



European Alliance for Personalised Medicine

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Here comes summer.. Or not?

Greetings all, and welcome to the June edition of the EAPM newsletter as we all continue to fight our way through this COVID-19 situation, not just in Europe, but across the globe.

As lockdowns continue to be variously gently undone and fully dismantled at various speeds across the world, one bit of bad news - or expected grim reality, of you prefer - is that the World Health Organization's has said it's unlikely that COVID-19 will gradually lose its virulence, in the way that Sars-Cov and Mers-Cov did.

The WHO's **Ranieri Guerra** said it's "much more like the influenza virus, and has infected millions and caused hundreds of thousands of deaths," while adding that this risk underscores the importance of finding a vaccine - of which a little more later.

Right now, he said, there is little variation between different strains of the novel coronavirus to raise the conclusion that might be causing the difference in mortality rates in different countries. Such variations are more likely attributable to other factors, such as age and the presence of comorbidities, Guerra was prompted to add.

And when it comes to summer holidays, more bad news comes with the fact that if we look once more at previous pandemics there will be more than one wave.

This was underscored recently by European Centre for Disease Prevention and Control (ECDC) head **Andrea Ammon**, who says that lifting lockdown restrictions too quickly without maintaining social distancing and ensuring enough testing and contact tracing could trigger the next wave.

It's a fact that the general public are thinking about international travel - or at least wishfully thinking it - and many countries are suggesting opening up their skies and airports, albeit often in picky and restrictive fashion. This won't help the risk, at an educated guess.

Certainly **Erika Vlieghe**, who leads the infectious diseases department at the Antwerp University hospital and is the top "deconfinement" adviser to the Belgian government, doesn't think so.

Until a vaccine is actually developed (she is optimistic) "it will be a bit like driving and braking and driving and braking and being careful," she said.

The behaviour of the general public in being sensible will be crucial but is not, of course, predictable.

In the EAPM pipeline:

- **30 June: Bridging Conference, "Maintaining public trust in use of Big Data for health science" - Brussels, Belgium**
- **18-19 September: ESMO Roundtable - Madrid, Spain**
- **13-14 October: Virtual conference: "Building a decentralised, data-rich testing space to speed better testing and care in a Covid and post-Covid world" - Brussels, Belgium**
- **Ongoing March-October: Biomarker testing series of events**
- **17-18 November: German Presidency Conference - Brussels, Belgium**

Speaking of international flights, Alliance friend, collaborator and MEP **Peter Liese** has said that he welcomes guidelines published by the European Aviation Safety Agency (EASA) and the European Centre for Disease Prevention and Control (ECDC) to prevent the spread of COVID-19 in aircraft.

The health spokesman for the EPP called the recommendations "overdue," adding: "I think it is completely disproportionate that we allow restaurant owners, fitness studio operators and others to work only under strict conditions and with the necessary distance, but that airlines still have the option of operating aircraft down to the last seat."

As it stands, the guidelines recommend that "where allowed by the passenger load, cabin configuration and mass and balance requirements, airlines should ensure, to the extent possible, physical distancing among passengers".

They also recommend leaving two rows empty to serve as a makeshift "isolation area" for passengers who show COVID-19 symptoms on board. That sort of occurrence should cheer up a journey, eh? Happy holidays!

Staying sane

Europe's Health Commissioner **Stella Kyriakides** recently ran



a webinar on the coronavirus' impact on society, with a focus on how the virus puts the EU's most vulnerable groups at risk, as well as how lockdowns affect people's mental health.

Kyriakides (pictured above) said: "For some groups of our societies this difficult experience will be harder to overcome and the consequences will be felt for a longer period of time."

The commissioner is of the belief that as a society, "we need to take this into consideration and pay particular attention to these groups".

The BMJ also recently addressed the subject, with a medical student - **Ashwin Venkatesh** - writing that isolation and quarantine can "have precipitated depression and anxiety" and that, as a result, "government, media, and healthcare professionals should communicate clear and accurate public health guidance".

Latest on drug shortages

The situation is worsening, to nobody's surprise, really. And the European Public Health Alliance (EPHA) has warned that shortages are now affecting medicines for patients with COVID-19. Again, somewhat inevitable.

The EPHA recently published a clutch of recommendations on this, including strengthening the EU's legislative framework on pharmaceuticals in order to give better notification of medicine shortages.

Charlotte Roffiaen, France Assos Santé's European Affairs Adviser, was quoted as saying: "Medicine shortages have gone out of control in most EU countries, with devastating effects on patient health.

"We need increased European coordination and strong EU initiatives to fight this plague, as no member state is in a position to solve this crisis on its own."

In the Netherlands, the Amsterdam powers-that-be will spend €115 million in a bid to prevent drug shortages and improve medicine safety between now and the end of 2024, according to the country's health ministry.

And **Guido Rasi**, currently executive director of the European Medicines Agency (EMA), has told the European Parliament's health committee about the agency's work during the COVID-19 outbreak, while DG SANTE Director **Anne Bucher** told the committee that the Commission is talking to states about how to ensure access to medicines, not least in the face of Malta's Health Minister **Chris Fearne** going public that smaller countries risk being sidelined when it comes to access to medicines and protective equipment.

Chris, who has worked many times with EAPM, said: "We want to see solidarity among us, not just on paper."

While back at the EMA, the agency says it has also taken on a larger role in tackling drug shortages, which as noted above have been "aggravated" by the coronavirus outbreak.

A dedicated steering committee is addressing the issue, building a new network for drug companies to report possible supply issues.

According to Rasi, EMA is also allowing some regulatory flexibility to ensure the supply of medicines and increase manufacturing capacity.

However, longer-term solutions will need to be addressed in the Commission's pharmaceutical strategy, the chief added.



Prepare now for a rare mention of **Brexit** here, these days - but it's tied to shortages. **Steve Bates**, chief executive of the BioIndustry Association, has described the lack of any mention of the supply of medicines between Northern Ireland and Great Britain in the latest document on the Northern Ireland Protocol as "deeply disappointing".

The recently released document sets out the UK approach to the Protocol and pretty much finally admits that there will be a trade border down the Irish Sea.

"The UK's approach to the supply of medicines in the Northern Ireland Protocol is sadly missing in the document published," said Bates, who added that the government had been aware that this was a "major issue" for the bioindustry for more than six months, and that said industry needs detailed guidance on a legal framework to ensure the continued dispensing of medicines to the National Health Service in Northern Ireland from January next year.

Another headache for Prime Minister **Boris Johnson**, who certainly seems to have plenty to worry about right now, not least the lockdown travel behaviour of his chief advisor...

Vax to the max

We've already mentioned DG SANTE's Director-General Anne Bucher talking to the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee and, during that time, she warned that needs to have enough production capacity in place to meet demand for an eventual coronavirus vaccine.

She believes that, right now, such capacity is lacking.

However, the Commission is currently evaluating a number of policy proposals to make sure that the EU can manufacture as much as necessary. Now all we need is the vaccine, right?

At the meeting, the European People Party's health spokesman **Peter Liese** (above), went back to a favourite topic of his of compulsory licensing. This allows countries to circumvent intellectual property laws to manufacture medicines in certain situations.

Peter asked Bucher whether the Commission has a role in organising member states to ensure the supply of any medicine developed against the coronavirus, mentioning broad concerns that the US administration might reserve the supply exclusively for itself.

Bucher was having none of it at the minute, arguing that right now compulsory licensing would be premature, and was down the list of early options.

Regarding the vexed question of "who gets a vaccine first", the pharmaceutical industry's message is that it's aiming to work to ensure global access to any future vaccine.

David Talbot, who is senior director of international government affairs at Eli Lilly, said that "in general" he saw "a sense of cooperation among industry globally which understands the scale of the challenge and the fact the spotlight is on us".

Regardless of the above, there are examples proving the importance of the broadest possible vaccination strategy.

For example, the smallpox vaccine was around for years before it successfully helped eradicate the disease., and the key difference was vaccinating developing countries.

These had poor access to the vaccine for years, according to **David Heymann**, who is a highly regarded fellow at Chatham House's Global Health Programme as well as the executive director of the World Health Organization's Communicable Diseases Cluster.



Stanimir Hasurdjiev, Chairperson, National Patients' Organization Bulgaria, spoke at the EAPM event

He says: "Smallpox eradication not only signalled that success in public health and getting rid of smallpox, but it also was the first time when there was universal access" to a vaccine.

He added that ensuring developing countries got access to vaccines also led to "great progress" in fighting polio.

Heymann went on to say that: "The equitable distribution of vaccines was solved for smallpox eradication and polio eradication, [but] it hasn't been solved for many other infections, such as endemic influenza."

Back in 2007, for example, Indonesia helped share virus samples of the H5N1 avian influenza with the WHO, which in turn shared them with a vaccine developer. However, when the Indonesian health minister tried to purchase a flu vaccine from the developer, the company said it had been sold to other countries.

Heymann says that case made clear the principle of "equal benefits for equal sharing" given that the minister had shared a virus sample even though the country didn't benefit from it.

On the back of this, the WHO developed a framework in which companies agreed to provide a certain percentage of their vaccines to the organization during any pandemic.

"But," says Heymann, "this is a very small percentage of all production, and it certainly won't be something that is equitably distributed through all countries around the world".

"We have made progress in vaccines, we have made progress

in equitable distribution, but those problems will certainly continue."

Heymann took the opportunity to highlight that many countries do not allow companies to export vaccines manufactured 'at home' until national demand is satisfied. Obviously this could have the effect that nations with more manufacturing capacity could get a coronavirus vaccine first.

It's an issue "that will cause an even greater problem in making sure that there's a fair and equitable distribution of vaccines," Heymann noted, considering that friendly countries are "competing for the same masks or the same ventilators and offering to pay higher prices in order to get them".

EAPM events latest

The Alliance has certainly been doing its bit in the ongoing battle that we're all facing right now, not least with its recent Future Proofing event (8 May), held regarding the situation in our particular area and arena of expertise, yet with a lean also towards Asia - which shares many of the same issues and challenges that we're dealing with in Europe.

We are happy to report that it was a great success as a 'virtual' conference, with in the region of 1,000 speakers and delegates 'tuning in'.

Chaired by **Jeremy Lin**, Leading Public Health Expert, University of Singapore, and EAPM's **Denis Horgan**, the title of the international session was '*Building Resilient Health Systems*'. Well, we need them everywhere, it turns out...



Among the many issues up for discussion during the event were how to allocate resources which, of course, comes partly as a knock-on effect of how we define 'value' (and from whose perspective) - in essence, the big question of who decides?

EAPM and many others have debated this many times as every stakeholder has their own viewpoint - patients, payers, manufacturers et al. And, of course, everybody wants the best healthcare for their citizens and themselves.

In the meantime, as a huge part of that process, our researchers want to produce the best research, patient/citizens was earlier diagnosis, higher standards of care, earlier access and the most cutting-edge and effective of treatments, and industry wants to produce amazing new drugs making the very best of rapidly emerging science.

In the case of new science and new uses for science, it must be remembered that personalised medicine in-and-of itself is a serious push towards greater value, in every context, certainly in the long term.

By giving the right treatment to the right patient at the right time, personalised medicine is crucial here.

Writing about the conference in *Politico*, Denis and Jeremy explained that the currently reality is that even western countries with the most consistent attachment to liberal values have had to operate robustly in their responses to the coronavirus pandemic.

Even customarily open societies have had to accept the spectacle of uniformed police forcibly removing members of the public from beaches and parks, or dispersing cheerful street parties. Indeed, the contortions that major European countries are now going through in extricating themselves from extensive mandatory lockdowns of their populations only serve to demonstrate quite how radical the effect of COVID-19 has been in so many distinct regions of the world.

And **Brigitte Nolet**, general manager of Roche Belgium, noted:

"When we first started hearing about COVID-19 at the end of last year, no one could predict how significantly our lives would change in a matter of months."

Panelists at the conference - from Australia, Belgium, Bulgaria, China, Denmark, India, Ireland, Singapore and the UK - agreed that the world is now a different place, and that the response will have to factor in the need for new approaches in the face of a disease that knows no borders.

Citizens must work together with their governments in line with science-based advice. And new forms of cooperation are needed.

Jeremy and former Irish health minister **Mary Harney** (above) both lamented "the disappointing record" of dialogue across geographies and cultures and political systems, as did **Chunlin Jin** - but he also saw the epidemic "strengthening the global village concept".

Central to a solution, both to combat the immediate pandemic and to build greater resilience into health systems, is a decisive health-sector engagement with digital technology.

Resilience requires a new generation of data collection in which indicators are robust, comparable across countries and relevant, so they can help guide health systems in real time to diagnose, track and treat diseases, and to predict ill health.

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Still, too much of the wealth of health-related data goes to waste, prompting Harney to speak of "a hugely missed opportunity to deliver better outcomes". Challenges over technology, usage and - above all - privacy persist.

Joanne Hackett, former chief commercial officer of Genomics England, picked that up saying that the patient should retain data ownership.



Hrvatsko predsjedanje
Croatian Presidency of the
Vijećem Europske unije
Council of the European Union

This was in contrast to the view from **Krishna Reddy**, director of India's Access Health International, that the privacy of the individual "is subservient to the population's greater good", or the caution expressed by Bogi Eliassen of the Copenhagen Institute of Futures Studies over an obsessive demand for anonymity.

But there was some consensus that imaginative frameworks could provide the necessary level of trust and transparency. The pandemic is, in effect, a wake-up call, said Harney, or as another described it: "a useful push to a systems approach to digital health".

Lim, meanwhile, insisted that data must be given the priority it deserves, "because the world cannot tolerate another lockdown of this magnitude".

The pandemic is, in effect, a wake-up call - a useful push to a systems approach to digital health.

Resilience is necessary to avert the collateral damage that the pandemic is already inflicting among patients with other diseases who are denied or discouraged from seeking treatment during the crisis.

Growing evidence of increased mortality and morbidity among this population obliges acknowledgement that if the overall aim is to drive better health, one-in-three people in Europe getting cancer each year is legitimately described by patient groups as "also a pandemic of a sort".

In terms of crude numbers, COVID-19 has caused fewer deaths than many other common conditions. Set against the annual world total of deaths from all causes of around 21 million, the 287,000 total deaths by 12 May from COVID-19 are, while personally tragic, still statistically hardly significant.

For example, malaria and suicides both have a higher death-toll, while communicable diseases overall have killed more than four million people already this year.

The data should and must guide allocation of resources and make it possible to overcome emotion and rhetoric.

Let's face it - the world cannot tolerate another lockdown of this magnitude.

So, the question is how to develop a framework to tackle this collectively. Better use of data has positive implications beyond the immediate challenges of the current pandemic, was EAPM's view:

"Knowing why and how people get sick will help us to do a better job of keeping them well. If fewer people need treatment, that frees up scarce resources to better manage public health. Health systems will be able to tackle challenges like increasing rates of cancer or dementia and be better equipped to manage any future crises like this pandemic."

Consensus reached

The consensus at the conference was not on the need for universal empowerment of state apparatus or for the elimination of personal data privacy, or for a dirigiste approach aimed at one or another particular health problem.

It was, on the contrary, a recognition of the transforming power of data used well, for a willingness to explore, jointly, how to reinvent the definition and scope and priorities of public health, integrating it more firmly, and with the resources it merits, into policymaking at national and international level.

More EU. Please!

Generally speaking, many would say that the crisis has shown a clear need for a governance framework across the whole EU. There is no joint decision-making between even bordering countries about when lockdowns are stepped back, and it all looks just as messy as what is going on in the US - no cohesion, individual states acting as they see fit, and so on.

Among items that will be discussed at EAPM's next major video conferencing event at the end of June will be whether the EU should have a bigger role in public health, particularly in the provision of health technology.

Registration is now open for the upcoming **Croatia-Germany EU Presidency bridging conference** on the 30th of the month,



World Health Organization

just before the Croatia presidency turns in to Germany's six months stint at the helm.

The conference is entitled "*Maintaining public trust in the use of Big Data for health science in a Covid and post-Covid world*", which certainly covers a multitude of topics but, even so, is still not a big enough title to cover all we'll be discussing!

Despite us not being able to meet face-to-face, events such as this still allow the pulling together of leading experts in the arena of personalised medicine drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives.

A key role of any EAPM conference is to bring together experts to agree policies by consensus and take our conclusions to policy makers.

On **whether the EU should have more influence in healthcare**, such a reality would of course impinge upon the closely guarded Member State competence in healthcare. So if this were to happen, how would that be?

Clearly we need to move on this fundamental quickly. We should have already done so, in fact, but perhaps the pandemic will (eventually) focus minds.

It will have to because linked to this question is how can the now very evident gaps be bridged in order to better protect protect Europe's health ahead of another crisis? What are the priorities? The broader question, as mentioned above, is whether it's time to give the EU a bigger role in protecting you, me and all of us.

As the pandemic has unravelled and lethally struck at the heart of Europe and the global community, the deficiencies in availability and supply of necessary assets for responding have become overtly clear.

We all know there have been huge shortages of personal protective equipment, such as face masks, as well as near misses in basic ICU equipment that should have plenty, and a lack in less well-provisioned countries, and much scrabbling around for key devices and within infrastructure constraints.

On top of this, there has been inadequate provision of high-tech procedures and processes, for testing (both for infection and for immunity), a shortage of medicine for symptomatic treatment, for any curative therapy, and (not surprisingly given the timescale) for preventive vaccines.

Systems have broken down at many levels and have not been totally salvaged in most cases.

While not delaying the hunt for a vaccine, Europe must produce an administrative system to support the public's ability to live with COVID-19.

Europe has lacked and - given the haphazard ways the lockdowns are being dismantled right now - still clearly lacks coordinated, sustained efforts by the EU and Member States to build capacities and rise to challenges.

We need much more coherence, now and going forward. We always have, but now it is surely blindingly obvious?

Cancer and the pandemic

A recent virtual event run by EFPIA, the European Federation of Pharmaceutical Industries and Associations, on oncology and COVID-19 saw participants agree that the pandemic was having an impact on cancer care provision, though it was still too early to say just how much.

For example, **Antonella Cardone**, director at the European Cancer Patient Coalition, cited a recent paper published by academics at the University College London which estimated that cancer deaths in England could rise by 20%, adding nearly 18,000 additional deaths because of delayed care, in an environment in which check-ups are rescheduled and cancer patients avoid hospitals for fear of contagion.

During the event speakers broadly agreed that the EU should play a bigger role in health policy. Now where have we heard that before?

For example, Croatian MEP **Tomislav Sokol** highlighted the risk that the pandemic exacerbates existing divisions in healthcare outcomes.



He said that more investment in cross-border healthcare infrastructure, for example in opening up data across countries or in telemedicine, would be an opportunity to allocate resources on a European level.

Again, nothing new here - let's get it done!

Funding moves

The European Innovation Council should get a "minimum" of €10 billion from the 2021-2027 EU budget.

So says the governing board set up to advise on how it is run, arguing it will need at least that much to support the EU's ongoing recovery from the coronavirus crisis.

The EIC (which is to be funded under the EU's Horizon Europe programme) is set to give venture capital to innovators, startups and spin offs.

Research and Innovation Commissioner Mariya Gabriel, while explaining that the Commission had received requests in excess of €10 billion from the programme in the last month alone, said "this clearly demonstrates how important it is to support high-impact innovation during the coronavirus recovery period and beyond".

About EAPM

The European Alliance for Personalised Medicine was launched in March 2012, with the aim of improving patient care by speeding development, delivery and uptake of personalised medicine and earlier diagnostics, through consensus.

EAPM began as a response to the need for a wider understanding of priorities in personalised medicine and a more integrated approach among stakeholders. It continues to fulfil that role, often via regular major events and media interaction.

Our stakeholders focus not just on the delivery of the right treatment for the right patient at the right time, but also on the right preventative measures to ensure reliable and sustainable healthcare.

The mix of EAPM members and its broader outreach provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry.

Relevant departments of the European Commission have observer status, as does the EMA, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.

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