The Belgian Medical Technology Industry
Facts & Figures 2018

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The Belgian healthcare system is facing major challenges. There is the aging population and a growing number of chronically ill people, both significantly increasing the need for care. There are also ever higher quality requirements, a growing shortage of healthcare professionals and increasingly critical and vocal healthcare consumers. Thanks to advances in medical technology and digitization efficient solutions are made available to address these challenges. They cover prevention, diagnostics and treatment. However, the care budget is limited, so choices need to be made. A transversal value-based approach is needed.

Our current healthcare system is under heavy pressure and will not remain sustainable in the long run. A paradigm shift towards value-driven care and a transversal approach is necessary to ensure the financial sustainability and quality of our care system. We need to change the silo-thinking of various healthcare actors, as this supports the budgetary silos. In addition, there are a number of dysfunctions in the current performance-based healthcare financing model that encourage volume and overconsumption. Care providers and institutions are all too often rewarded on the basis of the number of interventions they perform, not on the quality or efficacy of the care they offer.

These silos and the fragmented financing stand in the way of budget-efficient healthcare. From now on we need to succeed in doing more with the same budget and at the same level of quality. It is necessary to continue evolving towards value-driven care, where not only the costs of the products are looked at, but where all of the expenses and savings they entail along the entire care trajectory are put into the equation. In such a transversal approach, the goal is to search for efficiency gains in all care structures and arrive at a point where budgets will always be allocated to those solutions that create the greatest value throughout the entire care process.

The effective application of value-driven care in Belgium is and remains a challenge. The fragmentation of competencies complicates the process of raising awareness about our added value, because the effects of a technology usually do not stop where institutional competence ceases.
The good news is that the government is increasingly looking for efficiency gains and, amongst other things, the Medical Devices Pact confirms the realisation that medical technologies are part of the solution (an investment that pays off) and not part of the problem (a pure cost).

Maggie De Block’s action plan for hospital financing reform is also an important step in the right direction. One of the spearheads of this action plan is the establishment of hospital networks, allowing hospitals to jointly invest in the latest technology for diagnostics and therapy. Another principle that is being carefully introduced is the ‘pay 4 quality’ principle, where the hospital is rewarded for good quality of care and not on the basis of the number of interventions.

Yet another important pillar for us is the creation of a clear framework for home hospitalisation, a domain in which several of our members are active. Here too work is being done that offers further opportunities for cost efficiency. The basic principle of a value-driven healthcare system should be that care is provided at the most efficient place.

In the same spirit, a study is being conducted at the NIHDI where treatments are approached transversally. This concerns the replacement of pacemakers in a day hospital and the use of mechanical thrombectomy. The results of this study could help to bring about a serious change in thinking.

If we continue to think from a silo perspective, without paying attention to efficiency gains such as shorter hospital stays and a faster return to work, I fear that fewer and fewer innovative treatments will become available in Belgium. This is an aspect to which I wish to draw the attention of the health authorities.

Another important aspect is the increased awareness of the value of in vitro diagnostics (IVD), including in the domain of personalised medicine. In this context, Maggie De Block recently launched a new initiative aimed at optimising the use of modern DNA analysis techniques (next-generation sequencing) in cancer prevention.

There is also a lot going on in e-health. The Mobile Health Belgium initiative and the eHealth Action Plan show that digital technologies have their place in the Belgian healthcare landscape. Recently, the platform www.mhealthbelgium.be was set up for the mobile health apps, which will soon contain detailed information about validated health apps in our country and their added value for patients and healthcare providers. Minister De Block also recently laid down the cornerstones for a regulatory framework for teleconsultations, in which patients will be able to rely on the same safety and quality guarantees in consultations from a distance as in those conducted face-to-face. We also welcome the recent launch of the “data for better health” initiative, which looks at how the enormous amount of clinical data, collected in part via medical technologies, can be opened up in an aggregated way to improve the effectiveness of diagnostics and treatment.

The digitization of healthcare needs to continue because there are many efficiency gains to be made.

The ever-accelerating developments in the field of artificial intelligence open up exciting prospects in the areas of diagnostics and care. The speed of this evolution does not allow us to have a clear picture yet of what healthcare will look like in the coming years. What is certain is that the changes will be profound and rapid. Hopefully, our healthcare system can benefit from these developments, while of course people, and especially the patients, remain the central point of focus.

beMedTech is keenly aware of the need for value-based care and offers a range of solutions that can help to achieve this. We want to continue working with the government and other actors in the sector to ensure both the quality of patient care and the sustainability of the healthcare system as a whole.

Annick De Keyzer
President beMedTech
WHAT IS MEDICAL TECHNOLOGY?
What is Medical Technology?

Medical technology are all products and equipment that fall within the scope of the European Directives for Medical Devices (93/42/EEC), Active Implantable Medical Devices (90/385/EEC) and In-Vitro Diagnostics (98/79/EEC). These directives are replaced by new European Regulations.

The scope of medical technology is very broad. It covers consumables (bandages, syringes, hearing aids, wheelchairs, ….), implants (hips and knees, stents, pacemakers, ….), medical equipment (imaging machinery, dialysis equipment, …) and in-vitro diagnostics.

Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices directives to two new regulations. From 26 May 2020, the new Regulation 2017/745/EU will fully apply to medical devices. Until this date, medical device manufacturers can choose to comply with either the Directives or the Regulation. From 26 May 2022, the new Regulation 2017/746/EU will fully apply to in-vitro diagnostics. Until this date, IVD manufacturers can choose to comply with either the Directive or the Regulation¹.

The healthcare landscape is in full transformation. The sector of medical technologies can play an important role in the whole chain of care, from prevention, diagnosing, monitoring, evaluating to treating patients. There are more than 500,000 medical technologies currently available in Belgium.

¹ The European Medical Technology Industry – in figures / 2018 by MedTech Europe
3 ABOUT BEMEDTECH
About beMedTech

beMedTech is the Belgian federation of the medical technology industry and has more than 200 affiliated companies. Its members are manufacturers and/or distributors and are divided into five product segments: in-vitro diagnostics (IVD), consumables, implants, medical investment goods (MES) and Extra Muros solutions, including Digital Health. Together they represent over 500,000 technologies for an annual turnover of € 2.4 billion not including export and they account for approximately 16,820 FTEs in Belgium*. beMedTech estimates that the total medical device industry has a turnover of about € 3.5 billion and employs about 20,000 people.

Our mission

beMedTech unites the Belgian manufacturers and distributors of medical devices to emphasize their positive role for the healthcare sector. The beMedTech members invest in innovative medical technologies and in the training and education of health professionals. Together with its members, the federation contributes in a responsible manner, both to the quality of patient care and to the sustainability of the healthcare system.

*Data on file at beMedTech, survey among its members, 2018. Figures do not include the non-responders to the survey and the (made-to-measure) devices that are custom-made (by dental labs, orthotists, prosthetists,...) or sold directly to end-users (such as hearing aids, eyewear,...).
**Timeline beMedTech**

**1958**
“U.N.A.M.E.C. - Union des Négociants en Appareils et Accessoires médicaux, chirurgicaux et pharmaceutiques - Union professionnelle” is founded by 4 distributors in medical material.

**1959**

**1987**
Creation of "v.z.w UNAMEC- Beroepsvereniging van fabrikanten, invoerders en verdelers van medisch materiaal en uitrusting" - "a.s.b.l. UNAMEC- Association professionnelle de fabricants, importateurs et distributeurs de matériel et équipement médicaux"

President André Fockedey establishes a membership fee system to raise the financial means to have a permanent secretariat and organizes the members in sections.

**1990**
UNAMEC represents 100 members

European Directive Active Implantable Medical Devices (90/385/EEC)

**1993**
UNAMEC represents 188 members

European Directive Medical Devices (93/42/EEC)

**1998**
European Directive In-Vitro Diagnostics (98/79/EEC)

UNAMEC represents 188 members

**2000**
UNAMEC becomes: "Beroepsvereniging van fabrikanten, invoerders en verdelers van medische hulpmiddelen” "Association Professionnelle des fabricants, importateurs et distributeurs de dispositifs médicaux”

**2001**
President Philippe Biart enlarges the permanent secretariat with experts active within the sector.

**2009**
UNAMEC changes its branding

UNAMEC publishes an elaborate analysis of the medical devices sector in Belgium

**2010**
UNAMEC creates executive committees (ExeCo’s) for the different product groups it represents (Consumables, Medical Equipment & Systems, Implants, Diagnostics)

The database for notified implants is introduced

**2011**
The "Agreement Commission for Implants" becomes the CRIDMI/CTIIMH

A new section "Medische Voeding” – “Alimentation Médicale” is created

**2012**
Laurette Onkelinx, Minister of Health, announces the "Plan Medical Devices", aiming to improve the traceability, assessment and supervision of MDs

UNAMEC changes from a professional association to a federation: "Fédération belge de l’industrie des Technologies médicales a.s.b.l.” / "Belgische Federatie van de industrie van de medische technologieën v.z.w."

UFPI becomes the UNAMEC section "Hoorapparaten - Appareils auditifs”

**2013**
UNAMEC organizes its first training "External staff in the operating theater" together with Zorgnet
2003
In order to enhance the image of the federation, the offices move from Vilvoorde to Wemmel and the federation starts to focus more on its communication with the outside world.

2004
UNAMEC becomes a member of the Technical Board for the Wheelchairs (TBW) of the National Institute for Health and Disability Insurance (NIHDI).

2006
The Federal Agency for Medicines and Health Products (FAMHP) is created by law in July 2006, with UNAMEC representing the medical device industry in the Transparency Committee. Mdeon, the ethical health platform, is created – UNAMEC, with director and driving force Richard Van den Broeck, is one of the founding members.

2007
UNAMEC works closely together with NIHDI for the introduction of new regulation on reimbursement of implants. UNAMEC publishes its first Annual Report.

2008
Under the presidency of Paul Soenen, the IVD companies join UNAMEC (transferring from pharma.be). UNAMEC is selected as the sectoral operator for The Belgian Bureau for Standardisation (NBN), responsible for developing, publishing and selling standards in Belgium.

2015
Launch of the disclosure platform betransparent.be.

2016
Publication of new European regulation for medical devices and in vitro diagnostic medical devices. Voluntary disclosure of interactions between medical device industry and healthcare professionals and institutions on betransparent.be.

2017
Together with Agoria and the Belgian Federation of Hospital Directors, HealthTech.Belgium is launched, an initiative to make Belgium the preferred region for researching and testing of Health Tech.

2018
4 THE BELGIAN PACT ON MEDICAL TECHNOLOGIES
Background

In October 2016 the “Pact on Medical Technologies” was signed between Maggie De Block, Minister of Public Health, and beMedTech. The pact was a result of intense and constructive discussions between the federation and the 3 main administrations (Federal Public Service Health, the reimbursement agency National Institute for Health and Disability Insurance (NIHDI), and the Federal Agency of Medicinal and Health Products (FAMHP). It was the first time such a dialogue had taken place, and it resulted in an agreement to work around 32 topics. The objective of the Minister was clear: through agreements, laws and rules provide the highest possible guarantee to safe and accessible medical devices. Some of the 32 topics are transversal, across the different types of medical devices. The implementation of the new Medical Device and IVD Regulations, a new framework on care outside of hospitals, a transversal evaluation of medical devices inside NIHDI are examples of such transversal topics.

Other topics relate to the specific nature of some groups of medical devices, like implants, IVD, consumables or medical equipment.

Summary of main achievements

Transversal Topic #2: Autocontrol

The objective was to make sure that all medical device actors (manufacturers, distributors, importers, ...) are known by the FAMHP and that these actors go through a self-assessment, which, in turn, optimizes the inspection efforts. The legal base is set in the Royal Decree of November 15, 2017.

With the contribution from the industry through the meddev tax, the FAMHP set up a web-based platform, resulting in a registration of 2,000 (and counting) additional actors, formerly unknown to the FAMHP.

Transversal Topic #3: Services & Technologies Home Assistance (STHA)

The objective was to provide a legal framework for companies that currently support care outside hospitals by installing, maintaining and repairing medical systems, by providing the consumables that go with it, and by educating the patient on the proper usage. The framework entails the development of a General Guide and Therapy-specific guides. Registered STHA companies will have to indicate in the Autocontrol system whether they follow these guides.

The law of December 18, 2016 adapted the law regarding medical devices of December 13, 2015, to allow for the Guides. Efforts of FAMHP and beMedTech resulted in the development General Guide, expected to be published by end 2018. The first therapy-specific guides, as well as the financing models are expected in 2019.
Transversal Topic #11:
Deontology and transparency
Through Mdeon, founded in 2006, the industry took various initiatives to self-regulate the interactions between industry and healthcare providers and professionals. In 2017, the members of pharma.be and beMedTech voluntarily disclosed the interactions, on www.betransparent.be. As of May 2018, after the Royal Decree of the Sunshine Act of 14th of June 2017, all actors are legally obliged to yearly disclose their interactions with healthcare professionals, thus creating a transparent and level playing field.

Transversal Topic #12:
Administrative Simplification
The market access, vigilance and regulatory services regarding IVD moved from Sciensano (formerly WIV-ISP) to the FAMHP. It’s a small step in the Redesign, in which the 3 large administrations (Federal Public Service Health, NIHDI and FAMHP) will move into one building, with the objective to create synergies. However, resources to support IVD inside the FAMHP are still limited, despite the contribution from the IVD industry through the meddev tax.

The analysis regarding the synergies with the Federal Agency for Nuclear Control (FANC) has not taken place yet.

Transversal Topic #15:
Financing of the Pact
The increased need for evaluators of medical technologies inside the NIHDI is supported by the medical device industry by a structural and yearly contribution of 500,000 EUR. It is financed with the meddev tax, and flows through via the FAMHP.

Transversal Topic #16:
Monitoring of the Pact
A Steering Committee, with members of the cabinet, FAMHP, NIHDI and beMedTech meets every 10 weeks, to evaluate the progress on the various components of the Pact.

Implants, Topic #17:
Traceability of implants
At the initiative with NIHDI with the efforts of the industry, all available implants are searchable in one single database. The ownership of this database moves from NIHDI to FAMHP by end 2018. As for a Central Traceability Registry, providing insights into which patient has received which implant, this is supported today by a limited amount of hospitals. However, this doesn’t mean there is no traceability. Within their decentralised databases, all hospitals are able to trace all implants, all the way to the patients.

Implants, Topic #20:
Commission reimbursement of implants and invasive medical devices
This commission needed some improvements regarding their procedures. After an internal evaluation some adaptations are planned, moving in the right direction. These are foreseen in the law but need to be made concrete by subsequent Royal Decrees. The following adaptations have been made: The Commission can involve experts, to enhance the scientific discussion. Scientific associations can request reimbursement of various technologies. The possibilities to request a “Limited Clinical Usage” will be expanded. There will be the possibility for alternative, negotiated, financing models that include, for example, risk sharing.

Consumables, Topic #28:
Optimizing the Technical Council for Diagnostical and Care Products (TRDVM-CTMDS)
The objective was to simplify and harmonize the procedures of this council, to enable patients faster access to new technologies/provisions. It has changed its name to the “Commission for reimbursement of pharmaceutical products and procurements”. The Royal Decree should be published at the end of 2019, and be in effect as of 2020. The industry will be present, without voting rights, in the commission itself, as well as in the working groups that prepare the dossiers for the commission. The turnaround time of a dossier is set to a maximum of 370 days.
Medical Equipment, Topic #29: 
**Cadaster of heavy equipment for medical imaging**
As of 2018, all hospitals that have heavy medical imaging equipment declare their assets, so that government can manage and control the supply of medical imaging. It is part of the solution to decrease the radiation exposure. The objective is to reduce the number of CT-scans by offering MRI examinations instead. The Cadaster is now fully up and running, at first by the input of beMedTech member companies, now by the hospitals themselves. It is now managed by a collaboration between FPS Health, NIHDI, FANC and the Belgian Medtech industry.

Medical Equipment, Topic #30:
**Maintenance of medical equipment**
It is critical for the quality of care that medical equipment is used in an optimal way. Therefore a legal framework around the education of operators and the maintenance of the equipment is desirable. Initial consultations with the umbrella organizations of hospitals and biotechnicians have taken place during 2018.

Medical Equipment, Topic #31:
**Mobile Applications**
This action item resulted out of the Action Plan e-health, in which dedicated attention was put to mobile health (m-health). The 24 approved pilot projects ran until 2017 and were evaluated early 2018. It resulted in a framework in which m-health applications will be evaluated and published according to 3 levels: CE-Marking as medical device and GDPR compliance, interoperability with the governmental e-health services and financing. beMedTech and Agoria, in partnership with FAMHP, NIHDI and the e-health services launched the website mhealthbelgium.be. It soon will provide the necessary qualitative information to patients and healthcare providers regarding the available mobile applications.

Overview of topics that are work-in-progress

Transversal Topic #1: 
**New European Regulations**
Frequent interactions with the FAMHP are taking place, but have not yet resulted in any local legislation or actions, also because the implementing acts have not been clarified at the European level. The current ongoing discussions between FAMHP, beMedTech and other stakeholders related mainly to the frameworks around: the distribution channels of medical devices, the re-use of single-use devices, and the lab-developed in vitro diagnostics (“In-House tests”).

Transversal Topic #5:
**Vigilance**
An information campaign around materiovigilance and medical devices is being developed by the FAMHP. Regarding the Central Tracing Registry of Implants, it is in place, but not used across the board, as the actual IT-solution does not avoid double work for hospitals. However, decentralised information in every hospital allows to trace exactly where each implant has been implanted, especially for reimbursed implants. The solution for full traceability of all implants lies in the implementation of the UDI (Unique Device Identifier), expected in March 2020.

Transversal Topic #6:
**National Cadaster of medical devices**
The authentic source of all available medical devices (MDR Eudamed) is a European initiative and is supposed to be ready in March 2020. This will serve as the reference for Belgium. The industry is fully preparing itself by implementing the UDI (Unique Device Identifier). As for the cadastre of the available implants in Belgium, this has been available for a while now. The management of this cadastre will move from NIHDI to the FAMHP by end 2018.
Transversal Topic #8: 
**Working Group Budget and Evaluation of Medical Devices**

The industry has kept its commitment to save 41 m. EUR inside the budget of the implants, as agreed in the pact.

Unfortunately we cannot report that the permanent Working Group inside the NIHDI has been set up. It means that the budgetary impact of the interventions of the health insurance cannot be analysed for all medical devices. It also means we cannot measure the transversal efficiencies that innovative medical devices can bring. As a result, the opportunities of medical devices are not fully captured. For more details, see the Memorandum 2019-2024, and the recommendations 1, 4 and 5.

Transversal Topic #9: 
**3D-printing**

As planned, the KCE-report (297A) regarding 3D Printing was published early 2018. beMedTech took part in the dialogue between authorities, KCE and industry. Final conclusions regarding the framework around regulatory and reimbursement have not yet been reached.

Transversal Topic #10: 
**Diabetes convention**

In the Royal Decree of March 1st 2018 that addresses the diabetic convention there are some issues with the verbiage of the clauses on the educational information that patients receive from the industry. beMedTech and some of its members started a procedure at the Council of State to resolve these issues. In order to avoid such problems and to optimize the execution of the convention as well as accelerate the access of patients to new technologies beMedTech has requested to get a seat on the board of agreement (akkoordraad/conseil d’accord) of the diabetic convention inside the NIHDI.

Implants Topic #18: 
**The optimal use of implants**

The goal is to optimize specific and complex treatments by concentrating them in specialized centers. The objective criteria to determine these centers of excellence are not yet set. As a result, some innovative technologies do not find their way to the patients, not even in the framework of the Limited Clinical Application.

Implants, Topic #19: 
**Big Data**

With the increased demand for data regarding the usage of medical devices, and the need for data to support the health-economic argumentation for new technologies, it was the objective to investigate how data could be made available to the industry. We cannot report much progress. Still today, there is no procedure for the medical device industry to access any of the available data at the Inter Mutualistic Agency (IMA). It is however mentioned in IMA’s plan for 2019, under the umbrella of dataforbetterhealth.be, which is supported by Sciensano. The policy note on dataforbetterhealth.be will be presented by the Minister of Health in February 2019.

IVD, Topic #22: 
**In-House tests**

At the initiative of the FAMHP, the first initial meeting around the framework of in-house tests took place in September 2018. The first step is to analyze and agree on what is meant by the rules set out by the IVDR.

IVD, Topic #23: 
**Point-of-care-testing**

Point-of-care tests are the decentralized tests, outside of labs, close to the patient, done by first-line physicians or by patients themselves. The efforts around a clear regulatory framework, to ensure the correct execution of the tests, have resulted in a final document that was drafted by Sciensano, in consultation with the industry. It is currently in the pipeline to be transposed into legislation, the timeline is unknown.
IVD, Topic #24:
Specific reimbursement procedure for IVD-tests
One of the cornerstones of the pact was to define a faster and more transparent procedure for IVD. Today such a procedure still does not exist. The activities within the working group Clinical Biology remain opaque, without any transparency regarding agendas, timelines and decisions. This is surprising, given the increasing role that IVD play in prevention, diagnosis and treatment. The IVD industry requests an urgent follow up.

IVD, Topic #25:
Next Generation Sequencing (NGS)
The pilot projects to test targeted NGS in real life are ongoing, and will run until 2021. The objective is to introduce targeted NGS inside the molecular diagnostics in oncology after the pilot projects.

Consumables, Topic #27:
Re-use and sterilization of products in-house
Medical devices that are CE-marked for single use are sometimes reprocessed by hospitals. The upcoming European regulation gives the autonomy to the FAMHP to define a set of rules to which the hospitals need to adhere to in Belgium.

A working group with all relevant stakeholders has been set up by the FAHMP. A survey among hospitals on their current practices has been held, and the results have been presented in September 2018. The final rules and procedures for hospitals around quality, safety, hygiene and patient consent have not yet been defined.

Overview of topics that have not yet started

Transversal Topic #4:
Training and Education of healthcare professionals on medical devices
This project, where cooperation is needed between beMedTech, FAMHP and universities, has not yet started.

Transversal Topic #7:
Quality Analysis
Inside the MDR and IVDR a framework for European and uniform quality inspection rules is to be set up. In Belgium some national reference labs are already analysing the performance and safety of medical devices. This project refers to the analysis of the feasibility of the access of Belgian quality assessment labs to the EU-network. It has not yet started.

Transversal Topic #13:
Classification procedure
The project around the improvement of the classification procedure of borderline products by the “Mixed Commission” has not yet started. It is also linked with the European efforts, where the goal is to have a uniform European classification procedure.

Transversal Topic #14:
Medical Devices and Animal Health
The reflection around the framework of the usage of medical devices for animal health has not yet started.
Implants Topic #21:

**Procedure for the price stipulation**

Unfortunately no progress to report on the simplification of the price procedure for implants. Costly double work still takes place at the Federal Public Service Economy and NIHDI, leading to a delay in bringing the latest technology to patients. Furthermore, the harmonization of the VAT tariff for all implants and invasive medical devices has not yet been addressed. We continue to have a situation where, without a clear rationale, some implants or invasive medical devices have a tariff of 6% VAT, others have a VAT of 21%. In comparison, all medicines have a VAT tariff of 6%.

IVD, Topic #26:

**Prevention protocols**

This project around the coordination between federal and regional authorities of IVD for prevention and screening has not yet started.

Medical Equipment, Topic #32:

**Follow-up of technological evolutions**

The research to investigate whether or not a monitoring group can be set up inside the House of the Future to follow up the technological evolutions has not yet started.
5
THE MEDICAL TECHNOLOGY MARKET IN BELGIUM
Important notice:
All following facts & figures are based on a survey amongst member companies of following industry associations Agoria, beMedTech, LifeTech Brussels, MedTech Flanders & MedTech Wallonia. In total 106 companies participated to this survey. Most of the companies that participated to this survey are suppliers to the in-hospital care and out-of-hospital care. The results of this survey do not include the non-responders to the survey and the (made-to-measure) devices that are custom-made (by dental labs, orthotists, prosthethists, …) or sold directly to end-users (such as hearing aids, eyewear, …).

Active in medical devices

In total 94.3 % of participating companies indicated that they are active in the field of medical devices in at least one type of activity in Belgium

Activities of the medical device companies*

- **30,0 %** Headquarter services (regional or global)
- **28,0 %** Manufacturing
- **90,0 %** Distribution
- **33,0 %** R&D

* Percentage of participating companies active in medical devices per type of activity
The medical technology market in Belgium

ACTIVITIES

Active in IVD (In Vitro Diagnostics)

In total 17.9% of participating companies indicated that they are active in the field of IVD in at least one type of activity in Belgium.

Activities of the IVD companies*

- **15.8%** Headquarter services (regional or global)
- **10.5%** Manufacturing
- **94.7%** Distribution
- **10.5%** R&D

* Percentage of participating companies active in IVD per type of activity
The medical technology market in Belgium

Active in pharmaceutical products

In total **12.7 %** of companies indicated that they are active in the field of pharmaceutical products in at least one type of activity in Belgium.

*Percentage of participating companies active in pharmaceutical products per type of activity*

**Activities of the companies active in pharmaceutical products**

- **30.8 %** Headquarter services (regional or global)
- **23.1 %** Manufacturing
- **100.0 %** Distribution
- **23.1 %** R&D

* Percentage of participating companies active in pharmaceutical products per type of activity
In total 6.6% of participating companies indicated that they are active in the field of para-pharmaceuticals / beauty products, all are only active in distribution of these products.

Activities of the companies active in para-pharmaceuticals / beauty products*

- Headquarter services (regional or global) - 0
- Manufacturing - 0
- Distribution - 100,0%
- R&D - 0

* Percentage of participating companies active in para-pharmaceuticals / beauty products per type of activity
The medical technology market in Belgium

PRODUCT PORTFOLIO

Product portfolio*

- **6,6 %**  
  Para-pharmaceuticals / beauty products

- **12,7 %**  
  Pharmaceutical products

- **15,1 %**  
  IVD

- **30,2 %**  
  Services (inside or outside the hospital walls)

- **43,4 %**  
  Medical device software and/or Digital Health Applications

- **67,9 %**  
  Medical devices - consumables

- **45,3 %**  
  Medical Equipment and systems (medical investment goods)

- **40,6 %**  
  Implants

* Percentage of participating companies indicating that they have at least one product of this category of products in portfolio
# The medical technology market in Belgium

## Market

<table>
<thead>
<tr>
<th><strong>Market Size</strong></th>
<th><strong>Export</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 2.4 BILLION*</td>
<td>37.74 %*</td>
</tr>
</tbody>
</table>

* total yearly turnover in Belgium of medical devices/IVD excluding export (2017, excl. VAT)

We estimate that the total medical technology sector in Belgium including the non-responders to the survey and the (made-to-measure) devices that are custom-made (by dental labs, orthotists, prosthetists, ...) or sold directly to end-users (such as hearing aids, eyewear, ...) represents a total yearly turnover of around 3.5 billion EUR.

* based on the answers of 106 participating companies
Based on the survey results, our hypothesis is that the total workforce of medical technology sector in Belgium employs about 20,000 people.

* based on the answers of 106 participating companies
PAST & FUTURE TRENDS MEDICAL DEVICES/IVD
Past & future trends Medical devices/IVD

Sales revenue have been trending upwards in the last 5 years for most of participating companies, and these companies predict a continuation of this trend.

A similar upward trend is seen in the development of the workforce, although with a lower growth rate. Also, a higher percentage of companies indicate that the workforce will not grow.

For clinical trials in the last 5 years, 22% of the medical device companies indicate that they ran pre-market clinical trials in Belgium, compared to only 5% of the IVD companies.

For clinical research post CE-mark in the last 5 years, the picture is very similar: 29% of medical device companies ran clinical trials, versus 4% for the IVD sector.

When asked about the intentions to perform clinical trials in the future, the signals are alarming: only 15% of medical device companies plan to perform pre-market studies, and 17% of them plan post-market studies.

For IVD even less research projects are planned: 2% of companies plan pre-market research, 1% plans post-market research. We can conclude that, especially regarding IVD, Belgium is not yet seen as a country to perform research.
Sales revenue

The past

Sales revenue: trend past 5 years*

- Seriously declining (> -5% on average per year)
- Slightly declining (between 1 and -5% on average per year)
- Flat (about 0% on average)
- Slightly increasing (between 1 and +5% on average per year)
- Seriously growing (> +5% on average per year)
- No answer

The future

Sales revenue: expected trend next 5 years*

- Seriously declining (> -5% on average per year)
- Slightly declining (between 1 and -5% on average per year)
- Flat (about 0% on average)
- Slightly increasing (between 1 and +5% on average per year)
- Seriously growing (> +5% on average per year)
- No answer

* Trend of the sales revenues (CAGR, Compounded Average Growth Rate) during the last 5 years

* Expected trend of the sales revenues (CAGR, Compounded Average Growth Rate) for the next 5 years

Results based on the answers of 106 participating companies
Workforce

The past

Workforce: trend past 5 years*

- 4% Seriously declining (> -5% on average per year)
- 10% Slightly declining (between 1 and -5% on average per year)
- 21% Flat (about 0% on average)
- 30% Slightly increasing (between 1 and +5% on average per year)
- 29% Seriously growing (> +5% on average per year)
- 6% No answer

The future

Workforce: expected trend next 5 years*

- 2% Seriously declining (> -5% on average per year)
- 9% Slightly declining (between 1 and -5% on average per year)
- 25% Flat (about 0% on average)
- 32% Slightly increasing (between 1 and +5% on average per year)
- 4% Seriously growing (> +5% on average per year)
- 2% No answer

* Trend of the number of employees dedicated to medical devices/IVD over the last 5 years (CAGR, Compounded Average Growth Rate)

* Expected trend of the number of employees dedicated to medical devices/IVD over the next 5 years (CAGR, Compounded Average Growth Rate)

Results based on the answers of 106 participating companies
Clinical research: the past

Pre-market

Pre-market CT medical devices
2013 - 2017*

- YES: 25%
- NO: 8%
- NOT APPLICABLE: 22%
- NO ANSWER: 45%

Pre-market CT IVD
2013 - 2017*

- YES: 37%
- NO: 9%
- NOT APPLICABLE: 5%
- NO ANSWER: 37%

* Company has done pre-market (pre-CE) clinical trials with one or more of its medical devices in Belgium over the period 2013 – 2017

Results based on the answers of 106 participating companies
Clinical research: the past

Post-market

Post-market CT medical devices
2013 - 2017*

- Company has done **post-market (post-CE)** clinical trials with one or more of its **medical devices**, in Belgium, over the period 2013 – 2017

- Results based on the answers of 106 participating companies

Post-market CT IVD
2013 - 2017*

- Company has done **post-market (post-CE)** clinical trials with one or more of its **IVD**, in Belgium, over the period 2013 – 2017
Pre-market

Expected trend pre-market CT medical devices*

- Our company will not start a new pre-market clinical trial in the next 5 years: 26%
- Our company may start a new pre-market clinical trial in the next 5 years: 26%
- Our company will for sure start one or more new pre-market clinical trials in the next 5 years: 15%
- Not applicable: 10%
- No answer: 23%

Expected trend pre-market CT IVD*

- Our company will not start a new pre-market clinical trial in the next 5 years: 62%
- Our company may start a new pre-market clinical trial in the next 5 years: 8%
- Our company will for sure start one or more new pre-market clinical trials in the next 5 years: 17%
- Not applicable: 2%
- No answer: 11%

* Company’s expectation for the trend regarding pre-market (pre-CE) clinical trials with one or more of its medical devices in Belgium

Results based on the answers of 106 participating companies
Clinical research: the future

Post-market

Expected trend post-market
CT medical devices*

- Our company will not start a new post-market clinical trial in the next 5 years: 30%
- Our company may start a new post-market clinical trial in the next 5 years: 24%
- Our company will for sure start one or more new post-market clinical trials in the next 5 years: 19%
- Not applicable: 17%
- No answer: 10%

Expected trend post-market
CT IVD*

- Our company will not start a new post-market clinical trial in the next 5 years: 67%
- Our company may start a new post-market clinical trial in the next 5 years: 15%
- Our company will for sure start one or more new post-market clinical trials in the next 5 years: 10%
- Not applicable: 7%
- No answer: 1%

* Company’s expectation for the trend regarding post-market (post-CE) clinical trials with one or more of its medical devices in Belgium

Results based on the answers of 106 participating companies
Clinical trials

Approved clinical trials with medical devices 2018, by therapeutic area

In 2018 (clockstop 18/09/2018) in total **48** clinical investigations were approved.

*Source: Federal Agency for Medicines and Health Products (FAMHP)*
Clinical trials

Phases of the approved clinical trials with medical devices, 2018

Source: Federal Agency for Medicines and Health Products (FAMHP)
Structural (dis)investments:

The past

31.2% of companies **invested significantly** in medical devices/IVD in Belgium over the period 2013-2017*

39.4% of these investments were specifically linked to **R&D** for medical devices/IVD*

* Investments for a total of > 2 million EUR in setting up one or more activities in Belgium (new sales team, research, product development, production, logistics, …)

Only 3.8% disinvested **significantly** in medical devices/IVD in Belgium over the period 2013-2017*

None of these disinvestments were specifically linked to R&D for medical devices/IVD*

* Disinvestments for a total of > 2 million EUR in reducing or closing down one or more activities in Belgium (reduction of sales team, less research, less product development, lower production, reduced logistics, …)

The future

34.9% of companies will **invest significantly** in medical devices/IVD in Belgium in the next 5 years*

In 46% of these companies these investments will be specifically linked to **R&D** for medical devices/IVD*

* Investments for a total of > 2 million EUR in setting up one or more activities in Belgium (new sales team, research, product development, production, logistics, …)

Results based on the answers of 106 participating companies
IMPACT ASSESSMENT OF BELGIAN & EUROPEAN TRENDS ON PROFITABILITY
Impact assessment of Belgian & European trends on profitability

The healthcare environment undergoes many trends. Some of them are perceived as having a negative impact on profitability, others are seen as positive. The majority of companies see the implementation of the hospital networks as a trend with a negative impact on profitability, but also indicate that the negative impact is rather small in itself. The implementation of Low Variable care and the regionalization of healthcare policies show a similar negative impact.

The two trends that are clearly seen as opportunities are the digitalization of health, and the shift of care outside the hospitals, closer to the patient’s home setting.

Expected impact of the following trends on the profitability of company’s business in the next 5 years

**Scale used in following graphics:**

-5 = Drastic Negative Impact,
-3 = Strong Negative Impact,
-1 = Slightly Negative Impact,
0 = No Impact,
1 = Slightly Positive Impact,
3 = Strong Positive Impact,
5 = Drastic Positive Impact
The implementation of the Hospitals Networks

Almost half of the participating companies expect a slightly negative impact of the implementation of the hospital networks on their profitability in the next 5 years. Around 18% are more positive about this development.

The implementation of the lump sum reimbursement for low Variable Care

Approximately half of the participating companies estimate that the new regulation on low variable care will not impact their results or didn’t answer the question. However, one out of three companies expect a slightly negative impact on their profitability in the next 5 years.

Results based on the answers of 106 participating companies
Expected impact of implementation of regionalization of healthcare policies
The regionalization of healthcare policies (from federal to regional)

Half of the participating companies expect no impact of the regionalization of healthcare policies (from federal to regional) or didn’t answer the question. More than one out of three foresee a slightly negative impact in the next 5 years.

Expected impact of digital health
Digital Health (Artificial Intelligence, new apps, Real World Data, remote monitoring,...)

More than half of the participating companies expect a slight to drastic positive impact of the further digitization of healthcare on their profitability in the next 5 years.

Results based on the answers of 106 participating companies
Almost half of the participating companies expect a slight to drastic positive impact of the shift from healthcare from the hospitals to the private (home) setting on their profitability in the next 5 years. Around 10% of companies expect a slightly negative impact.

More than half of the participating companies expect no impact from the liberalization of the distribution of medical devices on their profitability in the next 5 years or didn’t answer the question. One out of four expects a positive impact, 16% expect a slightly negative impact.

Results based on the answers of 106 participating companies
Almost half of the participating companies expect no impact from the implementation of the new European medical device regulation on their profitability in the next 5 years. One out of four expect a slightly negative impact.

As only around 18% of the participating companies are active in the field of IVD, most indicated that they expect no impact from the implementation of the new European IVD regulation on their profitability in the next 5 years or didn’t answer this question. For those active in this field the answers are both positive and negative.

Results based on the answers of 106 participating companies
Approximately four out of ten participating companies expect a positive impact of value-based assessments of health technologies at a national level (by the National Institute for Health and Disability Insurance - NIHDI). However, 15% estimate this to have a negative effect on their profitability for the next 5 years.

*Results based on the answers of 106 participating companies*
9 PATIENT ACCESS
Patient access

When asked about the patient access to their technology, participating companies provide a mixed picture. Some companies consider the patient access as satisfactory, others as unsatisfactory. The remarks on the reasons behind the lack of access have invariably all to do with the reimbursement levels or procedures. Our hypothesis is that this is sector related. Medical devices contain many different product groups, like consumables, IVD, implants and medical equipment. Within those product groups various segments with different financing methods can be distinguished.

Satisfaction with patient access*

32% of companies are not at all or hardly satisfied with the access to their products.

* Indication of satisfaction with the access that patients or hospitals have to company’s overall product portfolio

Results based on the answers of 106 participating companies
THE TOP 5 MAIN REASONS THAT WERE GIVEN FOR DISSATISFACTION WITH PATIENT ACCESS:

1. Our product(s) is (are) not reimbursed
2. Complication & lack of transparency reimbursement policy
3. Prices are too low
4. Current reimbursement policies complicate innovation
5. Requirements of clinical data for smaller populations are unrealistic
TOP 10 PRIORITIES FOR NEW BELGIAN LEGISLATURE
Top 10 priorities for new Belgian legislature
In the survey, participating companies were asked where the Minister of Health for the next legislature should focus on. Multiple answers were allowed. Afterwards the answers were clustered and translated into 10 priorities.

THE TOP 10 PRIORITIES INDICATED MOST OFTEN WERE (IN ORDER OF FREQUENCY):

1. Simplification of the reimbursement system
2. Faster reimbursement for innovative products
3. Transversal approach and value-based procurement
4. Improved dialogue from authorities with the sector
5. Clear roadmap and policy for digital health
6. More attention for SMEs, driven by innovation
7. Faster consolidation of hospitals to free up budgets
8. Introduction of transparent reimbursement system for IVD
9. Focus on extra- & transmural care
10. Investments to make Belgium an attractive med tech country
Following members of Agoria, beMedTech, LifeTech Brussels, MedTech Flanders & MedTech Wallonia participated to the survey:

- be medical
- 3M
- Abbott Medical Belgium
- ABBOTT S.A.
- ACCURAY
- AdlerOrtho
- ANALIS SA
- Arémis ASBL
- Arthrex BVBA
- Ascensia Diabetes Care nv-sa
- ATLAS Neuroengineering
- B. Braun Medical
- Barco
- Bauerfeind Benelux
- Baxter
- BD
- BeWell Innovations
- Bingli
- Biocartis
- bioMérieux
- BIOTRONIK Belgium
- BlooMEDical Benelux bv
- Boston Scientific Benelux (and Guidant Europe)
- Bracco Imaging Europe
- CADskills BVBA
- Canon Medical Systems Belgium
- Cardinal Health Belgium 505 BVBA
- Carl Zeiss NV
- CEFALY Technology
- Cerhum
- Cochlear Technology Centre
- Coloplast Belgium n.v.
- Corin Belgium
- De Ceunynck Medical
- Dentsply Sirona
- DIASORIN SA/NV
- Eckert & Ziegler BEBIG s.a.
- Edwards Lifesciences
- epihunter
- Erbe Belgium bvba
- Essity
- ezez
- Flen Pharma
- fluidda
- GE Healthcare BVBA/SPRL
- Globus Medical Belgium
- HEPHAESTUS Surgical
- Heraeus Medical Belgium
- HOLLISTER
- Hospidex nv
- IBA
- Johnson & Johnson
- Laméris Group
- Linde Homecare Belgium
- Linvatec Europe BVBA
- Materialise
- Mathys Orthopaedics Belux
- Medacta Belgium
- medi Belgium bvba
- Medical Distribution Partners cvba
- MEDITRONIC BELGIUM
- Menarini Diagnostics
- Merz Pharma Benelux B.V.
- Mölnlycke Health Care SA/NV
- moveUP
- Mymedicoach SPRL
- Neoma Labs SPRL
- NiniX Technologies NV
- Nobel Biocare
- Norgine
- Nutricia
- NV Stryker
- Olympus Belgium
- OneLife S.A.
- OPHTEC
- Orfit Industries
- orthogèse
- Osimis SA
- Oxycure belgium sa-nv.
- Oxysphair
- Oxysphair - Messer
- Paul Hartmann
- Permobil
- PETERS SURGICAL
- Philips COMMERCIAL NV
- Qompium
- remedus
- ResMed Epn Ltd. Belgian Branch
- Roche Diagnostics Belgium
- SA PHARMA BELGIUM BELMEDIS NV
- Sebbin Benelux
- Sebia Benelux
- Siemens Healthcare NV
- Sivantos
- Sonova Retail Belgium
- Spentys
- Stago
- Stöpler NV
- Straumann NV
- Surgical Sensors
- Surgi-Tec nv
- Sysmex
- Therabel Pharma
- Thuasne Benelux
- Vitamed
- VIVISOL B