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The BioMed Alliance calls on the German EU Council Presidency to guide Member States into adopting a position on the Regulation of Health Technology Assessment

The Biomedical Alliance in Europe (BioMed Alliance) is a non-profit organisation representing 33 leading European research and medical societies uniting more than 400,000 researchers and healthcare professionals, making daily use of health technologies.

In July 2019, the Biomedical Alliance in Europe issued a Statement urging Member States to support EU-level Health Technology Assessment (HTA). Health technologies are used for the diagnosis, treatment and management of diseases. Those health technologies are as fundamental to good healthcare as the clinical expertise of Medical Societies is to the evaluation of new technologies. The Biomedical Alliance welcomed the Commission¹ and European Parliament proposals² for a Regulation on HTA as contributing to create a robust and effective framework for collaborative EU-level HTA.

Today we want to re-affirm our <u>statement</u> and emphasize that the COVID-19 pandemic shows the importance of having a legally sound and functioning HTA system in place.

The European Union is facing a decisive challenge with the COVID-19 pandemic and the German EU Council presidency is understandably focused on overcoming the consequences of the coronavirus crisis for the long term. We strongly support and praise this prioritisation. However, we ask the German presidency to work in parallel on the HTA dossier. We would like to stress that a strong HTA system would help to manage and hence overcome the consequences of the unprecedent coronavirus crisis.

Faced with the pandemic, some member states awarded contracts for medical supplies that proved to be of disastrous quality. Some serologic tests or ventilators could have been disqualified beforehand if member states would have shared information on pricing and lack of clinical efficacy. An efficient and rapid HTA consultation would have provided a rationale for some of the purchases while disqualifying others. Therefore, an established framework for voluntary cooperation between HTA bodies could help to efficiently organise the public procurement of high-quality, cost-effective medical devices.

Moreover, enhanced EU-level cooperation on HTA would be extremely useful to understand the impact of COVID-19 on public health interventions in terms of collateral damage, and to propose measures to mitigate such damage in future waves. **EU-level HTA could be used to assess patient safety and budget impact of online consultations/telemedicine.** In a broader context, EU-level HTA will be extremely useful to evaluate the rationale and effectiveness of mandatory anti-SARS-CoV-2 vaccination policies and therapeutic interventions as well as their cost effectiveness.

The impact of COVID-19 on the quality and costs of healthcare has shown that EU-level HTA is needed more than ever. We urge the German Presidency to take the lead in breaking the deadlock on this important topic. The Council should finally join the European Commission and the European Parliament in responding to the call from healthcare professionals and patients – and almost all other stakeholders – to deliver an effective mechanism for collaborative, harmonized HTA that will help ensure the sustained quality, affordability and accessibility of healthcare in Europe.

¹ Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

² European Parliament legislative resolution of 14 February 2019