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Response to JCA implementing act

The Danish Association of the Pharmaceutical Industry (Lif) represents 41 Danish and international pharmaceutical companies that develop, produce, sell or market medicines in Denmark and which have approximately 20,000 employees in Denmark. Lif is a member of the European federation of Pharmaceutical Industries and Associations (EFPIA). In addition to the response below we also refer to the EFPIA submission to the public consultation on the JCA implementing act.

Lif represents companies in Denmark with extensive experience with submitting HTA dossiers to support national decision making regarding the use of medicines, this experience guides the comments below.

The EU HTA Regulation has the potential to accelerate and improve access to new medicines for patients as well as reduce inefficiencies, duplications and administrative burdens for member states and companies. The EU HTA Regulation is therefore crucial and will affect HTA bodies, health technology developers and their technologies as well as patients and clinicians already from January 2025.

The success of the EU HTA Regulation depends on the ability of the system to deliver high-quality JCA reports which provide added-value to national decision-makers. Lif has several concerns with the draft JCA implementing act, especially regarding the lack of involvement of the HTD, the workability of the JCA process, and the lack of transparency all of which undermines the capacity of the HTD to provide a good quality submission.

Lack of involvement of the HTD

The JCA process must facilitate early engagement with the HTD to ensure a timely and optimally informed start of the process and to enable the systematic exchange of relevant information with the HTD. Meaningful participation of the HTDs at key steps of the process is a foundation for an effective process and a JCA report of high quality. Therefore, the HTD should have an opportunity to meet and discuss with the assessor/co-assessor its views on the draft assessment scope. The early and continuous involvement of the HTD has proven to be an advantage for all parties in the Danish HTA-system because it makes it possible to address and unclarities when they arise.

Workability og the JCA process

The draft JCA implementing act has a strongly unbalanced time allocation between scoping and submission stages. The timelines must guarantee sufficient time for HTDs to conduct the relevant analyses required for preparing and finalizing their clinical evidence submission dossier. The timelines must also allow assessors sufficient time to review the JCA dossier and to develop a high-quality JCA report.

Therefore, 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. 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.

Lack of transparency

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 at the earliest possible stage. The ability to develop a high-quality submission response will depend on the HTD having appropriate time. The process should provide all participants with the necessary information and evidence for the scoping and assessment.

The draft JCA implementing acts set limits to the visibility on submission's scope, which is coupled with the expected size/complexity of the assessment scope driven from a mechanistic need to satisfy all needs of all Member States

Lif believes that the draft JCA implementing act can set the path towards a successful EU JCA system if it recognizes the role key stakeholder in the process and enables a rebalancing of workload in line with respective remits and obligations. In practice, this means that:

These suggested procedural changes are in Lif's opinion necessary to safeguard the success of the JCA system. Furthermore, Lif refers to EFPIAs submission and the proposals for procedural changes and proposed amendments that are necessary to ensure a solid JCA system.