European Alliance for Personalised Medicine

EAPM Bulletin: Issue 49, April 2019 www.euapm.eu

There'll be no April Fools at EAPM conference

The times they are a-changing. Yes, they literally are, with the clocks going forward at the end of March (not quite for the last time, it appears). It's not much fun losing an hour's sleep, but there have certainly been a few sleepless nights in the UK of late.

April of course always gets under way with 'All Fools Day' yet, when it comes to the silliness that has surrounded Brexit, there's nothing new to see here.

The UK's ideas of future cooperation with the EU may remain a mystery to most of us - we'll know more, perhaps, in the next few days - but one thing is for certain, despite a distinct lack of cooperation in the House of Commons, Europe needs to cooperate more on healthcare, with or without Britain.

Current and would-be MEPs are certainly aware of that, ahead of the late-May European Parliament elections.

The ongoing debate around the health research budget for Horizon Europe, and arguments over mandatory joint action on HTA, need to come to a pan-European conclusion as soon as possible, preparing the ground for going forward.

Of course, the Brexit process continues to throw up scenario after scenario - with the EU 27 having granted an extension to 22 May if the UK's 'divorce bill' passes at the third attempt.

The date falls one day before polls open for the European elections in which, as time of writing, the UK will play no part.

The pressure is really on Britain's Prime Minister **Theresa May** (yes, again), with another momentous week in the House of Commons ongoing.

Deal or no deal? April 12 or May 22? Never? We still don't have a clue even though more than 1000 days have already passed since the referendum.

Elsewhere in this newsletter you'll find a section devoted to 'no deal' scenarios, in the UK and beyond, in respect of healthcare.

Clearly nothing much is certain, as we're all getting used to, but the date of EAPM's 7th annual Presidency conference is fixed for 8-9 April in Brussels, so on that you can rely.

Register here

Amidst all the chaos, the Alliance is 'getting on with other business', and this year's event (under the auspices of the Romanian Presidency of the EU) is entitled "*Forward as one: Healthcare Innovation and the need for policymaker engagement*".

In the pipeline:

- **8-9 April: EAPM 7th annual presidency conference, Brussels**
- **19-22 June: 4th annual Summer School for HCPs, Leuven**
- **3-5 December: EAPM 3rd annual Congress, Brussels**

As ever, the conference will allow for a bridge to legislators and others in order to further build on the developments that the Alliance has helped to architect in various policy areas.

A special event on lung-cancer screening also forms part of this year's busy programme, so don't miss this opportunity to join large numbers of industry professionals, government regulators, patients, academics, researchers, healthcare journalists and more into driving insights into action.

Congress to gather in December

From 3-5 December, also in Brussels, EAPM will hold its 3rd annual Congress after the successes of Belfast and Milan.

Entitled '*Forward together with innovation: The importance of policy making in the era of personalised medicine*', it will be held in the Belgian capital to make the most of the fact that the new Parliament will be in place after the summer elections - it is political group week in the Brussels seat - while a new European Commission will be in the process of being formed, ready to formally move into the Berlaymont not long afterwards.

The event will be held under the auspices of the Finnish Presidency of the EU, which will run from July to December.

As well as acting as a one-stop shop for all aspects of the growing field of personalised medicine, attendees and partners will be able to meet and interact with policy makers in the shape of MEPs old and new, Commission officials and Member State government representatives.

The opportunity will be firmly grasped to engage relevant Directorates-General in order to pass on needs and aims while prioritising work plans going forward, especially on the complex

topics surrounding fully integrating innovation into Europe's healthcare systems.

To aid the ongoing process, regulators, payers, investors and, of course, medical experts, patients and healthcare journalists will also be present.

As mentioned, a key aspect is that the event will be held at the perfect time to engage incoming Members of the European Parliament, who will have only recently been designated their dossiers for the five-year term.

Not only that, but the timing at the end of the year means that many conferences and Congresses will already have taken place across 2019, allowing EAPM and its attendees to review the latest developments and communicate with policy makers.

Essentially, the 3rd annual Congress will provide the ideal space to allow for a meeting of minds and expertise and represents a vital opportunity for top-level discussion and the formulation of real action plans, for example in the area of translational research.

It is expected that up to 1,000 Life Sciences thought leaders will convene at the event, which will bring together key audiences who contribute to the vast programme content, themed tracks, and vital knowledge exchange.

Cancer on the agenda

EAPM's December Congress also has a special session on cancer.

According to the World Health Organization, new cases of cancer globally are expected to increase by 70% over the next 20 years, from around 14 million to 25m.

In Europe, the battle against cancer needs to be fought at EU level - and this may be aided by the fast-growing field of personalised medicine, with its goal of giving the right treatment to the right patient at the right time.

Few national cancer plans incorporate personalised medicine as this new science was in its infancy when most NCPs were established. EU Member States may need support in developing their NCPs to incorporate biomarker testing as an essential and standard part of best clinical practice.

What has become clear during the emergence of personalised medicine, with all the new technologies underpinning it, is that there is a need for investment in healthcare professionals to bring them up-to-speed with modern methodologies, and therefore ensure that the necessary skills are out there in the marketplace.

This is as true, if not truer, in oncology as in any other sphere.

On top of this, smarter use of resources needs to be brought to bear to future-proof healthcare systems, which are creaking under the strain of a lack of hard cash and more people with chronic diseases.

Healthcare Battle of Britain

Britain's famous National Health Service is treating record numbers of people these days - but waiting times for non-urgent care and cancer treatment are worsening.

This was announced in a report from the National Audit Office. Staff shortages in diagnostic services, a lack of available beds and emergency care pressures are all contributing to the problem.

Maybe nursing grants will help? A report from the Nuffield Trust, King's Fund and Health Foundation made recommendations in order to prevent the health and care workforce crisis from getting even worse.

The cure could be more nurse training places bringing 5,000 more students onto courses each year, plus an increase, by a factor of three, in the number of people training as post-graduates. An increase in overseas recruitment is also suggested. Good luck with that. Which brings us to...

EAPM

7th Annual Conference

BRUSSELS

8–9 April 2019

4th EAPM SUMMER SCHOOL

19–22 June 2019 // Leuven

EAPM

3rd Annual Congress

BRUSSELS

3-5 December 2019

What if the UK leaves with 'no deal'?

Britain's Health Minister **Stephen Hammond** (pictured) has pledged that retired Britons living in the EU would have their healthcare costs covered for a year in a no-deal scenario.

London has asked the EU-27 that current reciprocal arrangements continue until the end of 2020 in the event of a no-deal, in order to "minimise disruption".

Hammond explained that: "This would mean that we will continue to pay for healthcare costs for current or former UK residents for whom the UK has responsibility who are living or working in or visiting the EU and EFTA states, where individuals are not covered by the EFTA Citizens' Rights Agreements."

Other Member States need to agree to that and, if they don't, then the 12-month pledge kicks in.

The minister also said that anyone forced to come back to the UK for health reasons will have access to the National Health Service.

Hammond has, however, been a little more circumspect with regards to the rights of Europeans in the country.

While he has said that their healthcare rights will be protected in a no-deal scenario if they are "living lawfully in the UK on exit day", he avoided any mention of rights for European or EFTA visitors to Britain who may need emergency care.

This is currently provided for under the European Health Insurance Card.

(Hammond's colleague, Parliamentary Under Secretary of State for Health **Steve Brine**, quit this week, by the way, after defiying the government over, you guessed it, Brexit.)

Meanwhile, Care Minister **Caroline Dinenage** has warned social care providers not to stockpile medicines in preparation for a no-deal Brexit.

She has advised care providers to "plan for longer lead times" for medicines to arrive from the EU, up from one-to-two days to probably three.

And prior to developments this week, the UK government had already published a swathe of no-deal guidance documents including advice on how to change a centrally authorised marketing authorisation, known as an MA, to a UK one.

This will happen automatically with firms having one year to submit the necessary data to support the MAs. Up-till-then, companies won't be able to submit variations to their products, "unless there are exceptional circumstances relating to public health".

In the Netherlands, the country's Health Minister **Bruno Bruins** has called on the Commission to take a "coordinated approach" to avoiding medical device shortages in a no-deal scenario.

Bruins added that, otherwise, he'll go DIY and accept medtech certified by UK notified bodies as valid and safe, albeit with strict conditions.

At around the same time, Lithuania became a further EU Member State to warn about the impact on its own medical device supplies.

Good news, bad news...

Good news has emerged from a recent study of breast-cancer screening, with age-standardised mortality rates for the disease across the EU set to tumble to by 9% in 2019 compared to five years ago.

In not so good news, the study, released by *Annals of Oncology*, shows that raw numbers of breast cancer deaths are growing due to Europe's ageing populations, while Eastern Europe is on course to have mortality rates increase across the age groups.

The best trends shown are among women aged 50-69, which is the age group generally targeted by screening programmes, the researchers note.

Also not so good for women is that lung-cancer death rates are falling in men, but rising in females, while pancreatic cancer is set to rise slightly in women. It is stable for men.

Over to bladder cancer and a new patients' group is up-and-running - the **World Bladder Cancer Patient Coalition** - which links groups from the UK, the US and Canada.

And in cervical cancer screening, Britain is seeing what has been described as a "meltdown" in the wake of a government public awareness campaign that encouraged more women to get smears.

The problem being that the campaign launched not long after the planned closure of dozens of laboratories.

As it happens, and as we've flagged before, it transpires that one-in-six UK cancer centres now has fewer clinical oncology consultants than five years ago, with vacancies for clinical oncology posts now double what they were in 2013.

More than 50% of vacant posts have been empty for a year or more, according to the Royal College of Radiologists, with the UK's clinical oncology workforce currently understaffed by 18%.

The lack of investment in staff, says the report, will make it difficult to introduce innovations including immunotherapies.

In Malta, meanwhile, one of the country's current MEPs **Francis Zammit Dimech** praised Valletta's cancer screening programmes but added that more has to be done to raise awareness.

As a member of the EPP, he repeated the party's campaign line that the EU should increase funding for cancer research.

Clinical trials

Over in Italy, the country's drug regulator AIFA put out a report highlighting that, between 2015 and 2017, 885 "deviations" were detected from 197 inspections into good clinical practice.

It called 79 of these critical, 347 major and 459 minor.

AIFA pointed out that clinical trial guidelines are intended to guarantee participants' protection and data reliability, but there have been management failures, poor patient records and failures in drafting clinical study reports.

EAPM has long said that the clinical trial paradigm needs to change, while clinical practices need to be modernised.

Meanwhile, in Denmark, a subgroup of Europe's Heads of Medicines Agencies has adopted a set of recommendations for how to conduct complex clinical trials for personalised medicines in the EU.

The guidelines outline how to assess side effects, the safety of trial subjects and the transparency of data.

On the Horizon...

The deal on Horizon Europe has at last been agreed in principle after a meeting mid-March to reach a political deal on details of the research programme, which runs from 2021.

The European Parliament wants changes to the language on the proposed funding for health research, asking for an emphasis on precision medicine in rare diseases, cardiovascular diseases, rehabilitation for children affected by disabling

pathologies, and new treatment methods for infectious diseases to counteract antimicrobial resistance.

The Commission has proposed €7.7 billion for health research across the seven-year programme, and Parliament is also demanding a say over how the so-called missions will be shaped.

It also wants big increases in salaries for researchers from less-well-off Member States.

Latest on e-health

In the Netherlands, the country's Health Minister Bruno Bruins announced that the government has set up a scheme, albeit temporary, to finance apps allowing citizens to access their electronic health records and support a healthy lifestyle, with developers of chosen apps receiving €7.50 per user.

In the Czech Republic, meanwhile, doctors have been required to start issuing e-prescriptions as of the first day of this year.

Prague's next step, according to Health Minister **Adam Vojtěch**, is to share electronic medical records among providers. This would let GPs, specialist doctors and some staff access electronic records and will "increase both patient safety and quality of care, and promise to reduce duplicate examinations", the minister said.

Ill-fitting genes?

The World Health Organization has essentially just called for an immediate halt to experiments, globally, into human germline gene editing, which changes heritable DNA in humans.

Margaret Hamburg, co-chair of the relevant WHO committee and a former FDA commissioner, is quoted as saying: "The committee agrees it's irresponsible for anyone to continue with clinical applications of human germline gene editing," adding that this "reflects the state of the science and the desire to undertake responsible stewardship of important scientific technologies".

Among the committee's jobs for the next two years is to develop a global standard for human gene editing, and Hamburg said the committee will look at "how there can be a framework for responsible research".

Another plan is to develop a registry for all human gene editing research, to improve transparency and accountability, with funders being obliged to register.

Health-brief MEPs to stand down

Several high-profile MEPs working on health legislation will not be seeking re-election in May.

France's pro-pharma **Françoise Grossetête**, elected in 1994, is grumpy about the direction her party is taking, and asked not to be renominated to the list.

Grossetête told French media outlet *Le Point*: "…today, in our 'bunkerised' party, differences of opinion are ignored and experience is despised".

Meanwhile, Spain's **Luis de Grandes Pascual**, (pictured) notable for being the lead rapporteur on the supplementary protection certificate waivers, won't run again either.

And, perhaps the most surprising of all, rising star **Soledad**

Photo: medkit.info

Cabezón Ruiz (also Spanish), and rapporteur on the health technology assessment legislation, has Tweeted: "I leave grateful," adding that she told her party that she "wanted to start another stage" and is "not about drama or noise."

That may be so, but after just one term she's going out with a bang after her HTA work.

Sticking with HTA, a survey of 26 OECD and EU countries has found that "while routine data are widely collected, they are not systematically used to inform pharmaceutical policies".

Drug pricing

In Italy, the pharmacy lobby Farmindustria has defended the pricing practices of its member companies. This in the wake of Health Minister **Giulia Grillo** (pictured) presenting an international resolution on pharmaceutical pricing transparency calling for a "common systematic approach".

Grillo says this is required to overcome fragmented transparency efforts when it comes to R&D spending and drug pricing.

"Without transparency in the market of medicines there cannot be true competition," she said.

For its part, Farmindustria said pharmaceutical companies are transparent in respect of prices and discounts in Italy.

Meanwhile, Italy's drugs agency AIFA aims to save some €3 billion by removing some medicines from its reimbursement list. These will be those drugs it deems either don't bring benefits to patients or could even be harmful.

And over in the United States, big pharmaceutical bodies are trying to have the EU put on an intellectual property watch-list over concerns related to EU and national pharmaceutical policies, including pricing agreements.

They are also not happy about the stockpiling provision of the supplementary protection certificate waiver, which allows generic drugmakers to stockpile medicines to sell the day after the SPC expires.

The new scheme will include the imposition of HTA for innovative devices to determine if they're actually effective.

Member State news in brief

It's all happening in **Italy**, with the aforementioned busy Health Minister Giulia Grillo turning her attention to a plan for regulating medical devices.

The new scheme will include the imposition of HTA for innovative devices to determine if they're actually effective.

Over in **Romania**, Bucharest has been discussing allowing medical cannabis for patients with chronic diseases to "provide access to innovative treatments that benefit patients".

Also in Romania, the country has agreed to cooperate with Hungary on lung transplants. The country lacks the necessary infrastructure to conduct enough lung transplants domestically, according to newspaper *Adevarul*.

Meanwhile, Romania's Health Minister **Sorina Pintea** has been in talks with private medical care providers to discuss the possibility of government reimbursement for certain services not provided by public hospitals.

The rationale is that such a move would help patients avoid having to go abroad "when the public system cannot provide the necessary services," she said.

And in **Croatia**, Health Minister **Milan Kujundžić** has unveiled plans for a national children's hospital in the capital Zagreb, plus a national cancer prevention plan, the improvement of emergency medical services, the introduction of mobile clinics and changes to the law on mandatory health insurance.

Members of Parliament in **France**, meantime, have proposed an amendment allowing pharmacists to prescribe medicines for certain conditions.

Doctors have called it "an attack on two of their fundamental prerogatives: diagnosis and prescription". Ah, well. That good old silo thinking…

In **Sweden**, the hunt is on for new suppliers of large quantities of flu vaccine to tackle any possible pandemic from next year, when current contracts expire.

Social Minister **Lena Hallengren** said in a statement: "We are now looking to secure access to influenza vaccine in the future."

Germany's parliament, meanwhile, has recently adopted legislation geared towards improving healthcare for users of the statutory health insurance system. The goal is to reduce waiting times and offer more appointments.

Health Minister **Jens Spahn** (pictured) said: "Patients should receive medical appointments faster.

"They are also entitled to good medical care in rural areas. And they rightly demand that we make everyday life easier with digital solutions. In a vital area like healthcare, the state has to work."

The legislation will also mean that health insurers will have to offer electronic health records by 2021.

Also in Germany, the country's Conservative politicians want to ban online pharmacies from offering discounts.

This comes against a backdrop of a warning from the European Commission that Germany's pharmacy pricing restrictions violate the EU's free movement of goods.

In **Denmark**, the government has unveiled its strategy on artificial intelligence, including ethical elements. Health Minister **Ellen Trane Nørby** said in a statement: "We must work to ensure that AI solutions can contribute with everyday life, both for doctors and nurses, where it makes sense."

And finally...

It's a real case of 'oldies, not but goldies' in **Belgium**, where a real tale of woe has emerged from the country. It has shockingly been revealed that 40% of Belgians would cut healthcare for the elderly given the chance.

According to *Le Soir*, four-in-ten citizens who are worried about the sustainability of the social security system say they back "no longer administering expensive treatments that prolong life to those over 85 years old".

Meanwhile, 17% would administer a slap to those falling ill through personal choices such as smoking tobacco and being obese (apparently 'a personal choice'), saying they back the refusal of payments in such cases.

This hardly supports the idea of access to the best healthcare available for all EU citizens, which is a basic human right.

Also in Belgium, the health ministry has updated an online health portal to add their reports of side effects. There may well be a side effect of any Belgian going to visit grandma...

In the news

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

How April could be the end of May… (and the case for lung-cancer screening)

AFCO finds digital role in European election engagement

Brexit bogging down Europe as well as Westminster

Health care: All the latest news from around Europe

Blustery times ahead across Europe

Healthcare gets the personalised touch in Poland

The diseases may be rare, but the problems are common

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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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