Navigating Implementation of the EU HTA Regulation for Medical Devices: Insights from National HTA Bodies Across Europe

Rasha A. Alshaikh [1], Kieran A. Walsh [1,2], Susan Spillane [2], Patricia Harrington [2], Michelle O'Neill [2], Conor Teljeur [2], Máirín Ryan[2,3], Caitriona M. O'Driscoll [1],

[1] School of Pharmacy, University College Cork, Cork, Ireland.
[2] Health Technology Assessment Directorate, Health Information and Quality Authority, Cork, Ireland.
[3] Department of Pharmacology & Therapeutics, Trinity College Dublin, Dublin, Ireland.

Introduction

- The EU Health Technology Assessment Regulation (HTAR) introduces Joint Clinical Assessments (JCAs) as a mechanism to harmonise clinical evidence evaluation across Member States.
- JCAs for high-risk medical devices (MD) and in-vitro diagnostics (IVD) commence in 2026. Little is known about how national health technology assessment (HTA) bodies are preparing for the implementation for high-risk MD/IVD.
- This study aims to explore how selected EU/EEA HTA bodies are planning for the implementation of the HTAR for high-risk MD/IVD.

Methods

- Semi-structured interviews were conducted with representatives from HTA agencies in 11 EU/EEA countries. A total of 15 participants were interviewed (4 interviews had 2 participants), with an average of 12 years of experience in HTA and related fields.
- The interviews explored HTAR preparedness, anticipated changes, opportunities, and challenges.
- Interviews were recorded, transcribed verbatim, pseudonymised; and coded in NVivo (R14.23.3).
- Data were analysed using reflexive thematic analysis.

Results and discussion

1. Current national structure & challenges in MD/IVD HTA

- There is substantial variability in how Member States structure HTA for high-risk MD/IVD. Some jurisdiction's device assessments are mandatory and bound to legally defined timelines and templates, while in others HTA is optional/ad-hoc, triggered by clinician or hospital requests or other means.
- One of the most cited challenges for national MD/IVD assessment was the low quality of evidence available for decision-making.

"The quality of the dossiers that are submitted [for MD] is very poor, and the data are very scarce." [Interview 7]

- Participants from four Member States described the link between HTA and reimbursement of high-risk devices in their countries as weak.

2. Planned or expected adaptations in national structures in response to HTAR

- Multiple participants indicated that their countries were beginning to review or adjust their national steps and decision-making processes to accommodate the integration of JCA outputs.

"At this moment, we have plans that we use these assessments that are coming from the EU [the JCA], as the basic situation that we build our own assessment on." [Interview 3].

- Despite observed need for adjustment, most participants noted a lack of progress in terms of substantial legal or structural reforms within their member states.

[When asked if they would change anything in the legally defined process timelines to fit the JCA] ***"I'm not so sure because this process is so established and I think there will be a lot of resistance from many actors, they are very used to this process and it's working really well." [Interview 10]***

3. Expected long-term benefits of HTAR implementation:

- HTAR is driving reforms in HTA frameworks for MD/IVD.
- Representatives of HTA agencies showed strong optimism about the long-term impact of HTAR.
- They highlighted a wide range of anticipated benefits, including the potential to streamline and simplify national HTA processes **(Figure 1).**

Figure 1. Key expected benefits and long-term opportunities of HTAR.

4. Expected challenges in adapting to HTAR:

- Stakeholders also noted that HTAR implementation might be accompanied by many challenges.
- These include legal and procedural misalignment, limited national capacity, and uncertainties around how JCA will be integrated into existing decision-making pathways.
- Key challenges are highlighted in Figure 2.

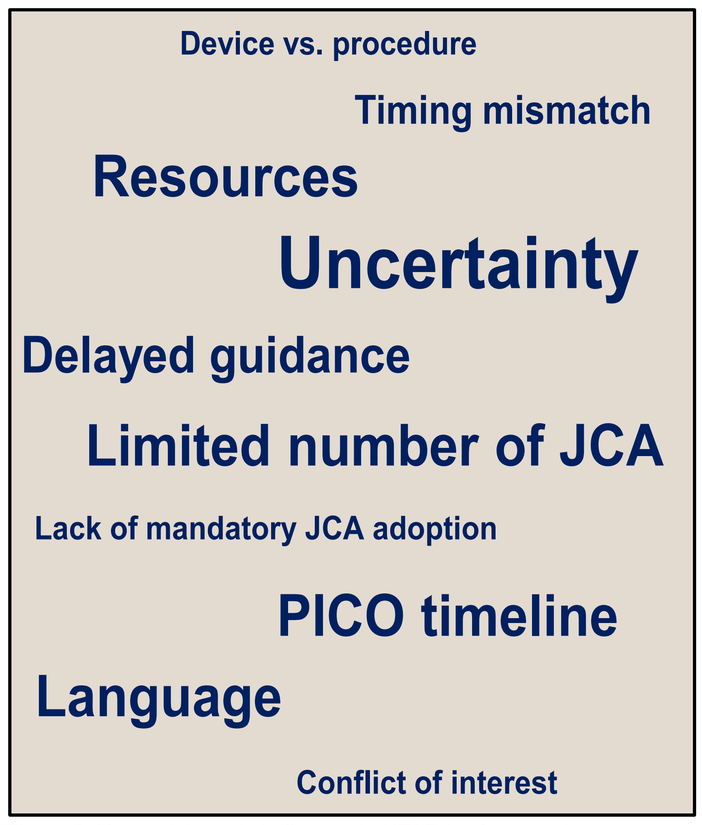

Figure 2. Key anticipated challenges in HTAR implementation

Conclusions

- **This study reveals substantial variation in HTAR readiness and pathways for high-risk MD/IVD across EU/EEA Member States.**
- **Participants expressed strong support for the HTAR but had some concerns regarding the implementation challenges.**
- **Effective HTAR adoption for high-risk MD/IVD will depend not only on the technical quality of JCAs but also on how effectively the process is aligned with diverse national decision-making frameworks.**

This publication has emanated from research conducted with the financial support of Research Ireland under grant number 13/RC/2073_P2.