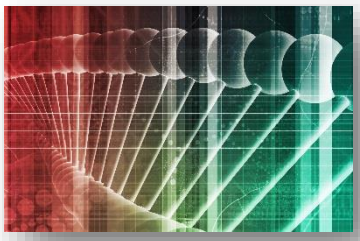
Personalised Medicine: tackling challenges for healthcare systems and patients

Next Tuesday 14 March, personalised medicine will be a topic on the agenda of the joint meeting of the Patients and Consumer Organisations and Healthcare Professionals' Organisations Working Groups at EMA. During the meeting the views of the payers on the challenges posed by personalised therapies and solutions to tackle them will be presented based on an ESIP paper launched today.



In its paper ESIP highlights the weaknesses of current market access schemes faced with the complexity of targeted therapies based on multiple components (biomarker, diagnostic and medicinal product). This calls for **a comprehensive, consistent and transparent EU regulatory framework**. ESIP argues that rather than "softening" the requirements of market access, the nature of personalised medicine requires **strong clinical evidence** of the potential benefit and risks for the targeted population **prior to marketing authorisation**. **Early access schemes should remain an exception** and be subject to strict conditional market authorisation rules and high standards for post-market studies.

The high expectations for personalised medicine have yet to be realised; significant breakthroughs remain limited to only a few disease areas. At the same time, experience shows that personalised therapies have a high price label. Therefore, **strong pricing and reimbursement policies** are necessary **to ensure the sustainability of healthcare systems and patients' access to care**. Evidence on the added therapeutic benefit and/or cost effectiveness of a personalised therapy needs to be available prior to its admission for reimbursement. In this context, **specific methodologies appropriate to personalised medicine** could be the **focus of enhanced cooperation on HTA at EU level**. ESIP proposes further specific policy measures around the use of **centres of expertise**, **voluntary cooperation** and exchange of best practice **between** relevant **competent bodies** and **Member States to address** the issue of **affordability**.

Personalised medicine also raises challenges in terms of **access to data, data protection and patients' privacy**. The new EU Regulation on data protection to be fully respected to protect patients against the use of their data for commercial interest. Early and full **access to clinical trial data and international registries** by competent authorities is essential for assessment and reassessment purposes while **quality standards for registries** developed at EU level will facilitate the exchange and comparability of data.

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Finally, **patient empowerment** has a special importance in the field of personalised medicine. This requires that both **patients and healthcare providers** are **well informed**. Appropriate information should be provided to patients, where there is a lack of clear evidence of the benefit and risks associated with a new therapy as well as requirements for use of their data. In addition, the development of **guidelines for healthcare providers** is crucial to ensure informed decision decisions and appropriate use.

With this paper, ESIP aims to inform the debate, future policies and actions around access to and use of personalised medicine. Find out more in the position paper.

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