



# European Alliance for Personalised Medicine

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## Finland takes over Presidential hot seat

Welcome to the July newsletter from EAPM, as Finland takes over the reins of the EU Presidency for the third time. You can check out the logo and some key health players on pages 2 and 3.

This month will see the crowning of a new prime minister in the UK, albeit an unelected one, and the fight is now on between the final pair of contenders - **Boris Johnson** and **Jeremy Hunt**.

It remains to be seen whether a general election will be in the offing any time soon, but with BoJo promising that the UK will exit the EU on 31 October - deal or no deal, "do or die" - don't rule out a nationwide poll.

Why? Because the EU says it won't renegotiate, and the British Parliament has already said it won't allow a no-deal Brexit, so a general election may well be the only way to break the impasse.

It would be surprising if the European Union backed down, not least because the Irish border issue (the main sticking point) is not going to go away, and because it has certainly enough on its plate already as the new European Parliament gets ready to sit for the first time and the battle is on to choose the leaders of several institutions as we look ahead for the next five years.

Parliament has, in fact, suggested that it may postpone the election of its own new president by 24 hours. This is in order to give more time for EU leaders to decide on the other top jobs in the European institutions. Not least who will replace current Commission President **Jean-Claude Juncker** (as we finalised this newsletter, the EPP's **Martin Weber**'s candidacy was looking doomed to failure).

The Parliament's political party group leaders will make their minds up on whether to extend while EU heads of state and government meet in Brussels on Sunday (30 June), for a special summit.

The vote on what **Emmanuel Macron**, **Angela Merkel** *et al* decide at the weekend is due in Strasbourg on Tuesday 2 July, but may now be put off until Wednesday.

**Donald Tusk**, meanwhile, will meet the aforementioned Parliament group leaders in the official format of the Conference of Presidents prior to the summit. Then he's off to meet the Member State leaders.

Tusk has already said that he wants a result this time, after the failure to agree at the most recent summit.

"If necessary, the meeting may continue with a breakfast on

### In the EAPM pipeline:

- **26-27 September: HARMONY General Assembly, Florence**
- **27 September-1 October: ESMO Congress, Barcelona**
- **3-5 December: EAPM 3rd annual Congress, Brussels**

1 July 2019," we're told. Not too much strong coffee overnight, please. Just ask **Tony Blair** about that...

### Meanwhile, over in Helsinki...

Amid all this uncertainty, we can tell you that EAPM will be working hard with the Finnish Presidency which, of course, will still be in the chair as the Alliance holds its 3rd annual Congress on personalised medicine in Brussels in December

Prior to taking over the rotating presidency from Romania, Finland tested the water on how best to handle genomic data, against the backdrop of its draft plans to create a genomic centre to store and manage genomic information generated by biobanks and more.

The proposal covers conditions for carrying out health-related genetic analyses, not least consent.

Also going forward, and despite having a few political problems with its own healthcare structure, Finland is putting a focus on the economy of wellbeing.

Finland says it wants EU decision-makers to recognise that wellbeing increases economic growth and social and economic stability and that economic growth helps improve wellbeing.

Public funds are invested in improving people's wellbeing, it says, and this means that people are healthier, more innovative and productive, they work and they pay taxes.

Finland's aim is that the Council of the EU adopts conclusions on the economy of wellbeing this coming October.

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The conclusions will include recommendations for measures to be taken by Member States and the Commission.

During its Presidency of the Council of the EU, Finland has pledged to organise a high-level conference on the economy of wellbeing on 18–19 September in Helsinki.

Meanwhile, at June's Health Council gathering in Luxembourg, and just a week into her new job as the country's health minister, **Krista Kiuru** told listeners that the economy of wellbeing will be the overarching theme, adding that Finland will also work to "strengthen the influence of the EU as a leader in global health, promoting our European values and protecting multilateralism".

Helsinki plans to launch a long-term project that will last for six consecutive Council presidencies.

At the same meeting the long-running debate on the Commission's proposals to boost EU-wide HTA was touched upon - but only in the sense that the Romanian Presidency presented a progress report.

While speaking, Romanian Health Minister **Sorina Pintea** wished the Finnish Presidency good luck with the ongoing brief. So do we...

## Good access rings a bell

During the European Council summit in Brussels in June, good access to healthcare was touted as one ingredient that "will help Europe preserve its way of life."

One would hope that it also goes without saying that it will also preserve actual life, not to mention the quality of it. (Who actually drafts these agendas??!)

This comes as a part of at the strategic plan for the next five years adopted by EU leaders - each of whom had probably figured the above out all by themselves.

We told you the following in our last members' update, but it bears recapping in this newsletter...at that Health Council meeting in Luxembourg, the European Commission said it's not planning new legislation to give pharmaceutical companies incentives to come up with new antibiotics, but some countries are not overly happy about that.

These include the UK, Luxembourg and Malta, who definitely do want incentives in the case of antimicrobial resistance (AMR).

The meeting was reminded that Denmark is working with the World Bank to establish an international research centre for global solutions on AMR, while the Netherlands is holding an international ministerial conference to see what's been achieved on AMR in the past five years.

Meanwhile, those troublesome medical devices regs, which enter into force in less than a year, prompted Germany's high-profile Health Minister **Jens Spahn** to ask the Commission for "a longer grace period for certain products".

The EU's Health Commissioner **Vytienis Andriukaitis** gave an unequivocal 'no'.

Also up for discussion were East-West divisions over EU funds as the health chiefs talked about how best to use existing and future EU cash to invest in health systems.

Hungary and Bulgaria wanted a hands-off approach from the Commission when it comes to setting priorities, but Germany gave a large hint that such guidance is important.

Meanwhile, as we wait to see which MEPs end up undertaking which responsibilities, the Alliance (and media) has its eye on the ENVI committee in particular.

The Environment, Public Health and Food Safety committee has, in fact, already been the subject of a leaked internal document from the European People's Party's Romanian delegation, which *Politico* managed to get hold of.



## **Finnish presidency of the EU, some key players in the healthcare arena**

**Pictured left is Health Minister Krista Kiuru, centre is MEP Sirpa Pietikäinen, and at the bottom is Finland's Health Counsellor Pasi Mustonen**





# European Court of Auditors

## Guardians of the EU finances



It turns out that one of EAPM's stalwarts, **Cristian Silviu Buşoi**, is keen to renew his membership, as is **Adina Vălean**, the former ENVI chair. We'll soon find out, so watch this space...

### War on drugs...prices

French health campaigners have shifted up a gear following the adoption of the World Health Assembly's drug-pricing transparency resolution.

One civil society group has launched the *Observatoire Transparence Médicaments* in order to keep EU and other countries to the resolution's commitments.

This is according to *Health Policy Watch*, which adds that the French group also want governments to go beyond the resolution by implementing measures that first saw the light of day in Italy's original draft.

Well, good luck with that, as countries such as the UK and Germany had issues with the Italian suggestion that companies should reveal R&D costs.

### Irish PrEP for HIV, UK 'relegated'

In the wake of Ireland's Health Information and Quality Authority (HIQA) saying that pre-exposure prophylaxis (PrEP) can help prevent HIV infection - while also acting as a cost-effective solution to lowering HIV prevalence - the country's health ministry has pledged to roll this out later in the year.

Health Minister **Simon Harris**, who many will remember spoke at our first annual Congress in Belfast, said: "This report not only confirms that PrEP can help to prevent HIV amongst those who are high risk, it also shows how a PrEP programme could save money."

Over in the UK, scientists say that Brexit will see the nation drop out of the 'Champions League' of science unless London nails a deal to access European research programmes.

No less than 72 leading scientists put forward the view in

a survey carried out by the Francis Crick Institute, adding that the government needs to negotiate access to Horizon Europe, which starts in 2021.

Crick Institute Director **Paul Nurse** said that a no deal departure is "absolutely not a realistic option", adding that: "If we turn our back on Europe why would they let us cherry pick? This is a political issue and that's why we've got to raise it higher on the political agenda."

Back in Ireland, the country's health ministry has published a report Tuesday into the CervicalCheck scandal. As many readers will know, this saw some women given false negative results when screened for cervical cancer as part of a public programme.

The report focused on the 18 laboratories that analysed the results, finding that the use of many of them was not approved in advance by the Irish health service or the National Screening Service, nor was their use known to these services.

As it transpires, a laboratory used for CervicalCheck screening, in Manchester, UK, was retrospectively accredited during time periods when its existence was unknown to the Irish National Accreditation Board.

The report states: "Notwithstanding these concerns, we have not identified any evidence that the laboratory services used in the past, or those currently in use by CervicalCheck, have provided, or are providing, a service which does not meet acceptable standards in their country of operation."

It adds, however, that "the system in place in Ireland for responding to errors in screening is inadequate to the task".

### ERNs under the auditors' microscope

The European Court of Auditors were busy in June, issuing a report that underlined that cross-border healthcare remains marginal in comparison to healthcare that is delivered domestically,



in some situations, the most accessible or appropriate care for a patient is available in a Member State other than their home country.

The report noted that the Cross-Border Healthcare Directive “facilitates closer cooperation in a number of areas: notably the cross-border exchange of patients’ data and access to healthcare for patients with rare diseases”.

The Court’s report noted that “the concept of European Reference Networks for rare disease is widely supported by EU stakeholders (patients’ organisations, doctors and healthcare providers)”.

No denying that it’s a great idea. However, “the Commission has not provided a clear vision for their future financing and how to develop and integrate them into national healthcare systems”.

When it comes to cross-border initiatives for rare-disease patients, the specificities of such diseases led the Council of the European Union to single out cooperation in this field as “as a unique domain of very high added value of action at Community level”, the auditors say.

Networks were launched in 2017 for different classes of rare diseases. Each receives €1 million funding over five years from the EU Health Programme. The Commission also finances patient registries and support activities for the ERNs as well as the development of IT tools, notably through the Connecting Europe Facility.

The EU is currently considering the future of the European Reference Networks for rare diseases. “EU citizens still don’t benefit enough from the ambitious actions set out

in the Cross-Border Healthcare Directive,” auditor **Janusz Wojciechowski** has said.

Meanwhile, on a more optimistic note, Germany and France have signed an agreement allowing residents in Saar and Moselle to receive healthcare on both sides of the border without prior authorisation.

The MOSAR agreement, as it’s been called, means that if a resident has (let’s say) a heart attack, they will be treated by the best relevant centre closest to their homes. The agreement covers cardiology, and neurosurgery, with nuclear medicine and rehabilitation to follow.

### Legal eagles circle

The European Commission is, of course, still undertaking a review on intellectual property incentives for the pharmaceutical industry (it’s due by the end of the year) with the pressure on to make new medicines more affordable.

Lawyers from Medicines Law & Policy stated a few cases at the recent European Public Health Alliance event in Brussels and called for national patent authorities - who are considering demands for an Supplementary Protection Certificate to compensate pharmaceutical companies for a timeline between discovery and market approval - to think about asking said companies to prove that the basic patent was not long enough to cover their investment.

The lawyers also feel that the EU should drop its demand that countries or regions provide similar data-exclusivity periods for medicines manufacturers when negotiating free trade



agreements. On top of this, it was suggested that the Commission should define what is sufficient and what is excessive profitability from an orphan drug, then work out what is sufficient return on investment.

The problem here is that **Olga Solomon**, who is head of unit for medicines at DG SANTE, responded that this year's report would not actually make any policy recommendations. That will be up to the next Commission.

Over in Germany, plans are a foot to improve working conditions for nursing staff in order to reduce shortages.

Proposals have emerged jointly from Health Minister Jens Spahn, Labor Minister **Hubertus Heil** and Family Minister **Franziska Giffey**, who foresee higher salaries, better and cheaper training and new apprenticeships.

The three ministers also reckon that workers from abroad should be able to enter the country more easily.

The Greens' health spokesperson **Kordula Schulz-Asche** was somewhat sceptical, saying that the government had "no idea how to finance the additional costs" of their proposals.

On the subject of training and education, the Health Policy Partnership research group has said in a report that policymakers must improve education, awareness and management of fatty liver disease, specifically non-alcoholic steatohepatitis (NASH), to avoid the ticking time bomb in prevalence and subsequent health costs.

The report maintains there are no medicines to treat NASH, adding that while patients are managed with lifestyle changes such as diet, most fail to lose the required bodyweight to have a significant impact.

A liver transplant is often the only option, but many patients have other health problems that prevent surgery.

## EU on access for children and rare disease

In a recent speech, Europe's health commissioner **Vytenis Andriukaitis** (pictured on Page 5) told an audience that improving access to medicines for children and rare diseases is "a noble aim but it is a difficult process, and one that involves a wide range of stakeholders".

He said he has met many representatives of patient organisations, who have urged him to do more to improve the situation of children and rare disease patients.

Andriukaitis said that good progress has been made in improving access to specialised care "with the establishment of the European Reference Networks, which are now operational and working towards expanding their activities to research".

"But I recognise this is not enough," the Commissioner said, adding: "This is why patients' organisations, Member States, European institutions, the pharmaceutical industry, and medical researchers all play a crucial role, in many different ways, to make further progress."

Andriukaitis explained that, in 2000, the EU Regulation for medicines for rare diseases came into force, with the Regulation for medicines for children following in 2007.

Calling them "game changers!", the Commissioner explained that "the aim of these two Regulations was simple - to increase the therapeutic choices for children and patients suffering from rare diseases by offering more targeted medicinal products".

"It meant," he added, "that companies could no longer ignore paediatric drug development, and put an end to the dogma that children should be protected from clinical research."

Andriukaitis pointed out that, since that time, the Commission has authorised more 160 orphan medicinal products and 260 medicines for children. He said: "I am sure that this has had a positive impact on patients and their families across Europe. It is important to recognise this progress."

Moving forward, he said, it is important to listen to critical voices, recognise the flaws in the system, and examine its effectiveness.

# Political programme - what happens next?

**In the wake of the European Parliamentary elections, which saw more than 200 million Europeans vote at the end of May, the new legislature will start on 2 July.**

**Prior to that are political group constitutive meetings. The rules state that any political group must consist of at least 25 MEPs elected in at least one-quarter of Member States. To be officially recognised as of 2 July, political groups have to notify their composition to the President by 1 July.**

**Plenary sitting 2-4 July: Newly elected MEPs will meet in Parliament's constituent plenary sitting in Strasbourg to elect their President, 14 Vice-Presidents and five Quaestors.**

**The European Parliament will also vote on the numerical composition of its standing and sub committees - and launch the next legislative term.**

**In the weeks that follow, the committees will then hold their first meetings to elect their respective Chairs and Vice-Chairs.**

**The second July session (15-18) represents the first opportunity for the European Parliament to elect the Commission President. He or she needs an absolute majority in Parliament (376). If this doesn't happen, Member States will have to propose another candidate within one month.**

**On a legal note, any votes taken by the EP before the elections remain legally valid for the next Parliament. Legislative business that didn't make it to plenary before the elections, the work done during the previous parliamentary term lapses.**

**This is the default position, although the new Parliament's Conference of Presidents can decide to continue the work already done on the relevant files.**

One major flaw, he acknowledged, is that "there is simply not enough development of some medicines to address specific and urgent needs in children".

The Commissioner highlighted "a substantial difference in the level of access to affordable treatments, both between and within Member States" which, he said, "fundamentally increases health inequalities".

However, Andriukaitis pointed out: "Horizon Europe will open the door to new approaches and new solutions for tackling some of the shortcomings I have touched on."

Then he challenged the pharmaceutical industry: "Children and patients suffering from rare diseases are among the most vulnerable members of our society. We have to take particular care of them.

"In this context, I would like to underline the responsibility of our industrial partners - the pharmaceutical industry.

"This responsibility should go beyond the letter of the law in order to fully consider the usefulness of products they develop in relation to children.

"There is no justification as to why the knowledge and better understanding accumulated over the last decade in developing anti-cancer medicines for adults should not be fully used to the benefit of children.

"As legislators, industry and medical professionals, we all need to do more to ensure equal access to affordable, innovative and effective medicine."

Andriukaitis finished by saying that: "We know where the problems lie. And there is a wealth of experience, knowledge and commitment... So let us put it to good use and work together for a more equal and healthier future."

## Spanish socialists on health

Spain's Socialist Party is the biggest national delegation in the European Parliament's Socialist group in the wake of the May election and can, therefore, be expected to exert some considerable influence in the hemicycle.

Madrid's Health Minister **María Luisa Carcedo** has said that health going forward will be guided by two principles that are "irrevocable" for social democrats, namely universalism and equity.

That sounds great but, lest we forget, Spain has emerged as a major opponent of the European Commission's mandatory aspects of HTA.

Speaking to *Politico*, Carcedo explained that her party's health priorities in the EP Parliament would be "universalism" at the top and "the accessibility to national health systems to medical services and health protection" second.

The minister said that: "Health protection is realised through the environmental policies of fighting climate change and all the consequences it has on health and through [policies on] social determinants.

"Then of course there's access to medicines. This has to do a lot with EU policies, with the role of the European Medicines Agency, with how research is used for new medicines and the way prices create difficulties for access and for the sustainability of national health systems."

She had a particular comment on personalised medicine, saying: "With personalised medicines and the introduction of genomics, all of this is a big challenge. For us...the principles of universalism and equity are irrevocable."

After backing up her country's stance on HTA, she said:





"We share the idea of cooperation, research, sharing knowledge and cooperating. But that this is mandatory is a jump that we don't [agree to]"

On a no-deal Brexit, the minister said there are two relevant policies: "The first one is guaranteeing mutual medical assistance. We solved this with a legislative decree that was ratified by the Spanish parliament to ensure mutual medical assistance for the citizens of both countries."

Regarding the second, trade in medicines, she said: "We have specific points for border checks, to check products that will enter, that we are planning to improve. We are aware that there will be a bigger workload and we are working in that direction."

She added that she hoped there would be no medicine shortages due to Brexit.

"There may be some mismatches at times. But let's hope that they can be solved. There are alternative therapies in all cases. In specific shortages, we always have some therapeutic alternatives. And I hope this doesn't cause a problem for health and for treating diseases," the minister said.

## eHealth on the rise

A new study, suggests that eHealth adoption in primary healthcare has increased in the EU from 2013 to 2018, although large differences exist between Member States - at least the ones in the survey.

During the time period analysed, the amount of general practitioners enthusiastic about eHealth has doubled with its use routine among the countries with the highest level of adoption. These are, alphabetically, Denmark, Estonia, Finland, Spain, Sweden and the UK.

Those countries with the lowest level of adoption (Greece, Lithuania, Luxembourg, Malta, Romania and Slovakia) do not have widespread use of eHealth.

Four categories were used in the survey. First up is electronic health records - currently available across all analysed EU countries with nearly all GPs (96%) using it in their practice.

It seems that basic health data and information and order-entry functionalities are almost fully adopted in all countries, and in more than half of the countries most GPs are routinely using clinical decision support functionalities and administrative data routinely.

Next, health informatics exchange adoption is lower than EHR adoption. The degree of exchange of clinical, administrative and management is still not very high across the analysed countries.

On the plus side, since 2013, there has been a large increase in the adoption of certifying sick leaves and transferring prescriptions to pharmacists.

Telehealth is showing progress, with the downside being that its availability and use are still low in most analysed countries. Training and education functionalities are now available to half of GPs, while they were only available to 36% of those surveyed in 2013.

The survey notes that the availability of consultations with patients (12%) and tele-monitoring (4%) is still low.

The adoption of Personal Health Record (PHR) shows a similar pattern to Telehealth. Availability of the functionalities to request appointments and prescriptions has increased, as have the functionalities allowing patients to view their medical records and test results.

Meanwhile doctors in Luxembourg can now receive digital Patient Summaries of travellers coming from the Czech Republic.

The summaries provide background information on health-related aspects such as allergies, current medication, previous illness and surgeries. In other good news, Finland and Croatia are now exchanging ePrescriptions.





European Health and Food Safety Commissioner Vytenis Andriukaitis congratulated the countries for taking steps in eHealth cooperation.

The Commissioner added: "I hope other countries will follow soon. Sharing Patient Summaries and ePrescriptions is important for patient safety as it can help doctors to understand better the patient's medical history, can reduce the risks of incorrect medication and can contribute to better care.

"In an emergency situation, this can save lives," he said.

## EU quizzed on digital health legislation

MEP **Antanas Guoga** has addressed the Commission stating: "On 25 April 2018, the Commission published its communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.

"Digital health initiatives use innovative solutions to reform health and care systems. The initiatives set out to make these systems more resilient, accessible and effective at providing quality care to EU citizens. However, few legislative initiatives have been put forward regarding the exchange of patients' electronic health records across borders in the EU, such as the Privacy Code of Conduct on mobile health applications."

Guoga asked the Executive specifically: "What is the status of the implementation of these initiatives? And what steps will the Commission take to improve digital health services in the EU in the next term?"

**Mariya Gabriel**, pictured above, the current European Commissioner for Digital Economy and Society, replied explaining that on 6 February this year the Commission adopted a recommendation on a European Electronic Health Record

exchange format seeking to facilitate cross-border interoperability of health data.

She said: "It can also contribute to further develop the e-Health Digital Service Infrastructure that allows exchanging e-prescriptions and summaries of patient health records between Member States."

On top of this, she said that the Commission "expects the review of Commission Implementing Decision to be adopted before the end of 2019, in order to clarify the role of the eHealth Network in the governance of this infrastructure and its operational requirements".

The Commissioner pointed out that the digital transformation is supported under the Horizon 2020 programme, and through initiatives various programmes, adding that, until next year, the European Regional Development Fund invests more than €1 billion in Information and Communications Technologies solutions. This addresses healthy active ageing and e-Health.

Commissioner Gabriel pointed to the continued support for the digital transformation of health and care, "including interoperability, Artificial Intelligence and security of health information systems, through instruments such as Horizon Europe, Structural Funds and the Digital Europe Programme".

The latter, she said, will provide a planned €9.2 billion across all sectors and with health as a key sector.

In addition: "The European Regional Development Fund will support equal access to healthcare through developing infrastructure, including primary care."

## EAPM December Congress

EAPM will be following all relevant topics at its 3rd Annual



Congress in December, to be held in Brussels (above) this year. The theme of the event, under the auspices of the Finnish Presidency, will be *“Forward together with innovation: The importance of policy making in the era of personalised medicine.”*

The Belgian capital has been chosen to host the event as the new Parliament will of course be in place, while the next European Commission will also, by then, be in the Berlaymont under its new president.

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.

As always, the Congress will be in a focused format to allow concrete issues to be tackled and to have a dialogue with our policymakers, and is a follow-on from the past two successful editions in Belfast and Milan, as well as seven well-attended and influential annual conferences.

Meanwhile, the report from EAPM's April 2019 conference can be found [here](#).

## In the news

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

[Time to collaborate further: The \(real-world\) evidence is clear](#)

[Update: Nordics to the fore, as well as some new faces](#)

[Who holds the trump cards for Europe's and the UK's top jobs?](#)

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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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