Statement

Science should take precedent, not politics: the COVID-19 vaccine assessment process

8 December 2020 - There are lots of comments in the media about the pace of the approval of the vaccines, as the UK begins vaccinating its population against COVID-19 this week.

At EURORDIS we are following the mechanisms and approval process of medicines at the European Medicines Agency (EMA) and national levels closely, so we wanted to establish what we know and understand about the processes for assessing the COVID-19 vaccines in the UK and at European Union level.

We believe that science should take precedent, not politics in the approval and roll out of vaccines to prevent COVID-19. We believe that the European Union is doing everything it can to pave the way to immunise its citizens in the safest way possible, with limited risks. We hope that this will mean that the 30 million people living with a rare disease, often amongst the most vulnerable in society, will be able to benefit from these scientific advances soon.

What was the nature of the UK's decision to begin vaccinating?

The UK is in a politically sensitive situation as it prepares to leave the European Union on 1 January, especially with the risk of a "no deal" still on the cards at the time of writing.

This introduces additional stakes in assessing and importing vaccines: if the UK leaves Europe with no deal, they will not be able to benefit from a EU Marketing Authorisation if granted by the European Commission, and might in addition face major problems in getting vaccines into the country, as the free circulation of goods will end on 31 December 2020. The BioNTech vaccine, in collaboration with Pfizer, which was given the temporary authorisation in the UK is being manufactured in Belgium and the US.

It is important to understand that the BioNTech/Pfizer vaccine did not receive a UK marketing authorisation (as is the on-going process in the EU), but has given authorisation for temporary use by its regulatory body (MHRA). This is possible in certain types of public health emergencies, such as COVID-19. This decision was taken in a very specific context as explained above.

When will we have the vaccine in the European Union?

The EU has all the wheels in motion to assess the COVID-19 vaccine.

This is what we know about the EMA process:

- **The EMA could not be going any faster.** The vaccines are going through an extremely accelerated assessment with a rolling review, meaning that some data and information has been assessed as soon as it is provided to the EMA. This is instead of all information being presented at once.
- **The formal assessment by the EMA cannot begin until the company files a Marketing Authorisation application**. This was received by the EMA for both the BioNTech/Pfizer and the Moderna vaccine on 1 December 2020.
- **The assessment of the vaccines are performed by the EMA's scientific committee for human medicines (CHMP), based on the benefit-risk ratio principles.** If the data submitted are robust enough to conclude on the quality, safety and effectiveness of the vaccine, there will be an extraordinary meeting on 29 December of this committee to conclude the assessment of the Pfizer/Biogen vaccine, and at the latest on the 12 January for the Moderna vaccine.
- **The European Commission is ready to sign and approve the Marketing Authorisation quickly.** If there is a positive opinion from the CHMP, the European Commission is expected to sign and approve the Marketing Authorisation within days of this opinion.
- **Regulators and vaccine developers are mobilising extra resources to monitor safety and manage risk in the pandemic.** Although large numbers of people will receive COVID-19 vaccines in clinical trials, this is important because exceptionally large numbers of people are expected to receive them once authorised.

The European Union is therefore working towards a Conditional Marketing Authorisation (CMA), allowing marketing of the medicine, as opposed to an emergency use authorisation. This will offer a wider choice of vaccines ultimately, within a more robust and legally binding framework.

What is happening in Hungary?

Hungary has received doses of Russia's Sputnik V vaccine in order to start clinical trials. This vaccine has not yet been authorised by the European Commission based on the EMA's recommendation: under EU rules it must have this stamp before it can be marketed in any EU Member State. However, in the case of clinical trials, it is the national regulatory body who approves this process, not the EMA.

Hear from the EMA and FDA about their assessment processes

In October, EURORDIS wrote jointly with EPF to Guido Rasi, the then Executive Director of the EMA, and it's new Executive Director, Emer Cooke, requesting a public meeting on COVID-19 vaccines. We are pleased that the European Medicines Agency (EMA) accepted this proposal and is holding a virtual public stakeholder meeting on 11 December to inform citizens about EMA's role in the pandemic and of EU regulatory procedures.

The public meeting will be broadcast live and will be open to all citizens. It will also give the opportunity to the public and stakeholder groups to speak and share their needs and expectations. We encourage you to join!

The Food and Drug Administration (FDA) in the United States will also be doing a public hearing on the BioNTech/Pfizer vaccine on 10 Dec, and on the Moderna vaccine a week later on the 17 December.

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About EURORDIS-Rare Diseases Europe

EURORDIS-Rare Diseases Europe is a unique, non-profit alliance of over 930 rare disease patient organisations from 73 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe. By connecting patients, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services.

About rare diseases

The European Union considers a disease as rare when it affects less than 1 in 2,000 citizens. Over 6,000 different rare diseases have been identified to date affecting an estimated 30 million people in Europe and 300 million worldwide. 72% of rare diseases are genetic whilst others are the result of infections (bacterial or viral), allergies and environmental causes, or are degenerative and proliferative. 70% of those genetic rare diseases start in childhood.

Due to the low prevalence of each disease, medical expertise is rare, knowledge is scarce, care offerings inadequate and research limited. Despite their great overall number, rare disease patients are the orphans of health systems, often denied diagnosis, treatment and the benefits of research.