

Check against delivery

HERA

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Minister Valek, Deputy Minister Dvoracek, MEP Trillet-Lenoir, Commissioner Kyriakides, Director General Delsaux, Dear Colleagues and Friends,

First of all, I would like to congratulate the President, the Commissioner, the DG, and all HERA staff for a remarkable first year. What was launched as a must for Europe in President von der Leyen's State of the Union as recently as September 2020, has become a well established body, at the core of the new European Health Union and Pandemic Preparedness and Response system. Many thanks also to the European Parliament, the Council, and the Member States for their constructive support.

As Special Advisor to President von der Leyen, it has been a privilege to closely work with numerous people in the Commission and beyond on the conception and development of HERA.

The first State of Health Preparedness Report provides clear evidence that HERA is already making a difference for the lives of the citizens of Europe, though I trust that next year's edition of the report will discuss both biomedical measures as well as the equally important behavioural and societal measures. Our preparedness and response can only be comprehensive to be effective, and should not be determined by bureaucratic or political divisions of labour.

Above all, thanks to HERA, Europe finally has a mechanism for concerted action on epidemic and biosecurity threats, grounded in the principles of science, multisectoralism, engagement with civil society and business, and pragmatic and rapid action, with close collaboration with member states.

I see HERA as a kind of insurance broker to help protect Europe from the main threats it identified.

However, what we still lack is a comprehensive European strategy for biosecurity and other threats, as nations such as the U.S. and the U.K. have recently published.

Don't worry, I will not give a talk on “lessons learned from Covid” – there are more than enough reports, speeches, conferences on this....But let me be crystal clear that Covid is not over. It is even likely that SARS-COV-2 will be with us for our life time.

However, even if currently new infections and hospitalisations are again on the rise, it is safe to state that the pandemic is entering into yet another phase: Thanks to various degrees of immunity from vaccination and natural infection, we are on the path to “endemicity” in some form. That was also the collective view last week of the EU Covid Science Platform of national Covid coordinators, which Commissioner Kyriakides and I co-chair. We also thought that because of the ever growing spectrum of variants – all offspring of “Omicron”- the exact future trajectory, even for this winter, is hard to predict.

The emergence of variants such as BQ1.1 is concerning because of their higher degree of immune escape capacity than other variants, resulting among other issue in a failure of their inactivation by currently available monoclonal antibody-based therapies.

I am particularly concerned by the generally low uptake of the fourth vaccination, even among those at highest risk of severe disease or death from Covid – though there are parts of Europe where vaccination coverage is good to very good.

By the way, I suggest we no longer use the term “*booster*” for such repeat vaccinations, but simply *seasonal vaccination* as we do for influenza vaccination.

It is certainly not clear what form and shape Covid waves will have in the medium and long term. In the meantime, besides Covid, we are seeing a surge in RSV infections in several countries, and a major influenza epidemic or even pandemic is bound to happen one day...

As was the consensus at the Covid Science Platform last week, we must adapt our approaches and our tools to respond to epidemics when the situation changes. This will be a continuing challenge at many levels in Europe and the rest of the world.

Let me briefly discuss 5 issues which I believe are critical for a successful preparedness, response, and resilience to epidemics and other cross border threats in Europe. Obviously many other issues, are as important to succeed, in particular leadership, without which not much is possible.

1st. Now that Covid is still in our collective memory, this is the time to strengthen or create the structures, systems, fire-drill like simulations...which will all be key to ensure we are better prepared for the next crisis, while continue to effectively control the ongoing Covid epidemic.

We should be inspired by the level of preparedness that some Eastern and South Eastern Asian countries developed following their traumatic SARS experience in 2003. I am very pleased we have Singapore's Chief Health Scientist to share their experience, which ultimately resulted in much lower mortality than in Europe and other parts of the world – though societal trust and culture probably also contributed: just think of long standing positive attitudes towards face mask wearing.

Experience has also shown that such entities and policies must coherently integrate biomedical and so-called non-pharmaceutical interventions, instead of their artificial separation. This is also true for the various national and EU level committees. As always after a crisis, we should take a cold and hard look whether the various mechanisms, committees, and governance - in this case of health threats and biosecurity – are still optimal, effective and efficient, and what Europe ideally needs.

2nd. Research and innovation, and science advice, are essential parts of preparedness and response.

The rapid availability of vaccines was life saving for literally millions. But this could only happy thanks to decades of investment in research – with a major contribution from EU research funding and the Commission's Research & Innovation DG.

Such research is not limited to biomedical sciences, but must involve all relevant disciplines, and draw on both public and private efforts. HERA has a major leveraging role to play in this ecosystem.

Achieving a critical mass is vital for success and meaningful results in several areas of research. Europe has not done well enough in the rapid organisation of multi-country clinical trials in vaccines and therapies for Covid-19. And yet,

we have a world class, 60 year old, effective system of clinical trials in oncology through EORTC, showing it is possible to organise such multi-centre trials. However, a more efficient European system will require addressing a complex set of issues from data sharing and protection, ethical review, national regulatory matters, and above all a strong political will, and greater openness and flexibility of scientists, clinicians, and policy makers.

This week I attended an interesting briefing on the EU Cohorts Coordination Board, which brings together various cohorts related to Covid. Just imagine how quickly we could have evaluated vaccines, therapeutics, behavioural interventions, and risk determinants in large populations, if such cohorts had existed at the beginning of the pandemic. This is why we must fully support them for many years to come as “strategic cohorts”, as they will be invaluable when the next epidemic hits us, or when SARS-COV-2 changes drastically.

Similarly, two weeks ago RTD and HERA convened an inspiring meeting on broad spectrum antivirals. Again, we must massively invest in their development, as they can make a major difference for patients, for prophylaxis of infection particularly among vulnerable populations, and even for early containment of a new pathogen from a particular virus family.

3rd. HERA can only succeed if it is at the heart of a coherent ecosystem for health threats preparedness and response.

We often consider US BARDA as an inspiring model for what HERA could be, but let us not forget that BARDA can only deliver because it is so well integrated into a complex US Government system, closely working with industry, big and small, and also relying on institutions such as the National Institutes of Health for R&D. At EU level we don't have such an ecosystem, and in any case HERA will have to develop an approach which is fit for Europe.

As an EU institution, synergistic and complementary collaboration with the multiple Member State initiatives is a *conditio sine qua non* for success and usefulness for our citizens. This goes equally for governments, academia, industry and civil society. And it should apply for the relevant EU governing bodies.

As a Commission entity, seamless interaction and collaboration with other DGs such as Santé/Health, Research and Innovation, Internal Market, and International Partnerships, is a no-brainer. Citizens look at the Commission as a whole, and are not interested which part does what. In addition, we have

two highly relevant prime institutions, which are being strengthened as part of the European Health Union as highlighted by Commissioner Stella Kyriakides: European CDC and the European Medicines Agency. Crucially, we are fortunate to work under the overall leadership of the President of the Commission since the beginning of the Covid pandemic.

The development, manufacturing, and delivery of tools against epidemic pathogens happen in the first place in various parts of industry, and private philanthropy has been very active in this area as well – and I am pleased to see representatives from both the various public and private spheres at this meeting. Therefore a proactive public –private partnership around HERA is essential, while ensuring transparency and equity.

The combined forces of all actors inside and outside the Commission can make a huge difference if they are aligned.

4th. A major lesson, if not a surprise for some of us, has been the vital role of public trust and communication in this epidemic.

Science advice and communication can be challenging in the best of times, and certainly in times of crisis and great anxiety. And sometimes we scientists have been over optimistic, doom thinking or over promising. That hasn't helped either.

But with Covid, mis- and disinformation have come in a big way to the forefront of public opinion and policy making. This is not new: as long as there were vaccines, there have been scepticism, hesitancy, resistance and rejection on a wide range of grounds. But today we live in a world of social media, of polarisation to the extreme, and this had led to serious pandemic-related health problems in some populations, leading to numerous avoidable deaths – mainly because of lack of vaccination. Fortunately, much of Europe has some of the highest Covid vaccination rates in the world, so overall impact in most member states has been fairly limited, though in some populations vaccination uptake has been far too low.

And let's not be naïve: not all misinformation about vaccines, masks, testing, and social measures is spontaneous, but has been politically engineered, both domestic and foreign in origin. We are entering here the field of more classic security, not just health security.

Recent data on vaccine confidence in Europe suggest that despite good vaccination coverage against Covid, trust in vaccination, and uptake of even childhood vaccines has suffered in many countries. I had expected that given the spectacular impact of Covid vaccines to prevent serious illness and death, vaccination would have become much more popular...

What can we do? As the Vaccine Confidence Project recommends in the first place, is to listen carefully to what is on people's mind, as some of the concerns may be legitimate and can be addressed. But for the equivalent of "the earth is flat" views, rational debate is very difficult.

A major task now in health in general is to give a high priority to communication, support a science base for communication and trust in health, be proactive in addressing miscommunication, and invest in more tailor made communication and information. Such education should start in primary school, as was mentioned at the EU Covid Science Platform last week.

Without trust, epidemic preparedness and response are at risk to fail, even with the most sophisticated medical tools.

5th and close to my heart is international cooperation.

By definition a pandemic is worldwide, but we are also regularly facing regional epidemics. So, working together, exchanging information in full transparency and timely, is beneficial to all.

Such cooperation obviously starts with early warning, and openness in exchanging key epidemiologic, laboratory and clinical information. This is why we need strong global and regional multilateral organisations such as WHO, ECDC and Africa CDC.

There are at least 2 additional issues on which we must work together: First, access to products and tools. Our collective track record on equitable access to Covid vaccines is mixed, though the EU, through and in addition to COVAX, has been a main exporter of vaccines to low and middle income countries.

However, in general, scarcity is an enemy of equity, and national interests and wellbeing will logically be the prime concern of national leaders. That is why there is such a strong geopolitical imperative to invest in distributed or regional manufacturing, particularly in sub-Saharan Africa, which is still deprived of local vaccine and medicines manufacturing and development. In my view, this is the only realistic way we can avoid a repetition of a major

deficit in access in the poorest countries. I am very pleased that Team Europe is resolutely investing in such manufacturing in Africa, working closely with the AU. I have witnessed major progress in this area in Senegal at the Institut Pasteur de Dakar, which has been producing yellow fever vaccines for many decades, demonstrating that such capacity exists in Africa – though it has to be brought to scale using the latest technologies.

Secondly, science and innovation operate across borders, and the EU and Member States are supporting multiple initiatives inside and outside Europe. Again, here we should join forces among initiatives in Europe and with countries such as Japan, Singapore, the UK, and the USA.

Finally, we should play our role in multinational initiatives such as CEPI, which was created after the tragic West Africa Ebola epidemic to stimulate the development of vaccines particularly in cases of lack of market incentives. I am pleased that CEPI's CEO, Richard Hatchett, is with us today and that an agreement has been signed between HERA and CEPI, illustrating HERA's international role.

Let me conclude by saying that whereas no two epidemics are identical, even if caused by the same pathogen, the basics of preparedness and response are the same. As EU we are much stronger together than each member state individually. Efficient coordination is not just a dull bureaucratic exercise, but a hall mark of providing health security to our citizens, and saving lives.

An overall key challenge is political: how to maintain commitment and funding for pandemic preparedness and response in times of a devastating war on Ukraine, an energy crisis, rampant inflation and growing inequities.

We have done a lot together, but can and must do better, and that is why we need HERA – one of the key components of the European Health Union.