

Delayed Access to Innovative Medicines in Romania: A Comprehensive Analysis of the Reimbursement Processes (2015-2024)

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Background

After being approved by the European Medicines Agency, drugs applying for reimbursement in Romania are formally assessed through a scorecard HTA system¹. This assessment can result in either a denial of reimbursement or a positive decision for reimbursement that can be unconditional or conditional.

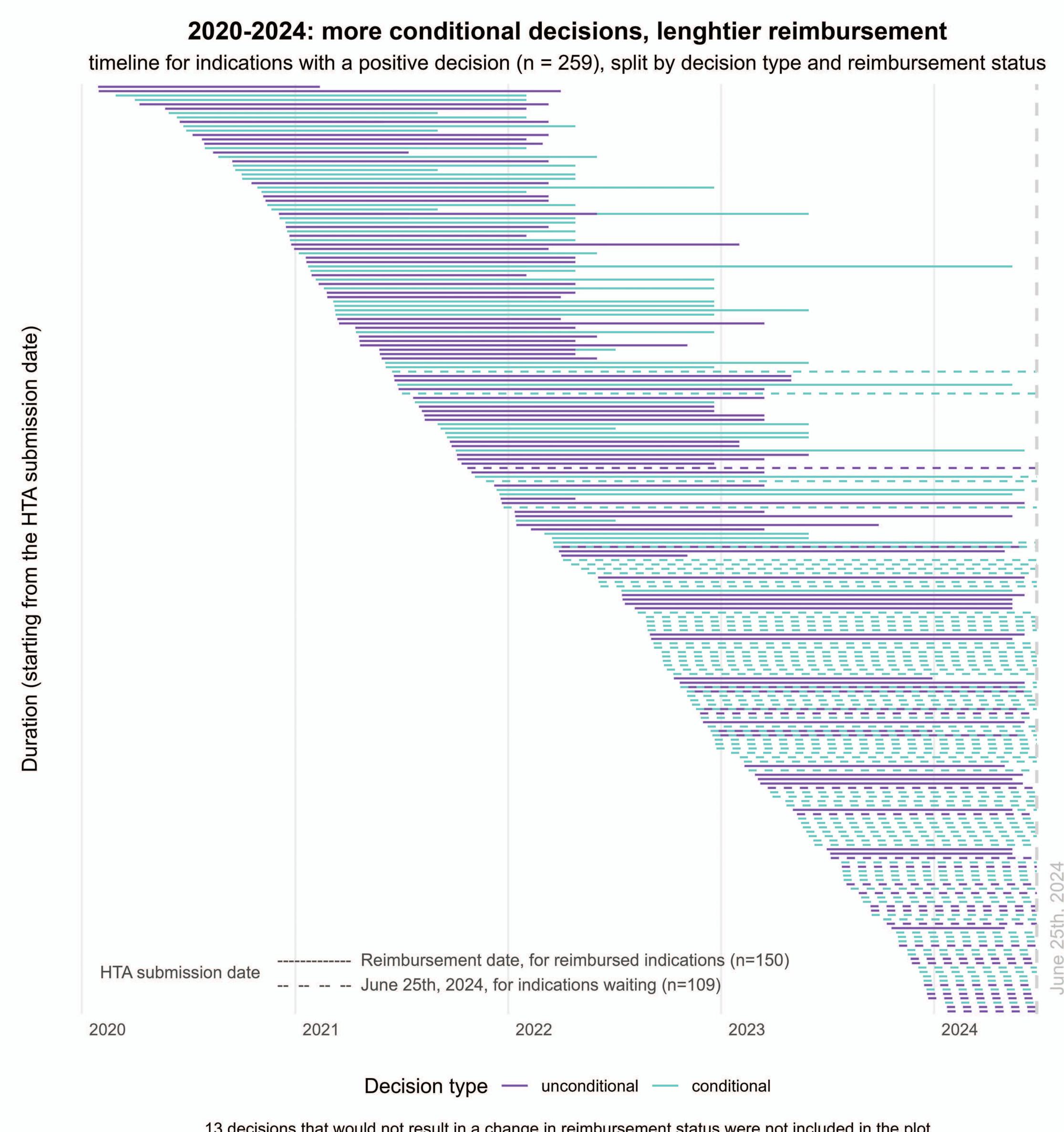
The national legal framework requires multiple steps for innovative drugs to become reimbursed unconditionally: HTA, inclusion in the reimbursement list, and publication of the prescription protocols. Additional procedures are required for conditional reimbursements, involving Cost-Volume and Cost-Volume-Result agreements with a separate, more limited budget. The same budget pool covers both new conditional reimbursements, as well as yearly renewals of previous agreements. This framework for Managed Entry Agreements was first introduced in 2015 and has undergone only minor adjustments since². Considerable delays in reimbursement have accumulated over recent years, restricting Romanian patients' access to innovative medicines³.

Methods

We processed all publicly available HTA reports available on Romania's National Drug Agency (NDA) website, submitted between January 2015 and June 2024. In certain cases, the NDA split indications by target populations, some HTA dossiers receiving both an unconditional and a conditional decision; we considered these instances as separate indications. Some HTA decisions were appealed; for these, the post-appeal decision was considered final. We reviewed all existing versions of the National Drug Reimbursement List and Therapeutic Protocols to accurately identify the reimbursement dates. For drugs still awaiting reimbursement, June 25, 2024 was the cut-off date. All durations were calculated in days. Automated data extraction and statistical analysis were performed using advanced software tools (Python and R).

Results

We identified 496 HTA reports corresponding to 523 indications approved for reimbursement. The number of indications with a positive decision increased steadily over the years. At the same time, the proportion of conditional decisions increased from 41% in 2015 to 63% in 2023. Despite more conditional decisions and more drugs competing for the same budget pool, the negotiation cap for conditional reimbursements has remained roughly the same since 2019.



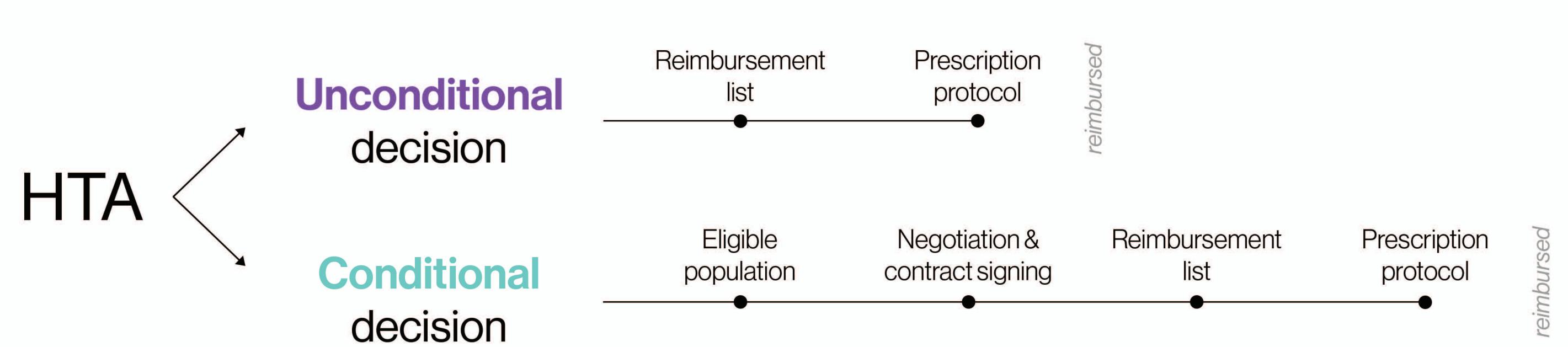
Using the submission year as reference, the duration from HTA decision to reimbursement for 2021 submissions reached 470 days (95% CI: 385, 556) for conditional, 250 days (95% CI: 214, 286) more compared to unconditional. This perspective is limited by many dossiers that started their wait in 2021.

Looking at the reimbursement year however, for drugs reimbursed in 2024, the average wait was 709 days (95% CI: 580, 837) for conditional versus 407 days (95% CI: 348, 466) for unconditional decisions, a difference of 302 days (95% CI: 215, 389), 74.2% longer. This gap has been steadily increasing from previous years, highlighting growing delays for conditional reimbursements.

For drugs still awaiting reimbursement as of June 25, 2024, the average wait since the HTA decision was 327 days (95% CI: 291, 362), with the maximum wait being 690 days.

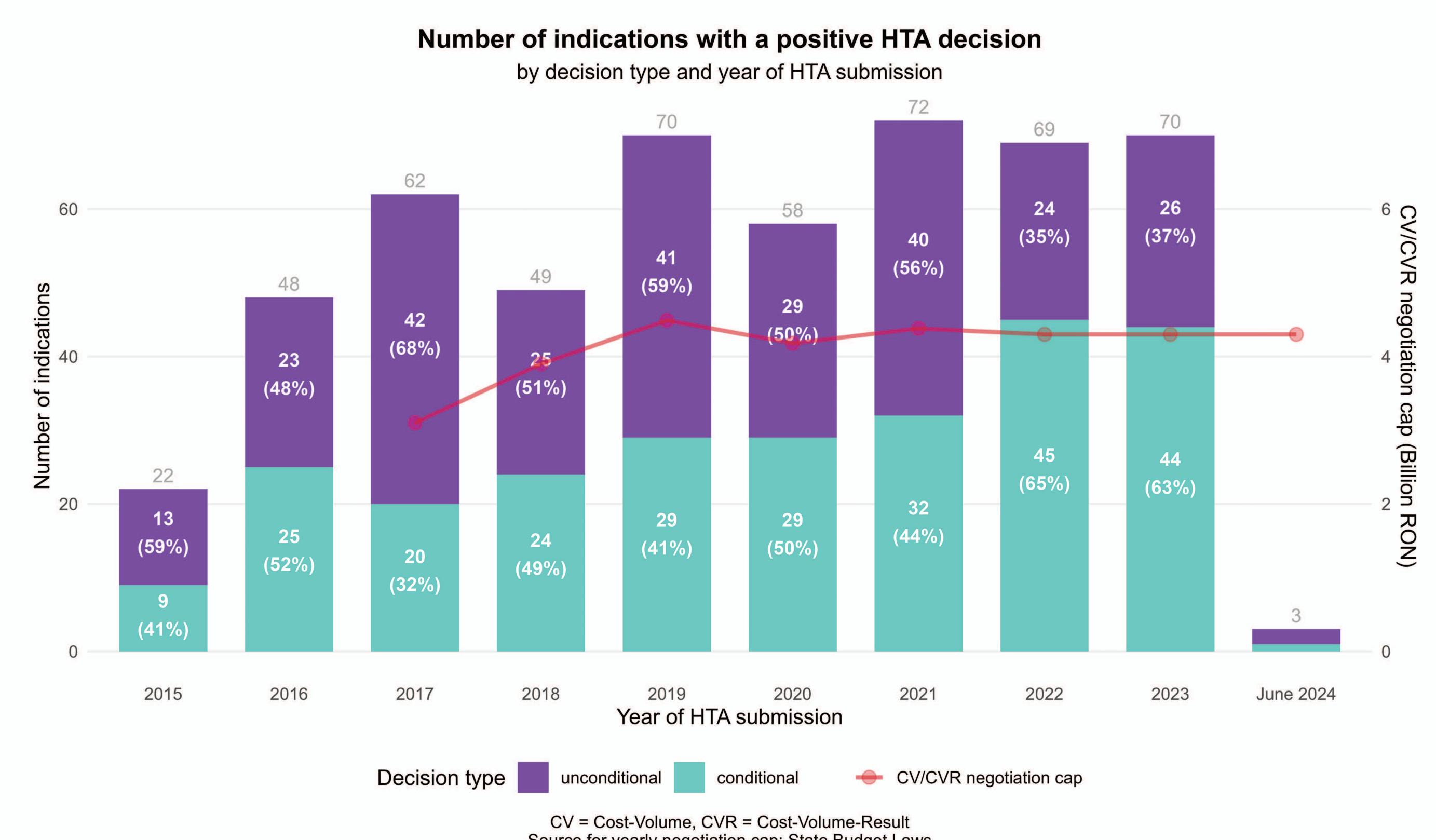
Conclusions

Although promising in the beginning, the reimbursement process in Romania became increasingly unpredictable in the last 3 years. Despite more drugs receiving HTA approval, faster, reimbursement is becoming less and less likely. Coupled with insufficient funding, the current framework for conditional reimbursement is restrictive, administratively burdensome, and seems inefficient in addressing the financial uncertainty of new drugs. Companies and health authorities should partner to adopt more flexible and effective Managed Entry Agreements, as well as a predictable funding mechanism, to ensure patients get timely access to innovative medicines.



Objectives

This study aims to assess the delays and identify their main causes to inform updates to the reimbursement framework, focusing on the timeline between local HTA and reimbursement.



Of all indications analyzed, only 361 (69%) were reimbursed as of June 2024. On June 25th, 2024, there were 109 indications with a positive decision still waiting for reimbursement: 9.7% of HTA submissions in 2021, 58% - 2022, 84.3% - 2023 and 100% - 2024. Among the indications waiting for reimbursement, 80.7% had a conditional decision.

The duration of the HTA process has improved considerably in recent years, decreasing from a mean of 205 days (95% CI: 181, 229) for submissions made in 2020, down to 115 days (95% CI: 107, 123) for 2023 submissions.

