European Alliance for Personalised Medicine

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Brexit uncertainty, but healthcare moves on…

Greetings, all, and welcome to EAPM's March newsletter. At the risk of sounding overly optimistic, winter seems to be slowly on the wane and spring on the way in, so hopefully we'll see some permanent changes in the weather soon, in the wake of some surprisingly warm days.

Even if the weather doesn't change as we would like, as soon as we would like, the end of March and early April certainly look set to bring about changes anyway.

First of all, don't forget that the clocks go forward one hour at 01.00 on Sunday 31 March, so you'll have one less hour that day to cook up that delicious Sunday lunch.

Meanwhile, at midnight CET two days earlier (29th), another major change will come into play - well, probably - with the UK set to leave the EU after much to-ing and fro-ing, ooh-ing and aah-ing, head scratching, conscience-and-soul searching, dark mutterings, arguments and counterarguments, bluffing, blustering, gnashing of teeth, resignations and recriminations, and not a little confusion and chaos.

As if that were not enough, with talk of extending Article 50 amid all this 'guessmology', the will we/won't we? Brexit could have an impact on the upcoming European elections. Why? Because the UK is due to give up its seats in Brussels and Strasbourg after it leaves, with no candidates set to stand in May.

However, if the Article gets an add-on period, then everything is up in the air again. It was ever thus, it seems.

Either way, EAPM will be holding its 7th annual Presidency conference in the Belgian capital on 8-9 April during which, of course, life post-Brexit (or otherwise) in the field of healthcare will be a hot topic for discussion. Meanwhile, all members and associates can rest assured that the Alliance will be heavily engaged in the run-up to the polls.

In fact, in advance of this, during recent weeks EAPM has held a string of video interviews with sitting MEPs on aspects of healthcare, as well as many written interviews with stakeholders. All of this is geared towards gauging the levels of support for personalised healthcare in all its many facets. Links to these will be disseminated in due course.

In the pipeline:

- **8-9 April: EAPM 7th annual presidency conference, Brussels**
- **19-22 June: 4th annual Summer School for HCPs, Leuven**
- **18-20 November: EAPM 3rd annual Congress, Brussels**

What's been happening?

It recently emerged from Eurostat that an average 34% of EU citizens find that **healthcare** is "somewhat" of a **financial burden**, while an extra 11% describe it as "heavy".

It seems that the burden falls mainly on households with two people, where one is at least aged 65. The remaining 55% feel that the amount they pay for medical care is not burdensome at all.

Meanwhile, Eurostat also reports that across 2017 around 38% of EU citizens saw their **general practitioner** once or twice. In the same year 25% saw their GP three times, with 14% seeing their doctor six times. The highest levels at both ends of the scale came with the Danish, of whom 28.6% went to the doctor's ten times or more while, in Greece, a massive 60.5% didn't see their GP at all during the same period.

A quick update, now, on Italy and its stance on **drug pricing**: *Politico* reports that the country's Health Minister **Giulia Grillo** has said that tackling pricing is a "moral obligation", with Italy campaigning hard for price transparency.

Prior to the World Health Assembly in May, Rome has called on global leaders to give the WHO an "authoritative mandate" to work on the transparency in the areas of R&D costs and the pricing of medicines.

This would task the WHO with collecting and analysing outcomes of clinical trials and adverse outcome reports, as well as providing a venue for governments to share drug pricing information, revenue, R&D costs, and more.

Italy, readers may remember, signed up to the Valletta declaration, making it one of a group of 10 countries trying - and so far failing - to negotiate drug pricing agreements *en masse*.

The head of Italy's medicines agency AIFA, **Luca Li Bassi**, said: "The goals and the spirit which animate the cooperation signed

in the Valletta Declaration are the same that are promoted in the draft resolution proposed by Italy to the WHO. This latter just gives evidence of the extent of the issue: a global question which urges a global framework of interaction and cooperation."

Over in the UK, the nation will undertake an independent review of its **national cancer screening programmes** - long-advocated by EAPM on a Europe-wide basis in the case of lung cancer - as London aims to boost earlier detection and, therefore, prevention.

Prof Sir Mike Richards, the first cancer director of the National Health Service, will recommend down-the-line how to upgrade current systems to ensure that patients get access to novel technologies and treatments. (Meanwhile, in Romania, a civil society-driven national registry of all cases of paediatric cancer from 2010 to 2017 has been introduced.)

Also in the UK, NICE seems to be making progress on patient-centred care, against a backdrop of concerns that patient preferences are not being included early enough in clinical trials.

Working in a pilot scheme with Novartis, NICE has now provided advice on how to design a patient-preference study. The pharmaceutical giant is developing treatments for chronic obstructive pulmonary disease.

And, goodness, we're certainly going to have to look further afield for newsletter items after the UK departs, as here comes another one from Britain:

Health Secretary **Matt Hancock** has promised "a chief information officer or a chief clinical information officer on the board of every local NHS organisation within the next three years".

This will amount to the introduction of steps the NHS should take to embrace digital technologies in healthcare.

Eric Tool, a US geneticist, was commissioned by the health ministry to write the review in support of the NHS long-term plan. He recommends, among other items:

- Establishing accredited training programmes for health professionals to incorporate genomic testing and counselling into their practice

- Assigning board-level responsibility for adopting digital technology

- Boosting genomics, data analytics and AI curricula within five years

- Offering healthcare students opportunities to study computer science, as well as trying to draw computer science students into the field of healthcare

SPCs

At last, we have clear movement on the **supplementary protection certificate manufacturing waiver**, after EU deputy ambassadors approved the deal to allow generic drugmakers to manufacture copycat drugs for export while still covered by the patent extension in Europe. Next, it should go to European Parliament plenary in Strasbourg (11-14 March).

The generics industry is reasonably happy, as the agreement as it stands includes a six-month stockpiling provision and applies to all SPCs, even if they haven't yet taken effect beyond 1 July, 2022.

This came in the wake of branded drugmakers opposing such stockpiling and pushing for a much later application date.

However, these same branded pharmaceutical companies won the fight over notification, with generics manufacturers required to notify the SPC holder and the national IP office of their intent to manufacture.

That must include the name of the EU country in which the manufacture will occur, plus the marketing authorisation reference number in the country to which they plan to export.

EAPM

7th Annual Conference

BRUSSELS

8–9 April 2019

4th EAPM SUMMER SCHOOL

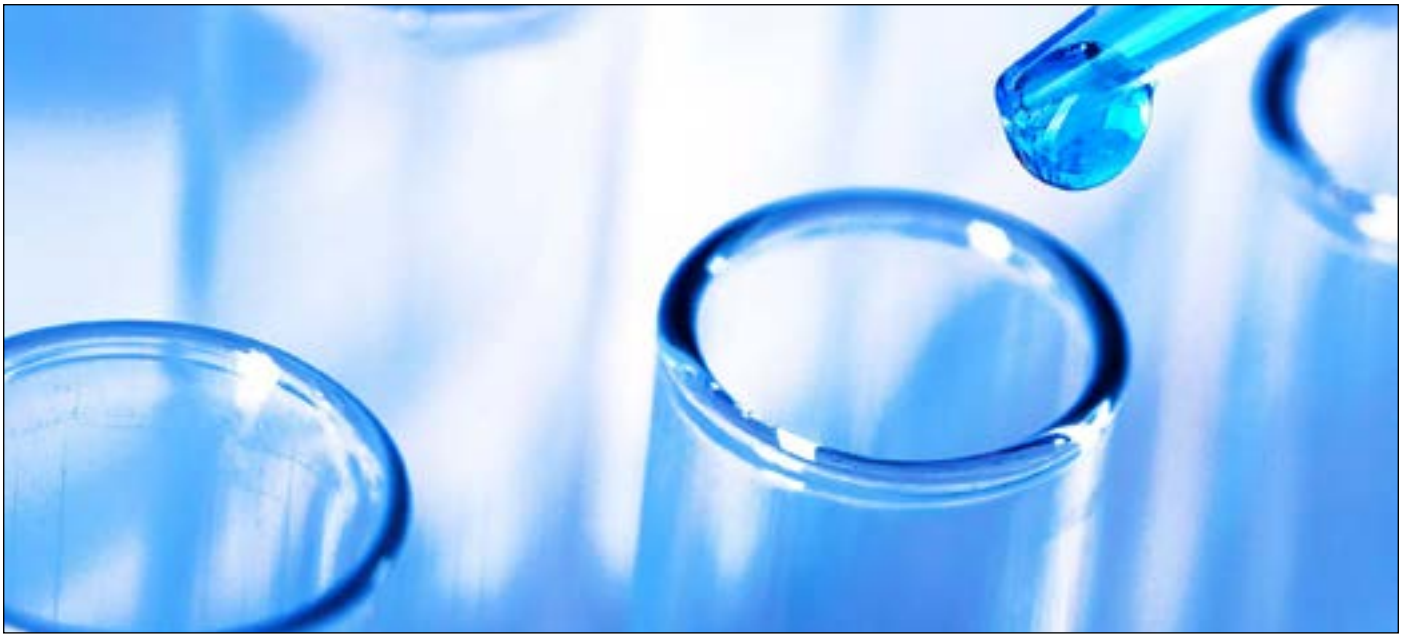
19–22 June 2019 // Leuven

EAPM

3rd Annual Congress

BRUSSELS

18–20 November 2019



Speaking on behalf of pharma lobby group EFPIA, **Andy Powrie-Smith**, described the notification process as "a means to ensure legal certainty and to allow practical monitoring of the compliance of the waiver's conditions".

EFPIA's generic counterpart, Medicine for Europe, is not so pleased as the notification will require their members to publish commercially sensitive information. Its legal affairs officer, **Sergio Napolitano**, went on record to say: "You are basically telling everyone…where you are going to launch your products."

EuropaBio isn't happy, either. The group represents biotech companies, including small ones working on rare disease treatments, and EuropaBio said the latter would be hit hardest by the waiver.

Its Secretary-General **Joanna Dupont-Inglis** described the waiver as "a regrettable example of well-meant but, ultimately, counterproductive policy making, with far-reaching negative impacts on EU competitiveness".

She added: "These companies, seeking treatments for some of our most devastating and difficult to tackle diseases, take the highest financial risks and rely heavily on investors' money, often without making any profits for years."

Cross-border healthcare in the mountains...

Health Commissioner **Vytenis Andriukaitis** and his colleague **Corina Creţu**, the Regional Policy Commissioner, recently took advantage of the launch of a pilot programme to improve cross-border healthcare in the Pyrenees to push the case to use cash from the EU budget's cohesion funds to invest in cross-border healthcare in the broader context.

Under the Pyrenees arrangement, France, Spain and Andorra will treat patients from across the borders in emergency situations.

The Commission had asked for 15% of cohesion funds to be used for such cross-border cooperation in its budget proposal for 2021-2027.

The health commissioner highlighted Eurobarometer data (that we've also mentioned many times) showing that 70% of Europeans want the EU to do more in health. Andriukaitis said that cohesion funds can "make a difference on the ground…and show that the demands expressed by fellow Europeans are not left unheard".

Meanwhile, given the well-justified concerns that the 2011 moves to implement cross-border healthcare have, let's be kind, been less successful than everyone hoped, MEPs now want the Commission to create guidelines for Member States to help patients compare the cost-effectiveness of treatment abroad against that in their own country.

On top of this are calls to encourage EU countries to build consistent reimbursement programmes for telemedicine, as well as a wish for the EU Executive to "negotiate a solid agreement with post-Brexit UK on health, devoting specific attention to cross-border rights for patients", and the European Reference Networks for rare diseases.

Research

More on cancer…EU ministers have met in Brussels on the topic of Horizon Europe, aiming for political endorsement in the (heavy spending) areas for missions and partnerships in the period post-2021.

They also spoke about a research mission on cancer, and a partnership covering "faster development and safer use of health innovations for European patients, and global health".

Any decision does not represent a formal Council one, but is a necessary step in the process - as is a public consultation, so the clock is ticking if the full Horizon Europe programme is to be agreed before the May elections (yes, another ticking clock…).

The latest version of the Council text is still being worked on, and is set to appear before Coreper on 8 March.

Back to the UK and (no surprises, here) Britain is set to lose access to major EU research streams under a no-deal Brexit, according to a House of Lords committee. This will include the European Research Council and the Marie Skłodowska-Curie Actions exchange programme.

The Lords EU Home Affairs sub-committee criticised the

European Commission for being "unwilling to engage" in talks on no-deal contingency plans.

On top of this, the committee said that **Theresa May**'s government should seek to negotiate participation in the 2021-2027 Erasmus exchange programme, as well as in Horizon Europe.

The report said that: "The Government should ensure UK universities retain full access to EU funding opportunities and can participate in, and lead, collaborative research projects," while backing agreements "to maintain the free flow of data and regulatory alignment for clinical trials and chemical registration".

Data protection and ethics

Everybody's old friend (or maybe not) Facebook is in the doghouse again, having been hit by a **patient privacy** challenge in the US.

The country's Federal Trade Commission has received a complaint saying that Facebook needs to cough up billions of dollars for misleading patients about the privacy of its online forums. Not only that, the online giant is accused of failing to notify patients of a major breach of sensitive health information.

This has arisen through Facebook's Groups platform, which hosts what appear to be closed groups which millions of people use as a "lifeline to help and support each other through traumatic experiences", often sharing sensitive medical information. However, the confidentiality of the groups is now in question, it seems.

The quote above, by the way, comes from **Andrea Downing**, who is co-moderator of a group for breast cancer patients. She added: "It's important for members of these groups to know they're at risk."

And in Ireland, Health Minister **Simon Harris** (pictured) has secured approval from the government for a bill to establish a national research ethics committee.

As it stands, there are a dozen research ethics committees in Ireland, which each assess all types of clinical trials for the entire country. 'Unnecessary duplication', anyone?

The minister wants to create one national committee, in order to "maximise synergies and value-for-money outcomes and make Ireland a more attractive international location for all health research", according to his ministry.

The development has been described as "long overdue" by **Darrin Morrissey**, the head of the Health Research Board.

eHealth

As mentioned previously in EAPM despatches, a task force of EU and national medicines regulators are working on ways to move forward with using Big Data to evaluate and monitor medicines.

A new report by the Heads of Medicines Agencies-European Medicines Agency Joint Big Data Taskforce sets out 'what' needs to be addressed. But, it says, 'the which', 'the how' and 'the when' will need further work.

(It is perhaps superfluous to add here that EAPM has been pushing for exactly this for some considerable time, but we'll say it anyway.)

In a huge surprise to absolutely nobody at all, one key recommendation is data standardisation alongside promoting the use of global standards.

Among other suggestions are to establish minimum quality standards for data, promote data sharing and access, and ensure effective implementation of the new medical device regulations. At least somebody appears to be listening…

Meanwhile, an exchange between Health Commissioner Andriukaitis and Croatian MEP **Dubravka Šuica** (recently interviewed by EAPM) highlights the tension between the Commission's recommendation for the sharing of cross-border electronic health records and the reality.

Šuica, in a written question, said she understood the value of eHealth to facilitate cross-border communication and boost data sharing for research. "However," she added, "there are two major problems with eHealth systems.

She pointed out that older citizens are not computer literate and that there is a lack of infrastructure, citing many rural areas

in Croatia which may not have access to the internet.

Not surprisingly, the commissioner pointed out that healthcare services are a national competence and that it's up to Member States "to determine the speed of digital transformation of health and care systems and to ensure that it is done in a non-disruptive manner".

He added that the Commission's role is to "encourage cooperation" and "lend support", while noting that around €1 million in EU money from the existing seven-year budget has gone towards investment in skills such as digital literacy.

Andriukaitis (above) added that the next long-term budget will "support the underlying infrastructure expansion and improvements needed", such as greater broadband access.

But there are other problems out there, certainly with respect to those electronic health records, with the early results of a survey undertaken by the European Patients' Forum showing that "many patients across the EU either do not have access to their [electronic health records] or were not aware of it".

The EPF has called for patients' information to be "easily findable and understandable".

HTA (lest we forget...)

A healthcare body in Germany has highlighted what it calls a lack of transparency in the EMA approach to health technology assessment, targeting the European Medicines Agency approach to engaging early with pharmaceutical companies.

The Institute for Quality and Efficiency in Health Care (IQWiG), which represents the scientific half of Germany's two-tiered HTA, wrote in its reply to the European Ombudsman's consultation on the matter that the "lack of transparency" has already been "problematic" for German HTA.

It went on to say that: "There have been a number of cases, where medicine developers stated that specific study design features criticised in the discussion during the HTA, had been based on recommendations from regulatory scientific advice."

It contended that: "Without transparent information on the regulatory scientific advice in the public domain, the participants of the HTA discussion do not have the possibility to assess this information."

This is not the first and only gripe Germany has with HTA processes, of course, given its opposition to the Commission's plans for mandatory EU-wide joint HTA.

Meanwhile, as we all suspected, the Council won't be ready for trilogues on HTA ahead of the May Parliament elections.

The rapporteur for the file, **Soledad Cabezón Ruiz**, has referred to the current situation as '*Groundhog Day*,' in the wake of Member States resisting time-and-again the EU-wide HTA cooperation mentioned above.

Meanwhile, going briefly back to issues of **transparency**, it seems that in excess of half of all due **results from clinical trials** are missing from the EU's Clinical Trials Register, says a report by Health Action International.

All trials should be registered with the EU and a summary of the results reported within a year of trial completion. But, as of late January, 46% in this bracket were missing results.

On top of this, a huge number of long-completed trials are still listed as ongoing. Add all that up, and at least 3,500 due clinical trials are missing results.

It turns out that is is not largely the fault of the pharma industry as universities and non-profit organisations have a worse record for publishing trial results in the register.

The report suggests that a whopping 89% of trials sponsored by universities across Europe are missing results (not including the UK).

As ever, EAPM is fully engaged in political communication and political engagement on all of the above topics, both at an EU and Member State levels.

7th annual Presidency conference

Brexit or no Brexit, EAPM will hold its 7th Presidency Conference in Brussels on 8-9 April, with a half-day roundtable on

lung-cancer screening on the 8th, just prior to the annual Alliance event. Both will be held in association with the Romanian Presidency of the EU.

The 7th annual event, entitled "*Forward as one: Healthcare Innovation and the need for policymaker engagement*", comes on the back of the organisation's second annual Congress, which was held in Milan in November 2018.

This year's main Alliance conference will, of course, be slightly different from most of its previous large-scale events, in that the 2019 edition will take place during the run-up to the European Parliament elections in May and the new Commission entering the Berlaymont further down the line.

To register for the main conference, click here. Click here for the agenda.

All bets may be off at the moment, but Brexit may actually have happened by the time of conference and this year, above all years, sees a clear need for the EU to take a leadership role in the arena of healthcare, both for Europe's patients and citizens, as well as to create an ecosystem to generate necessary innovation.

On the other hand, as mentioned in this newsletter's intro, we may still see the Brits campaigning for seats again if Article 50 is extended.

Either way, the EAPM conference will allow for a bridge to national representatives in order to further build on the developments that the Alliance has helped to architect in various policy areas.

The event will attract 100s of Life Sciences thought-leaders, with a key aim of the event, as ever, being to allow cross-fertilisation between the different disease and policy areas, allowing delegates to gain a greater depth of knowledge into barriers in the field of personalised medicine.

An over-arching goal of EAPM conferences is, of course, to engage politicians and lawmakers in the fast-growing field of personalised medicine, and deliver political asks through our consensus-based process.

Europe needs to grasp the fact that health equals wealth and that investment in research and innovation, alongside laws and rules that are fit-for-purpose and reflect the swiftly changing world of medicine, are vital.

Hence the continued interaction with MEPs, Commissioners and Member State health leaders.

Key topics to be discussed in Brussels will include:

- Personalised medicine and the innovation agenda
- Technology developments
- Hematology with respect to personalised treatment
- Personalised prevention
- The regulatory framework surrounding pharmaceuticals and diagnostics

Also on the table at conference will be the development of the MEGA initiative (initially named by EAPM and standing for Million European Genomes Alliance), which has clearly demonstrated a willingness on the part of many Member States, and the regions within them, to collaborate when it comes to data sharing in healthcare.

But it is not only in genomics, but much broader (hence it is now MEGA+). Various data sets could and should be shared, from hospitals, electronic health records, digital phenotypes, wearables, biobanks and many more resources now available.

Once again, conference will bring together the different stakeholder streams in all topics in order to allow decision makers to understand changes that are required, across the spectrum of EU healthcare systems.

It is also geared towards offering up valuable evidence and stakeholder opinion on which policy makers can base their decision making on how better to integrate personalised

medicine into the EU's healthcare services, and acts a one-stop shop for all stakeholders in the arena.

Ahead of the conference, the roundtable will put forward the case for lung-cancer screening in an event entitled "*Saving Lives, Cutting Costs*".

Post-roundtable, EAPM expects to present a rationale explaining why current and incoming MEPs should support an EU-wide programme.

The Alliance has long had a focus on prevention, not least through screening programmes, and, during the course of several events on the topic since its formation, it has looked at the right preventative measures to ensure reliable and sustainable healthcare for the long-term benefit of patients now and in the future.

Among the arguments in screening's favour are the fact that the long-awaited and now released NELSON study into computed tomography, or CT, screening for lung cancer showed that it reduces lung cancer deaths by 26% in high-risk asymptomatic men. The findings also indicate that with screening the results could be even better in women.

It is clearly time to move forward, not least in the context that the disease kills more Europeans than any other cancer. A cornerstone of the strategy is to produce a coordinated plan on lung-cancer screening.

Among the speakers at the event will be **Corina Silvia Pop**, State Secretary, Ministry of Health, Romania, **Giulia Veronesi**, Humanitas Research Hospital, Milan, and **Regina Beets-Tan**, of The Netherlands Cancer Institute.

Several MEPs are expected to attend, including **Cristian Busoi** (pictured), **Francis Zammit Dimech** and **Adina Valean**, joined by Perm Rep Health Attachés from Finland, Hungary and Croatia.

Jorgen Vestbo, ERS Advocacy Council Chair, **Harry de Koning**, Department of Public Health, Erasmus MC, and a key representative from the European Commission will also take part, as will **John Field**, Professor of Molecular Oncology, University of Liverpool, **Jan Van Meerbeeck**, Head of ERS Thoracic Oncology Assembly, **Hans-Ulrich Kauczor**, Medical Director, Department of Diagnostic and Interventional Radiology, Heidelberg University Hospital, and **Ewelina Szmytke**, Vice-President, Lung Cancer Europe.

EAPM will be represented by its co-chair and cancer expert **Gordon McVie**, alongside executive director **Denis Horgan**.

And finally...

Researchers have genetically modified chickens that they say can lay eggs containing medicines for arthritis and some cancers.

Apparently, these medicines are 100 times cheaper to produce when laid than when being manufactured in the factories of pharmaceutical companies.

Those researchers working in the area believe that production can eventually be scaled up to produce medicines in commercial quantities.

According to **Dr Lissa Herron**, of Roslin Technologies in Edinburgh. the chickens do not suffer and are "pampered" compared to farm animals.

"As far as the chicken knows, it's just laying a normal egg. It doesn't affect its health in any way, it's just chugging away, laying eggs as normal," Dr Herron said.

The team in Edinburgh managed to reduce costs by inserting a human gene into the part of the chickens' DNA involved with producing the white in the chickens' eggs.

All the best to these, ahem, plucky researchers…

In the news

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

AI and Robots in the healthcare context: The pros and cons

Brexit confusion…but personalised medicine following a clear path

European Parliament confirms position on HTA as chance of pre-election deal disappears

Cross-border healthcare needs to be better implemented

Last Tango in Paris (and Madrid, and Budapest, and Amsterdam, and…)

Car trouble: Germany debates #DieselFumes ahead of Lung Cancer summit

MEPs face camera on healthcare in EU

Politics, people and healthcare across the spectrum

When you wish upon a star. Well, 12 stars, actually…

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About EAPM

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

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

The mix of EAPM members provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry. Relevant departments of the European Commission have observer status, as does the EMA. EAPM is funded by its members.

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