

Activity Report 2019





OUR PURPOSE

MedTech Europe's purpose is to make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path.

OUR MISSION

- Be the **European voice** of the medical technology industries – in Europe and beyond
- Highlight the **value and contribution** of medical technologies, services and solutions, for patients, healthcare systems and society
- **Contribute actively** to EU health-related policies and legislations
- **Facilitate access** to medical technologies for people, patients, healthcare professionals, healthcare operators and healthcare systems
- Be a **trusted partner** to EU policy-makers and other key stakeholders
- Foster the **highest ethical standards** in the medical technology industry and for all activities related to trainings, medical education and professional relationships with Healthcare Professionals (HCPs)

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Foreword by Serge Bernasconi CEO, MedTech Europe

What a year! In preparing the MedTech Europe Annual Report, our team had the opportunity to reflect on a highly active and productive period – defined by strong collaboration and rapid change.

We operate in a dynamic environment. Regulations are changing, markets are evolving, and technological innovation is moving at unprecedented speed. Representing the medical technology sector means staying ahead of the curve and engaging with policymakers across a broad range of topics.

In 2019, we were focused on not only preparing for the application of the MDR and IVDR – crucial landmarks for our sector – but also on environmental and chemical legislation, GDPR implementation, market access, Transparent MedTech and the Ethical Code. And that's without mentioning the small matter of life after Brexit.

While working on pressing issues shaping our sector today and tomorrow, we are also thinking strategically about the long-term future. MedTech Europe is a respected voice in dialogue on digital health, driving future EU innovation partnerships and connecting members with European research funding opportunities.

All this work is member driven. Members devise our strategy, lead our working groups and craft our position papers. In return, the MedTech Europe team strives to deliver value at every turn. Along with representing members' interests, we provide opportunities to learn and network; deliver high-quality market data services; and produce top quality events such as the MedTech Forum and CEO Summit.

We also add value to the wider healthcare ecosystem. Yes, this is an opportunity to showcase the positive impact of medical technologies, but it is also a chance to deliver on our promise to engage with stakeholders to find shared solutions to the healthcare challenges we must face together. In 2019, our public affairs activity and EU engagement has been essential to building relationships with new policymakers in Brussels. We have also continued to work with other industry associations and with patient representatives through the Patient-MedTech Dialogue.

At every step, our communications team has worked to communicate our many activities by engaging with the media, amplifying our message through digital channels, and driving MedTech Week across the continent.

These accomplishments are possible only with the support of our members, leadership and staff.

As we look back on a successful year, we should draw fresh inspiration to be an industry that strives for more in 2020.



Foreword

by Rob Ten Hoedt

Chairman, MedTech Europe

Annual Reports are not about the past – they are about the future. As you read about the work MedTech Europe did in 2019 on behalf of our industry, it will be clear that the focus is always on the road ahead. It's about new legislation coming over the horizon; new technologies that can change healthcare; and new challenges that we will face together.

While change is a constant, the fundamental driver of everything we do as an industry remains unshaken: our mission is to deliver medical technologies that save and improve people's lives. Our innovations may be highly technical and the operating environment increasingly complex, but our goal is simple.

In representing our diverse industry, MedTech Europe helps us to prepare for the future. Whether it's revised regulations or evolving trading conditions, our trade association ensures our voice is heard when key decisions are being taken.

More than that, engaging with policymakers and other stakeholders is an opportunity to highlight the daily contribution that medical technology makes in the lives of citizens. Our companies should be recognised for the positive impact we have on personal and public health, on job creation and innovation, and in creating sustainable, efficient health systems.

We are also innovative by instinct and open by nature. Our sector will continue to embrace new solutions like data and artificial intelligence and embrace advances in diagnostics and digital health, while working with others to ensure markets and health systems are ready to incorporate valuable innovation.

As an industry, we bring to the table a clear vision of a better healthcare future. At the same time, it is essential that we remain grounded: helping to save and improve people's lives will always be our top priority.



Regulations and Industrial Policy

Before medical technologies can reach patients and bring value to European healthcare systems, they must first be lawfully brought to market. MedTech Europe's Regulations & Industrial Policy team supports members and represents their interests with respect to EU legislations affecting medical technologies. Key priorities for 2019 included the new IVD and medical devices regulations (IVDR and MDR), which enter into full application in May 2022 and May 2020 respectively.

Another key focus for the team has been the many pieces of EU legislation that regulate chemicals in products, companies' environmental footprint, and so on.

The nine-person team coordinates more than 35 MedTech Europe committees and working groups, in which members come together to reach consensus on the industry's priorities, positions and activities in the EU regulatory space.

2019 HIGHLIGHTS

IVDR/MDR

- Outreach: Our industry remains very concerned that, despite companies' intense efforts to get ready for the IVDR and MDR, the EU is still moving slowly in building the new regulatory system for medical technologies. MedTech Europe's members and staff worked tirelessly in 2019 to alert all relevant stakeholders to the impact that this implementation progress may have for patients in Europe.
- Beyond frequent contacts with the European Commission, we've focused this year particularly on outreach to Notified Bodies, EU Member States, the European Medicines Agency, plus the many EU stakeholder groups representing hospitals, laboratories, patients, doctors and laboratory professionals.

- **Implementation:** MedTech Europe members were very active this year in contributing to dozens of European Commission consultations. Most of these were to offer industry point of views on the draft IVDR and MDR guidance documents that the Commission and competent authorities are developing.

- As of December 2019, the Commission has published more than 40 of these guidance documents since 2017, and at least another 40 are still in the pipeline. These documents lay out in practical terms how industry is expected to comply with the new Regulations, so continued engagement with these consultations is crucial.

- **Support for members:** In 2019, the Regulatory team put together a comprehensive overview of all IVDR/MDR implementation tools published by the EU authorities and by our industry. This document is available to all members and is updated at least once per quarter.

For the calendar year 2019, a total of 24 members-only support materials were developed and published by MedTech Europe, equating to one new support tool every two weeks, to complement the work being done by the EU authorities.

Notified Bodies (NBs) – A Key Pillar of the Medical Technology Regulatory System
Last updated on 10 May 2019

Notified Bodies are responsible for assessing medical devices (MDs) and in vitro diagnostics (IVDs). They are an indispensable part of the regulatory system since they grant a CE mark to each device before it can be placed in the EU market.

Notified Bodies are undergoing a significant revamp in order to comply with their greater obligations according to the new Medical Device and In Vitro Diagnostic Regulations.

Key facts about Notified Bodies

- Independent
- Impartial
- Designated and supervised by National Authorities
- Grant EU-wide product approval
- Public or private
- Identified by a 4-digit number, placed with the CE mark

How many Notified Bodies (re-)certify MDs and IVDs?*

Year	MDs	IVDs
2012	57 NBs	1 NB
2019	59 NBs	1 NB
2020	7 NBs	1 NB

*Countries can have a different amount of NBs: none, one or several

The New Regulations

Competence in assessing products and quality of the design process includes four steps and is...
...the new regulations can assess and...
...are designated for the new regulations can assess and...
...and -50,000 of 40,000 IVDs currently CE marked need to be...
...There are approximately 55,000 certificates issued under the...
...the work load that NBs face before May 2020 because - many...
...- eligible products would still need to be re-certified by May 2020.

Body (NB) Workload

Tomorrow
NBs will have to follow additional and more stringent requirements under the new regulations (e.g. on clinical and post-market surveillance aspects). This will have further impact on the available time to review products.

Challenges

- Lack of capacity**
NBs are facing challenges in finding, hiring and training staff to address the requirements of the new regulations. NBs have been busy with the new regulations and have not had time to absorb higher workload. NBs have been busy with the new regulations and have not had time to absorb higher workload.
- Lack of available experts**
NBs are facing challenges in finding, hiring and training staff to address the requirements of the new regulations. NBs have been busy with the new regulations and have not had time to absorb higher workload.

The EU as a whole
The EU as a whole is facing a risk of loss of competitiveness against global constituencies (US, China, etc).

Environment & Sustainability

- **Chemicals:** MedTech Europe established itself as primary representative of the industry to the European Chemicals Agency (ECHA) on several chemical dossiers, notably microplastics in IVDs. As part of this engagement, for the first time ever, our industry was able to directly participate in ECHA's scientific committees on risk assessment and socio-economic analysis.

- **Training:** We provided our members and the industry at large with multiple training sessions and guidance. One area of particularly high activity related to the chemical requirements in the new MDR. Here, we held five webinar sessions, which each attracted more than 300 participants, and have been recorded and disseminated for companies' ongoing internal use.



Market Access and Economic Policies

The Market Access & Economic Policies (MAEP) team's focus is to ensure timely access and use of medical technologies in European health and social care systems. To support appropriate financing of innovation and reward for value created, our goal is to:

- Stimulate investments by supporting innovation-friendly, value-driven ecosystem, and comprehensive value frameworks across Europe
- Foster adoption of value and innovation-based access models
- Recognise the value proposition of medical technologies and partner for solutions by deploying a 'value-driven' access model
- Highlight the value proposition of medical technologies for patients, health care professionals, health systems and society

We support the shift towards value-based health systems with cost-efficient care delivery. To make value and innovation-based access models a reality, the MAEP team focuses on value-based procurement; value-based contracting; value of diagnostic information (VODI); value-based HTA; real-world evidence generation; innovation funding schemes and value-based funding models. We engage with key stakeholders to co-create and deploy these new instruments and to build communities of practice to support the transformation of systems.

2019 HIGHLIGHTS

EU HTA Regulation

The MAEP team, supported by MedTech Europe's External Affairs team, represented the industry's position on the proposed EU HTA Regulation. We engaged and provided input on technical issues with working party members of the European Council, with specific focus on EU HTA legislation and medical technologies. The team also presented the industry's views across relevant networks (EUnetHTA; ISPOR; HTAi; H2020) to advocate for a modern HTA within a value-based system.

H2020 Funding programme: EURIPHI*

MedTech Europe is the coordinator of EURIPHI, an 18-month project that provides new ways of conducting cross-border value-based procurement for diagnostics and integrated care. For the first time in MedTech Europe history, this European consortium was developed with the support of a grant received from the H2020 funding programme. This Coordination and Supportive Action fosters the use of value-based public procurement of innovative solutions (PPI) or pre-commercial procurement (PCP). More information: www.euriphi.eu

*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825922-EURIPHI

Value-Based Procurement

This year, MedTech Europe broadened and re-branded the scope of our value-based procurement project. The MAEP team formalised the Value-Based Procurement Community of Practice (VBP CoP) where 32 industry members are currently part of this initiative. At the same time, the team also finalized more than ten value-based procurement cases. The first MEAT VBP pilot by UniHA with competitive dialogue was also completed and promoted. We also engaged with procurement organisations across Europe through the 1st Value Based Procurement Conference which attracted more than 20 leading procurement organisations responsible for 20 million Europeans in ten countries.

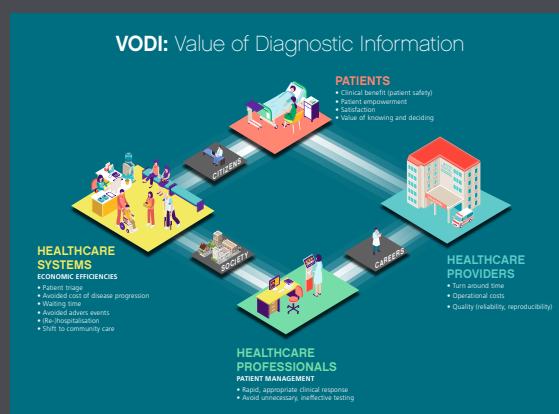


Value of Diagnostic Information (VODI)

In 2019, the team worked to enhance the awareness on the value of diagnostic information.

Our industry remains concerned that in vitro-diagnostics (IVDs) are still not assessed and rewarded based on the actual value they deliver. This hinders both investment in innovative IVDs but also cause inequality in healthcare access.

In 2019, MedTech Europe commissioned a VODI concept paper entitled '[The Value of Diagnostic Information in Personalized Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems](#)'¹ and published it in the Public Health Genomics Journal. We also published easy-to-read material (including a [visual](#)) on VODI to enable a more intuitive understanding of this subject. Finally, a set of case examples is in development to illustrate the full breadth of value that diagnostic information can provide along the patient pathway.



Learn more: www.medtecheurope.org/access-to-medical-technology

1) Wurcel V., Cicchetti A., Garrison L., Kip M.M.A., Koffijberg H., Kolbe A., Leeflang M.M.G., Merlin T., Mestre-Ferrandiz J., Oortwijn W., Oosterwijk C., Tunis S., Zamora B., Public Health Genomics 2019;22:8–15, <https://www.karger.com/Article/FullText/501832>



Market Data

The Market Data team produces a wealth of data on medical devices and IVDs. MedTech Europe's Market Data Trackers and publications are the go-to source of information for market size and trends, helping our members and partners take informed business decisions based on accurate knowledge of the economic environment.

The Market Data Trackers are tailor-made to better address the specificities of each market segment. They are developed through close continuous collaboration with participating companies.

The team also compiles MedTech Europe's Facts & Figures consisting of indicators that captures the activity of our industry and showcases its contribution to health and the economy in Europe.

Data are collated by an experienced team, supported by the 25 Market Survey Groups, Market Research Committee and Market Intelligence & Customer Insight Group.

Timely and accurate market data, compliance with competition legislation and data confidentiality are the three pillars of the Market Data team.

2019 HIGHLIGHTS

In 2019, the Market Data team prepared 2,600 reports for more than 115 company divisions and national associations, collecting data for over 1,300 medical technologies in 80 countries.

94% Members Satisfaction

In 2019, the MedTech Europe Market Data team carried out a Medical Devices Trackers customer satisfaction survey to collect direct feedback from members and improve understanding of our data users' needs. Based on the results, 94% of participants stated that they are satisfied with the provided services. Our Market Data Trackers are once again referred as the preferred and most trusted source of market size and dynamics information. 90% of respondents said data are used by professionals in Marketing and Market Intelligence, as well as 70% of Strategy and Business Development executives and Product Managers. Over 60% stated that executive officers directly receive, or read reports based on, the market data provided by MedTech Europe.

2 New Market Trackers

In 2019, the team developed two new Market Data Trackers.

First, the team launched the Orthopaedic Reconstructive Market Tracker covering the United States. This brought the expanding portfolio of the Orthopaedic projects to seven and affirms MedTech Europe as the preferred data provider for the sector globally. The ongoing Orthopaedic Reconstructive projects collect sales data from the major hip, knee, extremities implants and bone cement & accessories companies for Europe, the Middle East and Africa, Asia Pacific, Latin America and now the US.

Second, MedTech Europe also established a new Energy Medical Devices Tracker for the EMEA region. It includes quarterly sales reports for Generators, Advanced Energy and Electrosurgery from the leading manufacturers on the market.

15 New Companies and Project Development

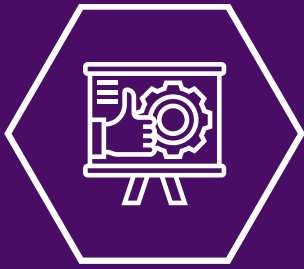
The team takes regular action to guarantee high market coverage. In 2019, 15 more companies joined either the existing medical device/IVD trackers or the newly established ones. Further developments in our Market Data Trackers offering include reporting of additional geographies, inclusion of new products, revision of segmentation and granularity. The team organized five trainings and workshops aiming to improve reporting and data accessibility, ensure methodology alignment and transparency, address compliance with competition legislation guidelines, and discuss the latest trends in market research.

4 Publications

Facts & Figures, European IVD Report, Statistics for Cardiac Rhythm Management, and Orthopaedic implants are four unique sources of information for our stakeholders. More than 1,000 printed copies were distributed and the online version was viewed more than 11,000 times. Crucial industry data and analytical support were provided for pivotal projects and topics for the association – Value of MedTech, R&I, Notified Bodies, Brexit, MedTech Europe Code of Ethical Business Practice and others.



Learn more: www.medtecheurope.org/market-data



Legal and Compliance

The Legal & Compliance team supports the medical technology industry in all legal and compliance matters by developing guidance, monitoring legal developments affecting the industry, sharing best practices, defining industry positions and leading self-regulation initiatives in the field of anti-corruption.

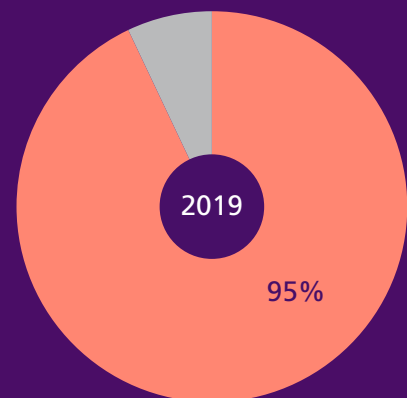
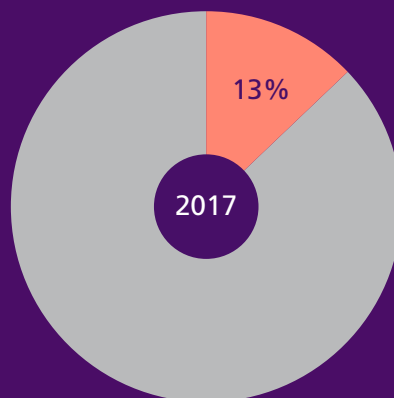
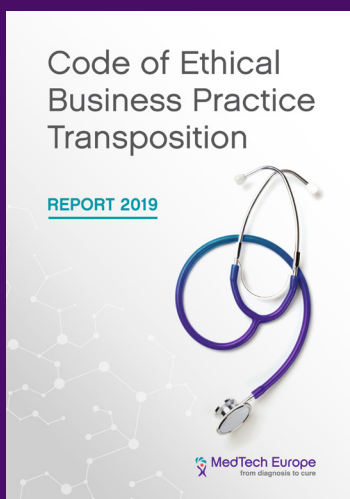
MedTech Europe members have committed to a high level of ethical business practices and have put in place strict guidelines on how to collaborate ethically with healthcare professionals (HCPs). In 2015, members signed up to the MedTech Europe Code of Ethical Business Practice ('the Code'), which entered into force for companies on 1 January 2017, and for National Associations (NAs) on 1 January 2020. The team supports and monitors implementation of the Code by members. The Legal and Compliance team also supports the Conference Vetting System (CVS) and Transparent MedTech, a platform for disclosing Educational Grants.

2019 HIGHLIGHTS

MedTech Europe Code implementation

Code implementation by 95% NAs

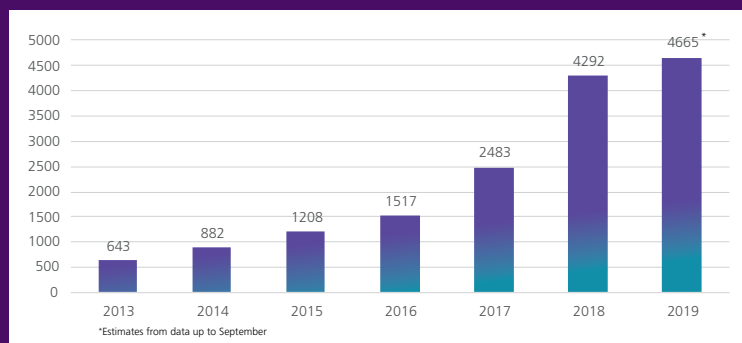
The implementation of the Code by 95% of NAs is a significant achievement for the Legal and Compliance team. Detailed facts and figures, as well as the evolution of the Code's transposition, are available in the Compliance Report 2019, a publication developed by the team in 2019.



- National Associations that have banned direct sponsorship.
- National Associations that haven't banned direct sponsorship yet.

Conference Vetting System (CVS):

inclusion of Third-Party Procedure Training and assessment of more than 5,000 events



Directly linked with the Code implementation, the CVS system reviews the compliance of Third-Party Organised Educational Events (TPOE) with the Code. Started as a pilot project in 2013, it became compulsory for MedTech Europe members as of 1 January 2017. This year, more than 5,000 TPOE were assessed. In addition, since this year, Third-Party Procedure Trainings (TPPT) are also being assessed through the system.

140 chartered organisations

The Ethical Charter is an additional instrument developed to support buy-in from third parties organising medical events. It takes the form of a voluntary training session in the Code for Healthcare Organisations (HCOs) and Professional Conference Organisers (PCOs) leading to certification. Launched in July 2017, the number of certified HCOs and PCOs globally has grown rapidly and has reached 140 this year.

New guidance

In 2019, several guidance documents on legal and compliance topics have been developed. These include: guidance on ethical aspects of Artificial Intelligence; new guidance on Data Protection; a guidance on placement of capital equipment; and new training material for distributors.

Organisation of events:

- the first GMTA (Global Medical Technology Alliance) Compliance Network meeting, which brought together compliance leaders from all over the world, to discuss code harmonisation across the healthcare industry (May)
- Integration of the Global MedTech Compliance Conference (GMTCC) into the MedTech Forum (May)
- Workshop on Collective Redress long-term alternatives co-organised with the European Federation of Pharmaceutical Industries and Associations (EFPIA) (June)
- Second data protection in health research workshop, co-organised with EFPIA and the International Pharmaceutical & Medical Device Privacy Consortium (IPMPC). More than 100 participants attended, including representatives from authorities and the European Data Protection Board (EDPB) (November)

Collective redress ('class actions' Directive)

The secretariat has been monitoring the Collective Redress file for years. The secretariat supported academic research in this field, via its membership of the European Justice Forum. Following July's Board recommendation to bring the sector to the discussion, a number of actions have been taken:

- Awareness raising; bringing members up to speed on the file, coupled with a thorough impact assessment
- Healthcare-focused workshop in June 2019; increased sectorial alignment on industry goals.
- Development and implementation of an outreach plan and an engagement plan with relevant stakeholders
- Support members' outreach by providing a full toolkit of resources
- Information sharing and coordination with members through a dedicated Task Force



International Affairs

Medical technology benefits people in every corner of the world, but sometimes it needs a little help getting there. That, in a nutshell, is the role of International Affairs within MedTech Europe – to ensure that medical technology can reach markets and patients beyond Europe and around the world.

We engage in bilateral trade and regulatory discussions with major medical technology markets such as those in the US, China, India, Russia or Brazil. We contribute to global health policy discussions with the WHO and the UN, demonstrating the value of medical technology in achieving the Sustainable Development Goals and, in particular, the deployment of universal health coverage.

Different parts of the world face diverse healthcare challenges but, in all cases, we strive to ensure that the value of medical technology for all people is recognized globally by policy and decision makers.

2019 HIGHLIGHTS

Keeping the EU market together

While a new regulation for medical devices is being implemented in Europe, there are challenges in keeping devices flowing through the market.

Brexit has proven a big challenge to manage in 2019 due to the great uncertainty not only in the process but in the potential outcome. Looking back, the most important achievement was to ensure that medical technologies were recognised as a key sector by the EU and the UK, both of whom ensured proper contingency measures were in place to minimise disruption to patients. This shows the continued value of medical technologies to patients, society and economic growth.

Challenges have also arisen in other parts of Europe. Medical devices have been flowing back and forth from the EU market to Switzerland and Turkey thanks to existing and, at times, complex trade agreements – the Mutual Recognition Agreement with Switzerland and the Customs Union Agreement with Turkey. Both of these need to be updated before the MDR comes into force in Europe to ensure continued free movement of devices in the entire area.

Bilateral dialogues

The EU maintains a series of bilateral dialogues with its major trade partners. 2019 was especially active for engagement with the US, China and India where questions regarding procurement and market access were at the forefront of the discussions. Keeping access to these large markets is key to ensure the overall global competitiveness of the industry. Mitigating the effects of trade wars for medical devices was a key policy in 2019.

Impact of MDR and IVDR around the world

European legislation on medical devices has been influential around the world for decades. Many jurisdictions across the globe rely on CE marked devices both for regulatory purposes and for procurement. With the implementation of the new MDR and IVDR it is important that the changes are understood and recognized so that disruption in the access to medical technologies is minimised. Work has been ongoing in the Middle East, ASEAN, Australia, New Zealand, Brazil and Canada amongst others to ensure everyone is ready for the new European rules.

IMDRF & MDSAP

Regulatory alignment is difficult – each authority is independent and responsible for keeping its citizens safe. 2019 saw stronger cooperation in areas such as cybersecurity and AI and triggered the start of a review of the core framework for in vitro diagnostics. In addition, the EU began in earnest to consider ways in which it could benefit from using the Medical Devices Single Audit Programme within its own system.



Learn more: www.medtecheurope.org/international



External Affairs

The External Affairs Team leads the Government Affairs and Communication activities of MedTech Europe. External Affairs is tasked with establishing and delivering the association's overall stakeholder and advocacy strategy, building and maintaining strategic relationships, and identifying opportunities to improve external impact. The team is focused on five key goals:

- Manage the reputation of the industry across external stakeholder groups, including building awareness of the value of the medical technology sector
- Understand and contribute to the regulatory, pre-legislative and legislative policy agenda
- Maintain and develop long-term relationships with key external stakeholders
- Ensure effective communications with MedTech Europe members
- Work across teams to ensure the development of high-quality and professional internal and external-facing materials

2019 HIGHLIGHTS

Reputation and Value

- MedTech Week: Industry-wide promotion on the value of medical technologies. The event inspired more than 130 activities across 22 countries, jointly delivered together with over 50 members and external partners
- Value of MedTech Campaign: Kick-off of an EU engagement plan aimed at the new European Parliament and Commission. A visual toolkit was developed for policymakers, including welcome letters, first aid kits and social media video stories, to help promote the value of the industry.



Internal and External Communication

- Continuous growth in activities and engagement on MedTech Europe's key digital platforms:
 - Over 180,000 MedTech Europe website visits
 - Over 3,000 subscribers to MedTech Europe's newsletters
 - Over 40,000 followers of MedTech Europe's social media channels (LinkedIn, Facebook and Twitter), plus more than 70 recorded online engagements with top-ranking decision makers
- Increasing engagement with influential media institutions
 - 250+ Media mentions in major publications
 - 'Media readiness structures' strengthened: guidelines and trainings, member coordination, media monitoring

Advocacy Strategy and External Outreach

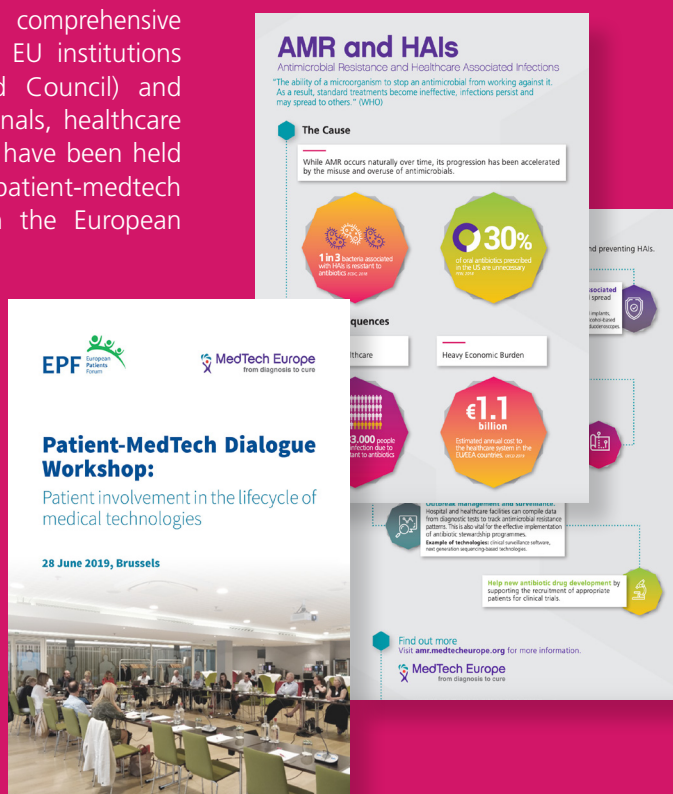
The External Affairs Team has done its utmost to drive advocacy on MedTech Europe priorities:

- MDR and IVDR implementation
- Market access & economic policies (with a focus on procurement & HTA)
- Legal & compliance (with a focus on collective redress)
- Sustainability (with a focus on environment),
- Digital health
- Anti-microbial resistance
- Brexit & international affairs
- Horizon Europe

In total 10+ resource toolkits on key policy topics were developed, actively used and shared with members.

Engagement with EU Policymakers

External Affairs has developed and implemented comprehensive strategies to extend and deepen engagement with EU institutions (European Commission, European Parliament and Council) and external stakeholders (patients, healthcare professionals, healthcare institutions). Numerous meetings with policymakers have been held with the support of the External Affairs Team. A patient-medtech dialogue workshop was held in partnership with the European Patients Forum.





Digital Health

Medical technologies generate information and data that are critical for the prevention, diagnosis, treatment, monitoring and management of health and lifestyle. More and more of this data is now digitised; it can be stored and accessed on electronic health records and personal devices, shared among patients and healthcare professionals, and aggregated and processed with advanced analytics.

MedTech Europe works with policymakers and relevant stakeholders to realise the potential of data-driven healthcare. Together we focus on legal and regulatory issues (privacy, safety), technology (cybersecurity, interoperability), the business case (incentives, reimbursement), and emerging technologies (precision medicine, artificial intelligence).

2019 HIGHLIGHTS

In 2019, the MedTech Europe digital health team worked with its members to define the priorities of the medical technology industry in digital health and determine how these might be addressed.

Two issues emerged as top priorities:

- **Finances:** the structures of European healthcare systems to pay and reimburse need to be updated to incentivise and reward digital health solutions
- **Technology:** lack of interoperability is a critical impediment to data sharing and aggregation, with healthcare data trapped in silos and incompatible formats

There are other critical barriers for the digital transformation of healthcare, including rules and regulations that sometimes block innovation, and a lack of trust and skills among users of digital health services.

In 2019 MedTech Europe made contributions to address many of these issues.

- In July 2019, MedTech Europe prepared its position paper on digital health interoperability, committing to an interoperable data ecosystem for digital health and calling for other industries to do the same
- The position paper on artificial intelligence followed in November 2019, discussing the challenges for the use of data and AI in healthcare, and recommending specific policies to address them
- MedTech Europe was also one of the contributors to the April 2019 eHealth Stakeholder Group paper on reimbursement, outlining the challenges and needs that digital health technologies face

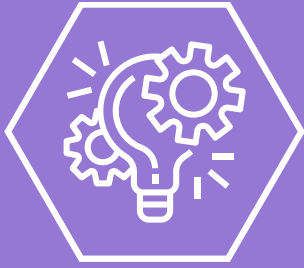
MedTech Europe also participated in several consultations that declared industry positions and reactions to proposed policy documents, including the European Commission's consultations on the Ethical Guidelines for Trustworthy AI (January), the Digital Europe Programme (October) and the Trustworthy AI assessment list (December).

In addition, MedTech Europe contributed to the WHO Global Strategy on Digital Health (April), and on the IMDRF's Principles and Practices for Medical Device Cybersecurity (December). MedTech Europe also engaged with other stakeholder to address systemic challenges to digital health.

MedTech Europe will work with Integrating the Healthcare Enterprise, arguably the most important global digital health interoperability initiative, on its flagship European event in March 2020, the IHE Europe Connectathon and the IHE World Summit.

MedTech Europe also formally joined two major health data initiatives in the autumn of 2019: the European Patients' Forum Data Saves Lives campaign will inform patients and citizens of the benefits of using data for healthcare delivery and research; the European Institute for Innovation through Health Data (i~HD) promotes uses of health data and interoperability for optimising health and knowledge discovery.





Research and Innovation

MedTech Europe supports members in engaging with EU funding schemes, equipping them with the knowledge and skills required to play an active role in this new era of healthcare research and innovation (R&I).

Our expert team deliver webinars and training, access to a library of support tools, official templates, a calendar of calls and details of work programmes. We are committed to helping medical technology innovators of all sizes be a part of Europe's R&I ecosystem.

2019 HIGHLIGHTS

In September 2019, MedTech Europe formed the EU Research & Innovation Partnerships team. It results from a decision of the Board of MedTech Europe to offer a new service to its members and help them benefit from the opportunities offered under the Horizon Europe framework (2021-2027).

18 member companies joined the newly established Research & Innovation Committee and were tasked with preparing and communicating the position of the medical technology sector on issues relating to EU R&I funding and policy. The Research & Innovation Committee is the place to develop the R&I community with our member companies and associations, as well as fostering greater European R&I cooperation. Training programme with webinars and workshops provides our members with basic information and insights into the EU R&I funding mechanisms and programmes. The activities of the committee will intensify in 2020 to make sure everybody interested in EU funding and new Horizon Europe Framework Programme is ready.

MedTech Europe also has the mission to drive the future Partnership on Health Innovation alongside the European Commission and the other industrial associations. Industrial experts from member companies, as well as from our team, are bringing the voice of the medical technology sector into the working groups that are preparing and defining the Partnership on Health Innovation.

Learn more: www.medtecheurope.org/research-and-innovation

Flagship Events



The MedTech Forum is the largest health and medical technology industry conference in Europe and a key event since 2007. In 2019, MedTech Europe's annual Forum began touring Europe, making its first stop in Paris in May. This edition of The MedTech Forum included, for the first time, the Global MedTech Compliance Conference (GMTCC) and was held in conjunction with the Start-up Day organised by the French Medical Device Association, SNITEM. More information: www.themedtechforum.eu



The CEO Summit is a unique opportunity for medical technology leaders to get the latest updates and discuss important managerial, innovation and policy trends in Europe that affect and influence their leadership roles. The agenda took a deep dive into Digital Strategy, Research & Innovation EU funding, and the MedTech Europe Code of Ethical Business Practices

Held in July, this event brought together 42 European leaders of MedTech Europe's corporate members and representatives of the MedTech Europe Board. Participation in this event is by invitation only.

Medtech Europe Members

AS OF DECEMBER 2019

CORPORATE MEMBERS		
3M		MD
Abbott	IVD	MD
Acelity		MD
Agfa Healthcare		MD
Agilent Technologies	IVD	
AIDIAN	IVD	
Alcon		MD
Ansell		MD
Arthrex GmbH		MD
Ascensia	IVD	
AVANOS		MD
B Braun		MD
Baxter		MD
BD	IVD	MD
Beckman Coulter	IVD	
Biocartis	IVD	
bioMérieux	IVD	
Bio-Rad	IVD	
BioSystems	IVD	
Biotronik		MD
BlueWind Medical	<i>New in 2019</i>	MD
Boston Scientific		MD
BTG		MD
Cardinal Health		MD
Cepheid	IVD	
Cerus		MD
CMR Surgical	<i>New in 2019</i>	MD
Coloplast		MD
Convatec		MD
Cook Medical		MD
Corin Group	<i>New in 2019</i>	MD
CROMA Pharma		MD
Devyser	IVD	
Dexcom		MD
DiAgam	<i>New in 2019</i>	IVD
DiaSorin		IVD
DiaSys		IVD
Edwards		MD
EKF Diagnostics	<i>New in 2019</i>	IVD
Endologix		MD
Essity Hygiene and Health		MD
Exact Sciences	IVD	
Fresenius		MD
Fujirebio	IVD	

GE Healthcare		IVD
Grifols		IVD
Haemonetics		MD
Hartmann		MD
Hemocue		IVD
Hillrom		MD
Hollister		MD
Hologic		IVD MD
IDEXX Laboratories	<i>New in 2019</i>	IVD
Illumina		IVD
Insulet		MD
Integra LifeSciences		MD
Intuitive Surgical		MD
Johnson & Johnson		MD
Laborie		MD
LifeScan	<i>New in 2019</i>	IVD
LivaNova		MD
Luminex		IVD
Materialise	<i>New in 2019</i>	MD
Medacta		MD
Medela		MD
Medline		MD
Medtronic		MD
Merit Medical		MD
MicroPort		MD
Mölnlycke Healthcare		MD
Myriad Genetics		IVD
Nevro		MD
Nipro Medical Europe	<i>New in 2019</i>	IVD MD
Nobel Biocare		MD
Novo Nordisk		MD
O&M Halyard		MD
Olympus Europa		MD
Ortho Clinical Diagnostics		IVD
Orthofix		MD
PerkinElmer		IVD
Philips		IVD MD
PikDare		MD
QIAGEN		IVD
Quotient	<i>New in 2019</i>	IVD
Radiometer		IVD MD
ReCor Medical	<i>New in 2019</i>	MD
ResMed		MD
Roche		IVD MD
RTI Surgical		MD

Sebia	IVD
Second Sight Medical Products	MD
Sekisui	IVD
Siemens	IVD
SkylineDx	<i>New in 2019</i> IVD
Smith & Nephew	MD
Smiths Medical	MD
Stago	IVD
Stryker	MD
Sysmex	IVD
Tecan	IVD
Teleflex Medical Europe	MD
Terumo	MD
The Binding Site	IVD
Therakos	MD
Thermo Fisher Scientific	IVD
Thiebaud	MD
Tosoh	IVD
W.L. Gore	MD
Werfen	IVD
Wright Medical Technology	MD
Zimmer Biomet	MD

ASSOCIATE CORPORATE MEMBERS

1Worldsync	<i>New in 2019</i>	IVD	MD
ArisGlobal	<i>New in 2019</i>	IVD	MD
Assent Compliance		IVD	MD
Atrify		IVD	MD
BIT Analytical Instruments		IVD	MD
CEA		IVD	MD
Dupont	<i>New in 2019</i>		
GHX Europe		IVD	MD
innovit	<i>New in 2019</i>	IVD	MD
JSR Micro		IVD	MD
Orange		IVD	MD
Reed Tech		IVD	MD
Sophia Genetics		IVD	MD
USDM		IVD	MD

ASSOCIATE NATIONAL ASSOCIATIONS

ARTED (Turkey)	IVD	MD
European Association of the Surgical Suture Industry		MD
IMEDA (Russia)		MD
IMSTA (Ireland)		MD
IPQ		MD
Mecomed (Middle East)		MD
Spectaris (Germany)		MD
Technomed (Poland)		MD

SUPPORTING ORGANISATION

Europa Organisation	IVD	MD
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NATIONAL ASSOCIATIONS

ABHI (United Kingdom)		MD
AFPM (Romania)	IVD	MD
AMDMD (Hungary)		MD
APIFARMA (Portugal)	IVD	
APORMED (Portugal)		MD
AUSTROMED (Austria)		MD
beMedTech (Belgium)	IVD	MD
BIVDA (United Kingdom)	IVD	
BVMED (Germany)		MD
Confindustria Dispositivi Medici (Italy)	IVD	MD
CROMED (Croatia)	IVD	MD
CZECHMED (Czech Republic)		MD
CZEDMA (Czech Republic)	IVD	
DIAGNED (Netherlands)	IVD	
DIALAB (Denmark)	IVD	
EDANA		MD
FENIN (Spain)	IVD	MD
FHI (Netherlands)		MD
HIVDA (Hungary)	IVD	N
Irish Medtech Association (Ireland)	IVD	MD
MEDICOINDUSTRIEN (Denmark)		MD
MedTech Baltics (Lithuania, Latvia, Estonia)	IVD	MD
MedTech Polska (Poland)	IVD	
Melanor (Norway)	IVD	MD
NEFEMED (Netherlands)		MD
POLMED (Poland)		MD
SAIEEK (Cyprus)	IVD	MD
Sailab – MedTech Finland (Finland)	IVD	MD
SBA		MD
SEDMA (Slovakia)	IVD	
SEIV (Greece)	IVD	MD
SIDIV (France)	IVD	
SIEDMA (Slovenia)	IVD	
SK-MED (Slovakia)		MD
Slo-med (Slovenia)		MD
SNITEM (France)		MD
SVDI ASID (Switzerland)	IVD	
SWEDISH LABTECH (Sweden)	IVD	
SWEDISH MEDTECH (Sweden)		MD
Swiss Medtech (Switzerland)		MD
VDGH (Germany)	IVD	

Medtech Europe Staff

AS OF DECEMBER 2019

TEAM	NAME	TITLE
Chief Executive Officer	Serge Bernasconi	CEO
Regulations & Industrial Policy	Oliver Bisazza	Director Regulations & Industrial Policy
	Petra Zoellner	Senior Manager Regulations & Industrial Policy
	Dario Pirovano	Senior Regulatory Adviser - Consultant
	Merlin Rietschel	Senior Manager Regulations & Industrial Policy
	Katalin Máté	Manager Regulations & Industrial Policy
	Kira Meyerovich	Manager Regulations & Industrial Policy
	Nathalie Buijs	Manager Regulations & Industrial Policy
	Jana Moravcova	Manager Regulations & Industrial Policy
	Tatiana Dias	Officer Regulations & Industrial Policy
Market Access & Economic Policies	Yves Verboven	Director Market Access & Economic Policies
	Sophie Koettlitz	Manager Market Access & Economic Policies
	Sophie Meiser	Manager Market Access & Economic Policies
	Cristina Macovei	Project Manager EURIPHI
	Isabella Notarangelo	Manager Market Access & Economic Policies
	Aline Topouchian	HTA Project Adviser
Market Data	Cristian Manoiu	Senior Manager Market Data
	Teodora Angelova	Manager Market Data
	Orsolya Küttel	Officer Market Data
	Dario Belluomini	Officer Market Data
	Zefira Bazoteva	Intern Digital Health & Market Data
Legal & Compliance	Aline Lautenberg	Director Legal & Compliance - General Counsel
	Pablo Rojas Abad	Manager Legal & Compliance
	Clarisse Aillet	Consultant Medical Education & Training
	Caterina Marcon	Analyst Legal & Compliance
International Affairs	Jesús Rueda Rodriguez	Director International Affairs
	Diana Kanecka	Manager International Affairs
External Affairs	Tanja Valentin	Director External Affairs
	Jerick Parrone	Senior Manager Communications
	Jessica Imbert	Senior Manager Government Affairs & Public Policy
	Marie-Hélène Lattes	Manager Communications
	Kalina Bozhkova	Manager Government Affairs & Public Policy
	Emma Kollatou	Manager Government Affairs & Public Policy
	Gianluca Peinetti	Manager Communications
	Giulia Meneghin	Officer Communications
	Allbina Tzintoli	Coordinator Communications
	Giovanni Dalle Nogare	Officer Government Affairs & Public Policy
	Felix van den Broeck	Trainee Government Affairs & Public Policy
Digital Health	Michael Strübin	Director Digital Health
	Zefira Bazoteva	Intern Digital Health & Market Data
Research & Innovation	Patrick Boisseau	Director Research & Innovation
HR & Finance	Nicolas Van Mele	Director Finance, HR & Operations
	Patricia De Buyl	Senior Manager HR & Finance
Membership & Events	Christopher Breyel	Director MD Member Relations & MedTech Europe Events
	Jean-Noël Bouillon	Director IVD Member Relations
	Laurence Couturier	Manager Events
Administration	Caroline Raets	Manager Administration
	Rie Santos	Executive Assistant to CEO
	Aurélien Godet	All-round Assistant

Medtech Europe Board Members

AS OF DECEMBER 2019

NAME	ORGANISATION	CATEGORY	ROLE
Rob ten Hoedt	Medtronic	Corporate Representatives	Chairman/OMC member
Michelle Brennan	Johnson & Johnson	Corporate Representatives	OMC member
Philippe Jacon	Cepheid	Corporate Representatives	OMC member
Yasha Mitrotti	bioMérieux	Corporate Representatives	OMC member
Kerstin Wagner	Siemens	Corporate Representatives	OMC member
Christian Parry	(Stago) – SIDIV (France IVD)	National Associations representatives	OMC member
Meinrad Lugan	(BBraun) – BV MED (Germany MD)	National Associations representatives	Treasurer /OMC Member
Greg Ahlberg	Abbott	Corporate Representatives	
Ian Bell	Alcon/Novartis	Corporate Representatives	
Massimiliano Colella	Smith & Nephew	Corporate Representatives	
Claude Dartiguelongue	Thermo Fisher Scientific	Corporate Representatives	
Cristiano Franzi	Baxter Healthcare	Corporate Representatives	
Michael Heuer	Roche	Corporate Representatives	
Stuart Silk	Stryker	Corporate Representatives	
Benoit Traineau	DiaSorin	Corporate Representatives	
Nicolas Chandellier	(BD) – SNITEM (France MD)	National Associations representatives	
Peter Ellingworth	ABHI (UK MD)	National Associations representatives	
Jozef Jakubiec	MedTech Polska (Poland (IVD)	National Associations representatives	
Philipp Lindinger	Austromed (Austria IVD & MD)	National Associations representatives	
Carlos Sisternas	FENIN (Spain IVD & MD)	National Associations representatives	
Martin Walger	VDGH (Germany IVD)	National Associations representatives	



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