# Integrated Scientific Advice during the COVID-19 Pandemic

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The process of seeking scientific advice from regulatory agencies and health technology assessment (HTA) bodies has expanded in recent years and more pharmaceutical companies are looking to take advantage of the opportunity. The most prolific providers of this scientific advice is the European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) in Europe. They offer two different parallel consultation pathways – Consolidated Parallel Consultation and Individual Parallel Consultation – in which the EMA provides advice alongside multiple HTA bodies from different European countries (coordinated by EUnetHTA). This advice is intended to enhance manufacturers' clinical development and plans for economic assessment, and there are 11 monthly slots available for submissions.

The COVID-19 pandemic, however, has affected EUnetHTA's ability to participate in Parallel Consultation due to the heavy involvement of healthcare practitioners and bodies in aiding those affected by the pandemic. As a result, EUnetHTA had to temporarily suspend/reduce their input into the Parallel Consultation procedure for submissions made in March and April of 2020. The organization is assessing on a monthly basis based on the status of the pandemic and is updating their website accordingly (https://eunethta.eu/eunethta-response-to-covid-19).

In the meantime, companies are still seeking counsel on scientific advice to keep their products moving forward in the drug development process, and there are still options available.

1. National bodies such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom still have time slots available for 2020 with an expected timeline of approximately 18 weeks, and others such as the Federal Joint Committee (G-BA) in Germany are already booking slots for 2021, with openings now for the end of Q1.

2. Evidera can alternatively assemble a panel of national HTA specialists who can provide advice on the basis of your briefing package if you are no longer able to submit through formal scientific advice procedures and have limited time to inform your development program.

Although the pandemic continues to have far reaching consequences, both within the healthcare industry and more broadly, there are still avenues that exist to allow our work to continue. The reduced availability and consequent delays of formal procedures do not mean companies have no recourse. There are alternative means to understanding the expectations of regulators and HTA bodies early in planning to position your products for overall success. While the current pandemic may be making things more challenging, it has not blocked your access. Resources and experts are still available who can help navigate the path and optimize your drug development program. The important thing is to continue exploring those avenues to reach your ultimate destination. ■

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