European Alliance for Personalised Medicine

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Numbers game: All eyes on new-look EP

Welcome to the June newsletter from EAPM, on the back of a busy and certainly very interesting merry month of May.

And not just the actual 'month' of May, with the news that the end of (**Theresa**) **May** will come in June, at least in respect of her term as leader of the UK's Conservative Party - although she will stay on as Britain's prime minister until the upcoming leadership contest is resolved.

'Mayxit', anyone?

Meanwhile, the European election results have sprung a few surprises in the sense that the liberals and Greens have done well (their numbers are in what we could call 'Ascension' (given Thursday's celebrations), the EPP and S&D have seen losses and can no longer form a majority, and the far-right plus the Eurosceptic parties have done pretty well, but not as well as expected.

Perhaps most surprising of all is the bump in voter engagement, with the biggest turn-out in a couple of decades.

As this newsletter went to press the main numbers after the elections are seeing the EPP with +/-178 seats, the socialists (+/-153), liberal ALDE and partners (+/-105), and the Greens/EFA with +/-69.

In the run-up to the elections, most of the parties named their top candidate, or *Spitzenkandida*t, and the Treaty of Lisbon makes it clear that the result of the polls should be taken into account by the European Council when it proposes a candidate for the post of Commission chief.

The nominee then goes to the European Parliament for approval (as do all proposed Commissioners) with the institution voting by majority.

Parliament has called for the *Spitzenkandidaten* process to be applied in this year's elections, although that is by no means certain to happen, and in Brussels yesterday European leaders gathered to discuss filling the top jobs that are about to become available, with at least Germany and France prefering different candidates. So here we go...

Interesting times lie ahead, not least for **Martin Weber**, **Frans Timmermans**, **Margrethe Vestager** and (it's rumoured) **Michel Barnier**, to name but a few candidates to replace **Jean-Claude Juncker** as Europe's top dog.

In the pipeline:

- **13-16 June: EHA Congress, Amsterdam**
- **19 June: EAPM roundtable with Member State health attachés, Brussels**
- **20 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**

High-level meetings coming up

Against the backdrop of political manoeuvring EAPM has plenty on its plate in June, which will see two roundtables in the Brussels seat of parliament.

These commence on 19 June, with MEPs in the Members Salon, to enable all present - deputies old and new - to gain a better understanding of the issues involved in personalised healthcare.

A second, technically minded roundtable, with Member State representatives on Real World Evidence and HTA ,will take place the day after (20 June) and be structured around an initial framework-setter, followed by various case examples.

A vital part of EAPM's role has always been engagement with EU health attachés and MEPs, as well as continuous involvement in ongoing discussions in our arena.

The long-running STEPs (Specialised Treatment for Europe's Patients) interest group of MEPs, will continue, no doubt with some new faces added in the wake of the EU elections.

Decision on drug prices and transparency

Discussions lasted a while, but the World Health Assembly (WHA) has finally adopted a resolution put forward by Italy geared towards improving access to medicines.

It was never going to be univerally popular, and that has proven to be the case in a deal that has boosted transparency in terms of the pricing of medicines, but still leaves a curtain drawn around key costs for research and development.

Italy's resolution, which was co-sponsored by 20 other countries, is viewed as a way for cash-strapped countries to have better control over their spending on drugs - a problem around the globe, including for richer nations.

The resolution aims to enhance the sharing of information on prices paid by governments and other buyers, and greater transparency on patents, clinical trial results and other price determinants along the value chain from bench-to-bedside.

The process is geared towards allowing countries to make more informed decisions, negotiate more affordable prices and improve access for patients to health products.

Ahead of the WHA meet-up, the health minister of the Netherlands, **Bruno Bruin**s, had called out high drug prices on several occasions, having a particular pop at the EU's policy on orphan drug marketing exclusivity.

Also, through MP **Pia Dijkstra**, the Dutch have said that EU countries should join together to negotiate prices and for negotiations between the Netherlands and pharmaceutical companies for high-cost medicines to be transparent.

Incidentally, the country, with Belgium, Luxembourg, Austria and Ireland, forms the Beneluxa negotiating group, which has reached an underwhelming *one* pricing agreement over medicines in two years.

The same Dutch MP is also calling for the "whole research trajectory with both the positive and negative results" of pharmaceutical research and development to be "open knowledge" and freely accessible.

The Netherlands has plenty going on in the healthcare field, including its ambition for the EU to reconsider the relative interests of the pharmaceutical industry and patients under the next European Commission.

Among its priorities for 2020-2025, the Dutch say that that the EU should "seek to review its legislative framework over the coming years" for medicines, "fostering the development of innovative medicines that contribute to better care and quality of life, at realistic and socially sustainable prices".

The scales need to be rebalanced, the Netherlands feels, and has added that: "The functioning of the supplementary protection mechanisms that are specific for pharmaceutical products shall be looked at closely and adjusted accordingly. The results of the Commission's evaluation of the legislation on medicines for children and rare diseases will be very useful in this respect.

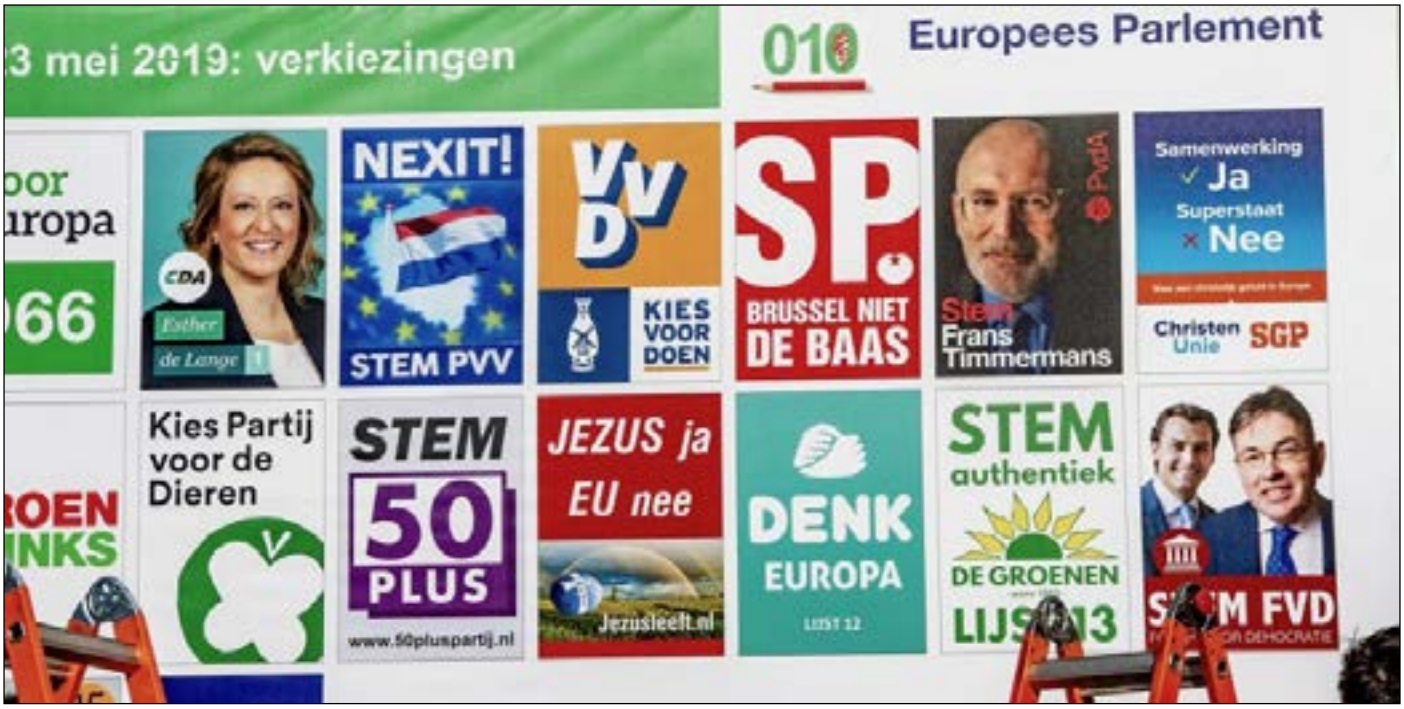
"In addition, the safety of online purchased medicinal products should have more attention."

The Dutch also cite medicines shortages as "an increasing problem" and want "a discussion on the vulnerability of the production and distribution of medicinal products".

Meanwhile: "Equal access to medicinal products that have a centralised marketing authorisation, should be realised."

"The Netherlands will continue to argue that equal access should be pursued, for the benefit of the European patients."

Over in Warsaw, there's an ongoing tiff about whether the president of the Polish National Health Fund (NFZ) can veto contracts that the country's hospitals make with medicines manufacturers.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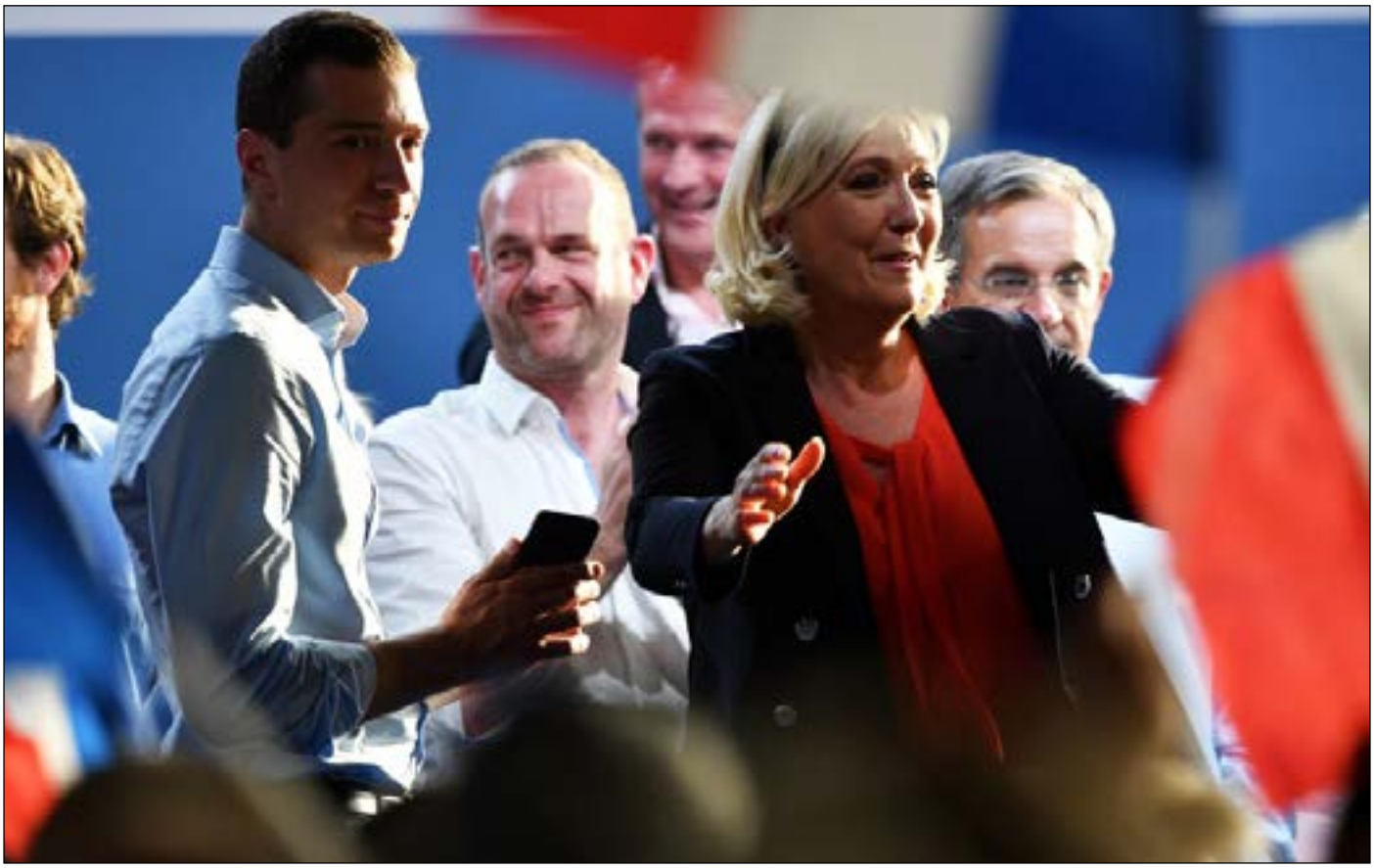


Apparently, hospitals in Poland have been known to make deals with branded drugmakers for a portfolio of medicines that effectively block generic drugmakers from contracts.

Since last July, the president of the public payer has had the right to veto such deals.

HTA never far from the agenda

The battle royal over joint HTA in the EU has been ranging alongside the Brexit to-ing and fro-ing and has filled column inches time-and-again in this newsletter as well as elsewhere.

Now Lithuania, Poland, Slovakia, the Czech Republic and Hungary are thinking seriously about how to conduct joint assessments of medicines, on the back of a cooperation agreement signed between the countries in Warsaw.

This represents a "very important step forward" in the evaluation of products, with the Member States set to meet again soon to pursue their options.

"This agreement between the five states will not only share good practice, but also improve certain activities in the evaluation of drugs, their prices, decisions on their emergence in the market," a statement read.

Meanwhile, Lithuania's health ministry has rushed to clarify its HTA after media reports fuelled fears among the public that the government may limit per-patient spending on medicines to €30,000.

No, no, no said Lithuania, saying that there is "no plan to set limits for the cost of treating one patient". It added that the media reports were "distorting the numbers that are planned to be used in negotiations with manufacturers on drug prices".

While the UK is still with us...

The British government announced plans in May to rework and upgrade a programme that grants speedier approvals to medicines and diagnostics that offer promise in respect of diseases such as cancer, dementia and diabetes.

This Accelerated Access Collaborative programme has supported a dozen what it calls "rapid uptake products" up-to-press, with these including a blood test for pre-eclampsia.

Meanwhile, the UK's Junior Health Minister **Nicola Blackwood** (pictured) has announced that health technology assessment body NICE will undertake a review of its methodology for assessing the cost-effectiveness of new medicines.

According to *Politico*, NICE has until the end of this year to report back on new proposals, and Blackwood has urged companies to come forward with proposals that are "reasonable, fair and evidence based".

Staying in Britain, hospitals in England are preparing for severe disruption to healthcare services in the event of a no-deal Brexit. These could include ward closures, clinical trial suspensions and Parkinson's diagnostics.

Also in the UK, the government has released a one-year review of its artificial intelligence (AI) sector deal, geared towards boosting Britain's industry and investment post-Brexit.

The review states that the UK is a "world leading AI ecosystem" which is home to "twice as many" AI companies as other EU countries.

In the healthcare arena, the AI deal included £50 million to launch five centres of excellence in respect of digital pathology and imaging, plus £50 million to go towards incorporating the technologies into the NHS.

On a less-positive note, NHS England failed to hit its

recommended patient targets for any of the four healthcare screening programmes looked at by the House of Commons Public Accounts Committee.

A report noted that screening for cervical cancer hit a 21-year-low, with just 71.7% of the eligible population actually tested.

Said Labour MP and committee chair **Meg Hillier**: "Our inquiry has exposed a health service that is losing its grip on health screening programmes."

A key reason is an outdated IT infrastructure, which has been "unfit for purpose" since 2011.

But potential good news (well, sort of) for the UK's patients is in the pipeline with the Royal College of Physicians announcing a 2030 vision that will include 15-minute face-to-face patient consultations.

Before you scoff, they currently average less than 10 minutes. It's all relative, right?

And over in the US...

The Food and Drug Administration has approved Bulgaria and Cyprus as part of a mutual recognition agreement for good manufacturing practice inspections for medicines. This allows the two Member States and America to carry out inspections for each other.

There are now 24 EU Member States taking part in the arrangement with the European Medicines Agency expecting all EU countries to be on board by 15 July.

Big Data, big birthday

The month of May saw the first birthday of the General Data Protection Regulation (GDPR) - many happy returns - but, of course, the use of medical data in respect of research and clinical trials is still not fully resolved. This is a favourite topic of the head of the EMA, **Guido Rasi**, who has previously called for urgent clarification in respect of the reuse of data for research beyond the initial purpose for which the patient consented.

Rasi was also widely reported when asking what happens if a maliciously motivated actor is able to identify anonymised data. By which he also meant 'who is responsible?'

The EMA is "continuing to work" with the Commission "so that a good understanding of some concerns expressed by scientists and an application of the GDPR that is compatible with the further development of clinical trials in Europe is achieved, both at national and EU level".

No birthday time off for GDPR, then…

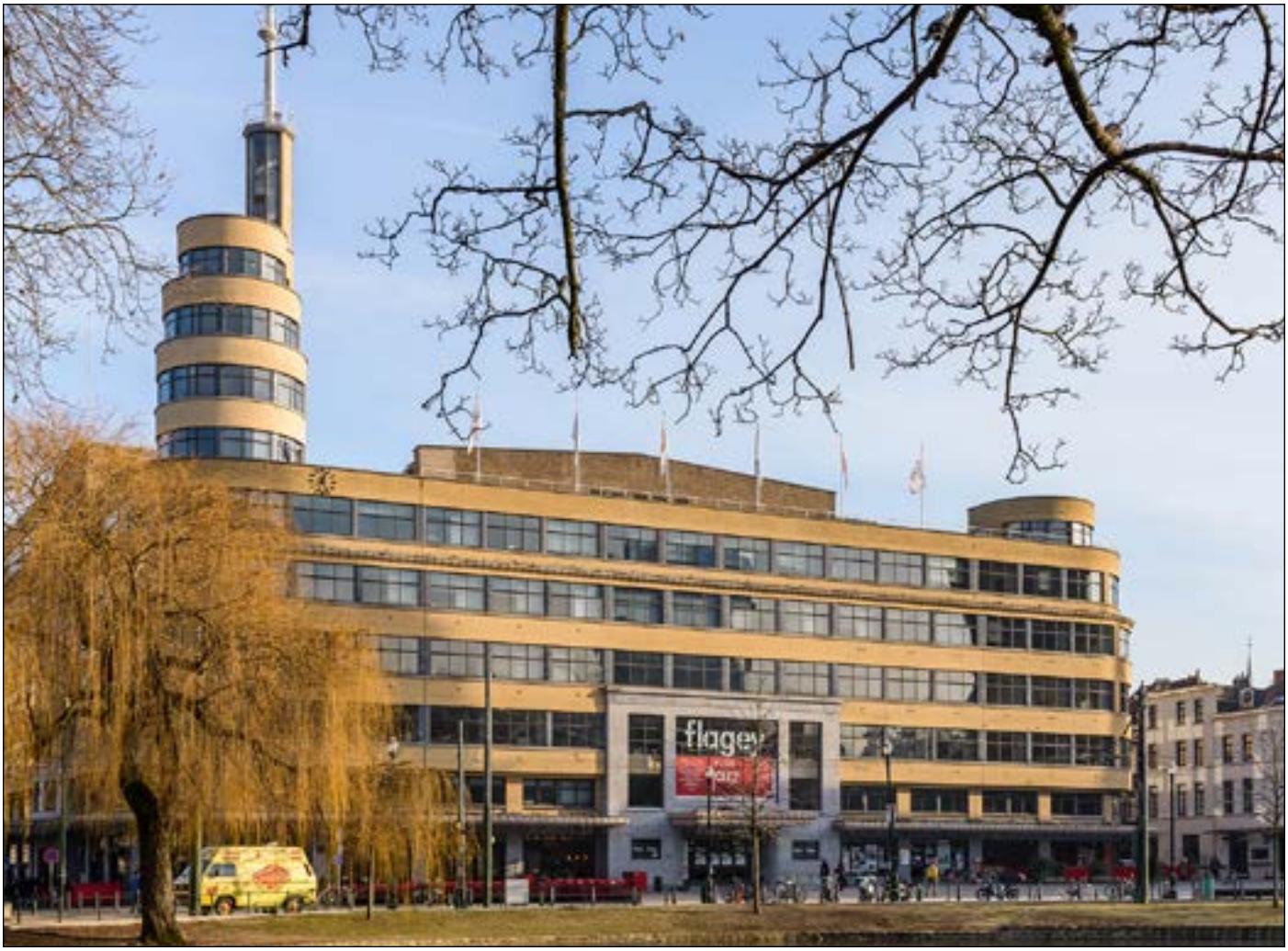
Medical device regs just a year away

And speaking of birthdays, or at least upcoming ones, last weekend (Sunday 26 May) marked a year until the medical device regulations enter into force.

As it stands, there are still only two notified bodies cleared to issue around 55,000 device approvals necessary in the coming twelve months and it's fair to say that stakeholders are getting a little edgy already.

These include Ireland and Germany, both big hitters in the medtech area, who have requested an agenda item at the upcoming Health Council meeting (14 June) to discuss the readiness, or lack thereof, of implementing the regulation in good time.

Current estimates reckon that only 20 notified bodies will be good-to-go by the end of this year. At the moment, the 'old' rules are enforced by no less than 60.



Genomics latest

As mentioned before in our updates, Finland asked for comments 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 *et al*.

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

Meanwhile, in Germany, the German Ethics Council in May concluded there should be a moratorium on human germline interventions, putting the country in line with plenty of academics and researchers across the globe.

It described such work as "ethically irresponsible at the present time because of the associated incalculable risks".

And in Denmark, its new genomics centre was launched on the first day of May, with a showpiece supercomputer system geared towards ensuring "that all patients will have the same opportunities for high quality genetic analysis, no matter where they live in the country".

Not such happy news from France, however, as in excess of 100 doctors called for a boycott of a health ministry database used to allocate resources during emergencies, in the wake of data relating to injured Yellow Jacket protesters apparently having been inappropriately exposed via the system. The doctors want a parliamentary enquiry.

CAR-T

Staying in France, the country's HTA body says it will re-evaluate Yescarta and Kymriah in the midst of concern about the longer-term effects of the expensive CAR-T cancer treatments.

French HTA organisation HAS says it wants annual real-world data so it can "verify the efficacy, tolerance and quality of life in the medium- and long-term of these treatments".

HAS says that understanding how the medicines work after short-term clinical trials is important to "fixing or revaluing the price".

It adds that there "is currently no data on efficiency and security in the medium and long term".

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.

Member states must act together. And communicate better…

Personalised medicine agenda moves to Milan and Sofia

More questions than answers? Let's change that in the Personalised Medicine Era

Prioritizing prostate cancer in Europe (via Berlin) – HTA/Payer Alignment

Talk, talk, talk as politicians set out stalls for upcoming elections

And the winner is…the EU?

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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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