long-term effects simply cannot be available at the present time. Thus, the current state of knowledge provides no evidence of a positive benefit/risk ratio for the vast majority of the population, and there are no sufficient data for specific risk groups.

As a pharmacist and natural scientist, I consider it highly irresponsible to offer such vaccines to the broad masses, and as a human being, I think it would be criminal to make basic human rights such as freedom of movement dependent on the proof of a vaccination, as has been proposed in several countries.

As the EMA is responsible for public health, I expect it to consider these facts in the benefit/risk assessment within the authorisation process of COVID-19 vaccines as well as all other future medicinal products, and strongly believe it will do so.

Tiago Villanueva, European Union of General Practitioners (UEMO), Portugal & Sally Kendall, European Forum for Primary Care (EFPC), United Kingdom (joint intervention)

Primary Care has been at the frontline of the pandemic from the outset. GP's or family physicians and the PHC team have managed more than 90% of cases of covid-19, namely those that are mild/moderate and that can be managed in the outpatient setting and don't require hospitalization. That involved assessing patients face to face in covid assessment centres or "hot hubs" and following up infected patients via telemedicine while also trying to maintain care to non-covid patients as much as possible. GPs and nurses have also paid a heavy price for their exposure and commitment to the communities of patients they serve. The death toll of PHC professionals during the pandemic is enormous, and according to the International Council of Nursing, more nurses worldwide have now died from COVID-19 as in the First World War, and many worked in primary and community care. The death toll among GPs includes a 28-year-old GP in Spain.

General practice and primary care, in general, are ideally placed to provide a major role in vaccination for covid-19 across Europe due to their longstanding experience and expertise in delivering nationwide vaccination programs. However, there are doubts whether primary care has the adequate infrastructure to maintain the cold chain and deliver vaccines that have significant storage requirements such as the Pfizer vaccine. So it may be more feasible for primary care to administer other vaccines that offer less logistical constraints and we will therefore need clear implementation pathways. There will be even greater challenges for primary health care in rural and remote areas.

GP's and nurses will be pivotal to instill confidence in their patients about the covid-19 vaccines since patients turn to primary care as their first point of contact, and we are often the most trusted by patients. GPs, nurses and other PC health workers including pharmacists know our patients very well and are thus ideally placed to adjust our communication to the patient's level of health literacy.

But in turn we need to be well briefed about the vaccines and have easy access to high-quality and clearly reported scientific information from, for example, EMA or the ECDC (but also from other trustworthy sources), in order to be able to accurately inform our patients and answer their ongoing questions and concerns about the vaccines including explaining the meaning of emergency approval or conditional marketing authorization for a COVID-19 vaccine.

All PC staff must have access to education and the same level of knowledge and skill to ensure that optimal uptake is achieved. This requires rapid action, including on the part of regulators, to ensure that the scientific evidence is available in a readily accessible format, including e-learning, that it is acceptable, used and transferable to the community being vaccinated. This includes the understanding of risk-benefit to the individual and the population in order to provide strong messaging to tackle vaccine hesitancy and resistance. It also requires a workforce who are familiar with shared decision making, human rights and the jurisdiction of the country of delivery.

It will be essential to have the summary of product characteristics data and product liability properly sorted out as PHC staff needs to be fully indemnified. We also recommend that EMA adopts a FAQ approach - Frequently asked questions - approach in Europe to ensure a consistent coherent message. This needs to be in "Plain English" or other language equivalence.

We are also in a good position to assess the real time effectiveness of the vaccine and notify any major adverse events, with appropriate digital technology in place to ensure rapid and accurate reporting.

Despite all the attention lying in vaccines right now, GP's are also awaiting with expectation the approval of eventual drugs for prophylaxis or treatment of mild disease, since those are likely to be prescribed mostly in primary care.

If GP's and the Primary Care workforce are well informed and have confidence in the whole regulatory process for covid-19 vaccines, then our patients will be more likely to take up the vaccine.

Tjalling van der Schors, European Association of Hospital Pharmacists (EAHP), Netherlands & Ilaria Passarani, Pharmaceutical Group of the European Union (PGEU), Belgium (joint intervention)

Thank you very much for providing me with the opportunity to share the views of both community and hospital pharmacists on COVID-19 vaccines and their role in the administration process. Some of the points that I will raise fall outside the remit of the EMA, but I would like to touch on them nevertheless. I would like to start by highlighting that the challenges will not be over once one or several vaccines have been authorised for use in the EU. The administration process for the COVID-19 vaccine will be equally challenging.

Since the beginning of the COVID-19 crisis pharmacists have been working with tireless commitment and determination to guarantee patients continued access to treatments. Community pharmacists have been accessible 24/7 also during the lockdown and have arranged home delivery services for the most vulnerable people. Hospital pharmacists, together with other healthcare professionals, attended daily to the needs of Europe's COVID-19 patients in hospitals providing treatments despite serious shortages. Throughout the crisis, pharmacists in the communities have been the first line of advice, treatment and referral for many European citizens on common ailments, successfully preventing unnecessary visits to emergency rooms.

We strongly encourage national governments to make use of the widely accessible network of pharmacies across Europe to assist in efficient immunisation strategies and broaden vaccination opportunities.

At the point of administration primarily there will have to be good logistics in place for both goods and persons receiving the vaccine. Equally important is the record keeping, for several reasons. Mass vaccination will be a challenge in itself, especially with different vaccines. Some of the vaccines in the approval process require the administration of an additional dose. The timing between doses can vary per vaccine. Thus, registration of which person receives which vaccine and which dose of the vaccine is paramount. The setting up and utilisation of a database, preferably linked to a personal health environment, will be essential for monitoring pharmacovigilance and adherence as well as for other purposes such as batch level registration for side effects monitoring and re-calls. Such a database could be useful for much-needed research purposes as well. To facilitate this process the use of scannable codes on the primary packaging is indispensable. A scannable code on the primary packaging should be part of the quality requirement of the vaccine as it is not only the product that is important, but also the way it is used and the follow up. Vaccination records should be an integral part of the medication record, so they can be used throughout the healthcare system.

Pharmacists are trained healthcare professionals and a trusted source of information. They can play a key role in identifying patients in risk groups – such as elderly, patients with chronic diseases, immunocompromised and others – and increasing public confidence in vaccination.

The knowledge and expertise of pharmacists should be utilized in the planning and execution of COVID-19 vaccination programmes. As all health care providers, they should be included in priority access groups for the vaccine.

Zoi Dorothea Pana, Ministry of Health Cyprus, Cyprus

Subgroup analysis of data from covid19 vaccines: to assess efficacy for immunocompromised, children etc.

Post market assessment tool: maybe to have a harmonized electronic tool from the EU countries to enter data and vigilance data so that these data are comparable and correctly assessed.

Academia

Carlos Alberto Guzman, Helmholtz Centre for Infection Research GmbH, Germany

The exceptional emergency needs deriving from the current pandemic have resulted in an unprecedented pace for the development and rollout of COVID-19 vaccines. This has created unavoidable knowledge gaps and potential risks. In this regard, there are two aspects requiring particular attention. First, we need a worldwide, comprehensive and long-lasting pharmacovigilance program to assess safety and efficacy parameters. This program should be tightly-coupled to pre-established workflows to enable rapid reaction and adjustment of vaccine implementation policies, as well as to secure optimal matching between selected vaccines and sub-population groups of vaccinees, according to the risk/benefit balance. Second, we should critically assess the administration of vaccines to children who are not at high risk for severe forms of COVID-19, since ongoing vaccine trials will be unable to provide evidence for rare or long-term adverse events. Even though modelling may suggest the apparent strategic advantage resulting from vaccinating children first, these methods are not yet able by design to take into account the age-specific risks for delayed or rare adverse events. There are good reasons to expect that young vaccinees will display a different risk pattern than other age groups because of their immune responsiveness profile. We need to learn from previous experiences, like in the influenza pandemic of 2009, where unexpected rare serious adverse events were observed, even for a well-known vaccine developed with standard technologies (i.e. not first in class). There is an ethical conundrum in accepting the exposure of children to a potential jeopardy, by offering protection against a disease that represents for them a comparative minimal threat, in order to reduce risks for other individuals who can be directly protected by those vaccines. In particular considering the entity of the potential burden for the vaccinees, the health care systems and the whole society.

Christos Lionis, University of Crete, Greece

We welcome the EMA effort particularly given the infodemic accompanying the COVID-19 pandemic. We also welcome the Joint Statement of HMA & EMA on ensuring robust scientific opinions, a challenging task given the short timeframes. We believe the EMA is instrumental to advise on quality, safety and efficacy, and uniquely position to establish sound communication and information dissemination mechanisms to combat vaccine hesitancy.

The acceleration of procedures has generated apprehension in the general public; whilst on one hand a safe and effective COVID-19 vaccine is considered a magic bullet, on the other hand, limited understanding on the mechanisms involved, e.g., rolling review, emergency authorisation, approval, CMA, etc., generates confusion and may adversely contribute to vaccine uptake and compliance.

It is essential to ensure sound communication on all aspects pertaining to the benefit/risk ratio, and what it means for individuals, groups and communities. This can only be achieved through integration of public health and PC in terms of harmonised communication, incl. regarding risk perception, and

timely updates as new data emerges. The trust of people to their local provider is the cornerstone of uptake and compliance; PC practitioners need to be comprehensively informed, to feel and be empowered to support people in their communities. Additionally, culturally appropriate mass vaccination programmes can only be achieved through thorough information regarding safety and efficacy on specific population groups (e.g., immunocompromised, the chronically ill, the vulnerable, etc). In terms of safety reporting, PC will be instrumental to generate safety profiles. Practitioners ought to be supported in to ensure sound reporting across EU and beyond. They could be an important link with local stakeholders, an important and strong partner in the management of this pandemic. We look forward to the EMA engaging with academia, researchers and practitioners.

Christos Petrou, University of Nicosia, Cyprus

Benefits of vaccination VS long term effects:

Concerns about the long-term effects of vaccines, contributes to the skepticism on the vaccination value.

Risks have to be weighed against benefits. Short and long-term benefits of vaccination (potential high-level protection from COVID-19 disease) outweighs the complications caused by natural infection, such as the risks of COVID-19 disease, as well as the consequences of the societal discomfort the pandemic causes. The same principle of risk/benefit balance must be applied on the possibility of adverse reactions with delayed (long-term) onset.

History of vaccines and vaccination has approved that vaccines usually do not result in long-term complications and such complications are extremely unlikely because of how vaccines work. Most side effects of the vaccines occur immediately or shortly after the vaccination. Vaccines are unlikely to cause any delayed effects or long-term health complications. Of course, we can never fully exclude the possibility of adverse reactions with delayed onset. However, the longer the delay the less likely such reactions to be associated with vaccination.

Phase III are designed, in not general to detect very rare reactions or reactions with delayed onset. Such reactions usually become apparent sometime after the completion of the trials. Trial subjects and vaccinees will continue to be monitored for long-term effects. Analytical epidemiological and post authorization safety studies and pharmacovigilance will continue to make sure there are no further side effects or long-term risks by evaluating the risk-benefit balance and will link any possible delayed adverse reaction to vaccination, when such a causal relationship is established.

It is of utmost importance to communicate that the effects of the COVID-19 disease can be much worse than any possible adverse reaction that could occur in the long future and that the reporting of suspected adverse reactions, through the strong system being in place can contribute to ensure safe and effective use of vaccines.

Emre Öztoprak, Turkey

I want to learn which type of vaccine is more safer and effective and also when people can get vaccines.

Gabriella Marcelja, SIRIUS GLOBAL - Academic Diplomacy 4.0, Italy

On behalf of our research centre and International Medical Community (IMC) led by the international organization SIRIUS GLOBAL - Academic Diplomacy 4.0 (Rome, Italy), we would be interested in addressing the following topics:

- public awareness on the safety of the vaccine and timely identification of fake news around it
- post COVID-19: 1) how to prevent future epidemics, 2) role of civil society, 3) sustainability, environmental & biodiversity loss and climate change effects on diseases transferable to humans
- current MedTech COVID-19 innovations and solutions

Hüseyin Sancar Bozkurt, Turkey

I would like to talk about my scientific opinions about m-RNA vaccines shortly, also I would like to talk about our new approach for COVID19 management via Probiotic Bifidobacteria which could carry active treatment and vaccine models in covid19 management

<https://journals.sagepub.com/doi/full/10.1177/2058738420961304>

If you could provide a short talk, I would be so happy

Klaudia Chrzastek, Poland

I would like to talk about the possibility to track the coronavirus using whole genome sequencing. I am working to develop fast methods that would allowed for whole genome assembly of coronavirus. I think this is a next step that we should already put in place to be sure that we have a methods to track the changes in viral genome after applying vaccination in EU or globally. We are expecting virus to mutate, and there might be minor population of viruses that will carry the mutation throw human population that will arise in specific condition and spread throughout the population. We need be aware that the vaccination will push the virus to escape from immune system and we should already have a system that will allow to track virus changes globally.

I would like to rise this point and present the opportunities for random priming viral genome amplification and how we can use it for virus tracking.

Nikolas Dietis, University of Cyprus, Cyprus

Views

- Importance of meeting: The University of Cyprus would like to thank and congratulate the EMA for this important and historic event. The intention to inform the public about the COVID vaccine processes and listen to the concerns and expectations of the Citizens of Europe, showcases the fact that the Agency is not only a guardian of European public health safety but also a champion of public outreach and seeker of continuous improvement.
- Importance of vaccines: The COVID vaccines and the related vaccination programs are one of the most critical tools in this pandemic against the SARS-CoV2. Vaccines have always been invaluable in the fight against a number of viruses, some of which have been nearly eradicated from the planet. Nevertheless, vaccines will not be a panacea for this pandemic. They will need to be combined with adherence to personal protective measures (masks, socio-physical distancing, hand hygiene) in order to eradicate this virus completely and as fast as possible.
- Importance of health safety: Vaccines, unlike medicines, are given to healthy people. It is therefore of ultimate importance that we protect public health safety through the approval of safe vaccines. It is the safety of vaccines and their benefit over the risk of disease that drive people to trust vaccines and vaccinate. And we know that it is the vaccinations that save peoples' lives, not the vaccines. We therefore need to protect this sacred line of safety-trust-vaccination. Safety is the first crucial step.

- Importance of people's trust to regulatory process: We live in an age of multi-information, over-information and non-stop information. Misconceptions and conspiracies regarding medicines & vaccines are transmitted like a virus and is often amplified by the failures of political systems, the various economic scandals and system corruption. In this environment, the stability offered by a trustworthy, open and transparent regulatory process is invaluable.
- Importance of evidence-based science: The vast majority of the public trusts the scientific process because of its critical awareness, rigor and solidity. Nevertheless, in today's era, science is seen by a minority as a tool for exploiting public tolerance and submission. The only answer to these false claims is the value of evidence. Evidence-based science outlasts every conspiracy theory, every false intent and every misconception. The value of evidence has an immense weight particularly in a vaccination approval process. Jumps in conclusions and effortless generalizations could undermine this process and should be avoided.

Needs

- Answered and unanswered questions: We need a thorough and analytical report on each vaccine's approval decision. We need to know exactly for which questions we have data-derived answers regarding vaccine safety & efficacy and for which questions we do not. A clear distinction between these two will provide increased confidence and reassurance to health scientists and the public.
- Target population for vaccinations: We need to know which people can take the vaccine and which do not and why. It is important for the public to understand that although specific population groups may have not been represented in the study and by the data, we have specific reasons to believe that can be vaccinated safely. We need to be as clear and as specific as possible regarding the rationale behind the inclusion or exclusion of each particular group.
- Risk & Benefit: The assessment of risk and benefit for every vaccine and drug is a key concept that all health scientists try to convey across the public as plainly as possible. We need the Agency to provide this assessment. What are the risks and the benefits of an approved vaccine and why the decision tips the balance towards one side.
- Post-approval surveillance: Another concept that we as health scientists try to convey to the public is that vaccine safety oversight never stops, even after approval. We need to know what the mechanisms will be that will be used for identifying new safety information, quickly enough to allow interventions. Vaccinations may roll quickly as all countries and citizens are eagerly awaiting to receive the vaccine that will protect them from this pandemic. We need the reassurance that this oversight will be effective and incorporate a rapid feedback response to the Agency and the citizens.
- Access to application data: Finally, we need to help our scientists understand the scientific rationale behind the final decision of the Agency, with as many details as possible. We need access to the application folder and the data collected. We need data-focused conclusions in the Agency's final decision in order to facilitate scientific critical appraisal and be able to communicate the outcome more effectively to the public.

Concerns

We have two main concerns that we hope will be addressed by the Agency:

- The first is the potential underestimation of any safety concerns or the lack of long-term safety data associated with a vaccine, due to public health pressure & the urgency to end this pandemic. Underestimation is a dangerous concept. We believe that this can be averted by the actions that have been mentioned in this address.

- The second is the potential overestimation of the vaccine efficacy data with respect to its effectiveness through vaccinations in the fight against the pandemic. We believe that clarity of what the vaccine can or cannot do regarding the spread of infections or the manifestation of the disease is important in order to avert low adherence to protective measures during and after vaccinations.

Expectations

- We have expectations of total transparency during the approval process. Dates that have been scheduled, Committees that have been formed, criteria that have been set, procedures that will be followed. This transparency is a key ingredient to rebuild the lost trust of some members in our communities.
- We have expectations of clarity & detailed information regarding the process outcome and final decision.
- We have expectations of openness regarding all identified or estimated associated risks that come with each vaccine.
- We have expectations of detailed & clear information regarding the scientific process & data collection methods followed by each applicant.
- We have expectations of high quality and speedy safety surveillance mechanisms post-approval.
- Lastly, we have expectations of a clear & concise final message on what is expected by each vaccine to achieve after vaccinating the population: averting infections or averting disease.

Others

Adrian-Andrei Oltean, Romania

[Journalist freelancer]

I believe that the information that will be made public is essential for any European citizen - and Romanian, of course, for this difficult period from a medical point of view. Thank you in advance.

Ana Cadete, The Non-Conformist Scientist, Portugal

[Science communication]

The way social media (newspapers, television, etc.) have been contributing to the miscommunication of relevant scientific findings is appalling. Headlines are sensationalized to drive "clicks" promoting the fast propagation of misinformation. Content is often lacking credible sources and results are overinterpreted beyond their scientific validity. This issue is exacerbated in countries where English is not the first language, due to poor translations. There is a generalized confusion around efficacy, safety, distribution and the availability of a vaccine to everyone. As a result, the society is looking at the development of a Covid-19 vaccine as a means of profit for big pharma and feeling hesitant to take it.

I'm a scientist and the founder of "The Non-Conformist Scientist", a platform created to share ideas and projects. Together with other 6 scientists and science communicators, we started "Science in 3 minutes" (translated from the Portuguese) a YouTube channel where we share short videos that explain Covid-19 and clarify many of its related topics to the general public. We are currently working on three videos for the vaccines. The first one is related with "The importance of vaccination for the public health" and the other two focus on vaccine development, types of vaccines, and the overall

clinical development process. All the videos are currently in Portuguese. In Europe, we urge credible sources like EMA to provide accessible information about the vaccine, translated into all languages. I don't know how we can stop spreading the misinformation, but we are certainly doing our part.

See our latest video here: <https://youtu.be/yaQCpg-oCnE>

Andrea Rappagliosi, Edwards LifeSciences, Switzerland

[Medical Devices Industry]

My question is related to the vaccination policies and programmes. I appreciate that EMA is mainly focussing on the regulatory approval process, but i consider that the condition of utilization and the potential FUMs and/or confirmatory data collection may impact the prioritization in vaccination as base for high quality data collection. This is critical for Class III Medical Devices (high risk implantable) where Industry Clinical Specialists are in the operating room and/or in the CatLabs to secure that the intervention. Without them, the intervention will not take places.

On the contrary, this specific populations together with the HCWs may provide a robust and solid pool for RWE/RWD collection.

Hope this provide sufficient background.

Angela Rossoni, Italy

[Engineer]

Vaccines should be distributed for free to the high-risk population (elderly people, pregnant women, healthcare professionals, etc). I propose to make vaccines available also to the low-risk population, not waiting that a first vaccine campaign for high-risk individuals is concluded. A share of the doses should be reserved to lower-risk citizens, at a controlled price. The logistics of distribution of vaccines should be coordinated at European level. To avoid crowd gathering during the vaccination campaign, vaccine distribution at local level should be managed by general practitioners, preferably through home visits.

Bandana Uniyal, India

[Independent researcher from Shri Radheykrishna Oaj (AIDS VACCINE) Organization]

The global scientific community faced an unprecedented pandemic caused by an un imagined virus named as SARS -Co-2.

The scientific community applied all their knowledge gained through past viral infection experience but not so fruitful.

I think, It is time to re-think out -of-box idea to develop therapeutic vaccine against COVID-19.

The clue to develop therapeutic vaccine against SARS-Co-2 is hidden behind in environmental (Seasonal) factors. The unconventional Seasonal adjuvant that work against SARS-Co-2 and mitigate the overdrive immune response or immunomodulation.

These environmental factors changes immune system configuration inside the human and animal host.

The ongoing preventive and therapeutic vaccine approaches based on idea to elicit neutrilizing antibodies against SARS-Co-2 but i hope these approaches might be successful.

The present preventive vaccine data from big companies is not a efficacy data but showing only safety data. The treatment option also not very convincing on Anti viral drugs platform.

The unconventional Seasonal adjuvant's therapeutic vaccine is best approach to tackle pandemic.

Catherine Bruce, Business Insider, United Kingdom, but covering European news

[Journalist]

How similar are the MHRA and EMA processes? Could we be in a situation where the MHRA could approve a vaccine but the EMA doesn't (or vice versa)? How would the EMA respond in this situation?

Davide De Luca, Diatech Pharmacogenetics, Italy

[Biotechnology]

We are involved in molecular diagnostics for oncology and Covid testing. Interested in being updated about the EMA approach to this pandemic and everything related with the vaccine/ diagnostics related.

Gary Finnegan, Vaccines Today, Ireland

[Journalist & consultant]

#VaccinesWork but only if the public accepts them.

In parallel with the significant efforts of manufacturers and health systems to deliver/administer vaccines, communication campaigns should be rolled out now - before the vaccines are even available. These should address the (entirely reasonable) questions people have about how quickly the vaccines were developed; the rationale behind prioritisation; and timelines for vaccination. They should address questions about new vaccine technologies, particularly mRNA platforms.

We need to see the scientists who developed the vaccines and know that they will be vaccinated; that their vulnerable family members will be vaccinated in the first phase of vaccine rollout. We need to see regulators and hear their personal views to ensure they are seen as people/citizens/parents/spouses/children of older loved ones.

These campaigns should include social media campaigns. They should be devised and executed by communication professionals and social/behavioural scientists based on research. Evidence-based communication is the only acceptable approach to public engagement on evidence-based interventions.

The narrative around COVID vaccines is bedding down now. Communication campaigns need to happen now. To act swiftly, existing networks/coalitions must act (e.g. WHO Vaccine Safety Net; the Commission's Coalition on Vaccination etc.) and existing social media accounts that address vaccines.

Lorenzo Montrasio, Council of Europe - Bioethics Unit, France

[International organisation]

The EU regulatory system on pharmaceuticals is recognised as a well-developed reliable and mature system. Several efforts have been made to increase transparency and independency from possible conflicts of interests. However, in the public the regulatory system tends to appear abstract. There is also a perception of lack of transparency. This is both in the general public and among health workers.

What could be done to increase the awareness of the regulatory system on people concerns and increase trust?

Engaging in public dialogue through public debate is a way to go forward and we would like to congratulate EMA for this initiative. Public debate is an important source of information and views and it is important for public trust. It contributes to the responsible introduction of biomedical developments and technologies provided that is really committed to collect inputs on the fundamental ethical questions that concern people. The Council of Europe has published a Guide to Public Debate on Human Rights and Biomedicine <https://www.coe.int/en/web/bioethics/public-debate>.

A communication strategy based also on the human factor and not only on procedural aspects could be useful. The EU regulatory system is made of thousands of experts and officials working hard and taking responsibilities for quality, safe and effective products.

I would be honoured to participate to the EMA event and to make a speech of 5 min. on the above-mentioned issues.

Loretta Bolgan, Federazione Rinascimento Italia, Italy

[Scientific consultant]

I'm interested to have more information regarding what are the results on the quality (what kind of impurities could be present in the vaccines and how they are purified, studies to define the mutagenetic/oncogenetic effect of the vaccine, and the impact on the environment, how it will be resolved the problem about the storage at low temperature), the safety (how they were studied and what is the incidence of the antibody-dependent enhancement and other potential immunopathologies in the preclinical and clinical studies) and the efficacy (how it was studied on the preclinical studies, if it's available a correlate of protection, and if it's under investigation the impact of the quasispecies of the virus on the efficacy)

These questions regard some concerns that I have from the review of the preclinical and clinical data so far published:

- **Quality:** the manufacturing of a large scale of doses is too fast to guarantee an accurate purification and control of the finished product; since these vaccines are GMO products, the impact on the human genomic and microbiota DNA, and the impact on the environment should be verified in detail before to release them
- **Safety:** the previous studies on SARS/Dengue vaccines proved the existence of ADE and other kinds of immunopathologies, and since they are life-threatening it should be imperative to know the incidence before the marketing authorization. Also, since it's missing the control group of the never vaccinated people it will be not possible to define the real incidence of the adverse reaction. Finally, the time frame for active pharmacovigilance is too short to evaluate middle and long-term adverse events.
- **Efficacy:** it is well documented that the SARS-Cov-2 forms quasispecies and that the spike protein is already widely mutated, so efficacy, in this case, is a theoretical concept that it's not preclinically/clinical supported.

Matteo Lapini, Italy

[Regulatory Affairs Manager]

First of all thank you for the organisation of this public meeting and for the work the Agency is doing evaluating as fast as possible all the amounts of data received on COVID-19 vaccines. I would like to understand better the expected average timelines for approval of the regulatory applications involving the COVID-19 vaccines. Which is the procedural timetable of the formal regulatory submission if the

rolling review cycles have been applied? After positive CHMP Opinion, are the 67 days still applicable for receiving the official European Commission decision allowing the commercialization of the vaccine or the timelines will be significantly shortened?

Mihaela Mihai, Romania

[Journalist]

I am interested in safety of a vaccine.

Richard Staines, Pharmaphorum, United Kingdom

[Media]

I would like to listen and write an account of proceedings for the pharmaphorum website.

Sameera Thanathparambil, Research Quality Association, United Kingdom

[Professional Membership Association]

The importance of quality management in the fast-track development of medicines, and what RQA is doing to support its members engaged in research and development.

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ⁱ The list of interventions is in alphabetical order by Stakeholder type.