

Why Personalised Medicine (PM) is the way forward

We're well into 2015 now and we live, today, in a multi-state Europe that celebrates a rich diversity in culture and languages yet also relies upon our similarities and shared goals. The European Union of which we are all a part has, as one of its core values, the ideal of equality.

One way to measure this equality is through the well-being of all 500 million citizens spread across 28 member states and, as part of that well-being, one key aspect is health. Ask any citizen, anywhere, and health and health care will be high on the agenda – now and into the future.

In the area of health much progress is being made scientifically, with breakthroughs in, for example, the way we can diagnose and treat rare diseases. New technologies are developing swiftly and coming more-and-more to the fore, while the potential value of Big Data cannot be underestimated.

Yes, there is a necessity for up-to-date incentives and rewards in research, better education for clinicians in respect of new methods, interoperability issues exist and, in the case of Big Data; there are collection and sharing complications as well as huge, fundamental questions concerning ethics and privacy.

These represent very real barriers to access for patients who need quick and efficacious assessment to help them live longer and healthier lives by receiving the right treatment at the right time. PM, based on an individual's unique genetic make-up and life-style, is the way forward in this respect.

It is incumbent upon all stakeholders in the realm of health care – and especially the policymakers and legislators – to ensure that every citizen of Europe has the same rights and access to the same high quality care as his neighbour. At the moment we have different standards of health care in different countries, different price structures in many of them, and problems in affordability when it comes to cross-border access for patients.

Of course, cost is a major issue and often leads to a sharp intake of breath when PM is mentioned. It's true that keeping the population of Europe healthy is an expensive business – and there are key questions about the cost-effectiveness of new and even existing treatments.

Yet PM is an innovative, speedily growing method of treating patients that uses as much available research, data and up-to-the-minute technology as possible to provide better diagnostics and follow-up for citizens as an one-size-fits-all model. It uses genetic information to discern whether a particular drug or regime will work for a particular person and, crucially, helps a clinician to quickly decide which treatment will be the most effective.

'Too expensive' is not the case in the medium- to long-term; better diagnostics will ease the burden on health-care systems in two ways – firstly it will allow a more preventative approach in that gene technology will flag up the likelihood of a particular individual developing a particular disease and provide a good idea of how it will develop, thereby encouraging early intervention. Secondly, efficacious prevention and treatment means patients are much less likely to require expensive hospital beds and are more able to continue working and contributing to Europe's economy.

There is no point giving, for example, a cancer patient chemotherapy if there is a large chance that it will not work. This is a waste of time and money and, potentially, a human life. It is far better to know in advance what the best treatment will be and to discuss the individual treatment options in a fully transparent way with the patient.

The European Alliance for PM is a collaboration of multiple stakeholders such as patients, clinicians, researchers, academics, industry partners, Member State affiliates, policymakers, lawmakers and more, striving to make PM part of the agenda for the next 20 years and beyond in the arena of EU policy.

More and more patient groups and individual citizens are becoming aware of the potential of PM, and they want to have their illnesses and the treatment options explained in a transparent, understandable yet non-patronising manner (from a clinician with up-to-date knowledge) to allow them to become involved in co-decision. Meanwhile, they want to own – and have unreserved access to – their own medical data as well as greater access to clinical trials and cross-border treatments that could improve their lives and, in some cases, save them.

Among the ways to achieve this are better training for health-care professionals in up-to-the-minute technologies, a different mind-set from those same clinicians that allows the patient to participate in discussion and decision-making at all levels, the setting up of data co-operatives allowing patients not only access to all of their personal data on request but giving them control over who uses it, how it is used and when, and; changes from the European Parliament and European Commission to make clinical trials more accessible and affordable cross-border treatments a reality and not just a dream.

In a 500 million citizen-strong EU staring into the abyss of a society with an aging population that will inevitably become ill at some stage, giving patients access to the best possible treatment available in Europe is not just a moral issue, it's a financial one, too, as mentioned earlier.

The downturn in the economy almost crippled several member states and, of course, high on the list of austerity measures has been the short-sighted, counter-productive reeling in of health services, even to the point of dropping certain cancer drugs from the available list, as will happen in England soon. Slashing health budgets is a patent nonsense. A healthy Europe is a

wealthy Europe and the EU in general, and health-care systems in particular, need to see what's staring them in the face.

So, where do we go from here? In line with EAPM's Specialised Treatment for Europe's Patients initiative (STEPS) we call on the EU to commit to the following:

- **STEP 1:** To ensuring a regulatory environment which allows early patient access to novel and efficacious PM
- **STEP 2:** To increasing R&D for PM, while also recognising its value
- **STEP 3:** To improving the education and training of health-care professionals
- **STEP 4:** To supporting new approaches to reimbursement and HTA, required for patient access to PM
- **STEP 5:** To increasing awareness and understanding of PM

In addition, EAPM would like to see the following: The Data Protection Regulation should permit the primary and secondary use of data for health research purposes bearing in mind the safeguards already in place across the EU. Meanwhile, clinical trials improvements should not be undone by the data regulation.

Also a five-year transition period for IVDs is needed for manufacturers to be able to fully comply with various new requirements.

Furthermore, EAPM believes that health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries and in the regions of the larger ones. We call this a SMART approach – Smaller Member states and Regions together. This will be further developed at EAPM's annual conference on 2 and 3 June. The conference is timed to coincide with the end of the Latvian presidency and the start of Luxembourg's – two of our smaller countries.

Finally, the EU Semester process's Country Specific Recommendations (CSRs) must be focused and balanced, rather than looking for sweeping cuts in the bigger budget areas such as health. EAPM believes that all decisions and recommendations under the Semester should of course promote growth, but alongside research and efficiency, especially in the areas of health and PM. The Alliance is of the view that if the presidencies, the European Parliament and the Commission work towards delivering the above it will improve the quality of life for patients in every country in Europe.

ENDS

Note to editors

PerMed is a Coordination and Support Action (CSA), financed by the European Commission, of 27 partners representing key decision makers in research and research policy, industry, health care and patient organisations.

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