European Alliance for Personalised Medicine

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Election month, but will UK go to the polls?

Greetings, and welcome to the May edition of the EAPM newsletter. We trust you all had a good break during the Easter period, which may well prove to have been necessary as we roll into what is certain to be a busy election month.

As it stands, the UK may well have to put up election candidates which means that, at least temporarily, there will remain 751 seats up-for-grabs across the 28 Member States.

The idea of the Brits getting elected then leaving their seats a few months later is a little concerning, but there are plenty of other matters that are causing consternation - especially in the healthcare sector.

Jitters in the healthcare arena

Given the rise of populist parties, it is being seen by some as likely that at least one country will nominate a Eurosceptic member for the incoming Commission. That could mean less pan-EU collaboration, an eventuality which healthcare could frankly do without.

It was arguably bad enough under ***Jean-Claude Juncker***, with any advances in cooperation in the field achieved despite the Luxembourger's presidency, given that he particularly failed to prioritise health.

Of course, Member States have competence for healthcare, so any Eurosceptic health commissioner would end up with a brief over which the EU Executive holds limited powers anyway.

Fears are that this could spell the end for the Commission's plans for joint-cooperation on HTA and even see the end of DG SANTE - the Directorate General for Health and Food Safety.

OK, that wouldn't exactly be the end of the world, as medical devices come under DG GROW, health innovation under DG Research, cross-border healthcare under Employment, Social Affairs and Inclusion, and so on.

Meanwhile, the entire health budget in the next financial cycle is already set to become an element of the European Social Fund+.

Many want a specific Commission vice-president to handle health (the European Patients Forum and other groups having been particularly vocal on this), while others just want DG SANTE to stay pretty-much as it is.

However, the EPF's soon-to-depart chief ***Nicola Bedlington*** was recently quoted in *Politico* as saying: "I think we shouldn't keep fighting for SANTE as SANTE. It's what it is and what it does and what it stands for that is really important."

In the pipeline:

- **9 May: Regions4PerMed Conference, Milan**
- **13-14 May: Pioneer General Assembly, Berlin**
- **13-16 June: EHA Congress, Amsterdam**
- **June: EAPM high-level round table on real-world evidence and HTA, Brussels**
- **26-27 September: HARMONY General Assembly, Florence**
- **27 September-1 October: ESMO Congress, Barcelona**
- **3-5 December: EAPM 3rd annual Congress, Brussels**

In the meantime, Commission Vice President ***Jyrki Katainen*** has taken over the health and food safety brief from Commissioner ***Vytenis Andriukaitis***.

The latter is out-and-about whipping up support to be the next Commission President. *Spitzenkandidaten* process, anyone? It appears Vytenis may not have heard of it…

Going back to those Eurosceptics, many fear that the likes of Italy and Austria will upset the health policy apple cart in a broader sense. Lest we forget, Italian leader ***Matteo Salvini*** has been hesitant over vaccines while Vienna's coalition government reversed a ban on indoor smoking.

EPHA, the European Public Health Alliance, expressed fears via its Secretary-General ***Fiona Godfrey***, who said that populist parties "are traditionally not friends of public health. And they're not supportive of the population interventions needed to tackle the problems we have in public health at the EU level".

Meanwhile, Brussels-based NGOs, who get a goodly proportion

of money from the European Commission, fear that they are about to stare down the barrel of a loss-of-funding gun.

EPHA's Godfrey said: "We risk finding our voices are cut off," adding that the "pot of money has become smaller and smaller each year".

Healthcare and Parliament

Meanwhile, in the European Parliament, one of the biggest pals of the powerful pharmaceutical lobby will not make a reappearance (at least not as an MEP) after the elections at the end of the month, namely French Conservative ***Françoise Grossetête***, who is nicknamed 'Mme Pharma'.

The Commission is currently working on what is viewed as a major review of incentives for developing medicines for rare diseases sufferers and children, so Big Pharma may have liked to have her around. (Not least because, on 17 June, there'll be a meeting to discuss the functioning of the EU's regulations on orphan drugs and pediatric medicines.)

On the other hand, pharma companies probably won't miss Spanish MEP ***Soledad Cabezón Ruiz*** quite so much.

As well as making her name in just one term, not least by being the rapporteur for the HTA process, she's also fought for measures to bring down the price of drugs.

EU-wide healthcare stakeholders will rightfully be sorry to lose her as, let's face it, there's something of a shortage of the bright sparks in healthcare buzzing into Brussels. They tend to stay away, given the Member State competence for the brief.

For example, French Health Minister ***Agnès Buzyn*** was recently considered by President ***Emmanuel Macron*** to lead his European Parliament list but declined the opportunity. And with the new Parliament expected to be at least 50% made up of first-timers, there is apparently a fear in the Belgian capital that new would-be stars in the Hemicycle won't be up to snuff…

(As an aside, Buzyn has appointed Professor ***Frank Bellivier*** as ministerial delegate for mental health and psychiatry. Bellivier will take charge of a mental health and psychiatry plan.)

MEPs active in healthcare during previous terms who are also not standing include ***Luis de Grandes Pascual*** (generics), ***Karin Kadenbach*** (European action plan on antimicrobial resistance) and ***Nessa Childers*** (cancer and women's health).

Also not standing this time are ***Daciana Sârbu*** (children's nutrition), and ***Gesine Meißner*** (shadow rapporteur on HTA).

Having another go at being elected, however, are EAPM friends and stalwarts ***Peter Liese***, ***Alojz Peterle,*** and ***Cristian-Silviu Buşoi.*** And ***Lieve Wierinck***, who was named best MEP for health by *Parliament Magazine*, is standing, as is ***Dubravka Šuica***.

Good luck, ladies and gentlemen!

Liese off the leash

Speaking of MEP Peter Liese, the German deputy recently basically said that EU funds should be available to level-out differences in access to cancer treatments - despite Member State competence etc etc.

Peter said: "You can use regional funds for this. Some people argue you can't do it… It's also a question of priority. Maybe it's more important to invest in health infrastructure rather than nice town halls."

He and the Anticancer Fund are clearly singing from the same song sheet, as the latter have said that the EU should provide more funding to research the possibility of using existing medicines to target cancer where commercial interest is missing.

Liese, meanwhile, also had a pop at his own health minister, ***Jens Spahn***, over the Commission's plans for compulsory pan-EU HTA, which Germany has opposed. "I argued a lot with him and he just wants to do it voluntary, which I think is a waste of resources," the MEP said.

Cristian-Silviu Buşoi MEP
Photo: Simon Pugh Photography

STEPs in the right direction

There's just no getting away from the May elections, and EAPM will hold a roundtable event in late June in their wake.

This will be focused in part on the issues surrounding cooperation on the ongoing health technology assessment file, with contributions from stakeholders including payers and Member State health attachés.

A further session will target engaging with MEPs due to take their seats in the newly elected European Parliament.

It will aim to introduce the core issues around data sharing and access to data, plus other potential methods of prevention, while also reformulating EAPM's STEPs group of MEPs.

STEPs stands for *Specialised Treatment for Europe's Patients* and has regularly engaged with many deputies down the years, several of whom are standing again and are mentioned in the section on Page 2 of this newsletter.

The over-riding objective of the June event is for all present to gain a better understanding of each other's issues and find optimal ways to move forward.

EAPM December Congress

However things pan out, EAPM will definitely be following these and other topics at its 3rd Annual Congress in December, also in Brussels.

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 recent conference can be found here.

Access all areas

Speaking at the recent informal meeting of health ministers in Bucharest, the Commission's top health official ***Anne Bucher*** bemoaned the state of access to medicines in Europe saying the situation is getting worse.

The director-general of DG SANTE said: "There's an increasing concern that this problem is not going away and it's becoming more acute when it comes to the availability of innovative medicines, also to some of the pricing issues."

The EU executive is taking a long, hard look at orphan and paediatric drugs regulations and, as mentioned, plans a meeting down the line to see whether there's a need for changes,

At the same gathering, Romanian Health Minister ***Sorina Pintea*** (whose country's presidency hosted the event) said that in respect of her own country prices of medicines were recalculated for the first time in a long time, but it's hard "to solve the problem in one year".

Meanwhile, over Stockholm way, it transpires that Sweden is investing in speeding up hospital patient discharges. This, according to Social Minister ***Lena Hallengren***, is "to shorten the queues for healthcare and build a stronger society". Developing a coordinated homecare plan for elderly patients is also in the pipeline for Sweden during 2019.

Horizon Europe

At the April Parliamentary plenary in Strasbourg, a political deal was finally reached on details of the EU's future backing for research and innovation in respect of the 2021-2027 Horizon Europe programme.

Well, sort of…

As it stands, the deal hasn't nailed actual figures - fairly important, one would think - nor has it addressed future UK involvement (or that of non-EU countries in general).

There's still an argument regarding who-wants-what spent on R&D - the Commission threw in a figure of €83.5 billion at current prices while Parliament wants to up it to €120 billion.

A near-€40 billion difference. Almost fifty percent of the original figure. No problem sorting that one out, right?

What *has* been settled is that a European Innovation Council and new research missions across areas including cancer will come into play.

But there was no certainty for British researchers. Which is hardly surprising as there's no certainty about pretty much anything in the UK at the moment as regards Europe.

Medicines pricing

Member States in the Valletta group, whose stated goal is to negotiate cheaper pharma prices, are turning to medicines yet to be approved by the European Medicines Agency, or are not yet available in any of the countries involved in the group.

These could include cancer drugs, biosimilars and rare diseases medicines.

The Valletta group is made up of Croatia, Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania, Slovenia and Spain, and is looking at a legal framework for joint negotiations, although more time is needed for members to reach consensus.

(Speaking of biosimilars, it was recently suggested by American economists that US medicines regulators should abandon biosimilars. They should instead focus on price controls for expensive biological medicines if they want to meaningfully lower costs.

The country's ex-Food and Drug Administration Commissioner ***Scott Gottlieb*** was having none of it. He took to Twitter to write: "it's far too early to throw in the towel on biosimilars."

Adrian van den Hoven, director general of Medicines for Europe, was even more blunt: "Ridiculous," he said.)

Meanwhile, Latvia's Health Minister ***Ilze Viņķele*** has suggested that a review of the small Member State's current system for reference is imminent, given that the reimbursement levels of medicines and devices by its health system are not allowed to be higher than the third-lowest price in the Czech Republic, Denmark, Hungary, Romania, and Slovakia.

Nor can it be higher than the price in Latvia's neighbouring Baltic states. Pretty simple, then…

Over in Amsterdam, Health Minister for The Netherlands ***Bruno Bruins*** has floated the idea of limiting the market exclusivity for orphan drugs by half - down from ten years to five.

"Why should a manufacturer have a monopoly for 10 years if there are no high investment costs?" Bruins said. Big Pharma, for its part, probably said: "Ouch!"

And that's not all, with the news that the European Medicines Agency has put the idea out there that regulators could only recommend authorisations for medicines with an added value compared to existing treatments. If this is a new concept, then it shouldn't be, surely?

"The aim of these proposals is to contain the rising cost of what is often perceived as the nebulous concept of 'innovation'," according to EMA boss ***Guido Rasi***.

On HTA, meanwhile, the French pharmaceutical lobby group Leem wants a European system for clinical evaluation that would harmonise clinical data requirements and remove duplicate national authority assessments.

Um, so does the Commission, and Parliament, but France (alongside others such as Germany) is so far blocking any mandatory cooperation at Council level.

Make your minds up, France, whydontcha?

Supplementary protection certificates (again)

Back in Strasbourg, meanwhile, the European Parliament held a debate on the provisional agreement via inter-institutional negotiations with the Council of the EU on the supplementary protection certificate waiver for medicinal products.

The following day, Parliament comfortably approved it.

The argument around supplementary protection certificates, or SPCs, runs that, while the patent and the supplementary period of protection is still valid, companies could not store protected products, not even for exports for third countries where the patent protection does not exist or has expired.

On the other hand, other countries that do not have SPCs are in a position to do just that. As such, manufacturers of biosimilars and generics elsewhere in the world have a competitive advantage.

Speaking to deputies, Jyrki Katainen, Vice-President of the European Commission, said that the SPC waiver was an important element of the Commission's Single Market Strategy, and an important deliverable for Parliament.

Croatia busy ahead of presidency

Once Romania has handed over the baton to Finland on 1 July, the next in line for the EU's rotating presidency will be Croatia (1 January 2020).

In an encouraging early sign, it will soon become the fifth EU Member State able to send and receive e-prescriptions across borders and get patient summaries from other countries.

Already doing this are Finland and Estonia, swapping e-prescriptions since January, plus the Czech Republic and Luxembourg. The latter pair will, in the next few months, begin exchanging patient summaries.

The e-prescription programme is being gradually rolled out across all EU Member States, with patient summaries offering background info on the likes of allergies, medications, previous illness and surgeries.

Meanwhile, Albania and North Macedonia are not thus far taking part in such exchanges, but apparently will have to be ready to do so before they join the EU.

Blimey! They'd better move quickly then…

Data and trials

The European Commission recently tried to clarify in a document what it calls the "interplay" between the clinical trial regulation and data privacy laws.

The head of the European Medicines Agency Guido Rasi is already on record as worrying that the General Data Protection Regulation (GDPR) could threaten medical research in some cases, such as secondary use of medical data harvested from a particular and specific trial.

Under GDPR, there must be a "valid legal ground" if a researcher wants to use the personal health data "for any other purposes than the one defined by the clinical trial protocol".

The "valid legal ground" covers a public interest in safeguarding public health, the legitimate interest of the organisation or the person's explicit consent.

The document states that it would be possible for the secondary use to fall under the same legal basis used for the original processing of the data, but that this is not guaranteed.

Under GDPR it transpires that obtaining informed consent for a citizen to participate in a clinical trial is also distinct from the requirements of getting the person's consent to process their personal data.

In the news

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

Still no Brexit date, but you can make a date with EAPM

Calm before the storm: Brexit and the small matter of a personalised healthcare conference

EAPM and ERS event aims for 'Big Screen'

Time to 'redouble efforts' on personalised medicine

EAPM – Conference, Digital Day 3, and the rights of patients

Halloween and Easter rolled into one. Perhaps not the best plan…

The holidays are here, and not before time

Patient access and SPC waivers dominate health business

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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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