EPF's reaction to the draft Implementing Act on Joint Scientific Consultations on Medical Devices and In Vitro Diagnostic Medical Devices

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The European Patients' Forum (EPF) welcomes the publication of the draft Implementing Act on Joint Scientific Consultations on medical devices and in vitro diagnostic medical devices. This is an important step towards ensuring mandatory and meaningful patient involvement in EU health technology assessments (HTA).

We call for **robust, transparent, legitimate and expert participation in joint scientific consultations (JSCs)** to guide the development of technologies that truly meet patient needs.

Patient involvement is essential at all stages of the technology lifecycle, from initial design to implementation and ongoing evaluation. By sharing their experiences, patients provide essential insight into the benefits that matter most to them and the risks they are willing to accept. Their involvement also challenges researchers' assumptions and fosters better alignment of HTA priorities and patients' needs. This is particularly valid in areas such as the safety of technologies, data protection and governance and patient education, which are critical to supporting the direct use of technologies, especially in self-management.

Many patients may find it difficult to interpret or effectively control data from health technologies covered by this Regulation. It is essential to ensure that patients can access and understand safety information on medical devices, as required by the Medical Devices Regulation. In addition, patients need support to develop the literacy necessary to use new technologies, including those that incorporate digital tools and artificial intelligence, to optimise treatment and monitoring. Patient input fosters meaningful innovation, improves transparency, enhances legitimacy and delivers better, more relevant outcomes.

In the context of JSCs, patient involvement ensures that specific needs are articulated and contributes to the development of medical devices that meet those needs. This involvement strengthens patients' sense of active participation, which promotes successful adoption and use of new technologies.

As with the previous proposal on JSCs for medicinal products, practical measures are needed to ensure that patient involvement in JSCs for medical devices is structured and effective. EPF reiterates the key points outlined in its feedback on joint scientific consultations for medicinal products. These include the need for:

- Guidelines for patient participation drafted in collaboration with patient organisations;
- Diversity of patient representation and use of patient experience data;
- Compensation for patient participation;
- Onboarding process for patients by the HTA Secretariat;
- Patient-friendly timelines for input to the JSC;
- Support for digital participation;
- Accessible and patient-friendly documents;
- Protection of patient data.

In addition, we call for mandatory inclusion of patients in the expert panel of the European Medicines Agency (EMA) to ensure the patient perspective in the regulatory process. Further clarification is needed regarding the EMA conflict-of-interest rules for patient participation in expert panels and exchanges of views. Specifically, it should be clarified whether having interests in a healthcare company, such as a pharmaceutical company, would disqualify an individual from participating in medical device procedures, or vice versa. Transparent and consistent guidelines are crucial to ensuring trust and confidence in the process.

The Implementing Act should also explicitly **recognise the role of patient organisations**. These organisations play a crucial role in providing an aggregated perspective of the patient community and in providing evidence-based information that accurately reflects the burden of the disease and the value of treatment, especially in cases where symptoms and their impact vary widely. In rare diseases or diseases with low survival rates, finding individual expert patients can be challenging, making the involvement of patient organisations even more critical. We welcome the possibility for patient organisations to be involved in JSCs but we call for this engagement to be as far as possible predictable to foster sustainable and meaningful involvement. Patient organisations should be actively involved in the selection of patients. Through their networks and established governance and transparency mechanisms, European-level patient organisations can better identify appropriate and EU-wide representative expert profiles. Patient organisations can also assist the HTA secretariat in disseminating information, motivating patients and organisations, and preparing them to participate in EU HTA.

With the invaluable support of its member organisations, EPF will continue to work closely with the European Commission and Member States to ensure that joint HTA rules enable meaningful patient involvement.

ABOUT EPF

EPF is an umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

For all media inquiries please contact EPF Communication Manager Flavia Topan at flavia.topan@eupatient.eu