European Access Academy

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EU HTA – Procedural Insights & First Learnings

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Impulse Presentation

Speaker name

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Title of the Talk

Challenges for small to mid-sized companies with EU HTA

Abstract

EUCOPE is pleased to partner with EAA for this year's fall convention to organise a pre-conference focused on the needs of small to mid-sized companies.

The very first Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC) have now begun, and we have come one step closer to achieving the idea for a "one-stop-shop" for health technology assessment at the European level.

When the new framework for joint work was first proposed by the European Commission it was welcomed by the pharmaceutical industry, as a unique opportunity for greater alignment on HTA requirements and reduction of duplicative assessments, thereby reducing the burden faced by companies.

For the smaller biopharmaceutical companies, more harmonised HTA requirements will be especially important, since they typically have much smaller market access teams, less resources available for evidence generation, and smaller portfolios, making it much more difficult for such companies to successfully navigate the fragmented HTA landscape in Europe.

While no JCA has been completed yet, a few issues, and certainly valuable lessons, have already been drawn from the first JCAs. To list a few, there has been a need for clarity of the timelines and communicating these early on, awareness of the procedure for early notifications from companies prior to the start of JCA, and the additional clarifications on the scope of products subject to JCA.

With the increasing number of JCAs, additional lessons will be learned, and it will be essential to maintain an ongoing dialogue to address any potential issues as soon as possible. The HTA Stakeholder Network will be an important resource going forward to support the European Commission HTA Secretariat and the HTA Coordination Group (CG), with diverse and in-depth expertise on HTA.

EUCOPE has taken an active role in preparing our member companies for the implementation and has organised a series of webinars and in-person workshops over the last year. With input from our member companies, we are also gathering practical experiences and look forward to sharing lessons learned with the HTA CG and HTA Secretariat, to help continuously improving the functioning of the procedures.

A critical need for companies is the ability to receive scientific advice prior to the JCA. While the first JSCs have begun this year, not all companies that have applied could receive an advice meeting due to limited capacity. The number of request periods and advice meetings will be scaled up from next year, however with Orphan Medicinal Products subject to JCA from 13 January 2028, the need for additional JSC slots will only increase.

There is therefore an urgent need for solutions for providing additional capacity for advice meetings. Possible options could include an earlier introduction of the fee-paying mechanism, or the continuation of the interim scientific advice that was coordinated by G-BA, to offer additional advice meetings beyond the JSC slots that will be available next year.