



European Alliance for Personalised Medicine

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Next EAPM events

March 8th Presidency Conference 'Forward together with innovation: The why, what and how of tackling the Implementation Gap for healthcare in the EU, Portuguese Presidency of the EU

July, 2021 Building Consensus and taking action to bring Personalised Medicine and RWE into healthcare systems', Slovenia Presidency of the EU

Welcome, health colleagues, to the European Alliance for Personalised Medicine (EAPM) February Newsletter. It has been a busy month, with the formal launch of the Europe Beating Cancer Plan on 3 February, in which personalised medicine was substantially included, and EAPM has also held a round table meeting on serology, the report is available [here](#), and lung cancer fact-sheets have also been published. More information is available in this newsletter, writes EAPM Executive Director Dr. Denis Horgan.

9th EAPM EU Presidency Conference



EAPM's 9th EU Presidency conference, under the auspices of the Portuguese EU Presidency, will take place on 8 March from 9-16, and is entitled 'Forward together with innovation: The why, what and how of tackling the implementation gap for health care in the EU Portuguese Presidency'. Please find the link to register [here](#) and the agenda [here](#).

One of the key sessions during the conference will concern 'The why, what and how of promoting innovation to tackle rare diseases' - in considering what sort of change the regulation may need, it is crucial to recall the intention that regulators and policymakers had when it was developed and introduced. If the aim was indeed that "patients suffering from rare conditions should be entitled to the same quality of treatment as other patients", then it must be concluded that the objective has not yet been met. Far from it.

If it has not yet delivered on its aims, does that mean that the regulation is misguided and misconceived? That would hardly be a conclusion consistent with the evidence, given that in the

relatively short (in the context of drug development timetables) period of its existence it has in fact led to the generation of a large number of highly effective new therapies. It therefore remains the case, as it was in 2000, that it is “necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry.”

And again, in the spirit and letter of the regulation, this means it is still necessary “to provide incentives” for the process, through mechanisms through which “orphan medicinal products eligible for incentives should be easily and unequivocally identified,” and on the basis of “objective criteria”. If the aim is to be pursued, what may be appropriate two decades on is to review the operation of the regulation, in light of imperfections that have been identified as inimical to its objectives, and in light also of the changes – often dramatic – that have occurred in the underlying science and technology and that have opened up new dimensions to the understanding of disease and of therapy.

Europe’s ability to respond effectively to health threats has already been called into question by the coronavirus pandemic. Heroic collaboration between researchers and policymakers has made the first vaccines available at record speed, but Europe still stands before a major challenge that goes way beyond the current COVID crisis.

Sharper identification of the nature of the virus – and any of its mutated variants – as well as greater precision over the effectiveness of vaccines and measurements of immunity are still urgently needed. The mechanisms are available to bring that precision and clarification. Notably, serology testing can help confirm the efficacy of vaccination, and can be used to establish a threshold for protection or immunity. It can also confirm an initial antibody response from vaccination, and provide subsequent tracking of antibody levels at regular intervals.

This was the theme of the recent EAPM round table, the report is [available here](#).

Tumour agnostic therapies

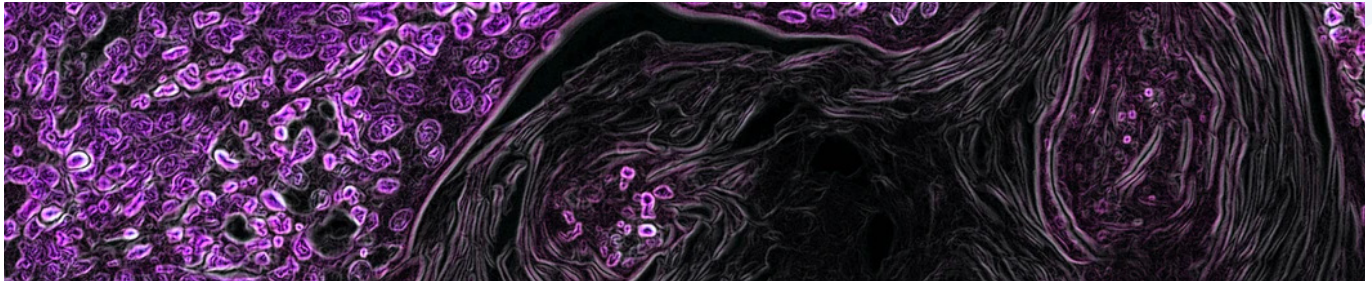
Tumour agnostic therapies was the theme of a recent MDPI report. Entitled ‘Bringing Onco-Innovation to Europe’s Healthcare Systems: The Potential of Biomarker Testing, Real World Evidence, Tumour Agnostic Therapies to Empower Personalised Medicine’.

The increasing number of data supporting use of a personalized approach in cancer treatment, is changing the path of patient’s management. In the same time, the availability of technologies should allow patients to receive the best test for the specific individual condition. This is theoretically true, when a specific test is designed for the specific disease condition, while it is difficult to implement in the setting of agnostic therapies.

Financial sources availability related to the non-homogeneous health systems working in the different countries do not allow for an immediate implementation of the technologies and test commercially available. Future perspectives for targeted oncology include tumoragnostic drugs, which target a given mutation and could be used in treating cancers from multiple organ types. Therefore, the present paper is aimed to both underline a how much important is this new view and also to sensitize the international bodies that supervise health policies at the decision-making level, with the aim of harmonizing cancer treatment pathways in at least all European countries.

The report is [available here](#).

Putting Europe Beating Cancer Plan into practice and tackling lung cancer



The European Commission will be looking to seek consensus from member states' health ministers to move the action plan forward, and it will be an interesting challenge to observe the levels of co-operation from member states on health-related matters following on from the coronavirus pandemic. While member states are in control of health policies, there has nevertheless been divergence between them concerning the COVID-19 re-sponses prepared by the Commission.

Whether member states will align with the ambition as set in cancer plan with the action committee on cancer within the European Commission is unclear but, given that Eurostat's latest data shows that lung cancer is the third leading cause of death in the EU-27, exceeded only by ischaemic heart disease and cerebrovascular disease, one can only hope that the relevant policymakers and institutions will be able to work together.

In 2020, 2.7 million people were diagnosed with cancer and another 1.3 million people lost their lives to it in the European Union. In addition to causing heavy physical and emotional distress for patients and those around them, it places a heavy burden on our health systems, our economy, and on our society. The overall economic impact of cancer in Europe is estimated to exceed €100 billion annually. In all, Europe accounts for a tenth of the world's population, but a quarter of the world's cancer cases. By 2035 cases are set to increase by almost 25%, making it the leading cause of death in the EU. These figures highlight the EU's need to step up its work on cancer with concrete policies. Moreover, the COVID-19 pandemic has severely impacted cancer care, disrupting prevention and treatment, delay-ing diagnosis, and affecting access to medicines.

The EU has indeed been working to tackle cancer for decades. Its actions include tobacco control and protection from hazardous substances, which have already contributed to saving and prolonging lives.

However, the last European action plan against cancer was developed in the early 1990s. Since then, initiatives on cancer prevention and control have included the European Commission Initiative on Breast Cancer (ECIBC) and the European Cancer Information System (ECIS), both coordinated by the Joint Research Centre. The Health Programme has also contributed to joint actions on European Partnership (EPAAC), comprehensive cancer control (CANCON), Innovative Partnership on Action against Cancer (iPAAC) and the European Code Against Cancer (ECAC). The world has seen major progress in cancer treatment in the years since those initiatives were launched. Personalised medicine – tailored to individual situations and needs – has radically changed patients' prognoses.

Meanwhile, research and innovation with the help of digital technologies, have dramatically advanced our understanding of cancer initiation and progression, prevention and diagnosis. Europe urgently needs to renew its commitment to cancer prevention, treatment and care that recognises the growing challenges around cancer and reflects the developments in cancer care. A comprehensive approach across government is needed that focuses on the patient and harnesses the potential of new technologies and in-sights; strengthens cooperation; eradicates inequalities in access to cancer knowledge, prevention, diagnosis and care; and delivers improved health outcomes to patients.



Europe's citizens and patients would benefit from wider adoption of risk-based screening, early use of advanced diagnostics, early access to the growing number of personalized treatment options, better patient follow-up and remote monitoring, and systematic exploitation of data.

With the correct application of new technologies and methods, the principal beneficiaries will be today's – and still more, tomorrow's – patients and their carers and entourage. And correctly implemented, these technologies could even allow healthcare spending and even national economics to gain from a reduction in the consequences and even in the incidence and mortality of lung cancer.

As Europe enters the third decade of the century, significant evidence has already justified action to implement lung cancer screening. It is not the time to be debating whether the evidence is sufficient. The evidence is in. "There is evidence of a benefit of low-dose CT screening compared to no screening," says one of the recent studies.

With its policy objectives, supported by ten flagship initiatives and multiple supporting actions, the Europe Beating Cancer Plan aspires to help member states turn the tide against cancer.

Key flagships will be launched such as the new 'Cancer Diagnostic and Treatment for All' initiative, to be launched by end of 2021, which will help improve access to innovative cancer diagnosis and treatments. It will use the 'next generation sequencing' technology for quick and efficient genetic profiles of tumour cells, allowing Cancer Centres to share cancer profiles and applying the same or similar diagnostic and therapeutic approaches to patients with comparable cancer profiles.

The initiative will ultimately help optimise cancer diagnosis and treatment and reduce unequal access to personalised medicine in cancer care, greatly benefiting patients.

These are key issues that EAPM worked with our members on such as the European Society of Medical Oncology as well as the broader agenda to put on the political agenda. Various academic publications supported this policy.

On imaging, it was announced that the European Cancer Imaging Initiative will be set up in 2022 to develop an EU 'atlas' of cancer-related images, making anonymised images accessible to a wide range of stakeholders across the ecosystem of hospitals, researchers and innovators.

This was the key issue that we have worked with the European Society of Radiology over the years to bring the attention to this unmet need for more coordination at the EU level.

Lest we forget registries, in 2021, the Commission will establish a Cancer Inequalities Registry. It will identify trends, disparities and inequalities between member states and regions. Alongside regular qualitative assessments of the country-specific situation, the Registry will identify challenges and specific areas of action to guide investment and interventions at EU, national and regional level under Europe's Beating Cancer Plan.

Of course, partnership will be launched and there will be a new Partnership on Personalised Medicine, due to be set up in 2023 and funded under Horizon Europe, will identify priorities for research and education in personalised medicine, support research projects on cancer prevention, diagnosis and treatment, and make recommendations for the roll-out of personalised medicine approaches in daily medical practice.

The EU Beating Cancer Plan is [available here](#).

Lung cancer factsheets

Reimbursement of Molecular Testing
Source: Lung Cancer Europe 2020 Position Paper, supplemented by expert input

Country	ALK	EGFR	PD-L1	ROS1	BRAF	MET	KRAS
Croatia	✓	✓	✓	✓	✗	✗	✗
Denmark	✓	✓	✓	✓	✓	✓	✓
Finland	✓	✓	✓	✓	✗	✗	✗
France	✓	✓	✓	✓	✓	✓	✓
Germany	✓	✓	✓	✓	✓	✓	✓

All seven molecular tests for lung cancer are available and reimbursed in Portugal, a better situation than in neighbouring Spain. The stage at which CGP Tests are performed is unclear.

Clinical Implementation in Key Centres
CGP tests performed before initiating treatment:

EAPM has, for the past six months, been very hard at work on developing country-oriented factsheets with leading experts in the field and looks to combat lung cancer across key pillars. Stakeholders' views on national barriers and enablers in tackling lung cancer were obtained via an online survey during seven structured expert panels. Stakeholder groups represented pathologists, lung specialists, the regulatory field, health systems, industry representatives and patient perspectives.

Factsheets covered the following countries and are available here:

[Slovenia](#), [Greece](#), [Portugal](#), [Germany](#), [Denmark](#), [Italy](#), [Belgium](#), [Netherlands](#), [Switzerland](#), [Sweden](#), [Poland](#), [Bulgaria](#), [Croatia](#), [Israel](#) and [Romania](#).

As far as the factsheets are concerned, each concentrate on seven core aspects of lung cancer care, which are as follows:

1. Screening programmes
2. Access to molecular testing
3. Personalised treatment decisions
4. Early and broad access to personalised treatments
5. Remote monitoring and personalized interventions
6. Data empowerment and advanced analytics
7. Prioritization within national health strategy

In addition, each factsheet for each country provides a policy checklist in conclusion.

In the news

‘Mistakes made’ in regulation of coronavirus serology tests, FDA officials acknowledge

In a recent commentary in the New England Journal of Medicine, Jeffrey Shuren, director of the Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA,) and Timothy Stenzel, director of the FDA’s Office of In Vitro Diagnostics and Radiological Health, recounted the agency’s decisions around SARS-CoV-2 serology testing and how an overly lax regulatory stance led to test misuse and confusion within the medical community and population at large. Serology tests look for the presence of host antibodies against disease, which can indicate whether a person has been exposed to an infectious agent and potentially whether they have developed a measure of immunity against it. Development of serology testing for SARS-CoV-2 began to ramp up in the early months of the pandemic. Shuren said: “There are some circumstances in which they have been used, but typically they don’t play much of a role.”

UK adverts urge people to ‘keep going’ and remain at home

An advertising campaign has been launched to encourage people across the UK to “keep going” and remain at home. The government adverts come amid falling infection rates, the success of the vaccine rollout and the launch of the road map out of lockdown. People are also being urged to continue behavioural changes, including social distancing, hand washing and wearing face masks. The campaign will also run on radio, advertising billboards and social media. On Wednesday, a further 9,938 cases were recorded across the UK as well as 442 deaths within 28 days of a positive test, according to government figures. It takes the death toll by that measure to 121,747.

More than 18 million coronavirus jabs now administered in UK

More than 18 million people have now received their first dose of a coronavirus vaccine in the UK. The NHS has been edging towards the milestone over the past few days amid a slight drop-off in the number of jabs being administered, which the deputy chief medical officer has blamed on “supply fluctuations”. Another 326,692 first doses have been given out, taking the total to 18,242,873, while the number of second doses has climbed by a record 26,317 to 669,105. Meanwhile, 9,938 more cases and 442 deaths within 28 days of a positive COVID-19 test have also been reported.

And that is all for now, stay safe and well, and don’t forget EAPM’s upcoming EU Presidency Conference on 8 March, please find the link to register [here](#) and the agenda [here](#).

Links

[EAPM: Long time, no see... The journey through a diagnosis](#)

[EAPM update: How to put Europe Beating Cancer Plan into practice](#)

[EAPM: Fighting for lung cancer patients in the upcoming EU Beating Can-cer Plan](#)

[- The time has come](#)

[‘Recruiting serology to the long fight ahead against pandemics’](#)