



European Alliance for
Personalised Medicine

Press release

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For immediate release

Press Release: Council Conclusions ‘realistic’ on implementing personalised medicine

Yesterday (Monday 7 December) Luxembourg, the current holder of the EU’s rotating presidency, unveiled its long-awaited Council Conclusions on personalised medicine. While these are, of course, merely recommendations and invitations to Member States to act in certain areas, and carry little political weight, they have been welcomed in many quarters as a significant step forward in pushing the agenda in this exciting new field.

The main focus of the conclusions is rightly on patients and their access to innovative new treatments and, in a Europe with an ageing population of 500 million citizens, this can only be for the good.

Luxembourg’s health minister, Lydia Mutsch, said on Monday: “We all know that, nowadays, patients get more and more involved in their own treatment. Social media allow for access to all sorts of information. If we want to make access to targeted treatment easier, it is important that we enable patients to make informed choices.

“Governmental authorities should have an active role to play because they give the guarantee that their information is based on objective and balanced data - which is not always the case when this information is provided by industry.”

The latter remark is a solid one although there was, it has to be said, some watering down of sections, such as that on pricing, due to Member State pressure (the EU has no overall competence on health, it is for individual countries to decide on the majority of health-related policy, and they are notoriously reluctant to give up power in some areas).

This has brought about most of the criticism in certain circles, but can be considered unfair and even unrealistic, given that drug pricing and reimbursement mostly fall under the authority of these national governments.

The Conclusions mention pricing and reimbursement only as a “challenge” for individuals and health systems, which weakens an earlier sentence in the August draft document. That draft used the stronger recommendation that Member States “consider innovative methods of pricing” to ensure the uptake of personalised medicines across Europe.

However, the pricing and reimbursement issue is just one element when it comes to integrating this exciting new science - based mainly on an individual’s genetic make up - into EU-

wide healthcare systems. And at least one stakeholder group has said that its members (which include patients, academics, researchers and, front-line healthcare workers) as well as the wider public should not feel disappointed.

Denis Horgan, Executive Director of the Brussels-based European Alliance for Personalised Medicine (EAPM), said: "It is important that reactions to these first ever Council Conclusions on personalised medicine - an area that has seen a €1 billion-plus development investment by the EU from 2007-2013 - take the optimistic, 'glass half-full' viewpoint. It is necessary to bear in mind what can realistically be achieved, taking into account national competences and the political and fiscal climate that we live in.

"There is certainly a long way to go to fully integrate personalised medicines into society - for example, stakeholders need to leave their silos and cooperate, both within countries and across borders - but there are clear signs that this is happening more and more."

"New technologies can only help," added Horgan, "and sensible data protection legislation that safeguards the rights of individuals, while also allowing for the necessary use of vital data in medical research, will be a key driver of long-term success in this area."

Part of the Conclusions also read that the EU-28 should take into account, "inter alia, added value from the patient's perspective as well as enhanced cooperation and exchange of best practices," while respecting member country competences.

Horgan remarked: "There is a very strong argument that the concept of 'value' should always be seen from the customer's point of view, in this case, the patient."

On data, Health Minister Mutsch added: "Data sharing is a crucial element of the integration of personalised medicine into our healthcare systems. References to this aspect in our Conclusions are numerous.

"We follow the works on the General Data Protection Regulation very closely and hope that a workable solution can be found with the European Parliament on this sensitive and very important issue."

The Conclusions were formally adopted at the end of meetings in the European Council's Justus Lipsius building, and the full document on personalised medicine is available here:

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