

Overview 2019

Sections and Working Groups



beMedTech - Sections 2019



ExeCo Implants

Section Overview 2019



Implants - ANGIO-PERI :

IMPROVE

Alle perifere stents, abdominale en thoracale vasculaire (endo)protheses, epidurale en intratecale implantpoorten en alle materiaal specifiek voor de vaatheelkunde.
Tous les tuteurs périphériques, (endo)prothèses vasculaires, chambres implantables épidurales ou intratécales et tout le matériel spécifique pour la chirurgie vasculaire.

| | Description |
|---|--|
| General Objective | Improving collaboration with scientific organisations (vasc. Surg. & radiol.) |
| Funding Objective | Higher reimbursement for peripheral embolization Higher reimbursement for venous procedures |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Contact MTEU for Statistics |
| Specific Goal(s) 2018-19 ? | MEAT Tender E17 hospital network |
| Internal financial resources Needed in 2018-19 ? | To be evaluate if needed for funding objectives |
| Owner | Koen Bruylant |

Implants - CIC :

CONSOLIDATE

Chirurgische instrumentatie: Alle chirurgische instrumenten en toebehoren.
Instrumentation chirurgicale: *Tous les instruments chirurgicaux et accessoires.*

| | Description |
|---|---|
| General Objective | Inform members correctly about (future) legislation and regulatory issues for MD in general and for surgical instruments more specific. |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | / |
| Owner | Wim Vandenberghe |

Implants - COH :

CONSOLIDATE

Oogheelkunde: Visco-elastische stoffen voor oogheelkunde, irrigatievloeistoffen (met CE), intra-oculaire lenzen, synthetische orbitavloervervanging, glaucoomkleppen, enz.

Chirurgie oculaire: Tissus viscoélastiques pour chirurgie oculaire, liquides d'irrigation (avec CE), lentilles intraoculaires, remplacement synthétique de la surface orbitale, valves en cas de glaucome etc.

| | Description |
|---|--|
| General Objective | Logistic synergy with Contactology Solve issue with distribution Extra Muros (allowed to delivered to HCP) by prescription needed with “addendum 14” (former Y-Form) |
| Funding Objective | Get reimbursement for 3-D diagnostic imaging |
| Regulatory Objective | Distribution implants extra-muros Follow up on Traceability register, avoid additional burden, once-only |
| Market Intelligence & Data Objective and activities | NIHDI data unreliable. Objective to find source of problem and solve it |
| Specific Goal(s) 2018-19 ? | Push new distribution framework short term (EU MDR). If not possible consider writing execution decree and work with FAGG. Royal Decree has been published, but Execution Decree hasn't. |
| Internal financial resources Needed in 2018-19 ? | 3-4 meetings/year Legal support needed to follow up (and write if necessary) on general framework distribution channels |
| Owner | Koen Bruylant |

Implants - CORO :

CONSOLIDATE

Coronair : alle invasief materiaal, zoals drug eluting stents, ballonnen,,voor interventionele cardiologie.

Coronaire: tout matériel invasif, tel que les drug eluting stents, ballons,...., pour la cardiologie interventionnelle.

| | Description |
|---|--|
| General Objective | Improving relation with BWGIC |
| Funding Objective | Monitor changes in reimbursement. (project Prof. Taeymans) |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Copy of Qermid long term data presentation |
| Specific Goal(s) 2018-19 ? | Could become 'Change' depending on changes in point 2. |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |

Implants - CRM :

IMPROVE

Cardiac Rhythm Management

Pacemakers en implanteerbare hartdefibrillatoren en bijhorende elektroden.

Stimulateurs cardiaques et défibrillateurs implantables et électrodes.

| | Description |
|---|--|
| General Objective | Get funding for telemonitoring Enhance collaboration with BeHRA/young cardiologists |
| Funding Objective | Pacemaker exchange in day-clinic Telemonitoring New technologies (cf. leadless PM) |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Date PM/ICD OK Start with collection statistics heart monitor |
| Specific Goal(s) 2018-19 ? | Redefine strategy for telemonitoring + Project KCE |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |

Implants - CT :

IMPROVE

Cardio-Thorax:

Implantaten en toebehoren gebruikt in cardiale en thoracale heelkunde, zoals hartkleppen en annuloplastieringen, cabg, chirurgische ablatiesystemen, systemen voor myocardstabilisatie, cardiemiesets (materiaal voor extracorporele circulatie), enz.

Implants et accessoires utilisés en chirurgie cardiaque et thoracique, tels que valves cardiaques, anneaux d'angioplastie, cabg, systèmes d'ablation chirurgicale, systèmes pour stabilisation du myocarde, sets de cardiomye (matériel pour circulation extracorporelle) etc.

| | Description |
|---|--|
| General Objective | Facilitate reimbursement new technologies |
| Funding Objective | Most new reimbursement in this section accepted: mitra/tavi/laa, lvad (actually only bridge to transplant and bridge to decision ongoing). |
| Regulatory Objective) | Follow up on traceability register, avoid additional burden, once-only |
| Market Intelligence & Data Objective and activities | Own statistics: ok |
| Specific Goal(s) 2018-19 ? | Lvad destination therapy: get reimbursement for indication extension. File is submitted Section horizon scanning: what's coming? |
| Internal financial resources Needed in 2018-19 ? | Valves = 1/year Other group meet only with specific action items |
| Owner | Koen Bruylant |

Implants - DID :

IMPROVE

Dentaal implantaten
Implants dentaires

| | Description |
|---|---|
| General Objective | Act and communicate as a clustered and united group of professional and ethical compliant dental implant industry towards other stakeholders (users - scientific organisations - government) Discuss regulatory issues and create a level playing |
| Funding Objective | Reimbursement is controlled by users (in NIHDI/INAMI) No change wanted |
| Regulatory Objective | Defend direct delivery to the users as the most safe, reliable and qualitative solution FAGG should make it mandatory for users (Private & Hospitals) only to work with officially “notified” distributors |
| Market Intelligence & Data Objective and activities | Strengthen current data analysis system : timely follow-up |
| Specific Goal(s) 2018-19 ? | Sales Data must be entered no longer than 1 month after Q |
| Internal financial resources Needed in 2018-19 ? | - |
| Owner | Wim Vandenberghe |

Implants - ENDO :

CONSOLIDATE

Endoscopie & viscerosynthese:

Alle invasieve MH die niet sorteren onder één van de andere omschrijvingen, zoals bvb voor uro-, nefro- en gastrologische toepassingen.

Tous les DM invasifs qui ne sont pas classés sous un des autres descriptifs, comme p.ex. pour les interventions en urologie, néphrologie ou gastrologie.

| | Description |
|---|--|
| General Objective | New name and new recruitment |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | Brainstorming on new activities |
| Internal financial resources Needed in 2018-19 ? | No common activities actually - case by case action Cfr vaginal mesh 2016 |
| Owner | Koen Bruylant |

Implants - GITA (Ortho & Trauma):

CHANGE

Implantaten voor gewrichtsreconstructie voor de ledematen alsook alle implantaten voor botreconstructie na trauma (behalve van de wervelkolom) en alle implantaten voor de cranio-maxillo-faciale heelkunde en arthro.

Implants pour reconstruction articulaire des membres ainsi que tous les implants pour la reconstruction osseuse après un traumatisme. (excepté la colonne vertébrale) et tous les implants pour la chirurgie cranio-maxillo-faciale et arthro.

| | Description |
|---|---|
| General Objective | Gain insights and share all relevant information for the orthopaedic implants business Create a stronger involvement with authorities & other stakeholders Monitor and try to influence the evolutions in healthcare financing with special attention for Low Variable Care & move towards forfeits |
| Funding Objective | Keep or make the reimbursement system value-based Keep or re-install differentiated patient co-payment (low for basic care - higher for sophisticated and innovative technologies) Improve the decision-making process within the CTIIMH-CRIDMI (conflicts of interest - budget transferability - etc.) |
| Regulatory Objective | Create level playing field within bMT based on art.10 Be involved with FAGG-AFMPS in implementing the MDR |
| Market Intelligence & Data Objective and activities | Make Big Data available to all : Try to gain access to data from other stakeholders (Registries - Claim Data from Sickness Funds - Anonymised Patient Data - Anonymised Hospitals Records ...) |
| Specific Goal(s) 2018-19 ? | Suppress pricing procedure at F.P.S Economy where it doesn't bring any value Try to establish a possibility for reimbursement for implant-related technologies : PSI-MIC-3Dsolutions |
| Internal financial resources Needed in 2018-19 ? | - |
| Owner | Wim Vandenberghe |

Implants - IERI :

IMPROVE

Esthetische en reconstructie implantaten: onderhuidse borstimplantaten voor esthetische en reconstructieve chirurgie, weefselexpanders, inspuitbare implantaten voor rimpelbehandeling, enz...
Implants esthétiques et réconstructifs: implants mammaires sous-cutanés pour la chirurgie esthétique et reconstructive, épanseurs tissulaires, implants injectables, traitement des rides, etc...

| | Description |
|---|---|
| General Objective | Move towards direct distribution to the users, at least for “fillers”. Monitor and take part in discussions on “publicity” issues. |
| Funding Objective | Not a priority but reimbursement for reconstruction has decreased and should not be cut “again” |
| Regulatory Objective | Changes in “distribution chain” (cf. general objective) + FAGG should make it mandatory <u>for users</u> (Drs & Clinics) only to work with “notified” distributors |
| Market Intelligence & Data Objective and activities | Now : Only NIHDI data on reconstruction Future : Start in 2019 with sales stats on breast implants , expanders & ADM’s |
| Specific Goal(s) 2018-19 ? | Start Data collection in 2019 |
| Internal financial resources Needed in 2018-19 ? | - |
| Owner | Wim Vandenberghe |

Implants - NKO - ORL :

IMPROVE

Neus-Keel-Oor: cochleaire implantaten, protheses bij doofheid, botverankerde hoorapparaten, spraakprothesen en toebehoren, enz.

Oto-Rhino-Laryngologie: implants cochléaires, prothèses en cas de surdit , appareils auditifs ancr s au niveau osseux, prothèses de la parole et accessoires, etc.

| | Description |
|---|---|
| General Objective | Monitor and actively be involved in improved reimbursement for implantable hearing solutions |
| Funding Objective | <ul style="list-style-type: none">- Push approval for extended CI Criteria- Push approval for improved reimbursement for Bone Conduction Devices (surgical/non-surgical) including a new reimbursement for children < 7y in collaboration with "HAA section" within beMedTech |
| Regulatory Objective | None |
| Market Intelligence & Data Objective and activities | Initiate Standard of Care: <ul style="list-style-type: none">- insights in treatment pathway for implantable hearing solutions (number of visits, fitting, rehabilitation)- Insights in reimbursement for care and service activities for Implantable hearing solutions |
| Specific Goal(s) 2018-19 ? | <ul style="list-style-type: none">- Align stakeholders to receive approval for new CI criteria- Alignment with WHO workgroup in Belgium- Quality standards for implantable hearing solution treatments |
| Internal financial resources Needed in 2018-19 ? | No specific financial resources needed. Minimal 2-3 meetings needed / year |
| Owner | Wim Vandenberghe |

Implants - NEURO :

IMPROVE

Implanteerbare neurostimulatoren en intratecale toedieningspompen, aneurysmaclips, synthetische dura mater substituten, externe ventrikeldrainage , hydrocefaluskleppen en alle toebehoren.
Neurostimulateurs implantables, réservoirs avec cathéters implantables intra-thécaux, clips d'anévrisme, substituts synthétiques de dure-mère, drainage ventriculaire externe , valves hydro céphaliques et tous les accessoires.

| | Description |
|--|--|
| General Objective | Create awareness about added value of our therapies (existing & new) |
| Funding Objective | Tabling reimbursement files for new stimulation in common approach, followed by individual company files after expert advise which data are required (optimizing Bewell innovations app) Facilitate market access also for 'non-pain therapy related' neurologic procedures |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Investigate possibility to make BELGIAN statistics by beMedTech (cfr. ICD,PM,..) |
| Specific Goal(s) 2018-19 ? (Inspanning en/of Resultaat) | <ul style="list-style-type: none">- Start initiative reimbursement CRPS- Evaluate collaboration with patient group(s) |
| Internal financial resources Needed in 2018-19 ? | Eventually if initiatives specific goals become concrete and update of existing figures is required |
| Owner | Koen Bruylant |

Implants - SPINE :

IMPROVE

Alle implantaten en toebehoren gebruikt bij rug- en nekchirurgie: zoals osteosynthesemateriaal, dynamische stabilisatie, kypho- en vertebroplastie, discusprothesen, enz.

Tous les implants et accessoires utilisés en cas de chirurgie du dos ou du cou tels que le matériel d'ostéosynthèse, la stabilisation dynamique, la kypho- et la vertébroplastie, les prothèses discales

| | Description |
|---|--|
| General Objective | To be informed on trends and intentions of other stakeholders in the field of SPINE (NIHDI,FAGG, HCP's...) and to defend the interests of the members by ensuring acces to innovation and high quality evidence based SPINE-devices |
| Funding Objective | Optimize funding in line with latest scientific evidence and innovations in order to ensure the best care for patients (e.g. Kypho- & vertebroplasty, TDR , ...) |
| Regulatory Objective | Avoid local hurdels for market acces. Monitor and ensure correct application of legislation on Ethics. The industry needs to be consulted priorly on new initiatives considered by the regulatory authorities to avoid conflicts with internal procedures. |
| Market Intelligence & Data Objective and activities | Exchange relevant sales data to document the spine market and its evolution |
| Specific Goal(s) 2018-19 ? | Start the preparations for the roll-out of the Medical Device Regulation from the EU in 2020. Lobby for the 20% proposed price increase after the reimbursement impact of 1/04/2015. If volume decreased |
| Internal financial resources Needed in 2018-19 ? | Three meetings per year of the members - regular updates by medtech on contacts & evolutions with other stakeholders in the field of spine |
| Owner | Wim Vandenberghe |

Implants - VISCO :

CONSOLIDATE

Visco-elastische stoffen voor gewrichten.
Produits viscoélastiques pour les articulations

| | Description |
|---|--|
| General Objective | The members want to be correctly informed about (future) legislation and regulatory issues for MD in general and (V.E.-) implants more specific. Direct distribution to end-users should be allowed |
| Funding Objective | No need to strive for reimbursement (free market) |
| Regulatory Objective | V.E. direct distribution to end-user (cf general objective) |
| Market Intelligence & Data Objective and activities | No (to specific - not enough players) |
| Specific Goal(s) 2018-19 ? | Monitor evolution in “depots”-legislation |
| Internal financial resources Needed in 2018-19 ? | No |
| Owner | Wim Vandenberghe |

ExeCo Consumables

Section Overview 2019



Medical Consumables - AMV :

IMPROVE

Medische voeding
Alimentation médicale

| | Description |
|---|---|
| General Objective | Open up the distribution channel of FSMP (ONS & Enteral nutrition) <ul style="list-style-type: none">- Revision of TRDVM (Working group Medical Nutrition), timelines and seat in group ⇒ Working group has Impact STHA (Homecare providers) <ul style="list-style-type: none">- ENHA-ONCA ⇒ Stay informed during this multistakeholder platform. |
| Funding Objective | TRDVM/CTMDS ⇒ Working group Medical nutrition ⇒ ONS & STHA, timelines and seat in group |
| Regulatory Objective | FOD Volksgezondheid / SPF Santé Publique ⇒ Open up the FSMP-distribution channel |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | One more attempt in resurrecting data project. |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Steven Vandeput |

Medical Consumables - BPM:

CONSOLIDATE

Borstprothesen: niet-chirurgische uitwendige hulpmiddelen na gedeeltelijke of volledige mammectomie.
Prothèses mammaires: Dispositifs externes non chirurgicaux après mammectomie partielle ou totale.

| | Description |
|---|---|
| General Objective | |
| Funding Objective | Follow up within NIHDI regarding the proposal of 2014 (conversion into legal drafts and Royal Decree) NIHDI Nomenclature ART 27. In agreement commissions within NIHDI, we are at times consulted, seldom heard. Get a structural involvement. |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | NIHDI data |
| Specific Goal(s) 2018-19 ? | Get internal clarity and preferably a joint position with other concerned sections on position around price transparency. Meet with BBOT, get consensus and counter the “safety-margin” initiative from NIHDI. |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - BVT-PSAV:

CONSOLIDATE

Bloedafname & veneuze toegangssystemen: met inbegrip van spuiten, naalden en safety devices, vleugelnalden, veneuze katheters, transfusie- en infusie -toebehoren, bloedzakken, naaldcontainers, dialyse, enz. (specifieke werkgroep Safety).

Systèmes de prise de sang & d'accès veineux: y compris seringues, aiguilles et safety devices, aiguilles à ailettes, cathéters veineux, accessoires pour transfusion et infusion, poches à sang, conteneurs pour aiguilles, dialyse, etc. (groupe de travail spécifique Safety).

| | Description |
|---|--|
| General Objective | In the light of the directive 2010/32/EU on prevention from sharp injuries in the hospital and healthcare sector awareness is still needed in the Belgian market to stress the importance of the use of safety devices |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | The members provide annual data on the transferral to safety devices. |
| Specific Goal(s) 2018-19 ? | Create more awareness in the Belgian market (users and government) on the importance of use of safety devices in general. |
| Internal financial resources Needed in 2018-19 ? | For the future development of the website: www.safetymedproducts.be |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - C/OST:

IMPROVE

Contenance / Ostomy:

Stomamateriaal, incontinentiemateriaal (opvang- of andere continentiesystemen), materiaal voor autosondage (droge sondes, katheters met geïntegreerd glijmiddel, meer geavanceerde katheters).
Matériel pour stomie, matériel pour l'incontinence (systèmes collecteurs ou systèmes de continence), matériel pour autosondage (sondes avec lubrifiant intégré - sondes avancées - sondes sèches).

| | Description |
|---|--|
| General Objective | In the context of the revised nomenclature Art 27 maintain or preserve the interest of the patients and maintain viable economic environment for all stakeholders. |
| Funding Objective | Work on better co-operation with NIHDI (for all products related nomenclat. 27,28&8,29). Improve reimbursement process for new products. |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Market data from NIHDI available. Internal bMT data available and working well. |
| Specific Goal(s) 2018-19 ? | Improve collaboration Afiscep & VLAS , STOMA Vlaanderen. (Preparation Communicate revised nomenclature) |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - CTL :

CONSOLIDATE

Contactologie:

Harde en zachte contactlenzen en toebehoren.

Lentilles de contact dures et souples et accessoires.

| | Description |
|--|--|
| General Objective | recognition optician and optometrist Garantuee accessibility contact lenses contacts with the professional associations to take a joint position synergy with implants section COH (ophtalmology) |
| Funding Objective | / |
| Regulatory Objective | contact cabinet Royal Decree status Medical Devices Regulations |
| Market Intelligence & Data Objective and activities | EUROMCONTACT |
| Specific Goal(s) 2018-19 ? | Create awareness CTL |
| Internal financial resources needed in 2018-19 ? | 4-5 meetings a year |
| Owner | Koen Bruylant |

Medical Consumables - DMD :

CONSOLIDATE

Dentaal materiaal: Toestellen, verbruiksgoederen en instrumenten specifiek voor tandartsen en tandtechnici.
Matériel dentaire: Appareils, consommables et instruments spécifiques pour dentistes et techniciens dentaires.

| | Description |
|---|--|
| General Objective | Define objectives with current members |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - HAA :

CHANGE

Hoorapparaten: alle medisch materiaal dat geacht wordt onder de bevoegdheid te vallen van de gehoorprothesisten (audiciens) (art. 31 van de NIHDI nomenclatuur)

Appareils auditifs: tous les dispositifs médicaux qui sont considérés comme relevant de la compétence des prothésistes-acousticiens (audiciens) (art. 31 de la nomenclature INAMI)

| | Description |
|---|---|
| General Objective | Inform the sector about rules and legislations - autoregulation Share information between distribution channels (retail-wholesale) Promote the usage of hearing instruments |
| Funding Objective | NIHDI-INAMI - close collaboration with CEUPA-UCBA members to contribute positively to the setup of the new reimbursement system |
| Regulatory Objective | FAGG-AFMPS to control access to distribution by adding manufacturer approval |
| Market Intelligence & Data Objective and activities | Collect number of hearing instruments distributed by members in the country. Total units excluding units sold to other members of the section. Collect and share any other key figures related with our sector |
| Specific Goal(s) 2018-19 ? | A new reimbursement system is to be implemented in 2019. It should be in line with the law aiming for more transparency in the distribution of medical devices. Our section needs to keep contact with all stakeholders of the sector to move towards a beneficial reimbursement system |
| Internal financial resources Needed in 2018-19 ? | Legal advice, political support,.. |
| Owner | Wim Vandenberghe |

Medical Consumables - INCO:

CONSOLIDATE

Incontinentie: absorberende beschermingen, zoals volwassenenluiers, onderleggers, enz..

Incontinence: protections absorbantes, telles que langes pour adultes, alèzes etc..

| | Description |
|---|---|
| General Objective | Get clarity on current situation in Belgium regarding incontinence materials (today scattered); cooperate with KCE on getting the picture. Make sure that recommendations from KCE are in line with industry interests. Understand potential unmet needs. |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | Market data is available (INAMI), but unmet need is unknown. Due to taboo, the unmet need is unclear. |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - INFECT:

CHANGE

Healthcare associated infections (HAI's) (was a working group - becomes a section in 2019)

| | Description |
|---|---|
| General Objective | Technological solutions exist to prevent and control HAIs; so focus should be on creating and raising awareness about the value that medical devices can bring to hospitals in reducing HAIs, how improvement in hospitals can be achieved, and this by providing therapy focused solutions based on the patient pathway. |
| Funding Objective | |
| Regulatory Objective | A legal framework may facilitate and help to reach higher quality in hospitals and reduction of the rate of infections : implementation of checklists, quality criteria. Transparent/public mandatory reporting of infection rates, complications,... |
| Market Intelligence & Data Objective and activities | Use of patient-reported outcome and experience measures in patient care and policy. |
| Specific Goal(s) 2018-19 ? | Prove the value-based outcome, reduction of rate of infections: moving from a price only approach to a value approach in hospital procurement. |
| Internal financial resources Needed in 2018-19 ? | In function of the next awareness activity |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - ORT:

CONSOLIDATE

Orthesen: alle externe orthopedische hulpmiddelen zoals braces, abdominale gordels, enz...

Orthèses: tous les dispositifs orthopédiques externes tels que attelles, ceintures abdominales, etc...

| | Description |
|---|---|
| General Objective | |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | Get internal clarity and preferably a joint position with other concerned sections on position around price transparency. Meet with BBOT. Solve problem info/communication with NIHDI for all products related nomenclat. 27, 29. Counter the “safety-margin” initiative from NIHDI. |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - ORTHODON:

CONSOLIDATE

Orthodontie:
Materiaal voor orthodontie.
Matériel pour orthodontie.

| | Description |
|---|--|
| General Objective | Define objectives with current members |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - PIP:

CONSOLIDATE

Ambulante infuuspompen: niet elektrische draagbare pompen voor ambulante gebruik zoals elastomeerpompen en pompen met veerdruksysteem.
Pompes à infusion ambulatoires: pompes portables non-électriques à usage ambulatoire telles que pompes élastomères et pompes avec système à ressort.

| | Description |
|---|---|
| General Objective | Organise a meeting with this section when necessary |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - RESPI:

CONSOLIDATE

Respiratoire zorgen: MD voor zuurstoftherapie (lang en kort), slaapgerelateerde ademhalingsstoornissen, beademing, verneveling,...

Soins respiratoires: DM pour la oxygénothérapie (longue et courte), troubles respiratoires du sommeil, respiration de sauvetage, nébulisation,....

| | Description |
|---|---|
| General Objective | Section: structure and organize workgroups according to the needs of the members and current situation and define if the working groups (O2, CPAP, home ventilation, nebulisation) should be active or not. Working groups: Define point of view and proposals on future Regulations and Reimbursement for certain technologies and care pathways: Discuss these internally and defend them externally (Government,...). |
| Funding Objective | O2 and CPAP actions are in progress but via STHA workgroup (Extra Muros ExeCo) and will be addressed there. |
| Regulatory Objective | O2 and CPAP actions are in progress but via STHA workgroup (Extra Muros ExeCo) and will be addressed there. |
| Market Intelligence & Data Objective and activities | No change desired. |
| Specific Goal(s) 2018-19 ? | O2 and CPAP actions are in progress but via STHA workgroup (Extra Muros ExeCo) and will be addressed there |
| Internal financial resources Needed in 2018-19 ? | No resource needs planned |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - REVA:

IMPROVE

REVABEL:

Hulpmiddelen voor personen met een beperking, zoals rolstoelen, looprekken, assisterende technologieën,...

Aides pour des personnes avec un handicap, telles que voitures, cadres de marche, technologies d'assistance, ...

| | Description |
|---|--|
| General Objective | Understand the impact of the 6th State Reform and prepare our members. Educate regional governments to influence the decisions (eg renting, reimbursement,..) |
| Funding Objective | Federal level: Technische Raad Rolstoelen (NIHDI) until 1/1/2019 Smooth transition to Regional level: now it's VAPH, AWIPH, PHARE & Dienststelle für Personen mit Behinderung. In 2019 these structures may change. Now: mixed reimbursement by federal and regional. After 2019: reimbursement only by the regions. |
| Regulatory Objective | / |
| Market Intelligence & Data Objective and activities | NIHDI has great data which is yearly published. No additional needs. 60% of market are members (30% = Vermeiren). |
| Specific Goal(s) 2018-19 ? | Consultation with the 4 regional governments => smooth transition. Inform members; |
| Internal financial resources Needed in 2018-19 ? | Live meetings with regions. 3 meetings with section. Legal support for the validation. |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - VP:

CHANGE

Verbandstoffen: Kompressen, pleisters, windels, verbanddozen, extern hechtingsmateriaal, afdek materiaal, gipsverbanden, enz.
Pansements: Compresses, sparadraps, bandages, boîtes de secours, matériel de suture externe, drapages, plâtres etc.

| | Description |
|---|--|
| General Objective | Put the importance of a global wound care approach on the agenda |
| Funding Objective | Take into account transversal budget impact of wound healing - improve reimbursement in line with surrounding countries. |
| Regulatory Objective | NIHDI optimisation TRDVM/CTMDS |
| Market Intelligence & Data Objective and activities | To check (existing statistics) and collect - existing studies other countries |
| Specific Goal(s) 2018-19 ? | Involvement in decision making of reimbursement in wound care. Improve speed of approval of reimbursement for innovations. Genuine political commitment. Increase awareness of advanced wound care and its impact on patients life's and society. |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

Medical Consumables - Others:

CONSOLIDATE

Medical Consumables die niet onder één van de overige secties kunnen geïnclassificeerd worden.
Medical consumables qui ne peuvent pas être classés sous une des autres sections existantes.

| | Description |
|---|---------------------|
| General Objective | |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Hadewijch Van Hoeij |

ExeCo Medical Equipment and Systems

Section Overview 2019



Medical Equipment & Systems - IMB:

CHANGE

Medische beeldvorming: Toestellen voor medische beeldvorming waaronder radiologie/scopie, NMR, CT, PET, ultrasound, monitoring, enz.
Imagerie Médicale: Appareils pour imagerie médicale, p.ex. radiologie/scopie, NMR, CT, PET, résonance magnétique, monitoring etc.

| | Description |
|--|---|
| General Objective | Bringing innovation imaging techniques quicker to the patient. Enlarge & autom. of heavy equipment cartography |
| Funding Objective | Create pathway for reimbursement: Market access action BELMIP. (3 to 5 pilot cases). |
| Regulatory Objective | Continue/Optimize relation with FANC National dose register |
| Market Intelligence & Data Objective and activities | NIHDI-data (2x/year) analysis AIMBV |
| Specific Goal(s) 2018-19 ? | Reach out guide line tenders |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |

Medical Equipment & Systems - EM / Others:

IMPROVE

Elektro-medische toestellen: Toestellen (o.a. voor dialyse), systemen en toebehoren voor navigatie, chirurgische microscopen, enz. (die niet vallen onder beeldvorming of radiotherapie).
Appareils électro-médicaux: Appareils (p.ex. pour dialyse), systèmes et accessoires destinés à la navigation, microscopes électroniques etc. (qui ne sont pas classés sous les catégories Imagerie médicale ou radiothérapie).

| | Description |
|---|--|
| General Objective | Create pathway for reimbursement. Training Biotechnicians Enhance maintenance policy in hospitals |
| Funding Objective | Dialyse new funding |
| Regulatory Objective | VAT Dialyseconc. |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | Install stakeholder platform for defining framework disinfection flexible endoscopes First Training Biotechnicians Q4 |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |

Medical Equipment & Systems - RADIOTHERAPIE

CHANGE

Medische apparatuur voor radiotherapie en producten voor radiopharmaca.
Appareillage médical pour la radiothérapie et des produits radiopharmaceutiques.

| | Description |
|---|--|
| General Objective | Create Radiotherapy-oncology Awareness and Visibility. Monitor existing legislation & changes Training Biotechnicians Enhance maintenance policy in hospitals |
| Funding Objective | Start with Breast cancer for radiotherapy. |
| Regulatory Objective | Continue/Optimize relation with FANC National dose register |
| Market Intelligence & Data Objective and activities | Follow up BRAVO-symposium |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | evt. communication budget BRAVO-symposium innovation in breast cancer (co-financed industry) expert document |
| Owner | Koen Bruylant |

ExeCo Extra Muros

Section Overview 2019



Extra-Muros - Digital Health:

CHANGE

Medische gezondheidsinformatiesystemen, mobiele gezondheidsapplicaties (mHealth) en e-Health.
Systèmes d'information médicaux, applications mobiles de la santé (mHealth) et e-Health.

| | Description |
|---|--|
| General Objective | Create better framework for Digital Health applications (ref position paper) |
| Funding Objective | Integration of DH-applications in different reimbursement pathways |
| Regulatory Objective | Pyramid system => Set-up site/VZW with the government |
| Market Intelligence & Data Objective and activities | Not needed => Diverse product portfolio in our members |
| Specific Goal(s) 2018-19 ? | Launch website/VZW (pyramid system) => business case |
| Internal financial resources Needed in 2018-19 ? | Monthly meetings with members, communication plan for the launch of the site/VZW |
| Owner | Steven Vandeput |

Extra-Muros - STHA:

CHANGE

Services & Technologies Home Assistance:

Thuisondersteuning voor de installatie, het onderhoud en de verwijdering van medische hulpmiddelen.

Service au domicile pour l'installation, l'entretien et l'enlèvement de dispositifs médicaux.

| | Description |
|---|---|
| General Objective | Framework and Reimbursement for homecare provider |
| Funding Objective | Integration of STHA in dialysis convention, with the goal of a separate and direct funding mechanism (not indirect through hospitals outsourcing) |
| Regulatory Objective | Guideline, including legal direct deliveries to patients at home |
| Market Intelligence & Data Objective and activities | Not needed => Diverse product portfolio in our members |
| Specific Goal(s) 2018-19 ? | Creation of subguideline (= bMT). Approval by FAGG Clarity and alignment on INAMI approach and timelines needed |
| Internal financial resources Needed in 2018-19 ? | +/- 4-5 live meetings (sectie/workgroup) expected. Check with legal needed |
| Owner | Steven Vandeput |

Extra-Muros - SELFC:

CONSOLIDATE

Self care medical devices:

MH in een farmaceutische verschijningsvorm met een fysieke werking, voor zover dat is bestemd om zonder tussenkomst van een beroepsmatige optredende zorgverlener door het publiek zelf te worden gebruikt.

DM sous une forme pharmaceutique avec un effet physique, pour autant qu'il est destiné à être utilisé par le public même sans l'intervention d'un professionnel de la sante.

| | Description |
|---|----------------------------------|
| General Objective | To be defined by section members |
| Funding Objective | |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Steven Vandeput |

ExeCo In-Vitro Diagnostics

Section Overview 2019



IVD - New Sections

Until 2019

- CoreLab - POCT - separate fee
- Diabetics - separate fee

As of 2019

- Regulatory
- Reimbursement
- Value of Diagnostics
- Diabetics - separate fee

One fee of
2,000,- EUR
Includes access
to all 3
sections

In-vitro Diagnostics - DIAB :

CHANGE

Producten & toebehoren voor diabetes patiënten.
Produits & accessoires pour diabétiques.

| | Description |
|---|---|
| General Objective | <ul style="list-style-type: none"> • Give patients access to tailor-made solutions to empower patients so that he/she can optimally manage the diabetes. • Measure and serve the unmet clinical need (500,000 Type II) by 2023 |
| Funding Objective | <ul style="list-style-type: none"> • Accurate & transparent utilization of existing convention spending (view on material vs education) • Evaluate Investments in Type I vs Type II, and increase budget for Type II, taking in account the transversal benefits • Evidence-based decision making for optimal use of technologies (per type of patient, implants, telemonitoring,..) • Clear canvas and procedure for access to innovation • Participation in the set-up of diabetes conventions |
| Regulatory Objective | <ul style="list-style-type: none"> • Distribution of diabetes consumables through recognized retail channels (officina-pharmacies, care-shops) instead of hospitals • Understand the substitution practices in care-paths (what's prescribed should be delivered) |
| Market Intelligence & Data Objective and activities | <p>No available data today. What is needed:</p> <ul style="list-style-type: none"> • # of patients, Type I, type II, patients in care paths, non-diagnosed patients, ... • Set up of registry (see UK, Germany) • Optimization of industry data, including overall view for all players |
| Specific Goal(s) 2018-19 ? | What is the specific goal, or the effort, for 2018 |
| Internal financial resources Needed in 2018-19 ? | What resources are needed? |
| Owner | Koen Bruylant |

IVD - Regulatory



In-vitro Diagnostics - Regulatory :

CHANGE

| | Description |
|---|---|
| General Objective | To be defined early 2019 For more details concerning the new sections regarding IVD, please check the complete presentation on our website https://www.bemedtech.be/membres/diagnostics/ |
| Clusters | <ul style="list-style-type: none">- Competent Authorities- Impact of IVDR- GDPR- Tenders |
| Hot Topics | <ul style="list-style-type: none">- Competencies FAGG-WIV?- Inspections of Labs - which authority?- Definition/clarification FAGG authority?- Impact IVDR - main items to work on?- Other |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | To be defined early 2019 |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Lieselot De Vos |

The 4 REGULATORY Clusters to work on...

**Competent
Authorities**

Impact of IVDR

GDPR

TENDERS

IVD - Reimbursement



In-vitro Diagnostics - Reimbursement :

CHANGE

| | Description |
|---|--|
| General Objective | To be defined early 2019 For more details concerning the new IVD sections, please check the complete presentation on our website https://www.bemedtech.be/membres/diagnostics/ |
| Clusters | <ul style="list-style-type: none">- System- Valuation & Budget- Policy making |
| Hot topics | <ul style="list-style-type: none">- Define the list of structural issues inside RIZIV/INAMI- Are these issues different whether we look at Companion Diagnostics, self-tests, POCT, NGS,... |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Lieselot De Vos |

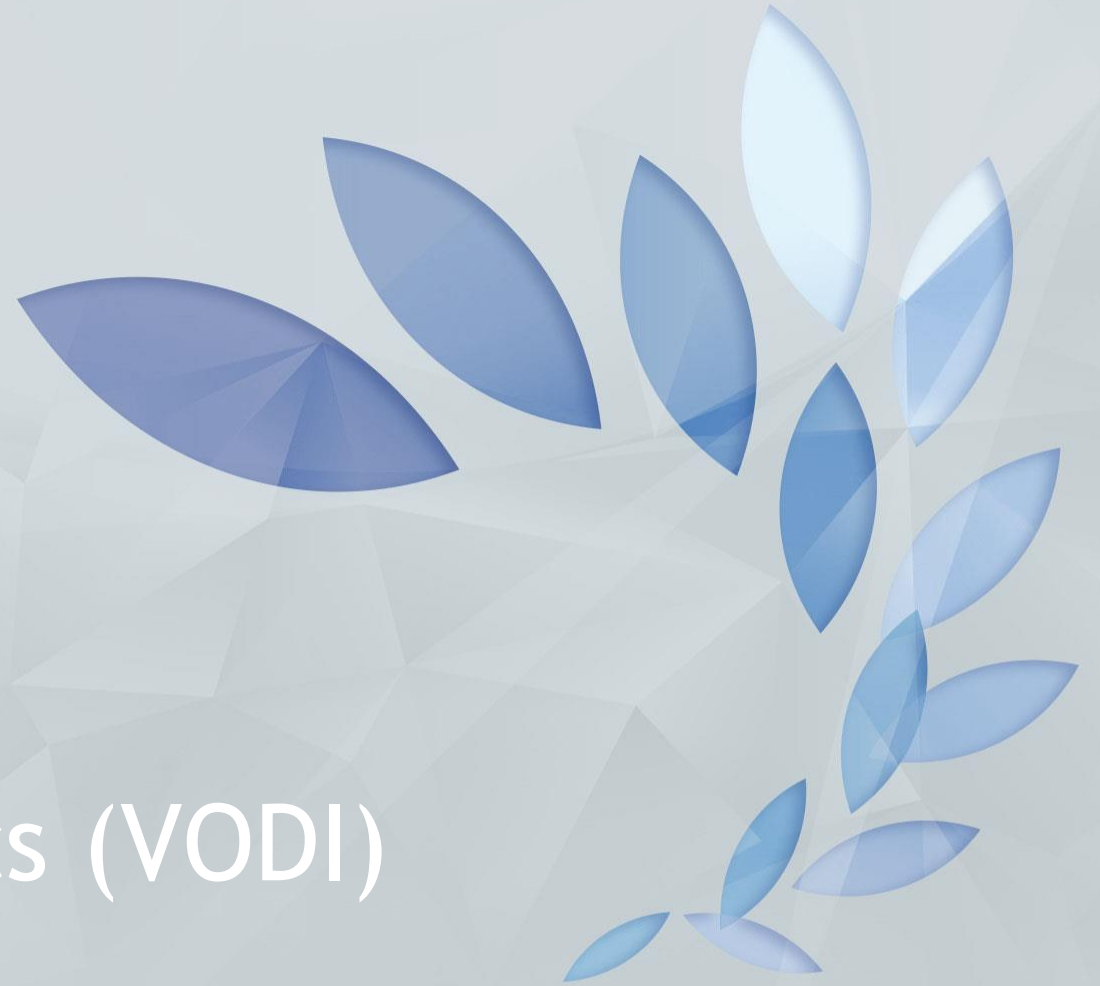
3 REIMBURSEMENT Clusters to work on...

SYSTEM

**VALUATION &
BUDGET**

POLICY Making

IVD - Value of Diagnostics (VODI)



In-vitro Diagnostics - Value of Diagnostics :

CHANGE

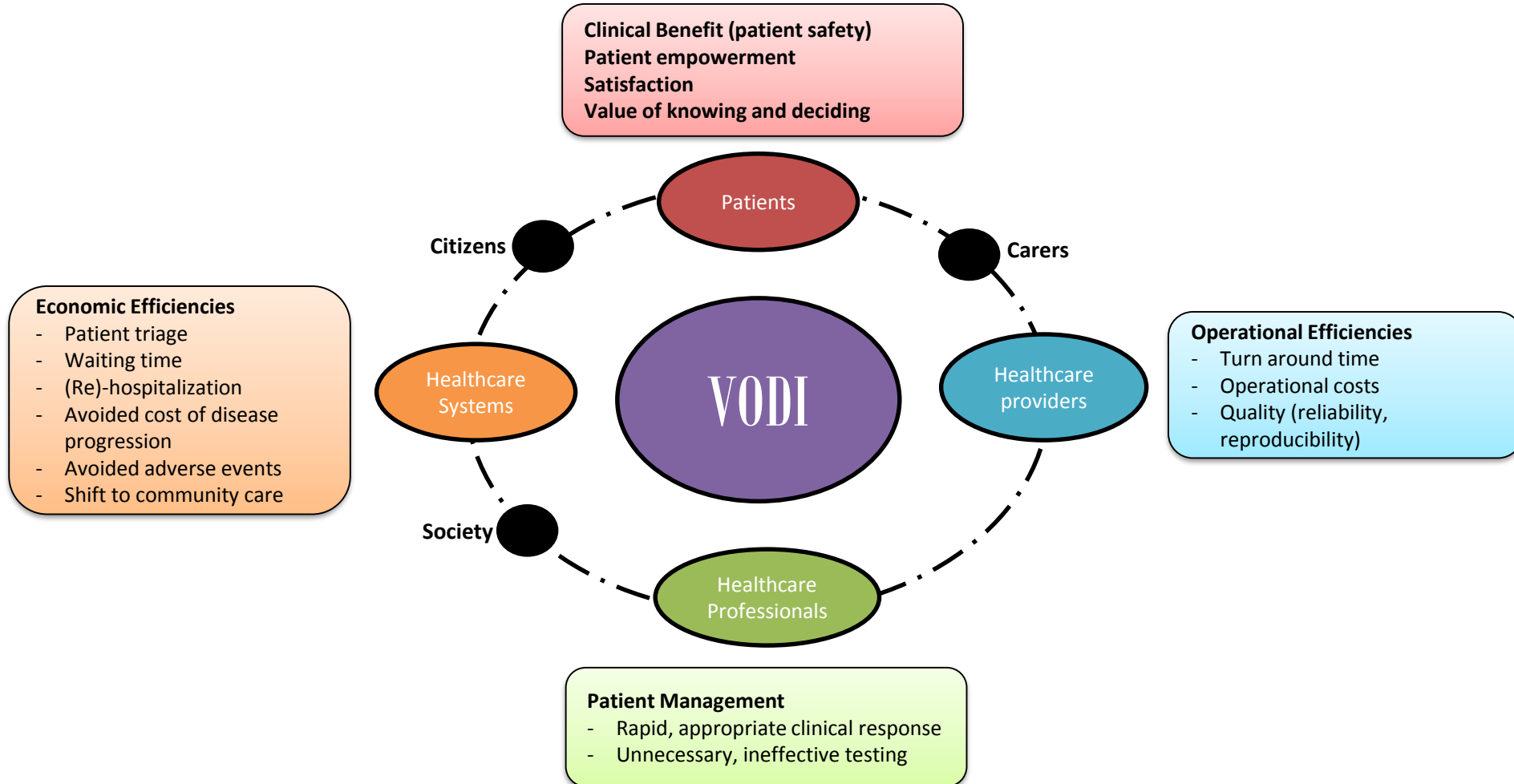
| | Description |
|---|---|
| General Objective | To be defined early 2019. For more details concerning the new IVD sections, please check the complete presentation on our website https://www.bemedtech.be/membres/diagnostics/ |
| Funding Objective | VODI: Develop a method with a specific tool to capture the value of diagnostic information to support an IVD value-based access model in Europe |
| Regulatory Objective | |
| Market Intelligence & Data Objective and activities | |
| Specific Goal(s) 2018-19 ? | |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Lieselot De Vos |

VODI (*Value Of Diagnostic Information*)

Objective

Develop a method with a specific tool to capture the value of diagnostic information to support an IVD value based access model in Europe

Diagnostic Information Brings Multidimensional Value



beMedTech - Transversal Working Groups



| | Description |
|--|--|
| General Objective | <ul style="list-style-type: none">• Define the ethical code of the federation, provide input of the working group to questions from AFMHP and Mdeon, inform the members on changes in the law.• Make sure that specificities of the medical device industry are taken into account when it comes to law-making.• Start-up sub working groups focused on:<ul style="list-style-type: none">• Educational grant + Fellowship at hospital paid for by the industry• Actualisation beMedTech code• Fair Market Value• Development of templates for<ul style="list-style-type: none">• Clinical Trials• Consignation• GDPR• Tenders |
| Specific Goal(s) 2018-19 ? | Smooth transition towards Ban of Direct Sponsoring Info-session on March 22 regarding Code, fellowships, tenders, beTransparent.be, ... Define Corporate Governance rules for the federation |
| Internal financial resources Needed in 2018-19 ? | May be legal support regarding drafting new Code |
| Owner | Marnix Denys / Luc De Clerck |

| | Description |
|--|--|
| General Objective | Facilitate clinical studies for medical devices in BEL |
| Specific Goal(s) 2018-19 ? | Meeting FAGG Template study contract With 'VLAAMSE VERENIGING ZIEKENHUISJURISTEN' Organize beMedTech Academy on clinical studies |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |

| | Description |
|--|---|
| General Objective | Create a 'beMedTech LU' affiliate |
| Specific Goal(s) 2018-19 ? | Create a relationship with LU competent authorities Help/Advice members with LU related issues |
| Internal financial resources Needed in 2018-19 ? | |
| Owner | Koen Bruylant |