# Towards sustainable devices in healthcare

To: the Minister of Health, Welfare and Sport
No. 2022/22e, The Hague, September 13, 2022

Health Council of the Netherlands

# contents

# summary

In line with European climate targets, the Dutch government has set itself strict goals in the areas of sustainability and circularity. This will require a transition supported by all sectors. The healthcare sector is responsible for a substantial part of national $CO_2$ emissions, consumes scarce resources, and produces waste on a large scale. Improving sustainability still presents a huge challenge, particularly when it comes to medical devices and personal protective equipment. The Minister for Medical Care and Sport has therefore asked the Health Council of the Netherlands to provide insight into the barriers to the more sustainable use of medical devices and personal protective equipment in healthcare (referred to in the rest of this report as devices). The Minister has also asked how sustainability improvements and the sustainable use of devices in healthcare institutions can be accelerated. To answer these questions, the Council set up the Medical Devices Sustainability Committee. In this report, the Committee understands 'sustainability improvements' to mean lowering environmental impact by reducing $CO_2$ emissions, the use of water, resources and land, and pollution.

**More and more devices, with more and more single-use products**

Population ageing and expanding medical treatment options are leading to a growing demand for healthcare in the Netherlands. The result is an increase in the use of devices such as gloves, wound management supplies, surgical instruments, medical equipment, diagnostic tests and implants. Healthcare provision is reliant on these products. Over the past few decades, there has been a shift from reusable devices to single-use devices. This includes advanced instruments such as surgical staplers. Overuse and a lack of emphasis on repairs (to equipment) and the reuse of components or materials are also commonplace. This behaviour stems from assumptions about the safety (hygiene), ease of use (efficiency) and costs of single-use devices.

**Sustainable care initiatives are difficult to get off the ground**

Recent years have seen a growing awareness that healthcare and the use of devices can and must become more sustainable, as improvements in this area benefit the environment and ultimately public health. The government still largely leaves the sustainability of devices to the market, and measures are voluntary. Current initiatives to improve sustainability come primarily from healthcare employees in the workplace, who identify opportunities for a more sustainable approach. Due to a number of different factors, these initiatives generally remain small scale. For example, initiators are hindered by a lack of

support from the healthcare institution (in the form of funding, manpower and knowledge) and dependence on other parties in the healthcare supply chain. Existing procedures and protocols also play a role, as well as a lack of backing and sense of urgency.

**Take sustainability into account as an explicit value in healthcare**

Healthcare is geared towards the provision of 'good care' to the individual patient. The key values of good care are enshrined in laws and regulations, and include safety, efficiency, effectiveness and client focus.

Little consideration is given to environmental impact in healthcare decision-making.

The Committee notes that the absence of sustainability as an explicit value within the current frameworks is a barrier to more sustainable device use. The Committee believes that there is every reason to take sustainability into account as an explicit value and to enshrine this value in law, for example by including it as an explicit element of 'good care' in the Healthcare Quality, Complaints and Disputes Act (*Wet kwaliteit, klachten en geschillen zorg*, Wkkgz). Policymakers, healthcare institutions and healthcare employees will then be prompted to consider sustainability in their decisions and to look for ways of providing good care that is also sustainable. As a medical decision-making tool, the Committee has identified the need to develop an assessment framework that takes sustainability into consideration alongside existing values of good care. On top of this, healthcare institutions themselves must take action, for instance by including sustainability in their strategic vision, medical guidelines, procurement policy and healthcare staff training, and by adopting a conscious approach to devices in practice.

**Changes needed in design, production, use and waste processing**

The healthcare sector cannot make devices more sustainable on its own. Achieving this will require a transition from a linear to a circular economy, which involves changes throughout the chain of design, production, use and waste stages. The available sustainable devices are currently very limited. Manufacturers have a responsibility to work towards sustainable innovation and business models. At the same time, healthcare institutions can create demand for sustainable products through their procurement activities, thereby influencing supply. In order to extend the use stage, a stronger focus is required on aspects such as the reuse, repair and refurbishing of equipment. Closer attention needs to be paid in the waste stage to the reuse and recycling of components or materials. Not many companies are doing this yet. The Committee believes that the transition calls for the promotion of innovation, knowledge development and exchange, new business models and the reorganisation of facilities and logistics in healthcare institutions. Government policy establishes a foundation for a circular economy, however sufficient attention is not yet being paid to the healthcare and devices sectors. The Committee advocates greater interministerial collaboration to develop policy

and set sustainability goals for the transition to circular device use in healthcare. In addition, the Committee recommends encouraging innovation by more effectively combining knowledge from relevant public and private sectors. Examples include universities, healthcare institutions, research institutes, medical technology companies and waste processors.

**A compulsory approach through law**

The Committee believes that policy alone is not enough to achieve sufficient progress in making devices more sustainable: a more compulsory approach enshrined in law is needed. There are a number of possible solutions at both European and national level. One solution is to incorporate sustainability into laws and regulations that specifically apply to devices, for example by imposing sustainability requirements on the composition of a device and by holding manufacturers that market single-use devices accountable. It is also important to ensure that general regulations that encourage sustainability also apply to the devices sector. At present, that is not sufficiently the case. Possible measures include greater responsibility on the part of manufacturers and guidelines for ecodesign.

The Committee recommends that the Netherlands take on a leading role in enshrining sustainability requirements for devices in European legislation.

**Advice**

The Committee considers state intervention to be urgently needed in order to make the use of medical devices and personal protective equipment in the healthcare sector more sustainable. This requires fundamental changes and measures that have an impact not only on device use, but also on the healthcare sector as a whole.

In summary, the Committee's recommendations are as follows:

- Make sustainability an explicit value of good care and develop an assessment framework for this purpose.
- Embed sustainability throughout the organisational structure of healthcare institutions.
- Ensure that sustainability is taken into account in medical guidelines, standards and insured care.
- Develop an interministerial policy agenda for making devices more sustainable.
- Draw up legal requirements in relation to sustainability.
- Focus on innovation of products and services for reuse, reprocessing and waste processing to accelerate the transition process.
- Facilitate research into sustainable products and processes and monitor the environmental impact.

# 01 introduction

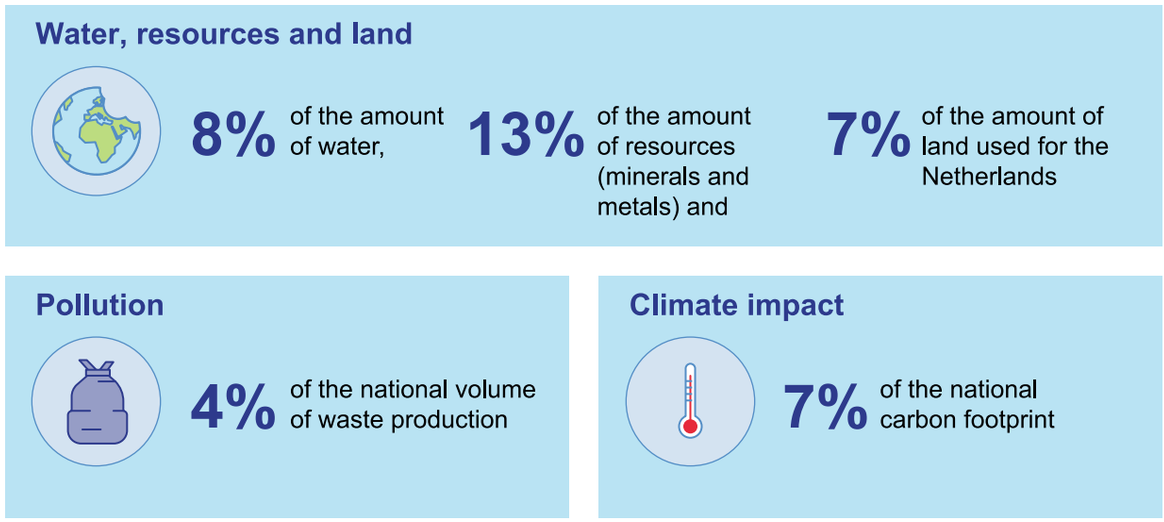
## 1.1 Background and request for advice

The government adopted the ambitious targets from the European Climate Act in its coalition agreement. The goal is to reduce $CO_2$ emissions by 55% in 2030 compared to 1990, and for the Netherlands to become climate neutral by 2050. In addition, resource consumption must be reduced by 50% by 2030, with a fully circular economy by 2050.[1] All sectors, including the healthcare sector, need to play their part in achieving this transition.

The negative environmental impact of healthcare takes a number of forms, including greenhouse gas emissions, the use of water, resources and land, and pollution (figure 1). The environmental impact not only affects the Netherlands, but also other countries to some degree, for example because medicines or medical devices are produced there.[2] Together this has a major impact on climate change and on ecosystems, which ultimately also has repercussions on the public health of current and future generations.[3] In the Netherlands, the healthcare sector is responsible for 7% of the national carbon footprint.[2,4] Healthcare institutions are also responsible for a significant proportion of water, resource and land use (8%, 13% and 7% of national consumption respectively) and produce a large amount of waste (4% of the national volume).[2] A total of 328 million kilos of waste was produced in 2018.[5] Most of this came from elderly care, hospital care, pharmacies and domestic device use.[5] There is room for improvement: an estimated 80% of hospital waste is incinerated as residual waste.[6]

**The environmental impact of healthcare takes a number of forms, including greenhouse gas emissions, the use of water, resources and land, and pollution**

Healthcare is responsible for:




Source: Rijksinstituut voor Volksgezondheid en Milieu (RIVM). Rapport 2022-0127. *Het effect van de Nederlandse zorg op het milieu. Methode voor milieuvoetafdruk en voorbeelden voor een gezonde zorgomgeving*. Conceptversie 5 september 2022.

**Figure 1** The environmental impact of heathcare

The government promotes sustainability in healthcare through the Ministry of Health, Welfare and Sport (*Volksgezondheid, Welzijn en Sport*, VWS) Sustainable Healthcare programme. Concrete steps include the signing of the first ‘green deal’ in sustainable healthcare by authorities, healthcare institutions and businesses in 2015.[7] This was followed in 2018 by the ‘Green Deal in Sustainable Healthcare for a healthy future’, in which even

more parties signed up to the joint targets to lessen the negative environmental impact of the healthcare sector.[8] The targets relate to the reduction of $CO_2$ emissions, circularity, combating drug residues in waste water, and ensuring a healthy living environment in and around healthcare institutions. In addition, the Minister of VWS committed in the run-up to the 2021 climate conference in Glasgow to a UK initiative for environmentally sustainable and climate-resilient healthcare.[9] The Netherlands' commitments relate to measuring the ecological footprint of the healthcare sector, supporting the sector in making sustainability improvements and developing a sustainable supply chain.

In efforts to improve the sustainability of healthcare, the emphasis to date lies mainly on reducing carbon emissions. Specific targets have been set for reducing the energy consumption of buildings, transport movements and manufacturing of medicines, because these activities contribute significantly to $CO_2$ emissions.[10] Little progress has been made towards achieving circularity in the healthcare sector.[10] A huge challenge lies ahead, particularly when it comes to the sustainability of the product groups medical devices and personal protective equipment. Without these products, healthcare institutions and professionals cannot provide care. Many of the medical devices and personal protective equipment are disposed of after one use and few sustainable alternatives are available.[11-13] However, it is still difficult to quantify the contribution made by these product groups to the environmental impact and its various aspects.[2,14] Current initiatives to make devices more sustainable also show that it is no easy task. Healthcare institutions focus primarily on providing good and safe care to patients. Care for the environment comes second. What is more, healthcare institutions rely on the entire chain of manufacturers, suppliers and waste processors for the availability of devices.

The Minister for Medical Care and Sport has asked the Health Council of the Netherlands to provide insight into the current barriers to the more sustainable use of medical devices and personal protective equipment in healthcare. The Minister has also asked how sustainability improvements and the sustainable use of medical devices and personal protective equipment in healthcare institutions can be accelerated.

## 1.2 The Committee

To answer the Minister's questions, the Council set up the Medical Devices Sustainability Committee. The Committee is made up of professionals with expertise in the medical sciences, medical technology, infection control, procurement management, psychology, ethics, sustainability and law. A list of the Committee's members can be found at the end of this advisory report.

## 1.3 Mission statement and working method

In its advisory report, the Committee describes opportunities for and barriers to improving the sustainability of medical devices and personal protective equipment and their use. It sought to identify ways to improve sustainability throughout the chain of design, production, use and processing of devices. In this report, the Committee focuses primarily on opportunities for the Ministry of VWS. It also sets out what action healthcare institutions and manufacturers themselves can take.

The Committee based its activities on the existing frameworks of effective and safe care. The Committee did not carry out its own comparative analyses of the environmental impact or efficiency of specific devices. Scientific literature was gathered on devices from a medical, ethical, behavioural, legal and sustainability perspective. In addition, the Committee identified general barriers to, and ways of, improving sustainability on the basis of three case studies of specific products. This was done for the different life stages of the product in question: design, production, use and (re-)processing. The case studies were selected from different groups of devices (figure 2). The choice was based mainly on diversity in the types of devices that are widely used in healthcare institutions and not so much on the environmental gains to be achieved. The case studies relate to:

- gloves (medical consumables, personal protective equipment);
- surgical stapler (medical consumables/medical devices requiring sterilisation);
- ultrasound device (medical equipment).

The report describes the case studies by way of illustration. The other groups of medical devices (implants, *in vitro* diagnostics and medical information technology) are addressed less explicitly, although they do fall within the scope of this report.

The Committee has consulted various experts in the field. These experts were employed by healthcare institutions in the areas of infection control, environmental sciences, waste processing, procurement and sterilisation, or are actively involved in making healthcare more sustainable. The Committee also spoke to the sector association of healthcare organisations, companies that manufacture or reprocess devices, the National Institute for Public Health and the Environment (RIVM) and Dutch members of the Medical Device Coordination Group. A full list of the experts consulted can be found at the end of this advisory report. The report has been reviewed by the Health Council's standing committee.

## In this advice, 'device' refers to the group of personal protective equipment as well as six groups of medical devices

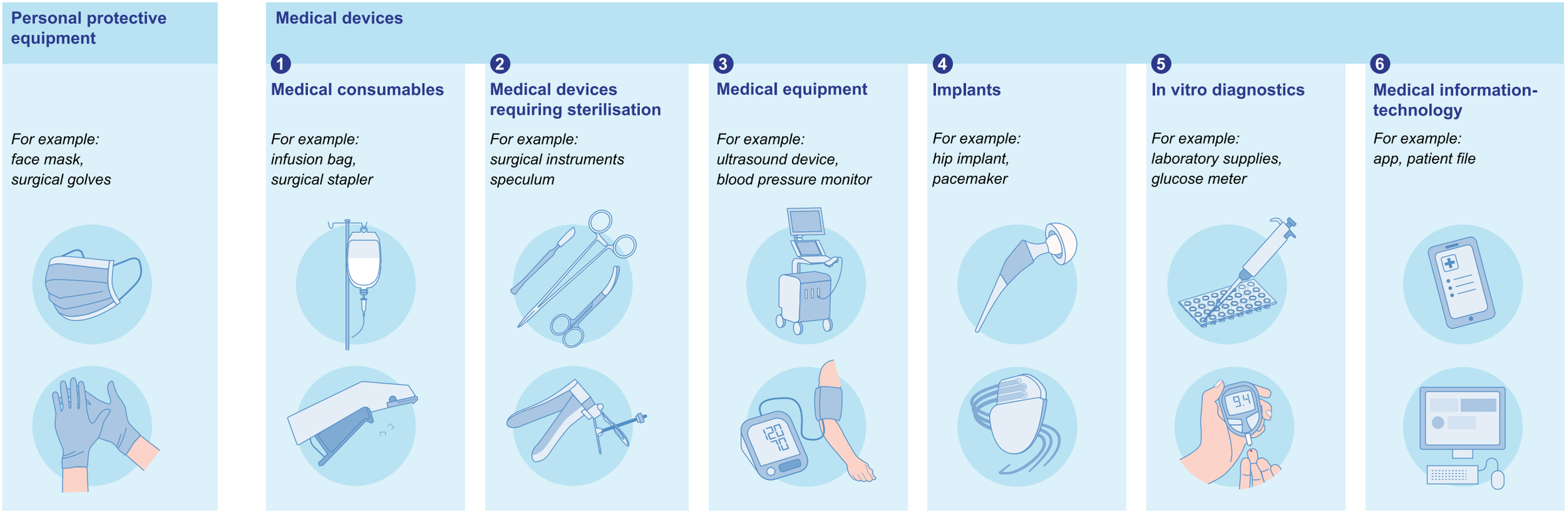



**Figure 2** Different groups of devices

## 1.4 Keywords

**Medical device** - the term ‘medical devices’ refers to a wide range of products. In the EU regulation, ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for a medical purpose.[15] This purpose can relate to prevention, diagnosis, monitoring, prediction, prognosis, treatment or alleviation of disease, an injury or disability. It can also relate to investigation of the anatomy or state of health and providing information by means of *in vitro* examination.[15] The medical technology covenant identifies six groups of medical devices: medical equipment, medical information technology, medical devices requiring sterilisation, medical consumables, implants and *in vitro* diagnostics (figure 2).[16]

‘Single-use device’ means a device that is intended to be used in a single individual during a single procedure. Reusable devices are devices designed by the manufacturer to be used again after appropriate action has been taken, such as cleaning, disinfecting and sterilising.[15]
Modular devices are devices consisting of multiple components. Modular devices can be designed so that one or more components can be reused. Modular devices can have several functions thanks to the option to switch components.

**Personal protective equipment** - personal protective equipment is equipment designed to protect the user against one or more risks to health or safety.[17] Examples in the healthcare sector include gloves, face masks and aprons. In some cases, items may be intended to protect both the user (healthcare employee) and the patient (such as a medical face mask).

**Device** - in this report, the Committee uses the term device as an abbreviated, umbrella term for a medical device and/or personal protective equipment. Where specific reference is made to the group of medical devices or personal protective equipment, these specific terms are used.

**Sustainability** - sustainability refers to both the environment and social and economic aspects (people, planet, prosperity), in accordance with the United Nation’s international sustainable development goals.[18] In this report, the term sustainability refers mainly to the environmental impact of the healthcare sector and the use of devices.

**Environmental impact** - the environmental impact is the impact of products on various aspects of the environment such as greenhouse gas emissions, pollution, and the use of water, resources and land.
This impact can be calculated based on a life cycle analysis, which calculates data on emissions and resource consumption throughout a product’s life cycle.

Achieving a circular economy is a vital step on the road to a more sustainable society. The R-ladder describes various strategies in the pursuit of circularity (see figure 4, chapter 4). This R-ladder reflects the general principle of circularity that the reduction in the practical value of resources, materials and products must be minimised during production and use.[19] The 10 Rs refer to strategies in decreasing order of effectiveness. Not using and reducing use (refuse and reduce) are the most sustainable options. This is therefore the preferred strategy when improving sustainability, above options to extend the lifetime of, or to reuse, the materials.

**Healthcare institution** - by healthcare institutions the Committee means all institutions that provide primary, secondary and tertiary healthcare. Examples include hospitals, care homes, nursing homes, GP and dental practices, rehabilitation centres and private clinics.

## 1.5 Reading guide

In chapter 2, the Committee outlines the values that play a role in healthcare and in the use of devices. Chapter 3 then goes on to look at what healthcare institutions can do to make their use of devices more sustainable. In chapter 4, the Committee describes what a circular economy of devices looks like and how this circularity can be encouraged through policy. In chapter 5 the Committee lists the laws and regulations that apply to devices and identifies opportunities to improve sustainability in this area. Finally, the Committee consolidates its advice and recommendations in chapter 6.

# 02
# sustainability in the frameworks for good care

The current use of devices in the healthcare sector is unsustainable and initiatives to improve sustainability remain small in scale. The reason for this is that sustainability is not part of the current frameworks for 'good care' in the same way as safety, efficiency, effectiveness and client focus. This is hampering a transition to the sustainable use of devices.
The Committee believes that sustainability must be taken into account as an explicit value in the provision of good care.

## 2.1 Developments in the use of devices

Population ageing and expanding medical treatment options are leading to a growing general demand for healthcare in the Netherlands, a trend which is expected to continue.[20] This growing demand for care is accompanied by a rise in the use of devices.[21] In 2016, the costs of medical devices (excluding personal protective equipment) amounted to around 5% of the total healthcare budget in the Netherlands.[22] Most of the expenditure on medical devices in the Netherlands takes place in hospitals. This mainly concerns costs of single-use care products (incontinence supplies, wound management), diagnostic tests and imaging technologies, devices for visual impairments, orthopaedics and cardiology. Changes in the use of devices are to be expected as a result of trends in medical technology such as digitisation, the use of artificial intelligence, introduction of robots, personalised care and remote care. Changes in device use can also be expected due to increased focus on prevention and early treatment, as well as due to the implementation of legislation such as the European Medical Device Regulation.[23] Trends in relation to the use of medical information technology can have both a positive and negative impact on sustainability. For instance, data-intensive technology (computer models or imaging technology) can be deployed in order to better predict diseases, thus contributing to prevention and less healthcare. On the other hand, such technologies consume large amounts of electricity, which will result in increased energy consumption and $CO_2$ emissions.[24]

The past few decades have seen a shift from reusable devices to single-use devices.[25,26] This trend is not limited to simple, relatively inexpensive devices such as face masks or aprons. A more complex instrument containing electronics such as a surgical stapler is also usually only suitable for single use.[27] Due to their design, complex surgical instruments are difficult to clean or sterilise. Endoscopes (an instrument used for visual examination), for example, contain small passages or cavities that are difficult to clean, which has led in the past to outbreaks of bacteria, including resistant strains.[28] Moreover, not all materials are suitable for the same cleaning and sterilisation method. The development towards more single use was initially viewed as positive, because the supplier guarantees that the devices are sterile and of consistent quality.[26,27]
The assumption is that this increases safety in healthcare. Although this may indeed be the case for certain groups of devices that are difficult to clean and designed for invasive use (such as syringes and needles), it

has not been proven for all groups of devices.[26,29] Nevertheless, single-use devices have become the standard in healthcare institutions, due in part to their wide availability on the market and low price. Healthcare institutions have now primarily geared their facilities and logistics towards waste processing and less towards reuse. All of this means that it is difficult in practice to reverse the single use of devices, even if the safety of reusable devices is guaranteed. For instance, the risk of prion infection prompted the avoidance of reusable laryngoscope blades.[30] Sterilisation guidelines have now been developed, but the single-use laryngoscope is still widely used, including in the Netherlands.[25,31] Good manuals have now also been produced for the cleaning, disinfection and sterilisation of endoscopes.[32,33] However, the US Food and Drug Administration recently advised healthcare institutions to switch to single-use colonoscopes or module colonoscopes (whereby only the cap must be discarded after use) to limit infection risks.[34] The industry has been supplying single-use endoscopes for some time now.[28,35,36] This has repercussions on the international market supply, which the Netherlands also uses.

Single use is also the standard for personal protective equipment, such as face masks, aprons and gloves. The consequences of this became apparent during the COVID-19 pandemic.[37] The healthcare system proved to be vulnerable due to its dependence on the supply of single-use devices primarily from Asia.[38,39] Another thing that became apparent was the amount of waste generated. The World Health Organisation drew attention to the negative environmental impact caused by the extensive use of personal protective equipment.[38] Sustainability of healthcare was highlighted as never before.

**More devices and more and more single-use products**

The case studies examined by the Committee illustrate that the use of devices in healthcare is, in many ways, unsustainable.

**Gloves**

Gloves serve as both personal protective equipment and as a medical device. They are overused in both applications.[40,41] For example, employees wear gloves for their own protection during activities that do not require their use. The role of gloves in preventing patient infection is also overestimated.[42,43] Their incorrect use, for instance as a substitute for regular hand hygiene, has even been shown to potentially increase the risk of infection.[44-46] The Good Glove Use project has demonstrated that things can be done differently: adherence to guidelines in care homes improved, with no difference in the number of infections. [47] [48,49] The scale of the reduction in glove use was not reported, however other research shows that a 30% fall in usage is achievable.[50]

A further issue is a lack of sustainability in the glove production process. The majority of the negative environmental impact is caused by the use of chemicals and $CO_2$ emissions during the production process.[51-53] Gloves are often made of nitrile (synthetic rubber). They are largely produced in Asia, outside the scope of European law.

**Surgical stapler**

An instrument that has become more widely used in the operating theatre is the surgical stapler. This device replaces the traditional use of needle, sutures and scissors.[54] Although instruments were initially reusable, recent decades have seen a shift towards single-use staplers.[29] The underlying reasons for this shift relate to safety, costs and ease of use. Reusable staplers are also often discarded after a single use, because the procedures for reuse are perceived as complex.[27,55] Single use results in unnecessary waste and resource consumption. Research shows that repeated use of a reusable version generates 40–70% less waste (depending on procedure type), while consuming 92–96% less resources.[27]

**Ultrasound device**

There has been a surge in the use of ultrasound in recent years. Every year, around four million ultrasound examinations are performed in Dutch hospitals for various purposes, including the visualisation of tissues and organs.[56] All medical disciplines use their own types of ultrasound devices, which vary in size and function. The European Society of Radiology encourages the use of up-to-date equipment due to improved safety and image quality.[57] Nevertheless, a device can often be retained past the recommended replacement date. This requires updates to be made possible, and proper maintenance and repairs must be carried out.

In addition, old devices are often not returned to the manufacturer despite the fact that parts can be reused to repair other devices or to produce a new device. Although much has already been done in recent years to reduce the energy consumption of ultrasound devices, there is room for improvement in this area. Research shows that considerable energy savings are possible if medical equipment goes into sleep mode after a procedure and is switched off entirely at the end of the working day.[58]

## 2.2 Improving sustainability: current initiatives and barriers

Current sustainability initiatives often originate in the workplace. Sometimes encouraged by the Green Deal in Sustainable Healthcare, healthcare employees identify opportunities for a more sustainable approach to device use. Out of a need to pool and exchange knowledge and experience, healthcare employees join forces in groups such as ‘green teams’ which function primarily within healthcare institutions. A number of national structures for sustainability improvements in healthcare have also arisen, such as the *Groene Zorg Alliantie* (Green Healthcare Alliance), a platform that green teams can join, and the national network *De Groene OK* (The Green OR). Examples of improvements in the sustainability of device use achieved within these green teams include the introduction of reusable blood pressure cuffs, surgical gowns and laryngoscopes, as well as the longer use of opened disinfectant containers.

However, there are still many barriers to improving the sustainability of devices. One barrier experienced by healthcare workers is that sustainability is not one of their primary tasks. They also perceive a lack of backing and sense of urgency within healthcare institutions. As a result, there is no budget for investments and not enough knowledge and manpower available.[10] Initiators also run up against existing habits, procedures and protocols in healthcare.[10,59] All of this hinders measures such as investment in reusable devices, the setting up of processes for device reuse, and the implementation and scaling up of successful initiatives in the workplace. Finally, dependence on other parties in the chain is mentioned as a barrier to further improving the sustainability of device use.

The Committee has identified that the process of making devices more sustainable is not currently embedded in the healthcare sector, depending instead on voluntary initiatives by healthcare employees in the workplace who are already working under considerable pressure. As a result, opportunities to improve the sustainability of devices are limited, while current initiatives remain small scale and have too little impact. More is therefore needed to make the use of devices in healthcare institutions more sustainable: a transition is required from a linear to a circular economy for devices. Such a transition will only take place when innovative (small-scale) practices are supported by changes at system level: political and economic (legislation, business models), social and cultural (standards, values, awareness, patterns of consumption and market supply) and technical (through innovation).[60,61] The Committee looks at these aspects in greater detail later in this report.

## 2.3 Frameworks for good care

### 2.3.1 Existing frameworks

The provision of good care to the individual patient is the guiding principle in healthcare. The Healthcare Quality, Complaints and Disputes Act (Wkkgz) defines good care: “good care is always safe, effective, efficient and client-focused, is always provided in a timely manner, and is tailored to the client’s actual needs” (Wkkgz Article 2). These frameworks for good care are enshrined in various ways: in law, in policy, in the insurance or non-insurance of healthcare, in medical guidelines and in the visions of healthcare organisations.

The safety and effectiveness of medical devices is enshrined in law, for instance in the EU Medical Device Regulation (MDR), which governs which devices can be placed on the market (see chapter 5). In the law, safety relates to the avoidance of harmful physical or chemical effects and of infections resulting from the design of the device. Hygiene and infection control measures to be adopted during the use of devices in healthcare are also laid down in medical guidelines.[62]

The efficiency of healthcare has become increasingly important in recent years.[63] Efficient care means achieving the greatest possible health benefits using the available financial and other resources. Efficiency relates mainly to the deployment of healthcare, but can also impact on the choice of medical devices, particularly when it comes to the use of costly resources such as a surgical robot.[64] Client focus plays a role in the use of devices, based on the importance of minimising patient discomfort. In addition to the frameworks for good care, ease of use for the healthcare worker is also a factor in the use of devices. Devices must be easy and efficient for healthcare employees to use, to ensure that the medical treatment can be carried out in the best possible way. Client focus and ease of use for the healthcare employee contribute to some extent to effective and safe care.[63]

### 2.3.2 Sustainability as a value in healthcare

The current frameworks for good care do not explicitly include sustainability aspects such as the environmental impact. The frameworks are dictated by what is of direct importance to the individual patient’s health. Indirect or long-term effects on public health caused by negative environmental impact are rarely taken into consideration in healthcare decisions. Although, for a long time, the environmental impact of healthcare was also not a priority for policymakers, the situation has changed in recent years.[65] The Committee believes there are strong grounds to incorporate environmental impact within the frameworks for good care (Figure 3 on the next page). A comparable model has been described by the UK Royal College of Physicians. [157]

### Sustainability deserves a place within the framework of good healthcare

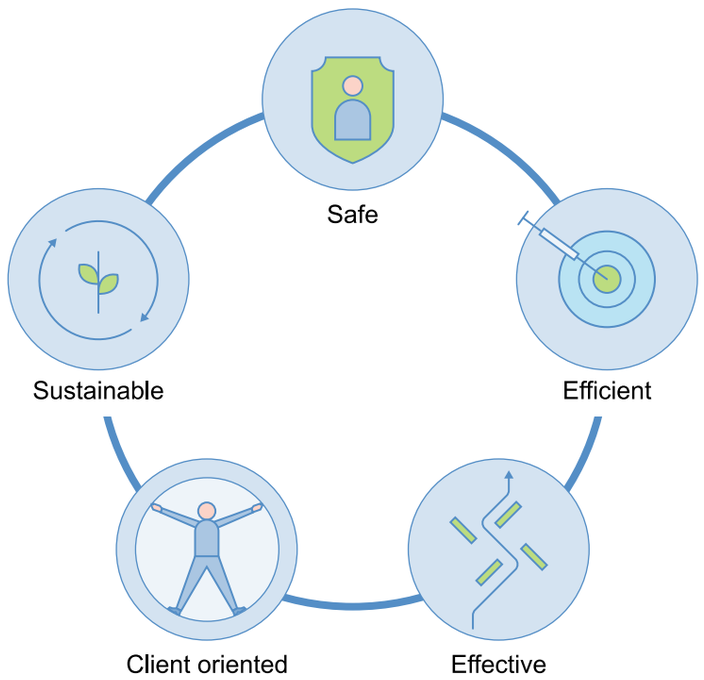



**Figure 3** Frameworks for good care

Scientific knowledge about the effects of climate change on the living environment and health has increased. The 2019 Lancet Countdown report states that climate change and its effects pose a huge threat to public health.[3] Healthcare itself has also been found to contribute towards the problem of an unhealthy living environment.[2,4] Since then, there have been calls for sustainability improvements from various parties and in particular from the healthcare sector itself.[11,66-70] The main reason for improving sustainability in this area is to achieve health.

Another argument in favour of including environmental impact in the definition of good care is that the environment, nature and ecosystems are valuable in themselves.[71] The intrinsic value of nature has long been advocated by parties such as environmental ethicists, who focus not on humans but on the ecosystem (ecocentrists). This vision has become more important in light of climate change and biodiversity loss. These kinds of environmental ethics concepts have also become an increasingly hot topic in medical ethics over the past few years.[72]

Finally, there is a growing awareness that the health of humans, animals and the environment are inextricably linked. This type of integrated approach is reflected in the United Nations ambitions for a sustainable future, which encompass humans, the environment and economic progress, and which advocate an approach that views these three aspects in conjunction with one another (people, planet and prosperity).[73] In the field of science, too, there is a trend towards integrated research that takes into account the environment and health. Examples include relatively new scientific approaches such as one health, planetary health and green bioethics.[74-76]

The Committee believes that the above developments in knowledge of, and insight into, the interdependence between the living environment and health constitute grounds to incorporate sustainability into the frameworks for good care. Such an approach is also in line with the Constitution,

which stipulates that the government must take measures to promote public health (Article 22) and must protect and improve the living environment (Article 21). The Committee addresses this subject in greater detail in the following paragraphs.

### 2.3.3 Making sustainability an explicit value

In order to make the use of devices in healthcare sustainable, the Committee believes that sustainability must be made an explicit value in all areas of healthcare. According to the Committee, this requires that sustainability be enshrined in law, for example by including it as an explicit element of good care in Article 2 of the Wkkgz. The Committee acknowledges that such a measure has implications not only for device use (the request for advice), but for healthcare as a whole.
The importance of improving sustainability is high, however, and the arguments set out in favour of sustainability improvements are just as applicable to healthcare as a whole as they are to devices.

Once values have been made explicit, it becomes possible to see where decisions affect different values. It is then important to seek a solution that does the greatest possible justice to all values. The first relevant question is whether there is actually a conflict of values or whether incorrect assumptions perhaps play a role. Does the more sustainable option actually pose a higher risk of infection? Does the fact that a reusable device is made of metal really cause patient discomfort? Are the costs of more sustainable devices actually higher or do investments pay for themselves in the longer term? Conflicting values are an incentive to search for solutions. For example, if the use of reusable devices is desirable for reasons of sustainability, but there are doubts regarding safety (risks of infection), other ways of guaranteeing safety can be sought such as risk monitoring or cleaning protocols. Another option is to explore the possibility of changing the design of a device. Making values explicit therefore helps to create transparency in healthcare decision-making and in the use of devices, which is important in order to justify decisions in areas such as policy.

Making sustainability an explicit value of good care is not enough. It says nothing about how this value should be taken into consideration, or the importance that should be assigned to it. An assessment framework is essential to look at these issues in greater detail. Such a framework would address the proportionality of the values, determine preconditions and focus on the goal of optimising all values. The Netherlands Centre for Ethics and Health (CEG) identified the need for such an assessment framework back in 2012.[65] Green bioethics, a new approach in the domain of ethics, also proposes an integrated assessment of values of health and the living environment for the purpose of sustainable healthcare.[77]

Questions that can be addressed when producing an assessment framework for sustainable care can include:

- Is care for the environment a separate value or do we need to broaden the definition of health (one health)?
- Is there a hierarchy of values, or are they all equally important?
- When should sustainability aspects be decisive and when should they not?
- How do we take the effects of negative environmental impact on public health and on the health of future generations into consideration?
- How do we ensure that patient safety is not placed at risk?
- Are we willing and able to accept a certain level of infection risk?

Such questions cannot be answered by medical experts alone, but are relevant to society as a whole and to patients in particular.

The Committee is aware that it will not be easy to take sustainability into consideration as a value in the use of devices. Existing knowledge of the environmental impact of device use is still lacking in many cases. This knowledge will need to be generated over time. In addition, sustainability is a much less tangible value than direct patient interest and financial interests. The effects of non-sustainable decisions only become apparent in the longer term and largely unfold elsewhere. The negative environmental and societal consequences are also referred to as the hidden costs (see section 4.2.2). It is important to make these hidden costs as visible and tangible as possible so that they can be taken into consideration in the assessment framework.

The Committee recommends asking a multidisciplinary group of experts (such as medical, ethical, environmental and social scientists) to produce the desired assessment framework, and to also involve stakeholders such as patients, patient associations and the general public in this process.

# 03 opportunities to improve sustainability in healthcare

The effect of sustainability as a value of good care requires implementation of this value throughout the healthcare sector. The Committee believes that sustainability must be incorporated into the strategic vision of healthcare institutions, into medical guidelines, into healthcare practice and into the training of healthcare workers.

## 3.1 Strategic vision of healthcare institutions

The Committee believes that healthcare management boards should to take clear control of sustainability improvements. Responsibility in this area must lie with the management board, with the healthcare institution's supervisory board overseeing efforts. To achieve knock-on effects in all areas of healthcare, healthcare institutions should include sustainability as a value in their strategic vision. There is no need to wait for new government policy or legislation: this action can be implemented with immediate effect. Various healthcare organisations such as hospitals and sector associations have already included a number of sustainability goals in their strategic vision, however the goals are often too limited and mainly relate to reducing $CO_2$ emissions and the use of clean energy. There are not yet any specific objectives relating to device use. Experience of $CO_2$ reductions at healthcare institutions shows that setting specific objectives, along with road maps for achieving these objectives, is effective.[10]

The Committee has identified a number of important factors that should be considered when incorporating sustainability into a strategic vision. One is that the vision should preferably relate to the long term, in line with policy agendas for a circular economy and greenhouse gas emissions, which run up to 2030 and 2050. Another is that the vision must be given specific form in goals for improving the sustainability of devices and must relate to aspects such as policy on care indication and on the use of devices, business operations including procurement strategy, cleaning, disinfection and sterilisation facilities, and contracts with waste processors. It is also important that the vision is broadly promoted within healthcare institutions to healthcare employees and patients. According to the Committee, a greater impact can be achieved if healthcare institutions and organisations work together and set common goals. In the United Kingdom, the National Health Service has long been committed to sustainability improvements in healthcare.[78] This has now resulted in a sharp reduction in $CO_2$ emissions.[79] Collaboration is essential in order to achieve sustainability improvements on a similar scale.

A compulsory sustainability report is one option to encourage sustainability improvements and gain an idea of the progress made by sustainability measures. The EU Corporate Sustainability Reporting Directive applies to large companies – no equivalent exists for healthcare institutions (see chapter 5).

A strategic vision that includes sustainability and that is driven by the healthcare management board, provides support for existing sustainability

initiatives by groups such as green teams. In order to implement the sustainability goals in the strategic vision and support initiatives in the workplace, relevant expertise must be brought into the organisation. One way of doing this is by appointing a sustainability coordinator who is responsible for implementing sustainability policy. This person will be required to collaborate and liaise with relevant device users (healthcare employees) and professionals such as infection control experts, buyers, environmental services and technical services, where applicable.

The review of the Green Deal in Sustainable Healthcare revealed that healthcare institutions need a supporting structure to improve sustainability at national level.[10] Knowledge exchange, successful sustainability initiatives, and ideas for innovation can be shared within this structure and, where necessary, supported or passed on to other parties. The Committee believes that a national supporting structure that deals specifically with sustainability improvements in healthcare may be helpful for the various layers responsible for implementing sustainability: at administrative level, and for sustainability coordinators.

When setting sustainability goals, the Committee recommends prioritising the most effective strategies, such as the non-use or reduction of healthcare and medical intervention and the use of devices (refuse [R0] and reduce [R1]). These sustainability strategies fit in well with the focus placed in recent years on sensible and efficient healthcare and prevention.[80-83] Disease prevention is the most effective way of making healthcare more sustainable.[66] It is therefore logical for healthcare institutions to place a strong emphasis on this in their policy. In addition, a long-term strategic vision provides scope to eliminate any tension between values such as sustainability and efficiency. Sustainable investment, for example the purchase of reusable devices or the roll-out of programmes aimed at changing behaviour, can pay for themselves in the longer term (see section 3.4).

## 3.2 Medical guidelines

Sustainability or environmental impact is not currently a criterion in the development of healthcare guidelines. The recommendations for the provision of care in medical guidelines are based on systematic reviews of scientific research and assessments of the various healthcare options, supplemented with the expertise and experiential knowledge of healthcare professionals.[84] Guidelines are drawn up by occupational groups of medical professionals such as the Dutch Federation of Medical Specialists, the Dutch College of General Practitioners, the Netherlands Association of Nurses and Carers and the National Institute for Public Health and the Environment (RIVM) National Coordinator Infectious Disease Control. The Inspectorate for Health and Youth Care (IGJ) uses these guidelines as a benchmark during inspections. The Committee believes that sustainability should be explicitly incorporated into medical guidelines. Organisations that have made a start in this respect include

the National Health Care Institute (Zorginstituut Nederland), whose assessment framework places a focus on both efficient and sustainable healthcare.[85] The assessment framework is used to monitor the quality of care by assessing quality standards. An accompanying guide to efficiency and sustainability has been produced. The Committee takes the view that sustainability could be more firmly embedded in quality standards, for example by including in the conditions applicable to quality standards, which are laid down in law in Article 11b, paragraph 2, of the Wkkgz, that standards to be recorded must contain a section on sustainability explaining how this value has been taken into account.

A further impetus for the implementation of sustainability in guidelines is provided by the surgical disciplines. A guide to producing a section on sustainability in surgical guidelines is currently in development.[86] The guide is expected to be completed in 2022 and will serve as a tool for taking sustainability into account in surgical interventions. The guide may be used as input for the value assessment framework recommended by the Committee (see section 2.3.3). A logical next step would be to develop the guide for other medical guidelines. It is important that responsibility is assigned to the coordinating guideline committees. It is not necessary to wait for the regular review of a guideline in order to implement sustainability improvements. The Committee sees opportunities in the revision of guidelines by appointing a special working group for this purpose. This group can check existing guidelines for ways of reducing the use of devices without compromising other values. For example by identifying where clarification is needed on when devices do not need to be used. Removing interventions from the guidelines that offer little or no patient benefit also helps to improve sustainability.[87,88]

The Committee has identified two other relevant guidelines into which sustainability can be incorporated.

**Guideline on New Interventions**

The Dutch Federation of Medical Specialists published a Guideline on New Interventions in Clinical Practice (*Leidraad nieuwe interventies in de klinische praktijk*) in 2014.[89] This is a guide to the introduction of new technology, new medical techniques and process innovations in hospital daily practice. Including sustainability as a value in this guideline can mean that environmental impact is also taken into consideration in the development and introduction of new interventions.

The guideline can also contribute towards the controlled implementation of sustainable devices or processes. The Committee believes that the guideline can serve as a guide where there are grounds from a sustainability perspective to introduce new devices or new processes, but there is uncertainty about the effects of doing so.

**Infection control guidelines**

The *Samenwerkingsverband Richtlijnen Infectiepreventie* (national partnership for infection control guidelines) has been responsible for infection control guidelines since 2021.[62] This partnership is currently in the process of reviewing existing infection control guidelines: an opportunity to take sustainability considerations into account.

Sustainability can affect infection control guidelines in a number of ways. Avoiding or reducing the use of devices is the most effective approach in the pursuit of sustainability (refuse [R0] or reduce [R1]). To achieve this, it can be helpful to stipulate not only when infection control measures and personal protective equipment are required, but also when they are not required. A situation can then be avoided in which devices are used or actions are carried out to be on the safe side, in accordance with a guideline that has been interpreted too strictly. Other methods of administration that require no or fewer devices can also be explored (such as oral administration instead of via infusion), or the possibility of using devices for longer. The reuse of devices or their components subsequently offers potential to improve sustainability. Where single-use devices are chosen due to risks of infection, guideline committees could take a more critical look at the information supporting these risks. In many cases, no scientific research is available on the risks of infection associated with device use or reuse, and guidelines are based on estimates supported by general principles of microbiology and infection control.[26] Where doubts about infection risks exist, these risks could be monitored on the introduction of more sustainable devices or processes in line with the Guideline on New Interventions.[89]

Another way to incorporate sustainability into the guidelines is by substantiating procedures for device reuse. Reusable devices are generally more sustainable than single-use devices, provided they are reused more than once. Both proper guidelines and effective protocols (operating instructions) for device cleaning, disinfection and sterilisation are essential to enable reuse. Such guidelines and protocols provide healthcare institutions, and particularly the responsible sterilisation departments and infection control experts, with the necessary tools to guarantee the safety of reusable devices. Manufacturer-supplied instructions are also important for the development of protocols (see also chapter 5).

## 3.3 Insured care

The National Health Care Institute advises the Ministry of VWS on the content of the basic health insurance package. This is done on the basis of the Healthcare Insurance Act and the Long-Term Care Act. Care is assessed by weighting four criteria: necessity, effectiveness, cost effectiveness and feasibility.[90] Depending on the context there is scope for additional arguments, such as the reduction of health inequalities. The Committee believes that sustainability must be incorporated as an

additional value in decision-making related to insured care. Sustainability can be taken into account in minor (what type of device is used) but also major considerations (what type of treatment is offered).

Sustainability must also become a consideration in negotiations between healthcare institutions and healthcare buyers, such as healthcare insurers, care administration offices and municipalities. Healthcare insurers can play a key role in improving sustainability, for example by imposing targets on healthcare institutions and removing funding barriers.[5] Best value procurement can be a tool in this respect. In best value procurement, the buyer defines the goals that must be met, while the care provider (the healthcare institution) describes how it can help to achieve these goals.[91]

## 3.4 Sustainable behaviour in healthcare practice

Common values within healthcare institutions (which are explicitly laid down in documents such as strategic visions and medical guidelines) are reflected in the daily actions of healthcare professionals. That is why it is important that sustainability is broadly shared and promoted as an explicit value in healthcare, to facilitate behavioural change.

Intentions and habits both play a role in behavioural change.[92]
An awareness of the importance of a sustainable approach to devices and the individual's role in it is fundamental to the intention to change behaviour.[93] The behaviour of others is also important, particularly people who belong to the same group.[94] Healthcare professionals can therefore serve as a role model for other colleagues and raise each others awareness of the importance of sustainable behaviour.[95,96] In addition, training courses or behavioural interventions are needed to create awareness, break existing habits, and achieve permanent behavioural change in the workplace.

There are several examples of successful interventions that have originated in the workplace. The Good Glove Use project, for instance, has resulted in the safer, more economical and more sustainable use of gloves. It has also been shown that substantial reductions in the energy consumption of medical equipment are possible when awareness is raised among healthcare employees (see the box in chapter 2). Moreover, pilot projects have demonstrated that it is possible to reduce the number of surgical instruments used.[95,97,98] This results in less waste (single-use devices), less unnecessary cleaning, disinfecting and sterilising of reusable devices and smaller stocks of instruments. The background to these pilot projects is that standard pre-sterilised surgery packs are frequently used in operating theatres. These packs often contain more instruments than needed.[99]

The Committee recommends monitoring and reporting the effects of sustainability initiatives. This monitoring must relate to aspects of the environmental impact of healthcare in a broad sense to ensure that

environmental impact is not passed on to other areas of healthcare. It must also include the potential effects on healthcare for the patient, as proposed in the Guideline on New Interventions (see 3.2).[89]
Monitoring and reporting the effects of sustainability initiatives provides the opportunity to share the results at national level and to enable upscaling.

## 3.5 Training of healthcare employees

The professional field has already made a number of calls for the inclusion of sustainable healthcare and knowledge of this subject in medical training.[100,101] Incorporating sustainability into the frameworks for good care can contribute to this, as sustainability then becomes an integral part of healthcare work as a profession. Sustainable healthcare merits a place in both refresher training provided to current healthcare workers and in the training of the future generation. The manner and content of such training is to be defined.

# 04 medical devices in a circular economy

A transition to a circular economy of devices is essential to make the use of devices more sustainable. This involves changes throughout the chain, from design stage, production stage and use stage to waste stage.
The transition calls for innovation, knowledge development and exchange, and the reorganisation of facilities and logistics in healthcare. Government policy establishes a foundation for progress towards a circular economy, however the devices sector isn't sufficiently included. The Committee advocates interministerial collaboration in the development of policy designed to improve the sustainability of the device supply chain.

## 4.1 Circularity of devices

### 4.1.1 Strategies for circularity

A sustainable society is more than a circular economy alone, however a circular economy does have a major impact on sustainability improvements and meeting sustainability goals. Circularity means that resources, materials and products lose as little of their practical value as possible during their life cycle.[19] A fully circular economy requires little new resources and generates no waste. The strategies for circularity are formulated in a model known as the 10 Rs ladder. The 10 Rs refer to strategies in decreasing order of effectiveness (see figure 4). Circularity does not relate to device energy consumption, which must therefore be viewed separately.

**A higher step (and lower R-value) means greater value retention**

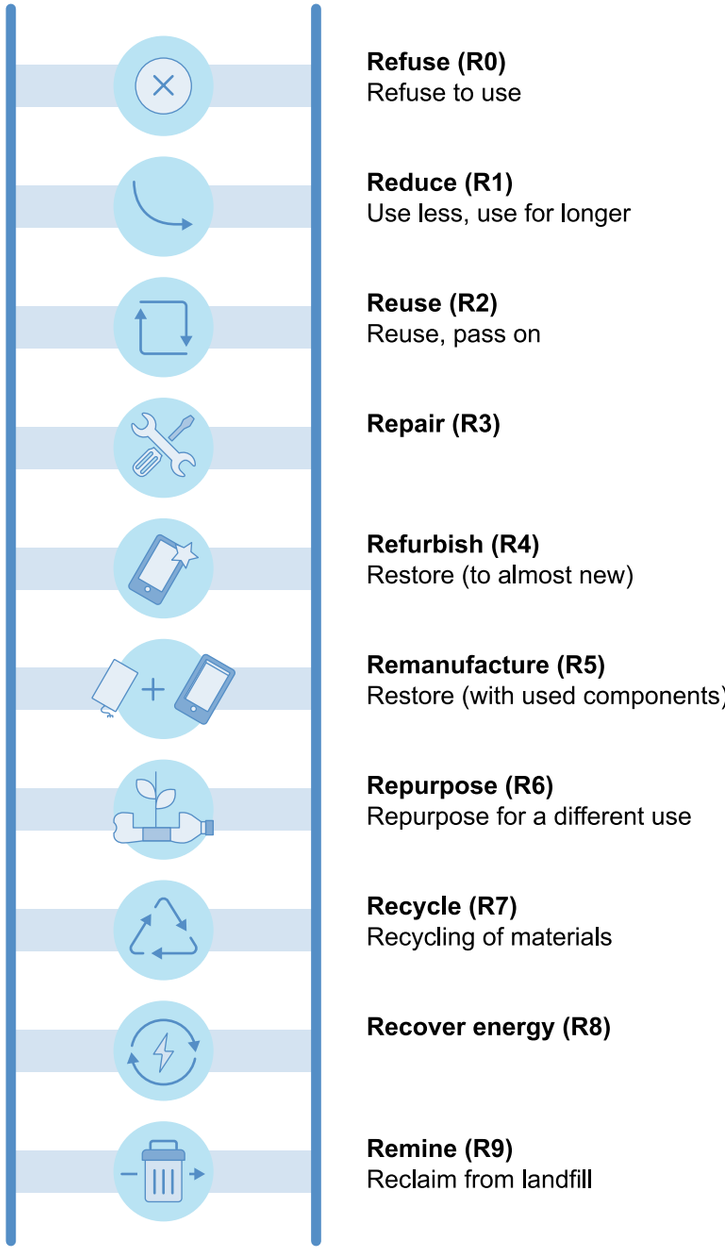



**Figure 4** The 10 Rs ladder

There are two ways of applying the 10 R strategies: to the life cycle of pre-designed and existing products, and to the life cycle of the concept and design of a new product to be developed.[19] Circular strategies for existing products include reuse and repair. The reuse of a product results in greater value retention than the reuse of the materials. Where new products are designed a more sustainable version can be achieved, for example through the use of innovative technology and renewable resources (resources that cannot be exhausted, such as vegetable crops or organic waste), or by ensuring by design that a product can be reused.[102,103] The aim in designing circular products is to minimise the value lost after use.

New business models for more sustainable devices can accelerate the transition to a circular economy.[104] Examples include services such as 'product as a service', sterilisation, reprocessing and repair services, platforms for second-hand sales or shared use, or the provision of refurbished devices.

Figure 5 illustrates a number of potential sustainability improvements for the case studies of gloves, surgical staplers and ultrasound devices.

**Application of the R strategies offers a wide range of opportunities to improve sustainability in the various groups of devices**

A few examples from the case studies on gloves, surgical staplers and ultrasound devices, by way of illustration

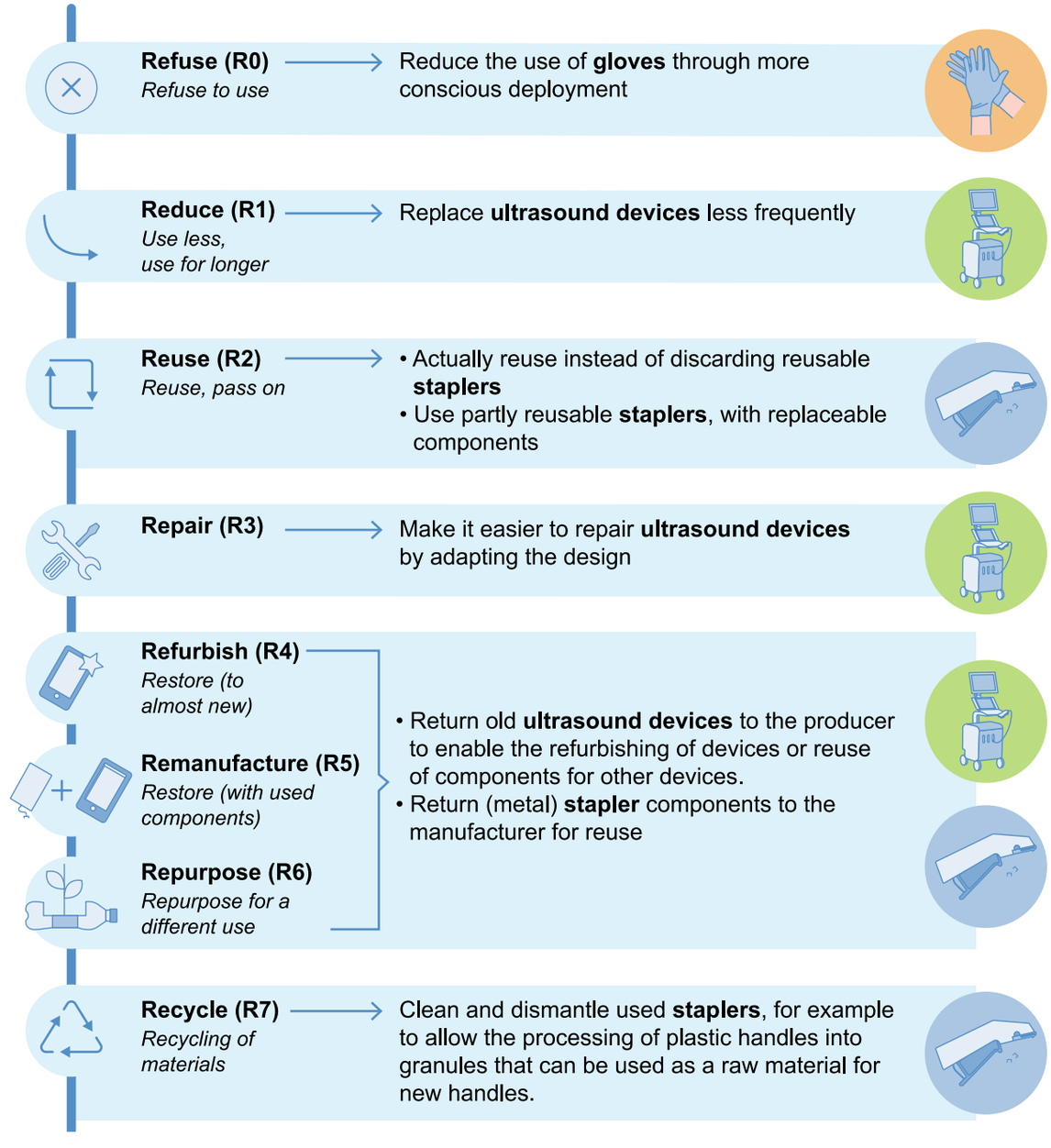



**Figure 5** Potential sustainability improvements

### 4.1.2 Design and production stage

The supply of energy-efficient, sustainably designed and produced devices is currently still very limited. For example, reusable versions of certain devices are not available and there are few devices whose components or materials can be reused. Moreover, renewable or recycled resources are rarely used for these products. This means that considerable gains can potentially be made by making devices circular through innovative design. However, circular design still does not appear to feature high on producers' innovation agenda.[105] At least until a few years ago, the same applied to the medical technology sector in the Netherlands, which mainly supplies diagnostic and monitoring equipment.[22] Two of the reasons for this are that very few sustainability requirements apply to the medical industry (chapter 5) and companies perceive a lack of market demand.[105] There are also technical challenges due to the need for reusable medical devices to be designed so that they can be properly cleaned, disinfected and/or sterilised.[29] As well as the design, there is still considerable scope to make the device production process more sustainable. Various life cycle analyses show that much of the environmental impact of devices is associated with the production stage.[51,106]

Demand for sustainably produced circular devices needs to be created at an international level. Nevertheless, healthcare institutions can exert significant influence on the supply of devices through their procurement decisions, thus creating market demand.[67] In order to better align demand and supply, healthcare institutions and suppliers need to make sustainability a topic of discussion during negotiations.[107]
Moreover, if healthcare institutions work together to generate demand for circular products they can exert even more influence on supply.
Circular procurement of devices is therefore an important means of improving the sustainability of the supply. The Committee has identified the following specific opportunities for improvement:

- better use of existing manuals for the drafting of sustainable procurement requirements for products;[108]
- addition of sustainability requirements to frequently used procurement guides such as PIANOo;[107,109]
- more intensive collaboration between procurement and suppliers in the area of sustainability, in which both parties jointly look for sustainable business models and/or innovations;[110]
- use of new procurement methods such as best value procurement or innovation procurement. Innovation procurement involves issuing a tender for an innovation rather than a ready-made product, of which the buyer is the first user.[111] In best value procurement, the buyer sets out the goals and the supplier determines how best to achieve them.[91] Sustainability can be incorporated into both methods of procurement;
- making circular procurement more compulsory (see chapter 5);
- offsetting the negative impact of a product on the environment and society in the product price ('hidden costs', see section 4.2.2).

Innovation and sustainable design can be a solution where conflicts of values occur, for instance between sustainability and safety.[112] In such cases, the manufacturer has a responsibility to make sustainability improvements possible through innovative solutions.[113]
Manufacturers themselves can also contribute towards norms and standards for sustainable devices, for example through the Netherlands Standardization Institute.[114]

### 4.1.3 Use stage

During the use stage of a product, the most effective strategies for value retention are once again ‘refuse’ and ‘reduce’. These strategies can partly be applied by users and healthcare employees themselves, as described in chapter 2. For example, they can focus on less, or more energy-efficient, use by adopting a conscious approach to devices. ‘Reduce’ can also be achieved through proper inventory management to minimise product wastage by monitoring expiry dates. For example, care should be taken to ensure that products are used up following a change in supplier. The shelf life and usage period of devices can also potentially be extended through research, innovation and adjustments to factors such as use, packaging, logistics and storage.

‘Reuse’ can be achieved through the use of reusable devices. Existing life cycle analyses show that reusable devices are more sustainable than single-use devices.[106,115-118] These studies take into account the environmental impact of the full product life cycle. This is important, as the cleaning and sterilisation process contributes significantly to the environmental impact of reusable devices.[55] A proper comparison of environmental impact can only be carried out if the full life cycle is taken into account. This approach also makes it possible to estimate how many times a reusable device needs to be used in order to be sustainable.
For example, a face mask that is reused five times has a 58% lower $CO_2$ footprint than a single-use face mask.[115] Life cycle analyses can therefore help to gain insight into the environmental impact of a device, however they are currently only carried out for a limited number of medical products and processes.[119] Furthermore, many of the studies only calculated one ($CO_2$ emissions) or a limited number of aspects of the environmental impact, whereas environmental impact encompasses multiple relevant aspects.[119]

In the transition to a circular economy, healthcare institutions must be organised in a way that allows the reuse of devices or materials. This requires additional facilities and/or logistics, depending on the type of healthcare institution. Examples include the establishment or expansion of repair services and cleaning, disinfection and sterilisation processes (internal or external), stock management and the digital tracking and tracing of instruments, as well as waste flow logistics.
Healthcare institutions will need to make organisational and financial investments in the short term to achieve this, although these investments

will be recouped in the long term. The Committee believes the government can play a role in supporting this.

#### 4.1.4 Disposal stage

Healthcare institutions generally separate their waste into paper, glass, residual waste and specific hospital waste. Almost all medical devices and personal protective equipment end up in residual waste or specific hospital waste. Residual waste is incinerated as industrial waste and specific hospital waste is collected separately, transported in sealed containers and incinerated by the special waste processor ZAVIN.
The number of recycling companies that recover and reuse device components or materials is currently limited. Moreover, the option of contracting different processors is unattractive to healthcare institutions. A small handful of companies in the Netherlands are currently experimenting with the reprocessing of used devices. Materials are then reused for other, lower value applications. For example, stainless steel medical instruments are used to make instrument nets (in which instruments are collected for sterilisation). Producing new medical devices from waste devices poses a bigger challenge, as this requires information about the exact composition of the recycled raw materials (which could be achieved by updating the regulations, see chapter 5). It is essential to prevent hazardous substances (such as plasticisers) from ending up in devices through the recycling process.[120]

Another way to encourage the reuse of products, components or materials is through the application of extended producer responsibility (see chapter 5). There is already a directive on the return of electronic equipment, but it is unclear to what extent this works within healthcare institutions.
To ensure that such directives work well, healthcare institutions must organise their logistics so that products are returned to the producer after the use stage.

### 4.2 Government policy

#### 4.2.1 Current policy in relation to a circular economy

To facilitate the transition to a circular economy, the government-wide 'Circular Netherlands in 2050' programme was launched in 2016 with the aim of reducing the use of raw materials (minerals, metals and fossils) by 50% by 2030, and achieving a fully circular economy by 2050.[1]
One element of the programme is the Raw Materials Agreement, in which the government, businesses, trade unions and environmental organisations have reached agreements in order to realise the transition to a circular economy. The agreement identifies three different routes to achieve a circular economy:

- raw materials in existing chains are used to their full potential;
- new raw materials are extracted from renewable and generally available sources;
- products are designed to be circular.

‘Transition agendas’ have been produced for a number of sectors, namely biomass & food, plastics, manufacturing, construction and consumer goods. According to the PBL Netherlands Environmental Assessment Agency (PBL), this policy has laid the foundation for a circular economy.[105] Efforts are currently focussed mainly on recycling and repairs, however, while innovations using alternative raw materials that enable high quality reuse are still lagging behind. There has been little change in total resource consumption in the Netherlands since 2010, and the volume of waste produced has actually grown in recent years. The PBL therefore calls for policy to be intensified in order to achieve the objectives.[105]

The healthcare industry and the devices sector are not partners in the transition agendas. For this reason, the Committee agrees with the findings of the PBL and other reviews that government-wide policy is urgently needed to promote a circular economy, since the transition affects a range of production chains and sectors.[5,105,121]

For the healthcare sector, public and private parties have reached agreements on circularity within the Green Deal in Sustainable Healthcare, although these agreements are less specific. The aim is to ensure that circularity becomes a permanent part of the procurement process, including through the dissemination of knowledge.[8] Progress in this area has proved to be slow.[10]

### 4.2.2 Opportunities to accelerate sustainability improvements

The government has a number of policy instruments to initiate, manage and accelerate sustainability improvements. A circular healthcare sector, and thus a sustainable policy on devices, calls for a different approach to health, safety, the environment, economy and innovation. The current organisational structure is not yet adequately equipped for this, and policy appears to be insufficiently coordinated between ministries.[10,105] In line with the PBL’s findings, the main need identified by the Committee is for interministerial collaboration between the Ministry of Health, Welfare and Sport (VWS), the Ministry of Infrastructure and Water Management (I&W) and the Ministry of Economic Affairs and Climate Policy (EZK), among others.

In addition, sustainability must be made an integral part of policy on health and other areas. The temporary VWS Sustainable Healthcare programme is a step in the right direction, but needs to be more widely supported and made more permanent. The Green Deal in Sustainable Healthcare 3.0 and the Comprehensive Care Agreement, which are currently in preparation, offer opportunities for the comprehensive implementation of sustainability improvements.[122] Compared to other initiatives, the transition to circular devices has barely started. The Committee recommends the development of a transition agenda for sustainable and circular healthcare, with a vision and strategy with measurable goals that transcend government terms of office. It considers this essential in order to achieve a

fully circular economy, including a circular healthcare sector, by 2050. A combination of policy measures is needed to make sufficient progress towards this goal.

To date, Dutch policy has focused mainly on voluntariness and market forces. The PBL concluded that more compulsory methods are needed for the transition to a circular economy. The Committee believes that the same applies to the healthcare sector. An EU-wide approach and legislation are essential (see chapter 5). Financial incentives such as levies and subsidies can also be used at national level to encourage sustainability improvements. EU Member States can give their own interpretation, for example by granting subsidies for circular and energy-efficient products and production processes, or imposing levies on environmentally unfriendly products. For example, the EU has drawn up a Waste Framework Directive that allows Member States to implement the principle of 'the polluter pays'.[123] Fiscal greening measures are already an option under the current EU legislation, such as a VAT reduction or refund on refurbished products and certain repair services.

It is easier to promote the more sustainable production of devices through laws and regulations aimed at producers when devices are manufactured closer to home. This also makes it easier to ensure device availability and security of supply.[124]

In addition, experts call for a financial system that offsets hidden costs in the product price, to ensure that the real price is paid. The hidden costs are the negative effects of a product on the environment and society.[66,125-127] In the current economy, these negative effects of production, use and waste processing are not offset in the price.[105] This means that non-sustainable products, including medical devices, can be offered at low prices. For example, stainless steel surgical scissors designed for single use can be purchased for just a few euros, and primary raw materials cost less than recycled raw materials. This system is untenable in a circular economy.

As prevention and sensible healthcare are effective strategies to improve sustainability, the Committee advises the government to permanently support, continue and expand programmes that are geared towards this.[80,83] The Committee also believes that the government needs to stimulate sustainable innovation. One way of doing this is by bringing together knowledge from public (universities, healthcare institutions and research institutes) and private sectors (manufacturers and waste processors) by funding new integrated knowledge development.
In addition, the Committee feels it is useful to incorporate sustainability into advice on innovations through platforms such as *Zorg voor Innoveren* (Care for Innovation) and Health Innovation Netherlands. Medical device developers can already visit these platforms for advice, however this advice does not yet include sustainable design and production.

# 05
# improving the sustainability of devices through laws and regulations

Policy alone is not enough to achieve sufficient progress in making devices more sustainable. A more compulsory approach enshrined in law is needed. The Committee argues that the Netherlands can and should play a leading role by committing itself at European and national level to improve the sustainability of both medical devices and personal protective equipment. It can do this by making sustainability part of laws and regulations that specifically apply to devices (vertical legislation) and by ensuring that general regulations that encourage sustainability improvements also apply to devices (horizontal legislation).

## 5.1 Applicable laws and regulations

### 5.1.1 Legislation relating to devices

Legislation exists that specifically applies to the product groups of medical devices and personal protective equipment. This is referred to as vertical legislation. These laws stipulate requirements that these products must meet. European regulations on personal protective equipment are set out in the Personal Protective Equipment Directive (PPE directive).[17] This directive contains requirements for the design and production of personal protective equipment with the aim of ensuring the health and safety of users. The directive has been implemented in the Netherlands in the Personal Protective Equipment (Commodities Act) Decree.[128]

European regulations on medical devices are set out in the Medical Device Regulation (MDR).[15] This regulation lays down safety and performance requirements that medical devices must meet in order to be marketed in Europe. This European legislation has direct effect in the Netherlands. Where the MDR provides scope to do so, Member States themselves are free to make certain decisions. In the case of the Netherlands, these decisions are set out in the Medical Devices Act, the Medical Devices Decree and the Medical Devices Regulations.[129-131]
Some products can fall under both the PPE directive and the MDR. The intended use of the device determines which legislation takes precedence. Separate legislation (the IVDR) applies to *in vitro* diagnostic medical devices.[132] The Committee will not specifically address the IVDR, however some of the opportunities it identifies for the MDR will also apply to the IVDR.

### 5.1.2 Other legislation

In addition to specific (vertical) legislation for devices, horizontal legislation applies to the healthcare sector or (parts of) the life cycle of personal protective equipment and medical devices. For more information see table 1a an 1b on page 40.

The European policy framework for improving sustainability includes the Green Deal: a road map for the modernisation of the economy to achieve a climate neutral Europe in 2050.[133] One of the key elements of the Green Deal is the circular economy action plan (CEAP).[134] The CEAP agenda stimulates the transition to a circular economy with the help of economic

players, social organisations, the general public and consumers.
The agenda focuses on the seven areas in which resource consumption and the potential for circularity is highest: electronics and ICT, plastics, textiles, foods, water and nutrients, packaging, batteries and vehicles, buildings and construction materials. In the first CEAP, the emphasis was on bringing together policy on the environment and raw materials.
Laws and regulations on the design, production and use of products are still largely lacking.[105] In 2020, the second CEAP included the goal to develop laws and regulations that affect more stages in a product life cycle. The desired situation is one in which products are made of sustainably sourced raw materials, last longer, are easier to reuse or repair and contain as many recycled materials as possible.

Legislation is a way to enshrine sustainability of medical devices.
This requires legislation at European level, as requirements then apply to products across the European market, including those produced abroad.
Manufacturers are thus encouraged to redesign products, the production process, use stage and waste stage, and the next step in making the world market more sustainable becomes easier.

## 5.2 Opportunities to improve sustainability

Improvements to the sustainability of devices can be promoted through both vertical and horizontal legislation and regulations (table 1a and 1b on the next page). Many of the current horizontal laws and regulations set out implementation measures for a select number of product categories.
The devices sector is not usually mentioned, which means that this sector often does not fall under the relevant legislation. Some of the horizontal legislation will be revised in the context of the Green Deal and the CEAP.[134] This includes a legislative proposal to substantiate green claims made by companies, the strategy for circular textiles, requirements on packaging and packaging waste and the Ecodesign directive.
Opportunities will therefore be created to include devices in the legislation and thus improve sustainability in the various stages of the life cycle.
It is important to focus on legislation on the entire life cycle of the product, from design stage, to use stage, to waste stage.

The Committee believes that the Netherlands should take on a leading role in enshrining sustainability in European and national law.
The Netherlands also did this during the drafting of the MDR.
The Netherlands can achieve this by joining forces with countries that signed a commitment to sustainable and climate-resistant healthcare in the run-up to the international climate conference in 2021 (COP26) or with countries that are active within the European Green Deal and the CEAP agenda.

**Table 1a** Vertical legislation relating to medical devices and personal protective equipment

| Law | Description |
|---|---|
| **Personal protective equipment** | |
| Personal Protective Equipment Regulation 2016/425/EU | European rules that personal protective equiment must comply with for the protection of the user against injury |
| Personal Protective Equipment Commodities Act | Dutch law based on the European Regulation on Personal Protective Equipment |
| **Medical devices** | |
| Medical Device Regulation 2017/745/EU | European law setting out frameworks and requirements to ensure the quality and safety of medical devices |
| Medical Devices Act | National rules on the implementation of the Medical Device Regulation and the *In vitro* Diagnostics Regulation |
| Medical Devices Decree | National rules on the use of medical devices such as nationally defined rules on the reprocessing of single-use devices |
| Medical Devices Regulations | Additional national rules such as the designation of competent authorities |
| *In Vitro* Diagnostic Regulation 2017/746/EU | European law setting out frameworks and requirements to ensure the quality and safety of *in vitro* diagnostics |

**Table 1b** Horizontal legislation relating to improved product sustainability

| Law | Description | Applicable to devices |
|---|---|---|
| Ecodesign Directive 2009/125/EG | European framework for the minimum ecodesign requirements for energy-related products | No |
| Waste Electrical and Electronic Equipment Directive (AEEA/WEEEE) 2012/19/EU | European rules to encourage the sustainable production and consumption of electrical and eletronic equipment/waste | Yes |
| Restriction of Hazardous substances (RoHS) Directive | European rules to limit the use of certain hazardous substances in electrical and electronic equipment | Yes |
| Packaging and Packaging Waste Directive 94/62/EG and 2018/852 | European rules to limit the production of packiging waste and to promote recycling and reuse | Yes |
| Single-use Plastic Directive 2019/904 | European rules to reduce single-use plastics | No |
| Registration, Evaluation, Authorization and restriction of CHemicals (REACH) EG 1907/2006 | European rules for the registration, evaluation and authorisation of chemical substances produced or imported in Europe | Yes |
| Corporate Sustainability Reporting Directive (CSRD) 2014/95/EU | EU legislation that requires certain large companies to provide information on how they operate and address environmental issues | No |
| Decree on Extended Producer Responsibility (EPR) | National and international rules governing an extended producer responsibility scheme for waste management | Yes, but only for electrical/electronic equipment |
| National Waste Management Plan (LAP3) | National legislation and regulations on waste management | Yes |
| Carriage of Dangerous Goods Act - BWBR0007606 | Nationale rules for the transport of hazardous substances by road, water and rail | Yes |

### 5.2.1 Impose requirements on the product

**Encourage a sustainable design**

The most effective approach is to look at the sustainability of a product and the production process in the design phase. This can be done, for instance, by ensuring that a product can be repaired and that the product is suitable for reuse and therefore easy to clean and sterilise. The PPE directive, the MDR, the IVDR and the associated national laws do not currently set any explicit greening goals, as they relate exclusively to product safety and efficacy. There are also no articles or sections that explicitly address environmental aspects or sustainability. There is scope, however, in the MDR and IVDR to do this by means of an implementing act to amend the design requirements in Annex 1. This is a relatively simple route that does not require a full review of the regulation, but that does require a political consensus within Europe. The proposal for the revision of the EU Construction Products Regulation can serve as an example,[135] which contains an advanced proposal for requirements on environmentally friendly and sustainable design in Article 22.
If sustainability is included as an essential requirement for devices in the MDR, harmonised standards can be drawn up that make sustainability a specific and applicable requirement.

Product design requirements relating to energy efficiency, reducing negative environmental impact, reusability and repair of products are set out in the Ecodesign Directive. It is currently being examined whether the Ecodesign Directive, which now applies mainly to consumer products such as electronics, ICT equipment, textiles and furniture, can be extended to other product groups.[136] The Committee believes that this should include the devices sector.

**Encourage a sustainable composition**

Devices are often made of new (virgin) and depletable raw materials such as metals and polymers. In addition, many devices consist of multiple components each made of a different type of material. Combining different types of materials in a single product makes reprocessing difficult or, in some cases, impossible. As with encouraging a sustainable design, an implementing act could be used to impose requirements on the material or composition, for example by making a specific percentage of reused materials compulsory in a product. The proposal for the revision of Article 22 of the EU Construction Products Regulation can once again serve as an example.[135]

Many devices are also made of polymers such as nylon, ABS plastic, PET, polypropylene and PVC, or combinations thereof. Discouraging the use of certain types of plastics and combinations of these plastics ensures that a higher percentage of products are suitable for reprocessing. Disposable plastic products such as plates, cutlery and straws are already subject to specific requirements on the use of certain plastics, which has led to a ban

on these plastic products.[137] These regulations could also be declared applicable to specific categories of devices.

**Provide information on materials used**

As part of the CEAP, it is being proposed under the Sustainable Products Initiative that information about the composition, production and circularity of a product is made compulsory.[134] One way of doing this is by introducing a product passport, digital or otherwise, providing information on the product and its raw materials across the entire production chain.[138] It is not clear whether the obligation will also apply to devices.
The Committee considers this desirable, as it would encourage device producers to adopt a responsible approach to raw materials while providing greater insight into negative environmental impact, and because such information can encourage sustainable purchasing.

It is currently difficult to use recycled materials as raw materials in devices. The reason is that, under the MDR, manufacturers are obliged to provide specifications of materials used in a device. These specifications are not usually available for recycled materials (MDR Annex II). This could be overcome under REACH (regulation on the production of and trade in chemical substances) by setting up a substance information exchange forum (SIEF) structure for recycled materials, such as plastics. A SIEF is a structure in which companies are obliged to share information about the composition of a specific material.[139] No such structure exists for recycled plastics. An alternative system is that a recycling technology can be approved if it achieves sufficient results for use within the scope of the MDR. This approach has already been put in place for foods under the Regulation on recycled plastic materials intended to come into contact with foods.[140]

**Extend producer responsibility**

Another way to encourage improved product sustainability is through the application of extended producer responsibility (EPR). The Dutch 'Decision on the extended producer responsibility scheme' stipulates that producers are responsible for environmental impact over the entire life cycle of their product, including the waste stage.[141] However, this compulsory EPR scheme only currently applies to a limited number of product categories, including electronic equipment. For example, there is the scheme for waste management of discarded electrical and electronic equipment.[142] This should also include electrical/electronic medical devices (excluding implanted and infected products) (categories 2D, 4B and 5B). In practice, it is not yet clear exactly which products are covered by the scheme. Moreover, categories are broader than just medical devices and compliance with the reporting obligation is below standard.[103,143] The government should also be able to make it mandatory for manufacturers to reuse a certain percentage of the products sold. New schemes are in the process of being developed for items such as mattresses and textile products.[103] The Committee recommends that the

EPR scheme should also apply to device producers. This will require coordination with existing legislation relating to devices, for example with the national regulations on the reuse of single-use devices.

Existing EPR applications do not yet encourage the development of new business models such as product as a service, or repair services. They are mainly focused on waste collection and processing.[103] However, if explicit goals are included to this end, the scheme can indeed encourage more sustainable business models. Making EPR compulsory by law (by declaring it universally applicable) would mean that producers are required to jointly collect and process waste. This mechanism is already being implemented for the collection of electronics waste by the Organisation for Producer Responsibility for E-waste Netherlands (OPEN) foundation in collaboration with partners in the chain.

**Justify single-use devices**

Many devices are single-use products. The design of reusable devices can be encouraged by holding manufacturers to account when they opt to market a single-use device instead of a reusable version. The same applies to modular products that can also be manufactured as a fully reusable product. This type of mechanism whereby use must be justified already exists in relation to the use of substances that are carcinogenic, that can alter DNA, or that affect reproduction.[144]

**Counter unjustified green claims**

A proposal has been made to counter unjustified green claims (greenwashing) through the EU Consumer Rights Directive and the new deal to strengthen consumer rights.[145,146] One way of doing this is through the use of environmental labels with substantiated criteria, such as the EU Ecolabel. It is not clear whether this will also apply to products used professionally such as devices. The Committee believes that this should be the case.

### 5.2.2 Impose requirements on waste processing and packaging

**Reduce specific medical waste**

Specific medical waste (SMW) is waste that poses an infection risk and is therefore collected separately, subject to strict transport requirements, and incinerated by a special processor (ZAVIN).[147,148] This is an unsustainable waste processing method. Many of the devices in treatment and operating rooms are currently placed in the SMW container out of habit or to be on the safe side. Both devices that do and devices that do not carry a risk of infection therefore regularly end up in SMW. This could be reduced by introducing clear guidelines in the workplace. A stricter definition of waste that poses an infection risk in the regulations could also be useful. The existing definition in the National Waste Management Plan (*Landelijk afvalbeheerplan*, LAP) can be interpreted broadly. This definition encompasses all waste featuring ‘undried blood and undried bodily secretions’.[147] Amendments in other areas of the regulations could also

contribute towards sustainable waste and materials management. The start currently being made on preparing a successor to the LAP, the circular materials plan, offers an opportunity to do so.[149]

However, the current regulations also offer opportunities to reduce SMW. For instance, certain infectious waste flows can undergo higher-quality processing if the product is first decontaminated. The risk of infection is then eliminated, and the product becomes suitable for transport to a reprocessor or a regular waste incineration plant.[147] A healthcare institution can therefore reduce the volume of SMW it generates by taking advantage of opportunities within the LAP and paying more attention to its implementation in the workplace.

**Avoid waste with clearer protocols for reuse**

The manufacturer has a responsibility to set out in the instructions for use how and under what conditions reusable devices can be reused (MDR, Annex I, Article 23.4). A harmonised standard exists for this purpose.[150] Before the MDR entered into force, reprocessing procedures provided by manufacturers were often found to be insufficient.[151,152] The result was a failure to reuse devices, which ended up in the waste flow. With the introduction of the MDR, this situation is expected to be improved. Manufacturers must now provide instructions for use that set out clearly applicable instructions for things like reprocessing procedures, sterilisation protocols and criteria for responsible reuse (when has a product or component thereof deteriorated to such an extent that it can no longer be used). The Committee believes it is important that applicability is tested in practice. Notified bodies must check these protocols, however sterilisation experts can also test applicability.

**Reduce medical device packaging**

Packaging waste makes up a substantial proportion of the hospital waste flow. Management of packaging waste is regulated in the EU Directive on packaging and packaging waste.[153] The aim of this directive is to reduce waste by harmonising packaging waste management. It specifically relates to prevention, promotion of reuse and recycling, and encouraging alternative applications. Article 20 provides the option to draw up separate rules for primary packaging of medical devices. The Committee does not consider this desirable: a situation in which an exception is made for device packaging waste should be avoided as much as possible. European packaging regulations are to be reviewed in the context of the CEAP, providing an opportunity to impose stricter sustainability requirements on packaging including for devices.

**More online instructions for use**

The instructions for use of a device often take the form of an extensive document in multiple languages. Instructions for use are in many cases only read on the purchase and first use of a new type of device. Whether the instructions for use of a device are compulsory depends on the risk

category to which the device belongs and whether instructions for use are necessary to ensure safe use (MDR Annex I, Art. 23.1). Where multiple devices are supplied, a single copy of the instructions for use may be provided (MDR Annex I, Art. 23.1). In practice, most devices are provided with instructions for use in paper format because this is the general rule (MDR Annex I, Art. 23.1). Instructions for use may also be provided in electronic format under certain conditions.[154] However, the many conditions and the small group of devices for which this is permitted mean that these rules are difficult for manufacturers to apply. The Committee believes that a review of these requirements could reduce the negative environmental impact of instructions for use, lower costs and lessen the workload for healthcare employees, without compromising safe use of the device. This could be achieved through a requirement to provide products with a QR code that links to digital instructions for use.

**Utilise the reprocessing of single-use devices as a transitional solution**

In the transition from single-use devices to reusable devices, the reprocessing of single-use medical devices is permitted in the Netherlands under strict conditions. Any natural or legal person who reprocesses a single-use device to make it suitable for further use is considered to be the manufacturer of a new medical device, with all of the associated obligations under the MDR (MDR Article 17). Little use is currently made of this option. Although the reuse of single-use medical devices is not the best possible solution, the Committee believes that it may be a transitional solution until there is an adequate supply of reusable medical devices.

### 5.2.3 Impose requirements on healthcare institutions

**Duty to disclose information on environmental impact**

Sustainability can be promoted by making details of the environmental impact of products, services and institutions public and transparent. The Corporate Sustainability Reporting Directive (CSRD) provides an incentive for companies to do so.[155] This directive includes rules on the public disclosure of the environmental impact of activities, long-term goals and progress in the area of sustainability. The aim is to encourage responsible business operations. The CSRD applies to large public interest companies with more than 500 employees and ‘other companies designated by the national authorities as public interest organisations’. As of 2023, more organisations will be required to report when two of the following criteria are met: more than 250 employees, a turnover that exceeds €40 or a balance sheet that exceeds €20 million.[156] It is not clear whether this also includes hospitals and other healthcare institutions in the Netherlands. The Committee believes that large healthcare organisations should fall within the scope of this directive. The Committee would like to see a sustainability report made a compulsory part of the annual report and the adoption of measurement methods and indicators for this report, to ensure that institutions can be compared at national level.

**Sustainable procurement**

Due to the considerable purchasing power of healthcare institutions, particularly where institutions work together, procurement is an effective means of motivating manufacturers to adopt sustainable manufacturing practices, to provide insight into environmental impact and to offer sustainable products. Procurement processes can apply the EU criteria for green public procurement set out in the CEAP in relation to products such as medical electrical equipment.[108] The criteria are designed to achieve a good balance between product specifications, sustainability performance, cost considerations and market availability. All, or only certain, requirements can be included in tender documents as needed and desired. Government services and academic hospitals (UMCs) can use these criteria in their public tendering procedures, including for the purchase of medical devices and personal protective equipment. However, healthcare institutions that are not required to issue a public tender (which applies to the majority of Dutch healthcare institutions) can also use these criteria during their procurement activities.

In the second CEAP, the European Commission proposes to introduce a minimum percentage of compulsory green public contracts.[134] The next step could be to introduce a compulsory percentage of green contracts for all product and service types, or to extend such a requirement to public and semi-public institutions and healthcare institutions that must comply with the guidelines for public tendering procedures.

# 06 advice

The more sustainable use of devices in healthcare benefits the living environment and, therefore, health. The Committee notes that this is a huge challenge. Sustainability initiatives at healthcare institutions currently have too little impact. Sustainability improvements require a transition of the entire political, economic and sociocultural system surrounding devices, in which all parties in the chain have a part to play. To facilitate this transition, the government must take control and develop inter-ministerial policy, laws and regulations. The necessary measures will have an impact not only on device use but also on the healthcare sector as a whole. This advisory report therefore identifies opportunities for sustainability improvements, which are needed in all areas of healthcare. The Committee calls for sustainability to be taken into account in all considerations and decisions in the healthcare and devices sector: from policymakers to producers and waste processors, from healthcare institutions to healthcare employees, healthcare insurers, educational institutions and researchers.

## 6.1 Make sustainability an explicit value of good care

In order to make the use of medical devices and personal protective equipment in the healthcare sector more sustainable, the Committee believes it is essential that sustainability is recognised as an explicit component of good care in the Wkkgz (Article 2). Healthcare institutions, healthcare employees and policymakers will then be prompted to consider sustainability in their decisions and to look for ways of providing good care that is also sustainable. In order to provide medical professionals with the tools to do so, a broadly supported value assessment framework needs to be developed by a multidisciplinary group of experts, with the involvement of patients and patient associations. Such a framework would address the proportionality of the values, determine preconditions and focus on the goal of optimising all values.

## 6.2 Implement sustainability as a value in healthcare institutions

The Committee believes that healthcare institutions need to take a more programmatic approach to improving sustainability. Sustainability must be embedded throughout the organisational structure of healthcare institutions, from management to the workplace. This process starts with healthcare management boards that are in charge of improving sustainability and take responsibility for doing so, and with supervisory boards that oversee these efforts. The Committee recommends encouraging healthcare management boards to draw up a long-term sustainability vision that sets out specific goals for a sustainable procurement policy, facilities and logistics for reuse and waste management. Monitoring the impact of sustainability initiatives and an annual sustainability report provide insight into this process. In order to initiate, continue and scale up sustainability improvement initiatives in the workplace and in procurement policy, this task must not fall to healthcare employees but rather to a position with the corresponding knowledge and

mandate, such as a sustainability coordinator. Collaboration between the sustainability coordinator, healthcare employees and relevant experts is essential. The Committee recommends providing a national structure for sustainable healthcare. Within this structure, collaboration will be encouraged, knowledge will be exchanged, ideas for innovation will be shared and where necessary supported by, or passed on, to other parties.

## 6.3 Ensure that sustainability is a consideration in medical decision-making

Sustainability must become a consideration in the drafting of all medical guidelines in the healthcare industry and in decision-making related to insured care. In order to embed sustainability more firmly in guidelines and quality standards, a section on sustainability accompanied by justification must become a compulsory part of all guidelines.
The government can address this through the Wkkgz (Article 11b paragraph 2). Responsibility for such a section must be clearly assigned to the various (coordinating) guideline committees. Sustainability in healthcare (behaviour and knowledge) must also become an integral theme of medical study programmes, as well as during refresher training and further training for healthcare employees.

## 6.4 Develop a policy agenda for making devices more sustainable

The Committee believes that policy, laws and regulations need to act as a catalyst for a transition to circular healthcare. To this end, the Committee recommends setting up a more intensive interministerial collaboration between VWS, I&W and EZK in order to develop comprehensive circular policy on devices. Policy on sustainable healthcare or circularity of devices can be fleshed out by drawing up an individual transition agenda within the government-wide Circular Economy implementation programme. This includes drawing up measurable interim and final goals for improving the sustainability of devices. Ways of achieving these goals include focusing on prevention and sensible healthcare, supporting healthcare institutions in the transition to circularity, and implementing methods that provide companies with a financial incentive to improve sustainability.

## 6.5 Draw up legal requirements in relation to sustainability

The Committee recommends that the Netherlands take on an initiating and leading role at European level to enshrine sustainability requirements for device producers in European law. This can be achieved through the legislative initiatives in development in the context of the European Green Deal, for example to extend sustainable design (Ecodesign) to medical devices and personal protective equipment. In addition, sustainability obligations in law aimed specifically at medical devices and personal

protective equipment can be addressed. Stricter requirements can also be imposed at national level, for instance in relation to extended producer responsibility. Sustainability improvements in the various life cycle stages of a product can be effectively promoted by focusing on several types of laws. It is important to seek cooperation with other European countries that have signed commitments to sustainable healthcare (COP26) or that are initiators within the European Green Deal.

## 6.6 Focus on innovation to accelerate the transition process

In view of the lack of sustainable product supply, innovation in sustainable product design and recycling techniques is urgently needed.

The Committee recommends intensive collaboration between various relevant public (universities, healthcare institutions and research institutes) and private sectors (Med Tech companies, waste processors) in the interest of innovative alternatives and solutions. Device producers would do well to prepare for increasing demand from the healthcare sector for sustainable products and to seek to cooperate with healthcare institutions to this end. Producers can also focus on sustainable business models, lead the way by developing standards and norms for sustainable devices, and prepare for more compulsory measures such as producer responsibility for the entire life cycle of products.

## 6.7 Facilitate research and monitor the environmental impact

The Committee argues that knowledge development plays an important role in the ability to scale up sustainability and sustainable device use. In order to make sustainability a consideration in healthcare decision-making, research is needed into the environmental impact of devices and groups of devices, which takes into account the entire life cycle and several aspects of environmental impact. Implementation research is also needed into sustainable devices or processes, which includes an assessment of effectiveness, safety and behaviour. In addition, methods that provide insight into aspects of sustainability and hidden costs of devices can make an important contribution. The Committee also recommends setting up national monitoring of the environmental impact of healthcare that can include monitoring the effects of sustainability improvement initiatives and of new policy on sustainability and other themes. Moreover, the Committee notes that the acquisition of knowledge does not need to put the brakes on current and future sustainability improvement initiatives and innovations: a lot can already be done without research.

**Concluding remarks**

All of the Committee’s recommendations can be adopted with immediate effect. Implementation of some recommendations will immediately deliver visible and measurable results, such as a more conscious approach to

devices in practice or pursuing a sustainable procurement policy. Other changes will take longer, such as developing and implementing a sustainability vision, updating medical guidelines, and product innovation. Changes to laws and regulations also take time and will only deliver results in the longer term. Such structural changes are essential, however, for the transition of the system. It is precisely because such processes are time consuming that it is vital to make a start as soon as possible.

Policymakers, healthcare institutions, healthcare employees and device producers must all take responsibility for providing good and sustainable healthcare: for the benefit of both health and the environment.

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## Committee and consulted experts[a]

**Members of the Medical Devices Sustainability Committee**

- Prof. Dr. M. Rovers, professor evidence based surgery, Radboudumc, Nijmegen, *chairperson*
- Dr. T. Bouman, assistant professor of environmental psychology, Rijksuniversiteit Groningen
- Prof. Dr. F.W. Jansen, professor of implementation of minimally invasive surgery techniques LUMC/ TU Delft, chairperson Medical Delta
- Prof. Dr. E. van Raaij, professor purchasing management in healthcare, Rotterdam School of Management, Erasmus University Rotterdam
- Prof. Dr. S. Roeser, professor ethics and head of Department of Values, Technology and Innovation, TU Delft
- Dr. W.J.V. Vermeulen, assistant professor governance systems for sustainability in business, Copernicus Institute of Sustainable Development, Universiteit Utrecht
- Prof. Dr. M. Vos, professor medical microbiology/infection prevention, Erasmus MC Rotterdam
- Ir. A.W. van Drongelen, senior inspector medical devices, Health and Youth Care Inspectorate, Utrecht, *structurally consulted expert*
- Mr. E.R. Vollebregt, lawyer and partner at Axon Lawyers, expert on medical devices and life science, *structurally consulted expert*

**Observers**[a]

- J.M. van den Berg, Health and Youth Care Inspectorate, The Hague
- Dr. E. Putman, Ministry of Health, Welfare and Sport, The Hague

**Scientific Secretaries**

- Dr. M.J. Alssema, Health Council of the Netherlands, The Hague
- Dr. R.J. Baines, Health Council of the Netherlands, The Hague (until 1 October 2021)
- Dr. L.E. van Nierop, Health Council of the Netherlands, The Hague (from 8 October 2021)

**Incidentally consulted experts**[a]

- L. Backx, independent consultant, AfvalBackx
- M. Boers, Actiz
- J. Buijs, Erasmus MC, Sterile Medical Device Experts Association
- J.B.J. Henderik, environmental consultant, Radboudumc
- T. Hoeben, purchase, Jeroen Bosch ziekenhuis
- Dr. T. Horeman (TU Delft and GreenCycl)
- Dr. N.G.M. Hunfeld (hospital pharmacist, projectleader sustainability Erasmus MC)
- T. Ilegems (operation assistant, Jeroen Bosch ziekenhuis)
- Drs. S. Lako (anesthetist Radboudumc)
- L. Manshanden (Siemens Healthineers)
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- P. Melger (Siemens Healthineers)

[a] Consulted experts are consulted by the committee because of their expertise. Consulted experts and observers are entitled to speak during the meeting. They do not have any voting rights and do not bear any responsibility for the content of the committee's advisory report.

- N. Mooren (Siemens Healthineers)
- K. Nolte (expert infectionprevention, Green Team VHIG)
- P. Senior (Actiz)
- J. Smit (Radboud UMC, Sterile Medical Device Experts Association)
- Drs. M. Steenmeijer (National Institute for Public Health and the Environment)
- B.J. van Straten (Van Straten Medical and GreenCycl)
- R. van Uden (purchase, Jeroen Bosch ziekenhuis)
- B. van der Veen (advisor Medical Information and Communication Technology, Jeroen Bosch ziekenhuis)
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