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ORIGINAL RESEARCH ARTICLE

Procedural activity and dynamics of the new Italian Scientific and Economic Committee (CSE): a one-year observational analysis

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ABSTRACT

Introduction: In January 2024, the Commissione Scientifica ed Economica (CSE) became the national body responsible for the integrated scientific and economic evaluation of medicines in Italy. This study provides the first systematic description of the CSE's activity during its initial operational year, focusing on procedural workload, timelines, and negotiation outcomes.

Methods: All publicly available "Esiti CSE" documents published by the Italian Medicines Agency (AIFA) between April 2024 and April 2025 were manually extracted and validated. Each record included the negotiation typology (TN-1 to TN-8), outcome, and iter duration. Descriptive analyses summarised distributions, median and mean durations, deferral rates, and trends over time.

Results: A total of 641 procedures (523 products, 446 INNs) generated 2,145 individual outcomes. Argomento rinviato (deferral) was the most frequent outcome (55.7% of all decisions; 51% of procedures). The average procedure involved 1.9 deferrals, and 83% experienced at least one. Mean overall duration was 269 days (median 196; IQR 133–350), with the longest timelines for TN-1 and TN-4 negotiations (298 and 322 days, respectively). Oncology (L01, L04) and metabolic agents (A10) showed the greatest variability, while antivirals (J05) recorded the longest average duration (549 days) but a lower incidence of deferral.

Conclusions: The first year of CSE activity reveals a high workload, variable timelines, and frequent deferrals, reflecting the complexity of integrating scientific and economic assessment within a single body. The results provide an empirical baseline for future monitoring and underscore the need for refinement of governance arrangements and procedural transparency in AIFA's new framework.

Keywords: Decision-making, Health technology assessment, Negotiation timelines, Scientific and Economic Committee

Introduction

In January 2024, a major institutional reform reshaped the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA), marking a structural change in the national framework for the evaluation and reimbursement of medicinal products. The Decreto del Ministro della Salute of 8 January 2024 (published in the *Gazzetta Ufficiale* on 15 January 2024) (1) established a single integrated body—the *Commissione Scientifica ed Economica del farmaco* (CSE)—replacing the former dual-committee structure composed of the *Commissione Tecnico-Scientifica* (CTS) and the *Comitato Prezzo e Rimborso* (CPR) (2). The reform aimed to integrate scientific and economic assessment within a unified deliberative process, with the stated objectives of improving procedural efficiency, internal coherence, and decision-making consistency.

Despite the institutional relevance of the reform and its generally positive reception, empirical evidence on the real-world functioning of the CSE remains limited. No systematic analyses have yet assessed its impact on key procedural outcomes, such as negotiation timelines or the frequency of deferrals (*rinvii*), historically a major source of delay in the Italian pricing and reimbursement process. It is also unclear

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whether integrating scientific and economic evaluation has influenced outcomes across negotiation typologies (e.g., TN-1, TN-4, TN-8) or therapeutic areas defined by the ATC classification (3).

This study examines the first year of CSE activity (April 2024–April 2025) using publicly available AIFA documentation to analyze workload, timelines, deferral patterns, and negotiation outcomes. By providing the first systematic description of CSE operations, it offers an empirical basis for assessing the new governance model and informing future monitoring of the Italian pricing and reimbursement framework.

Methods

Study design and objectives

This study is a retrospective, observational analysis of AIFA's CSE activity during its first year (April 2024–April 2025). Its primary aim was to characterize the procedural dynamics of the new decision-making framework and assess early performance in terms of workload, duration, and negotiation outcomes.

The analysis was not an institutional audit but a systematic description of routine CSE operations. By empirically reconstructing procedural activity, the study provides a basis for future monitoring and contributes evidence relevant to the refinement of governance and policy arrangements in the Italian pharmaceutical pricing and reimbursement system.

Data sources and extraction

All publicly available *"Esiti CSE"* reports published by AIFA under the *Settore HTA ed Economia del Farmaco* were collected and reviewed (4). Reports, issued as PDFs and organized by meeting date, list discussed medicinal products and provide key procedural information, including meeting typology, negotiation type, procedure ID, proprietary name, International Nonproprietary Names (INN), procedural duration, and decision outcome.

Information from these reports was manually extracted and entered into a dedicated Excel database. Additional variables not systematically reported in the *Esiti CSE* documents—such as Anatomical Therapeutic Chemical (ATC) classification, innovativeness status, and other verification elements—were retrieved from complementary AIFA and EMA public sources (5,6) and integrated into the final dataset. Each record was independently checked by two reviewers, and discrepancies were resolved by consensus.

The final dataset includes all procedures discussed between April 2024 and April 2025, comprising 641 negotiation procedures related to 523 unique medicinal products and 446 INNs, for a total of 2,145 individual decision outcomes.

Data organization and validation

Each negotiation procedure was characterized by negotiation type (TN-1 to TN-8, according to AIFA taxonomy), number of CSE outcomes per procedure, number and proportion of deferrals, total procedural duration (days), and final status as of April 2025. Where available, data were cross-validated with additional public sources, including AIFA press releases and Board of Directors (CdA) decisions, the Gazzetta Ufficiale (GU) for pricing and reimbursement decrees, the PAMonitor platform (Intexo) for regulatory timelines and ATC verification (3); and the official AIFA list of innovative medicines (7).

In cases of missing, incomplete, or ambiguous information, multiple public sources were triangulated to ensure internal coherence of the dataset.

Definitions and variables

Each procedure was classified according to AIFA's official negotiation taxonomy (*Tipologia Negoziale*, TN code) (4):

- TN-1: new active substances, orphan medicinal products, or new therapeutic indications.
- TN-2: medicines and/or indications already on the market.
- TN-3: medicines and/or therapeutic indications for active substances whose patents have expired or are due to expire.
- TN-4: renegotiation of existing pricing and reimbursement conditions.
- TN-5: special procedures – Law No. 648 of 1996 (early access)
- TN-6: other special procedures
- TN-7: parallel imports
- TN-8: generic medicinal products.

As for meeting outcomes (4):

- *Parere espresso*: opinion issued.
- *Argomento rinviato*: item postponed (deferral).
- *Procedura sospesa*: procedure suspended at the company's request.
- *Approfondimento CSE*: request for additional information or analysis.
- *Audizione CSE*: hearing requested.
- *Invio al CdA/Esito CdA*: transmission to, or outcome issued by, the AIFA Board of Directors (*Consiglio di Amministrazione*).
- *Procedura conclusa*: procedure finalized.

Duration of procedures

The duration of each negotiation procedure was measured in days from procedural intake to inclusion in the CSE agenda (*Ordine del Giorno*, ODG), in line with AIFA public reporting. This measure enables comparability across procedures but excludes periods of formal suspension requested by companies or imposed by AIFA under Article 3 of the Ministerial Decree of 2 August 2019. It should therefore be interpreted as a proxy for the duration of the active negotiation phase within the CSE remit, rather than overall time to reimbursement. It does not capture the interval between CSE discussion or opinion and publication in the GU, nor subsequent post-CSE implementation steps such as contractual arrangements, managed entry agreement activation, registry activation, or regional uptake.

Two complementary duration measures were derived: 1) *Provisional duration* reflects the time recorded at intermediate stages of the evaluation process, corresponding to

partial or non-final procedural outcomes; 2) *Final duration* represents the total time elapsed up to the last available CSE outcome within the observation period.

Comparing these measures allowed assessment of temporal dynamics, including procedural progression, accumulation, or backlog resolution, and differences across negotiation types and outcome categories.

Statistical analysis

A descriptive and exploratory analytical framework was applied. Continuous variables were summarised using mean, median, standard deviation (SD), and interquartile range (IQR), while categorical variables were reported as absolute and relative frequencies.

To explore differences across negotiation typologies, a two-stage inferential approach was adopted. For continuous variables (e.g., procedural duration), the non-parametric Kruskal–Wallis rank-sum test was used. When statistically significant differences were detected ($p < 0.05$), post-hoc pairwise comparisons were conducted using the Wilcoxon rank-sum test with continuity correction, with p-values adjusted for multiple testing using the Holm–Bonferroni method. For categorical comparisons, Fisher's exact test was applied where appropriate (8, 9).

Data organization was performed using Microsoft Excel 365. All inferential analyses were conducted using R software (version 4.4.1) (10). A two-sided p-value of < 0.05 was considered statistically significant.

Results

Overview of the dataset

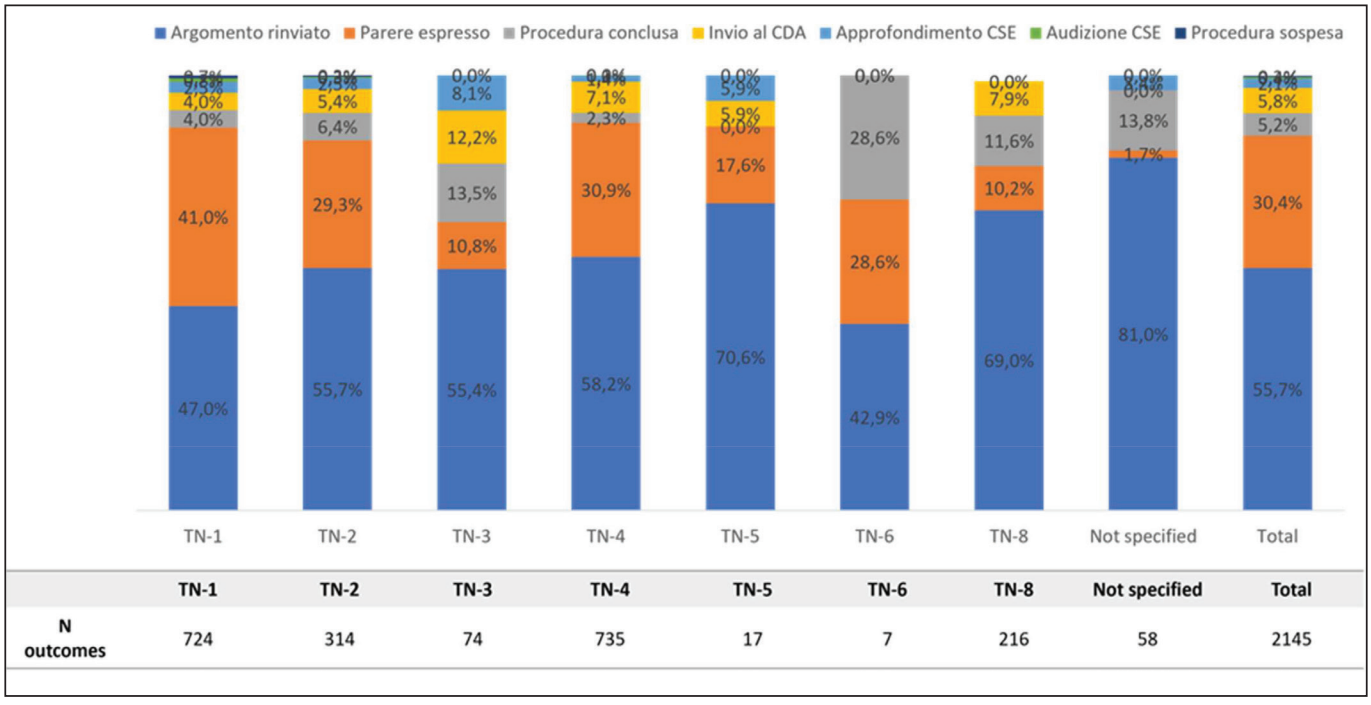
Between April 2024 and April 2025, the CSE reviewed 641 negotiation procedures involving 523 medicinal products and 446 INNs. Overall, 2,145 procedural outcomes were recorded, averaging 3.3 outcomes per procedure. Among the negotiation typologies (all present during the observation period), TN-1 and TN-4 were the most prevalent, each accounting for approximately one-third of all negotiation procedures.

Distribution of outcomes

Across CSE meetings, the most frequent outcome was *Argomento rinviato* ("item postponed"), accounting for 50.9% of procedures and 55.7% of outcomes. These complementary measures capture consistent aspects of decision-making: procedure-level data reflect the overall negotiation experience, while outcome-level data describe operational behaviour across meetings. The difference of under five percentage points supports dataset consistency and robustness across perspectives.

At the outcome level, *Parere espresso* ("opinion issued") accounted for 30.4% of outcomes, while *Invio al CdA, Procedura conclusa, Approfondimento CSE, Audizione CSE*, and *Procedura sospesa* together represented 18.9% (Fig. 1).

Outcome distributions varied by negotiation type. TN-1 procedures (35.1% of negotiations) showed fewer deferrals than the overall average (44.2% vs 50.9%), whereas TN-4 procedures (30.6%) had a slightly higher rate (51.9%) (Table 1).



	TN-1	TN-2	TN-3	TN-4	TN-5	TN-6	TN-8	Not specified	Total
N outcomes	724	314	74	735	17	7	216	58	2145

FIGURE 1 - Distribution of each outcome by type of negotiation (*outcome-level*).
Stacked bars represent the distribution of outcomes (Parere espresso, Argomento rinviato, Procedura conclusa, Invio al CdA, Approfondimento CSE, Audizione CSE, Procedura sospesa) for each negotiation type (TN-1 to TN-8). Deferrals (Argomento rinviato) were the most frequent outcome across all categories, accounting for approximately half of all recorded decisions. TN-1 and TN-4—covering new active substances, orphan drugs, and renegotiations - showed a deferral rate of 47.0% and 58.2%, thus slightly lower and higher, respectively, compared with the overall average (55.7%), while administrative or follow-up typologies exhibited higher closure rates.

TABLE 1 - Average duration and deferral rate per procedure type (procedure-level)

TN	N procedure	Average duration (days)	Average deferral rate (%)
TN-1	225	298.4	44.2%
TN-2	99	249.5	49.9%
TN-3	28	150.7	53.8%
TN-4	196	321.6	51.9%
TN-5	5	187.0	56.7%
TN-6	4	287.0	37.5%
TN-8	74	133.6	65.2%
Not specified	10	172.8	79.3%
Total	641	269.6	50.9%

The table reports, for each negotiation type (Tipologia Negoziale, TN-1 to TN-8), the number of procedures discussed, the mean duration in days, and the corresponding average deferral rate (Argomento rinviato). TN-1 and TN-4 show the longest average durations (298 and 322 days, respectively) with moderate deferral rates (44.2–51.9%), reflecting higher clinical and economic complexity. In contrast, TN-8 (generics) displays both shorter timelines (≈ 134 days) and the highest deferral rate (65.2%), indicating that even streamlined processes can require multiple rounds of discussion before completion.

TABLE 2 - Pairwise post-hoc p-values from Wilcoxon Rank Sum Tests

Post-hoc Comparisons	p-value
TN-1 vs TN-3	0.0009
TN-1 vs TN-8	< 0.0001
TN-2 vs TN-4	0.0036
TN-2 vs TN-8	< 0.0001
TN-3 vs TN-4	0.00005
TN-4 vs TN-8	< 0.0001
All other comparisons	≥ 0.05

The table reports the p-values from post-hoc pairwise comparisons using the Wilcoxon rank sum test with continuity correction for all group combinations. Values below 0.05 indicate statistically significant differences between the corresponding groups.

Average duration also differed by type (Table 1). TN-1 and TN-4 had the longest mean durations (298 and 322 days), reflecting more complex clinical and economic assessments despite TN-1's lower deferral rate. TN-3, TN-5, and TN-8 were shorter (151, 187, and 134 days).

Duration of procedures

Across procedures, the mean duration was 269 days (SD 208.2), median 196 (IQR 133-350). The shortest lasted 21 days and the longest 1,418, reflecting the inclusion of dossiers started before full CSE consolidation. These figures refer only to the CSE-related procedural duration captured in public AIFA documents and should not be interpreted as full time to reimbursement, publication in the GU, or effective patient access.

Among the concluded procedures, the duration varied by type. TN-4 was the longest (mean 377 days; median 330), followed by TN-1 (mean 364; median 303), consistent with more complex renegotiations and assessments of therapeutic value or economic impact. TN-8 was much shorter (mean 134 days), suggesting more streamlined, standardized negotiations (Figure 2).

The Kruskal-Wallis test showed significant differences across types ($\chi^2 = 101.11$, df = 7, $p < 0.001$). Post-hoc Wilcoxon tests (Holm–Bonferroni) found significant contrasts between TN-1 vs TN-3 and TN-1 vs TN-8 ($p < 0.001$), and between TN-2 vs TN-4, TN-2 vs TN-8, TN-3 vs TN-4, and TN-4 vs TN-8 (all $p < 0.01$). Other comparisons were not significant ($p \geq 0.05$).

Provisional vs final durations

Two complementary indicators were used to track procedural timelines in the first year of CSE activity: provisional duration (time to the latest available outcome) and final duration (time to the last recorded outcome within the observation window).

Figure 3 compares the monthly median provisional duration with the overall final median duration of 196 days; Δ represents the difference between these two measures.

In April–October 2024, the median provisional duration was about 227 days, corresponding to a positive Δ of approximately +31 days, indicating that procedures discussed in early meetings tended to exceed the overall final median observed at study end.

From November 2024 to April 2025, Δ became predominantly negative, with an average of approximately −62 days, indicating closer alignment with, or values below, the final median.

This pattern should be interpreted descriptively: it may reflect the closure of earlier procedures, changes in case mix, and gradual procedural stabilization, rather than a measurable gain in efficiency.

Deferrals and procedural dynamics

Deferrals (*Argomento rinviato*) were frequent in the CSE's first year: procedures averaged 1.9 postponements, and 83.0% experienced at least one, consistent with the overall share of postponed outcomes (50.9%). Deferrals varied by negotiation type, but TN-1 and TN-4 procedures—often involving new active substances, orphan drugs, or renegotiations—had lower rates than more administrative or generic types like TN-2 and TN-8. These differences should be interpreted descriptively. Since public *Esiti* CSE documents do not report the reasons for deferrals, the observed patterns cannot be attributed to specific drivers such as clinical uncertainty, economic negotiation, administrative requirements, workload, or prioritization. Temporal analysis showed clear fluctuations over the year. Months with higher procedural volumes - September 2024, February 2025, and March 2025 - coincided with peaks in deferrals, with the highest in February 2025 (80.6%). Conversely, the lowest incidence of deferrals occurred in July 2024 (32.2%), although the absence of information on the reasons for deferral prevents causal interpretation of these monthly fluctuations.

By the observation period's end, both deferral counts and proportions declined. The monthly pattern, however, shows alternating phases of backlog and clearance, reflecting variable inflow and gradual consolidation of internal procedures

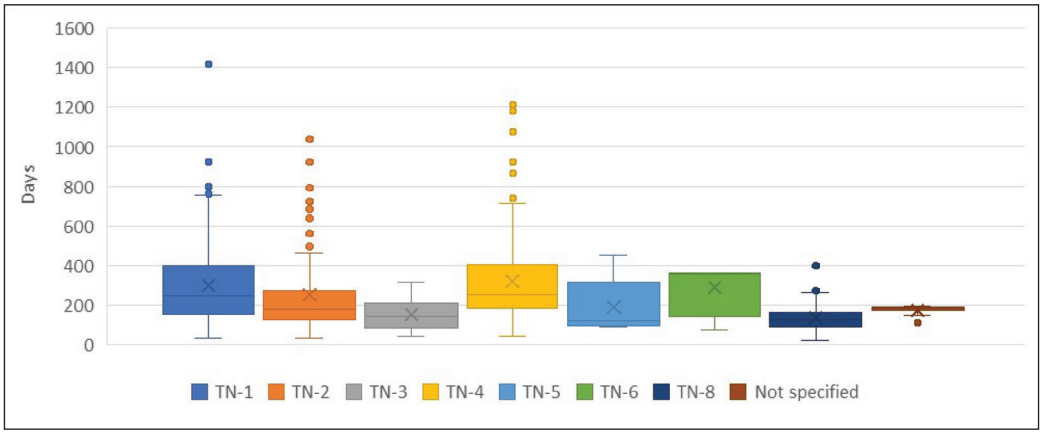


FIGURE 2 - Duration of proceedings (concluded and ongoing) by type of negotiation.
Each box represents the interquartile range (IQR) of the iter duration for a given negotiation type (TN-1 to TN-8), with the central line indicating the median and the "×" symbol marking the mean. Whiskers extend to 1.5× the IQR, and dots represent outliers. TN-1 and TN-4 show the widest dispersion and longest median durations, reflecting higher clinical and economic complexity, whereas TN-3, TN-5, and TN-8 display shorter and more homogeneous timelines.

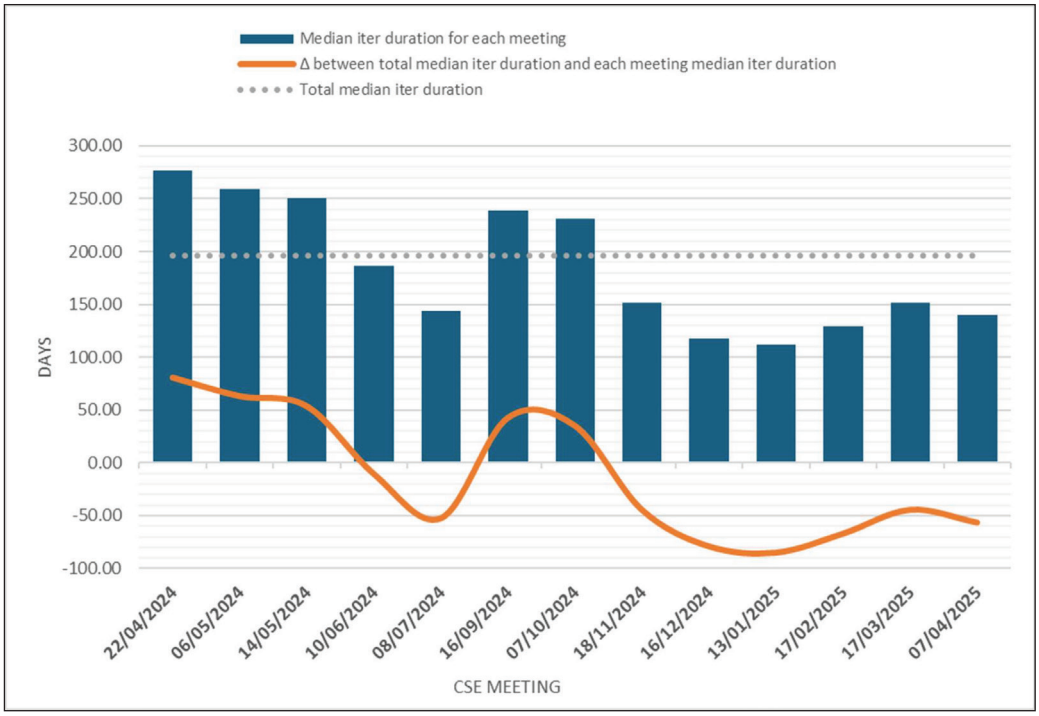


FIGURE 3 - Provisional vs final durations.
Monthly evolution of provisional and final median procedural durations (04/2024 – 04/2025). Blue bars show the median duration for procedures discussed in each monthly CSE meeting, used as a provisional measure. The grey dotted line indicates the overall median based on final CSE outcomes, used as the reference. The orange line represents the difference (Δ) between monthly provisional values and the final median. Positive Δ values indicate higher provisional durations, while negative values indicate lower ones. From November 2024 onward, Δ is mostly negative, suggesting closer alignment with or lower values than the final median. Results are descriptive and do not imply efficiency gains."

under the new governance framework. To examine timeline variability, procedures were split into "fast" and "slow" using the upper quartile (Q3 = 350 days). About 25.1% exceeded this threshold. TN-1 and TN-4 accounted for 83.9% of these cases, while administrative types rarely did. Among slow TN-1 and TN-4 procedures, only 81.7% were concluded by the end of observation, reflecting dossiers initiated under the previous committee structure.

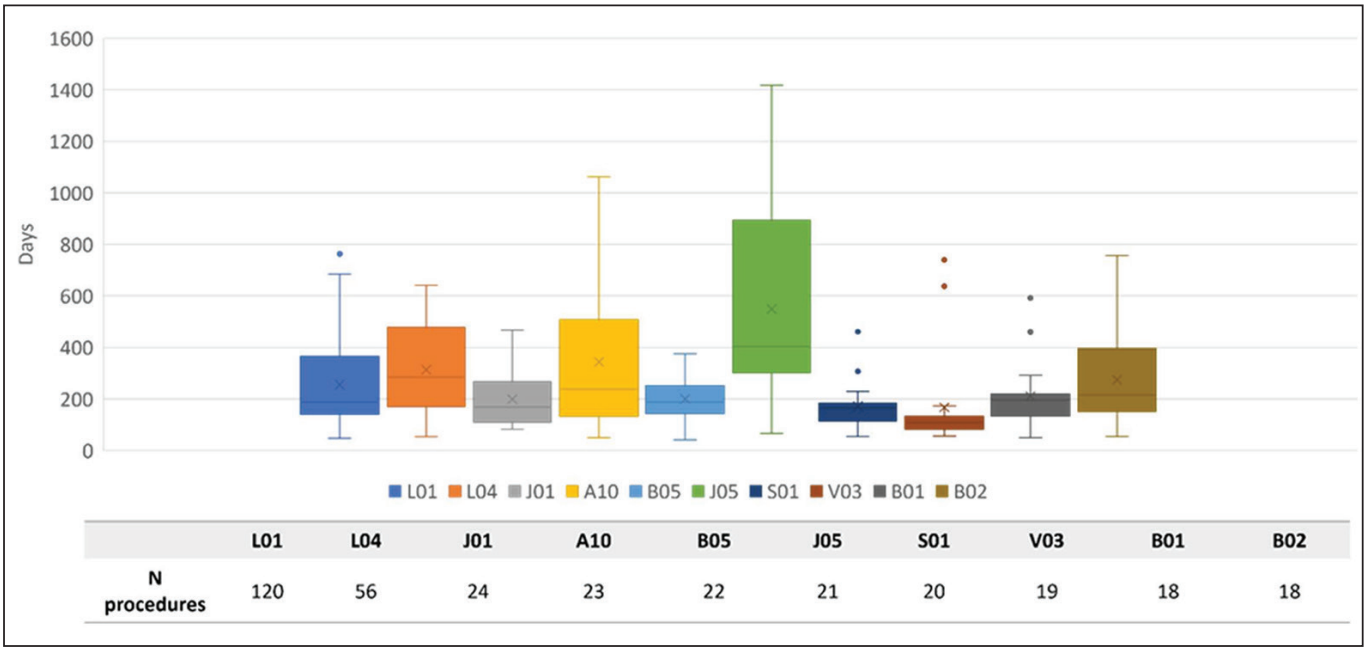
Therapeutic area distribution (ATC classification)

Procedures spanned many therapeutic classes, with higher concentrations in oncology (L01 = 120 procedures, L04 = 56 procedures), systemic antibiotics (J01 = 24 procedures), metabolic/diabetes drugs (A10 = 23 procedures), and blood substitutes (B05 = 22 procedures). Among the ten most represented ATC subgroups, procedural duration and deferral rates varied markedly (Fig. 4).

Oncology (L01, L04) and metabolic agents (A10) had longer, more variable timelines (mean 256-343 days) and moderate-to-high deferral rates (48-62%). Cardiovascular (B01, B02) and ophthalmological (S01) drugs showed shorter, more uniform procedures (167-274 days).

Antivirals (J05) had the longest mean duration (~549 days) but the lowest deferral rate (24%), driven by a single complex hepatitis C dossier that also produced the longest negotiation (1,418 days). B05 procedures had relatively low deferrals (26%) and intermediate durations (~200 days), suggesting more linear pathways.

Overall, innovative or high-impact areas—oncology, metabolic diseases, antivirals—were linked to longer negotiations



	L01	L04	J01	A10	B05	J05	S01	V03	B01	B02
N procedures	120	56	24	23	22	21	20	19	18	18

FIGURE 4 - Average duration—Top 10 short ATC.
Each boxplot represents the distribution of iter durations (in days) for the ten ATC subgroups with the largest number of procedures. Oncology (L01, L04) and metabolic agents (A10) show prolonged and variable timelines, while cardiovascular (B01, B02) and ophthalmologic (S01) agents display shorter durations. The antiviral class (J05) stands out for its exceptionally high mean duration (≈ 549 days) but the lowest deferral rate (24%), driven by one outlier case (medicinal product for hepatitis C) with the longest recorded negotiation time (1,418 days). Boxes indicate interquartile ranges (IQR), the central line denotes the median, and the "×" symbol represents the mean.

than areas with established comparators and stronger evidence bases. Results should be interpreted cautiously, as variability may reflect negotiation types and procedural stages within the observation period.

Since comparable pre-reform CTS/CPR data are unavailable, it is unclear whether observed durations reflect improvement or continuation of past patterns. This analysis provides a baseline for future evaluations of CSE performance across therapeutic areas.

Innovation status

Among TN-1 procedures, 35 included a request for innovation status; 11 (31.4%) were approved, while two did not lead to reimbursement. Approved cases had a slightly shorter mean duration (~307 days) than the TN-1 average.

This difference should be interpreted cautiously: it may reflect stronger evidence, internal prioritization, or simpler evaluation pathways, rather than acceleration due to innovation status itself.

Discussion

The first year of activity of the *Commissione scientifica ed economica del farmaco* (CSE) provides an initial opportunity to observe how Italy's new integrated framework for pharmaceutical pricing and reimbursement has operated in practice. Using exclusively publicly available information released by the Italian Medicines Agency (AIFA), this study offers a descriptive assessment of procedural workload, timelines, and negotiation outcomes during the CSE's initial operational phase.

Overall, the findings depict a system managing a substantial operational burden, characterized by marked variability in procedural durations and a high frequency of deferrals. More than half of all recorded outcomes were classified as *Argomento rinviato*, particularly among TN-1 and TN-4 procedures. This indicates that several procedures required repeated discussion before reaching a final recorded outcome and should be read in the context of the intrinsic complexity of combined clinical and economic assessment under the CSE framework. However, because the reasons for deferral are not reported in the public source, deferrals should be interpreted as an observed procedural outcome rather than as direct evidence of clinical uncertainty, economic disagreement, administrative delay, or inefficiency.

The analysis of provisional and final procedural durations shows that the gap between these two indicators progressively narrowed over the course of the year. While this pattern may suggest a more regular procedural flow as earlier cases reached completion, it should not be interpreted as evidence of improved efficiency. In the absence of pre-reform benchmarks, it is not possible to distinguish between genuine performance gains, the gradual resolution of an initial backlog, or the normal adjustment dynamics of a newly established governance structure. The results should therefore be interpreted as a baseline description of CSE activity during its first operational year.

Some operational features nonetheless emerge. The integration of scientific and economic evaluation within a single committee may support a more coordinated assessment process. At the same time, the persistently high proportion of deferrals is consistent with the iterative nature of decision-making within a single deliberative framework, where evidence generation, pricing expectations, and procedural timing need to be aligned. In this respect, deferrals may be viewed as a procedural signal that some procedures required repeated CSE discussion before reaching an outcome, rather than as a standalone marker of system performance.

Differences across therapeutic areas further illustrate this complexity. Oncology (L01, L04) and metabolic disorders (A10) were associated with longer and more variable timelines, while antivirals for systemic use (J05) exhibited particularly long durations but comparatively low deferral rates. In the latter case, this pattern was largely driven by a single highly complex dossier for chronic hepatitis C, which accounted for the longest negotiation observed in the dataset (1,418 days). These findings underscore how rapidly evolving or high-impact therapeutic areas tend to generate more complex and prolonged evaluation pathways, especially when uncertainty around comparative value and long-term impact remains.

Importantly, two key AIFA policy documents published after the period covered by this analysis: the revised criteria for the recognition of innovativeness (11) and the new guidelines for pricing, reimbursement, and HTA dossier submission (12), provide additional context for interpreting these findings. Both documents formalize expectations around evidence maturity, comparative positioning, economic modelling, and clearer alignment between evidentiary readiness and procedural progression. The patterns observed in this study - particularly the frequency of deferrals and the variability in timelines - provide relevant context for these updates, which address areas related to alignment between applicants and the Agency that proved most challenging during the CSE's first year.

Several limitations must be acknowledged. First, the absence of structured and comparable data from the former CTS/CPR system prevents direct comparison with pre-reform performance. Second, public *Esiti CSE* documents do not report the reasons underlying deferrals, precluding analysis of whether delays were driven primarily by clinical, economic, or administrative factors. Third, procedural duration was measured from intake to the last recorded CSE outcome and does not capture formal suspensions under the Ministerial Decree of 2 August 2019 (13), nor the interval between CSE decision and publication in the *Gazzetta Ufficiale*. Fourth, post-CSE phases, such as managed entry agreements, registry activation, and contractual implementation, were outside the scope of this analysis, despite their relevance for patient access and budget impact. Therefore, the duration metric should be interpreted as a CSE-phase procedural indicator and not as full time to reimbursement, implementation, or effective patient access. Finally, reliance on public data implies that completeness and accuracy depend on the consistency of AIFA's reporting practices.

Despite these limitations, the study provides a reproducible empirical reconstruction of the CSE's first year of activity. It portrays a system in transition, coping with a large and heterogeneous workload while progressively consolidating internal procedures. Future progress will likely depend on earlier and more structured interaction between AIFA and applicants, clearer articulation of evidence expectations—now partly addressed by the updated guidance—and more consistent public reporting of procedural milestones to support monitoring and accountability.

From a broader policy perspective, the Italian experience offers early insight into the practical implications of integrating scientific and economic evaluation within a single governance structure, an approach that will become increasingly relevant under the European HTA Regulation (EU) 2021/2282 (14). Future research should integrate quantitative monitoring with qualitative inquiry, including perspectives from institutions, industry, and patients, to better understand how integrated assessment models influence procedural functioning, transparency, and equitable access to medicines.

Conclusions

The first year of activity of the *Commissione scientifica ed economica del farmaco* marks a phase of institutional consolidation within Italy's pharmaceutical pricing and reimbursement system. Using publicly available AIFA data, this study provides the first empirical overview of the CSE's workload, timelines, and negotiation outcomes.

Findings indicate a high volume of heterogeneous procedures, marked variability in CSE-phase duration across negotiation types and therapeutic areas, and frequent use of deferrals within the decision-making process. These findings should be interpreted as procedural indicators rather than as measures of full-time to reimbursement or patient access. Some signs of procedural stabilization emerge over time, although the lack of historical benchmarks and the absence of information on the reasons for deferrals limit causal interpretation.

Overall, this analysis establishes a baseline for future monitoring of the CSE. In the context of updated innovativeness criteria and new P&R and HTA dossier guidelines, it offers an empirical reference for evaluating the impact of evolving governance, evidence requirements, and procedural transparency.

Disclosures

Conflict of interest: The authors declare no conflict of interest.

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Data availability statement: Data were created by analyzing all publicly available "Esiti CSE" documents published by the Italian Medicines Agency (AIFA) between April 2024 and April 2025.

References

1. Gazzetta ufficiale Della Repubblica Italiana. Serie generale n. 11, 15 gennaio 2024. Decreto del Ministro della Salute 8 gennaio 2024, n. 3, Regolamento recante modifiche al regolamento sull'organizzazione e sul funzionamento dell'Agenzia italiana del farmaco (AIFA). Online (Accessed February 2026)
2. Gazzetta Ufficiale della Repubblica Italiana.Decreto del Ministro della Salute 20 settembre 2004, n. 245, Regolamento

sull'organizzazione e sul funzionamento dell'Agenzia Italiana del Farmaco (AIFA), art. 19 (Commissione consultiva tecnico-scientifica – CTS e Comitato prezzi e rimborso – CPR). Health, Ministry of. 2004. Online (Accessed February 2026)
3. WHO Collaborating Centre for Drug Statistics. Anatomical Therapeutic Chemical (ATC) Classification System. World Health Organization. Methodology. Online (Accessed February 2026)
4. Agenzia Italiana del Farmaco (AIFA). Esiti CSE – Settore HTA ed Economia del Farmaco. Online (Accessed February 2026)
5. Agenzia Italiana del Farmaco (AIFA). Online (Accessed February 2026)
6. European Medicines Agency (EMA). Online. (Accessed February 2026)
7. AIFA. Innovative medicinal products: list of medicines recognized as innovative. Online (Accessed February 2026)
8. Fisher RA. Statistical methods for research workers. Edinburgh, UK: Oliver and Boyd: s.n., 1925. Online (Accessed February 2026)
9. Altman DG. Practical Statistics for Medical Research. [book auth.] Chapman & Hall/CRC; 1991. CrossRef
10. Computing, Core Team. R: A language and environment for statistical computing (Version 4.4.1). R Foundation for Statistical Computing. 2024. Online (Accessed February 2026).
11. Agenzia Italiana del Farmaco. Criteri di valutazione per l'attribuzione dell'innovatività terapeutica e sulla gestione. Determina n. Pres/966/2025 pubblicata nella Gazzetta Ufficiale n. 160 del 12 luglio 2025. Online (Accessed February 2026)
12. Agenzia Italiana del Farmaco. Linee guida per la compilazione del dossier a supporto dell'Health Technology Assessment di un medicinale ai fini della rimborsabilità e del prezzo a carico del Servizio Sanitario Nazionale. Determinazione DTS n. 88/2025, 23 dicembre 2025 (operative dal 1° aprile 2026). Online (Accessed February 2026)
13. Gazzetta Ufficiale della Repubblica Italiana, Serie Generale n. 185, 24 luglio 2020. Decreto 2 agosto 2019. Criteri e modalità con cui l'Agenzia Italiana del Farmaco determina, mediante negoziazione, i prezzi dei farmaci rimborsati dal Servizio sanitario nazionale. Online (Accessed February 2026)
14. Council of the European Union, European Parliament. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. Official Journal of the European Union. 2021;458:1-32. Online (Accessed February 2026)
15. Ministry of Health. Decreto del Ministro della Salute 20 settembre 2004, n. 245, Regolamento sull'organizzazione e sul funzionamento dell'Agenzia Italiana del Farmaco (AIFA), art. 19. Commissione consultiva tecnico-scientifica – CTS e CPR. Online (Accessed February 2026)