European Alliance for Personalised Medicine

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Launch of Call to Action to improve patient care by enabling access to personalised medicine in Europe

Leading cancer clinicians and patient associations have announced an initiative to stimulate European progress towards a more personalised approach to treatment.

The newly-created European Alliance for Personalised Medicine (EAPM) issued a call on Tuesday for the European Commission, the European Parliament and EU member states to help improve the regulatory environment to allow early patient access to personalised medicine and to boost research.

It also says there is a need for "new approaches to reimbursement and health technology assessment", since a change is required "for patient access to personalised medicine and its value to be recognised".

The alliance is co-chaired by former member of the European Parliament, John Bowis and former EU health commissioner David Byrne. The European Cancer Patient Coalition is providing the Secretariat for the Alliance.

The Alliance's Call to Action sets out 5 key calls to policy makers, politicians and regulators in the EU order to accelerate the development, delivery and uptake of personalise medicine and diagnostics.
These include:

1. Ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine
2. Increasing research and development for personalised medicine
3. Improving the education and training of healthcare professionals
4. Acknowledging new approaches to reimbursement and HTA assessment, which are required for patient access to personalised medicine and its value to be recognised
5. Increasing awareness and understanding of personalised medicine

It wants the upcoming revision of the clinical trials directive to "guarantee more harmonisation across the EU by establishing a process for coordinated assessment of the clinical trials application", and "this in turn would support personalised medicine by facilitating organisation of trials for patients with rare conditions."

The registration of new drugs will also have to be "adapted to complex clinical trial designs, investigating targeted new molecules and related biomarkers".

The regulations on data protection will also have to recognise the importance of the secondary use of data and sharing patient data internationally. "Personalised medicine depends on the identification of clinically valid biomarkers."

Change is needed because "in many cases, biomarkers emerge from academic work mid-way through or after a study has closed, and rapid re-analysis of existing data is vital to getting this new knowledge into novel personalised medicines", it says. "The legal framework needs to allow the re-analysis of existing data without the need to re-consent from patients involved in relevant trials."

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"The cost-effectiveness of personalised medicines will need to be acknowledged to overcome payer and government concerns about costs and value they bring", the alliance urges.

"By linking overall patient outcomes to value, it will be possible to demonstrate the cost-effectiveness of diagnosis and treatments and the impact any new drug or device has on the cost burden", it recommends.

Bowis also underlined the need to involve patients. "Patients will need to understand that a test may be necessary to decide on the right treatment."

SUPPORT FROM OFFICIALS AND POLITICIANS

Paola Testori Coggi, director general of the European Commission's health directorate general, gave her backing to the alliance. She told the inaugural meeting in Brussels on Tuesday that personalised medicine could prove more efficient and cost less, making a contribution to greater sustainability of health systems.

She noted, however, that the regulatory system for approving medicines should continue to be based on the established criteria of quality, safety and efficacy.

One of the close advisors to European research commissioner Maire Geoghegan Quinn also expressed support. Patricia Reilly spoke of the "need for personalised medicine," and of its potential in cancer and HIV.

She said the next call for proposals in the EU's multi-billion euro research programme would include a section on personalised medicine.

The initiative won the support of Cypriot health minister, Dr Stavros Malas, who is planning to launch a strategy on open innovation in healthcare when his country takes over the rotating chair of the EU Council in June.

He told the EAPM meeting in Brussels that he envisages bringing together a wide range of interests - not just biomedical researchers, drug development companies, and devices and diagnostics, but electronics, IT, telecommunications, consumer goods industries, and healthcare providers.

The aim would be to create an environment in Europe for an integrated approach to what he terms wellness monitoring, allowing the EU healthcare systems to use wider information than currently feasible, and to allow more informed choices for the public.

In addition, he advocates creating an EU framework that incentivises companies to develop diagnostic and other tools for early detection of disease and disease risk, and to aid patient stratification and the implementation of preventive strategies for high risk individuals.

Malas also wants to see cross EU-wide guidelines on stratification that will allow patients most likely to respond to a given treatment to be identified.

Tom Hudson, President of the European Cancer Patient Coalition welcomed the initiative and the support which the Alliance had received from the healthcare related community. 'Personalised medicine offers new hope to patients. The ECPC will work with members of the Alliance to educate and empower patients to understand the promise of personalised medicine and to advocate for the importance of patient access to these new technologies and therapies'.

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