



# European Alliance for Personalised Medicine

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## Conference a success despite Covid-19 crisis

Greetings, and welcome to our April 2020 newsletter. It's already been one helluva year and there's more of a rollercoaster ride to come, that's for sure.

Given the circumstances in which we all find ourselves, and the subsequent social distancing, self-isolating and inevitable cancelling of events, EAPM's 'virtual conference' of 24 March was an incredible success.

No less than 18 Members of the European Parliament were among the hundreds of stakeholder delegates tuning in and contributing. Three of the 18 deputies delivered speeches during the highly informative sessions.

It was a marathon conference, taking place throughout the whole day, and also involved were EMA representatives, plus speakers from the European Commission's DG SANTE, DG Connect and DG Research.

Importantly, one key outcome was that, from a particular poll and panel that took place on the day, EAPM will engage with stakeholders including industry to undertake scenario planning around bringing personalised healthcare in a post-Covid 19 healthcare world.

See later in this newsletter for a round-up, and don't forget that *a full report will be with you in due course.*

### Beyond the conference...

Pandemic or panic-demic? Plenty of EU countries are desperately trying to avoid the fates of Italy and Spain right now as the virus leaps borders and continues to spread.

But Member States are using different methods, with some initially trying to test everyone, and others choosing not to. Meanwhile, cases have continued to grow, often leaving Europe's countries unable to stick to earlier plans.

On top of this, do we really know the true numbers of infected people? Of course not, although the number of deaths - sadly - is more reliable.

Also reliable is the availability (or lack thereof) of critical-care beds in a nation's hospitals. The more properly staffed and available across an individual health system, the more chance of a Member State being able to cope.

There are, as ever, huge differences among country capacities. Germany is the best equipped, Luxembourg, Austria

### 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**
- **29-30 September: PIONEER General Assembly, Frankfurt, Germany**
- **15-16 October: HARMONY General Assembly, The Hague, the Netherlands**
- **17-18 November: German Presidency Conference "Building a decentralised, data-rich biomarker space to speed better cancer care" - Brussels, Belgium**

and Romania are doing more than OK, yet Portugal, The Netherlands, Slovenia, Finland, Greece and Sweden are in a weak position. As, in fact, is the UK.

When it comes to how many cases one critical-care bed is getting. Spain has 8.9 confirmed cases per critical-care bed - the highest across the EU. Germany, again, seems to be in a much stronger position, with currently just 1.3 confirmed cases per critical-care bed.

On the plus side for the UK and the Netherlands, both countries seem at the moment to be doing better than Spain and Italy's trajectory in respect of the numbers of cases and deaths. This may change as numbers rise, of course, due to the relative scarcity of critical-care beds.

Meanwhile, Luxembourg has the highest number of confirmed Covid-19 cases per capita in Europe, yet nevertheless has managed to take in several patients from one of its near-by French regions.

Back to Spain and, while it is difficult to forecast for a variety of reasons, given current available data the country looks to be on an even-worse trajectory than Italy, and may top it as the worst-hit nation in Europe.



And over in Italy, it has been reported that hospitals in the country's southern regions are ill-prepared for any big increase in Covid-19 case numbers, and could collapse under the weight if the crisis in the north is seen in the other half of the country.

### Bye-bye Strasbourg. For now...

The European Parliament is abandoning all trips to Strasbourg until at least September - but *not* for financial reasons.

Mini-plenaries will instead be held in the Brussels seat (above).

Meanwhile, Parliament staff were recently told: "As of today, no leave outside the country of your place of work should take place." On top of this, staff will have to inform their chiefs where, exactly, they're going: "This information is now required in order for a leave request to be processed."

### The lowdown on lockdowns

It seems that most people in Italy, Spain and France support the social distancing 'lockdown' measures being employed in their countries to slow down the spread of the virus.

As it stands, these are the three European countries worst-hit by the pandemic in terms of mortality rates, and polls have shown that citizens are more concerned about the impact of the virus on public health than they are about the economy (are you listening Donald Trump?).

An incredible 90% of those in Italy support strict social distancing measures, with 88% of those in Spain backing government rules. France was just a touch behind with 87%. These are huge numbers in favour.

In the end, lockdowns are primarily to buy time for countries,

and stagger the use of hospital beds. WHO chief **Tedros Adhanom Ghebreyesus** says that "On their own, these measures will not extinguish epidemics."

He suggested six key actions in order to attack the virus: expanding, training and deploying the healthcare workforce; implementing a system to find every suspected case; and increasing the production, capacity and availability of testing.

He also turned the spotlight on facilities to treat and isolate patients; having a clear plan and process to quarantine contacts of a confirmed case; and refocusing the whole of government to suppress and control the coronavirus.

### Time to 'get real'

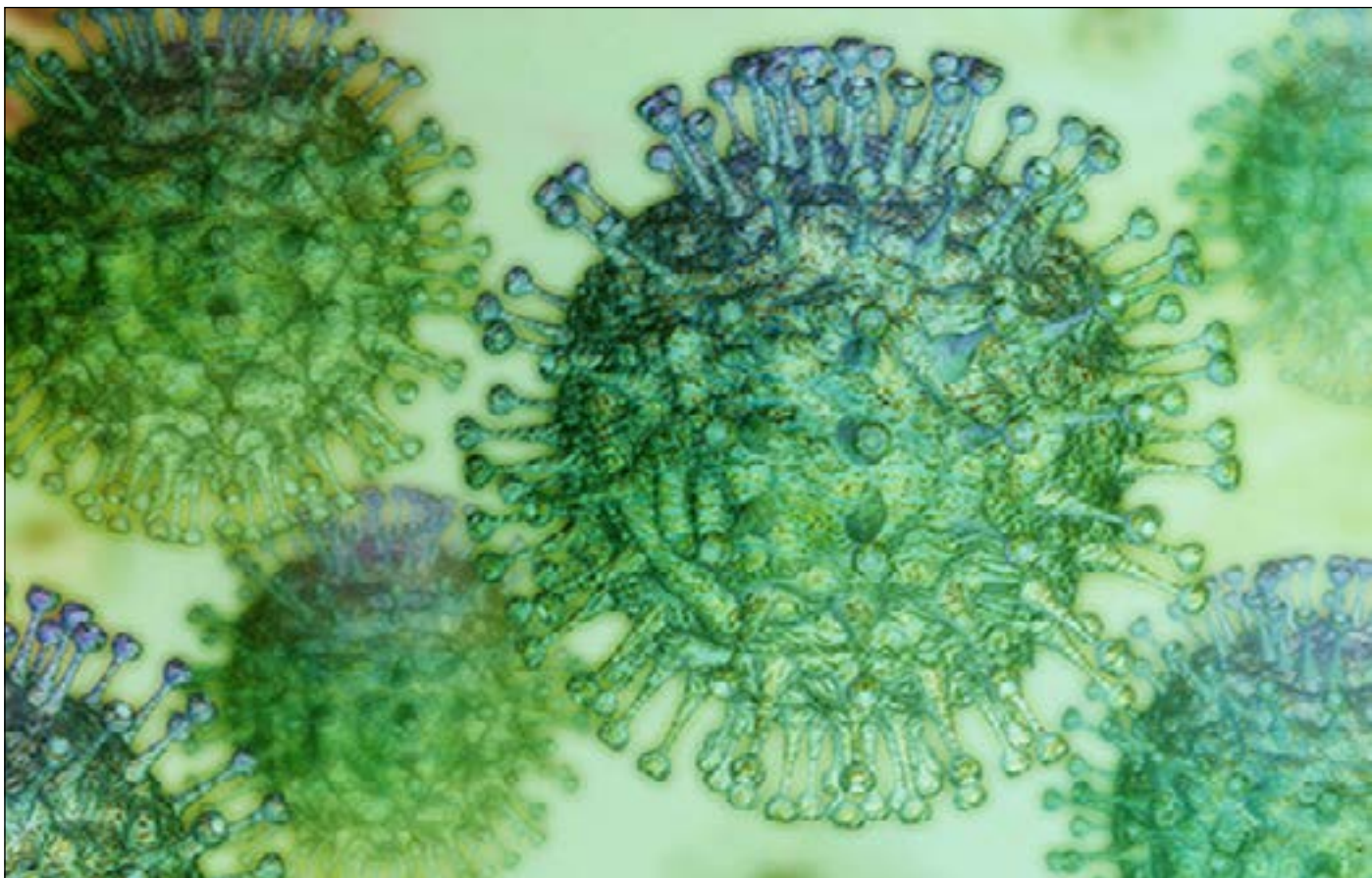
Meanwhile, it seems that the EU's politicians are failing to take decisions based on actual data - where have we heard *that* before?

This is according to **Christian Drosten**, who is a German virologist who developed the coronavirus test and has also given advise to the powers-that-be in Berlin on containment.

Dorset claims that curfews and school closures are driven by politicians' gut instincts and observational impressions. Epidemiologists, meanwhile, are working hard to bring in hard data to aid informed decision-making by Easter.

"We can't keep making the measures more and more stringent without knowing whether this will make any difference at all," Drosten said.

In any case, **Neil Ferguson**, an infectious disease expert from the UK's Imperial College London bluntly stated that: "The long-term exit of this is clearly the hopes of a vaccine."



That's a year away, minimum.

Lest we forget, Britain's Prime Minister **Boris Johnson** took a leap in the dark saying it would take about 12 weeks to turn the tide of the outbreak.

This doesn't gibe well with him also saying that his government would review the current measures in place in the UK in three weeks. He pledged to "relax them if the evidence shows we are able to". He and his politicians might want to actually look at some, then...

One of Johnson's ministers, **Michael Gove**, also recently said that the aim is to "reduce the rate of the infection in order to reduce the pressure on the [National Health Service]". He didn't say much else, unfortunately.

Over in France, an advisory panel report has recommended a minimum of six weeks' social distancing, suggesting that three weeks is not enough.

"We'll only be able to stop confinement when the epidemic curve allows it," said French Health Minister **Olivier Véran**, adding the the current lockdown would most likely be extended.

Of course, in the US, President **Donald Trump** has said he wants normality back in the frame as soon as possible. He suggested that this happening by Easter "would just be a beautiful timeline". A leap of faith if ever there was one, but presumably a boon for Easter egg sales.

## Experts, the media, and the public

Where are this experts when we need them? While opinions on Covid-19 may differ, and angles may vary, there is surely no benefit in having multi-stakeholders drowned out by loud 'noise' coming from ill-informed and often sensational sources.

Governments everywhere are under huge pressure to act, quickly and effectively, and there is an argument that effectively putting 16 million people under quarantine in Italy's northern powerhouse regions is a knee-jerk reaction and a very noisy way of saying "Well, at least we did what we could" further down the line.

In the meantime, every healthcare system in Europe needs support - no matter how good and efficient it is. This has always been the case - the need to reassure a head-scratching and, right now, nervous public with clear messages of how to stay or attempt to stay healthier.

On that topic - the responsibility of a well-informed population - you may not have read this in mainstream media but studies are already emerging from China that not only is the virus hitting the elderly hard, it is also hitting life-long smokers very hard. Yes, those who made arguably not the best lifestyle choice.

As it stands in Europe, everything from test kits to respirators are already in short supply and, while there are - and will continue to be - large queues of people awaiting testing and/or treatment, sensible precautions and actions need to be employed by responsible citizens in order to protect themselves as much as possible.

This is not merely in respect of Covid-19, this is a general healthcare pillar. Perhaps, at least sometimes, those who seek to inform the population via the media should lower the rate of sensationalising health news and up, up, up the advice on living healthy lifestyles?

## Community spirit?

How much of a community is the EU, really? Well, it's a little worried from a public relations point of view that China, Russia and Cuba have been seen to be helping Europe out by sending



protective equipment, ventilators and doctors. An official from France's Elysée Palace reportedly remarked on the topic: "This solidarity issue isn't a gimmick, it is the condition for the survival of the European project in the aftermath."

And a top EU diplomat was heard to say: "We must not lose the propaganda war by suddenly receiving all sorts of things from Cuba, Russia and China."

Internally, and all over the media, the bloc has seen certain countries put a ban on exports of protective gear. One such original Member State, Germany, for instance, is now desperately trying to reverse perceptions, not least with some of its regions now accepting small numbers of patients from Italy and France subject to available beds.

Unfortunately, it's unlikely that large numbers of coronavirus patients across the EU will be treated in another Member State, mainly due to logistics and issues ranging from safely transporting seriously ill patients to, of course, language problems.

Meanwhile, In the eastern EU, the Czech Republic went for radical measures over the virus, with health minister **Adam Vojtěch** saying that: "Medicines that are intended for the Czech market will remain only for Czech citizens and will not be exported to other countries."

Romania also recently banned the export of medicines needed to treat the virus.

On a definitely positive note, however, the EU's Health Commissioner **Stella Kyriakides** (above) has been urging companies across the EU to manufacture equipment for health workers.

"We are calling on all companies, big or small, to join the effort to provide #COVID19 healthcare workers with the support they need to save lives. Spirit of solidarity is now more important than ever," Kyriakides wrote in a Tweet.

## Cooperating in healthcare

It's been interesting to say the least in respect of the rare shows of EU solidarity in these times of Covid-19, self-isolation, business closures, flight cancellations, border shutdowns - and nowhere to have a coffee, tea or a beer except at home.

Despite the fact that countries in the bloc have been doing their own thing for weeks, with varying degrees of success or not, some of it seems to finally be coming together - at least in part - as everyone realises that each and every Member State faces essentially the same challenges from this particularly nasty virus.

While healthcare has always been a priority for citizens at the ballot box, whether at an individual (personalised healthcare) or/ and collective (population based healthcare) level, politicians are very often slow either to realise this or to do much about it once they do catch on.

Hopefully, this will start to change. Perhaps the recently diagnosed **Michel Barnier** can help with that? Turns out he's not so busy with Brexit negotiations at the moment...

EAPM has always argued that there needs to be an enhanced role for the EU to support better cooperation and coordination between nations to deliver better healthcare.

That it has taken such a dire emergency to put the much-guarded Member State competence in the area into perspective is regrettable, and the whole squabbling over HTA is starting to look, well, a bit silly.

### **So, what's the latest?**

Despite best intentions, a lot of important events are going right down the pan, as you may well have noticed, not least the Olympics, of course (a prime example of dithering, if ever there was one - are you listening Wimbledon?).

This state of affairs includes what would have been the latest



meeting due in the long-time-in-coming investment protection agreement between the EU and China.

A Beijing-based summit between Ursula von der Leyen and Chinese Premier **Li Keqiang** in Beijing, planned for the end of March, which has been postponed.

And don't expect such cancellations/postponements to end any time soon. Nor should you expect to suddenly be able to go out to meet your pals. According to French President **Emmanuel Macron**: "We don't know how many waves we're going to have and how the virus is going to behave and how we will absorb it."

As it turns out, the Commission, while putting back the deadlines for most Horizon 2020 grant applications, has thankfully not done so for one specific area. Step forward the Innovative Medicines Initiative calls. If ever that were needed, the time is surely now.

Beyond Paris and Brussels, and out across the EU, Germany's Chancellor **Angela Merkel**, meanwhile (above), at the end of March spoke to the public via TV and appealed for the nation to behave rationally and show solidarity.

The often-called 'leader of the free world' said: "We have to limit the risk that we infect one another as much as we can," and described the situation as "serious and open".

The chancellor made no bones about her disapproval of bulk buying and hoarding, and described such behaviour as useless and selfish, while appealing for solidarity.

She said: "Since German unification, no, since World War II, there has been no greater challenge to our country that depends so much on us acting together in solidarity."

In Belgium, Prime Minister **Sophie Wilmès** should be in charge for a minimum of six months after parliament voted to allow her the time to tackle the Covid-19 crisis. She will need to go back for a second confidence vote once the six months are up.

In the Netherlands, the country's under-the-cosh Medical Care

Minister **Bruno Bruins** suddenly resigned, saying: "Combating the corona crisis is like practicing sport at the highest level. And I have noticed that my body can no longer cope with this at the moment due to over exhaustion."

He had previously collapsed during a debate on the virus and its implications.

Italy, meanwhile, which remains the worst-affected country in the world as it stands, has warned that smokers are much-more likely to develop severe symptoms of the virus. Currently, 22% of Italians over the age of 15 smoke, which is not good news any way you look at it.

Back across in Denmark, the country's Medicines Agency has brought in an emergency procedure for applications to start clinical trials in respect of Covid-19, with the aim of turning assessments around in three days instead of the usual 35.

Meanwhile Bulgaria, as well as other Member States, has noted that a further downside of self-isolating, assuming most people aren't overly happy about it, is the fact that the number of blood donors has dropped.

Sofia's health ministry recently announced that the country's haematological staff will now work weekends and holidays where possible in order to supply the blood needed by healthcare facilities.

Other health supplies across the EU are suffering due to new restrictions on borders, it seems, while in other developments Interpol has been seizing counterfeit face masks, dodgy hand sanitiser and unauthorised antivirals from online sales.

Interpol says that the virus situation "has offered an opportunity for fast cash, as criminals take advantage of the high market demand for personal protection and hygiene products".

On a more general note, a group of organisations representing doctors, hospitals and social security bodies have written to the European Commission requesting a platform to meet on how to



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

respond to public health crises. It won't happen, though, until the current one is out of the way.

In their letter to the Commission, AIM (the International Association of Health Care Mutuals and Health Care Funds), CPME (Standing Committee of European Doctors), ESIP (European Social Insurance Platform) and HOPE (the European Hospital and Healthcare Federation) have called for a review of investments in R&D alongside a "serious discussion about Europe's dependency on single sourcing" in the production and distribution of medicines and medical devices outside the EU.

### What next?

When it comes to a Covid-19 vaccine, don't hold your breath, as it were. MEP and EAPM stalwart **Peter Liese** said in the last few days that there's "no scenario that all the Europeans will be vaccinated" in the next eight-or-so months, even if a vaccine against coronavirus comes to market by then.

Liese puts his immediate faith in finding therapies, and there's a "huge responsibility" for the European Medicines Agency as well as the European medical community to pool data and see which drugs are working, he added.

As for the economy going forward, beleaguered Spain's Prime Minister **Pedro Sánchez** has called for an EU "Marshall Plan" to fight the spread of Covid-19, as well as to rebuild the economy. He said: "We are making an extraordinary fiscal effort, but it is important that it is not only at the national level."

Encouragingly, the Commission has triggered a "general escape clause" in respect of the eurozone's rules on budgetary discipline.

Commission President Ursula von der Leyen said Friday: "This is new and never done before," and called on the bloc's finance ministers to approve the decision quickly.

### GDP and life expectancy

There is no denying that the Covid-19 outbreak has huge fiscal implications; Stock markets have been tumbling around the world, talk of an upcoming recession is everywhere and even computational biologists are getting involved.

One such, **Francois Balloux**, has argued on Twitter that:

"There's no such thing as a choice between managing the pandemic vs. protecting the economy."

He added that there's an "essentially perfect" correlation between GDP per capita and life expectancy.

"If the Covid-19 pandemic leads to a global economy collapse, many more lives will be lost than Covid-19 would ever be able to claim," he wrote.

In these fast-moving and fast-changing times it could be argued that an economic slowdown is not all bad, however. Take the environment - already, air quality is improving and emissions are down. That has a positive impact on health, of course. Good to know when good news is scarce.

### Cash concerns

Clearly, coordinated economic strategies are required to fight the impact of Covid-19. And EU leaders have been discussing this via videoconferencing.

A planned joint declaration just agreed says: "We welcome progress made by the Eurogroup to set up a Pandemic Crisis Support instrument, within the provisions of the ESM Treaty."

Regarding finance ministers: "We invite the Eurogroup to deliver without delay and develop the necessary technical specifications in the coming week. Our response should take into account the exceptional nature of the Covid-19 shock affecting all our countries and we will decide on further steps, as necessary, in light of developments," or thereabouts.

Nine EU leaders, meanwhile, led by Italy's **Giuseppe Conte** with the addition of those of Belgium, France, Greece, Ireland, Luxembourg, Portugal, Slovenia and Spain, want more.

In a letter to European Council President **Charles Michel**, they wrote: "We need to recognise the severity of the situation and the necessity for further action to buttress our economies today, in order to put them in the best condition for a rapid recovery tomorrow."

The nine leaders are effectively calling for what has unofficially been dubbed 'a coronabond'.

They add: "In particular, we need to work on a common debt instrument issued by a European institution to raise funds



on the market on the same basis and to the benefits of all Member States,” emphasising that there’s a “strong” case for such an instrument, given current circumstances and the fact that the EU faces “a symmetric external shock, for which no country bears responsibility, but whose negative consequences are endured by all”.

So that’s a third of Member States on board, then...

Meanwhile, European Commission President **Ursula von der Leyen**, late March said: “Today we are issuing guidelines to help Member States screen foreign direct investment and acquisition of control or influence.”

Von der Leyen bigged-up the importance of protecting key sectors including “health, medical research or strategic infrastructure”.

## Medical devices latest

MedTech Europe has given the thumbs-up to Commission plans to extend the Medical Device Regulation by a year, but it wants a “similar solution” for the In Vitro Device Regulation, due by May 26, 2020.

While MedTech has “welcomed” at least the MDR extension, for the rest, and for the record, it said it wants to focus on “the critical task of keeping diagnostic tests available, despite the challenges the pandemic is creating for their production and distribution”.

A couple of senior MEPs have said they’re in favour of the MDR extension, with EAPM-supporting Peter Liese (above) - the EPP’s health spokesperson - confident of the Parliament’s backing, an would work towards getting this as soon as possible.

**Mairead McGuinness**, meanwhile, who has also worked with EAPM and is vice president of the Parliament, believes: “It’s time to press the pause button,” on implementation of the rules. This

would allow time for things to get back to normal. As it stands, the Commission should get the proposal in front of Parliament and the European Council in the coming days.

## A new normal

Europe’s leaders are apparently already looking beyond the current crisis and will “start to prepare the measures necessary to get back to a normal functioning of our societies and to sustainable growth, drawing all lessons from the crisis”.

“This will require an exit strategy, a comprehensive recovery plan and unprecedented investment,” adds the statement, reports *Politico*.

To continue: “To this end we invite the Commission to start work on a proposal for a Roadmap for recovery accompanied by an Action Plan” by “the members of the European Council”.

Ultimately, this could mean the setting up of “a true European Crisis Management Centre” as “the time has come to put into place a more ambitious and wide-ranging crisis management system within the EU”.

“The urgency is presently on fighting the Coronavirus pandemic and its immediate consequences,” the draft reads. Exactly, and as if they weren’t busy enough, eh? Nevertheless, this would be a welcome measure.

Meanwhile, the draft continues: “We call on the Member States, together with the High Representative and the Commission, to further step up their efforts to ensure that EU citizens stranded in third countries who want to go home can do so.”

## Testing, testing...

To test or not to test? That is the question. And even if you think that testing is the absolute answer, access to it is all over the place at the moment. Europe’s health officials in Europe, and



some citizens are getting grumpy. Since infected people can spread the virus before symptoms show, more and more Europeans want to get tested. But this is proving difficult, to say the least.

**Jean-François Delfraissy**, President of the French Scientific Coronavirus Committee, believes that massive testing is necessary. As it stands, most EU countries are targeting the most severe cases for testing, as resources are scarce.

It has been suggested that a solution could lie with developing antibody tests that can detect whether people have been infected. False negatives are a distinct possibility, yet it could be handy to know down the line how many people were actually infected, even if they didn't have symptoms.

Meanwhile, the WHO is working with labs to find out whether those infected who come out of it at the other end relatively unscathed are then protected against the virus.

**Richard Pebody**, the WHO Europe Team Lead for High Threat Pathogens, says that such knowledge would gift us with the knowledge of the proportion of the population that is symptomatic, and, by extension, what proportion is infected.

The theory is that we could then understand the future course of the epidemic in different populations. "We haven't got it yet, but we're getting very close," Pebody said.

More negatively, some health experts, however, think we've already missed the boat for testing.

"We will not get that disease out of the world anymore," said **Mika Salminen**, who is director of health at the Finnish National Institute for Health and Welfare.

Salminen says he understands people's desire to be tested, but those who can ride out the virus at home won't benefit from it.

"The test is not a cure," he reminds us all.

## Back to the conference

While it was originally scheduled to be held 'live' in the Belgian capital of Brussels, it was reworked due to the Covid-19 crisis so the event could, nevertheless, take place online.

A swathe of stakeholders and experts came together for the key 'gathering', which was entitled "*Defining the healthcare ecosystem to determine value*". It was EAPM's 8th annual conference and, this year, was held under the auspices of the Croatia EU Presidency.

Those tuning into the lively and interactive sessions represented the multi stakeholder nature that has always characterised the Alliance since its formation - for example patients, scientists, clinicians, researchers, policy makers, national representatives, journalists and more.

One of the key aspects surrounding the invitation of patient speakers was to further our consistent goal of keeping the person in personalised medicine, as well as to ensure that the outcome of each session was inclusive, and represented shared decision making.

Said Executive Director **Denis Horgan** (above): "EAPM would like to thank all of our speakers, not least those doctors and clinicians who took time out from busy hospital duties to speak during relevant sessions. How do they do it? We are all in awe..."

Each session was as interactive as possible and saw panelists asked a key question at the start. This was followed by a poll of 'attendees' later.

For example - one question was 'How should the EU support Member States in tackling Covid-19?'

The options were 'financially', 're-allocation of medical requirement', 'setting and ensuring guidelines are followed', 're-allocation of medical staff', and 'ensuring essential medicines and diagnostics are developed.'

*Spoiler alert: the latter came out on top with 43%.*





Meanwhile during the conference, former DG SANTE official (he's still an advisor) **Antoni Montserrat** (pictured) found a moment to point out that some countries screen infants for a mere two congenital diseases, while others look for up to 42.

A regular at EAPM events, Antoni called for a common European framework on the screening of newborns.

So many important things are happening in Europe and beyond at the moment that, other than the above, we will not give too much detail of the event here. But rest assured that a report will follow in the near future...

## Our take on the news

[EAPM's response to Consultation on the Commission's Beating Cancer Plan](#)

[Worst-hit EU countries back 'lockdowns', while conference experts want more diagnostics](#)

[Experts to gather online at #EAPM healthcare conference](#)

[Co-operating in healthcare: Bad news can sometimes mean a little good news](#)

[Difficult to keep up, but here's the \(sort of\) latest in EU healthcare](#)

[Member states and Commission ramp up #Coronavirus measures](#)

[Songs in the key of life: Time to sing a single health-care tune](#)

[No substitute for evidence-based information](#)

[Tackling #Cancer is not just playing to the gallery](#)



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## 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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