The Crofter: Sustainable Communications

SECTION EDITORS

The EMWA Sustainability Special Interest Group

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Greetings from the croft!

I think it's a neat coincidence that I have the pleasure to write my first editorial to this edition of The Crofter in the *Medical Writing* special issue on mentorship. I don't have an official mentor but ever since I became a member of EMWA in 2019, I feel like I have been mentored in some way, organically, by each member I've met. In particular, my professional development has blossomed since joining the Sustainability Special Interest Group (SUS-SIG) in 2020. Now in 2021, I am thankful to be part of such an enthusiastic SIG that supports my efforts to learn more about sustainability in research, healthcare, and our medical writing profession. Thanks to Raquel Billiones and Carola Krause's support and encouragement, here I am as The Crofter's section editor.

Here in The Crofter, we aim to share regular articles to help support your interest in learning more about sustainability. In this issue, Carola Krause and I introduce the EU Green Deal, its impact on the healthcare industry, and what it means to us as medical writers and communicators. I learned a lot from writing this article, and I hope you do, too.

Kimi Uegaki

Impact of the European Green Deal on the healthcare industry

The European Green Deal: A road map to sustainability

The European Green Deal (hereafter referred to as the EU Green Deal) is a road map towards sustainable development. It aims to guide the EU policymakers as they journey through the policy-making process and ensure all policy initiatives steer the EU towards the efficient use of resources and a clean, circular economy.

The EU Green Deal was adopted on December 11, 2019. This marked the moment that climate change and environmental issues moved from the fringes into the heart of policy-making within the EU. The EU Green Deal aligns with the EU's commitment to the Paris Agreement (adopted in 2015)[1] and the UN's 17 sustainable development goals, which are at the heart of the UN's 2030 Agenda for Sustainable Development (adopted in 2015).[2,3]

> The EU Green Deal will form the basis for all policies in the healthcare, pharmaceutical and medical technology sectors

Moving forward, the EU Green Deal will drive changes to EU laws in all economic sectors, including the health care industry, so that the EU can achieve the following goals:

- to become climate neutral (i.e., no net emissions of greenhouse gases) by 2050;
- to invest in economic growth that is decoupled

from resource use (think resource-efficient and circular economy);
- to ensure no person or place is left behind (think fair and prosperous society);
- to protect, conserve and enhance the EU's natural capital; and
- to protect the health and well-being of its citizens from environmental risks (think air, water, and chemical pollution).[4]

The changes will be driven through transformative policies and enabling pillars (Figure 1). The eight policy areas cover the following aspects:
- becoming climate neutral;
- supplying clean, affordable and secure energy;
- mobilising industries for a clean, circular economy;
- building and renovating in an energy- and resource-efficient way;
- striving for zero-pollution and a toxic-free environment;
- preserving and restoring ecosystems and biodiversity;
- implementing a farm-to-fork (F2F) strategy; and
- accelerating the shift to sustainable and smart mobility.[4]

Actualising the transformative policies will be made possible through enabling pillars such as:
- dedicated investments and financial tools to ensure that the transition is fair and inclusive across all member states;
- a commitment to mobilising research and innovation;
- a commitment to building capacity for the transition by engaging active public participation through education and training; and
- a commitment to establishing a new pact for accountability between all citizens, national/regional/local authorities, civil society, industry, and the EU's institutions and consultative bodies.[4]

This article aims to discuss what the EU Green Deal means for the healthcare, pharmaceutical and medical technology sectors, and reflect on the impact of the EU Green Deal on the medical writing and communications profession.

What does the EU Green Deal mean for the healthcare industry?

Human health relies on the protection of communities and their environments. Within the EU Green Deal, the global healthcare principle of "do no harm" is imperative. Through new policies and regulations, the EU Green Deal paves the way for a sustainable healthcare industry. Figure 2 presents an overview of the EU Green Deal goals and their impact on selected healthcare industry segments. In the following sections, we provide a high-level overview of strategies that focus on the following:

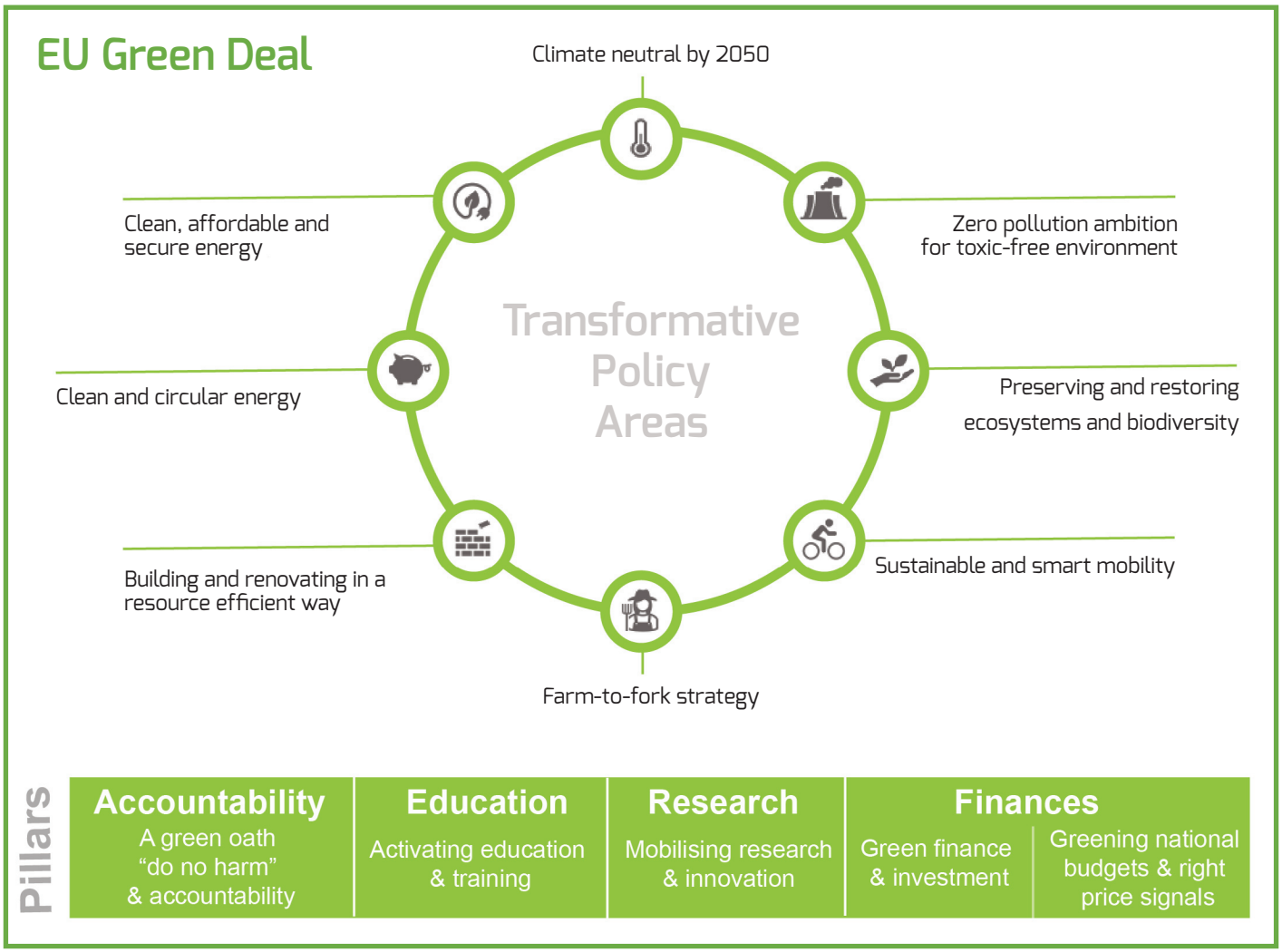

Figure 1. The transformative policy areas and enabling pillars that comprise the EU Green Deal.

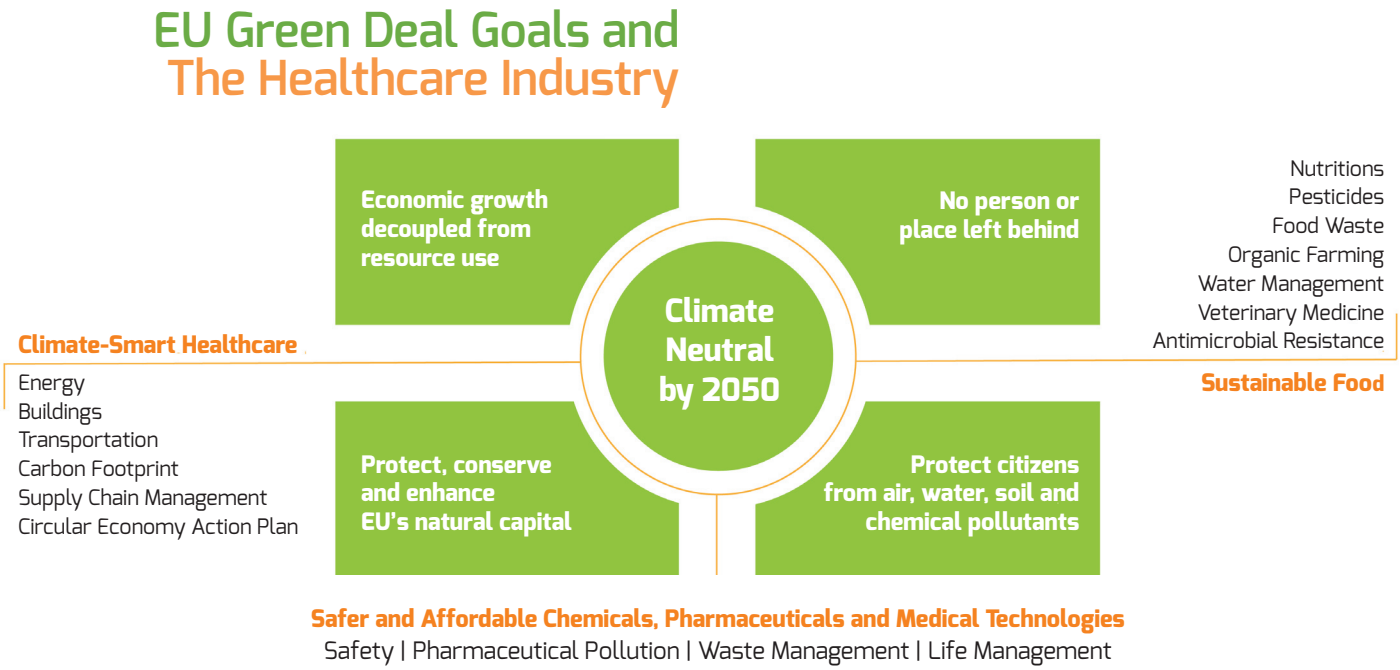

Figure 2. Overview of the EU Green Deal goals and their impact on selected healthcare industry segments

- Replacing harmful chemicals with safer and greener alternatives.
- Managing healthcare waste sustainably.
- Addressing pollution caused by the pharmaceutical industry and the development of green medicines.
- Transitioning to climate-smart healthcare.
- Enabling sustainable food practices.

Replacing harmful chemicals with safer alternatives

A substantial amount of chemicals, including those with well-documented adverse effects on health and the environment, are still used by the healthcare sector. Solutions that address the additive effects of different chemicals, nonbiodegradable chemicals, endocrine disruptors, and hazardous chemicals in all consumer products are acutely needed.[5] Therefore, the EU Green Deal includes plans to produce a Chemical Strategy for Sustainability. This strategy will be one of the steps toward a toxic-free environment and also contribute to the forthcoming Zero Pollution Action Plan (adopted by the EU in 2021).[6]

Managing health care waste sustainably

With its toxic and infectious properties, healthcare waste is an overlooked environmental and public health threat. Hospitals generate an estimated 5 million tons of waste each year, which translates to 13.2 kg of waste per bed per year.[7] The WHO and nongovernmental organisations such as Health Care Without Harm and Practice Green Health aim to transform healthcare worldwide so that the healthcare industry reduces its environmental footprint and becomes an anchor for sustainability.[8–10] Thanks to these organisations' efforts, healthcare waste management became one of the focus points within the EU Green Deal.

Under the EU Waste Framework Directive (Directive 2008/98/EC), a resource-efficient and circular economy will be promoted and an order of preference for waste management called the "waste hierarchy" will be introduced.[11] The waste hierarchy, which is based on the 3R's of reduce, reuse, recycle, categorises healthcare waste in four major types:

- general medical waste;
- infectious medical waste;
- hazardous medical waste; and
- radioactive medical waste.

> The universal healthcare principle of 'do no harm' is at the core of the EU Green Deal.

Thereby, the EU Green Deal bases its approach to healthcare waste management on the WHO release guideline, "Safe management of wastes from healthcare activities".[12]

Addressing pharmaceutical pollution and the development of green medicines

It is well recognised that pharmaceuticals, as a unique form of healthcare waste, are released into the environment with implications for human health, including antimicrobial resistance.[13] Globally, more than 600 active pharmaceutical substances (or their metabolites and transformation products), mainly antibiotics, analgesics, lipid-lowering drugs, beta-blockers, x-ray contrast media, and synthetic estrogens, have been detected in the environment in all sorts of environmental matrices.[14]

With the growing demand for pharmaceuticals around the world, the pharmaceutical industry's impact on the environment will be amplified.[13] With that in mind and in line with the EU Green Deal, the EU launched the Pharmaceutical Strategy in 2020, which aims to support innovation, competitiveness, and sustainability of the EU pharmaceutical industry. A core focus is to accelerate the development of safe, effective, and affordable "greener" medicines and medical technologies.[15] Thereby, the terminology "green" implies that the life cycles of medicines and medical technologies become relevant. The industry will be requested to evaluate, document, and report the environmental impact of a medicine or a medical technology on humans and animals. Thereby, the environmental impact, for instance, becomes a justification parameter for Biosimilar Market Authorisation Applications. Once approved, the pharmaceutical industry will be held accountable for the entire life cycle management of a medicine or medical technology.

Transitioning to climate-smart healthcare

That the climate crisis negatively impacts health is public knowledge; however, little is known about the healthcare sector's contribution to climate change. The healthcare sector contributes 4.7% of the total EU CO_2 emissions,[16] which putatively hinders achieving the EU's 2050 net-zero emission target documented in Europe's first legally binding Climate Law proposal.[17] Several initiatives such as the European Health Care Climate Council (EHCC) and Health Care Climate Challenge (HCCC) report that healthcare providers across Europe have committed to decarbonisation actions, green constructions (e.g., the use of antimicrobial wall coatings; overcrowding preventions; anti-viral ventilation systems), purchasing from circular economies, reducing hospital water consumption, using clean energy, and improving sustainable mobility options for patients and staff.[13,18] In the future, green healthcare systems will contribute to the health benefits of patients, workers, and visitors within healthcare facilities and outside them by promoting green construction and operation.[13]

Enabling sustainable food practices

The EU Green Deal informed the EC's Farm to Fork (F2F) Strategy to balance the impact of fair, healthy and environment-friendly food systems and farming. The F2F Strategy aims to achieve:

- a 50% reduction in the use and risk of chemical and hazardous pesticides;
- at least a 50% reduction in nutrient losses while ensuring that soil fertility is not decreased;
- at least a 20% reduction of fertiliser use;
- a 50% reduction in the sale of antimicrobials for use in farmed animals and aquaculture; and
- that 25% of total farmland is used for organic plant and animal farming by 2030.[19]

According to Health Care Without Harm, the healthcare sector, including many hospitals in Europe, have already transitioned to sustainable food systems. However, finding the balance between sustainable food systems and the ever-increasing climate crisis, with challenges such as water shortages, land and energy restrictions, and environmental pollution, is difficult.[20] Therefore, the EU aims to take the following steps to overcome these hurdles:

- Restructuring food environments so that consumers can make healthy and sustainable choices easily;
- Adding food labels so that consumers can choose healthy and sustainable foods;
- Stepping up the fight against food waste by cutting food waste by half;
- Promoting research and innovation;
- Improving animal welfare to improve animal health, which reduces the need for medication and preserves biodiversity.

Under the Horizon Europe Programme 2021-2027, the EU has earmarked €10 billion to invest in projects that aim to create innovative and secure ecosystems for plants and animals that make food healthier and greener while ensuring food security.[19–21] Additionally, the EU aims to intertwine the F2F Strategy with other healthcare initiatives such as the Europe Beating Cancer Plan in order to reduce the incidences of noncommunicable diseases through accessible and affordable healthier food.[13,20,22]

What does the EU Green Deal mean for the medical writing and communications profession?

As the EU Green Deal now forms the basis for all policies in the healthcare, pharmaceutical, and medical technology sectors, the need to address sustainability issues in certain regulatory

documents and grant applications will likely increase and become more explicit. Medical writers and communications specialists will need to stay abreast of new developments and requirements to prepare these documents for their clients adequately.

Regulatory documents

Medical writers are involved in preparing EMA marketing authorisation documents such as the Investigator Medicinal Product Dossier (IMPD; Module 3 of the eCTD dossier) and the Environmental Risk Assessment (ERA; Module 1.6 of the eCTD dossier). The IMPD aims to demonstrate the impact of medicinal products on humans. Thereby, data of all required chemicals, formulations, container closure and packaging systems, labelling, and the benefit-risk assessment, are collected in the IMPD (for further information, please join EMWA's DDA28 workshop).

The ERA aims to identify potential adverse effects of medicines on the environment due to use in practice (not manufacturing, transport, or storage) and to develop methods to minimise their release into our ecosystem. Such methods may include proper labelling for correct disposal of the medicinal product by patients, healthcare professionals, and keepers of companion or production animals.

In general, an ERA is conducted using a stepwise approach. In Phase 1, the medicinal product in question is evaluated in terms of its potential for bioaccumulation and persistence in the environment, that is, its so-called environmental exposure. If significant environmental exposure is anticipated or the active compound is associated with specific risks, known as the "however clause", then the evaluation continues to Phase 2. Phase 2 involves determining what happens to the medicinal products when they enter the environments (i.e., their "fate") and the product's potential effect on the organisms living in the ecosystem. If risks are identified, then the evaluation continues to Phase 3 to refine and extend the risk assessment. A negative Phase 3 result can be cause for rejecting authorisation for veterinary medicinal products but not human ones.[23]

Examples of ERA-related resources are listed in Table 1 for reference. With regards to veterinary medical products, new EU regulations will come into effect in January 2022; forthcoming changes for the veterinary ERAs will include a shift from a product-based to substance-based approach, new guidance for aquaculture, and updates to ERA guidelines before 2005.[23]

Nonregulatory documents

One of the EU Green Deal enabling pillars is "financing" and with it comes the healthcare industry's obligation to justify any EU-funded research. Of particular interest to the medical communicators is that the justification in EU grant applications needs to address UN Sustainability Development Goals.[24] Last year, the EU ran, for the first time, a call under the Horizon 2020 Framework Programme that invited research-driven small and mid-sized enterprises to submit a grant proposal with a "green" approach towards (medical) research.[21]

> The EU announced the launch of a €1 billion call for research and innovation projects that respond to the climate crisis.

In September 2020, the EU announced the launch of a €1 billion call to stimulate the development of innovative solutions that address the climate crisis and help protect the continent's unique ecosystems and biodiversity.[25] Under the Horizon Europe Framework Programme (the follow-up of the Horizon 2020 programme), these Green Deal calls will target research and economic concepts with a focus on long-term changes.[21] Therefore, medical communicators need to be educated on the UN Sustainability Development Goals in order to implement them into their application documents.

> Medical writers and communicators play a valuable role in bringing the message of sustainability to others

Lastly, another aspect that medical writers and communicators need to be aware of is the increasing attention that (inter)national funding agencies are placing on how data from research studies needs to be Findable, Accessible, Interoperable, and Reusable (FAIR).[26] This is aligned with the need to reduce and prevent research waste, such as unnecessary duplication of efforts. FAIR involves the creation of GDPR-compliant data systems in which all (meta)data are machine-readable and where real-time analyses are possible without the movement of (meta) data from their locations. FAIR data principles are advocated by organisations such as EMA and the Heads of Medicines Agencies,[27] EC,[28] and the WHO.[29]

Sustainability interest groups

Medical writers and communicators play a

Table 1. Examples of EU and EMA resources related to environmental risk assessments

Type of ERA	Resource
Human use medicinal products	• Directive 2001/83/EC – Community Code Relating to Medicinal Products for Human Use.[30] • Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use. Doc. Ref. EMEA/CHMP/SWP/4447/00 Rev. 1, 15 November 2018.[31] • Guideline on Environmental Risk Assessments for Medicinal Products Consisting of, or Containing, Genetically Modified Organisms (GMOs). Doc ref. EMEA/CHMP/BWP/473191/2006 – Corr.[32] • Guideline on Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products. Doc. Ref. EMEA/CHMP/GTWP/125491/2006[33]
Veterinary medicinal products	• Directive 2001/82/EC – Community Code Relating to Veterinary Medicinal Products[34a] • VICH GL6 Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase I – Step 7. CVMP/VICH/592/98-FINAL[35] • VICH GL38 Environmental Impact Assessment for Veterinary Medical Products Phase II. CVMP/VICH/790/03-FINAL[35] • Assessment of Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent and Very Bioaccumulative (vPvB) Substances in Veterinary Medicinal Product, EMA/CVMP/ERA/52740/2012.[35]

[a] Directive 2001/82/EC will be repealed when Regulation (EU) 2019/6 comes into effect on January 28, 2022.

valuable role in bringing the message of sustainability to others. Various sustainability interest groups for writers exist around the world, for instance:

- In-house sustainability groups within professional MedComms agencies.
- #GreenMedComms.
- The Environmental Writers Association (also known as turfwriters.org).
- The Society of Environmental Journalists.
- The Sustainability Special Interest Group (SUS-SIG) within EMWA (#EMWASUSSIG).

Conclusions

The EU Green Deal brings sustainability to the forefront of all economic sectors, including the healthcare industry. Moving forward, medical writers and communicators need to remain abreast of new developments and requirements for regulatory and nonregulatory documents so that they can adequately serve their clients.

Topics introduced in this article, such as environmental risk assessments, will be addressed more deeply in future editions of The Crofter. We also invite EMWA members who are interested in joining a dialogue about the EU Green Deal and its impact on the healthcare industry to join a **SUS-SIG Meet-and-Share Session** that will be scheduled in July 2021.

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Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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