European Alliance for Personalised Medicine

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End-of-year EAPM push as 2019 draws to a close

Greetings all, and welcome to our final newsletter of 2019. Which, of course, neatly coincides with our **3rd Annual Congress** in Brussels on 3-4 December.

Hopefully, you will have already decided to join us but, if not, EAPM will produce a report after the event.

Just ahead of this year's Congress proper, the Alliance will host a pre-meeting on the subject of biomarkers and will cover such important issues as their role in the diagnosis of cancer, testing for biomarkers in relation to patient access and potential availability of therapies, plus reliability and accuracy.

Also up for discussion will be the current limitations of biomarkers, the use of centralised databases, and advice that is, or should be, given to patients prior to biomarker testing.

These topics will be placed against a background of expected developments in the field of molecular diagnostics over the next five years years.

The theme of this year's Congress, held under the auspices of the Finnish Presidency, is "***Forward together with innovation: The importance of policy making in the era of personalised medicine***."

As ever, Congress will showcase different objectives which both the public and private sector can support, with a view to allowing the EU to present a common objective. It will take place in a focused format to allow concrete issues to be tackled and to have a dialogue with our policymakers.

Personalised medicine is becoming more-and-more mainstream, but we've still a long way to go. So the opening session on Day One of the event will cover facilitating an environment for delivery of better healthcare for the EU and Member States.

This will be followed by sessions on Big Data and healthcare, public health, translational research and bringing innovation into healthcare systems.

Day Two should be full and productive with sessions on the current hot topic of the Orphan regulation, evidence frameworks, plus value-based outcomes and biomarkers.

There will be much, more besides, and a brilliant opportunity to network before we take our messages back to Europe's policymakers.

In the EAPM pipeline:

- **15 March: 5th International Forum on Personalised Medicine, Warsaw**
- **24-25 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 German Presidency Conference, Brussels**

DG SANTE plans

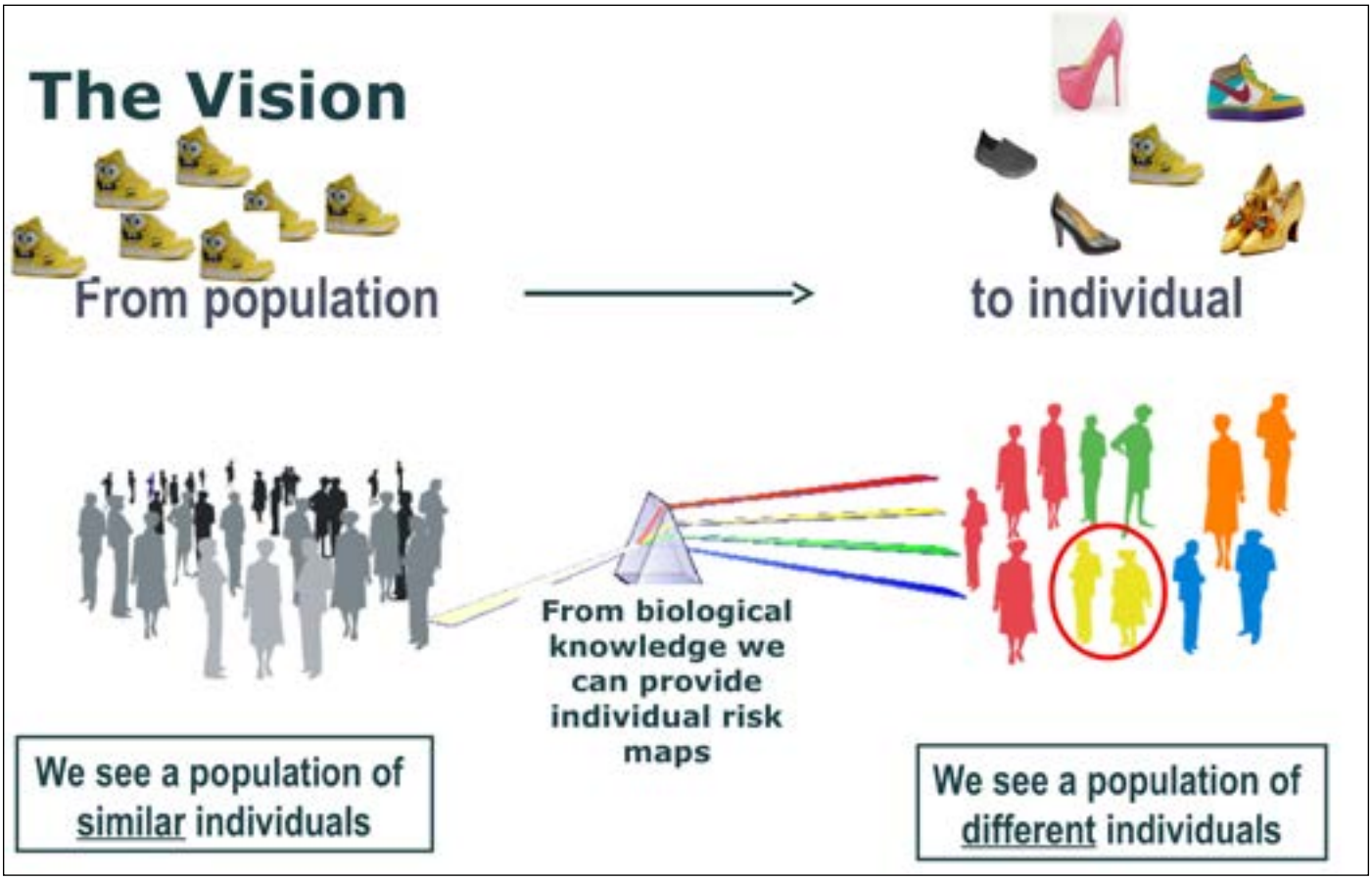
DG SANTE's deputy director-general, **Martin Seychell**, has said that Incoming Health Commissioner Stella Kyriakides has been given "one of the most ambitious agendas" of all health commissioners, also saying that the Commission has to prepare for some "robust conversations."

Challenges include the cancer mission, and Seychell told *Politico* that failures in cancer control are symptomatic of the failure in broader health systems. This explains why cancer was chosen as one of Horizon Europe's missions.

DG SANTE's man said that 40% of cancers are preventable. at a conservative estimate, adding: "This means we could substantially reduce morbidity and mortality by being much better at prevention -but we are not that good at prevention and that is a system failure."

On medical devices, Seychell said that "Not for one minute" would the Commission "underestimate" the challenges of the medical device file.

He also made it clear that Europe's healthcare sector could well do without uncertainty, which could "poison" any sort of debate and destroy trust. He highlighted the field of antimicrobial resistance as a possible "good area to build trust."



Prevention and personalised medicine

We often talk about public health matters coupled with prevention here at EAPM, so it's encouraging to note that EU countries are getting better at offering countrywide programmes for counselling on physical activity and exercise.

Also on the up are Member State promotion of physical activity at school and active school commutes.

A Commission report has shown that these improvements have taken place over the past three years, with the EU urging capitals "to continue strengthening the focus of their national programmes on children and young people, and to regularly provide information on their efforts".

This is as a result of the implementation of a 2013 Council recommendation on promoting health-enhancing physical activity across sectors.

Staying with public health, a World Health Organisation report has shown that healthcare in European prisons is usually overseen by the ministry of justice in the EU Member States and other European countries, rather than by the country's health ministry.

The report says that the lack of involvement of health ministries in some of the key areas of prison health "raises questions about the interface between prison health systems and larger public health systems in these countries".

The news comes as a result of a survey completed by 39 of the 52 member states in the WHO's European region, which also finds that several countries make inmates pay for at least some of their healthcare.

Two countries require full healthcare payment from inmates while, in a further ten, they must pay for either all or some of their prescription medication.

EMA news

European Medicines Agency chief **Guido Rasi** addressed MEPs on the Committee on Environment, Public Health and Food Safety recently, telling them that the agency is getting ready to work on some medtech approvals involving a combination of medicines and devices under the EU's incoming rules.

But Rasi said the EMA needs more people for this effort, and called the current cap on staffing "nonsense."

More generally, he added that: "The convergence of technology will probably also call for a convergence of regulation."

On the EU's plan to battle cancer, Rasi said that the opportunity to have a final cure for most cancers "is here, is real now, in the next four, five, 10 years", but that "the big problem will be the access".

"What we approve, fewer and fewer patients can access, because the price factor is creating a gap," he said.

Meanwhile, EMA has also been discussing its new science strategy for regulating medicines up until 2025.

Industry, payers, patients, healthcare professionals and NGOs have all been contributing to talks about issues the EMA will have to deal with in the near future.

These include approving personalised medicines, incorporating real-world data, speeding up access by interacting with health technology assessment bodies.

EMA chief Rasi wanted to know whether the draft strategy is

ambitious enough. And **Tony Humphreys**, who is the agency's lead on the strategy, unveiled the results of a consultation that asked which proposals will be most key for the EU health sector and would create the "most significant change in the regulatory system" over five years.

The feedback produced a top five, namely fostering innovation in clinical trials; promoting the use of high-quality real-world evidence; reinforcing patient relevance in decision-making; contributing to HTA preparedness downstream; and supporting developments in precision medicines, and biomarkers.

Rasi, as we know, steps down in the near future and the strategy he leaves behind is sure to be considered an important part of his legacy.

ENVI looks to budgets

The Environment, Public Health and Food Safety Committee (ENVI) is getting closer to giving the thumbs-up on how health-related EU agencies implemented 2018 budgets.

ENVI recommends granting discharge for the EMA and European Centre for Disease Prevention and Control. The latter, however, has been given a slapped wrist for not collecting all required annual declarations of interest from outside advisers and management board members.

Cross-border knowledge gap

In news that will surprise absolutely nobody in the sector, it turns out that the majority of EU citizens haven't a clue that they can access free healthcare in another EU country while having their own Member State pay for it.

Šarūnas Narbutas, chairman of the Youth Cancer Europe group, told the European Parliament that four-out-of-five people living in the EU don't know how to access treatment abroad.

He told MEPs: "In the European Union, there are 36 million people living with rare diseases, many of whom cannot get adequate treatment in their own country.

"Meanwhile, tens of thousands of young cancer patients are needlessly dying every year due to lack of information, not due to finances or lack of therapy options."

Health data 'behind the times'

The Organisation for Economic Cooperation and Development (OECD) has told the healthcare sector to get with the times, via a recent report.

The OECD highlighted that it's way behind other sectors in "harnessing the potential of data and digital technology, missing the opportunity to save a significant number of lives and billions of dollars".

Again, nobody is surprised - hence our efforts on MEGA+, for example.

It turns out that less than half of OECD countries provide patients with digital access to their health records, which is certainly an issue here in Europe.

When it comes to hard cash, the health sector is wasting lots-and-lots of it - possibly $1.3 trillion annually - on inefficiencies such as unnecessary practices and duplication. (Hello, HTA people!)

"A digital transformation is urgently needed and long overdue at a time of increasing pressure on health systems and budgets," the report says.

Ultimately, the OECD says, healthcare is "decades behind" other sectors such as education and banking, which have embraced the digital future by overhauling existing systems, rather than just digitising their existing ones. There is a need for "significant investment" as well as "resolute action" in the form of a comprehensive, overarching digital strategy.

On top of this, there is a need for improvement in the use and safety of health data, plus the preparation of the workforce and the public to use data and technology more efficiently, the report concludes.

Re-use of health data

The topic of medical data is, of course, always on the table, and a new report commissioned by pharmaceutical lobbyists EFPIA illustrates that the industry has, in latter days, been re-using health data for a wide range of purposes, such as the discovery of medicines and their subsequent development.

The RAND report says that the main types of re-used health data are electronic health records, data from health registries, and clinical trial data.

Also used are biobank data, prescribing and claims data, real-world data, plus data from social media and wearable devices.

So, how do they get the info? It's often accessed through co-operation with organisations, such as healthcare providers and universities, and used across different stages of development.

Worth noting is that the RAND report points out that safeguards vary between data owners, ethical approvals for data and security standards.

On a similar note, Google is coming under scrutiny from the US Department of Health and Human Services for the huge data-sharing agreement between the online giant and Ascension - an arrangement that was news to many.

The deal apparently started without explicit consent from patients and clinicians, and an answer to the question of whether legal protections have been fully implemented is not yet known.

Doing digital

In related news (sort of) **Germany**'s Bundestag recently adopted the Digital Supply Act, which aims to make digital healthcare easier.

Doctors will soon be able to prescribe digital health apps and offer online consultations, among other things, with the law expected to enter into force in January 2020.

The healthcare jigsaw

"Healthcare is probably one of the very few sectors in Europe that is still very fragmented." So says **Jan-Philipp Beck**, who is CEO of the EIT Health network.

"In all other areas, through the common market, we've seen a lot of joint regulation and things moving forward," he said, but Europe's health systems are still "fragmented".

Digitalisation issues g "on top of the already fragmented picture we have," Beck said. "And now comes uncertainty around regulatory approval."

He spoke of interoperability adding that there are "issues around data operability" as well as data access in EU countries.

Then there's the "huge" challenge of "getting access to data that is representative of different healthcare systems in Europe," he said.

On a more positive note, Beck spoke of "a great degree of awareness" of such issues across the EU, which gives "no reason for general pessimism".

Health standards and apps

Cecilia Malmström, soon to leave her post as EU Trade Commissioner, unveiled a study showing that protecting EU environmental and health standards was respondents' second-most important trade priority, after job creation.

Meantime, the European Committee for Standardisation is to develop a technical specification for the quality and reliability of health and wellness apps, on the back of a survey it has been undertaking.

This is geared towards helping the EU exploit data to empower citizens and build a healthier society.

Movement on HTA? Maybe...

Are those arguing over HTA inching closer to a deal? Well, the Finnish presidency of the Council has proposed a compromise which *could* lead to an agreement on how to take the file forward.

The word is that this compromise would delete Article 7 of the Commission proposal, which refers to a list of health technologies that have been officially assessed at the EU level.

Deleting the Commission's role in making a joint report official, under Article 7, would basically eliminate the requirement to use joint work, a requirement that has been opposed by Germany, France, Spain and Poland.

Remaining would be a requirement "not to duplicate the requests" for data from manufacturers.

The Commission's role would be diminished for sure, yet there's a possibility that some countries supportive of its initial proposal may accept the compromise just for forward movement.

"Unless we give in to Germany, France, Poland and Spain, we won't get anywhere," one health attaché was reported as saying.

A further meeting on the proposal has been pencilled in for 3 December, a few days before health ministers meet in Brussels on 9 December and coinciding with EAPM's Congress.

Staying with HTA, a report from the consultancy IQVIA says that changes to existing therapies that might make medicines easier to take are more likely to receive negative HTA decisions than totally new medicines.

This is apparently because national HTA bodies and payers are lacking processes to re-examine a medicine after it goes onto the market. This "creates a conundrum" for manufacturers, as they're hardly going to be motivated to collect data on patient experience if regulators have no means to use it.

Antibiotics market on the rocks

The director of the non-profit AMR partnership CARB-X **Kevin Outterson** has said that the antibiotics market is in "complete free-fall and collapse".

There are three possible solutions he said - namely a de-linkage or decoupling model; a subscription model a la Netflix; or market entry rewards for new antibiotics.

He claimed that, if governments don't act, within a year, "we will have seven or eight out of the last 16 antibiotics that have been brought to the market…[go into] bankruptcy or [they] will have gone through bankruptcy".

"That's how bad the market is."

Outterson believes that between £10 million-£25 million per year for access to an antibiotic for the rest of its patent life should do the trick.

Medicine prices....

Justin McCarthy, the senior vice president of the patient and health impact group at Pfizer, told an audience in London recently that the political pressure on medicine pricing is "very intense right now".

He mentioned the rise of personalised medicines; increasing demand for services in healthcare systems due to issues such as ageing populations; plus the lack of modernisation in payment systems.

According to McCarthy, despite advances in science and regulatory systems, payment reimbursement systems are standing still "They were designed decades ago for a completely different kind of medicine," he said.

The Pfizer man then cited an urgent need to introduce "real two-sided value-based agreements," in which "we get rewarded if our medicines over-perform and get penalised if they under-perform."

Photo: thegreekobserver.com

...and medicine shortages

Norway and **Portugal** have joined other countries in Europe by announcing plans to deal with the medicine shortages being widely experienced.

The Norwegian health ministry has notified the European Commission that it wants to give the country's drug regulator the power to prohibit the parallel export of medicines that are running short or at risk of running short.

"The only real possibility for national authorities to prevent or relieve medicine shortages is to impose measures on national market operators, such as wholesale distributors," the ministry wrote.

Over in **Portugal**, new rules published by the Member State's medicines agency have taken effect regarding shortages management. Wholesalers must have at least one month's worth of supplies, while medicine manufacturers must ensure two months worth.

Manufacturers, distributors and pharmacies must notify authorities of shortages within 24 hours of knowing while any pharmaceutical company aware of a looming shortage should notify the Portuguese authorities at least two months in advance.

Meanwhile, in **Poland,** the number of medicines, food products for particular nutritional uses and medical devices at risk of shortage has increased since September, says the health ministry, with insulin, blood glucose strips, influenza vaccines, plus milk replacement for children cited.

And **Greece**'s Health Minister, **Vassilis Kikilias** (pictured above), has said that the New Democracy government will keep its election promise to freeze drug prices in 2020.

He added that if the average price of medicines is higher than the two lowest different prices in the eurozone countries, that price should go down by 7% percent.

MS sufferers sidelined

A study by RAND Europe shows that patients with multiple sclerosis are often left out when it comes to research and policy agendas.

The study was commissioned by **Roche** and found that informal carers of those living with MS are often undertaking the task because national healthcare systems are not providing the necessary additional support.

MS is a chronic, progressive disease of the central nervous system, which affects more than 2.2 million people worldwide.

In addition to the health burden, the disease is associated with high costs in terms of both medical costs and wider economic costs to society, as well as requiring a high amount of informal care provided at home.

RAND Europe took the perspective of the individual with MS, their carers and broader society using a literature review and key informant interviews, and found that there are a range of impacts of MS on patients and on their carers.

Rand Europe's reports says: "Going forwards, greater investment in supporting the needs of carers for individuals with MS could support the informal care they provide, as well as supporting the carer as an individual."

There is no denying that treatments with a range of efficacy and risk of adverse events have become available for the management of MS. But the heterogeneity of clinical expression and responses to treatment pose major challenges to improving patient care.

There is a new focus on the individual patient. and personalised medicine in respect of MS is based on improving the precision of diagnosis for each patient in order to capture prognosis and provide an evidence-based framework for predicting treatment response and personalising patient monitoring.

Photo: healthline.com

It involves development of predictive models involving the integration of clinical and biological data with an understanding of the impact of disease on the lives of individual patients.

Around Europe

Back to Greece, and the country's Prime Minister, **Kyriakos Mitsotakis**, has declared that: "The enemy is tobacco smoke, not smokers," while presenting the country's action plan against smoking.

Some 95% of the Greek population is exposed to passive smoking, he said, and under his government's plan, smoking in public spaces will be banned following the enforcement of legislation, originally introduced in 2009, that had been contested.

New prevention measures will also be introduced, including increasing medical support for smokers attempting to quit and regulating tobacco products' circulation on the Greek market.

"Just as we learned to wear seat belts and helmets, we will learn to smoke outside bars and cafes," said the PM.

Over in **Hungary**, the health ministry is to introduce a measure to help children suffering from diabetes type 1. This will get underway after the turn of the year and will mean that diabetes support centres will receive extra funding, while cash will also go towards measures such as training kitchen staff in schools, as well as coaches and sports doctors.

The ministry says that type 1 diabetes affects in the region of 60,000 Hungarians, with type 2 affecting some 800,000.

And in **Lithuania,** the health ministry has urged hospitals to produce a list of recommended English-speaking doctors to allow foreign residents not fluent in Lithuanian better access.

Measles crisis

More than13,000 measles cases were reported in Europe between October 2018 and the end of September this year, the European Centre for Disease Prevention and Control has revealed.

France had around 2,700 cases (the highest), and was followed by Italy (1,811), Poland (1,582), Romania (1,485) and Bulgaria (1,175).

Eleven people died as a result, which comprised five in Romania, three in France and one in each of Hungary, Italy and the UK.

According to the Centre, the spread of measles is due to continuing suboptimal vaccination coverage across most of Europe, with only Hungary, Malta, Portugal, Slovakia and Sweden reporting the necessary 95% vaccination coverage for both required doses of the vaccine in 2018.

UK lead in commercial research - at least pre-Brexit

Brexit could challenge the UK's position as EU leaders in early commercial clinical research, according to an Association of British Pharmaceutical Industry report.

(The UK is behind Germany and Spain, though, in phase three trials testing medicines on large numbers of patients.)

Overall, the UK is third globally behind the US and China for early research while, for later stage research, it's fifth - again behind the US, Germany, and Spain, as well as Canada.

The Association has warned that the "continued uncertainty" about Britain's future relationship with the EU "undermines the attractiveness of the UK as a destination for clinical research".

And finally....

The European Parliament has shown itself to be prepared to vote on the incoming Commission despite the absence of a commissioner for the UK.

The Berlaymont's lagal department is, however, reportedly worried by the need to resolve Brexit once-and-for-all before the Executive has to make any big decisions down the line.

Current UK Premier **Boris Johnson** certainly doesn't seem too concerned, though, and is in **Saint Nicholas** mode already.

"My early Christmas present to the nation will be to bring the Brexit bill back before the festive break, and get parliament working for the people," he said at the weekend.

"As families sit down to carve up their turkeys this Christmas, I want them to enjoy their festive season free from the seemingly unending Brexit box-set drama."

No 'turkeys voting for Christmas' jokes, here, please. See you in the New Year!

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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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