

CMS Romania: Reorganisation of the Romanian National Agency for Medicine and Medical Devices

On 17 July 2019, law no. 134/2019 (“Law 134”) on the reorganization of the National Agency for Medicine and Medical Devices (“ANMDM”) was published in the Official Gazette.

The changes brought by Law 134 mainly relate to ANMDM’s dissolution and replacement by a new public institution called the National Agency for Medicine and Medical Devices from Romania (“ANMDMR” or the “Agency”), which will be overseen by the Ministry of Health.

Unlike ANMDM, which was fully funded from the state budget, ANMDMR will be only partially funded from the state budget. ANMDMR will also be partially funded from fees received for the performance of its activities (such as, administrative fees received for marketing authorizations of medicinal products). Law 134 also increases the total number of employees to 500, including the president and two vice presidents.

The aim of Law 134 is to align the Agency with other similar European agencies and avoid: (i) delays in evaluating the marketing authorization files for medicinal products; (ii) delays in evaluating the authorisation documentation for clinical trials; and (iii) significant delays in evaluating HTA files due to shortage of personnel.

According to the initiators of this piece of legislation, once Law 134 enters into force, the Agency shall hire more specialists and train sufficient personnel so that the Agency’s projects shall be ready on time.

It will be interesting to see if the expected increase of the Agency’s specialized personnel will also result in the Agency becoming a more active supervisory body in Romania with an enhanced activity in the area of inspections and controls.

For further information on Law 134, please contact our local expert, [Valentina Parvu](#), Senior Associate, Bucharest.