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**Personalised medicine coalition demands European support**

BRUSSELS, Sept 19 (APM) - More sophisticated drug authorisation procedures, clear links to companion diagnostics, and smarter reimbursement procedures that recognise the potential of personalised medicine are the priorities of a manifesto demanding that Europe adapts to take advantage of the opportunities of personalised medicine.

The manifesto was launched in Brussels on Sept 18 by the newly-formed European Alliance for Personalised Medicine (EAPM), which brings together patient groups, academia, health professionals and industry, as well as the European Commission and the European Medicines Agency.

## REGULATORY CHANGES

Adapting the authorisation procedures for medicines to take account of the innovative clinical trial designs that personalised medicine will depend on is the top ask of the alliance in terms of regulation.

New rules should provide for investigating targeted molecules and related biomarkers or which deploy nanotechnology or imaging, with greater acceptance of modelling, given the smaller patient cohorts in personalised medicine.

The current proposals to update the EU's clinical trial rules "are not sufficiently forward-looking", says EAPM. Specific provisions should be added to allow particularly for multinational trials, it says.

Guidelines or other 'soft law' mechanisms should ensure that researchers, doctors, pharmacists and patients have better access to information about ongoing trials. This can help avoid duplication, and streamline recruitment, allowing access to the patient numbers essential to speed effective new treatments into daily care practice.

EAPM also wants an agreed level of evidence in the development and validation of biomarkers, and a regulatory framework for the co-development and development of a biomarker and companion diagnostic.

The regulatory environment for biomarkers needs to reflect the speed with which biomarkers are being developed and clinically validated in order to personalise treatment, according to EAPM.

It envisages the establishment of European guidelines for biomarkers to ensure harmonisation across the EU.

## EAPM MAKES FAR-REACHING DEMANDS ON REIMBURSEMENT

It is in relation to reimbursement that the alliance makes the most far-reaching demands.

"Standard assessment mechanisms will need to be tailored to the specificities of personalised medicines to be able to demonstrate cost-effectiveness," it says.

In particular, it wants health technology assessment to take account of broader elements such as quality of life or patients' needs, rather than only budget and cost.

EAPM argues that personalised medicine can be highly cost-effective.

"When patient outcomes are taken into account in evaluating cost-effectiveness, the true value will emerge of new diagnoses and treatments, because it will be possible to demonstrate favourable impacts of new drugs or devices on overall healthcare costs."

It urges greater attention to late translational research, because "its focus on the clinical effectiveness of specific treatments is a valuable guide to cost-effectiveness".

This "can increase availability of effective treatments (and decrease use of sub-optimal treatments), and help identify priorities in healthcare provision".

But, EAPM points out, this requires comprehensive clinical registries, and this is an infrastructure that is insufficient in Europe today.

Other priorities in the manifesto include coordination on research in Europe, with better access to information for researchers, doctors, pharmacists and patients.

It also wants to see high-quality molecular testing facilities in Europe.

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And regulation should make allowance for scientific sharing of data , which could be impeded by EU data protection rules, it warns.

EAPM focuses on the needs for a multi-disciplinary approach to developing personalised medicine, and this extends to training for healthcare professionals in new approaches, and wider awareness among patients and the public of the rationale and potential of personalised medicine.

Nessa Childers, an Irish socialist MEP who hosted the launch of the manifesto, said: "Europe must not miss out on this opportunity to improve patient care - as well as to make healthcare more precise and effective".

But she emphasised that the potential would be realised only if "everyone involved, including policy makers and regulators, come together now to create the conditions on which the success of personalised medicine will depend".

John Bowis, a former UK health minister and MEP, who is the chair of EAPM, said: "Personalised medicine offers a chance for dramatically improved treatments and reduces the likelihood of adverse events for patients. However like any innovation it brings challenges to current systems and attitudes, and today we have sought to identify the priorities for policy makers in Europe to meet these challenges."

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