MedTech Europe Position Paper on Article 50 Negotiations between the European Union and the United Kingdom (Brexit)

MedTech Europe
from diagnosis to cure

POSITION PAPER

EXECUTIVE SUMMARY

MedTech Europe – the European trade association representing the medical technology industries operating in Europe – highlights the importance of the medical technology industry for public health and the need for sector-specific measures during the ongoing 'Brexit' negotiations between the European Union (EU) and the United Kingdom (UK). Not only would such measures prioritise patient safety by ensuring the supply of, and access to, medical technologies for patients and healthcare providers across Europe, but they would also ensure the future global competitiveness of an important sector for both the EU and UK economies.

This paper outlines the potential multiple consequences of 'Brexit' for the medical technology industry, together with suggested solutions for mitigation.

Two key concerns for the medical technology sector are:

1. The likely implications of a divergence in regulatory frameworks given the newly adopted *In Vitro* Diagnostic Medical Devices (IVDs) and Medical Devices (MDs) Regulations.
2. Time delays and increased cost on the free movement of goods and raw materials which will impact the Just In Time supply chain and therefore patient safety.

The EU wide IVDs and MDs legislations have played a key role in delivering high-quality care to patients for over 25 years, allowing them timely access to safe and effective medical technologies. In the event that there are two divergent regulatory systems as a result of Brexit, patient access to medical technologies risks to be hindered. As a consequence, both parties need to ensure the full availability of medical technologies for patients once the negotiations have come to an end. This is a heightened concern since the current CE marking system is significantly revamped by the recently adopted new regulations that undergo a transition phase of three (MDs) and five (IVDs) years, running in parallel with the Brexit negotiations.

The withdrawal of the United Kingdom from the European Union has also the likelihood to disrupt access to innovation and growth in the medical technology industry given any new rules and procedures on customs and free movement of goods. Predictability is of utmost importance to businesses; legal uncertainty in any form would be detrimental. Both negotiating parties need therefore to work constructively and swiftly on delivering clarity regarding transitional agreements, including trade and customs arrangements, with the aim to minimise disruption, costs and adverse patient impact.

In sum, the following overview of specific medical technology areas upon which Brexit would likely have implications for medical technology manufacturers, distributors, suppliers, hospitals, and lastly but most importantly, patients, provides a series of potential solutions to be considered by 'Brexit' negotiators on both sides of the table. This is by no means an exhaustive list; however, it gives an indication of the many consequences of Brexit on patients and businesses that MedTech Europe strongly encourages taking into account during negotiations.

OVERVIEW OF SPECIFIC MEDTECH AREAS POTENTIALLY IMPACTED BY BREXIT

ISSUE	IMPACT	SOLUTION FOR MITIGATION
REGULATORY UNCERTAINTY Uncertainty regarding the future regulatory framework in the UK.	A different regulatory system in the UK would affect the implementation of the newly adopted Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations, and the related secondary legislation. Manufacturers risk facing two divergent regulatory systems.	Full alignment with the EU27 regulatory system regarding Medical Devices (MDs) and *In Vitro* Diagnostic Medical Devices (IVDs), including related secondary legislation and guidelines.
EUROPEAN UNION WITHDRAWAL BILL EU Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations and related secondary legislation might not fully apply in the UK.	The UK will need to replicate or re-legislate in this area, and the EU27 and the UK risk having two divergent regulatory systems, which has implications for actors across the entire medical technology supply chain. This would affect manufacturers, distributors, suppliers, hospitals and patients.	UK law should include in full the provisions of the EU Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations. Relevant Free Trade Agreements (FTAs) should also be part of the bill.
NOTIFIED BODIES (NBs) UK NBs are used for a very large amount of CE marking activity, and the loss of this capacity could not be easily or quickly replaced. Certificates of conformity to the current EU Directives on MDs/IVDs that have been issued by UK NBs might be void earlier than in other EU27 countries.	Manufacturers would face a potential time delay in obtaining market authorisations before other EU27 NBs were able to pick up the capacity left by the UK leaving the European network. Manufacturers would need time and resources to adapt to the requirements of NBs with whom they are unfamiliar. Existing capacity concerns about the overall number of NB auditors available to make a success of the new Medical Device Regulation (MDR) would be exacerbated.	Continue to recognise existing and valid CE marking certificates issued by UK NBs until their expiration date. Ensure that UK NBs remain within the existing European network and oversight mechanisms, and continue to be designated to assess devices for the EU27 and UK markets, e.g., based on Swiss NB arrangements. In case a UK NB decides to move to the EU27, it is critical that all existing files are also taken along from the UK to the EU27 and remain valid. UK NBs to maintain their NB identification number independently of the future contractual arrangements, for manufacturers to avoid re-labelling challenges and

		related costs.
LEGAL ENTITIES: AUTHORISED REPRESENTATIVES (ARs), LEGAL MANUFACTURERS, IMPORTERS Legal entities may no longer be able to operate from the UK as EU based legal entities.	Non-EU manufacturers might have to set up contracts with EU27-based ARs. UK manufacturers could be required to do the same.	Find a Mutual Recognition Agreement (e.g. Swiss model) recognize legal entities (legal manufacturers, importers and authorized representatives) based in the UK as EU based legal entities to avoid the need for their relocation in the EU27 jurisdiction.
MANUFACTURERS LOCATED IN THE UK ONLY Risk of losing direct access to the EU market. As a result, a temporary disruption of the supply of UK products to patients in the EU27 might occur.	Products manufactured in the UK might face similar time delays as other manufacturers located in the US or Japan. Such time delays might increase the cost of supply to patients who might need to adapt to new products. This in turn will have an impact on patient safety, product price or scope for companies to grow and employ more people.	Customs arrangements and regulatory controls should allow medical technologies to cross borders in a timely manner to minimize the impact of the time of clearance on the movement of products and/or components across borders.
REFERENCE LABORATORIES UK laboratories may not be able to participate in the new network established under the new *In Vitro* Diagnostic Medical Devices Regulation, which will facilitate more coordinated and harmonised working methods regarding testing and assessment.	IVDs CE marked in the UK laboratories may need to be re-tested. EU27 would lose UK expertise and data.	A framework for collaboration in research and reference laboratory networks should be established. If this is not possible, there is a need to clarify what can be expected from reference laboratories both in the UK and the EU after Brexit.
COMPETENT AUTHORITIES (CAs) AND POST-MARKET SURVEILLANCE UK CAs might not have access to EU27 information held in the EU database for MDs and IVDs, (Eudamed) and vice versa.	Risk of information delay and lack of information concerning products on the market, clinical studies and data, reported adverse events and market surveillance, all of which might undermine patient safety.	Continued access to the EU27 Eudamed for the UK, and vice versa, should be ensured.
CROSS-BORDER HEALTHCARE SERVICES The Directive on patients' rights in cross-border healthcare may no longer apply.	EU patients will not have access to the UK healthcare system and vice versa.	A framework for ensuring efficient cross-border patient access for UK and EU citizens needs to be established, whether at EU27 or individual Member State level.

WAREHOUSING AND PLACING ON THE MARKET At the moment of the UK's departure from the Customs Union, products stored in UK warehouses, including those products of EU27 manufacturers, will no longer be eligible for being placed on the EU market.	The new Regulations allow for products that are on the market and compliant with the current MD and IVD Directives to continue to be made available to patients beyond the date of application (2020 for MDs/2022 for IVDs) until 2025 provided they are physically located in the EU. If Brexit happens before May 2020, medical devices stored in the UK between the Brexit date and May 2020 will not benefit from this option, which has significantly negative implications for business costs. The timing for IVDs is May 2022.	Precise clarification on warehousing arrangements and market eligibility from both the UK and the EU is required. An agreement allowing the use of UK-based warehouses, at least during an appropriate transition period post Brexit, should be found. If this is not possible, manufacturers based in the UK might consider using warehouses located in the EU27 to store their products, between Brexit and the dates of full MDR/IVDR applicability. Customs arrangements and regulatory controls should be considered to allow for timely transit of products.
RAW MATERIALS AND UNFINISHED PRODUCTS Raw materials and unfinished products that are needed in the UK might be delayed due to new customs arrangements or no longer be available if new tariffs discourage the provision of such materials to the UK market. This would also be applicable to companies manufacturing in EU27 who import raw materials and unfinished products from the UK**.**	The manufacturing, including assembling and sterilization of products might be affected.	The customs classification of raw materials and unfinished goods should be based on their intended use and destination, and not merely their properties, to ensure low tariffs and simple processes even for raw materials. There should be a simplified customs clearance procedure for materials and unfinished products which are being shipped between facilities belonging to the same company.
ANIMAL MATERIAL Veterinary controls to which animal materials and products containing animal materials may be subject, have the potential to disrupt the manufacturing processes if there is any disruption of the free movement of goods between the EU and the UK.	The medical technology industry draws upon many applications of biotechnology which require the use of animal materials, such as heart valves incorporating animal tissue and advanced diagnostics using complex antibody systems. This area is of particular concern as the UK is a key supplier of biotechnology	Customs and regulatory arrangements need to be put in place to expedite veterinary controls at customs, including those referring to Transmissible Spongiform Encephalopathies (TSE). Recognition of veterinary procedures and checks on both sides of the EU and UK border is necessary to enable the transfer of intermediate animal by-products and medical

	products.	devices containing animal material without the need for further inspections.
REFURBISHMENT AND REPAIR EU27 products used in the UK market, which need to be repaired or refurbished in the EU27 and vice versa, might face delays and increased costs due to new customs arrangements.	This might delay access to products for patients and impact business considerations on the location of such services. Tools and equipment used for repair or refurbishment can be considered waste, and waste cannot be shipped outside the EU. EU27 manufacturers, therefore, might not be allowed to bring needed tools to the UK for repair.	The implementation of the '*Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal'* on devices used for maintenance and repair in medical, nursing, dental, veterinary, or similar practices between the EU and the UK needs clarity to allow for the continued refurbishment and repair of medical equipment. Movement of medical equipment, for refurbishment and repair, between the EU and the UK should be explicitly permitted in any new customs arrangements. Devices which are subject to refurbishment and repair and cross non-EU borders would normally be subject to tariffs. In the case of medical technology, tariffs should not be applied when devices are being repaired in the UK and sent back to the EU and vice versa. This could be addressed through the development of specific WCO Harmonised System (HS) codes.
JUST-IN-TIME (JIT) DISTRIBUTION The disruption of JIT distribution, due to custom controls, may cause delays and increased costs, causing a competitive disadvantage for manufacturers in both the EU27 and the UK.	Some products, delivered just-in-time might be delayed due to customs controls, slowing down the free movement. This will ultimately impact patients who may be denied timely access to treatments.	Customs arrangements should be put in place to minimize the impact of the time of clearance on the movement of products and/or components across borders. Every effort must be made to avoid unnecessary duplication and disruption.
DUAL-USE PRODUCTS AND SUBSTANCES Some devices and components of devices are characterised as being dual-use goods.	A lack of specific customs agreements on the movement of such goods could result in a halt to the transfer of such devices between the EU27 and the UK.	The movement of dual-use goods between the UK and the EU27 should be explicitly permitted in any new customs arrangements.

TARIFFS MDs and IVDs might be subject to tariffs when moved to and from the UK.	Tariffs on these goods will impact on the competitiveness of manufacturers, public procurement arrangements and patient access to medical technologies.	Zero tariffs on the majority of MDs and IVDs should continue as per WTO rules. In case an individual MD or IVD does not qualify for WTO status, its regime should be as close to zero tariffs as possible in order to avoid increased costs for health systems or individual patients.
CLINICAL INVESTIGATION MATERIALS During clinical investigations, specific products and clinical samples can be moved across borders. In a 'no deal' scenario, and under WTO rules, this movement would be very complex as often the equipment is not yet fully compliant with regulations. The movement of samples of human origin also needs to be considered.	The ability to rapidly move products and/or samples as part of the investigation might be compromised.	Specific customs arrangements are required for a timely transfer of products and/or samples used in clinical investigations. This falls under the broader scope of movement of materials used in research and development.
HEALTH TECHNOLOGY ASSESSMENT (HTA) COOPERATION The UK is currently well represented at both strategic and technical levels in the European HTA Network (EUnetHTA), as respectively established by the Cross-Border Healthcare Directive, and through an ongoing Joint Action. Brexit may negatively affect such UK involvement.	Given the UK's leading expertise in assessing medical technologies, non-participation at strategic and/or operational level will lead to a significant loss in expertise. UK expertise is particularly relevant in assessing different medical technologies and ensuring appropriate stakeholder involvement.	Maintain participation in both the strategic HTA Network and the operational EuNetHTA platform.
PUBLIC PROCUREMENT The UK recently transposed the EU Public Procurement Directive of 2014, which provides the framework for purchasing through tenders and applies to the majority of MDs and IVDs. There is a risk of possible	Divergence in transposition might result in EU27 and UK manufacturers facing different legislations for public procurement. This may increase cost and complexity for manufacturers.	Full alignment with the EU27 legislative framework on public procurement.

divergence in the transposed measures compared to the EU27 procurement framework.		
OTHER RELEVANT REGULATIONS Uncertainty over the application of other relevant regulations, such as the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) and the Restriction of Hazardous Substances Directive (RoHS).	The EU27 and the UK risk having two divergent regulatory systems, which has implications for actors across the entire medical technology supply chain. This would affect manufacturers, distributors, suppliers, hospitals and patients.	UK law should include the provisions of other relevant regulations where necessary to ensure patient safety and frictionless trade.

ABOUT MEDTECH EUROPE

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide.

There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors.

Our sector employs more than 650,000 people. There are more than 26,000 medical technology companies in Europe, of which 95% are SMEs.

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