The new Italian Scientific and Economic Committee for Medicines: evaluation of its first months of activity

HTA357

Authors. Giulia Fagnocchi[1], Letizia Rossi[1], Giovanni Callegaro[1], Mariangela Prada[2]

[1] PLG Italy – Intexo Società Benefit, [2] PLG Global.

Background and Objectives.

On 15th January 2024, the Italian Decree of the Minister of Health of 8th January 2024 on "Changes to the regulation on the organization and functioning of Italian Medicines Agency (AIFA)" came into force. The new Regulation, among the various modifications and changes, replaced the former Technical Scientific Commission (CTS) and Pricing and Reimbursement Committee (CPR) with a new, and unique, "Scientific and Economic Committee for Medicines" (CSE), aimed at optimizing and speeding up the pricing and reimbursement process in Italy for the benefit of patients and their access to therapies. [1]

The CSE mandate is to consolidate into a single commission the tasks previously handled by the CTS and CPR, such as defining place in therapy and added therapeutic value of drugs, approving reimbursement by the National Health System (NHS), assigning the innovation status, proposing a negotiation framework possibly refined by NHS cost-control measures and tools. [1]

The purpose of this work is to analyze the first months of activity of the new CSE, so far.

Methods.

Outcomes of CSE meetings (HTA evaluations for medicinal products, MPs) was extracted from the AIFA website, from the first session (22-24/04/24) to the last available at the time of Poster submission (16-20/09/24). CSE sessions typically last five days, with results published one week after the session concludes. Regular CSE sessions are held monthly, with occasional extraordinary sessions to accommodate postponed activities from the regular meeting. [1]

The evaluations were made considering all the negotiation typologies identified by AIFA (from TN-1 to TN-8). The typologies are: TN-1 New active substance or new indications; TN-2 Drugs already on the market; TN-3 Drugs with patent expired; TN-4 Revisions to the conditions of eligibility for reimbursement; TN-5 Special procedures – Law 648/96; TN-6 Other special procedures; TN-7 Parallel importations; TN-8 Quicker and simpler procedures.

For each MPs' procedure, type of negotiation and outcome have been tracked.

Our task is to constantly update the commission's activity statistics to evaluate its progress.

REFERENCES

[1] Decree of 8 January 2024 (Official Italian Gazette 15 January 2024) «Regulation on amendments to the regulation on the organization and functioning of Italian Medicines Agency (AIFA)"

[2] Agenzia Italiana del Farmaco - AIFA website. Available at: https://www.aifa.gov.it/

Results.

To date, in 6 CSE sessions, 814 procedures were planned in agenda (n=390, 47,91% evaluated; n=424, 52,09% postponed). AIFA prioritized some regulatory procedures, focusing first on reducing a significant backlog, and over two months cleared around 400 pending cases. [2]

The percentage of assessed vs postponed procedures did not follow a clear trend over the months. In the first CSE, 42.75% of the files were evaluated (n=56/131). In the subsequent CSEs, 29.49% (n=23/78), 57.83% (n=48/83), 58.38% (n=108/185), 69.93% (n=100/143), 28.35% (n=55/194) of the procedures were assessed respectively.

The number of procedures discussed per day during each CSE session did not follow a clear trend over the months. From figure 3 we can see how after a slow start, AIFA has begun to fully enter into its new structure, progressively increasing the number of practices discussed per day. The session of 16-20 September went a bit against the trend of the previous months however.

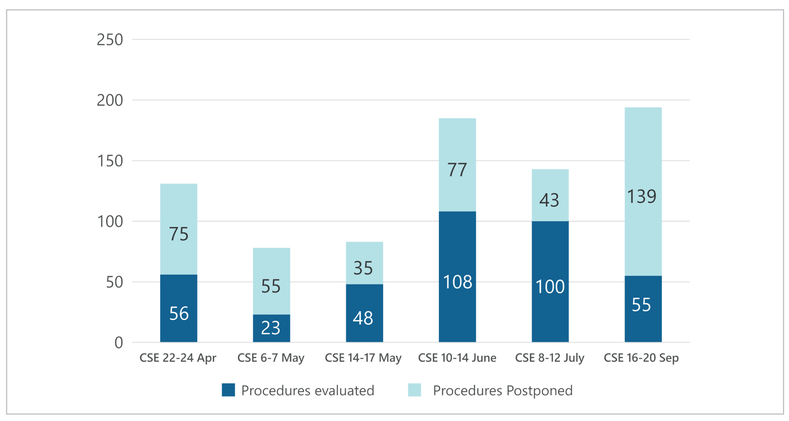

Figure 1: Procedures evaluated vs Procedures postponed (Apr '24 - Sept -24)

- TN-1 procedures (new drugs, orphan drugs, and/or new indications) were 37,71% of the total scheduled by AIFA (n=307/814). 166 of the 307 (54,07%) were discussed. In this typology, AIFA prioritized "Extension of indication" (n=73 evaluated on n=119 scheduled; 61,34% evaluated) and "Orphan drugs" (n=31 evaluated on n=60 scheduled; 51,67% evaluated), while the "New active substance" procedures have been assessed at 48,18% (n=53 evaluated on n=110 scheduled). The other sub-categories of negotiation types have numbers too small to be evaluated. [2]
- TN-2 procedures were 13,02% of the total scheduled by AIFA (n=106/814). 57 of the 106 (53,77%) were discussed. In this typology, AIFA prioritized "new packs" (n=16 evaluated on n=18 scheduled; 88,89% evaluated). The second prioritized category was "pack substitution of drugs already on the market" (n=27 evaluated on n=61 scheduled; 44,26% evaluated). The other sub-categories of negotiation types have numbers too small to be evaluated. [2]
- TN-3 procedures were 4,55% of the total scheduled by AIFA (n=37/814). 18 of the 37 (48,65%) were discussed. In this typology, the sub-categories are not clear enough to do deeper evaluations. [2]
- TN-4 procedures were 35,75% of the total scheduled by AIFA (n=291/814). 124 were assessed (42,61%; n=124/291). Within this typology, the majority of procedures (n=268) concerned renegotiations to revise the negotiation agreement. The other sub-categories of negotiation types have numbers too small to be evaluated. [2]
- TN-5 procedures were 0,86% of the total scheduled by AIFA (n=7/814). 3 were assessed (42,86%; n=3/7). [2]
- TN-6 procedures were 0,49% of the total scheduled by AIFA (n=4/814). 2 were assessed (50,00%; n=2/4). [2]

Parallel imports of drugs (type TN-7) were not mapped in the CSE evaluations. [2]

- TN-8 procedures were 7,25% of the total scheduled by AIFA (n=59/814). 20 were assessed (33,90%; n=20/59). [2]

In the total of 814 dossiers evaluated by the CSE, there are n=3 dossiers without specific type assignment. [2]

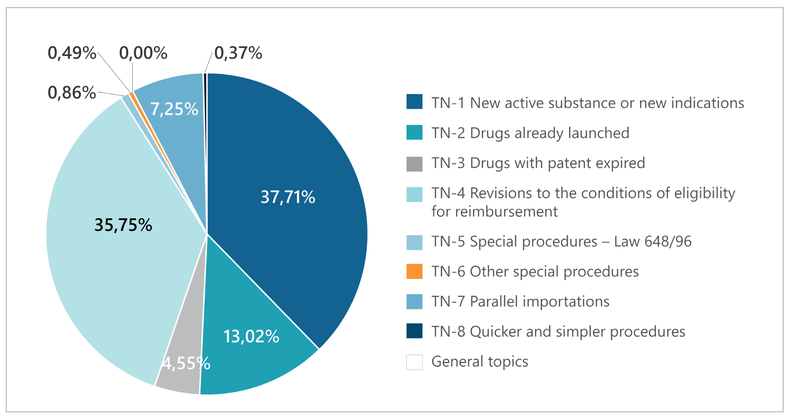

Figure 2: Negotiation types

Regarding the negotiation types discussed in each meeting, at the beginning of the CSE TN-1 procedures were the most discussed, probably due to the queue, and then the percentage stands at around 35/40%. TN-2 procedures represent the 27% of discussed procedures during the first meeting, but then they stabilized at around 15% in the last meeting. TN-3 procedures were very less present in almost all the meetings, as for TN-5, TN-8. For TN-4 the trend is less recognizable, as at the beginning the discussed procedures were around 10%, with a pick of 54% in the meeting of 14-17 May and then the percentage reduced at around 22% in the last meeting (16-20 September). In conclusion, the percentage of negotiation procedure types discussed in each meeting did not follow a clear trend up to date.

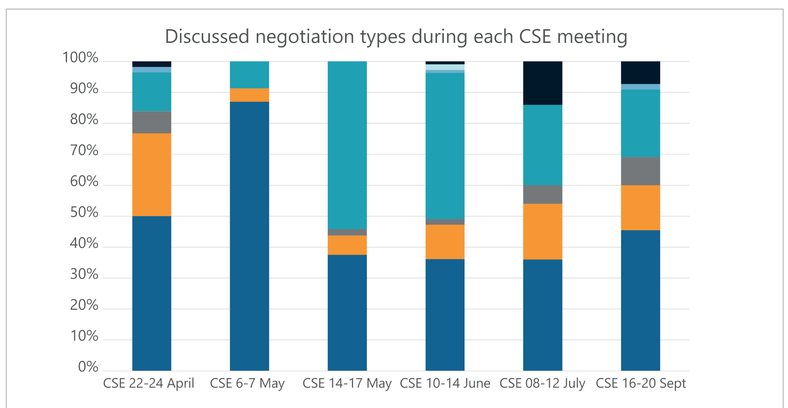

Figure 3: Negotiation procedure types discussed in each meeting

Conclusion.

One of the key goals of the new AIFA framework is to improve and accelerate the drug price and reimbursement process. Our data clearly show that since its beginning, the new CSE has been working in this direction, prioritizing new drugs, more specifically new drugs with an orphan designation, and more strategic procedures ("Extension of therapeutic indications" or "Revisions to the conditions of eligibility for reimbursement").

Based on the data analyzed from the meetings held between April and September 2024 (6 sessions) and considering all procedure typologies in the new CSE's agendas, 47,91% of cases were assessed (n=390/814), and 52,09% were postponed (n=424/814). [2] Although the Agency is working to reduce the time to reimbursement, the queue of practices (formed during the months in which the Agency has not been working) is weighing down the work. The benefits of the Unique Commission in terms of time reduction will be seen when the queue will be over.AIFA prioritized TN-1 procedures (n=307/814, evaluated n=166/307, 54,07%). Of the 307 TN-1 in the agenda during this period, 45,93% were postponed (n=141/307). [2] This is because the Agency has a mandate to promote innovation and therefore prioritizes TN-1 procedures of new, orphan drugs.

At this point it is premature to draw conclusions, whether this AIFA reform has brought the expected benefits. Our task will be to evaluate the impact of the new reform in the coming months.

In the next few months, having more mature data, we will be able to observe if the trend goes back up and we will also be able to observe the impact in terms of access time to patients.

intexo Società Benefit
A ProductLifeGroup Company

PLG ProductLifeGroup