

European Alliance for Personalised Medicine

EAPM Bulletin: Issue 45, December 2018

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Enjoy the break...but heads down for 2019

Welcome to the December issue of the EAPM bulletin, the last one of 2018, which flew by so fast. We'll be back in January after what will hopefully be a relaxing and enjoyable holiday period for everyone.

The year 2019 already looks busy, and we're not even there yet. Brexit, in whatever form, is due to take place on 29 March and the European Parliament elections follow in May.

A new European Commission will also be in place towards the end of next year - complete with a new leader as Jean-Claude Juncker steps down.

Meanwhile, Romania takes over the rotating presidency of the Council of the EU (January-June), followed by Finland (July-December) and that's not to mention the ongoing work of EAPM.

The latter will include a 7th Presidential Conference in Brussels, a 4th Summer School for HCPs in Leuven, and a 3rd annual Congress, also in the Belgian capital in November.

Speaking of our Congress, many thanks to all of you who attended the event in Milan, and a special hat-tip to our hosts the Lombardy Region. The week saw many topics covered including lung-cancer screening, prostate cancer and the new initiative Regions4PerMed.

In advance of Congress, EAPM even received a dedicated video on prostate cancer from survivor Stephen Fry, star of stage and screen. You can watch Stephen in all his glory, [here](#).

On top of this were sessions on hospitals, diabetes and pancreatic cancer, plus genomics, and a discussion between CEOs who debated and planned personalised medicine development down the line.

The last day saw additions to the regional track, a dedicated patients' track, the final day of the Winter School, rare diseases and translational research.

EAPM's executive director Denis Horgan said: "After a few days of reflection post-conference, all of us at the Alliance are delighted at how this Congress unfolded.

"We had many brilliant speakers, lots of interaction between all those present, and we covered a large amount of important topics, put in front of us by experts in their own fields.

"Now is the time to get our messages across to policymakers, all other stakeholders, Member States and their regions."

In the pipeline:

- **3 December: Personalised Health - Ensuring Sustainability, EP Brussels**

- **8-9 April: EAPM 7th annual presidency conference, Brussels**

- **26-28 June: 4th annual Summer School for HCPs, Leuven**

- **18-20 November: EAPM 3rd annual Congress, Brussels**

"All-in-all," Horgan added, "it was a great success and sets us up well for our key events coming up in Belgium next year."

"As our members know, our over-arching goal, as always, is to pass on the key 'asks' to policymakers – and set out ideas that have been drawn together through the expertise gathered at conferences and, in this instance, Congress."

See a selection of photos on pages 3-5. A report will follow.

Sustainability meeting in Parliament

Before we head into the New Year, EAPM will host a meeting on the topic of ensuring sustainability under the personalised health umbrella.

This will take place in the Brussels seat of Parliament (Members Salon) **tonight, 3 December**, under the title '*What does the future of sustainable healthcare look like?*'

The event is to mark the launch of *FutureProofing Healthcare: The Sustainability Index*, which is the brain-child of pharmaceutical company Roche, and gives a unique overview of the status of the current 28 EU healthcare systems.

It is based on the largest data set of its kind, all open source, interactive and verified by an independent panel of experts.

The index is available [here](#). Last-minute registration, [here](#)

EAPM will be co-hosting the event, with Sirpa Pietkainen, a



long-time advocate of personalised medicine, as sponsoring MEP. Roche will also co-host the event.

The Sustainability Index gives a unique overview of the status of the EU's healthcare systems.

Roche's Luc Dirckx said: "The index provides meaningful insights about healthcare sustainability across the EU and the panel of experts includes patient associations, policy experts, healthcare professionals and pharmaceutical companies.

"And it seeks to identify areas of improvement in each healthcare system to ensure that patients get the care they need in the coming decades."

The index enables a future-focused conversation that is based on fact and sharing best practice, among HCPs, media, patients and the general public across the European Union.

Focusing on breast cancer

It includes an in-depth analysis of the state of care throughout the patient journey for one specific disease each year. First up is breast cancer.

The Breast Cancer Index tracks the state of care for the disease, settling on one score for each country showing how systems support prevention and diagnosis, treatment, outcomes and survivorship, patient focus, and palliative care.

The over-arching goal is to answer perennial questions by working together with partners from across the healthcare system to use a complete picture of what Europe knows now to drive a conversation about the healthcare systems that patients will need next.

It asks questions such as wealthier countries always healthier, which countries get access to innovations first, is there a link between ratios of private health expenditure to public expenditure and health outcomes, and a link between public health spending in periods of recession and health outcomes?

Other questions include what is the correlation between countries with a universal health system and health outcomes,

is there a link between the quality of monitoring of population health needs and overall system performance, what is the correlation between disparities in health across the population and overall health outcomes?

One extremely important question (although they all are important) is what is the link between numbers accessing screening programmes and survival rates?

Roche says that there is already data out there to answer many of these questions, describing its new project as an annual index that will track key indicators through time - keeping track of remaining gaps and emerging best practices among European healthcare systems.

EAPM is part of the expert panel in this ongoing project and the view from the Alliance is that such indexes need to exist in all key disease areas, lung cancer included.

Hosting MEP Sirpa Pietikäinen said: "It is necessary to make policymakers and payers realise that investing now in advanced therapies and technologies, as well as in adequate regulatory and payer decision making frameworks, will be a key pre-requisite to see the long-term, cost-effective patient outcome benefits and more efficient healthcare systems materialise."

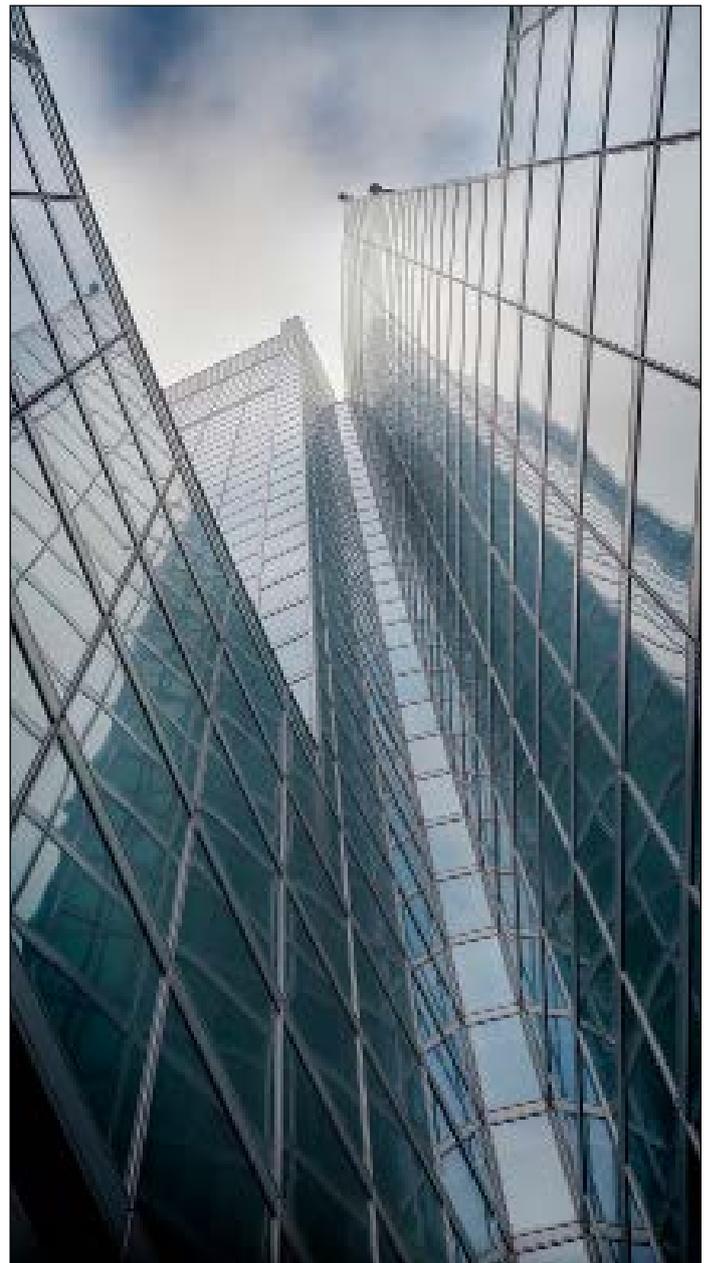
The Finnish MEP will be joined by Parliamentary colleagues Marian Harkin, Paul Rubig and Cristian Busoi. Mary Harney, former Deputy Prime Minister and Minister for Health in Ireland, and Tuula Helander, Ministry of Health, from Finland will also be among the guests.

Also present in the Parliament will be public health decision makers, representatives from the Commission, patient organisations, and EU-based associations active in the field of personalised medicine.

A look at what's been happening

Health is obviously a global issue, not just European, and the plain facts are that improvements in health across the planet appear to be slowing down.

Memories of Milan Congress, 2018



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A major review, in which more than 3,500 researchers took part, was published last month in *The Lancet*, and showed that improvements in mortality rates were less pronounced. Some countries even got worse when compared to last year, while others merely stayed level.

This was especially the case in men aged between 25 and 40.

Funded by the Bill and Melinda Gates Foundation, the review highlighted that, across the globe, high blood pressure, high blood glucose, high body mass index and, of course, smoking are risk factors accounting for more than half of the world's deaths.

It also established that 91 countries are not producing enough children to maintain their population size. Spain, Portugal, Norway and Cyprus are all on the list, with the latter having the lowest rate overall.

Perhaps even more of an eye-opener is that there are zero countries currently on target to meet the 2030 U.N. Sustainable Development Goals in respect of improving health.

Meanwhile, the Gates' foundation and the Wellcome Trust have backed an initiative for open-access to research papers, called Plan S. The two organisations are among the largest biomedical research funders around, and both have made it a prerequisite that any research they fund will be made available to the public at no charge once published.

For its part, the European Commission late last week said that improvements in life expectancy have slowed "markedly" in the EU.

A report prepared in tandem with the Organisation for Economic Co-operation and Development, and titled 'Health at a Glance: Europe 2018', put a focus on unnecessary hospital visits for chronic conditions (which come in at a staggering 37 million bed-days a year, on estimate), and the high price of medicines.

Not surprisingly, given that the report suggested better ways of using resources, HTA came up as a top tool. Are you listening Member States?

And so much for EU equality - those on low incomes are apparently five times more likely to have unmet care needs than the more well-heeled.

Meanwhile, 4% of GDP across Europe each year is lost through mental illness.

Individual country profiles are due next year, but how many reports that say exactly the same thing do we need before action is taken that actually makes a difference?

New Horizons

MEPs towards the end of November said that they want to set up a dedicated board to boost health's visibility in respect of the incoming Horizon Europe programme, which kicks off in 2021 and runs to 2027.

The idea is to coordinate health research and would include IMI, (the Innovative Medicines Initiative), and what has been dubbed the health moonshot "mission".

The idea is for between 15-20 health experts to target "coordination and synergies between EU and national health programmes" and "promote patients and society engagement".

Cost-wise, MEPs confirmed that they are looking for €120 billion for the Horizon Europe programme, with 8.2% of that going to health, although Member States are baulking at the figures. Stay tuned...

On a not-unconnected note, as reported in a recent EAPM briefing, the Parliament's Environment, Public Health and Food Safety Committee (ENVI) adopted 11 compromise amendments in respect of the European Social Fund Plus, known as ESF+.

One of the compromises aims to boost funding for the health strand from the Commission's proposed €413 million to €473m between 2021-2027.

Rapporteur Cristian-Silviu Buşoi (pictured), a long-time supporter of EAPM and its goals, is against plans to put the health budget under the larger umbrella of ESF+, with ENVI



noting that he “regrets” the withdrawal of health as a separate and robust programme, “finds unacceptable the proposed decrease of funding for health” and argues for increasing the budget to at least the same level as in the current Multi-annual Financial Framework.

This comes on the back of the European Economic and Social Committee (EESC) saying it was “highly critical” of any cuts to ESF+, currently tabled by the Commission at 6%.

EESC’s rapporteur Krzysztof Balon didn’t mince his words, saying it should be called ESF Minus instead of ESF Plus. Nice...

In other good sort-of quotes recently, *Politico* reports that MEP Dan Nica, when asked what his personal choice would be for a first moonshot-style research mission, said health. When asked for his second choice, he said...“Health”.

At least we know where Dan stands.

Still on funding, and November saw the Commission get a ‘good, but must try harder’ verdict from the European Court of Auditors in respect of the EU Executive’s efforts to make it easier for researchers and companies to win research funds.

Red tape has been reduced, the auditors’ special report noted, but it’s still not easy to apply for EU money. The report recommends improvements to the Horizon Europe programme in this regard that it believes will make life easier for SMEs *et al.*

Regulate, regulate

On 21 November, the heads of medicines agencies met in Vienna to discuss, among other matters, the medicinal use of cannabis as well as checking for new therapies that might push the boundaries of umbrella regulations.

European Medicines Agency boss Guido Rasi (pictured above)

gave a presentation, while EMA’s future move to Amsterdam was the subject of an impact assessment on telematics.

The EMA has been London-based, of course, and one bit of news from the UK is that Ian Hudson, chief executive officer of the country’s medicines and healthcare products regulatory agency is leaving his post in early 2019, in advance of Brexit.

Hudson explained the move saying: “My reasons for stepping down are both personal and professional. I feel the time is right for a new person to guide the agency and our work through its next phase, following the UK’s departure from the European Union next year.”

And on the broader subject of preparing for Brexit, according to the EMA’s Rasi, “some things are going well, some uncertainties still remain”.

Rasi revealed that the EMA is still working on a backstop strategy for a no-deal scenario, despite expectations that the EU and Britain will carry on recognising mutual medicine marketing authorisations, at least until the proposed transition period ends at the end of 2020.

More Brexit...

Debate and, indeed, disagreement continues in the pharmaceutical sector in respect of maintaining ties between the EU and Britain once the latter packs up its troubles in its old kit bag. Or, possibly, medicine bag.

EFPIA chief Nathalie Moll highlighted details in respect of health while EFPIA’s counterpart in the UK, ABPI, feels the transition will ensure “members can continue to supply medicines to patients without delay,” according to boss Mike Thompson.

And when it comes to backstops and contingency plans,



the Commission issued advice on preparations at airports and more in case of a no-deal Brexit. Guess what? It didn't cover healthcare, leaving those-in-the-know exasperated and worried about possible medicine shortages.

Pharmacists, meanwhile, are highlighting that there's already a problem with medicine shortages, and say it could get worse post-Brexit.

Almost 92% (up from 86% four years ago) flagged up the issue from a survey covering 1,600 pharmacists in 38 European countries. Antibiotics, vaccines and oncology medicines are most affected.

Brexit and aspects of its aftermath will be a key element of EAPM's 7th annual conference in Brussels next April, just days after the deadline of 29 March.

Money talking (again)

In a massive surprise to absolutely nobody, national healthcare payers told an audience in Brussels at the end of last month that current systems struggle to deal with new disruptive and expensive medicines.

The event was hosted by the European Public Health Alliance, logo up top, and participants heard that there's a tough balance between trying to speed up access to new medicines and treatments often in the absence of proof of benefit.

And then there's the money, of course...

Speaking of which, the cost of in-patient hospital care is going up-up-up in EU big-hitters Germany. Average costs per case has topped the €5,000 mark in some regions, with the cost of healthcare rising from €87.8 billion in 2016 to €91.3 billion in 2017.

And in Romania, three new hospitals are chasing funds from

the next EU budget. Well, we say 'new', but they haven't been built yet and are likely to be delayed...

Meanwhile, the Association of Mutual Benefit Societies, representing not-for-profit healthcare payers, has targeted next year's Parliamentary elections asking politicians to put more emphasis on health promotion and prevention.

The group also called for European institutions to review the incentive structure for pharmaceuticals to ensure "sustainable access" and promotion of innovation through programmes, such as Horizon Europe, in its election memo.

CART-T latest

In Spain, the Health Ministry has put forward a strategic plan ensuring access to CAR-T therapies, via a two-tiered model.

One part will designate reference centres to use CAR-T therapies, and there is no argument there, but proposals for the second tier have been taken to mean that the country wants to designate Spanish manufacturing sites for CAR-T therapies.

This isn't how things work at the moment, with approved therapies only being made in New Jersey (Novartis) and California (Gilead).

Back to EMA on this one, and its chief Guido Rasi said recently that the cell therapy is a "disruptive innovation that needs a radical rethink" regarding the way treatments are developed, assessed and delivered.

He called for early engagement between developers and the EMA to ensure fit-for-purpose clinical trial design.

Rasi was reported as saying: "We won't be able to provide a general guidance on how to develop classes of new medicines. Medicines of the future will require a unique approach and drug developers will be navigating uncharted territories."



Meanwhile, England is to overhaul its cancer screening programmes, not least it seems in the wake of NHS contractor Capita making a mess of 40,000 letters to women in respective breast-cancer screening.

This latest 'oops!' came on the back of a summer computer issue that also led to some 500,000 women missing reminders for screening. Nobody knows exactly how many avoidable deaths that may have caused.

SPCs

The Austrian Presidency of the EU last month has proposed a compromise on when the proposed supplementary protection certificate (SPC) manufacturing waiver should start applying.

Council will have the last say, but are not particularly close to agreement, as it stands. Meanwhile, Parliament can't make its mind up either, with the Legal Affairs Committee now getting involved.

Clinical trials and data sharing

Finland takes over the rotating presidency of the EU in July 2019 and its Ministry of Social Affairs and Health recently detailed its policy for sharing health data with police.

This came after some "misinformation" managed to ruffle the public's feathers.

HCPs can pass information to the police if someone is a public threat or at risk of being a victim of violence, under a relatively recent law (2015) that the ministry insisted has "never been to give the police access to confidential patient records".

It was intended, it added, to "strengthen security without

jeopardising the confidentiality of health data", and the police will now be advised as to how to implement the law properly.

Meanwhile, we all know that pharmaceutical companies could save resources by sharing data. But we all know that they're not overly happy about it.

However, the European Organisation for Research and Treatment of Cancer wants to work with the pharma sector on using its SPECTA database. EORTC's chief, Denis Lacombe, pictured, explained to *Politico* that persuasion hasn't been easy...

Health technology assessment

Regarding this ongoing topic, EAPM organised a meeting alongside Malta's permanent representation to the EU, which aimed to move the whole debate forward.

As well as Malta, Austrian MEP Paul Rubig, whose country holds the EU's rotating presidency, acted as co-host.

Healthcare representatives from Austria, Cyprus, Slovakia, Slovakia, Sweden, Hungary, Netherlands, Lithuania, Croatia, Greece, Germany and, of course, Malta, were present while representatives from industry and patient groups also took part.

The meeting looked at where Europe currently stands with regards to the Commission proposal on HTA, and addressed direct concerns and opportunities.

The gathering zoomed in on specific provisions and elements of the legislation proposal, in order to have a meaningful and practical discussion among key players, including EUnetHTA.

The roundtable featured presentations from representatives of EUnetHTA - which performs the function of the scientific and



technical cooperation of the HTA Network.

Meanwhile, as the whole HTA issue rumbles on, some at the meeting were losing patience with Germany, which is against the Commission's proposal for EU-wide assessment. The country's health attaché Ortwin Schulte came under the cosh, but it's fair to say he wasn't swayed.

To be continued next week/month/forever...

But Germany is not necessarily the bad guy. Last week, the nation's Federal Health Minister, Jens Spahn (pictured), said he wants to develop a health system that can make full use of personalised medicine. We like it, Jens.

At the first congress of the international consortium for personalised medicine (ICPerMed) in Berlin, the minister described such therapies as the "future of modern medicine".

Next year, Spahn's ministry will commit to national funding of €1.5 million, which will go into the ERA-Net PerMed fund. This is supported by the European Commission to align research strategies in the field. The news and the topic in general were, not surprisingly, aired at Congress in Milan.

Legal eagles decide

The Court of Justice has ruled that the reimbursement by a national healthcare insurance system of a medicinal product for a use not covered by its marketing authorisation - known as off-label use - is not contrary to EU law, although the product in question must still adhere to EU pharmaceutical rules.

Roche Italia holds the marketing authorisation, or MA, for Avastin, which is a biotechnological product intended for the treatment of certain cancers. But Avastin has been prescribed for treating an eye disease called age-related macular degeneration.

Its MA does not cover that condition.

The Court noted that EU law doesn't prohibit either the off-label prescription of a medicinal product or its repackaging for such use, but does require that they comply with the certain conditions, as we mentioned above.

The Court also decided that a new MA is not necessary where Avastin is, on the basis of an individual prescription, repackaged by a pharmacy lawfully authorised to that effect and administered in hospitals.



Latvia joins a MEGA party

In mid-November, Latvia became the 19th EU Member State to sign-up to the MEGA initiative, originally floated by EAPM.

MEGA - as you all must know by now - stands for Million European Genomes Alliance - and aims to sequence 1 million genomes by 2022 through a coalition of the willing.

A little goose for Christmas

In the spirit of pre-festivities good news, the European Commission's DG SANTE Director General Anne Bucher - in the job just a few short weeks and pictured above - has vowed to build on the work of Xavier Prats Monné, her predecessor, saying she will "stick to very strong priorities on health."

Bucher used an analogy of the V-shape of flying geese when stressing that communication and cooperation are key in the sector. In such a formation, she says, the geese "fly 70 percent more than...on their own".

In the news

As ever, the Alliance has been busy engaging with the media. Below you can find links to recent articles.

[#EAPM – Member states gather over latest #HTA proposals](#)

[#EAPM – The Twilight Zone is no place for personalised medicine](#)

[#EAPM – Search for 'Fountain of Youth' fails to make Congress agenda...](#)



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About EAPM

The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

As the European discussion on personalised medicine gathers pace. EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

The mix of EAPM members 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. EAPM is funded by its members.

**Contact: Denis Horgan
EAPM Executive Director
Avenue de l'Armee/Legerlaan 10, 1040 Brussels
Tel: + 32 4725 35 104
Website: www.euapm.eu**