KCE REPORT 249Cs

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

SUMMARY

TOWARDS A CONTROLLED AND PHASED INTRODUCTION OF HIGH-RISK MEDICAL DEVICES IN BELGIUM

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HEALTH SERVICES RESEARCH

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TOWARDS A CONTROLLED AND PHASED INTRODUCTION OF HIGH-RISK MEDICAL DEVICES IN BELGIUM

HANNE BAEYENS, CÉLINE POUPPEZ, PIERRE SLEGERS, IRM VINCK, FRANK HULSTAERT, MATTIAS NEYT

FOREWORD

If we genuinely want to nail our colours to the patient rights' mast - as we are all supposed to do - then it is high time that we pull up our socks when it comes to obtaining patients' informed consent and supporting patients' preferences. All too often, a patient's so-called informed choice makes for nothing other than a woeful caricature. A polite request to sign, here, at the bottom of this incomprehensible form, and that's the end of it.

To be fair, there are plenty of doctors and centres that do provide intelligible, timely information and really give their patients a chance to have an input of their own. But what if the care providers themselves don't have access to transparent, reliable information about the safety and the added value of a procedure for the patient? Take the area of invasive, high-risk medical devices for instance, which is what this report focuses on. How many doctors who offer their patient a new, innovative implant are honest and brave enough to tell their patient that the implant they are recommending has neither extensively nor conclusively been tested on humans? What they should say in fact is: “sir, madam, we could offer you a procedure with this new implant; we have reasons to believe that it will work for you, but so far we don't have any figures to back this up. So, in a certain sense, you are a human test subject (for want of a different phrase)”. What are the chances of your patient agreeing as readily on hearing that news? And if the patient does give his consent, it is perhaps a genuine desire to have his experiences recorded in a clinical study, so that at least others might benefit.

But let's not be naïve, this game is not played at our level, but at European, not to say global, level. A worrying development in this particular context is the fact that the Juncker Commission decided to retransfer competences for medicinal products and medical devices from the Directorate-General for Health and Food Safety (SANTE) to the Directorate-General for the Internal Market, Industry, Entrepreneurship and SMEs (GROW). International protest caused the decision regarding medicinal products to be reversed because Juncker agreed that these goods are not like any others. What we fail to understand however is why medical devices should be treated any differently. It all points to the fact that economic forces, backed by certain powerful Member States, are at work behind the scenes. With the result that the initially ambitious new medical devices directive was put on the long finger. Meanwhile, things seem to move again, but it is still unclear where exactly we will land. Does Europe need a second PIP breast implant scandal before it will resolutely put patient safety first?

This report takes stock of the situation and offers a number of ideas individual Member States could use to try their hand at addressing this issue. To be continued no doubt...

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KEY MESSAGES

Member States can take **appropriate measures to prevent (potential) risks to public health**, both within and outside the so-called harmonised areas. These measures must be **justified, necessary and proportional** and must be designed to protect the health of citizens.

1. Possible measures with regard to the placing on the market and the deployment of medical devices (= within the harmonised areas):

- Appropriate measures can be taken to **withdraw medical devices from the market or to ban/restrict their market access or the initial deployment**. These measures are based on the following articles:
  - Articles 8 and 18 of Directive 93/42, **if the medical devices do not meet the requirements** in terms of safety or performance (if they are not in conformity with the legislation in other words).
  - Article 14b, if there is a **(potential) risk**, associated with **the product** (and not with the actual use of the high-risk medical device), even if it is in conformity with EU legislation and thus fulfills the requirements of performance and safety (e.g. medical devices containing material of bovine origin).
- Within the harmonised areas, uncertainty about the efficacy / effectiveness of a medical device will in principle not suffice to ban or restrict the placing on the market and deployment of certain medical devices.
- Randomized controlled trials
  - By way of transitional measure, Belgium could introduce the obligation to test a high-risk medical device within the framework of an **RCT** before it is used routinely if there is no other, less invasive, way to control the risk associated with the part, the substance or the modes of action of the medical device. The **proportionality** of this measure will have to be assessed on a case-by-case basis.

2. Possible measures outside the harmonised areas for medical devices:

The **distribution, sale, requirements for actual use, advertising and reimbursement of medical devices** are not regulated under current European legislation or under the EU medical device regulations presently in the pipeline. This means that, in principle, Member States are entitled to impose their own restrictions.

On that account, in addition to those measures that already exist on sales, promotion, (conditional) reimbursement, etc, Belgium could take the following measures with regard to high-risk medical devices:

- **Restricting their actual use to centres of reference**
  - The Belgian Hospital Act already provides for **centres of reference** as a means to guarantee high-quality medical care. Restricting the use of high-risk medical devices to a limited number of care institutions over a certain period of time could be warranted in certain cases.
  - After market access, reference centers can be asked to perform an "appropriate study" (e.g. RCT) (with a case-by-case appreciation).
- Practice guidelines

- **Practice guidelines** could specify the procedures that can only be performed in specialist centres and by clinicians and teams that have been specifically trained and have the relevant experience in complex interventions. That having been said, the immediate impact of obtaining a CE label is limited as it usually takes a fair bit of time before these guidelines are drawn up and because they are non- binding.

- **Clarifying/Extending the responsibilities of care providers in the health care sector:**
  - Information is a crucial aspect, both for care providers when it comes to deciding whether or not to use a particular medical device, and for patients if they want to be able to make an **informed choice**. Patients must be thoroughly informed of the risks of and the possible alternatives to a new high-risk medical device. Simply stating that a medical device carries the CE label is not enough. On the other hand, doctors could be compelled to notify the administration before they perform a procedure involving the use of a high-risk medical device.
  - In principle, doctors' hands should not be tied by legalities when they decide on the means to make a diagnosis or treat their patients. **But this freedom should not prevent the administration from taking action to protect public health**. However, therapeutic freedom also entails that a doctor can be held liable if he opted for a method another, normally prudent, doctor would, given the same circumstances, have shied away from.
- Self-regulating systems
  - The **IDEAL** framework, established by a group of a.o. surgeons, researchers and methodologists, is an interesting framework to develop and assess medical devices in a staged fashion. It is marked by the following stages: idea, development, exploration, assessment and long-term follow-up. This framework can be applied to the European context for medical devices in combination with the self-regulating system proposed in the Netherlands described hereafter.
  - The Dutch Order of Medical Specialists (Nederlandse Orde van Medisch Specialisten - OMS) and the Dutch Health Care Insurance Board (Nederlands College voor Zorgverzekeringen - CVZ) have produced a guideline on the safe introduction and use of new medical innovations by care providers within regular care. This **Dutch 6-step plan** comprises the following: an assessment of the innovation class of the new intervention; determining the added value; determining the risk class in terms of safety, organisation, budget impact and financial risks; developing an introduction plan and an assessment of the (care) outcomes. Via this guideline, the 'guided introduction' of new techniques is, in as far as possible, regulated by the care providers themselves. The introduction of **a self-regulating system like this will more than likely pass the proportionality test**.

SUMMARY

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1. CONTEXT

1.1. Objective of the study

High-risk medical devices (class III - see frame) pose a greater risk to patients because they are inserted into the body for life for instance or because they come into contact with the heart or brain. The number of high-risk medical devices that are brought on the market is increasing.

A CE label, which can also be found on domestic appliances and toys, shows that the product meets the European standards to place it on the market. As soon as a manufacturer can affix a CE label to his device, it can be sold throughout the European market. Once the CE label has been obtained, EU Member States can in principle no longer ban the sale of the product in question.

Market access for medical devices and implants is far less stringent than for medicinal products. On the plus side, this means that new, sometimes life-saving, devices can be used quickly. On the other hand, the CE label does often provide insufficient certainty about the safety and the efficacy of the product. In other words, it is not always clear whether some devices are also of benefit to the patient.

On that account, this study wants to examine whether a (legal) framework for a **phased, controlled introduction** of high-risk medical devices carrying a CE label can be created in Belgium without contravening European legislation. This would entail that certain restrictions can be imposed before the device can be used routinely.

Medical devices are subdivided into a number of **risk classes**. These are a.o. determined on the basis of duration of use, invasiveness, and the parts of the body they come into contact with.

Class I: low risk (e.g. hospital bed, stethoscope, non-invasive electrodes for an ECG, sticking plaster or plaster cast)

Class IIa: medium risk (e.g.: hearing aid, contact lens or injection needle)

Class IIb: increased/medium to high risk (e.g. anaesthesia or radio-therapy device, external pacemaker or defibrillator, hyperbaric chamber, eye laser or blood bag)

Class III: high risk (e.g. heart catheters, ablation catheters, implantable pacemaker or defibrillator, hip prosthesis, endobronchial valves, heart valves, stents, etc.)

The risk class determines the requirements the product must meet before it can be placed on the market. In this study, we will focus on high-risk medical devices and implants.

1.2. Research questions

This report lists the minimal requirements high-risk devices must meet nowadays before they can be placed on the Belgian market. The report aims to answer the following questions:

- Which legal measures have a number of European countries taken already to provide for the phased market access of high-risk medical devices?
- What initiatives does Belgium need to take to facilitate the implementation of one or more of these measures or to introduce new measures without contravening European legislation?

The report focuses on what happens after CE certification has been obtained and before reimbursement comes into play or reimbursement by the mandatory health insurance was refused. After all, once a product carries the CE label, it can be sold across the market, irrespective of whether it qualifies for reimbursement or not. Thus, conditional reimbursement does not come within the scope of this study.

2. THE CURRENT EUROPEAN LEGISLATION AND ISSUE

The European legal framework that regulates market access and the deployment of medical devices comprises 3 Directives that cover a broad spectrum of products:

- Directive 90/385/EEC of 20/6/1990 relating to active implantable medical devices ('Directive 90/385')
- Directive 93/42/EEC of 14/6/1993 concerning medical devices ('Directive 93/42')
- Directive 98/79/EC of 27/10/1998 on in vitro diagnostic medical devices ('Directive 98/79')

These 3 basic Directives have been amended on several occasions. Their most recent review resulted in Directive 2007/47/EC of 5/9/2007.

New legislation that could replace and enhance the previous one is currently on the table.

2.1. CE label gives access to the entire European market

Before a high-risk device can qualify for a CE label, and hence gain market access, the manufacturer of the device must submit an application file to one of the 64 'Notified Bodies' (NBs)[a] within the EU. These are commercial test and research institutes the Member States have designated to perform **a '*pre-market*' assessment**, paid for by the manufacturer. Both this pre-market assessment and the subsequent market access are valid for the **European market as a whole.**

But the system is far from perfect: the quality of the NBs varies greatly and is not really checked. In its 2011 report (Report 158)[b], the KCE already stated that the NBs often lack the necessary clinical research expertise. This was also demonstrated in a Dutch study performed in 2010, which highlighted serious shortcomings in the pre-market file of 9 coronary stents, 7 complete hip implants and 9 silver-containing dressings.[c] As the manufacturers can pick their own NB, it is not beyond the bounds of possibility that they select an NB whom they feel might assess their specific device less rigorously.

2.2. Pre-market assessment

2.2.1. Clinical safety and performance is a requirement, efficacy not

Within the framework of a pre-market assessment, the NB will examine whether the device **is in conformity with European legislation.** The NB will more specifically examine the device's **clinical safety** and **performance** on the basis of the clinical data supplied by the manufacturer. Under EU legislation, a device is deemed to be **clinically safe** if, when used in line with the manufacturer's user instructions, it does not pose any unacceptable medical risks. The product is deemed to be **clinically performant** if it does what is says on the tin. However, **demonstrating the device's efficacy**, i.e. that the patient **derives the same or an even greater benefit from the new device than from the currently available standard treatment is not a requirement**.

a The list of all the Notified Bodies has been published in the Official Journal of the European Communities (93/42/ECC) and can be found via the Nando Information System: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13

b https://kce.fgov.be/sites/default/files/page_documents/kce_158a_innovatieve_hoogrisico_medische_hulpmiddelen.pdf

c Roszek B, de Bruijn A, Pot J, van Drongelen A. Assessment of technical documentation of Class III medical devices. National Institute for Public Health and the Environment, The Netherlands (RIVM); 2010. Report 360050021/2010 Available from: www.rivm.nl

2.2.2. Lack of scientifically sound research

The European Directives do no set any specific conditions with regard to the thoroughness and scope of pre-market assessments. There are no requirements to conduct randomized clinical trials (RCTs). Yet, RCTs should be considered to be the highest standard when it comes to documenting efficacy and safety. How, for instance, should a 10% 30-day mortality rate following a percutaneous aortic valve replacement be assessed if the only data to go on is a patient register? Should that mortality rate be considered high or low in comparison to the standard care? Without an RCT, this is often impossible to assess.

As RCTs are not a prerequisite but an expensive exercise that call for specialist staff and take up lots of valuable time, they tend to be the exception rather than the rule. Most studies are limited to performance studies, where "performance" is cross-checked against the producer's clinical claims. This makes that the device is seldom tested on a (large) number of patients in the pre-market stage.

Explorative or confirmatory studies and randomized clinical trials (RCTs)

Explorative studies are useful in terms of checking the effects of the use of a medical device on a limited scale. They tend to be small studies, carried out in one centre, that differ greatly from the major studies that must confirm a well-founded hypothesis. For medical devices, this is usually done on the basis of non-controlled studies/registers.

As against these, there are the **randomized trials**. In this type of study (randomized controlled trial – RCT) a large number of patients is randomly divided. One group is given the product, the other group a different type of intervention (the control group).

Neither patients nor care providers know who belongs to which group. The results are compared afterwards. RCTs are considered to be the most reliable model to identify the most effective medicines, medical devices and therapeutic strategies.

The choice of study subject (and whether to conduct a randomized trial or not) will therefore depend on the research question.

It is sometimes argued that an RCT to examine the efficacy/effectiveness of high-risk medical devices is not practicable on account of the control group issue for instance. Yet, in the US, where RCTs are often a prerequisite, the opposite is regularly demonstrated (see frame '*examples of the weaknesses of the EU system*'). Take **transcatheter aortic valve implantations (TAVIs)** for instance, which have been in use in the EU for years and in respect of which data of thousands of patients have been recorded. However, these could not be used to reliably demonstrate that the procedure had an added value for patients because of the lack of control group. Yet, in the US, they did manage to conduct the relevant randomized trials.[d]

2.2.3. No transparency

The (limited) **clinical data** that are used to award a CE label are **not publicly available.** Manufacturers are not inclined or obliged to publish the data they collected during the pre-market stage.

Research in Belgium, the Netherlands and the United Kingdom has shown that even when the competent authorities do look for these data the confidentiality argument is often used as a pretext not to disclose them. Yet, this goes against the **Declaration of Helsinki**[e] which a.o. stipulates that clinical investigations are permitted only if the research design is scientifically justified and the results are also published.

So, it is not clear on how many patients a high-risk medical device that carries a CE label is tested or what the results are. It is hard to justify that confidentiality takes precedence over transparency, both before a CE label

[d] https://kce.fgov.be/nl/publication/report/transcatheter-aortakunstklep-implantatie-tavi-een-health-technology-assessment-ac

[e] http://www.wma.net/en/20activities/10ethics/10helsinki/

is granted (to prevent the same mistakes being repeated over and over again), and after a product has obtained a CE label.

2.2.4. *Efficacy must only be demonstrated for reimbursement purposes*

As soon as a high-risk device is put on the market in Europe, the manufacturer can submit an application for reimbursement. In Belgium, that application must be submitted to the National Institute for Health and Disability Insurance (RIZIV/INAMI). Now, once the manufacturer decides to apply for reimbursement, he must be in a position to demonstrate the efficacy of his product. And without RCTs, that can prove to be a tall order.

Growing controversy about the functioning of the Notified Bodies

The NBs recently made the headlines following two undercover reports that exposed their casual approach. Journalists of the **British Medical Journal** and the **Daily Telegraph** compiled a file on a fictitious metal hip prosthesis, similar to other controversial metal hip prostheses that were known to have caused problems in the past. "*We contacted 14 NBs and asked them what evidence we should produce. Even though this concerned a high-risk device, and that the file stated that our prosthesis could release toxic substances into the patient's body, a minority of the NBs only looked for the results of a clinical study. The majority were happy to settle for a literature review of a similar prosthesis. Only 4 NBs expressed concerns about the application.*"[f]

Journalists of the Dutch TV programme Radar asked three NBs for a CE label for a vaginal mesh, a device that is implanted in women to correct pelvic floor prolapse. The journalists had manufactured the mesh themselves, using a net for mandarins no less.

For the design, they based themselves on models that had been withdrawn from the market before because they were harmful. Much to their amazement, the NBs never made the connection with these harmful meshes and led them to believe that their product stood a good chance of getting a CE label.

2.3. Belgian paradox

When there is no evidence as to the efficacy of a high-risk device, both a refusal to reimburse the procedure and a conditional reimbursement can lead to paradoxical situations:

- If a device that carries the CE label **is not refunded** because there is insufficient evidence of its safety and efficacy, doctors in Belgium are in principle still free to use it without any restrictions or conditions. This could lead to a large-scale distribution of high-risk devices throughout the European market, and uncertainty for the patient. In turn, this could create indirect pressure to reimburse the procedure anyhow.
- In Belgium, in cases where there is insufficient evidence as to a device's safety and efficacy, certain conditions can be attached to a **reimbursement by RIZIV/INAMI**. The health insurer can for instance rule that the device will only be reimbursed if the procedure is performed in certain hospitals. The paradox here is that, on the one hand, experience of the product can be centralised but, on the other hand, that reimbursement is difficult to justify if reliable data about the added value for the patient are lacking.

The cost of and responsibility for the clinical study for market access could also be passed on to the administration, once the device has obtained the CE label. By doing so, the safety of and the benefit to patients would be better ensured and followed up. But that kind of system for all high-risk devices would, from a budgetary point of view, be a non-starter for any administration. As we limited ourselves to the period after a CE label has

[f] Cohen D. How a fake hip showed up failings in European device regulation. BMJ. 2012;345:e7090.

been obtained and before the issue of reimbursement comes into play, that particular avenue falls outside the scope of this study however.

Another way to admit high-risk medical devices, whose added value has not been proven, to the market would seem desirable in other words.

Experience of a cardiologist working in a Belgian hospital:

"In the field of cardiovascular medicine over the past 10 years, there has been a veritable explosion of new techniques and implants that were easily granted a CE label, and hence market access, purely on the basis of feasibility studies. There is no shortage of examples: AAA (abdominal aortic aneurysm) prostheses, carotid stents, transcatheter aortic valve implantations (TAVIs), renal ablation to treat hypertension, etc. In some cases, the new interventions did not pass the test of more thorough studies and ultimately proved to be irrelevant.

However, there is still no proper guideline or legal framework on how these techniques or implants can be introduced and distributed in a scientifically and clinically sound manner.

Many new technologies also call for extensive expertise so the old rule "practice makes perfect" still stands. A number of techniques and implants soon became all the rage due to the mediatisation of technical medicine, the marketing by large companies, the competition between hospitals and other factors. This makes it almost impossible for the authorities or RIZIV/INAMI to adjust or curtail matters afterwards and leads to a financial drain and to expertise being spread over far too many techniques, to the detriment of patients. At that, training and certification is completely in the hands of the manufacturers concerned."

2.4. Market access in the US is far stricter than in the EU

In contrast to the EU, manufacturers who wish to get a foot on the ground in the US must not only demonstrate the safety but also the efficacy of most high-risk devices to the FDA (Food & Drug Administration) [g] (see Scientific report for further details).

The result of these stricter regulations is that far fewer market applications for devices are submitted in the US. The 2011 KCE study (Report 158) brought to light that only one in five of the 8,500 medical device companies that had approached the market in Europe had done likewise in the US. Another consequence of this is that there are often fewer types of a high-risk medical device or implant available in the US than in Europe. For instance, in 2011, 28 drug-eluting stents carried a CE label while only 5 received FDA approval.

At first sight, this may seem to put the US at a disadvantage, but it does increase the chances that any devices that are approved also have effective added value for patients. The difference with the situation in the EU, where no proof of efficacy must be delivered, is hence great. What's more, some devices even continue to be sold within the EU in spite of the fact that a clinical study for market access in the US already brought a lack of efficacy to light.

Even though the FDA system comes with its own limitations (see Scientific report), the RCTs that are conducted for the FDA have, on occasions, brought serious safety issues with regard to the use of devices to light. In those situations, the use of devices like these will often also be curtailed in the EU and reimbursements, if any, will be stopped, but, in the meantime, they have been used on thousands of European patients already.[h]

Unfortunately, the list of devices that are denied market access in the US is not published. At that, the results of clinical studies, that are used to substantiate the application file, are not always disclosed.

g www.fda.gov

h https://kce.fgov.be/nl/news/marktintroductie-van-hoogrisico-medische-hulpmiddelen-in-de-eu-versus-de-vs

Examples of the weaknesses of the EU system

Renal denervation is a relatively new therapy used to treat certain forms of treatment-resistant hypertension. It is a catheter-based procedure that uses electroablation to disconnect the nerve tracts from and to the kidneys. An RCT conducted for the FDA[i] showed that this technique did not have any added value for patients. Yet, this CE-label technique has so far been refunded in 13 other European countries,[j] even though there were no reliable results as to its efficacy.

Back in 2009, the KCE discovered that there was equally little evidence as to the efficacy and safety of **endobronchial valves**,[k] a technique that carries the CE label and is used to treat pulmonary emphysema by implanting tiny valves via the airways. As both the efficacy and safety of the procedure left a lot to be desired, the KCE advised against reimbursement in Belgium. In this case also, an RCT in the US showed that the product did not have any medically relevant added value, but that it did lead to an increase in hospital admissions.[l]

An FDA report[m] shows that cases like these are not the exception.

Key messages about the present situation

- Once medical devices have received the CE label, they can circulate freely within the EU.
- High-risk medical devices, that form the object of an application for market access in the **EU**, are assessed in terms of their **safety and performance** only. There is no requirement to demonstrate that they are effectively more or as beneficial to patients than the existing alternatives. So, a **CE label does not constitute proof of efficacy/effectiveness.**
- This in contrast to the US, where most new class-III (high-risk) medical devices are formally assessed in terms of their **safety and efficacy**.
- The market access assessment procedure as it stands is **not transparent.** The data that underpin market access are not accessible to the public.

i Bakris GL, Townsend RR, Liu M, Cohen SA, D'Agostino R, Flack JM, et al. Impact of renal denervation on 24-hour ambulatory blood pressure: results from SYMPLICITY HTN-3. J Am Coll Cardiol. 2014;64(11):1071-8.

j EUnetHTA WP5 Joint Action 2 Strand B. Renal denervation systems for treatment-resistant hypertension: Pilot rapid assessment of other health technologies using the HTA Core Model for Rapid Relative Effectiveness Assessment.

k https://kce.fgov.be/nl/publication/report/endobronchiale-kleppen-bij-de-behandeling-van-ernstig-longemfyseem-een-%E2%80%9Crapid%E2%80%9D-he

l Sciurba FC, Ernst A, Herth FJ, Strange C, Criner GJ, Marquette CH, et al. A randomized study of endobronchial valves for advanced emphysema. N Engl J Med. 2010;363(13):1233-44.

m http://kce.fgov.be/nl/news/marktintroductie-van-hoogrisico-medische-hulpmiddelen-in-de-eu-versus-de-vs

3. EUROPEAN INITIATIVES FOR A MORE STRINGENT LEGISLATION

The free movement of goods is one of the cornerstones of the European Union. It entails that the import, export or the sale of goods cannot be restricted within EU territory. This principle applies to medical devices also. However, if public health is at risk, the free movement of goods can be curtailed. After all, every European citizen has a fundamental right to safety and health care. In recent years, and especially after the fraud with the PIP breast implants (see frame), the EU has come to realise that the legislation on high-risk medical devices needs to be tightened.

PIP breast implant fraud

The fraud scandal about the breast implants manufactured by the French company Poly Implant Prothèse (PIP) erupted early 2012. It turned out that the implants contained an inferior, industrial-grade silicone gel, instead of the medical-grade gel the manufacturer had officially declared, which was 10 times more expensive.

The implants tore more readily and inferior quality silicone was released. Some 400,000 women across the world, amongst whom close on 700 Belgian women, had received PIP implants.

Pending new regulations on medical devices, which are currently in the pipeline, the European Commission took a number of interim measures. These strengthen and clarify the mission of the NBs. The introduction of the 'Unique Device Identification (UDI) System', which identifies and follows up all medical devices, should not only make for greater transparency with regard to their use but also for proper traceability.

Plan Medical Devices

Meanwhile, Belgium has already taken a step to realize this traceability. "*The Federal Agency for Medicines and Health Products (FAMHP), the National Institute for Health and Disability Insurance (RIZIV/INAMI), the Belgian federation of medical technology industry (UNAMEC) and hospital pharmacists and surgeons have together worked out the Plan Medical Devices.*
The plan foresees to set up a Central Register for the Traceability of medical devices (CRT), which includes all actors (= distributors, physicians, patients, etc.) and products. This register aims to trace implants that are delivered in our country, up to the patient. The improvement of the quality of the distribution network makes controls easier.
... If there are problems, FAMHP and physicians can intervene quickly and effectively because the implants and all possibly involved patients can be identified."[n]
This identification system is an ideal basis for the development into practice of what is addressed in this report (see e.g. the Dutch 6-step plan and IDEAL framework).

In addition, the European Commission formulated **proposals[o] for new regulations on medical devices**, which, once ratified by the European Parliament and Council of the EU, will take direct effect in the Member States and replace the three existing Directives. The most significant measures are believed to be the following (provided they are preserved in the final proposal):

- Performance of a pre-market assessment of high-risk medical devices by "**Special Notified Bodies**", who will be governed by more stringent requirements in terms of the qualifications and training of their staff and who will be appointed by the EMA (European Medicines Agency). An

[n] www.maggiedeblock.be/wp-content/uploads/2015/06/19-06-2015-NL-Europa-legt-de-basis-voor-een-nieuwe-verordeningrond-medische-hulpmiddelen.docx

[o] http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf

additional, thorough pre-market check can be performed by a new group of experts (MDCG - Medical Device Coordination Group) who can ask the experts of the Assessment Committee for Medical Devices (ACMD) to assess the clinical file.

- The introduction of an **electronic system to follow up clinical research in the European database for medical devices (Eudamed)**. This system will contain general information (name and contact details of the manufacturer, a description of the device, the objective and status of the study, a description of the comparator…) and will be accessible to the Commission, the Member States and to the public unless the confidentiality argument with regard to (part of) the data can be substantiated.
- For high-risk devices, the manufacturer will have to summarise the main safety and performance-related aspects and the outcome of the clinical research in a document that is **publicly available**.

Meanwhile, on June 19, 2015 the European Council of Ministers of Health has taken an important step which laid the basis for further negotiations with the European Parliament about a new regulation on medical devices.

However, these improvements will do little to address the current challenges, because:

- In principle, the additional, in-depth pre-market procedure will be the exception rather than the rule. Its effectiveness will also very much hinge on the role the MDCG will ultimately play.
- The (Special) Notified Bodies will still be selected and paid by the manufacturers.
- It is not clear how detailed the information to be entered into the system will be. Public access to these data is furthermore not (always) guaranteed either.
- It has not been specified what information the summary of the results of the clinical assessment of high-risk devices will need to contain.

None of these measures will ensure that also the added value or lack of added value of the device for the patient is demonstrated.

Both the European Parliament and the Commission are at one about the fact that the legal framework for medical devices, and especially the legal framework for high-risk medical devices, must be reviewed if patient safety is to be enhanced. What is clear is that the amendments the European Parliament has in mind are heading towards a stricter regulation of high-risk devices than what the Commission originally proposed and will put a stronger emphasis on safety and efficacy. One of the amendments is the introduction of the concept '**efficacy**', the definition of 'performance' and the reference to **RCTs** as the most appropriate form of clinical research to demonstrate the safety and efficacy of a product. Sadly enough, the Commission is not in favour of the concept 'efficacy' as one of the general requirements for clinical research. Neither does it plan to make RCTs a prerequisite.

At the time of going to press with this report, the issue is still object of debate at Council level (June 2015). It is difficult to predict at this moment in time what stance the Council of the EU, who, together with the Parliament, has the final say on the European Commission's proposals, will take. As a result, it remains unclear what this new piece of legislation will contain and, if it does arrive, when it will actually come into effect.

4. OPTIONS AS REGARDS PHASED, CONTROLLED MARKET ACCESS IN BELGIUM

Pending new EU legislation and in case the benefit to patients compared to existing alternatives was not to take centre stage in this piece of legislation, Belgium could take measures to phase market access for high-risk devices that carry the CE label. This would entail that Belgium would temporarily restrict and follow up their use because these devices can pose a risk to the health and safety of patients and/or because their efficacy has not yet been demonstrated.

When taking these measures, a distinction must be made between the area that is regulated by EU legislation (the so-called 'harmonised areas') already and matters that fall outside of the scope of that legislation and, as a result, come within the remit of the Member States.

Difference between a measure that comes within or falls outside the harmonised areas

Whether a measure comes within or falls outside the harmonised areas will depend on the ultimate goal: if the aim of the measure is to control or restrict **the placing on the market or the (initial) deployment** of a medical device (for instance, on account of a safety issue with the product itself), the measure comes within the harmonised areas.

If measures aim to assess and check a medical practice (i.e. **the actual use of the device**), they fall outside the harmonised areas.

4.1. Measures with regard to market access and the deployment of medical devices (governed by European legislation, the so-called 'harmonised areas')

4.1.1. Medical devices that do not meet the clinical safety and performance requirements ('not in conformity') and thus wrongfully obtained a CE label (art. 8 or 18 of Directive 93/42)

If clinical data show that a device that carries a CE label does not meet the clinical safety and performance requirements, in other words that the device is not in conformity, Belgium can, by way of interim measure, invoke articles 8 or 18 of Directive 93/42 and ban or restrict its market access and deployment. In that case, Belgium is obliged to forthwith notify the Commission to that effect and the latter will examine whether the measures in question are justified (art. 8.2). If it transpires that this is not the case, Belgium will be obliged to revoke its measures.

The above Directive was transposed into Belgian legislation.[p] However, these articles do not allow for limited or phased market access based on the fact that there is no proof of a device's efficacy. In fact, Directive 93/42 does not deem efficacy to be a prerequisite for conformity but only refers to clinical safety and performance.[q]

[p] Art. 13 RD 18/3/1999, art. 14 RD 15/7/1997 on active implantable medical devices and art. 8§1 of the In Vitro Diagnostic Devices Decree

[q] Art. 70 of the Commission's proposal takes over the current art. 8. New however is the fact that if neither another Member State nor the Commission raises any objections within 2 months of the measure having been notified, the measure is deemed to be justified.

4.1.2. Medical devices that put the health and safety of patients at risk (art. 14b of Directive 93/42)

If data and clinical evidence show that a device, even if it is in conformity with the Directive, can indeed pose a risk to the health and safety of patients, Belgium can rely on art. 14b of Directive 93/42 to restrict or ban its market access, pending a decision at EU level.[r] In most cases, this would relate to risks associated with the product itself, such as the material it is made of (e.g. devices containing animal tissue, see below) or a mechanism that could be harmful (e.g. hip prostheses whose grinding components cause metal flakes to shed into the patient's body).

Possible grounds for measures on foot of art. 14b could be **scientific uncertainty about the possible risks to citizens' health and safety** (see frame). However, the lack of evidence of a device's efficacy will not suffice to successfully invoke art. 14b.

Article 14b is based on the '**precautionary principle**', which provides that each Member State is entitled to take precautionary measures if a device may pose a risk to the health and safety of its citizens.

Once that article is invoked, there is no need to demonstrate that there is an issue with the device's conformity. The Member State in question must deliver proof of the possible health and safety risks however. That proof must not be conclusive but Member States cannot simply base themselves on hypotheses either. Demonstrating that scientific uncertainty prevails in the field in question will suffice however. In addition, the measures, in this instance, a restriction or ban on market access or initial deployment, must be **justified, proportional, strictly necessary** and non-discriminatory.

Here too, the Member State in question is obliged to immediately notify the Commission of the measures taken. The Commission will investigate their necessity and can always compel the Member State to revoke or adjust them.

Medical devices containing tissue of animal origin

One example of the scope of art. 14b are medical devices that contain tissue of animal origin. A number of Member States, France for one, decided to ban the production, market access and the use of certain implants made from materials of animal origin. The reason for this was the uncertainty about the possible transfer of spongiform encephalopathy (BSE - mad cow disease) to patients. So, it goes to show that it is possible to impose measures for similar devices presenting the same risk. In this particular instance, the measures ultimately led to a legislative initiative of the European Institutions in the form of Directive 2003/32/EC of 23/4/2003[s].

If a particular type of medical device is found to pose a certain risk, Belgium could restrict market access and demand that the device is tested by means of RCTs. In that case, Belgium will need to demonstrate that an RCT is the most appropriate way to protect patients' health, which could lead to some serious legal wrangling.

Pending a decision at EU level, the use of devices posing a safety could temporarily be **restricted to centres of reference.** However, on the basis of a study, the Belgian State will have to demonstrate that there effectively is a possible risk. But restricting the use of certain devices to specific centres is easier to justify as a measure that falls outside the harmonised areas (see below) because it relates to **the actual use** of the device and **not to the marketing of the device.**

At that, it cannot be excluded that the need for restrictive measures will become harder to justify once the stricter new European Regulations come into effect.

[r] Art. 74 of the Commission's proposal takes over the current art. 14b. It provides for the option to ban market access for high-risk devices if they pose a potential risk to the health and safety of patients, even if that risk has not yet been proven.

[s] OJ L 105, 26.04.2003

4.2. Measures with regard to the use, distribution, promotion and supply of medical devices (outside the 'harmonised areas')

4.2.1. Restrictions on the distribution, promotion and supply of medical devices

The distribution, promotion and supply of medical devices fall outside the scope of the European Directives in question. Pursuant to art. 10bis § 5 of the RD of 18/3/1999 and in line with the '**precautionary principle**' (see above), Belgium is in principle entitled to impose restrictive conditions in this respect. When doing so, it will need to take the European legislation on the free movement of goods into consideration.[t]

Examples of **possible measures**:

- Compelling the distributors of the product to furnish care providers with information in advance and to provide training for the medical teams.
- Compelling hospital pharmacists to document their selection of certain devices.
- Compelling hospitals to appoint staff with the relevant competences.
- Curbing the advertising for medical devices aimed at care providers.

These measures too must be **necessary, proportional and justified**. They can only be taken with patients' health and safety in mind.

4.2.2. Restrictions on the actual use of medical devices

Also measures with regard to the actual use of medical devices fall outside the scope of the European Directives. The option to designate **centres of reference** within accredited hospital services, departments, roles, medical and medico-technical services and care programmes was already provided for under article 14 of the Hospital Act. This provision was recently implemented on foot of two RDs concerning centres of reference for rare diseases.[u]

Restricting the use of a high-risk medical device to a centre of reference only can be justified if its use calls for very specific skills or precautionary measures and when there is a need for additional clinical research.

Prerequisite however is that this obligation is **necessary and proportional**, which a.o. matters entails that it can only be **temporary** in nature and must be **aimed at identifying an effective risk or at knowledge sharing**. Once these objectives have been attained or are no longer relevant, user restrictions must be lifted.

Neither can these measures be applied to all high-risk devices across the board because then they would no longer be deemed to be proportional. As a consequence, measures of this nature must be taken for each device or for certain well-defined categories of devices individually.

How to select the centres?

The various criteria used to select the centres of reference must be objective and measurable. They cannot only relate to the doctors involved but must also take the care teams and the infrastructure into consideration.

Some important selection criteria could be:

- The team's experience of the technology
- The extent to which the team is prepared to share its knowledge with other teams and to train colleagues working in other care institutions
- The team's participation in clinical studies on the device

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[t] Art 34-36 of the Treaty on the Functioning of the European Union

[u] The RD of 25 April 2014 declaring some provisions of the coordinated Act of 10 July 2008 on hospitals and other care institutions applicable to centres of reference for rare diseases, also referred to as centres of excellence, and the RD of 25 April 2014 laying down the specificities of the centres of reference for 'rare disease'', referred to as centres of excellence, within the accredited roles of 'rare diseases'.

In exchange for their accreditation, centres of reference could be asked to gather specific clinical data. And once the scientific evidence turns out to be positive, the administration could extend the use of the device to other centres. The establishment of "shared care networks", where the performance of the procedure is divided amongst centres of reference and other care centres or is performed under the supervision of a centre of reference, is another option.

Could these measures conflict with the therapeutic freedom of doctors?

On foot of articles 11 and 12 of RD no. 78 of 10/11/1967, doctors cannot be restricted by legislation if they want to use certain techniques to make a diagnosis or treat a patient.

This therapeutic freedom does entail however that the care provider is responsible for the choice he makes. In other words, he can be held liable if he opted for a method another, normally prudent, doctor would, in the same circumstances, not have chosen. If the doctor is aware of the foreseeable damage (i.e. damage that could reasonably have been foreseen), he must do everything in his power to contain the risk or at least to keep it under control as best as possible to ensure that the risk is proportional to the therapeutic objective.[v]

This **therapeutic freedom does not prevent the administration from taking action where necessary**. When the government capped the number of PET scanners in Belgium and saw its decision challenged by the European Commission, the Constitutional Court ruled that the legislator is vested with the widest possible discretionary powers when it comes to putting an optimum health care system in place.[w] In the end, the European Commission concluded that a restriction on the number of devices can be authorised in order to maintain the financial balance of the health insurance, which comes within the remit of the Member States.

4.2.3. Clarification of the obligations incumbent on care providers

4.2.3.1. Clarification of the obligation to provide patients with information

Under the patients' rights legislation[x], each care provider must **inform** his patient about the risks of and the possible alternatives to a certain treatment. Simply **stating that a medical device carries the CE label is not enough** to comply with this information obligation. Anyhow, compliance with this obligation should be standard practice nowadays.

For certain (high-risk) devices, listed by the administration, this obligation can be extended. The list in question must be compiled based on the criteria of necessity and proportionality and must specify the safety risk for each product.

Any care provider, who recommends one of these devices instead of the standard treatment, should explicitly explain the reasons for his choice to his/her patient. This should then be documented and logged in the medical file.

Yet, an extension of the information obligation of this nature requires an amendment to the Patient Rights Act. A self-regulating framework could also be helpful in this respect (see below).

4.2.3.2. Prior notification requirement and authorisation from the administration

Doctors can also be **compelled to notify a government agency in advance if they decide to opt for a certain group of high-risk devices carrying the CE label and to justify their choice.** This would facilitate a follow-up of the device's **suitability for use**. In that case, the risk must have been properly described by the administration and the latter must be able to demonstrate that the measure is proportional and that the mere obligation to inform patients does not suffice.

If the doctor's application is justified and the risk is acceptable, he/she can be granted permission to use the product. When the risk is too great, it could

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v Court of 1st Instance of Brussels, 23/01/2007

w Constitutional Court, no. 165/2003, 17/12/2003, B.5.2

x Patient Rights Act of 22 August 2002, B.S. [Belgian Official Gazette] 26 September 2002

also be decided that its use must be supervised by a qualified doctor from a centre of reference.

What makes a measure justified, necessary and proportional?

Over the years, these concepts have been interpreted by the European Court of Justice. The Scientific Report contains an overview of the case law and of how these concepts are interpreted.

4.2.3.3. Self-regulation by doctors: a Dutch example

The Dutch Order of Medical Specialists (OMS) and the Dutch Health Care Insurance Board (CVZ) have issued guidelines on the safe introduction and use of new medical techniques routinely used by doctors. Via this guideline, 'a supervised introduction' of new techniques is inasmuch as possible regulated by the care providers themselves. Doctors must follow a 6-step plan (see frame), and depending on the answers given, a number of measures are proposed. This will a.o. matters bring to light whether the doctor has any experience of the new technique and to what extent, what the financial and health risks are, what a training and follow-up plan would look like and, ultimately, whether the doctor can use the new technique.

The diligence exercised by the doctor, which is already used as a benchmark these days, will a.o. be assessed on the basis of the extent to which he adhered to the guideline. Doctors who disregard the guideline or who, in the event of a negative advice, choose to use the device anyhow would increase their risk of liability if it turns out that the device was harmful to the patient.

The correct application of a guideline that is similar to the Dutch one should ensure that the medical devices in question are used by competent doctors only and in the correct setting, so that the risk of danger to the patient can be contained.

A measure like this certainly seems proportional, all the more because, in comparison to the other measures proposed above, is the least intrusive and gives individual doctors discretionary powers.

The Dutch 6-step plan:[y]

Step 1: Determine the innovation class of the new intervention.

- This a.o. entails checking whether the new intervention qualifies as “experimental care”, i.e. has never been used before and (inter)national guidelines and knowledge are non-existent. If that is the case, local introduction is not recommended.

Step 2: Determine the added value of this new intervention.

- Does it, based on the data on its clinical effectiveness, make sense to introduce the new intervention? If insufficient research data are available, an introduction in a research context could be considered.

Step 3: Determine the risk class in terms of a) safety; and b) organisation, budget impact and financial risks.

- This a.o. allows one to establish whether the care providers in question are sufficiently qualified/have been adequately trained to safely carry out the intervention, whether and how the use in respect of all the relevant characteristics is monitored and logged, how patients are informed and whether (patient) information is available.

Step 4: Determine the general risk class.

- On the basis of the previous step, a general risk class is determined and the need for an extensive prospective risk inventory is assessed.

Step 5: Develop an introduction plan.

- This step allows for the development of a training protocol and a framework for data registration and monitoring.

Step 6: Assessment of the (care) outcomes.

[y] Dutch guidelines on the safe introduction and use of new medical innovations by specialists: Abridged version of the 6-step plan: http://kims.orde.nl/assets/structured-files/downloads/Stappenplan%20Nieuwe%20Interventies%20def.pdf

Unabridged version of the 6-step plan: http://kims.orde.nl/assets/structured-files/downloads/Leidraad%20Nieuwe%20interventies%20in%20de%20klinische%20praktijk%20def.pdf

- On the basis of the data collected, the results on safety and effectiveness then need to be looked at. If the assessment proves to be positive, a decision can be taken to continue with the intervention in the future.

4.2.3.4. IDEAL framework: no surgical innovation without evaluation

One approach that is complementary to that of the Dutch doctors discussed in the previous point is the one outlined by the IDEAL framework (http://www.ideal-collaboration.net/).[z] This model was designed by a group of experts including surgeons, scientists and methodologists for the introduction of surgical procedures. IDEAL stands for Idea, Development, Exploration, Assessment and Long-term study. It describes the steps that need to be followed in the development and assessment of new invasive techniques and procedures.

Idea: when a surgeon tries out a procedure for the first time (Idea/proof of concept)

All new interventions must automatically be reported to the hospital and logged in an online register accessible to all surgeons. Especially the undesirable effects and unsuccessful procedures must be published to ensure that history does not subsequently repeat itself.

Development: if the first reports indicate that the procedure has its advantages, others can also try out the procedure.

The procedure is performed on a limited group of patients. In this stage, experience is acquired and the technique is refined or adjusted. Precautionary measures are taken to prevent any negative effects on patients, for instance, through mentoring during the learning curve. All procedures must be entered into a register and must contain a clear report on the outcomes for every single case, nothing can be omitted.

Exploration: understanding the potential advantages and disadvantages

Once the procedure has been described and the main technical aspects have been elaborated, explorative prospective clinical studies without control group can be set up. This can be done in parallel with the launch of an RCT.

Assessment: Is this technique better than the existing alternatives in terms of clinical efficacy and cost effectiveness?

The aim of this stage is to assess the efficacy/effectiveness vis-à-vis the current alternatives. RCTs are the most suitable course of action in this respect and the choice of comparator is extremely important.

Long-term study

In this stage, established procedures are assessed on their rare and long-term outcomes. This is typically done with the help of a register. The value of the results will a.o. depend on the representativeness of the data. To encourage a comprehensive data input, it is recommended that only the most important outcomes and relevant information are collected.

[z] McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, et al. No surgical innovation without evaluation: the IDEAL recommendations. Lancet. 2009 Sep 26;374(9695):1105-12.

There is no specific moment that tells you when an "innovation" progresses from one stage to the next. A formal scientific evaluation of a new intervention, that compares it to existing alternatives, using a suitable research design, is recommended before the intervention in question is used on a large scale. Transparent reporting on the research protocols and results is also essential in each stage.

The integration of IDEAL into the Dutch 6-step plan would seem to be a responsible choice that has **various advantages**:

- It would make care providers think about the responsible use of high-risk medical devices that carry the CE label and about whether the device can be offered in a suitable environment. This measure alone could curtail the use of such high-risk devices without reliable evidence about the added value for patients and/or ensure that they are used in a responsible setting.
- Specialists can only assess and justify the use of a high-risk medical device if they themselves have the relevant data to hand. Indirectly, this could ensure that the manufacturers (are made to/will) supply the results of clinical studies in a transparent fashion.
- An assessment performed within the field itself would soon allow new high-risk interventions to be identified and assessed on their suitability for use in a research setting or routine use.
- The liability risk to care providers is contained if the step-by-step plan is followed correctly.

For these reasons, the **introduction of such a step-by-step plan seems a necessary and justified measure that is also proportional to the envisaged objective**.

4.2.4. Improving the use of registers

The new implants register introduced by the Act of 15 December 2013 is an instrument that facilitates the traceability and monitoring of devices. It is not intended for scientific research.

However, registers that are designed and used properly can help increase knowledge about the use of certain devices.

Any new registers that are established must be set up with a specific (research) objective in mind and serious thought must be put into the data to be collected beforehand. This would dispense with the issue of care providers spending their time completing registers that are barely looked at afterwards.

Registers are very useful in the exploration, development and long-term study stages of the IDEAL model. In the assessment stage however, a register usually does not provide enough reliable information about the efficacy of an intervention, as there is no control group. If that is the main question, a randomized study design would be more appropriate.

RECOMMENDATIONS[aa]

To the Belgian representatives in the European policy bodies

- **The European Regulation on medical devices, which is currently in the pipeline, should put patients' interests centre stage. Especially with regard to high-risk medical devices, the KCE makes the following recommendations:**
  - **To qualify for a CE label, not only the safety and performance of high-risk devices but also their clinical efficacy should be demonstrated. That proof should be delivered on the basis of the results of randomized clinical trials (RCTs), unless specific circumstances prevent the performance of an RCT.**
  - **Once a CE label has been awarded, all the clinical research data that were produced in support of this decision should be made accessible to the public, in line with the Declaration of Helsinki. These reports should be as detailed as the European public assessment reports (EPARs) for medicines.**
  - **The Eudamed database seems to be the most appropriate tool to centralise that information. The information in question should be up to date and complete and available to all stakeholders (care providers, HTA institutions, policy-makers and patients) in a transparent and user-friendly format.**
  - **The authority to issue a CE label for high-risk medical devices should be centralised with a European agency or reserved for a small number of specialist Notified Bodies, who should have the relevant clinical knowledge.**

To the doctors and care providers who wish to use these innovative high-risk medical devices:

- **Under the Patient Rights Act, patients who are offered an innovative high-risk medical device should timely receive objective and complete information about the safety and efficacy (including the degree of uncertainty) of the device and of its cost to him. This information should also specify the available alternatives and should be presented in a format that is intelligible to people who do not have a medical background. The patient's informed consent should be documented in the medical file.**

[aa] KCE bears sole responsibility for the recommendations.

To the Minister for Public Health and the competent bodies at RIZIV/INAMI, the FAMHP and the FPS Public Health:

- **There are various ways and means to contain the (potential) risk to patients associated with the use of a medical device that carries the CE label:**
  - **The use of the device can be limited to centres (of reference) that are specifically authorised to that effect. This could be justified if specific knowledge, experience, infrastructure, competences or a multi-disciplinary team are required to ensure its proper use.**
  - **If there is proof that a product does not meet the essential requirements (articles 8 and 18 of Directive 93/42) or if a medical device poses a specific (potential) risk (article 14b), Belgium can take measures to restrict or ban its market access (and notify the European Commission of that measure).**
  - **To apply the aforesaid procedures, the systems to collect national data must be enhanced.**
  - **The establishment of registers and the collection of health (care)-related data must be organised in consultation with Healthdata.be.**
  - **Belgium can introduce the requirement to use a high-risk medical devices in the context of an RCT, both inside and outside the harmonized areas, where it can demonstrate that this measure is justified, necessary and proportional.**
  - **In of view the implementation of a future regulation, the FAMHP needs to have expertise in the field of interpreting studies as well as the necessary expertise in engineering and material science.**

To the Minister for Public Health and the competent bodies at RIZIV/INAMI, the FAMHP and the FPS Public Health, including the care providers, the hospital accreditation bodies and the medical liability insurance providers:

- **The implementation of a self-regulating system is recommended. A guideline based on the Dutch approach which also applies the IDEAL framework can be drawn up by RIZIV/INAMI in collaboration with the scientific associations and the other relevant stakeholders.**
- **Under this system, care providers could be required to report and properly justify the use of any new high-risk medical device in the medical file. To make the system credible, the administration should have sufficient means of control.**

- **The proposed self-regulating system should form part of the hospital quality system.**
- **Adherence to this step-by-step plan can have an impact on the professional liability of the care provider.**
- **The measures taken must always be justified and proportional.**

COLOPHON

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