

CMS | Romanian law establishes new measures in pharma sector



The Romanian Parliament recently adopted a law establishing new measures in the health-care system. The draft law went to the Constitutional Court for review, but the court rejected the challenges on constitutionality. The law will soon be promulgated and enter into force.

The law is intended to ensure more equitable patient access to medical services, improve the quality of medical care, and promote efficient use of public funds. It also introduces financial and regulatory measures relevant to marketing authorisation holders (MAHs).

Key provisions

The law amends Healthcare Reform Law no. 95/2006 and other related legislation, introducing a series of structural, financial, and governance measures affecting the healthcare sector.

In brief, the main changes include:

- reorganisation of hospital governance: performance indicators in management contracts are set by the Minister of Health;
- heads of department, laboratory and medical service will be appointed on a competitive basis only.
- prioritisation of ambulatory care: hospital physicians must provide limited consultations in hospital outpatient clinics (around one hour/day average).
- financing and payment reforms: public outpatient labs receive a positive adjustment coefficient in contracts from 2026; private hospitals are capped at 2025 bed-contract levels until 2028.
- the takeover by the National Health Insurance House (CNAS), as of 1 January 2027, of the national role for hospital data collection and analysis.
- the extension of the European Health Insurance Card validity for pensioners 65 years and older and for children.

Provisions relevant to Marketing Authorisation Holders

The law introduces a controlled-access mechanism for medicines not included in the reimbursed medicine list (new Article 703¹ of Law 95/2006). Further details will be announced through a Government Decision.

Access to these medicines will be based on cost-sharing agreements between CNAS and MAHs. Physicians will also have a new responsibility to monitor patient results and report these results on a quarterly basis.

The goal is to introduce new, high-cost therapies in a way that is efficient, transparent, and fair.

A new article (Art. 19 added to GEO 77/2011) introduces a temporary solidarity contribution payable by MAHs, supplementing the existing quarterly claw-back contribution regime. The temporary contribution:

- applies to MAHs covered by the standard claw-back rules, with an exemption for products subject to cost–volume–outcome contracts.
- applies for a limited period, from the fourth quarter 2025 to the fourth quarter 2026.
- is calculated at 1.7% or 0.6% of quarterly consumption values, depending on the product category.

Administration, assessment, calculation, declaration and payment follow the existing rules applicable to quarterly claw-back contributions. This makes the solidarity contribution an overlay to the current claw-back framework, with differentiated rates by consumption category and with the same reporting and settlement infrastructure.

For more information on recent legislative developments in the Romanian health-care sector, contact your CMS partner or the CMS experts who wrote this article: **Cristina Popescu** and **Carmen Turcu**.

This article was written with the support of intern Narcisa Paun.