One year of EU HTA - Learnings from ongoing JCAs

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We have now passed the year-mark for the implementation of the Regulation (EU) 2021/2282 on health technology assessment and while everyone is still eagerly awaiting the first JCA report, constructive exchange around some of the Initial experiences from the first year already have already helped to improve the functioning of the system.

We are pleased to see that there is a gradual increase in the capacity for Joint Scientific Consultations with an increase in the number of slots for advice meetings in 2026. The doubling of the number of request periods throughout the year is also very welcome, since it will make it easier for companies to apply for a slot that matches their development timeline.

However, the overall number of advice meetings is still too low to meet the high demand from companies - and while some EUCOPE members have been able to secure an advice meeting for their product, others will enter into the JCA without having had this opportunity.

14 JCAs have been initiated at the time of writing, and eight of these products are being developed and launched by small or mid-sized companies, and in many cases by smaller biotechs that originate outside the EU.

During the 2025 EAA fall pre-convention, the EMA SME office presented the various ways that they offer to support smaller companies in preparing for the Marketing Authorisation Application by offering advice, guidance and assistance. This support includes the opportunity for companies to request briefing meetings, which consists of early dialogue and discussion of regulatory strategy or product development with the opportunity for follow-up guidance.

One of the initial learnings that we are seeing is that there is a need for additional opportunities for early interactions between the developers and HTA bodies, both while trials are still at the planning stage, and at the start of the JCA, to reduce the risk of misunderstandings regarding what evidence can be expected to be brought forward, which methods to apply and which comparators should be used for an assessment.

The JCA timeline is constructed with short turnaround times, and if misunderstandings are not resolved at the earliest possible stage, there is a higher risk of assessments becoming delayed, discontinued or of poor results.

To reduce this uncertainty, and to avoid poor quality assessments and market launch failures, additional points of interaction should be introduced in the JCA.