European Alliance for Personalised Medicine

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Marching into March with EAPM conference

Welcome to the latest newsletter from EAPM. As we enter March, the European Union is ready to start negotiations with the UK on trade and other arrangements in the wake of the Withdrawal Agreement - a very tight process that is scheduled to run until 31 December. Busy times ahead!

There are also busy times ahead for the Alliance, its members, associates and healthcare colleagues. Not least as our annual conference is looming large on the horizon.

So, here's just a reminder that registration is open for EAPM's **Annual Presidency Conference on 24 March in Brussels** and you can be sure to join us by heading to our website.

The conference, to be held under the auspices of the Croatia Presidency of the EU, will have as its over-arching goals ensuring that innovation makes its way into healthcare and future proofing Europe's healthcare systems.

This year, the conference is entitled '***Defining the healthcare ecosystem to determine value***'.

The event is timely to say the least because what we certainly need to do very quickly is re-align priorities to evaluate the needs of patients, healthcare professionals and health systems across the EU to facilitate improved and safer therapies, while enhancing collaboration between EU regulatory and payer groups.

At the event, our multi-stakeholder speakers and delegates will aim to address many questions.

Among the speakers expected to take part are ENVI Committee Chair and MEP **Pascal Canfin**, fellow MEP **Tiemo Wölken**, **Benedikt Westphalen**, Koordinator Molekulare Onkologie, Comprehensive Cancer Centre, and **Benjamin Horbach**, Health Systems Strategy Leader - Personalised Healthcare(PHC), at pharmaceutical giants Roche.

Tuula Helander, who is Senior Advisor, Ministry of Social Affairs and Health, Permanent Secretary's Cabinet; and Secretary General at the Finnish Cancer Institute, is also expected.

This session will be followed by those on *Biomarkers and Molecular Diagnostics, Prostate Cancer - Prevention and Early Diagnosis, the Orphan Regulation and Personalised Medicine, Realising the Potential of Data:The Million European Genome Declaration and the EU Digital Health Strategy*, and a closing session on *Bridging Forward*.

Among the speakers and chairs expected for these sessions are **Mark Lawler**, Chair in Translational Cancer Genomics Centre for Cancer Research and CellBiology, at Queen's University Belfast, **Falk Ehmann**, Science and Innovation Support, at the European Medicines Agency, **Paul Naish**, Director, Oncology Advocacy and GovernmentAffairs, at AstraZeneca and **Beata Jagielska**, of the Polish Alliance for Personalised Medicine.

They will be joined on stage by, among others, MEPs **Miriam Dalli** and **Monika Benova**. The European Commission will be represented during the day, as will Europa Uomo, the KU Leuven and the University of Barcelona.

A hot topic right now is the review of the EU's Orphan Regulation of late 1999. This came into being chiefly to ensure that patients suffering from rare conditions have the same quality of treatment as any other patient in the EU.

Ivana Cattaneo, Public Affairs Director Europe, Novartis will be leading discussions, here, which will also feature (among others) representatives from the European Commission, the Parliament, and EURORDIS.

In the EAPM pipeline:

- **15 March: 5th International Forum on Personalised Medicine, Warsaw**
- **24 March: EAPM Croatia Presidency Conference, Brussels**
- **15-17 April: eHealth week, Rovinj, Croatia**
- **29-30 April: Informal meeting of EU health ministers, Zagreb**
- **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**

And when it comes to the Declaration of Cooperation "*Towards access to at least 1 million sequenced genomes in the European Union by 2022*", signed in Brussels in April 2018, EAPM has now put in place MEGA+, which seeks to utilise all relevant medicaldata, not only genomes.

Clearly, coordination and support is needed to develop cross-border solutions for sharing expertise and linking genomic and other health data. There needs to be a shared vocabulary and data-set standards EU-wide.

The day-long conference will feature plenty of question and answer session to encourage full participation of those present and, as part of the event, there will be a cocktail, speeches and, as mentioned, dinner in the European Parliament, featuring keynote speeches from MEPs **Sirpa Pietikainen** and **Monica Semedo**.

Among those attending during that evening will be **Frederique Penault-Llorca**, Director, Centre de Lutte Contre le Cancer de Clermont-Ferrand, **Giulia Veronesi**, Chief of the Robotic Surgery Unit at the Humanitas Hospital in Milan, **Stefan Gijssels**, Executive Director, Digestive Cancers Europe, and **Boris Brkljacic**, President of the European Society of Radiology.

Speakers are, of course, subject to change but we certainly hope you can join us!

'Lottery' for children's drug under fire

European Health Commissioner **Stella Kyriakides** (above) has gone on record as criticising what has been described as a lottery system designed to give some children with a rare disease access to the world's most-expensive medicine.

The Commissioner replied to a written question from **Emmanuel Maure**, MEP, on the topic which has caused shock in many places, saying: "Making the medicine available free of charge to a limited number of children, is not a viable model."

The medicine in question comes from Novartis, which last year said it would make up to 100 doses of its spinal muscular atrophy therapy Zolgensma available for free to children under the age of two, by lottery. Its normal price is an eye-watering €1.9 million.

Health ministers from France, Belgium, Austria, the Netherlands, Luxembourg and Ireland have weighed in to criticise the scheme, and have been joined by some patient groups.

For its part, Novartis has reacted by saying it's working to "evolve the programme".

In Kyriakides' reply, she said that patients' health cannot become dependent on a game of chance. "Instead", she said, "it is for companies to develop a sustainable model that meets societal needs."

Meanwhile, the health commissioner has been busy trying to reassure the **European CanCer Organisation (ECCO**) and MEPs on cancer funding. Kyriakides acknowledged concerns, but said that there will be funding because cancer is a European Commission priority.

First, she said, there will be support for the Cancer Mission through Horizon Europe, "which will feed the cancer plan", while there will also be funding through the European Social Fund and future digital funds:

The Commissioner conceded: "I cannot tell you exactly how much these will be", but said she is "confident" cash will be available to deliver on the strategy.

Staying with cancer drugs, these are currently taking longer to get to patients in the UK's National Health Service (NHS) while, in the case some cancers - including of the brain and uterus - no new medicines are being licensed.

A paper, published in *Drug Discovery Today*, found that the average time for a medicine to move from patent priority date to being actually available on the NHS increased from 12.8 years between 2000-2008 to 14 years for those approved in 2009-2016.

On top of this, from 2000-2016, no new cancer drugs were licensed by the European Medicines Agency for oesophageal, brain, bladder, and uterine cancer.

The report stated: "There was evidence that the most innovative drugs were not being prioritised for EMA licensing and NICE approval."

Commission embraces digital age

We've mentioned our conference (of course) and obviously up for discussion at the event will be the European Commission's recently unveiled digital vision.

Obviously, one of the relatively recent new tools we have available now is digital healthcare and, fortunately, the new Commission seems to have already grasped the significance of personalised medicine and healthcare now and going forward, as it wrote in its ***European Strategy for Data***.

"Data will reshape the way we produce, consume and live. Benefits will be felt in every single aspect of our lives, ranging from more conscious energy consumption and product, material and food traceability, to healthier lives and better healthcare.

"Personalised medicine will better respond to the patients' needs by enabling doctors to take data-enabled decisions. This will make it possible to tailor the right therapeutic strategy to the needs of the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."

It goes on to explain that it is committed to develop sector-specific legislative or non-legislative measures for the European health data space, complementing the horizontal framework of the common data space.

It will take measures to strengthen citizens' access to health data and portability of these data and tackle barriers to cross-border provision of digital health services and products. It will facilitate the establishment, in accordance with Article 40 of the GDPR, of a Code of Conduct for processing of personal data in health sector.

These actions, it says, will build upon an ongoing mapping of the use of personal health data in Member States and the results of the Joint Action in the context of the Health programme 2020-2023.

EHRS

Heading into the near future, the Commission says it will deploy the data infrastructures, tools and computing capacity for the European health data space, more specifically support the development of national electronic health records (EHRs) and interoperability of health data through the application of the Electronic Health Record Exchange Format.

It aims to scale up cross-border exchange of health data; link and use, through secure, federated repositories, specific kinds of health information, such as EHRs, genomic information and digital health images, in compliance with the GDPR.

It will enable the exchange of electronic patient summaries and ePrescriptions between 22 Member States participating in the eHealth Digital Service Infrastructure (eHDSI) by 2022; start cross-border electronic exchanges through eHDSI of medical images, laboratory results and discharge reports and enhance the virtual consultation model and registries of European Reference Networks.

Meanwhile, it will support big data projects promoted by the network of regulators.

These actions, it says, will support prevention, diagnosis and treatment (in particular for cancer, rare diseases and common and complex diseases), research and innovation, policy-making and regulatory activities of Member States in the area of public health.

Empowerment through data

The Commission states that citizens should be empowered to make better decisions based on insights gleaned from non-personal data. And that data should be available to all – whether public or private, big or small, start-up or giant.

This will help society to get the most out of innovation and competition and ensure that everyone benefits from a digital dividend. This digital Europe should reflect the best of Europe - open, fair, diverse, democratic, and confident.

Ultimately, Europe aims to capture the benefits of better use of data, including greater productivity and competitive markets, but also improvements in health and well-being, environment, transparent governance and convenient public services.

A senior commission official recently went on record with *Politico* as saying digital "is a priority for us", adding "Let's hope it's also a priority for the Member States".

Eyeing AI

Of course, artificial intelligence is a key part of the new and fast-moving digital age and the EU Executive has said it wants high-risk AI technology to undergo rigorous testing prior to being used or sold within the internal market.

"So-called high-risk AI - this is AI that potentially interferes with people's rights - have to be tested and certified before they reach our single market," said European Commission President **Ursula von der Leyen**.

The EU's "*White Paper on Artificial Intelligence*" talks about introducing "conformity assessments" for those AI systems that pose significant risks in areas that include healthcare.

The White Paper also suggests that some AI systems may have to be reprogrammed or 'retrained' before going to market.

Here's a quote from the Paper on the issue: "In case the conformity assessment shows that an AI system does not meet the requirements for example relating to the data used to train it, the identified shortcomings will need to be remedied, for instance by re-training the system in the EU in such a way as to ensure that all applicable requirements are met."

German Presidency focus on meds shortages

Germany, during its EU presidency which starts on 1 July, will put some of its focus on medicines shortages, says **Thomas Müller**, the head of its health ministry's medicines office.

Germany is looking at a "bundle of measures" to tackle shortages, which could necessitate bringing the baby back to Europe. At a recent German Medicines Manufacturers' Association (BAH) meeting in Berlin, Müller pointedly pointed to the fact that most pharmaceutical production has shifted to countries such as China, India, Turkey and South Africa.

Parliament in Berlin seems to support the view that "measures to be taken". for example, by creating a framework that makes it worthwhile to bring production back to Europe again.

Müller however added Europe shouldn't get "hopes up too

high" but focus on getting the process started. "We move in a market economy" that's "highly regulated," especially at the national level, he said, on the topic of medicines supply.

HTA and the French connection

It seems that France is objecting to the Commission's plane on EU-wide HTA cooperation at least in part because it lacks confidence in health technology assessment bodies in EU Member States. Ouch!

Health Minister **Agnès Buzyn** said that concerns in Paris are not only based on "technical reasons" related to the procedure, "but also for very philosophical reasons, which are transparency".

As we all know, the HTA proposal is currently floating about in Council, because a blocking minority is against the requirement for Member States to use joint clinical assessment in their national HTA processes.

France and Germany are the big hitters objecting, but they are not alone.

Buzyn, meanwhile, gave the opinion that spreading HTA projects around the EU "would deny the complexity of this work and would require, at minimum, common evaluation procedures, which is not the case (at the moment)".

The minister added that, with Germany and the UK, there are "few" countries with HTA capacity equivalent to France.

Sticking the proverbial boot in she added that "in some countries, it is an office of four people in a ministry, even some [outside] experts".

Coronavirus in Europe

With the news of lockdowns in parts of Italy doe to the spread of the so-called Coronavirus, staff at the European Parliament were told to stay home if they've been to one of the infected areas of Italy within a certain timescale, as well as China, Singapore or South Korea.

Meanwhile, French children who spent the recent school break in Italy's Lombardy and Veneto regions, on top of any coming back from China, Hong Kong, Macao, Singapore and South Korea, have been asked to stay at home for 14 days.

As matters continue develop, a group of EU Member States, including Spain, Greece and Romania, in which at the time of writing this newsletter no cases of the virus have yet been reported, are working on showing readiness and avoiding panic.

For example, Spanish Health Minister **Salvador Illa Roca** has said people should trust the country's healthcare system and its professionals.

Future-proofing healthcare - EAPM style

Regarding future-proofing of healthcare, as well as its conference EAPM will host a **dinner in the European Parliament** this month on the topic, far ranging as it is.

The potential of personalised healthcare has been increasingly recognised over the last decade. The scope is almost unlimited for exploiting new understanding of disease epidemiology, precision medicine and pharmacogenomics, empowered by technologies such as genomics, single-cell sequencing, microbiome analysis and transcriptomics, as well as bioinformatics and digital innovations.

But for all these possibilities, unfortunately personal healthcare

has not yet delivered the benefits that it could. Among the many factors influencing personalised healthcare implementation, one of the most critical is the readiness of healthcare systems to respond to the opportunities offered.

Personalised care is a disruptive concept that challenges – and often runs into resistance from - many rigid and traditional patterns of thinking about health. In consequence, an approach to healthcare that is fit for the 21st century has only partially been exploited because of practices, presumptions and even prejudices that date from before the millennium.

Now, at the start of the 2020s, and with complex changes underway in European society and governance, the time is right to review how change can be leveraged to develop a policy framework that will permit maximisation of the potential of personalised healthcare.

The new era that is opening in Europe, with a new Commission, a freshly-elected Parliament, and a growing conviction among Europe's policymakers that people must be at the centre of any successful and sustainable strategy, provides the context.

The political guidelines issued previously by now-President of the European Commission Ursula von der Leyen made clear her ambition for a Europe that 'must lead the transition to a healthy planet and a new digital world'.

The same degree of ambition was evident in the message from the now-EU Health Commissioner Stella Kyriakides in her confirmatory hearing before the European Parliament, when she dais: "European citizens expect the peace of mind that comes with access to healthcare… and protection against epidemics and diseases."

She added: "We have some of the world's…most affordable, accessible and high-quality health systems to deliver on these expectations."

Clearly, now is the time for action.

Coming up...

EAPM's March conference is the first of a series of three, to tie-in with the Croatia and German Presidencies this year. The other two are:

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 **all EAPM events** (above) 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 showcasing developments and new ideas.

In the news

A European strategy for data in healthcare in personalised healthcare era

Conferences, cancer, and clinical trial info (or lack of it)

The fight against cancer is ongoing: #WorldCancerDay and the EU's broader health-care issues

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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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