



# European Alliance for Personalised Medicine

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## Boris in Number 10 as EU goes on holiday

Welcome to EAPM's August newsletter, and we hope you find some time to read this as you get your bags packed and the suntan lotion stowed away for the summer break. Well-earned, as ever, be sure to enjoy it.

So... We have a new British Prime Minister in **Boris Johnson**, and a new cabinet loaded with prominent Brexiteers as the most recent resident of 10 Downing Street aims to meet his promise of a 31 October exit from the EU, deal or no-deal, "do or die".

Speaking to his cabinet this week BoJo said: "As you all know we have a momentous task ahead of us, at a pivotal moment in our country's history. We are now committed, all of us, to leaving the European Union on October 31 or indeed earlier - no ifs, no buts."

One of the few ministers to hold onto their position is Health Minister **Matt Hancock** - so at least there's some stability in what may well be troubled times ahead for the UK's pharmaceutical industry, chemists, the NHS, GPs and, ultimately, patients.

Good luck to Johnson and Hancock, especially as they're probably going to need a lot of it - given that a still-united EU is maintaining that it will not renegotiate the deal already on the table, and the House of Commons will likely rebel at the prospect of a no-deal departure.

Indeed, after Prime Minister Johnson said he was committed to "getting rid" of the Irish border backstop, the EU's chief Brexit negotiator, **Michel Barnier**, said removing the backstop guarantee was unacceptable.

The Frenchman was backed up by soon-to-depart Commission President **Jean-Claude Juncker**, who told the new British premier that the already-negotiated withdrawal agreement was the best one possible.

The backstop is a last resort that guarantees a frictionless border if no better solution is devised in time - by maintaining close ties between the UK and EU until such a solution is found.

But Boris is having none of it. He said: "No country that values its independence, and indeed its self-respect, could agree to a treaty which signed away our economic independence and self-government as this backstop does."

On top this, he described the backstop as "divisive" and "anti-democratic".

### In the EAPM pipeline:

- **27 September: EAPM roundtable at ESMO Congress, Barcelona**
- **28 September: Pioneer roundtable (as above)**
- **16 October: MEP Roundtable, Brussels**
- **4-5 December: EAPM 3rd annual Congress, Brussels**

Hang on a minute, Boris... so you're effectively saying that a re-introduced border between an EU Member State, namely Ireland, and a demonstrably pro-EU Northern Ireland, wouldn't in itself be the epitome of "divisive" and "anti-democratic"?

Oh, ok then...

Anyway, once again, the clock is ticking and doubtless Ireland's Taoiseach **Leo Varadkar** is paying even more attention than most, given that the issue of an open-or-closed border between his country and the north clearly remains a key sticking point.

On a sort-of-connected note, it seems that the UK hasn't done itself too many favours in respect of allegations that it illegally snaffled classified personal information from a database reserved for members of the passport-free Schengen travel zone (to which the UK has never belonged).

Oopsie! Great timing. Said nobody, ever.

### Meanwhile, in Strasbourg...

The ENVI Committee was as busy-as-a-Boris this week, electing a new chair and giving the floor to the Finnish presidency's Minister of Family Affairs and Social Services **Krista Kiuru**.

Indeed, pretty-much the first thing Kiuru did was congratulate **Pascal Canfin** on his nomination as chair, saying she's convinced all new appointees (including vice-chairs and rapporteurs) will cooperate well during what is the third Finnish Presidency of its time in the EU.

Finland took the role in 1999 and 2006, and Kiuru said that while many things have changed since then, some things remain the same. On the latter point she stressed that, yet again,

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Finland has “an opportunity to strengthen close and pragmatic relationship between our institutions and work together for the future of our continent. That future should be socially, economically and ecologically sustainable”.

She reminded the ENVI Committee that the slogan for the Presidency is *Sustainable Europe – Sustainable Future*.

The minister said that the Finnish Presidency is committed to achieving progress on the health technology assessment file. This is a clear priority, she said, adding that Helsinki plans to tackle substantial issues in the proposal and is “dedicated to finding a way forward”.

This is perhaps just as well as Germany, which is two Presidencies down the line after Croatia takes the reins in the first half of 2020, remains opposed to the mandatory aspects of EU-wide joint HTA.

During the Presidency, said Kiuru, Finland will be introducing “a new concept of the *Economy of Wellbeing*, with the aim of adopting Council Conclusions in October”.

The very aim of the EU project, and the basis of its legitimacy, is to promote wellbeing of its citizens, she said.

“Wellbeing is one of the cornerstones of the Union and a common European value.”

The minister went on to explain that the *Economy of Wellbeing* provides for a holistic approach to policy-making. While people’s wellbeing is a value in itself, it is also vital for ensuring sustainable long-term economic growth and societal stability.

She echoed the comment made by the Commission's President-elect, **Ursula von der Leyen**, who said: “It’s not people that serve the economy. It’s the economy that serves people.”

Kiuru continued by saying there’s been a lot of talk about the future of health in the EU in recent times.

“We firmly believe that as a holistic, multi-sectoral approach that highlights the need to invest in people and their health, the *Economy of Wellbeing* can also be useful in making the case for strong EU health cooperation in the future,” she said.

Kiuru also made clear the EU’s responsibilities with regards to advancing global health, telling the ENVI Committee that: “Global health issues have gained increasing attention even at the highest political level, including at the upcoming UN General Assembly.” Meanwhile, “Well-functioning international cooperation is more important than ever,” she said.

She added that the EU and its Member States jointly constitute the biggest financial contributor to global health.

“In our assessment, the EU’s political significance in international health fora does not fully reach its potential at present,” she said, explaining that: “During the Presidency, we are initiating a joint EU Presidency project that aims at strengthening the EU’s role in global health cooperation. Our objective is to identify possible strategies and enhanced communication and working methods for the EU’s global health work in international settings. The multi-year initiative will involve two consecutive presidency trios.”

The minister then promised to organise two high-level health-related conferences in Helsinki and many more meetings at a technical level.

(The next major *Economy of Wellbeing* event will take place on 18-19 September in the Finnish capital.

Kiuru told ENVI that health systems all over Europe are struggling with increasing costs, higher patient expectations, technological transformation, shortage of skilled workforce, vaccine hesitancy and challenges related to availability of and access to medicines.

Resilience and capacity to adapt quickly to changes at every level of society are more important than ever, she said.



## Old and new faces for von der Leyen Commission? Current list of nominees - Page 7

Left, Malta's nominee Helena Dalli; centre left, the candidate from Ireland, Phil Hogan (currently serving); centre right, Slovakia's Maroš Šefčovič (currently serving), and; bottom, Margaritis Schinas of Greece





"In order to respond to the changes caused by those mega-trends and to achieve sustainable and inclusive growth, we need to promote the European social model", the minister insisted, adding: "It creates stability, which is a significant comparative advantage for the EU in the tightening global competition.

"The EU should aim to be not only the most competitive but also the most socially cohesive economy in the world."

Minister Kiuru said that this is the direction in which Finland would like to see the Union go during the next five years.

"The approach we are advocating, the *Economy of Wellbeing*, is only a first step on this path. We hope to provide the future Presidencies with a solid foundation on which they can build the further actions needed."

## From the floor

EAPM's friend and supporter MEP **Peter Liese** made one of many contributions by deputies in the wake of Minister Kiuru's address.

Liese stressed that while economic growth is important, health must be a priority. He pointed out that the treaties oblige that, where the EU has competencies, it must act.

He went on to describe the term of Health Commissioner **Vytenis Andriukaitis** (above) as a disappointment, adding that there is a need to seize the opportunity that the Commission President-elect is a doctor. He reiterated that his party, the EPP, has made the fight against cancer a priority.

**Véronique Trillet-Lenoir** said that while there is a fight against cancer there's also one regarding the problems associated with ageing, disabilities, mental illnesses, and sexual and reproductive health, for example. She called for a strong commitment from the Council to tackle all of this.

The French MEP added that cancers are responsible for many deaths and that much needs to be done in prevention, research and artificial intelligence.

The UK's **Seb Dance** said that he's worried that the current suspicion on some aspects of science can lead to numerous cases of measles. He wanted to know what measures can be taken to restore public faith in science, and called for a programme to educate citizens on the safety of vaccines.

In response, Minister Kiuru suggested that the question is how to guarantee that the vaccination is safe and that citizens have faith in vaccination. She pointed out that, in December 2018, the Council adopted recommendations and added that it is time to implement actions.

Polish deputy Joanna Kopcińska focused on antimicrobial resistance, saying that as a doctor she supported all measures. By 2050, she said, resistance is going to be a major issue affecting millions of people. It is important to promote health measures, she stressed.

Another EAPM stalwart, **Cristian-Silviu Buşoi**, said he hoped that health will be a priority for the Presidency.

E-health is a very important topic, he said, adding that he hoped that the health programme, part of the so-called ESF+, will receive a budget increase.

On HTA, the Romanian MEP said it is difficult to guarantee a result, but he added that he expected a positive outcome.

Spanish MEP **Dolors Montserrat** said, meanwhile, that national public health systems are making progress, but need to do more in prevention.

EAPM couldn't agree more.

## From Wellbeing to Wellcome

The UK charity Wellcome Trust has funded a research project that will aim to discover how human embryos develop in the first weeks and months after fertilisation. Wellcome says the aim is to improve the understanding of fertility, birth defects, and regenerative medicine.



The Trust is committing is providing £10 million to the Human Developmental Biology Initiative (or HDBI), which will build 'a family tree' of how cells divide and specialise during a five-year initiative.

This should allow an understanding of how tissues and organs develop while giving new insights into how it can all go wrong.

Some 3% of babies are born with developmental defects which can include heart defects, spina bifida and cleft palate, says the Trust. These emerging problems often start very early in pregnancy, and yet not much is known about why and how they happen.

Wellcome says that the project will involve donated human embryos and human foetal tissue, adding that limited access to human embryo tissue samples has held back research thus far, and pledged that HDBI will look closely at ethical issues and include a specific ethics and public engagement programme.

EAPM's upcoming **GOAL!** initiative will be paying very close attention to all aspects.

## The French Connection

In a similar vein, the French government recently announced major changes to its law on bioethics.

**Frédérique Vidal**, the French research minister, said that genome editing will be allowed for research purposes, subject to prior authorisation, while a ban on creating embryos for research purposes will remain.

Also in France, Health Minister **Agnès Buzyn** has said that a ban of using genetic tests for the general population, such as those offered online, will stay in place.

She said: "We think that the validity of the medical information given by these tests done abroad is not robust enough," adding that they risk making people worry about unconfirmed disease risk, and that "genome analysis has to be done in a medical framework". Again, GOAL! is watching developments closely.

## Drug prices (Part 462)

Consumer groups from Belgium and Italy have filed complaints with their own national competition authorities against pharmaceutical manufacturer Biogen for "inflating" the cost of a rare-disease drug called Spinraza, according to BEUC.

The Belgians and Italians claim that Biogen is abusing the market exclusivity given to medicines for rare diseases.

In response **Kris Schellens**, the Biogen Idec Belux managing director, told *De Morgen* newspaper that "it's not just about recovering the development costs. We have to invest today in tomorrow's medicines. The income from the medicines that we have on the market must make this possible."

## Theresa May on health

In a 'farewell' lambast for now-departed UK prime minister Theresa May (above, with **Jean-Claude Juncker**), Labour leader **Jeremy Corbyn** gave his former sparring partner a tongue-lashing on rising NHS waiting times and decreasing numbers of general practitioners during the ex-Tory leader's final Prime Minister's Questions in the House of Commons

It was not all bad news for May, however, as she was complimented (although not by Corbyn, of course) for her work on mental health.

On research, she was a bit circumspect, after being asked whether she would support a Brexit deal that prevents UK-based academics from working with their EU colleagues.

The now-backbench MP said: "I do want to see a relationship between the UK and the EU that enables our scientists, our academics, to work with those in the EU as well as those in the rest of the world to do the pioneering work... which is changing people's lives and improving them for the better."

On fighting obesity and smoking she said she was proud to have supported the "biggest cash boost" to the NHS ever, and to have pushed its long-term action plan focused on prevention.



As it happens, two days before her exit as premier, May oversaw the release of a consultation paper on tougher public health rules was released by the Department of Health and Social Care.

The paper talks about embedding genomics into routine healthcare and making England smoke-free by 2030 - although it doesn't suggest forcing Big Tobacco into paying for smoke-quitting services. Instead, it advocates inserts in tobacco products giving quitting advice.

Boris Johnson, for his part, spoke of his pride in Britain's life science sector, pointing out that the UK is using gene therapy "for the first time, to treat the most common form of blindness."

The new prime minister also zoomed in on the need to get hospitals and other infrastructure, such as banks and ports ready in order to "take advantage of Brexit".

And he added that plans are already afoot to upgrade 20 hospitals.

"My job is to make sure you don't have to wait three weeks to see your GP...and ensuring that money for the NHS really does get to the front line," he said.

### Anti-smoking message gets a leg up

Tobacco is in the news again. Not least because of the case of a Frenchman's claims that a picture of an amputated leg used as a deterrent on cigarette packets is his, and that he didn't give permission for it to be used.

The Metz-based man lost his leg as the result of a shooting in Albania, in 1997, and we're told that the operation had no link to smoking. It's about tie the guy had a break, to be fair...

The European Commission did confirm that "the individual mentioned is not depicted in the library of health warnings", while noting that the Commission has "taken adequate care to ensure that the production of the photos used as pictorial health

warnings was carefully documented and that all individuals depicted in the library of health warnings were fully informed of the use of their image and gave their consent to such a use".

Somebody somewhere clearly wasn't toe-ing the line...

### Greeks step up on smoking, at last

Public buildings in Greece will have now to observe the 2008 indoor smoking ban that few really bothered about.

A meeting between Greek Prime Minister **Kyriakos Mitsotakis**, Health Minister **Vasilis Kikilias** and Deputy Health Minister **Vasilis Kontozamanis** emerged with the news that the Greek parliament, government ministries, hospitals, schools and other public buildings will have to start enforcing the ban.

### The reign in Spain, and more...

Spanish caretaker Prime Minister **Pedro Sanchez** (above left, with **Donald Tusk**) is fighting to be re-appointed premier after hit-and-miss elections in April left him hanging in the wind.

He's pledged to expand the basic package of healthcare services reimbursed by his country's public health system, ramp-up dental care, and kick into touch a co-payment for medicines for vulnerable groups, according to Spanish Health Minister **Maria Luisa Carcedo**.

Over in **Sweden**, according to reports in the local media certain cancer patients in Stockholm are to be offered treatment in Finland because an unusually high number of people need radiation therapy.

And in **Estonia**, the social affairs ministry has resubmitted its Population Health Development Plan for 2020-2030.

It was originally rejected by the previous government's coordination group.

The plan focuses on boosting the "healthy life" years of the Balkan state's citizens, which are not matching the rise in life expectancy.

And on the topic of **life expectancy**, the EU's has slipped overall, with women seeing the biggest decline.

# Who's in the frame for the new Commission?

- **Austria - Johannes Hahn**
- **Bulgaria - Mariya Gabriel**
- **Denmark - Margrethe Vestage**
- **Estonia - Kadri Simson**
- **Finland - Jutta Urpilainen**
- **Greece - Margaritis Schinas**
- **Hungary - László Trócsányi**
- **Ireland - Phil Hogan**
- **Latvia - Valdis Dombrovskis**
- **Luxembourg - Nicolas Schmit**
- **Malta - Helena Dalli**
- **Netherlands - Frans Timmermans**
- **Romania - Ioan Mircea Pașcu (interim)**
- **Slovakia - Maroš Šefčovič**
- **Slovenia - Janez Lenarčič**
- **Spain - Josep Borrell**

Life expectancy at birth in the bloc was estimated at 80.9 years in 2017, which is 0.1 years lower than 2016, according Eurostat data.

Life expectancy was down 0.1% for women, while for men it in 2017 it was 78.3 years, or 0.1 years higher than 2016.

Happily for most, since the first such records in 2002, EU28 life expectancy has increased by 3.2 years, from 77.7 to 80.9 years. The breakdown sees +2.6 years for women and +3.8 years for men.

For those of us who are not mathematical geniuses, it may be handy to know that in all EU countries life expectancy at birth is higher for women than for their male counterparts.

## All change at the Berlaymont

European Commission secretary-general **Martin Selmayr** is on the move to Vienna, as we reported in an update earlier this month.

At the time we didn't quite know why, and nor did most people, but now we do... Selmayr will become the Commission's representative to Austria, starting in November.

We wish him a big Vienna Slice of luck.

Meanwhile, still on the Executive's merry-go-round, **Jivka Petkova** has been promoted to director in the Commission's secretariat-general for "strategy, better regulation and corporate governance".

And on to the country nominees: Malta has nominated its Minister for EU Affairs and Equality **Helena Dalli** as candidate for the von der Leyen Commission.

Prime Minister **Joseph Muscat** said on Twitter that he made

the decision after discussing profiles of two highly qualified individuals with von der Leyen.

And **Mariya Gabriel** has been put forward by Bulgaria to serve a second term as a commissioner, in what she calls "an honour and responsibility."

She is currently the European Commissioner for Digital Economy and Society, and becomes the 16th official proposal so far (including Germany's Ursula von der Leyen in the top job, Dalli, and potential second-term **Margrethe Vestager** of Denmark).

You'll find all current nominees listed in the box above.

## Good news and bad news?

The divorce bill for Britain's exit from the EU dropped to around €36 billion this month.

Time for a party at Number 10? Um, no. Not really.

The reason is that the UK is still a Member State and is paying its usual share into the EU pot while the status quo remains.

This will happen each month that Britain is stuck in pre-Brexit limbo, although it all adds up to the same amount of cash in the end. What? No champagne corks a-popping?

## EAPM December Congress

EAPM will be following all relevant topics at its 3rd Annual Congress on 4-5 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.

As we build up to that event, enjoy the summer break and see you in September (when Congress registration will open)!

## In the news

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

[All change at Number 10, but no change of stance in Brussels](#)

[Presidencies change...but Brexit lingers on](#)

[Plenty say 'nein', but Ushi seals top job...by nine](#)

[Von der Leyen, Fearne and a British baroness...](#)

[To agree, or not to agree. That is the question...in healthcare](#)

[Commission, committees and the cancer mission: PHC](#)

[Ursula who? German defence minister nominated for](#)



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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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