European Alliance for Personalised Medicine

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PM has more than the ghost of a chance

Welcome to the November issue of the EAPM bulletin. Hopefully you all made the most of the extra hour at the weekend, are well-rested and perhaps even ready for Halloween.

At least in spirit…

The day after All Hallows Eve is, of course, All Saints Day, and while we don't pretend to be 100% saintly here at the Alliance we do like to think we have our own way of bringing about 'good works'.

For example, as you will doubtless already know, the end of November will see Milan host our second annual Congress (26-28), following on from last year's successful event in Belfast.

As we head rapidly towards the end of 2018 we have, of course, the not-so-small matter of the European Parliament elections coming up (May 2019) and it is part of our ongoing mission – saintly or otherwise - to engage with MEPs from all over Europe, both the old hands and the new intake.

All of our annual events have played a huge part in this process and Milan will be no different.

Our goal is to pass on the key 'asks' to policymakers – and set out ideas that have been drawn together through the expertise of EAPM's multi-stakeholder members and associates working in consensus.

Through the sharing of ideas based on emerging opportunities against the backdrop of new doors being opened by innovation we can all help to successfully embed personalised medicine into the EU's healthcare systems.

If you haven't yet registered for Milan, you can do so, HERE.

A look back at October news...

There was plenty going on last month and this newsletter reviews:

- *Medtech developments*
- *Supplementary protection certificate waivers*
- *The gene genie*
- *HTA*
- *Research and clinical trials*

In the pipeline:

- **7 November: HTA meeting, Brussels**
- **26-28 November: Second Annual EAPM Congress, Milan**
- **4 December: Personalised Health: Ensuring Sustainabilty., EP Brussels**

- *Drug pricing*
- *Electronic health records*

ENVI wants answers on devices regulations

Late October in Strasbourg saw a debate at the European Parliament plenary on implementing the new EU regulations on medical devices (MD) and in-vitro diagnostics (IVD).

The regulations, aimed at strengthening EU patients' access to safe and effective medical devices and bolstering the EU's reputation in medical innovation, entered into force in May last year, with three year and five year transition periods respectively.

Parliament's Environment, Public Health and Food Safety (ENVI) committee tabled a question at the plenary stating that "it is proving difficult to prepare all the necessary elements of the system and, in particular, to designate the necessary notified bodies on time".

"In the interests of public health, efforts must be made to ensure there is no disruption to the supply of medical devices," says ENVI, while asking how the Commission will prevent any future disruption to the MD/IVD supply chain, whether the EU executive can clarify what steps it is taking to ensure coordination within relevant Commission DGs, and whether there are sufficient staff resources to provide the necessary support to the new system.

ENVI also asked the Commission what action it has taken to ensure that all aspects of the regulations will be ready by the end of the transitional period, whether it has considered the impact of Brexit, and whether Member States have the resources required for the successful implementation and coordination of the regulatory system.

Most observers believe that the Commission is generally on track, but EAPM and obviously ENVI will be watching with considerable interest.

Earlier in the same week, *Politico* reported that the managing director of the German medtech industry lobby BVMed, Joachim M. Schmitt, wrote: "The date of application of the EU Medical Device Regulation needs to be adjusted."

May 2020 marks the end of the transition period (it's May 2022 for IVDs), and Schmitt is not overly pleased that just 25% parts (two from eight) of the implementing legislation has been published thus far, while pointing out that the much-vaunted Eudamed database is yet to go live.

Meanwhile a less-than-encouraging 21 of Europe's 59 notified bodies have applied for the necessary re-approval.

If this slow progress is allowed to continue, Schmitt feels that: "The primary market for new medical devices - and with it increasingly research and production - will shift from Europe to the United States."

SPC waiver and generic drugs

Meanwhile, Parliament's International Trade committee (INTA) is debating the supplementary protection certificate (SPC) waiver, with its own draft opinion - under Lola Sánchez Caldentey MEP (pictured above) - recommending changes more favorable to the generics industry.

The waiver exists to allow makers of generic (and biosimilar) drugs to export their copies, despite the medicines being protected in the EU.

INTA also wants to see processes speeded up, and calls for the waiver's immediate applicability "once the public authorities have put in place appropriate arrangements to receive notifications" from manufacturers.

Earlier, the ENVI committee had suggested a stockpiling waiver to allow immediate sale within the EU and INTA's draft wants an amendment to allow "day-1 entry" into the Union's market.

However, ENVI's rapporteur on the matter, Tiemo Wölken, took at tilt at generics industry calls to allow waivers to existing SPCs as well as those down the line.

"It can't be retroactive," he said. "We have to make sure what you did in the old legislation is valid," *Politico* reported.

As for Member States, they are generally in favour of plans on SPC (although not exactly as per the original draft) but, as ever, not all are supportive of all of it.

Of course, as with all ongoing legislation, there is pressure to reach agreement before the May Parliamentary elections, so compromises will have to be worked out against the clock.

Early this month should see the next meeting of the Council's working party on intellectual property, which will discuss the SPC waiver.

Industry has said it wants increased notification responsibilities for generic manufacturers.

The gene genie

Late October also saw Paul Jones, the director of population genomics at Illumina, use his slot at IMI's Stakeholders Forum to highlight the importance of tech convergence.

Cost and time reductions in genomic sequencing mean that "all of a sudden the door has opened," he said, also citing the UK's 100,000 Genomes Project, and calling for positive public support for larger projects.

That support may already there judging by the burgeoning take up of an EU-wide initiative which has seen The Netherlands become the 18th country to join the project to sequence one million genomes by 2022 to enable health-data sharing for research.

Austria, the current holder of the rotating Presidency of the EU, also recently signed up to what began life as EAPM's MEGA initiative, joining those who put pen to paper in April.

At the European Commission's Digital Day 2018, Member States representatives co-signed a Joint Declaration indicating political support for linking existing and future genomic databanks, on a voluntary basis, in order to reach a cohort of one million sequenced genomes accessible by 2022.

The joint initiative aims to share genomic data across European countries in a secure way. Central to the plan is that the data-sharing effort should help to develop more

personalised medical treatments for cancer and other diseases, as well as aid vital prevention efforts.

In France, meanwhile, Health Minister Agnès wants to create a health data hub by early next year, developing a tool to let researchers, health professionals, citizens and more access data from the country's health system, while robustly respecting data privacy rules and ethics.

This will all no doubt please Vytenis Andriukaitis, European Commissioner for Health and Food Safety, who has urged Member States to prioritise digital health going forward.

To insure or not to insure

Meanwhile, Britain's government has signed an agreement with insurance companies which outlines how DNA info can and cannot be used.

The Association of British Insurers says it will not take into account the results of predictive genetic tests, except in cases where a life insurance policy is in excess of £500,000 alongside the suggestion that the person wanting insurance may develop Huntington's Disease.

And staying with insurance, Belgium has proposed a 'right to be forgotten' model under a 2016 French law that allows cancer and hepatitis C survivors the option to not mention the illnesses.

The industry obviously wasn't happy, saying that a history of cancer is one of the only ways for insurers to predict whether people will die from the illness.

HTA debate still bubbling away

Last week, as we have seen, was a busy one and HTA was up for discussion once again. EAPM has its own meeting coming up on 7 November, too.

All eyes are on whether France and Germany, alongside some of Europe's other big hitters, will fall into line with the wish of the Austrian Presidency of the EU, other Member States and Parliament to implement mandatory cooperation on health technology assessments (HTA).

On the other hand, key figures at Germany's Institute for Quality and Efficiency in Health Care say that more EU harmony would not be too terrible in HTA for medical devices.

And even the pharmaceutical industry's voice, EFPIA, has said that: "Delays, inconsistencies and duplication should not be an option: not for patients, not for health care systems and not for the research-based industry."

For its part, Austria is backing Member States' right to carry out additional work on top of the EU-wide assessments, but is keen not to budge on mandatory aspects.

Meanwhile, to nobody's real surprise (certainly not those of us in the Alliance), patients are less than happy that they have been given a lack of say in any newly defined process although, as reported in *Politico*, Austria looks set to ensure that patients and clinical experts will, in fact, be consulted.

Electronic health records (EHRs)

Towards the end of October the European Commission announced that there's now a focus on developing EHRs for the benefit of citizens travelling between countries, for example on holidays – not to mention migrant workers.

To recap briefly, an EHR is a digital version of a patient's previously-paper health chart and history. EHRs are designed to be patient-centered records that make information available instantly and securely to those users who are authorised.

They can contain a patient's diagnoses, medications, treatment plans and much more to create evidence-based tools allowing doctors anywhere to make decisions about a particular patient's treatment needs.

They are intended to share information between healthcare services, labs, specialists, pharmacies, emergency facilities, etc.

The idea is for a greater and more seamless flow of information within a digital healthcare structure in a bit to improve patient care, increase patient participation in decision making, boost coordination in care, as well as improving diagnoses and patient outcomes, upping efficiency and bringing down costs.

Unfortunately, the way EHRs currently function is sub-optimal, with different levels in different Member States. One bit of good news, however, is that Germany – which has perhaps surprisingly been something of a laggard in this respect – could well have decided that the potential benefits of the big data revolution can be balanced against privacy issues.

Newspaper *Handelsblatt* reported that stakeholders have thrashed out a plan that could see EHRs available by 2021 and, in a Tweet, the country's health ministry called it an "important milestone" adding that the government "will no longer accept delays".

Drug pricing, cancer and more...

EAPM was at the ESMO Congress in Munich and witnessed plenty of discussion on generics uptake and health technology assessment - hardly a shock, given the topics.

What was a shock, however, is that members of the European Society for Medical Oncology were shown by a survey to be nervous about not totally understanding the whole biosimilars thing, especially figuring out when they should be used.

As many as nine-out-of-10 oncologists said they want more education while showing only "moderate confidence in their understanding of key concepts".

Price Wars (Part 572...)

The Netherlands was in the news this month, as were Lithuania and Italy, under the catch-all, never-to-go-away topic of pricing of pharmaceuticals..

The Dutch have told the European Commission that, when it comes to calculating maximum drug prices, they will now use Norway rather than Germany as one yardstick.

Lithuania, meanwhile, released a quarterly pricing list of drugs it will reimburse, while recommending that patients plump for the cheapest option after pharmacists show them the lowest-priced drug containing the active ingredient they need, which has previously been identified by their doctor.

And Italy's competition authority has come under fire for targeting South Africa' s Aspen Pharmacare for the prices of its oncology products, albeit by Aspen's own lawyers.

According to *Politico*, the legal eagles argue that Italy is ignoring a key part of the test of excessive pricing - comparing the price level to other similar products.

Research and clinical trials

Research Commissioner Carlos Moedas was forced to ask EU ministers at a Competitiveness Council meeting recently to hold their horses after ministers said they plan to change the legal basis of the Horizon Europe proposal, which will define the bloc's research spending from 2021.

The Commission has given the Council and Parliament equal footing on agreeing the programme's details, but lawyers for the EU are of the opinion that the Council only has to consult MEPs. It's yet another bump in the road for the Commission's plans, and many stakeholders are playing wait-and-see.

Meanwhile, the EU's research funding may launch one of its already famous 'missions' into curing childhood cancer, at the same time as the European People's Party's launched its proposal to aim for "eradicating pediatric cancer" by 2030. Again, many eyes are watching developments.

Congress in Milan draws closer

As mentioned earlier in this newletter; the second annual EAPM-run Congress will take place in Milan from 26-28 November, with the Alliance working in partnership with the Regional Council of Lombardy for the event.

The Congress will pull together leading experts in the arena drawn from patient groups, payers, healthcare professionals plus industry, science, academic and research representatives. You can register now, here.

The event comes under the title '*Forward as One: Integrating Innovation into Europe's Healthcare Systems*', and will amount to an ideal 'one-stop shop' for stakeholders.

In the news

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

Time to sign up for the Congress that reports on congresses…

European Parliament backs EU-wide action but patients denied key influence

HTA debate moves to Sofia for key conference

The personalised touch: Interview with chair of #BAPPM board

Climate change is one thing, Mr President – changes in cancer treatments are another…

Diabetes 'spreading like wildfire' across the globe: Join us in Milan for our congress

ESMO pushing the agenda in the field of cancer – #EAPM ready to respond

Europe needs to make the most of electronic health records

Romania sets its stall out while US aims to trump drug prices

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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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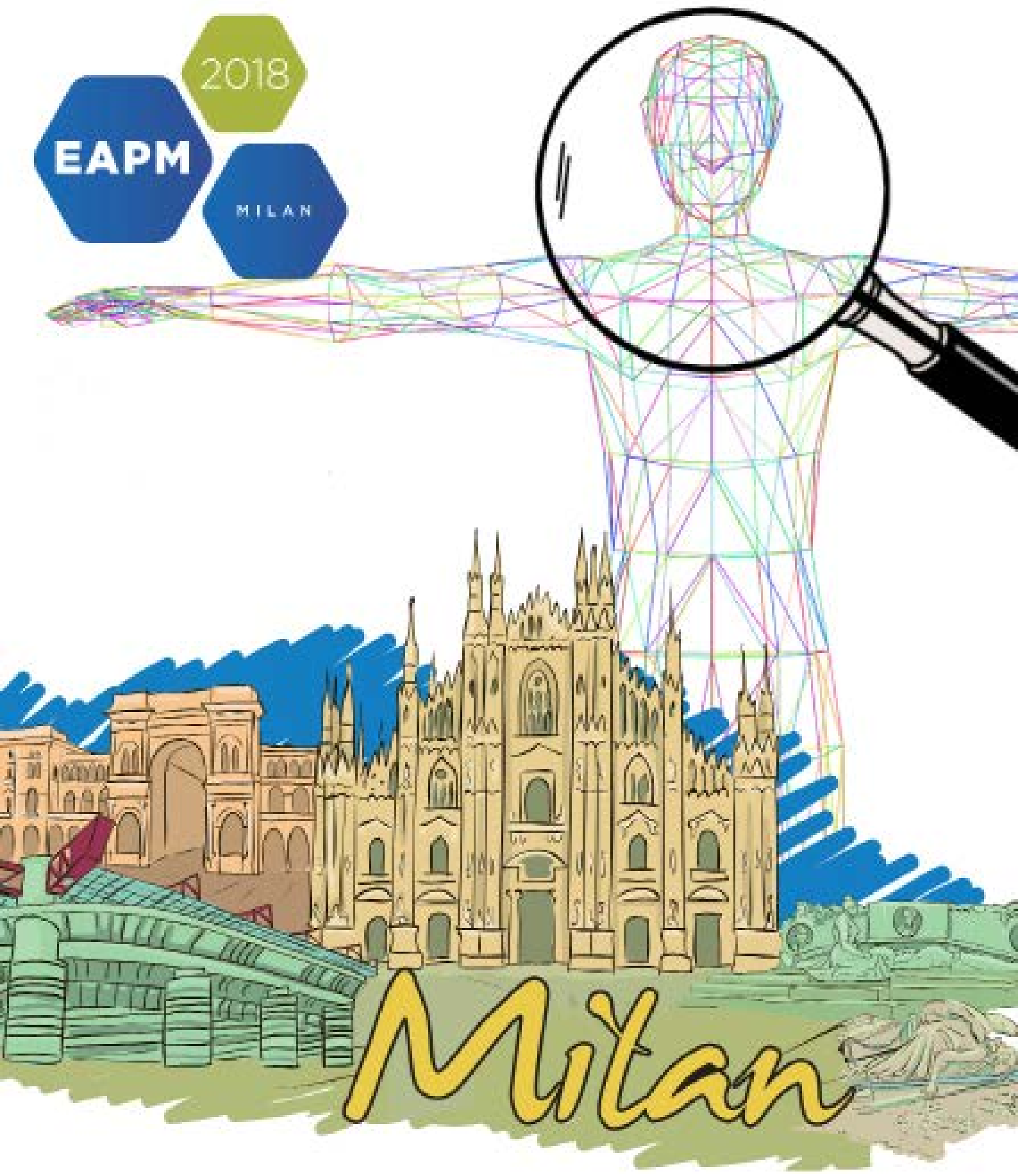

2nd European Alliance for Personalised Medicine Congress

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