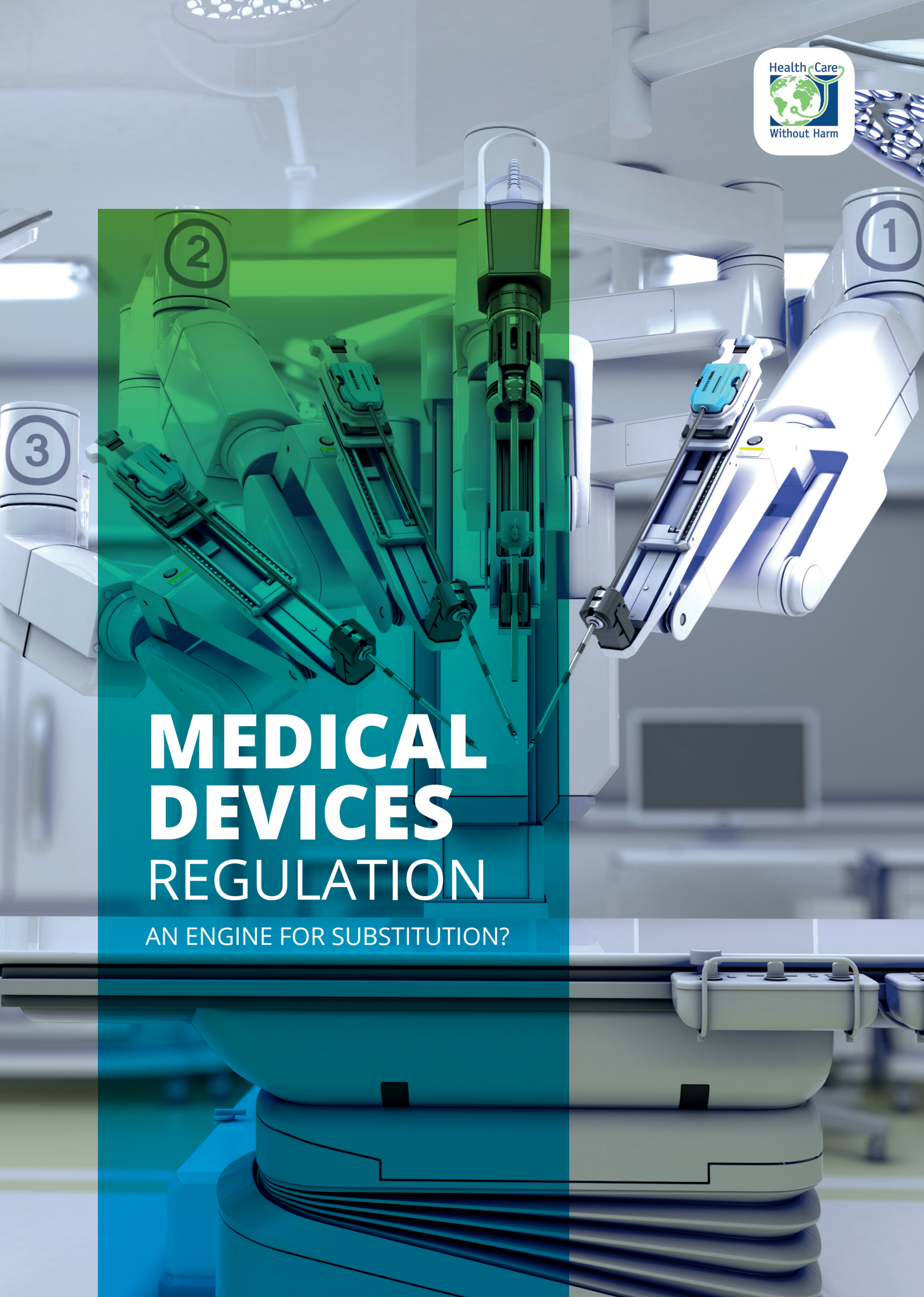


MEDICAL DEVICES REGULATION

AN ENGINE FOR SUBSTITUTION?

INTRODUCTION

This factsheet will provide some background to the new Medical Devices Regulation (MDR), information about the medical devices subject to the new regulation, as well as a snapshot of the medical devices market and the manufacturers of such devices in the EU.[1]

Importantly, we will also assess some of the provisions of the MDR that have the potential to act as an engine for substituting medical devices containing harmful chemicals with safer alternatives.

A history of the Medical Devices Regulation

On 7th March 2017, the European Council adopted new EU rules that overhauled the regulations applicable to medical devices placed on the EU market. The initial European Commission proposal for a Medical Devices Regulation was published half a decade earlier, in July 2012. This legislative process has straddled two Commissions and took in its stride a recent EU constitutional change. The main policy objectives of the revision were to ensure:

- A consistently high level of health and safety protection for EU citizens using these products
- The free and fair trade of such products throughout the EU
- That EU legislation is adapted to the significant technological and scientific progress occurring in this sector over the last 20 years[1]

This regulation is a "supernova" of a regulation in the medical device landscape, with an initial text that has expanded from 60 pages to six times that size. The full transitional provisions are detailed in Article 120, but put simply, the MDR entered into force on 25th May 2017 and will apply as of 26th May 2020.

THE ROLE OF COMPETENT AUTHORITIES AND NOTIFIED BODIES

Competent Authorities

A Competent Authority is an organisation that has been legally delegated authority in a specific policy area - in the case of the MDR, this is typically Member States' Ministries of Health, or an agency within the Ministry. Each Member State, therefore, has its own Competent Authority in charge of market surveillance that is also responsible for designating and monitoring the independent Conformity Assessment Bodies, which are referred to as a Notified Bodies in the MDR (see below).

Notified Bodies

Under the MDR, a Notified Body is an organisation selected by an EU country's Competent Authority to assess the conformity of medical devices before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation when a third party is required. The European Commission strives to maintain an up-to-date list of bodies notified by EU countries and make the necessary information available to all interested parties. Lists of Notified Bodies can be found on the NANDO website (New Approach Notified and Designated Organisations). Under the MDR, information about Notified Bodies will be included in the EUDAMED database (see page 5).

One of the most prominent changes of the MDR pertains to the role and responsibilities of Notified Bodies, which are now required to collaborate even more closely and transparently with Competent Authorities.

What are the key changes introduced by the MDR?

When the MDR takes effect in May 2020, it will replace the current directives and manufacturers will have to comply with new rules for almost every kind of product in the medical device spectrum.[2]

Manufacturers of medical devices (or their authorised representatives) that are selling (placing) medical devices onto the EU market will be subject to stricter rules. The national oversight bodies (national Competent Authorities) will see their powers increased with regards to their role with Notified Bodies (i.e. independent certification organisations that are "notified" by a European Member State's Competent Authority to determine if a product or system meets applicable requirements).

Key provisions of the MDR

The new MDR aims to create a new and improved landscape for the medical devices industry; under the new rules, the following changes will be introduced:

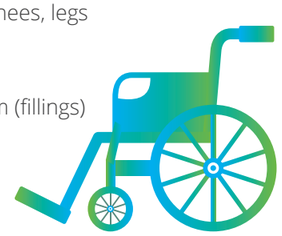
- Certain aesthetic devices are now included within the scope
- Minimum requirements related to reprocessing of single-use devices
- Stricter pre-market control of high-risk devices involving a pool of experts at EU level
- Reinforcement of rules on clinical and performance evaluation as well as clinical investigation and performance studies
- New classification system for in vitro diagnostic devices (IVDs) based on international guidance (80% of IVDs to be assessed by a Notified Body)
- Reinforced designation and oversight processes of Notified Bodies
- Clarification of the role and responsibilities of economic operators
- Establishment of a comprehensive EU database on medical devices (EUDAMED, see page 5) to be made publicly available
- Introduction of a Unique Device Identification (UDI) system
- **Stricter requirements related to the use of hazardous substances** (see page 96 of the MDR)[1]

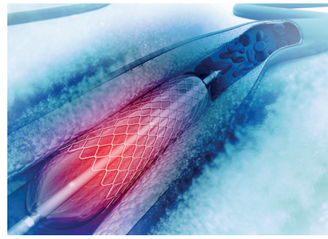
MEDICAL DEVICES

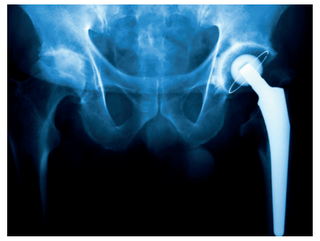
Medical devices, as defined by MedTech Europe, are innovative technologies available to hospitals, physicians, and patients that save lives, replace and restore body functions, prevent diseases development, monitor patients' conditions, and equip health institutions and homes. The definition of medical devices can be found under Article 2 of the MDR.[2]

Examples of medical devices

- Hospital beds, mattresses, sheets
- Surgical tools, gloves, tables
- Bandages
- Wheelchairs
- Surgical robots
- Active Implantable Medical Devices (AIMDs): pacemakers, defibrillators
- Stents
- Artificial hips, knees, legs
- Eye lenses
- Hearing aids
- Dental amalgam (fillings)







The EU medical devices market

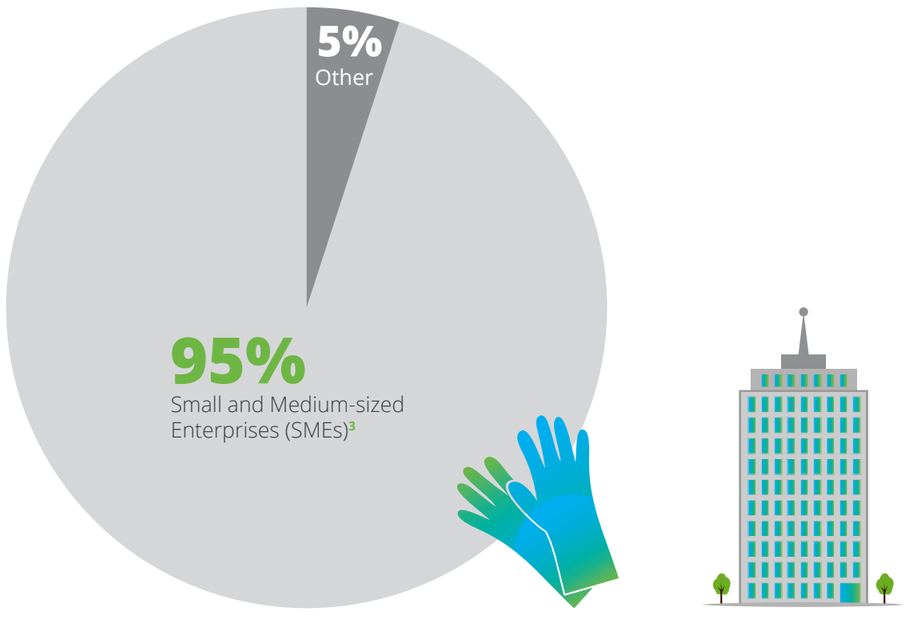
According to the European Commission, the sector has become increasingly important for the healthcare of EU citizens and impacts greatly on public expenditure. The medical devices industry is also a major employer in Europe, employing 575,000 people in the EU.[3]

TOTAL SALES:

€ 100 BILLION[3]

According to a 2015 study (*Medical Devices Sectoral Overview - Galway City and County Economic and Industrial Baseline Study*), Western Europe represents approximately 25% of the global medical device market, with Germany leading the market followed by France, the UK, and Italy. In Western Europe, 3.7% is the current compounded annual growth rate for the sector whilst Northern Europe is forecasted to have a 5.1% compounded annual growth rate in the next five years.[4]

THE SECTOR REPRESENTS APPROX. 25,000 COMPANIES[3]



HARMFUL CHEMICALS IN MEDICAL DEVICES

In 2014 HCWH Europe published a report entitled *Non-Toxic Healthcare: Alternatives to Phthalates and Bisphenol A in medical devices*.[5] Its main argument remains valid today - it is better to prevent diseases than to treat them, by choosing better alternative medical devices in daily healthcare to help prevent disease further down the line.

PVC (polyvinyl chloride) is a widely used plastic - often made more flexible by the use of the phthalate DEHP, long considered to have toxic characteristics.

We have known for decades that phthalates leach out of medical devices such as PVC tubing.[5] Alternatives were not available 30 years ago but now there is a choice to be made between safer alternatives or ignoring the potential dangers to patients.

Similarly, Bisphenol A (BPA) has been linked to endocrine disruption; initially developed as a synthetic oestrogen in 1891, BPA was not widely used until the second half of the twentieth century due to the availability of more potent synthetic oestrogens, such as thalidomide.[5] Now BPA is a major part of daily life: from the ink of cash register paper to the linings of beverage cans – and in medical devices.

European legislation was long in the making, but now with the MDR there is a real opportunity to accelerate the process of phasing-out these harmful chemicals.

CAN THE MDR BE AN ENGINE FOR SUBSTITUTION?

According to the MDR, medical devices will only be permitted to contain levels of certain hazardous chemicals above an established limit if a justification is provided to the Notified Body - which is overseen by the national Competent Authority (see box on page 2). The MDR contains provisions mirroring the REACH requirement for progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.[6]

How does that fit in the wider EU context?

The 7th Environment Action Program (7th EAP) states that: "The Union will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation. In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors. **The Union will also set out a comprehensive approach to minimising exposure to hazardous substances, including chemicals in products**".[7]

The **MDR 745/2017 - Annex I.II.10.4** introduces provisions that would help phase out endocrine disrupting chemicals (EDCs), Carcinogenic, mutagenic and reprotoxic substances (CMRs), and particularly phthalates in medical devices if safer alternatives are available and technically feasible.

Conformity assessment of devices

Manufacturers of medical devices are required to provide adequate justification to the Notified Body for the presence of CMRs 1A and 1B and/or endocrine disruptors that are:

- Contained in certain medical devices listed in the relevant provisions
- Above a certain concentration (0.1% weight by weight (w/w))[1]

Justification must also be based on scientific opinions from relevant scientific committees (when available).

The European Commission (EC) is required to provide the relevant scientific committee (the Scientific Committee on Health, Environmental and Emerging Risks [SCHEER]) with a mandate to prepare guidelines on the presence of phthalates in devices – which are to be adopted by the application date. Whenever appropriate, The EC should also mandate the SCHEER to produce guidelines for substances other than phthalates.

These guidelines shall cover at least a benefit-risk assessment of the presence of hazardous substances. The benefit-risk assessment will consider the availability of alternative substances, materials, designs, or medical treatments.

> "**Annex I.II.10.4.1** is therefore an open invitation to prioritise medical devices that are benign by design, allowing for the progressive substitution of dangerous chemicals."

Transparency

The presence of hazardous substances (subject to justification) will have to be indicated on the medical devices' labelling (in accordance with provisions laid down in Annex I 10.4.5). Information labelled in accordance with this annex is one of the mandatory Unique Device Identifiers (UDI) data elements to be provided by the manufacturer to the UDI database. This information on the devices will be accessible to the public via the European Database on Medical Devices (EUDAMED).

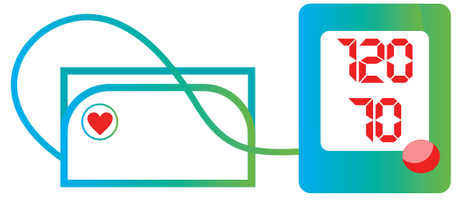
EUROPEAN DATABASE ON MEDICAL DEVICES (EUDAMED)

EUDAMED's purpose is to strengthen market surveillance and transparency in the field of medical devices, by providing national Competent Authorities with fast access to information. EUDAMED contains data on medical devices that has been collected and inputted by Competent Authorities and the European Commission and is currently only accessible by these same parties. The MDR, however, calls for EUDAMED to be revamped; the information will be more comprehensive and access will be extended.

Why is EUDAMED important?

EUDAMED will be the engine driving the new regulations - if the MDR EUDAMED fails, the new MDR will fail. The database will not only be used by the Competent Authorities and the European Commission, it will also be accessed by the Medical Devices Coordination Group (MDCG), Notified Bodies, Economic Operators (manufacturers, authorised representatives, importers, sponsors), experts, and the public, including medical institutions.

Creating more transparency will allow for a better understanding of what medical devices are placed on the EU market and who is ultimately responsible for them. The level of access, however, will differ between the types of user.



What type of data will be recorded in the MDR EUDAMED?

- Unique Device Identifiers (UDI) and depending on how this will be organised, EUDAMED may also issue a Device Identification in parallel
- Economic Operators will be identified by a Single Registration Number (SRN)
- Notified Body accreditation and designation, which are currently found in a separate database (NANDO) will be included
- Extended vigilance data, including post-market surveillance
- Applications for conformity assessment by Notified Bodies
- Summaries of safety and clinical performance (new in the MDR)
- Performance studies for in vitro diagnostics, similar to clinical investigations
- Market surveillance data[1]

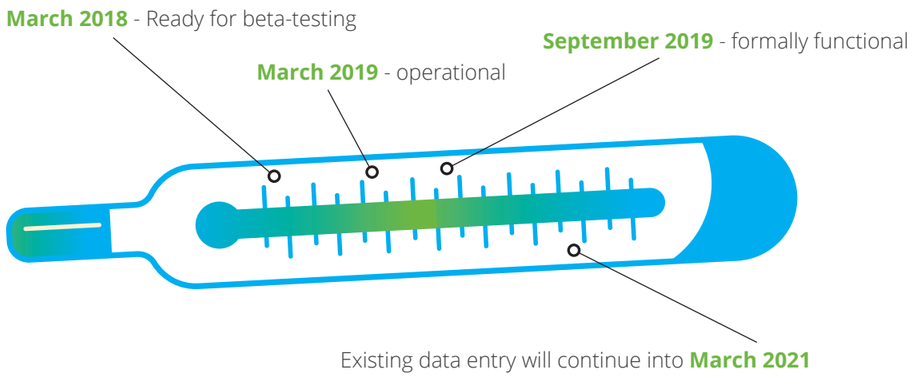
Improved functionalities of the MDR EUDAMED helping to identify safer alternatives

EUDAMED will allow for more robust forms of reporting, thanks to the use of artificial intelligence that will help monitor the quality of the data. Theoretically, procurers (such as hospitals and Competent Authorities) will be able to access, search, and filter the content of EUDAMED to identify safer medical devices for their procurement process.

CLOSING RECOMMENDATIONS

1. **Substitute where possible:** The parties involved in implementing the MDR should acknowledge that some provisions can be used to substitute medical devices containing harmful chemicals with safer alternatives. These provisions mirror the REACH requirement for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.
2. **The MDR should be implemented harmoniously in Member States:** The update of regulatory infrastructure with increased responsibility given to different actors, such as Notified Bodies and Competent Authorities, should be carried out in a consistent and coherent fashion to ensure a harmonious implementation of the MDR in all EU Member States.
3. **Make EUDAMED a tool for substitution:** EUDAMED will be the engine driving the new MDR, it is therefore crucial that the database offers search facilities enabling users to identify medical devices that provide alternatives to those containing harmful chemicals. It is also important that various stakeholders of the database's user community are given adequate access to data that is relevant for them.

MDR EUDAMED timeline[1]



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