



European Alliance for Personalised Medicine

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An extra day in February - plenty to do!

Greetings all, and welcome to the latest newsletter. Given that 2020 is a leap year, there will be an extra day this month - which is probably just as well given how busy things are!

As you read this, Brexit has finally happened (apart from the small matter of a sure-to-be-rushed agreement on the future relationship to be thrashed out), a new SARS-like virus has emerged from China, and **World Cancer Day** is upcoming.

In the case of the latter, which is on 4 February, we have some info here for you on cancer across Europe, just as the European Commission gets stuck into its Beating Cancer Plan.

It's certainly going to be a busy February onwards for all connected with the Alliance. For several years, now, EAPM has been in the vanguard of driving forward the concept of personalised medicine in Europe and beyond, with a special focus on bringing innovation into the healthcare arena, and this will not change.

With its broad base of stakeholders, drawn from industry, academia, science, research, the healthcare professions, patient groups, policymakers and more, the Alliance brings together key motivated and expert personnel from a wide range of EU Member States.

Now in its eighth year, EAPM has worked tirelessly to achieve the goal of 'the right treatment for the right patient at the right time' to help create a healthier Europe for its hundreds of millions of citizens across the Member States.

During its ongoing SMART Outreach campaign (SMART stands for Smaller Member states And Regions Together), EAPM has had considerable engagement with EU presidencies, individual Member States and the regions within them.

Continuing the theme, coming up this year we have:

- The organisation of three Presidency conferences - see later in this newsletter for more details
- Engagement in four EU projects, namely Pioneer, HARMONY, Digital Health Europe, and Promise
- Biomarker testing activity to promote its uptake into healthcare systems
- A roundtable series on Future-proofing the policy area for personalised healthcare

In the EAPM pipeline:

- **15 March: 5th International Forum on Personalised Medicine, Warsaw**
 - **24 March: EAPM Croatia Presidency Conference, Brussels**
 - **11-14 June: EHA congress, Frankfurt**
 - **30 June: EAPM Presidency Bridging Conference, Brussels**
 - **18-22 September: ESMO Congress, Madrid**
 - **17-18 November: EAPM Germany Presidency Conference, Brussels**
- An ESMO roundtable series
 - The GOAL initiative, which stands for Genomics Over A Lifetime, and which will be rolled out to Member States
 - Policy engagement on the EU framework for the Cancer Plan and AI/Digital Health
 - The MEGA+ initiative, to share all forms of relevant medical data, not only genomes
 - The Orphan Regulation in terms of personalised healthcare
 - And, of course, our constant emphasis on improving access for patients to the best treatments available

More on cancer across the EU

The Swedish Institute of Health Economics recently released its latest and much-respected *Comparator Report on Cancer in Europe*. The new edition shows that cancer diagnoses are increasing, alongside cancer deaths. We've also got a growing population which is living longer.

The latter of course affects the former, because while cancer mortality increased by 20% from 1995-2018, taking into account



population and ageing means that figure “would have decreased in almost all countries”. Meanwhile, cancer-related deaths among those below age 65 years are decreasing.

On top of this, survival after five years has increased for most key cancers, with the indirect cost of lost working years due to early death falling from €77 billion to €70 billion in Europe in that time period.

Also cash-wise, spending on cancer medicines is going through the roof, with total expenditure in Europe almost doubling between 2008-2018 to €32 billion. However, citizens don't need to spend as much time in hospital, with a shift to outpatient services saving money.

Unfortunately, the unequal access between rich and poor EU countries to medicines has hardly changed, with groundbreaking immunotherapy a new area of major disparities.

More than one of every four deaths (26%) in Europe is due to cancer. This makes cancer the second leading cause of death behind cardiovascular diseases.

Meanwhile, the number of newly diagnosed cancer cases is on the up. In fact, cancer incidence increased by some 50% from 2.1 million to 3.1 million cases between 1995-2018 in Europe.

According to the report, a strong driver of the increase is ageing, with projections suggesting that the expected further population ageing (plus some growth) will add 775,000 cases in incidence until 2040 without further improvements in cancer care and prevention.

Speaking of prevention - between 40-45% of all cancer cases are thought to be preventable. The report therefore calls for a stronger focus on primary prevention and screening with,

meanwhile, tobacco control cited as the single most important policy measure necessary.

Cancer research, the report says, has been fundamental to achieving improvements in survival, by leading to advances in screening, diagnostics, and medical treatment. Research has also increased knowledge in the battle against the various cancers.

The report notes that the latest development is activating the body's own immune system to attack a tumour, with immunotherapy now a cornerstone in multiple solid malignancies, and more than 2,000 clinical trials ongoing.

The authors believe that “cancer research in Europe might receive greater attention and funding from public sources in the coming years by the new European Commission”, while adding that there will be stronger focus on the cost-effectiveness of new cancer medicines in the future.

The upcoming World Cancer Day, which will see a dedicated event in the European Parliament under the banner of *Europe's Beating Cancer Plan - Let's Strive For More*.

Meanwhile, cancer researchers have warned that EU laws make conducting patient-centered research difficult. The rules are geared towards developers who have a commercial interest and “overshoot their initial objectives”.

Even when researchers stick to the laws, a slightly different interpretation by a Member State regulator can cause big issues, in the form of hurdles that “may drive the attention away from what really matters: patient safety and benefit”.

Finally, on cancer-related matters this month, IMI has weighed-in with a call for new proposals on cancer, as well as tuberculosis, vaccines, psoriatic arthritis and protein-based medicines.



The Innovative Medicines Initiative will contribute €133 million to the related projects, with industry and others due to add €140 million as in-kind contributions.

EU sets pace on AI regs

The EU wants to be first out of the starting blocks when it comes to passing laws for artificial intelligence, with the first step a white paper to be published post-19 February, the day that Commission Executive Vice-President **Margrethe Vestager** (above) will present a draft to her colleagues.

The draft flags up rules seeking to identify problems before they occur, and to shape the way businesses and authorities behave when they develop or apply AI.

Meanwhile, in spring, the Commission's high-level external group will release an update to its checklist for companies on whether the way they use AI can be considered "trustworthy."

Artificial intelligence, or AI, represents systems that display intelligent behaviour by analysing their environment and then taking actions to achieve specific goals. This is done with some degree of autonomy.

Examples around us include using a virtual assistant to organise things, self-driving vehicles, and suggestions from a phone in respect of maybe a restaurant you might enjoy, a song you might like, plus voice and face recognition and so on.

Advanced robots can use AI, as can 'internet of things' apps, drones and, of course, AI can be used in healthcare.

The field is already a large one and is predicted to grow phenomenally quickly in the next decade, and it is not exaggerating to say that AI is going to change our world.

HTA and drug pricing latest

Croatia's Health Minister **Milan Kujundžić** has responded to criticism from MEPs that his country's EU Presidency doesn't have plans for moving the HTA file forward.

The minister has been reported as saying that his government is aware of the difficulties, which is "why we will encourage the dialogue on this file, and we intend to continue to discuss key aspects of the proposal in the Council preparatory bodies".

Kujundžić says several meetings and stresses "that we are committed to work very hard toward finding an acceptable solution in the Council".

On the price of medicines, Minister Kujundžić has said that the EU should come together to negotiate lower prices, especially for expensive and innovative cancer treatments. He said: "We as a whole can speak to industry and get as low prices as possible for treatment," adding that the EU should "stand together and find consensus" in the future on medicines prices.

Surveying the landscape

If you haven't seen it already, EAPM has published its latest multi-stakeholder survey, undertaken over three months in 2019.

The survey explores the potential, and the challenges that stand in the way of mobilising health data for wider health benefits, and also takes in the existence and potential of AI.

Its title is '*Cooperating on data – the missing element in bringing real innovation to Europe's healthcare systems*'.

The full survey can be found [here](#)



Thanks a million, Germany!

EU big-hitters Germany have signed up for the initiative on One Million Genomes (which, as you will recall, began life championed by the Alliance as MEGA - now MEGA+).

Europe's economic powerhouse has joined 20 other EU Member States plus Norway, in the voluntary commitment to link EU-wide datasets containing genomic health data.

The idea is to give access to researchers to one million sequenced genomes by 2022, focused on cancer, rare diseases and more.

Of course, genomic sequencing already takes place in many EU countries, but overall the situation is fragmented, with more disconnect than connect. The project aims to rectify this situation for the ultimate benefit of Europe's patients, now and into the future.

The European Commission says: "Linking these datasets and making them accessible in a secure way will create a greater cohort of genomic data, which will facilitate the research on innovative solutions for precision medicine and public health."

The initiative was officially launched at the Commission's Digital Day in April 2018, and research Commissioner **Mariya Gabriel (above)** said: "Genomic data management and interoperability is ever more important in healthcare, but we still need to establish standard methods and tools."

Commissioner Gabriel was involved at the very beginning in her then role at the EU Executive.

Meanwhile, **Thierry Breton**, who is the EU Internal Market Commissioner, said that Germany joining the initiative would "further enhance the collective benefit of this cooperation and its potential to bring the best possible treatment and diagnostics to the European citizens".

Elsewhere, Novo Nordisk's Foundation, representing the

Danish pharmaceutical company, will put one billion Danish krone (which is in the region of €134,000) into the development of a National Genome Centre in the country, the health ministry has announced.

This will diagnose around 60,000 Danes more accurately within the next five years, with the ministry adding that it will store and use Danish patients' genetic data "with the highest level of security".

Patients must give written consent in respect of having their data used in the event of a comprehensive genetic analysis by the centre, and also will be the ones to decide whether their genetic information can be used for research.

Johnson to tackle the UK's NHS

Britain's Prime Minister **Boris Johnson** is planning the biggest shake-up of the UK's health system in decades in a bid to show that his Conservative party can be trusted to look after it

Johnson has stated that the NHS will be the number one priority for his government after Brexit. His Health Secretary **Matt Hancock** meanwhile said that "We need a long-term plan for the whole of health and social care which is bold, and confident and ambitious"

"And when we look back in 2030 to this moment, this once in a generation opportunity, where a political commitment and the financial resources are in perfect alignment with the overwhelming public mandate, I want us to be able to say 'yes, we got it right.'"

It's a tough ask. According to recent data, the National Health Service is performing at its worst-ever levels, missing key waiting-time targets, for example, in cancer treatment.

Johnson has promised to spend £33.9 billion on the NHS by 2023-24. There will also be a new NHS Artificial Intelligence Lab, at a cost of £250 million, which will promote the use of data-driven technology in healthcare.



MEPs to watch in 2020

Politico has published its MEPs to watch in 2020.

The notables include **Pascal Canfin**, chair of the Environment, Public Health and Food Safety (ENVI) Committee, and **Petra De Sutter**, who chairs the Internal Market and Consumer Protection (IMCO) Committee, and will be instrumental in coordinating the work between **Thierry Breton**, the Commission's internal market man, and digi-chief **Margrethe Vestager**.

Tiemo Wölken, above, who is the lead rapporteur in the ENVI Committee on health technology assessment, also gets a nod.

EMA wins case v PTC Therapeutics

The Luxembourg-based Court of Justice of the EU recently ruled in favour of the European Medicines Agency's decision to release PTC Therapeutics' clinical study reports to another pharma company.

The court' wrote that: "A mere unsubstantiated claim relating to a general risk of misuse cannot lead to those data being regarded as falling within the scope of the exception."

If a company finds a method of testing that shows "novelty in the models, assays or methodologies," the report might be kept confidential, the judges decided. But PTC Therapeutics had not demonstrated this, they concluded.

A very happy EMA said that the court upheld "the widest possible public access to documents held by Union institutions, bodies, offices and agencies" and that "the judges confirmed that transparency must be the rule and exceptions must be applied and construed narrowly".

Big Data and medicines latest

Representatives of the European Medicines Agency and the Heads of Medicines Agencies', among others operating as a task force, have put forward recommendations on how EU medicines regulators could use big data to approve medicines.

The task force says that the EU should create its own platform to access and analyse healthcare data from across the bloc, while also promoting the use of electronic health records, registries, genomics data and secure data availability across Member states.

Meanwhile, the Commission will - by the end of this year - produce a data strategy to include health data, according to European Commissioner for Health Stella Kyriakides.

The commissioner was speaking to MEPs in Strasbourg, who were examining the digitalisation of healthcare and highlighted the need to protect citizens' personal health data, as well as the importance of interoperability of systems.

Triple-presidency conferences: Forward as one into 2020

EAPM will be hosting three EU Presidency-themed conferences during 2020.

These will be, firstly, during the **Croatia Presidency**, followed by a bridging conference between the **Croatia and Germany** presidencies, and a final event while **Germany** is at the helm.

The Croatia presidency conference will take place in Brussels on **24 March**.

Not only do these conferences reflect the nature of the relative presidency policies in the healthcare arena, but also act as major



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

events during what will be the first full year of the two new legislative bodies - the Parliament and the Commission.

Croatia outlined four key priorities for its turn as EU President - a role it takes over as you read this.

While healthcare is not mentioned specifically, several issues will have an impact in that arena.

Croatian Prime Minister **Andrej Plenkovic** highlighted "a Europe that connects", and said that Croatia's four prioritised goals are a Europe that is growing and developing, a Europe that connects economically, energy-wise and infrastructure-wise, a Europe that protects and a Europe that is globally influential.

The prime minister stressed that a "Europe that connects" is needed and that it is therefore necessary to further develop transport, energy, and digital infrastructure.

"We will stand for a Europe that protects its citizens while respecting and protecting the rule of law," he said.

The Croatia presidency slogan is: "A strong Europe in a challenging world".

Bridging conference - Croatia and Germany Presidencies Maintaining public trust in use of Big Data for health science

Brussels
30 June 2020

Personalised healthcare brings us the opportunity to put citizens at the heart of decision making, including talking openly about what happens to data, who is using it, and what level of control people can, or cannot, expect.

We can apply ethical rigour every time data is used, shared or transferred to safeguard individual privacy, and ensure data is secure and provide guarantees that data will not be compromised by breaches that reveal personal information.

We can ensure that the public has trust in data science,

especially for large scale initiatives that enable significant breakthroughs in our understanding of human disease.

We can underpin public trust by advocating the value of health-data research to society and promote the need for robust, trustworthy and ethical approaches to deliver new health advances for our citizens.

Generally speaking, one of the great challenges to reduce both late-stage incidence and mortality is early diagnosis. But it has to be reliable. In this conference that bridges two Presidencies of the EU (Croatia and Germany), the emphasis is on public trust in health data and its uses.

One of the great opportunities to reduce both late stage incidence and mortality is early diagnosis. But it has to be reliable, of course.

German Presidency conference: Building a decentralised, data-rich biomarker space to speed better cancer care

Brussels
17-18 November 2020

Looking ahead to the next two decades, there will be a massive increase in cases of cancer in Europe.

Regulators, industry and healthcare professionals really need to step up to this new reality, and this also applies to citizens, who have a certain degree of responsibility for their own healthcare.

Lifestyle changes will be paramount, and could amount in many cases to the best form of prevention.

Stopping smoking, cutting down on alcohol, getting off the sofa and exercising, eating the right food - it all helps. Adhering to medicine regimes isn't a bad plan either...

However, biomarkers have a job to do, too, in modern personalised medicine. We need more of these that are relevant to treatment.



Certainly, we're churning out lots of data, but as more clinical trials and large scale epidemiological studies take place, new technologies such as blockchain will be urgently needed to handle the data.

And this has to be done without infringing regulations surrounding data protection (namely the General Data Protection Regulation (GDPR)).

Unfortunately, the barriers in respect of data sharing mean that risks related to data security and privacy can have a paralysing effect on progress.

One of the goals of EAPM events is to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process, while also aiming to showcase developments and new ideas.

Coronavirus reaches Germany

Regional health officials in Bavaria have announced that the first case of coronavirus has been identified in Germany.

According to the southern state's health ministry a man from the Starnberg area had been infected by the virus. He is, however, in "good condition."

There is a current global high alert for have been on high alert for the virus, which first broke out in the Chinese city of Wuhan just before the Chinese Lunar New year and can be fatal.

In the news from EAPM

['Patchwork' rules won't mend those genes](#)

[Update: Thanks a million, Germany!](#)



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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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