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## Medical societies call for evidence-based EU health policy and regulation

**Topics:** Medical device regulation, Health technology assessment, Artificial intelligence

**Embargo:** 22 April 2021 at 07:00 CEST

**Brussels, 22 April 2021:** Today medical societies will put forward the case for more robust, evidence-based EU health policies during a meeting of the European Parliament's Science and Technology Options Assessment Panel<sup>1</sup>.

Experts from the Biomedical Alliance in Europe<sup>2</sup>, the European Society of Cardiology<sup>3</sup>, the European Hematology Association<sup>4</sup> and the European Federation of Clinical Chemistry and Laboratory Medicine<sup>5</sup> will contribute to an online workshop with the European Commission and Members of the European Parliament.

The event will kick off with a discussion on the new In Vitro Diagnostics Regulation<sup>6</sup> and its consequences for the EU health system. In particular, how to ensure the continued availability of essential diagnostic tests, and how healthcare diagnostic providers and EU regulators can work together. Medical leaders appeal for sufficient numbers of notified bodies to complete device certification, legal clarity on the use of in-house devices by clinical laboratories, EU-wide emergency use authorisations of tests during pandemics and the creation of EU reference laboratories.

The second half of the meeting will be devoted to the importance of evidence-based health policies. Medical experts will outline the scientific and clinical rationale for joint health technology assessments and demonstrate how shared processes could have secured efficient public procurement of high-quality medical devices and pharmaceuticals during the COVID-19 crisis. In addition, doctors will illustrate how real-world clinical data and registries could help guide healthcare policies and outline priorities for regulation when using artificial intelligence in medicine.

Professor Piotr Szymanski, Chair of the ESC Regulatory Affairs Committee says: *"The ESC has been a pioneer in providing scientific input to the European Commission through our participation in a number of EU expert groups. We look forward to contributing to the European Health Data Space with our well-established registries programme, including EuroHeart."*

Professor Elizabeth Macintyre, Chair of In-Vitro Diagnostic Working Group and member of the Board of Directors of the BioMed Alliance comments: *"The workshop is an excellent opportunity for European learned societies such as the European Hematology Association, which have understood the importance of concerted action through the BioMed Alliance, to communicate with Members of the European Parliament and with the European Commission. We are convinced that being involved at appropriate stages of legislative innovation and implementation is in our patients' interest and will contribute to advancing medical science and public health in Europe."*

Professor Alan Fraser, Chair of the Task Force on Regulatory Affairs, BioMed Alliance says: *"European medical societies can play a very important role in supporting the development of evidence-based health policy. It is crucial to ensure that medical experts are more*

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*consistently involved throughout the EU decision-making process to compensate for the limited in-house scientific expertise of the European Commission and the European Parliament.”*

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**Notes to editor**

**References**

1. [The Panel for the Future of Science and Technology \(STOA\) of the European Parliament](#)
2. [The Biomedical Alliance in Europe \(BioMed Alliance\)](#)
3. [The European Society of Cardiology \(ESC\)](#)
4. [The European Hematology Association \(EHA\)](#)
5. [The European Federation of Clinical Chemistry and Laboratory Medicine \(EFLM\)](#)
6. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN>

**[About the European Society of Cardiology](#)**

The European Society of Cardiology brings together health care professionals from more than 150 countries, working to advance cardiovascular medicine and help people lead longer, healthier lives.

**[About the Biomedical Alliance in Europe](#)**

The Biomedical Alliance in Europe is the result of a unique initiative of 35 leading European medical societies that together include more than 400,000 researchers and health professionals.

**[About the European Hematology Association](#)**

The European Hematology Association (EHA) promotes excellence in patient care, research and education in hematology. EHA envisions a world without blood disorders by connecting hematologists worldwide, supporting their career development, harmonizing hematology education and advocating for the interests of hematology and hematologists at the

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European level. EHA's activities support clinicians and scientists in advancing hematology care for patients. Its annual congress is attended by some 15,000 hematologists.

**[About the European Federation of Clinical Chemistry and Laboratory Medicine](#)**

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) connects National Societies of Clinical Chemistry and Laboratory Medicine of 40 countries and creates a platform for all European "Specialists in Laboratory Medicine". EFLM provides European leadership in Clinical Chemistry and Laboratory Medicine to national professional societies, the diagnostic industry and to governmental and non-governmental organizations in order to serve the public interest in health care.