European Ombudsman

# Adapting to COVID: Defending the Public Interest in Vaccine and Medical Development

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Good morning. Let me begin by thanking Access to Medicines Ireland for the invitation to address you today. No one could have imagined that it would be taking place during a global pandemic, as the world looks to the scientific and medical communities for a way back to our normal lives and for an end to the suffering of increasing numbers of people.

Your work speaks directly to this crisis. Issues including research capacity, access, funding, data sharing, clinical trials and pricing in the development and rolling out of new therapies, medicines and vaccines come – or will come – sharply into focus revealing the extent to which control in the public interest is exerted over matters that will determine the ultimate human cost of this pandemic.

Inequalities are already laid bare. Families with no access to outdoor space, senior citizens exposed in nursing homes, poor and low skilled workers compelled to work in unsafe environments, refugees and asylum seekers unable to move to safety. How will these inequalities play out if and when the vaccines arrive?

Will health be viewed as a commodity or as a public good? Will political leaders recognise that national self- interest is best served through global collaboration? The Trump administration was reportedly attempting to buy its way to the top of the queue for vaccines with an effort made to attract a German pharmaceutical firm to produce a vaccine for its exclusive use, while reports of the effective piracy of essential medical supplies around the world are also growing.

The western world also paid attention to the development of a cure or treatment for a mass infection in the 1980s when the HIV epidemic took hold. At that time, and for many years afterwards, Aids was a death sentence. I knew several young Irishmen who died of the disease but later many others lucky enough eventually to receive the antiretroviral therapy that would save their lives.

But the Aids epidemic didn't end there. In 2018 over three quarters of a million people died of HIV related causes globally, 61 per cent in Africa. Dedicated work has nonetheless brought the global figure significantly down and mortality in Africa has also dropped by almost 40 percent since 2010. But the gap between the developed and the developing world when it came to the provision of life saving medicines was and is very clear. The history of that time is also

instructive vis a vis research funding, access, pharmaceutical and scientific rivalries, the extent to which governments do or do not exercise control over the development and roll out of therapies and treatments and who ultimately gets them.

The world is now in full panic mode with governments galvanised to find an end to an unprecedented crisis. People hope that the strike by the Corona virus at the epicentre of the world's largest economies will make the search for a vaccine or for effective treatments move very fast indeed.

The capacity of governments to take extraordinary measures if they choose to is clear – from the US administration ordering car manufacturers to produce medical devices, to the enforcement of highly restrictive lockdowns on citizens globally. The extent to which they will use their powers positively to intervene in the pharmaceutical and other relevant private industries to ensure optimum outcomes will be an important marker of how this situation is managed and – hopefully – resolved.

This is a unique situation, visible to all and with fewer hiding places for poor or unethical decision making by governments and by industry. People are normally unaware of access issues apart from times when a public plea is made for access to a drug judged either too experimental or too costly. Awareness is also raised when a medicine is found to cause harm and a subsequent trail of deception is unearthed.

As European Ombudsman, I monitor the EU institutions and agencies including the regulatory European Medicines Agency and I commend it for the accessible and useful information it is providing about the pandemic and the development of possible treatments and vaccines. EMA will approve any future vaccine, an enormous task given the tensions between the world's desperate need for a vaccine and EMA's fundamental duty to ensure the safety of any such vaccine.

The biggest issue I deal with concerning EMA is the transparency of the medicines data it holds. When the Ombudsman first inquired into the transparency of EMA in 2007, EMA was a black-box. It did not make publicly available all the information it had relating to the approval and monitoring process, citing the commercial interests of the pharmaceutical companies and data protection rules.

Our work, combined with pressure from the European Parliament, led EMA to change its entire policy. It now makes public all documentation relating to the approval of drugs, with the sole exception of the personal data of patients and despite significant pushback from the pharmaceutical industry.

I have also looked at the approval process. I recently received a complaint from an Irish citizen whose infant son suffers from a rare variant of cystic fibrosis. He believes that an as yet unapproved drug for children, Kalydeco, will help his son. My inquiry seeks to find out if EMA has dealt with the evaluation as quickly as possible, given that EMA must satisfy itself that the medicine is safe and effective in children.

That inquiry is of enormous importance for the child concerned and his family, especially as cystic fibrosis patients are particularly threatened by the Covid-19 pandemic.

It also has implications for future vaccine approval. EMA will be asked to conduct the approval processes as quickly as possible while trying to ensure that the approval process is scientifically and medically sound.

Vaccines are sensitive. Too weak an immune response provoked and they will not be effective, too strong and the illness may become even worse. Proof of safety and effectiveness will be shown only by complete and extensive clinical trials which will take time

When, hopefully, the vaccines do come on stream, the public will trust the approval process and the uptake of these vaccines will create necessary levels of immunity. The transparency of the approval process is therefore vital to building that necessary trust.

Health authorities will be under great pressure to act swiftly. They may be willing to pay any price for hope but that carries a risk of ineffective outcomes, even abuses.

The more eyes on the decision-making, therefore, the better.

History will look back on the actions we take today, and it will judge harshly those that did not base their decisions on sound principles and in the public interest. I commend the important work of Access to Medicines Ireland and I thank you again for inviting me to be part of today's seminar.