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## THERAPIES

### Giens Workshops 2023/Health technologies

#### How can the environmental sustainability of healthcare products be taken into account throughout their life cycle? \*

Bruno Laviolle<sup>a\*</sup>, Pierre-Frédéric Degon<sup>b</sup>, Cécile Gillet-Giraud<sup>c</sup>, Dominique Thiveaud<sup>d</sup>, Philippe Lechat<sup>e</sup>, Vera Boïko-Alaux<sup>f,1</sup>, Claire Fougerou<sup>g,1</sup>, Clara Jolly<sup>h,1</sup>, Abir Petit<sup>i,1</sup>, Isabelle Rémy-Jouet<sup>j,1</sup>, Raphaël Yven<sup>k,1</sup>, Laurence Bouret<sup>l,1</sup>, Laurie Marraud<sup>m,1</sup>, Marie-Pierre Vaslet<sup>n,1</sup>, Virginie Delay<sup>o,1</sup>, Anne-Laure Gavory<sup>p,1</sup>, Florence Olle<sup>q,1</sup>, Julie Langevin<sup>r,1</sup>, Louise Forteau<sup>s,1</sup>

<sup>a</sup> *CHU Rennes, Univ Rennes, Inserm, UMR\_S 1085 (IRSET), CIC Inserm 1414, 35000 Rennes, France*

<sup>b</sup> *Abbott, 94593 Rungis, France*

<sup>c</sup> *B. Braun Medical, 92210 Saint-Cloud, France*

<sup>d</sup> *Euro-Pharmat, 31300 Toulouse, France*

<sup>e</sup> *AP-HP, 75610 Paris, France*

<sup>f</sup> *CHU Clermont-Ferrand, 63000 Clermont-Ferrand, France*

<sup>g</sup> *CHU Rennes, 35000 Rennes, France*

<sup>h</sup> *CHU Nancy, 54035 Nancy, France*

<sup>i</sup> *CHU Amiens, 80000 Amiens, France*

<sup>j</sup> *INSERM, 49000 Angers, France*

<sup>k</sup> *CHU Bordeaux, 33404 Bordeaux, France*

<sup>l</sup> *DASTRI, 75116, Paris, France*

<sup>m</sup> *EHESP, 35043 Rennes, France*

<sup>n</sup> *Université de Tours, 37000 Tours, France*

<sup>o</sup> *SGH Medical Pharma, 38160 Saint-Marcellin, France*

<sup>p</sup> *SNITEM, 92400 Courbevoie, France*

<sup>q</sup> *Medtronic France, 75014 Paris, France*

<sup>r</sup> *LEEM, 75017 Paris, France*

<sup>s</sup> *O2M Lab, 49170 Saint-Léger-de-Linières, France*

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**\*Corresponding author.** Centre d'investigation clinique, 2, rue Henri Le Guilloux, CHU de Rennes, 35033 Rennes cedex 09, France.

*E-mail address* : [bruno.laviolle@univ-rennes.fr](mailto:bruno.laviolle@univ-rennes.fr) (B. Laviolle)

\*The articles, analyses and proposals from the Nouveaux Ateliers de Giens are those of the authors and do not prejudge the proposals of their organisation.

<sup>1</sup> Participants in the round table discussion “Health technologies” of Giens Workshops 2023

## Summary

Healthcare product procurement accounts for around 50% of the French healthcare system's greenhouse gas emissions. This lesson learned from the publication of the Shift Project's work in November 2021 has been a catalyst within the healthcare system, accelerating the consideration and implementation of actions aimed at reducing the environmental impact of the healthcare system, before, during and after care. In addition to their carbon footprint, healthcare products have a wide range of environmental impacts, including on water, air and soil, throughout their entire life cycle. We have chosen to divide this life cycle into four main stages: from research and development to production, distribution and market access, use and finally end-of-life management. Analysis of the regulatory framework at each stage and of existing initiatives described in the literature or by those in the field have structured and fuelled our thinking. We found that existing regulations focus exclusively on the health risk, with little or no consideration of the environmental risk, which is in itself a health risk. Furthermore, the implementation of certain structuring actions during the first 3 stages of the life cycle would make it possible to simplify or even eliminate the major problem of waste management associated with the end-of-life of healthcare products. With this in mind, we have produced 9 recommendations to ensure that the environmental impact of healthcare products is better taken into account throughout their life cycle.

## KEYWORDS

Medicinal products; Medical devices; Life cycle; Environmental impact; Healthcare system

## Abbreviations

ADEME	<i>Agence de la transition écologique</i> - formerly the <i>Agence de l'environnement et de la maîtrise de l'énergie</i> (Environment and Energy Management Agency)
AGEC	<i>loi anti-gaspillage et économie circulaire</i> (French Anti-Waste and Circular Economy Law)
ANSM	<i>Agence nationale de la sécurité du médicament et des produits de santé</i> (French National Agency for Medicines and Health Products Safety)
CCP	<i>Code de la commande publique</i> (French Public Procurement Code)

CEDIAG	<i>Commission d'évaluation des technologies diagnostiques, pronostiques et prédictives</i> (French Committee for the Evaluation of Diagnostic, Prognostic and Predictive Technologies)
CEESP	<i>Commission d'évaluation et de santé publique</i> (French Commission for Economic and Public Health Evaluation)
CEPS	<i>Comité économique des produits de santé</i> (French Economic Committee for Health Products)
CNEDiM TS	<i>Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé</i> (Medical Device and Health Technology Evaluation Committee) (part of the HAS)
CSP	<i>Code de la santé publique</i> (French Public Health Code)
CSR	corporate social responsibility
CT	<i>Commission de transparence</i> (Transparency Committee)
DAE	<i>Direction des achats de l'état</i> (French Department for Public Procurement) (part of the Ministry of the Economy, Finance, etc.)
DAJ	<i>Direction des affaires juridiques</i> (French Legal Affairs Department)
DGOS	<i>Direction générale de l'organisation des soins</i> (French Directorate of Hospitalisation and Care Management)
DGS	<i>Direction générale de la santé</i> (French Directorate-General for Health)
DGPR	<i>Direction générale de la prévention des risques</i> (Risk Prevention Department)
DSS	<i>Direction de la Sécurité sociale</i> (French Directorate of Social Security)
ECC-Net	European consumer center network
EPR	Extended Producer Responsibility
EMA	European Medicine Agency
EU	European Union
HAS	<i>Haute autorité de santé</i> (French National Authority for Health)
IVDMD	in vitro diagnostic medical device
LCA	life cycle assessment
MD	medical devices
MDR	European MD Regulation (EU) 2017/745
MNU	<i>médicament à usage humain non-utilisé</i> (unused medicines for human use)
NHS	National Health Service
NICE	National Institute for Health and Care Excellence

OBSAR	<i>Observatoire des achats responsables</i> (French observatory for sustainable procurement)
OBSAR	<i>Observatoire des achats responsables</i> (French observatory for sustainable procurement)
OECD	Organisation for Economic Co-operation and Development
PFAS	perfluoroalkyl and polyfluoroalkyl substances
PNAD	<i>Plan national des achats durables</i> (National sustainable procurement plan)
REACH	regulation on the registration, evaluation, authorisation and restriction of chemicals
ROHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
SFAR	<i>Société française d'anesthésie et de réanimation</i> (French Society of Anaesthesia and Intensive Care Medicine)
SF2H	<i>Société française d'hygiène hospitalière</i> (French Society of Hospital Hygiene)
SFPC	<i>Société française de pharmacie clinique</i> (French Society of Clinical Pharmacy)
UN	United Nations

## Introduction

Raising the question of the environmental sustainability of healthcare products throughout their life cycle is the first step towards answering it. Indeed, addressing this question today sheds new light on the regulatory, legislative and economic context of healthcare products, which until now has always focused on the implementation of a framework for healthcare products through the lens of the benefit/risk balance for patients.

The discussions at this round table are part of a major legislative initiative in which France has adopted a number of important laws, including the Anti-Waste and Circular Economy Law (AGEC) law, the Climate and Resilience Law and, more recently, the Green Industries Law. In addition, the Ministry of Health and Prevention has published a roadmap on environmental planning for the healthcare system, proposing recommendations and an action plan. The French Health Insurance (*Assurance maladie*) itself has made the decarbonisation of the healthcare system one of the focuses of its 2024 Report on Costs and Revenues [1], which also calls for strong measures. The hospital sector is heavily involved, with a number of commendable initiatives that provide examples of good practice that have fed into our work. Finally, the European Union is not to be overlooked, since the

European Green Deal agenda is underpinning many structural measures (e.g. regulation on the registration, evaluation, authorisation and restriction of chemicals [REACH], etc.), and neighbouring countries are committed to far-reaching agendas such as the NHS in the United Kingdom.

These busy times call for a fresh look at the environmental sustainability of healthcare products. The issue is not a new one, since a large number of existing regulations and initiatives already address this *Haute autorité de santé* (French National Authority for Health – HAS) certification of healthcare institutions, regulations on eco-toxicity, regulations on substances, corporate social responsibility (CSR) policies, etc. What is new is that the issue needs to be tackled as a whole, covering the entire life cycle of healthcare products and their impact on public health. The numerous studies carried out in the field of global health, or One Health, have undeniably given impetus to this new approach. Health and environmental approaches should no longer be seen as opposites or complements, but as one and the same approach.

During the group's preliminary discussions, it was decided to restrict the scope of the study to all the actions that could limit the impact of healthcare products on the environment, whether medicinal products or medical devices, whether they are used in health care institutions or in the community. This article does not deal with the broader concept of sustainable development but focuses on a life cycle approach based on four key stages for which we felt an environmental impact was relevant. It is not intended to be exhaustive, and consequently certain topics such as ecopharmacovigilance are not covered. It will therefore deal successively with the design and production of the healthcare product, its marketing and distribution, given the very strong economic leverage of this stage, the prescription and distribution phase, and then the end-of-life phase, with particular reference to waste management. The article will not deal with the issue of product sustainability analyses.

Our discussions are therefore a first step in the collective work that the Ateliers de Giens brings together each year, and we have no doubt that further work will be needed to deepen and strengthen certain analyses. In other words, the subject is far from finished. The life-cycle approach (Fig.1) provides a linear view of the healthcare product, and each of the four sections covers an analysis of the regulatory context, its scope and the current state of play, with a view to making recommendations.

An appendix containing the main key definitions used during the discussions is available at the end of the article.

## **Design-production: focus on research, industrial development and production**

### **Regulatory context and analysis of the situation**

#### Research

Our work has revealed that there are almost no regulatory constraints on the environmental aspect of medical research. At international level, our only reference is the Declaration of Helsinki [2], which dates back to 1964 and has been revised several times since it was first adopted by the World Medical Association.

The Declaration of Helsinki is presented as “*a statement of ethical principles for medical research involving human subjects*” (it should be noted that all research activities involving animals are therefore outside this scope). The statement mentions in its general principles that “*Medical research should be conducted in a manner that minimises possible harm to the environment.*”

In France, there have been a number of recent initiatives that subject those involved in public research, and therefore medical research, to the State's commitments to green public services [3,4], the climate-biodiversity and ecological transition plan for higher education and research [5] commits those involved to speeding up the reduction of the environmental footprint of research activities and to stepping up disruptive research and innovation actions in favour of the ecological transition.

In June 2023, the Ministry of Higher Education and Research published its “Sustainable Development - Social and Environmental Responsibility” master plan [6], which deals in particular with the decarbonisation of research establishments, energy sobriety and the overall environmental impact of the day-to-day running of research establishments.

Technological innovations are also emerging, harnessing fewer resources, such as animals with organoids (mimicking organs), although they still have limited functionalities.

In terms of the research itself, since the end of the 2000s there have been a number of publications looking at how to measure the environmental impact of research, particularly from the perspective of the carbon footprint [7]. The recommendations arising from this work (commendable for having been carried out despite the lack of available data and expertise on the subject) have been incorporated into the decarbonisation guidelines of the UK's National Institute for Health Research [8].



The conclusions are in line with our own considerations and stress the need to strengthen the environmental dimension both in the research areas, in order to have more data, and in the conduct of the research itself, in order to reduce its impact. Although the literature shows that there is an increasingly shared approach to integrating environmental issues into research activities [9,10,11], studies on the subject account for a very small proportion of medical research activities and focus largely on the carbon footprint.

At this early stage in the life cycle, this illustrates the difficulty of integrating all the impacts over the entire life cycle of healthcare products.

## Development

Unlike the previous stage, the development stage of healthcare products is subject to a relatively comprehensive regulatory framework, particularly at European level, which sets out separate requirements for medicinal products and medical devices.

- For medicinal products, the European Medicines Agency (EMA) requires an environmental risk assessment to be carried out during phases I and II for molecules under development via the Environmental Risk Assessment of medicinal products for human use [12], the results of which form an integral part of the application submitted for marketing authorisation, regardless of the procedure applied for (centralised, mutual recognition, decentralised or national). The purpose of the analyses carried out in this context is to assess the risk of toxicity associated with the use of medicinal products, in particular persistence and bioaccumulation in soil and water. Despite their mandatory nature, the results of these studies are not a discriminating factor in obtaining marketing authorisation. The current discussions on a new European regulation could, depending on the final outcome, change this situation drastically in the future.
- With regard to medical devices, the European regulation adopted in 2017 and applicable from May 2021 for obtaining medical CE marking does not include a section that takes into account the environmental impact of products [13]. All of the constraints applying under these regulations are designed to ensure patient safety. A great deal of evidence is therefore required, for example concerning the stability or toxicity of the materials used, however, this is only assessed from the angle of safety for patients or users of the devices.

In addition, other regulations not specific to the healthcare products sector, aimed at controlling the environmental impact of consumer goods, apply to medical devices. These include the REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals), the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) directive (restrictions on the use of 10 hazardous chemicals) and the SUP directive (single-use plastics), which have led to the AGEC law in France.

This accumulation of regulations and legislation clearly demonstrates that manufacturers are obliged to provide data that can be assessed to take account of their environmental impact, although this is not necessarily the case today. Systematic analysis of the data already available from an environmental risk perspective would represent real progress on the existing situation. However, this would need to be supplemented if the carbon footprint of products is to be considered, or to have an exhaustive view of impacts throughout the life of products. We note that the impact of these products on the environment is mainly studied during their use and end of life, and less during their development and production.

## Production

The production stage is understood here as the entire manufacturing chain leading to the finished product, including the extraction and manufacture of raw materials, components and/or semi-finished products, then their assembly and packaging. As mentioned in the introduction, the group has deliberately excluded transport from its analysis.

Production is a real issue, both because it represents a major stage in terms of environmental impact, and because the question of its location, which is bound to be multiple and diverse given our field of study, makes its regulatory framework complex to study. Without sidestepping the issue, we do not intend to list and analyse all the existing regulatory constraints in the world. The main existing legislation is not specific to healthcare products but comes under the environmental laws of the countries concerned.

In France, the environmental code provides a precise framework for all industrial activity in the country, both before an industrial site is set up and during its operation. It includes limit standards and control procedures to limit all impacts on water, soil, air and atmosphere (including greenhouse gas emissions), biodiversity, etc.

A large part of the environmental code is the transposition into French law of European directives [14]. Europe now has one of the most comprehensive legislative and regulatory packages in the world, including for limiting the environmental impact of industry.

If we look at the legislation specifically governing the manufacture of healthcare products:

- The “Good Manufacturing Practices” (GMP) [15], published worldwide by the World Health Organization (WHO) and in France by the *Agence nationale de la sécurité du médicament et des produits de santé* (French National Agency for Medicines and Health Products Safety – ANSM), detail the standard operating procedures, the critical stages that must be validated and the qualification of facilities for the manufacture, control, storage and transport of medicinal products. They do not include measures to protect the environment, which is the responsibility of the local legal framework.
- The ISO 13485 standard [16] sets out the requirements relating to the quality management system of a manufacturer of medical devices or associated services and enables them to demonstrate their ability to supply them correctly and in compliance with the regulations in force. Although it is not a legal requirement, in practice this certification is essential for manufacturers of medical devices. Like GMP, it does not imply any specific constraints relating to environmental impacts, which are specified in the environmental law of the manufacturing countries.

Beyond the regulatory framework, the limited ability to measure the environmental impact of the production of healthcare products in Europe is also due to the fact that certain stages are carried out elsewhere in the world. For example, the extraction of raw materials or their components, such as silicone or certain rare metals used in the manufacture of medical devices, is only carried out in Asia, as these materials are not currently available or exploited elsewhere in the world. Similarly, many active pharmaceutical ingredients are produced in India or China, which limits the amount of information available on the environmental impact of these components.

Lower carbon impacts are expected from changes in manufacturing processes, but these may be difficult to achieve, particularly given the diversity of production. Each change requires changes to marketing authorisations. As the issue of relocating some of these activities has already been the subject of numerous studies and reports, the Group has not examined this point in detail and has not included it in its recommendations.

## Market access – Reimbursement and purchase

### Regulatory context

#### Market access - reimbursement

Access to the French market for healthcare products with regard to reimbursement by society is the responsibility of two main stakeholders: the *Haute autorité de santé* (French National Authority for Health - HAS) and the *Comité économique des produits de santé* (French Economic Committee for Health Products - CEPS).

#### **HAS**

The rules defined by the HAS focus on the benefit/risk balance of a healthcare product, from the point of view of improving the expected or delivered benefit. This evaluation is well codified and is overseen by two bodies for medicinal products (CT and French Commission for Economic and Public Health Evaluation - CEESP) and one for medical devices (*Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé* [Medical Device and Health Technology Evaluation Committee] - CNEDiMTS). The missions of the HAS are defined in the French Public Health Code: art L 161-37, art L 161-39 and art. R 161-71-1, art. R161-71 -3.

#### **CEPS**

This committee is an interministerial body placed under the joint authority of the ministers responsible for health, social security and the economy. It is defined in the French Social Security Code: art. L162-17-3. Its remit is to set the prices of medicinal products and medical devices for individual use covered by compulsory health insurance, in line with the targets set each year by the Social Security Financing Act.

Purchasing health products

### ***General information***

In its 2030 Agenda for Sustainable Development [17], the UN has set 17 goals, the twelfth of which, entitled “*Ensure sustainable consumption and production patterns*”, specifies in point 7 a target specific to procurement: “*promote public procurement practices that are sustainable, in accordance with national policies and priorities*”.

The European Union, in 2014, set a regulatory framework for public procurement through its Directive 2014/24/EU [18].

In France, sustainable development is an obligation defined in article L2111-1 of the Public Procurement Code: “*The nature and extent of the needs to be met are precisely determined before the consultation is launched, taking into account sustainable development objectives in their economic, social and environmental dimensions*”. This concept, which is broader than environmental impact alone, is therefore a relatively old obligation (it appeared in August 2006).

This consideration was reinforced more recently by Law no. 2021-1104 of 22 August 2021 [19], which amended or added a number of provisions to the French Public Procurement Code (CCP). In particular, article 35 of this law introduced article L.3.1: “*Public procurement helps to achieve sustainable development objectives, in their economic, social and environmental dimensions, under the conditions defined by this code*”. This same article added to article L. 2111.3 [20] of the CCP, concerning schemes to promote sustainable procurement, that the latter: “*also contribute to the promotion of a circular economy*”. Furthermore, article 36 of the Law states that “*by 1 January 2025 at the latest, the State shall provide contracting authorities with operational tools for defining and analysing the life cycle cost of goods for the main purchasing segments. These tools will include the overall cost associated with the acquisition, use, maintenance and end-of-life of goods as well as, where relevant, the external costs borne by society as a whole, such as atmospheric pollution, greenhouse gas emissions, loss of biodiversity or deforestation*”.

### ***Hospital procurement***

As a public sector activity, hospital purchases must comply with the requirements of this code regarding the consideration of environmental impact in purchasing procedures. Article R.2111-10 [21] states that technical specifications “*may include environmental characteristics...*”. Article R2111-12 [22] mentions the possibility of referring to labels. A fact sheet from the Legal Affairs Directorate (DAJ), published in 2019 [23], sets out how to define the need.

For healthcare products, a guide [24] was also drawn up in 2013 on sustainable procurement applied to healthcare products, in which purchasers are offered questionnaires for suppliers of medicinal products and/or medical devices/in vitro diagnostic medical device (MDs/IVDMDs). In each case, the questions must be related to the subject of the contract.

A guide [25] was made available in 2016 to help people take into account the life cycle assessment approach.

More recently, as part of its support for hospital procurement, the PHARE mission within the *Direction générale de l'organisation des soins* (French Directorate of Hospitalisation and Care Management – DGOS) published an instruction [26] in May 2022 on the procurement of innovative products. Although the scope of this instruction is restricted to the innovative sector, it mentions as a major guideline “*encouraging the implementation of sustainable development approaches, particularly with regard to the environmental aspect, especially for the drugs chain, but also the social aspect*”. The purchasing segments concerned are medicinal products, MDs and IVDMDs, with the exception of “*large equipment*” medical devices. It states that “*environmental quality ... will be targeted, particularly in terms of water and energy consumption and gaseous or liquid effluent discharges. A carbon footprint of production and supply processes will be required (from the end of 2023). The recycling rate for production waste will be requested and can be verified at any time. Similarly, actions to reduce and recycle packaging will be rated positively. Significant penalties will be applied if the values stated in the bids are not met*”. It was suggested that the environmental and social quality criterion should be weighted at a minimum of 10%. It also announced the publication of a guide to purchasing innovative products, which has since been published (January 2023) [27].

## **Critical analysis - Situation**

Market access - reimbursement

To date, it is clear that the criteria used to evaluate and/or reimburse healthcare products take into account only their performance and efficiency and, ultimately, compliance with a budget. Among the methodological documents published by the HAS concerning the various evaluation structures [28-33], only one methodological document takes into account the potential environmental impact of healthcare technologies, whether positive or negative [34]. It identifies a criterion (3.4 last) concerning the impact on the ecological footprint; however, none of the decisions to date has really taken this into consideration.

As far as the CEPS is concerned, the environmental impact of healthcare products is relatively non-existent, except in the very limited case of healthcare products leading to waste from puncturing healthcare products used by patients (decree no. 2021-1176 of 10 September 2021) [35], in pursuance of the so-called AGEC law (*loi anti-gaspillage et économie circulaire* (French Anti-Waste and Circular Economy Law)).

It should be noted that during the course of our discussions, the roadmap on environmental planning for the healthcare system [36], was published, in which it is stated that the *Assurance Maladie* is asked to commit to sustainable purchasing, in particular by proposing “*the integration of environmental criteria as part of the negotiation of the CEPS framework agreement*”. It is also expected to consider the possibility of introducing a carbon score, similar to the Nutri-Score, as part of a harmonised approach at European level.

### Purchasing healthcare products

Although, as we have seen, the environmental impact of products in purchasing procedures has been taken into account in the CCP, the fact remains that, in the case of healthcare products, this impact has been emphasised above all in the context of innovative products. However, while the concept of the “lowest bidder” has been replaced by that of the “best bidder”, the environmental criterion remains minor and in some cases is not even applicable.

The national plan for sustainable purchasing and development 2022-2025 [37] sets as its first objective the exhaustiveness of public procurement contracts that include at least one environmental consideration. Health products are therefore implicitly included. However, it should be noted that the

concept of the environmental dimension is very broad, and as a result, the number of environmental considerations can be high, leading to very divergent points of view among “purchasers”.

The concept of sustainable or responsible procurement, defined by AFNOR as “*the purchase of goods (...) from a supplier selected to minimise environmental and societal impacts, and to encourage good practice in terms of ethics and human rights*”, is promoted and explained by the DAJ of the Ministry of the Economy and Finance [38]. It also clashes with an approach based on autarky, which has been exacerbated by the current shortage of healthcare products. This recourse to a certain 'sovereignty' of production, involving short circuits, may have the collateral effect of reducing environmental impact. The reality of this remains to be seen.

More generally, purchasing is a pivotal step in the deployment of a sustainable or circular economy, and its impact will be felt both during procurement (timing of orders, transport, shrink-wrapping or plastic film packaging combining several packaging units, etc.) and during use (correct use, correct prescription, correct care), as well as at the end-of-life (waste disposal, recycling, etc.). Matching the product to the need also means taking into account the purchasing prescription and raising the awareness of all those involved, not just during the “legal” procedure for awarding contracts, which is still predominant. All the support tools that are already available, as we have seen, are usually only available to the purchasing department and are virtually unknown to those who prescribe the purchase, based on the needs corresponding to optimal patient care.

Responsible purchasing covers the entire supply chain and has an impact on both suppliers/manufacturers and customers/buyers/users. Both parties can draw on international standards such as ISO 26000 [39] and ISO 20400 [40]. However, it is difficult to ascertain whether they have been implemented..

#### Situations abroad

We looked at existing approaches to market access and purchasing of healthcare products outside France.



### *The United Kingdom*

Since 2008, the National Health Service (NHS) has been working to reduce the carbon footprint of the entire sector it covers, i.e. both the community and hospital sectors. It is the first healthcare system in the world to incorporate carbon neutrality into its regulations [41]. The aim is to achieve zero emissions by 2040. Healthcare products (medicinal products and medical devices) alone account for 30% of the UK's carbon footprint (20% and 10% respectively) [42]. A number of tools have been developed for purchasers/suppliers with this objective in mind [43]. The approach focuses on medicinal products, anaesthetic gases and inhalation aerosols, because of their “greenhouse effect”.

To support this approach, NICE (the British assessment body corresponding to the HAS in France) has clearly stated in its 2021-2025 strategy [44] that environmental sustainability should be taken into account for all healthcare products.

### *Sweden*

In the early 2000s, following an environmental audit showing the presence of medicinal products in the aquatic environment, Sweden decided to introduce tools to limit this pollution. A PBT (Persistent Bioaccumulative and Toxic) index was developed to classify medicinal products according to their risk, while measuring their effectiveness and cost. This classification was published in 2012 and repeated in 2015 [45] to inform both prescribers and users of the environmental risks of medicinal products. In 2020, a Swedish team published an interesting feedback report [46].

This approach, initiated in Sweden, was taken up by the European Union; in 2013, for example, in a broader directive [47] on water policy, it introduced the measurement of the risk to the aquatic environment of pharmaceutical substances. A roadmap [48] was drawn up in April 2017, leading to a communication [49] from the European Commission. At the end of 2022, the Commission proposed a revision of the directive [50] with a view to an EU water policy that takes into account not only pharmaceutical substances, but also plastic pollutants (PFAS and microplastics) that may be used in the composition of medical devices.

### **Prescription, distribution and use**

## Regulatory context and critical analysis

The prime lever for adopting a responsible attitude is correct prescribing, which is the proper use of the healthcare product. There are many sources of information available to practitioners. There are, for example, booklets on good prescribing practice in hospitals, which should be kept up to date and available for consultation. Learned societies also publish good use factsheets and good practice guidelines, such as Euro-Pharmat, *Société française d'anesthésie et de réanimation* (French Society of Anaesthesia and Intensive Care Medicine – SFAR), *Société française d'hygiène hospitalière* (French Society of Hospital Hygiene - SF2H) and *Société française de pharmacie clinique* (French Society of Clinical Pharmacy – SFPC), which have, for example, published guidelines for reducing the environmental impact of general anaesthesia [51]. Another example is the decree of 8 September 2021 on the quality management of implantable medical devices in healthcare institutions and cosmetic surgery facilities, which sets out recommendations for ensuring the safety of implantable medical devices [52].

## Critical analysis - Situation

### Prescription

As far as prescribing is concerned, despite all the recommendations and sources of information mentioned above, there are still many discrepancies. In France, the majority of medicinal products are sold in the community (80%, compared with 20% in hospitals), and a study has shown that only 21% of prescriptions are compliant on discharge from hospital. A pharmacy thesis defended at the University of Bordeaux [53] also highlighted prescribing errors in 98% of dressing prescriptions requiring pharmaceutical intervention. One of the problems raised by the group was the lack of awareness among prescribers about environmental sustainability, particularly in surgery and among paramedics, but all areas are concerned. This illustrates the importance of providing teaching in this area. A first initiative should see the light of day from the start of the 2023 academic year with the introduction of an environmental health module in medical studies, which will be optional and will not, however, directly address the eco-design dimension of healthcare. The group recommends that this module should be made compulsory and supplemented by the latter dimension.

If we take the example of dressings, one way of improving prescriptions on discharge from hospital would be to promote prescriptions by nurses, who are familiar with the inpatient's treatment

and would better meet the needs of private practice nurses for care on discharge from hospital. A decree of 20 March 2012 sets out the list of medical devices that nurses are authorised to prescribe, but they require an initial medical prescription that may be inappropriate as it is usually written by interns who have no knowledge of the dressings used during hospitalisation. Another suggestion would be to set up sustainable development committees in all hospitals, which could address the issue of prescriptions.

In addition to guidelines for practitioners, we also need to take account of the societal dimension of the problem, and in particular raise awareness among users. In France, for example, in 2005, 90% of GP consultations ended with a prescription (compared with 72.3% in Germany and just 43.2% in the Netherlands), reflecting society's clear over-investment in medicinal products [54].

### Distribution and dispensing

As far as distribution is concerned, based on what happens in care establishments, there are supply and logistics circuits covering all stages of the MD or medicinal product circuit, from receipt to use. Pharmacists are at the centre of this system, which illustrates the importance of demand analysis by qualified personnel, based on the compliance of the supply, the user's needs and the suitability of the medical device or medicinal product for the desired use. A detailed analysis of the various stages: dispensing, transport, receipt by departments, storage in departments is therefore required to reduce expiries, optimise off-site stocks and thus avoid waste and/or misuse.

The group recommends that profit-sharing mechanisms be introduced based on the savings generated in institutions, as well as a review of the organisation of pharmacies to optimise stock levels with a view to optimising the frequency of orders.

According to a study carried out by the eco-organisation Cyclamed, 22% of medicinal products sold in the community are not used [55]. This generates enormous waste, a risk of misuse and self-medication due to the accumulation of medicinal products in patients' homes, and an environmental risk linked to the waste generated by these medicinal products, because even if they are returned to pharmacies by patients, they cannot be put back into the dispensing circuit. Among their recommendations, the authors of this study stress the need to adapt packaging. This raises the question of the usefulness of per-unit dispensing, along the lines of what is done in the United States, for example, or of better optimisation of packaging, particularly for acute treatments, or for certain non-reimbursable and non-prescription medicinal products, which are often packaged in large, unsuitable containers. This would require regulatory changes, as European regulations on the

serialisation of medicinal products stipulate a traceability obligation that requires individual labelling. The Group is aware that such a measure would have a major economic impact on manufacturers, who would have to review their production lines in response to changes in prescriptions. The environmental impact of per-unit dispensing would also need to be studied. The same problem may be encountered in in-house pharmacies, but the generalisation of nominative daily dispensing requires significant investment in suitable robots.

## Usage

As far as use is concerned, the discussions highlighted waste. The case of single-use MDs is typical. A study of 50 surgical procedures carried out in the operating theatre of the Nîmes University Hospital estimated the cost of wastage at €100k per year, mainly due to the premature opening of consumables or MDs [56]. Similar results were found in a study carried out at Amiens University Hospital, with an estimated loss of nearly €150k per year, generated by consumables opened in advance and not used [57]. The group also pointed out the lack of data on wastage in in-house pharmacies and pharmacies, and on stock shortages.

## The end-of-life of healthcare products or the issue of waste management

The end-of-life of healthcare products means addressing the issue of how to manage the product after it has been used, or even not used at all when it is considered to be spent, out-of-date or unused. Waste reduction is currently the 4<sup>th</sup> objective of the roadmap on environmental planning of the Ministry of Health and Prevention, with the aim of accelerating waste reduction and recovery by 2030 and optimising the scope of DASRI (infectious hospital waste) to limit it as much as possible by 2024. Our work focuses specifically on healthcare products, but it is interesting to note that, according to this roadmap and the work of the think tank The Shift Project “*emissions from the sector's 'waste' category are estimated at 0.4 MtCO<sub>2</sub>e. These emissions are divided between DASRI (waste from healthcare activities with infectious risks), DAOM (waste assimilated to household waste) and wastewater treatment. The sector is estimated to produce 700,000 tonnes of waste of all kinds every year, or 3.5% of national production. 20-30% of hospital waste comes from operating theatres, and the average carbon equivalent produced per surgical operation has been estimated at 184 kgCO<sub>2</sub>e.*

*The environmental and ecological impact of treating medical waste is significantly greater than treating household waste”.*

First of all, what is meant by waste? Article L.541-1-1 of the French environmental code defines waste as “*any residue from a production, transformation or use process, any substance, material, product or, more generally, any movable property that is abandoned or that the holder intends to abandon*”. Household waste (HW) is waste resulting from household activities, collected by the usual or separate collections as well as non-household waste collected under the same conditions (waste produced by craftsmen, shopkeepers, offices, etc.) called assimilated waste. In France, local authorities charge a special fee for the collection and treatment of similar waste.

In the community, the need for good management and information on waste sorting is also seen as a priority, despite the fact that 20% of institutions do not sort their waste [58]. Throughout a product's life cycle, as we saw earlier, the issue of its end-of-life, i.e. its sorting, treatment and possible recycling, are all factors that need to be integrated as levers of performance in terms of eco-responsibility. For example, a purchaser can integrate criteria linked to sustainable purchasing from the National Plan for Sustainable Procurement (*PNAD*). We will see later that the question of how waste is treated depends to a large extent on the producer (professional or patient), and that these parties have a number of responsibilities.

## **Regulatory context**

### Current situation

Hospital and pharmacy channels are faced with the challenge of managing the waste from various healthcare products, in particular medical devices and unused medicinal products, but patients themselves (considered to be 'consumers' under environmental law) also play a major role.

Reading the legal framework applicable to end-of-life products carefully is crucial to ensure that the right sorting practices are applied.

There are three key parties in managing the end-of-life of healthcare products:

- **Healthcare institutions and professionals:** waste generated by hospitals is considered to be waste from economic activities [59], or professional waste. As healthcare institutions are legally considered to be waste producers, outside the scope of professional extended producer

responsibility (EPRs), the management of this waste depends on the procedures put in place by the institutions [60], and, where applicable, regulatory obligations such as the treatment of *DASRI*.

- **Companies under EPR:** Article L. 541-10-1 sets out the principle of Extended Producer Responsibility (EPR), which takes up the polluter pays principle by making companies that put products on the market responsible for the end-of-life of their healthcare products. In France, companies have the choice of exercising their responsibility in one of two ways: either directly, by taking responsibility for the collection and end-of-life management of waste (principle of the individual system), or by pooling collection and recycling via dedicated organisations called “Eco-organisations”, depending on the type of waste from their product(s) [61]. In both cases, the schemes are government-approved (the principle of EPR schemes is also developing in Europe and in other countries outside the EU, with the Organisation for Economic Co-operation and Development (OECD) even working on the subject as a matter of best practice). In the specific context of healthcare products, two eco-organisations have been set up on the principle of pooling certain situations in the community, and a number of other initiatives and tools exist:
  - **CYCLAMED** for unused medicinal products: Since 1993, the government-approved eco-organisation Cyclamed has led the national programme for sorting and recovering unused medicinal products for human use.
  - **DASTRI** for medical puncturing devices used by patients undergoing self-treatment and users of self-tests [62], including electrical or electronic equipment associated with such devices.
  - **OTHER INITIATIVES:** It should be noted that other eco-organisations are also involved in packaging (ADELPHE, CITEO), electronic equipment waste (ECOLOGIC) and batteries (COREPILE), which may be part of medical devices or medicinal products. Individual systems also exist, supported and approved by the government for specific products.
  
- **Patients:**
  - **Waste from patients in the community** is dealt with either via the eco-organisations as indicated above, according to very specific perimeters, with the rest being considered as household waste. In other words, waste that does not fall into any of the categories listed above must be disposed of as household waste, for example test strips

for diabetic patients. This latter point creates a large number of sorting errors and areas for improvement.

The applicable channels [63] in question can be listed as follows in Table 1, using diabetes as an example:

Major projects underway, in particular the issue of re-use of medical devices: the difficult boundary between restoration to suitable condition of use and fully refurbishing

With regard to medical devices, the AGECE law has gone further on this issue by dealing with:

- Availability of spare parts;
- Donations to associations for reconditioning;
- EPR technical aids;
- The possibility of reimbursement by the health insurance scheme for products that have been restored to a suitable condition of use.

As a reminder, the placing on the market of medical devices, as well as their post-marketing follow-up and the placing on the market of parts and components, is governed by a European regulatory framework. EU Regulation 2017/745, which came into force on 26 May 2021, replaces Directive 93/42/EC.

- The concept of “restoration to suitable condition of use” has no finalised regulatory or legislative definition at either French or European level. This concept can be understood as verification, before a medical device that has already been used is made available to a new user, that the MD concerned has been serviced in accordance with the manufacturer's recommendations, particularly in terms of cleaning and maintenance, and that the MD is therefore suitable for re-use.

As an indication, a draft standard NF S97-414 “Restoration to suitable condition for use of medical devices for individual use” indicates, in application of French public health code art L5212-1-1: “*Certain medical devices for individual use appearing on a list drawn up by decree of the ministers*

*responsible for health and social security may be restored to suitable condition of use with a view to reuse by patients other than those who initially used them.*

*This restoration to suitable condition of use is subject to:*

*1° Compliance with criteria guaranteeing the quality and safety of use of the medical device restored to suitable condition of use good condition;*

*2° An approval procedure for centres or professionals authorised to restore to suitable condition of use."*

- The concept of “fully refurbishing”, for its part, benefits from a regulatory definition (article 2.31) of EU regulation 2017/745 and leads to a medical CE marking certification process, with the refurbishing operator then becoming a legal manufacturer under the regulation. Similarly, an item that is intended to replace a part or component and which significantly changes the performance or safety characteristics or the intended use of the device is considered to be a device and must be CE marked as such (Article 23.2 of Regulation 2017/745).

The boundary between these activities must therefore be clearly defined to avoid a situation where a refurbishment is considered by the operator as being in a suitable condition of use, thereby avoiding the CE marking certification process, or where parts and components that could have an impact on product safety are placed on the market without CE marking.

## **Recommendations (Table 2)**

### **On the design-production stages:**

In the light of our analysis of the regulatory context and discussions on existing initiatives, we believe that 3 recommendations or avenues of work should be prioritised for these stages of the life cycle:

- In view of the poor representation of this subject in published data, we believe it is essential that the dimension of environmental criteria be more widely introduced into medical research: not only in the research themes themselves, but also in the conditions under which it is carried



out and in the way it is promoted, in order to encourage researchers to focus on these issues. This must of course be accompanied by funding. It should be noted that the French Roadmap on Environmental Planning for the healthcare system published in May 2023 introduces measures along these lines, and that the implementation of these actions would need to be monitored.

- Although the healthcare industry's activities are already largely regulated, we note that little attention is currently paid to the environmental impact of these activities. However, if environmental issues were addressed in a major way right from the early stages of product development, all stages of the product life cycle would be improved, as we shall see later. The AGECE law now addresses issues such as reuse and the reparability index, which involve medical devices. We believe that manufacturers need to be encouraged more vigorously, in every possible way, to develop the eco-design of their products: both in the development of raw materials that limit the impact that is currently very significant, and by giving priority to the concept of multiple use from the initial design stage. One solution, for example, would be to include the environmental dimension in the research tax credit, or to promote applications to modify marketing authorisations in order to improve the carbon impact of authorised medicinal products through mechanisms for rapid access and/or reduction of associated costs.
- Finally, it is a regular occurrence in the life of health products that two regulatory frameworks are combined: one 'general' in terms of the environment, and the other very specific in terms of health safety. These two systems sometimes coexist in a paradoxical or even contradictory way, at both European and French level. This calls for joint governance between the Ministries of Health and the Environment to ensure that the specific features of health and environmental regulations are consistent.

### **On the purchasing and market access stages**

In view of the relatively comprehensive regulatory framework and the observations we have made, we recommend the following actions to improve the situation at these two stages of the healthcare product cycle:

- Define a common method/standard for selecting and scoring healthcare products according to environmental criteria defined as part of a European approach, at the very least.

- Establish an HAS doctrine for taking environmental criteria into account in the evaluation of healthcare products, which would be financially rewarded by the CEPS and in hospital procurement (notion of acceptance of associated additional costs).
- Strengthen and harmonise the environmental sustainability criteria in hospital contracts to raise the bar for manufacturers and promote genuinely responsible stakeholders, without undermining the freedom of choice of products.

### **On the prescription, dispensing and use stages**

There are several ways of optimising the use of MDs to reduce waste. Favouring reusability should be obvious but this requires a list of reusable MDs and the conditions under which they can be reused. Harmonisation of practices, with the creation of checklists for each type of surgery and of MDs to be opened in advance, and improved traceability of the products used in the operating theatre, as well as raising awareness among operating theatre staff. In the community, the reuse of second-hand medical devices (crutches, wheelchairs, splints, etc.) is beginning to become an option, with initiatives such as Libel'up, supported by Eurasanté, aimed at collecting, reconditioning and redistributing used, broken-down or unused medical equipment, giving a second life to the equipment collected by restoring it to a suitable condition of use and safety, in conjunction with regional manufacturers. With regard to the use of medicinal products, an in-depth study of the impact of per-unit would appear to be necessary, in order to review the most appropriate packaging for each situation.

### **On the end-of-life stage for healthcare products and waste management**

Like other stages in the life cycle of healthcare products, the regulatory landscape is still at a crossroads between health imperatives and the desire to build a new environmental framework. The issue of how to define infectious risk is an important factor in this respect, and one on which numerous projects [64] are seeking to make progress in order to limit the number of items of medical waste, and therefore the volume of waste incinerated. This is not without its difficulties: incineration is currently the least environmentally friendly method of destruction, giving rise to numerous problems of toxic emissions [65]. The working group noted that there were many initiatives in the hospital sector, but also in the community, through actions led by eco-organisations, direct manufacturers and community professionals, and that patients wanted more support. The group therefore focused its recommendations on the following points.

- Better communication is needed on existing downstream channels, as well as the introduction of certification or a label to support hospitals in their waste management.

From the point of view of a life-cycle approach to healthcare products, we considered it appropriate to increase communication on downstream waste management channels (community or hospital), so that upstream, better knowledge and understanding of these channels would enable practices to be changed at all stages. Knowledge, and therefore the very development of these downstream channels, is a priority for those involved.

The development of these recycling channels also requires special support through labelling, or at least work to standardise good practice and raise awareness of it among stakeholders.

A special effort would need to be made with patients to promote awareness campaigns in order to prevent pharmaceutical products from being discharged into the wastewater circuit.

- The question of communication tools to support sorting can also come up against rules governing the promotion of healthcare products

For “consumer” patients, who have a role to play in the sorting process, there is the question of better communication, even beyond the principles of proper use, on the sorting process and the existence of channels. The ANSM, the *Direction générale de la santé* (French Directorate - General for Health – DGS) and the *Direction générale de la prévention des risques* (Risk Prevention Department – DGPR) could work together to draw up a policy on the communication tools that are relevant to the sorting process, in order to avoid confusion with the rules governing the promotion of healthcare products.

### **Disclosure of interests**

Authors have no competing interest to declare related to this article.

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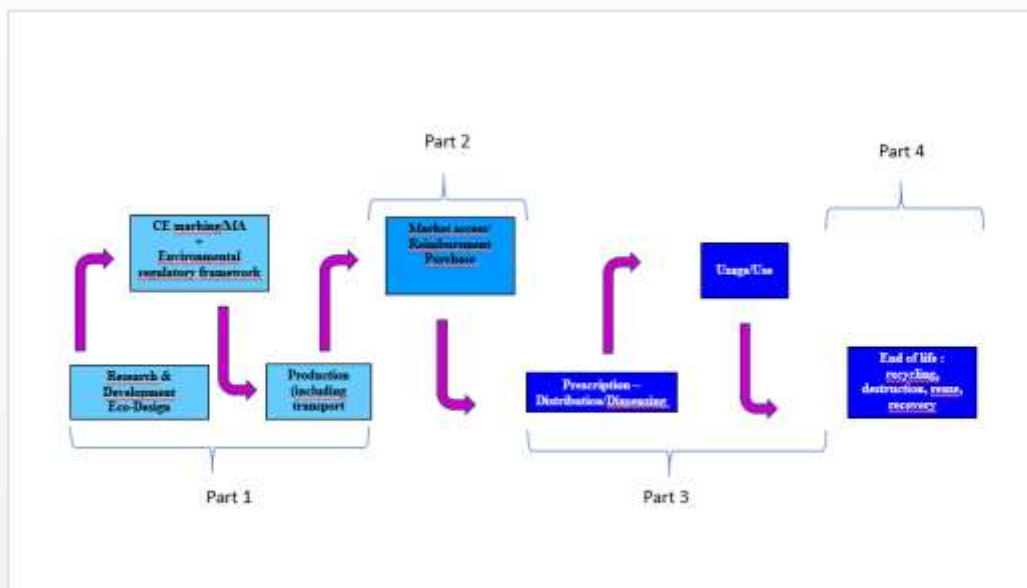
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**Figure 1.** Product lifecycle, segmented by “part”.



**Table 1.** Applicable pathways with the example of diabetes

Types of waste	Examples (non-exhaustive list)
Packaging	- Cardboard boxes - Primary packaging
Paper	- Leaflets - Paper inserts
Electrical and electronic equipment	- Blood glucose monitors - Certain brands of blood glucose sensors
Batteries and accumulators	- Blood glucose monitor batteries
Medicines	- Insulin vials or other injectables - Oral antidiabetics
Medical puncturing devices used by patients undergoing self-treatment and users of self-tests, including electrical or electronic equipment associated with such a device (where they present an infectious risk).	- Syringes - Sensor applicators - Needles - Lancets - Lancing devices - Insulin pumps - Certain brands of blood glucose sensors

**Table 2.** Summary table of recommendations

1	Introduce environmental criteria into the themes, conditions and promotion of clinical research by targeting funding.
2	Encourage industrial R&D in eco-design.
3	Establish joint governance between the Ministries of Health and the Environment.
4	Define a common method/standard for selecting and scoring healthcare products according to environmental criteria defined as part of a European approach, at the very least.
5	Establish an HAS doctrine for taking environmental criteria into account in the evaluation of healthcare products, which would be financially rewarded by the CEPS and in hospital procurement.
6	Strengthen and harmonise environmental sustainability criteria in hospital contracts, to raise the bar for manufacturers and promote genuinely responsible stakeholders.
7	<p>Promote environmental sustainability in healthcare, both in the community and in hospitals, in particular:</p> <ul style="list-style-type: none"> <li>• Initial and continuing training for healthcare professionals, hospital civil servants, institutional stakeholders (ANSM, HAS, etc.) and community professionals.</li> <li>• Use existing best practice guidelines as a basis, adding/integrating the environmental benefits of best practice.</li> <li>• Include a criterion for the eco-design of care pathways in the HAS certification standards for healthcare institutions.</li> <li>• Optimising the organisation of in-house pharmacy and pharmacy orders to avoid waste and optimise deliveries.</li> </ul>
8	Assess the environmental impact of per-unit dispensing (medicinal products and certain single-use MDs such as dressings).
9	Communicate and share knowledge about hospital and municipal waste collection and treatment systems.

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## APPENDIX. Definitions

### Responsible procurement:

- Purchasing in support of public policies to protect and enhance the environment and promote social progress (DAE - Ministry of the Economy, Finance, etc.)
- the purchase of goods or services from a supplier or service provider selected to minimise environmental and societal impacts and to encourage good practice in terms of ethics and human rights (AFNOR).

LCA - Life Cycle Assessment: Life Cycle Assessment (LCA) identifies and quantifies the physical flows of matter and energy associated with human activities throughout the life of a product. It assesses the potential impacts and then interprets the results obtained according to its initial objectives.<sup>1</sup>

Life cycle: all consecutive and/or interlinked stages, including research and development to be carried out, production, trading and its conditions, transport, use and maintenance, throughout the existence of the product or the works or the provision of the service, from raw material acquisition or generation of resources to disposal, clearance and end of service or utilisation (Directive 2014/24/ EU of 26 February 2014)

Environmental dimension: this is understood in the broadest sense, such as, for example, the reduction of resource extraction, the composition of products and in particular their ecological/polluting/toxic nature, the reusable/recycled/refurbished/recyclable nature of products, energy savings, the prevention of waste production and the recovery of waste, the environmental practices applied to the way in which the services are provided, and in particular the policies for reducing greenhouse gas emissions, performance in terms of protecting the environment and biodiversity, the fight against

deforestation, pollution, food and energy waste, the development of renewable energies, etc. in line with the service commissioned (PNAD 2022-2025).

Per-unit dispensing: per-unit dispensing of antibiotics is a way of ensuring the correct use of medicinal products, helping to reduce wastage and combating antibiotic resistance.<sup>2</sup>

Eco-design: Eco-design involves integrating environmental protection into the design of goods or services. Its aim is to reduce the environmental impact of products throughout their life cycle: extraction of raw materials, production, distribution, use and end of life. It is characterised by a global vision of these environmental impacts: it is a multi-stage approach (taking into account the various stages of the life cycle) and multi-criteria. It is implemented by a company or a public body, but it involves a large number of stakeholders throughout the product value chain and even beyond, including consumers or users and right up to recovery and recycling companies. Its value lies in examining the relationships that exist between the design choices made for a product and the resulting flows of materials and energy throughout its life cycle.

Sustainable product: a product that has less impact on the environment throughout its life cycle, i.e. from the extraction of its raw materials to its design, transport, use and recycling (ECC-Net).

Eco-design of care: Eco-designing healthcare means producing healthcare that has less impact on health, the economy, society and the environment in the short, medium and long term. The aim is to control the ecological and energy footprint of a product.<sup>3</sup>

Greenhouse gas: a gas in the atmosphere that retains some of the heat received by the sun.

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<sup>1</sup> Qu'est-ce que l'ACV ? - Ademe. (n.d.). Agence de la transition écologique. <https://urlz.fr/mEZs>

<sup>2</sup> Dispensation à l'unité des médicaments. (n.d.). ameli.fr | Pharmacien. <https://urlz.fr/mEZ6>

<sup>3</sup> Éco-conception des soins - Anfh. <https://urlz.fr/mFMf>, consulted on 15/09/2023