

CMS | Romania introduces patients' right to personalised medicine



On 25 April 2023, Romania's Chamber of Deputies adopted a draft law for supplementing Law no. 46/2003 on patients' rights, giving each patient the right to personalised medicine, based on a medical recommendation.

This Draft Law defines personalised medicine as “healthcare provided based on a medical model that uses the characterisation of the phenotypes and genotypes of individuals, which consists in providing preventive, diagnostic, curative, rehabilitative and terminal care to each patient”.

In order to ensure the right to personalised medicine, healthcare professionals are obliged to provide the patient with reliable, relevant and understandable information on the options for any proposed medical interventions, including benefits and risks.

Patient consent will be required for each medical intervention specific to personalised medicine. The collection and management of data necessary for the development and application of personalised medicine will be carried out in accordance with data-protection legislation.

The provisions of the Draft Law will enter into force **six months** after its publication of the Official Gazette.

According to the explanatory memorandum, the Romanian public health system is built on the principle of **evidence-based medicine**. Introducing the concept of personalised medicine (i.e. applying the evidence to the specifics of each patient) into Romanian legislation would represent a positive step forward for the public health system.

The initiative is also in line with the recommendation of the Council of the European Union in the Council conclusions on personalised medicine for patients (2015/C 421/03), inviting EU member states to support access to clinically effective and financially sustainable personalised medicine by developing patient-centred policies including patient empowerment and interrogation of patient perspectives in the development of regulation processes, all done in cooperation with patient organisations and other relevant stakeholders.

For more information on this Draft Law and Romania's healthcare system, contact your CMS client partner or CMS experts: **Cristina Popescu** and **Carmen Turcu**.