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## Official optimism over EU HTA, despite widely contrasting views

by Peter O'Donnell

BRUSSELS, Feb 9 (APM) - The European Commission is remaining optimistic on the prospects for closer cooperation between member states on health technology assessment, even as opposing views on the future continue to pour in.

"I prefer to see the glass as half-full rather than half-empty," Commission official Flora Giorgio told a Wednesday meeting in the European Parliament, where further divergences of view were on show.

She found encouragement in the consensus she said was emerging from responses to the Commission consultation on the need for cooperation and for quality.

The Commission received 63 comments from 21 member state authorities (with the Netherlands, Italy, France and Spain submitting as many as eight responses), she revealed, with the majority believing further cooperation was useful, and more than half considering it unnecessary for national or regional authorities to conduct parallel clinical assessments of the same technology.

A further 150 replies came from public authorities, patients and consumers, hospitals, industry, payers and academia, again showing support for continued cooperation beyond 2020, she said.

The Commission intends to publish its analysis in March, along with the submissions. It is also aiming to stimulate debate in national capitals, to promote the concept that "cooperation presents an opportunity for everybody," said Giorgio.

Her hierarchical superior, Commission director Andrzej Rys, said the process was "typical of Europe" - starting from hearing everyone's positions, then providing assistance to identify and overcome challenges, investing in solutions and reaching decisions.

"I expect there will be decisions arising from what the Commission will recommend later this year that will be implementable by all," he told the meeting.

## **Diversity of views**

However, other speakers meeting expressed more heterogeneous views. Hans-Peter Dauben, head of the German agency for health technology assessment DAHTA, warned against EU-level misunderstanding arising from divergent interpretations of HTA in other countries, settings, or languages, and Susanna Axelsson, head of Swedish HTA agency SBU, warned against underestimating the challenges even of translating national HTA reports into other languages.

National complexities were on display too. Carlo Favaretti, HTA head at the European Public Health Association, spoke of concerns that the trend in Italy towards a national HTA system would become too bureaucratic.

Yannis Natsis of the European Public Health Alliance repeated his view that HTA should play a role in easing access to genuine innovation at a time when "high prices have become the main barrier".

And Edith Frénoy of European pharma trade body EFPIA underlined the industry view that greater political will was needed to ensure uptake of the joint relative efficacy assessments that cooperation might usefully produce.

## **New demands**

Meanwhile, the latest consultation comments seen by APM introduce additional challenges to the reflections.

Health Action International, whose members include consumers, healthcare professionals, academia and public health organisations, manifests deep suspicion of the process and of the risks of industry manipulation.

It speaks of "poor evaluation standards" that ignore clinically relevant outcomes, and of industry fees that "compromise the independence of HTA bodies and favour a situation of regulatory capture which undermines the quality of assessment and decision-making".

It suggests that the current system does not promote "genuine public health needs" because of "opaque and fee-based scientific advice that poses concerns from the perspective of regulatory capture."

And it flatly rejects any centralisation. "HTA assessments must be decentralised and done by national/regional HTA bodies," it says.

## **Cancer coalition focuses on pricing**

The submission from the European Cancer Patients Coalition focuses heavily on pricing, access and patient involvement.

But overall, it favours "the creation and implementation of pan-European full HTA assessment" including cost-effectiveness evaluations - a much more ambitious plan than merely assessing relative efficacy, but which ECPC says is "perfectly in line and within the spirit of the EU treaties".

Such an approach "would lead to substantially fairer and more sustainable pricing negotiations," it argues.

It also sees inadequacies in the influence of current national HTA processes, since "non-binding reports undermine the principle of evidence-based policymaking".

It wants to see Europe develop a system in which "a body independent from medicines agencies and national ministries should be in charge of producing HTA reports, to avoid any possible conflict of interests and/or exploitation of HTA for political or economic reasons."

Wim Goettsch, head of EUnetHTA3, the latest EU attempt to promote cooperation, acknowledged the challenges but said "the path towards a solution" is open as member states become more aware of the underlying issues.

"There is some willingness to adapt national approaches, but some countries are more resistant to change, and we have to find where we can fit in."

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