# MedTech Europe calls for a workable transposition of the Directive for Representative Actions

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**MedTech Europe acknowledges the recent agreement on the Directive on representative actions for the protection of the collective interests of consumers. After years of preparation, decision-makers have reached an agreement during the Croatian EU Council Presidency.**

**MedTech Europe has always been supportive of the EU's intention to build a balanced, modern and efficient legal framework that protects the collective rights of patients and consumers, and at the same time, provides certainty and transparent and workable rules for businesses. The transposition of the Directive into national laws now needs to aim at embracing these objectives in the intended way.**
**In this respect, MedTech Europe is particularly looking forward to the upcoming discussions on Alternative Dispute Resolution (ADR) mechanisms. There are a number of well-functioning ADR mechanisms existing in healthcare across Europe on which member states can build upon for the transposition process.**

**Progress and remaining uncertainties on the way towards an efficient legal framework**
The agreed text includes a series of safeguards and principles aimed at preventing potential abuse that could damage trust in our civil justice systems. For example, the introduction of transparency requirements for Qualified Entities. Nevertheless, we believe the discussions could have gone further in harmonising the rules at European level by providing a unified set of criteria to designate Qualified Entities for domestic and cross-border collective actions, to ensure equal access to redress for all European consumers. We rely on the constructive transposition by member states.

We welcome the new requirement to study the establishment of a European ombudsperson for collective redress. Out-of-court mechanisms in healthcare have proven to be an efficient way to settle claims, bring justice to patients, and clarity to businesses.

**Impact on patients, healthcare systems and medical technology manufacturers**
A major concern remains regarding the inclusion of the entire Chapter II of the Medical Devices and the In-Vitro Diagnostics Regulations in the Scope of the Directive (Annex I). This inclusion establishes de facto a parallel private jurisdiction on top of the existing public authority system that is responsible for the safeguarding of all requirements established in the Medical Devices Regulations. This double jurisdiction could severely jeopardise the implementation of these Regulations for all parties involved - patients, healthcare authorities and manufacturers- by creating legal challenges, uncertainty and confusion.

Including the entirety of Chapter II of the Medical Devices Regulations, rather than the parts dealing specifically with consumer information, is all the more worrisome. This risks to lead to a fragmented

enforcement of these Regulations across Europe, going against their very objectives to create an EU-wide harmonized market surveillance system.

MedTech Europe and its members remain supportive of the overall aims of the Directive and stand ready to collaborate with national governments as they will start transposing the final text into their national legal systems.

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**About MedTech Europe**

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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