9th HTA conference

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DIVANI CARAVEL

Industry Perspective on Navigating the new HTA landscape

Olympios PAPADIMITRIOU

President of the Hellenic Association of Pharmaceutical Companies (SFEE) &

General Manager, Novo Nordisk Hellas

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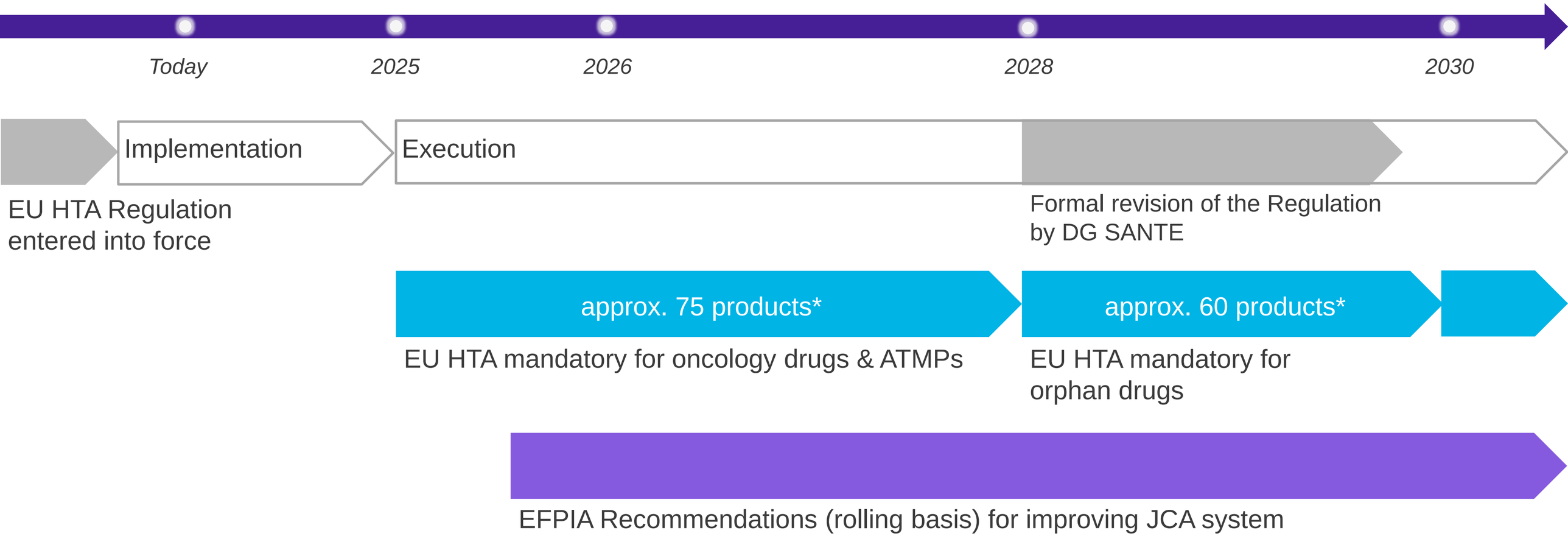
HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

The EU HTA Regulation comes into force beginning 2025



* Medicinal products of EFPIA members (rough calculations based on internal EFPIA survey which estimated 25 products in scope in 2025)

Success of EU HTA depends on JCA reports

The success of the EU HTA Regulation is contingent on the ability of the system to deliver high-quality JCA reports which provide added-value to national decision-makers.

As such, the JCA process needs to:

- facilitate **early engagement with the health technology developer** (HTD), to ensure a timely and optimally informed start of the process and to enable the systematic exchange of relevant information with the HTD
- provide all participants with the necessary **information and evidence** for the scoping and assessment
- guarantee **sufficient time for HTDs** to conduct the relevant analyses required for preparing and finalizing their clinical evidence submission dossier
- allow assessors **sufficient time to review** the JCA dossier and to develop a high-quality JCA report

Concerns about JCA implementing act

EFPIA & SFEE are concerned about **several glaring shortcoming in this draft JCA** implementing act, especially regarding the workability of the JCA process, where it undermines the capacity of the HTD (from SMEs and biotech to larger pharmaceutical companies) to provide a good quality submission to the assessors and co-assessors.

Several reasons drive this concern:

- the unbalanced time allocation between scoping and submission stages,
- the absence of visibility on submission's scope coupled with
- the expected size/complexity of the assessment scope driven from a mechanistic need to satisfy all needs of all Member States and
- the lack of meaningful participation of the HTDs at key steps of the process

Our proposals

- **The need for workable timelines and more time for dossier preparation**: the assessment scope should be finalized within 90 days of the start of the JCA procedure and the HTD should have at least 135 days to prepare a high-quality submission dossier.

- **More clarity on the exchange of information with EMA:** the HTD should have the opportunity to leverage all relevant information, evidence, and knowledge as a key input into the definition of the assessment scope.

- **Scoping meetings with all companies**: the HTD should have an opportunity to meet and discuss with the assessor/co-assessor its views on the draft assessment scope.

- **More efficient PICO process by including information from companies:** the HTD should have visibility on the draft assessment scope proposed by the assessor/co-assessor as well as on the PICO survey responses from Member States (in an anonymized manner) at the earliest possible stage, to be able appropriate time to submit a high-quality submission response.

- **Confidentiality of commercially sensitive data**

Impact for Greece

- The EU HTA Regulation represents an **opportunity not to be missed**.
- For that to happen, the recently established Greek National HTA Body needs to be **adequately staffed**, both in numbers and expertise.
- **Technical assistance** in the period before the implementation is crucial, as is the continuous training and support after the implementation.
- At the local level, since all the **legislative changes** that will allow for national alignment with the EU Regulation need to happen within the short period of the next few months, the Greek Government needs to be pushed so as not to miss the strict deadline.

Conclusions

- The EU HTA Regulation represents a step-change in the assessment of clinical evidence of new technologies at EU level and has the **potential to accelerate and improve access to patients** as well as reduce inefficiencies and duplications, goals that the pharmaceutical industry shares.

- The EU HTA Regulation is a reality and **will start to affect HTA bodies**, health technology developers and their technologies as well as patients and clinicians in **less than 10 months' time**.

- The draft JCA implementing act can set the path towards a successful EU JCA system if it **recognizes the role of key stakeholders** in the process and enables a rebalancing of workload in line with respective remits and obligations.

- The proposed **procedural changes** are the minimum necessary to safeguard the future JCA system.

Thank you!