Challenges and Solutions for Health Innovation in Europe

Policymakers recognize the vital role of scientific research and innovation in our society.[1] However, **regulatory initiatives at both the Belgian and European levels are increasingly complex, hampering the ability of universities and (university) hospitals to navigate and anticipate the regulatory landscape**. Not only has the number of laws affecting scientific research expanded, also the interpretations of these laws by various authorities are not harmonized and inconsistent.

A specific area of concern is (medical) research & innovation in a healthcare setting. On May 26th, 2021, the **Medical Device Regulation** (MDR, EU 2017/745) was implemented, succeeded by the **In-Vitro Diagnostics Regulation** (IVDR, EU 2017/746) the following year. These regulations aim to enhance patient safety and product reliability and are commendable in this regard. Yet, they present significant unintended challenges for medical device-related research, innovation, and development within healthcare settings. Recent regulatory changes are even posing risks to the continuity of care for patients.

As Belgian knowledge institutions and (university) hospitals, and in line with European research and innovation actors and hospitals, **we express profound concerns about the adverse impacts of these regulations on health institutions and (their collaborations with) knowledge institutions.**[2] [3]

We present **four key issues arising from MDR and IVDR regulations affecting patient care and healthcare innovation**:

1. **Impact on Patient Care**
    - **Reduced availability of CE-certified medical devices**: Delays in approvals by Notified Bodies and delayed submissions by manufacturers have drastically lowered the availability of essential medical devices.[4]
    - **Potential product discontinuation**: Manufacturers are considering reducing their product lines by an estimated average of 33%.[4] This results in limited to no availability of products for rare diseases/interventions which are a significant part of the patient care in university hospitals. Niche markets, such as paediatric cardiology[5], are strongly affected. The high costs and time-consuming nature of renewing certification are key factors.

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[1] European Commission (2024). Why investing in research and innovation matters for a competitive, green, and fair Europe – A rationale for public and private action. Brussels: European Commission.

[2] This statement is to a great extent based on the work of the European University Hospital Alliance and other stakeholder organisations referred to in this text.

[3] Similar concerns have been shared by the European Society of Human Genetics (ESHG), EURORDIS-Rare Diseases Europe and the European Reference Networks (ERNs) Coordinators Group (joint letter) and the European medical technologies industry (open letter).

[4] For example, see the 2022 MedTech Europe survey reports for MDR and IVDR, and the statement from the BioMedical Alliance.

[5] (AEPC), Association for European Paediatric and Congenital Cardiology. Letter to Health and Youth care Inspectorate Netherlands. 2022

- **Risk for market monopolies:** Reduced manufacturer diversity could lead to increased dependency on fewer suppliers, which will increase healthcare costs and pose continuity risks due to monopolistic practices.
- **Reduced individual patient care:** Legislation makes it difficult to assist patients on an individual basis, such as with prosthetics and diagnostics for rare diseases.

2. **Barriers to Innovation within the EU**
   - **Decreased enthusiasm to innovate:** The heightened regulatory environment, complex compliance processes, and increased costs diminish the enthusiasm of researchers and clinicians within university and healthcare settings to engage in and valorise cutting-edge research.
   - **Extended time for ethical approval:** While important, obtaining ethical approval for cutting-edge research becomes more time consuming due to the extra complexity of MDR/IVDR. Sometimes the ethical review process takes longer than the research itself, discouraging researchers from pursuing the topic altogether.
   - **Focus on re-certification over innovation:** Regulatory requirements divert critical resources from new product development to maintaining existing certifications.
   - **Diversion of clinical research and product launches**: High regulatory hurdles and increased Notified Body timelines result in additional costs, pushing researchers to test technologies outside of the EU and companies to prioritize markets outside Europe, such as the US and Asia, for new product launches. Regulations and processes from agencies like the US Food and Drug Administration are more attuned to facilitating innovation.
   - **Unclear scope of clinical evidence:** It is often unclear what clinical evidence should be collected for a new device, with different Notified Bodies may having various requirements and diverging opinions. Since there are almost no device-specific common technical specifications in the EU, a manufacturer cannot be sure that the evidence that it plans to collect, will be acceptable. In addition, there is little transparency on the decision of Notified Bodies.
   - **Accessing Notified Bodies:** Difficulties in accessing Notified Bodies result in less innovation in Europe and less innovative products being available on the European market.

3. **Challenges for In-house Developed Medical / IVD Devices within Health Institutions**
   - **Increased administrative burden**: The administrative workload not only increases for the development of new medical devices, but also when altering commercially available devices to match the hospital's requirements or hospital environment.
   - **Limited sharing of innovations with other health institutions**: The inability to share in-house innovations outside the legal entity of a health institution prevents the adoption of innovative solutions in other health institutions and can inhibit network formation. This pertains particularly to devices/tests developed under the health institution exception (MDR art. 5). To give an example: even the smallest software tool that falls within the scope of MDR / IVDR can no longer be shared with other hospitals. In addition, healthcare systems are organised differently in different member states. The concept of legal entity can differ, resulting in further fragmentation and loss of collaboration (cf. 4. Lack of Harmonisation).

- **Reduced collaboration with knowledge institutions:** Legal and regulatory constraints hinder partnerships between (university) hospitals and knowledge institutions in developing new medical technologies.
- **Health institutions' position and mission:** Health institutions are not always able to become a legal manufacturer and to invest time and budget in Notified Body registration. It is oftentimes not inscribed in their mission.

- **Restrictions to in-house development of medical devices in health institutions:**
    - In-house development is restricted to situations where no equivalent product is available on the market.
    - As most health institutions do not have the resources to obtain CE marking,
        - they are forced to purchase the (only) available product on the market, resulting in monopoly positions and increased healthcare costs.
        - they are forced to withdraw its in-house product and purchase a commercial product once a (industrial) competitor for the in-house developed product becomes commercially available, resulting in a waste of investment in the in-house developed product.
    - The articles in the Regulations relevant to in-house development are very strict and justifiably prioritize patient safety. However, there is an imbalance in protecting the commercial importance of manufacturers versus the social and economic advantages that can be derived from in-house development of medical devices.
    - The guidance document MDCG 2023-1 states that custom-made devices are out of scope of Article 5(5) and should follow the relevant requirement of the MDR. However, article 5.5 MDR itself does not exclude custom-made devices from its scope. MDCG 2023-1 contradicts the MDR itself on this point.

4. **Lack of Harmonisation across Member States:**
    - **Inconsistent regulations and interpretations:** Variations in national regulations, for example concerning the reprocessing of single-use medical devices, complicate collaborative efforts and can lead to inefficient resource utilization and shortages. Likewise, Member States are giving different interpretations to the scope of "within health institutions" and the requirement that "devices are not transferred to another legal entity" (art. 5.5 MDR). This leads to "cherry picking" by industries, which conduct their studies in member states where regulatory hurdles and complexities are minimal. This has caused multinational studies to move from Belgium to other EU member states.

Example within a Belgian context:

Context: The advanced miniaturization of electronics and the ever-improving battery technology today make it possible to develop affordable, small sensor modules. By integrating such sensor modules into custom-made aids, such as orthoses, prostheses, or wheelchairs, we can extract objective parameters. Based on these data, health specialists can fit the right aid more quickly and better monitor the process, resulting in an increased quality of life for the users.

Problem: The Tetra Instant project aims to detect problems with aids early using sensors. A request to the Federal Agency for Medicines and Health Products (FAGG) was made to understand if testing proof-of-concept aids with CE-approved sensors fitted would fall under the MDR. We believe that testing a proof-of-concept before proceeding to a prototype is not covered by the MDR and that approval from a Medical Ethical Committee would suffice. The FAGG, however, maintains that there is no distinction in Belgian law between commercial and non-commercial studies, meaning both fall within the remit of the MDR, and that an application with the FAGG should be submitted.

Proposal

Legislative and regulatory actions should be more attuned to the potential negative impact on patient care in health institutions and the innovation capacity of knowledge institutions, research organisations and industry. A review of the current framework to mitigate these negative effects is urgently needed.

Specifically in relation to the implementation of the MDR, we ask for a greater role of stakeholders in the formulation of new / updated regulations and guidelines from a.o. the Medical Device Coordination Group (MDCG), ensuring effective and uniform application of laws concerning healthcare products. In particular, the MDCG 2023-01 document requires significant updates and revisions:

1. Enhanced clarification of terms including “in-house medical device”, “healthcare institution”, “legal entity”, and “industrial scale”.
    a. Easing the regulations for health institutions to use medical devices beyond the off-label use by a single healthcare professional.
    b. More precise criteria for the use of Research Use Only products and an explicit exemption of ‘Orphan Medical Devices’ and ‘Orphan diagnostics’ (cf. the regulation for orphan medicinal products).[6]
    c. Deletion of the note that custom-made devices are out of scope of art. 5(5).
2. Extension of the transition period specified in Article 5.5 for the quality management systems under IVDR, with additional details for ISO15189 accredited laboratories.
3. Extended options for sharing in-house developed devices among health institutions to leverage the societal contributions of (university) hospitals.
4. Harmonization across member states.

We conclude by stating that the challenges outlined in this letter are not isolated. Numerous areas exist where legislation is enacted without adequately considering its impact on research, education, and innovation. Examples include GDPR, AI, and labour market regulations. Consequently, we reiterate the call of many stakeholder organisations for a mandatory review mechanism that assesses the effects of proposed legislation (whether regional, national, or EU-wide) on these fields. This measure would

[6] See also the joint letter (2023) on behalf of the European Society of Human Genetics (ESHG), EURORDIS-Rare Diseases Europe and the European Reference Networks (ERNs) Coordinators Group to ask to exempt rare disease diagnostics from the IVDR.

help prevent potential hindrances to the work of universities and seem critical to keep EU competitive on the global scale with respect to research and innovation.[7]

We are eager to discuss these issues and are available for further in-person or email conversations on this critical topic for European healthcare.

[7] LERU (2024). Research-Intensive Universities Serving Society.