EFPIA recommendations towards the Upcoming Circular Economy Act

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Executive summary

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and its members support the EU's ambition to advance a circular economy and share the objective of fostering sustainability while safeguarding public health and the resilience of global supply chains. We are committed to innovation, sustainable manufacturing, and responsible resource use. At the same time, we would like to bring forward recommendations to ensure the Circular Economy (CE) Act supports these goals with realistic, coherent and sector-specific measures.

To build an effective and forward-looking framework that meets the unique needs of the pharmaceutical sector, we encourage authorities to promote a circular approach grounded in collaboration. By engaging early with industry, regulators, and other stakeholders, the circular economy framework can uphold patient safety and support sustainability goals. Given the complexity of the healthcare sector — where thousands of highly regulated products depend on carefully validated materials and global supply chains — such dialogue will help ensure that legislative expectations are not only ambitious but also practical, fostering innovation and long-term resilience across the sector.

We recommend the following key principles guide the Circular Economy Act from a healthcare lens:

- Safety must be ensured: Certain materials cannot be easily substituted without creating a safety, efficacy or quality risk. Regulatory flexibility, from both environmental as well as pharmaceutical perspective, is key to ensure circular economy principles can be expanded within the pharmaceutical sector without compromising on safety.
- Plan for reality: Product and design changes take years. Transition periods must be appropriate to safeguard the safety of our products for patients.
- Coherence first: Avoid conflicting requirements across EU legislations. Align circularity rules with existing pharmaceutical, MedTech and adjacent frameworks impacting the healthcare sector (e.g. packaging & packaging waste regulation, waste of electrical and electronic equipment directive).
- One harmonised EU, not 27 versions: We need harmonised labelling, digital reporting and EPR systems. Fragmented requirements of single markets hamper a globally competitive EU.
- Global mindset: EU actions shape global supply chains. The EU must be a leading partner in global collaboration and alignment.
- Reward green efforts: Companies investing in circular solutions — for products and associated manufacturing processes— should be supported with incentives, not struggling against red tape. We support creating a single harmonised market for waste and secondary raw materials, as well as EU investment in the recycling industry to promote innovation, cost comparability with virgin fossil equivalents and a robust supply of quality material to promote stable demand for recycled content and spark deeper innovation in circular solutions.

At EFPIA, members are already engaging in circular initiatives[1]. Our continued innovation and engagement depend on a regulatory system which adequately considers and accommodates the specificity of our sector. A well-structured Circular Economy Act can help us get there — supporting innovation, patient access and sustainability.

[1] https://www.efpia.eu/news-events/the-efpia-view/efpia-news/white-paper-on-circular-economy

Part 1: General Recommendations towards the upcoming Circular Economy Act

Introduction

We welcome the EU's actions and policy plans to date in driving a fit-for-purpose regulatory environment in support of the circular economy ambition. A range of regulatory frameworks require adapting and/or careful implementation to further circular economy.

The pharmaceutical sector is proactively driving forward circularity and innovation during the development, manufacturing and supply of our pharmaceutical products. However, environmental regulatory requirements often fail to consider the highly regulated nature and the complexities of pharmaceutical, diagnostics, and healthcare supply chains. Similarly, pharmaceutical legislative frameworks do not offer flexibility to allow for rapid integration of more circular practices.

We therefore urge the upcoming Circular Economy (CE) Act to ensure regulatory coherence, avoid duplication, and incentivize ongoing sustainability efforts and accommodate a range of varied sectors, including healthcare. Europe's framework must foster an environment encouraging innovation and sustainability while safeguarding patient safety, product quality, and global supply chains.

An effective CE Act must address overlapping frameworks, further incentivize the development of sustainable products, and recognize the pharmaceutical sector's actual and potential contributions to the objectives of the circular economy. We encourage authorities across the themes of environment and health to facilitate rather than hinder sustainable transformation through harmonized, pragmatic, and sector-specific policies.

Key Opportunities and Concerns with Current Frameworks Driving Circular Economy in Europe

Opportunities

- **Setting the scene**: The EU is pioneering the integration of circular economy principles into industrial trade policies, fostering sustainable practices. Through global partnerships, Europe is setting the scene towards international standards for sustainability and circular resource management, as well as the handling of hazardous materials. This comes with important opportunities to define and standardized terminology to drive common understanding and streamline practical implementation of circular economy projects across the value chain.
- **Climate Action advancement**: Minimization, increased re-use and recovery of materials through recycling reduces the EU's dependency on virgin resources, and directly contributing to Europe's climate and emissions reduction goals. A strong secondary raw materials sector also strengthens supply chain resilience and through domestic resource loops supports strategic autonomy.
- **Innovation and Economic Competitiveness**: Horizontal legislation (Packaging & Packaging Waste Regulation[2], Directive on Waste of Electrical and Electronic Equipment[3], etc., and now also including the Circular Economy Act) can drive sustainable innovation in healthcare and actively support the reduction of waste across sectors, especially if they (i) accommodate sector-specific issues like adaptation timeline for regulated sector, (ii) engage industry across the value chain to develop appropriate implementation guidelines and share best practices, and (iii) avoid regulatory overlap and contradictory provisions.

[2] Packaging and Packaging Waste Regulation 2025/40 (PPWR). https://environment.ec.europa.eu/topics/waste-and-recycling/packaging-waste_en

[3] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012L0019-20240408

- **Digitalization tools** have the potential to enable transparent and efficient circular value chains and foster economic modernization as well as support a coherent regulatory ecosystem. We look forward to further collaboration in defining tools such as the Digital Product Passport[4] application in the pharmaceutical sector.

Challenges

- **Fragmentation and Complexity across the environment framework**: From burdensome, non-harmonized/standardized reporting requirements to numerous PROs across or even within Member States, conflicting definitions, and divergent national implementations create significant barriers within the EU market, failing to make it a united one. An increasing number of legislations (like REACH[5], CLP[6], PPWR[2]) create compliance burdens without clear practical alignment for implementation, creating regulatory uncertainties, inconsistencies and are thereby hindering innovative strategies, often impacting international market access.
- **Misalignment between pharmaceutical and environmental requirements[7]**: We encourage the Commission to align their ambitions across relevant framework and avoid inconsistent or contradictory mandates and regulatory obligations. Circularity in the pharmaceutical sector can only be implemented with the development of specific quality requirements for the use of non-virgin materials. The current food contact grade requirements do not fit the pharmaceutical regulatory quality imperatives for drug delivery devices and immediate packaging. We would strongly encourage early engagement with the EMA as a critical stakeholder to ensure alignment with patient safety requirements.
- **Transition Disruptions**: Sector-specific timelines in a highly regulated sector like medicines and medical technologies which can include material qualification and testing, clinical trial, regulatory approval) are not sufficiently considered in transition planning. It fails to consider the already stringent requirements from the EU pharmaceutical[8] and MedTech[9] frameworks, making it challenging and unrealistic to transition within the timelines set for other sectors while remaining compliant and without impacting patient access.
- **Implementation Difficulties and Supply Risks**: Transition to re-use systems is technically and logistically complex, requiring fundamental product redesign whilst maintaining patient safety and medicines efficacy, re-evaluation of interconnected processes and supply chains. Requirements for recycled materials must be balanced against safety and quality standards, especially critical in healthcare settings for product contact materials.
- **Lack of Global Coordination**: Lack of alignment risks fragmenting global supply chains for medicines and healthcare products and hence global access to relevant medicines.

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[4] Ecodesign for Sustainable Products Regulation. https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/ecodesign-sustainable-products-regulation_en

[5] Regulation concerning the Registration, Authorisation and Restricton of Chemicals. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20250901

[6] Regulation on classification, labelling and packaging of substances and mixtures. https://eur-lex.europa.eu/eli/reg/2024/2865/oj/eng

[7] EFPIA Thematic Analysis on Cumulative Legislative Impacts. https://www.efpia.eu/media/i0ihfkys/efpia-cumulative-legislative-impacts.pdf

[8] Pharmaceutical Regulation COM/2023/193 final and the Pharmaceutical Directive COM/2023/192 final. https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en

[9] EU Sustainable Prosperity and Competitiveness: priorities for the EU Circular Economy Act, MedTech Europe. https://www.medtecheurope.org/resource-library/eu-sustainable-prosperity-and-competitiveness-priorities-for-the-eu-circular-economy-act/

Recommendations for Reforming Circular Economy in Europe through the Upcoming CE Act

Transition Flexibility

- Introduce flexible, **sector-specific transition periods** reflecting critical healthcare timelines and product lifecycles. This should be evaluated in alignment with the industry and the EMA.
- Recognize the **specifics of healthcare products** where rapid material substitution or reuse timelines will risk patient safety and conflict with the sector legislation.
- Ensure that **product safety and public health remain primary considerations** during material transition phases. Early engagement with industry and the EMA can ensure that the current regulatory hurdles can be lifted (e.g recycled content used both for packaging as well as during manufacturing processes) while maintaining patient safety, quality and efficacy.

Realistic Transition Planning

- Integrate sectoral expertise (e.g. through EMA involvement) early in the legislative process to avoid contradicting requirements, reflect regulated timelines, safety standards, and criticality of healthcare products.
- Ensure realistic recycling and reuse requirements considering validation cycles, quality assurance, and regulatory obligations, and accommodate the cumulative impact of regulatory changes[7]. The timeline should also account for the need to support global supply chain resilience and allow our global suppliers to upscale availability of recyclable materials of appropriate quality and continuity of supply, as well as testing after import needs[10].

Assess, Revise and Simplify Overlapping and Conflicting EU Frameworks

- Systematically assess existing and upcoming regulatory requirements to eliminate redundancies, resolve conflicting requirements and ease the cumulative regulatory burden (e.g., labelling between PPWR[Error! Bookmark not defined.], GPL[11] and CLP[6]).
- Promote end-to-end digital compliance solutions, enabling automation and simplification of registration and reporting through unified EU platforms[4].
- Incorporate digital compliance standards to enable integration into corporate compliance systems and support automation.

Design for circularity while safeguarding product quality

- Engage across policy siloes to introduce circular design guidelines which are fit for the pharmaceutical sector, including for supply and waste[12].
- Standardize the quality assessment of non-virgin material to support the design of circular products while supporting patient safety imperatives.
- Any recyclability guidance should be the result of cross-stakeholder collaboration and be aligned with pharmaceutical framework. In particular, the involvement of EMA is essential to ensure the pharmaceutical framework also fits the needs for a circular framework.

Harmonisation Across EU Member States

- Drive harmonization of reporting and compliance requirements, including labelling, EPR schemes, and secondary waste management across Member States to strengthen a unified European market and to avoid fragmentation
- Encourage the creation of EU-wide Producer Responsibility Organizations (PROs) to improve compliance processes and promote free circulation of goods.

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[10] Packaging & Packaging Waste Regulation and what it means for manufacturers and supply chains. https://www.acquiscompliance.com/blog/eu-packaging-and-packaging-waste-regulation-ppwr-compliance/

[11] General Pharmaceutical Legislation

[12] EU Waste Framework Directive 2008/98/EC. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20240218

- Harmonize waste collection, transportation and recycling requirements and processes to simplify cross-border circulation and waste management in healthcare.

Shift Towards Incentivising Systems

The CE Act could play a critical role in catalyzing investments of innovation in the EU, such as boosting the secondary raw materials economy. It could be fostered by:

- Financial incentives (e.g. reduced EPR fees, subsidized sustainable and local materials) and regulatory incentives (e.g. expedited reviews / streamlined review processes for sustainable product changes, aligned with EMA and other authorities) should be embedded to foster innovation and reward sustainable innovations[13].
- Encourage public-private collaboration to develop new sustainable materials and capabilities, fostering innovations that benefit patients, companies, and the environment. For example, the trans regional circularity hubs referenced in the Clean Industrial Deal could serve as a collaborative cross-stakeholder platform[14].
- Recognize full lifecycle cost-benefit analyses, rewarding upfront investments that lead to long-term sustainability savings.

Engage Globally

- Coordinate global dialogue with international healthcare regulators[15] to ensure that Europe's approach does not disrupt supply chains or market access for critical products.
- The FDA has an existing guidance document to set food quality standards for materials recyclability & recycled content[16]. Alignment with similar guidance in EU and how that can be translated in pharma quality standards is recommended.
- Promote shared sustainability objectives globally, ensuring that recycling, circularity, and secondary raw materials standards are internationally aligned.
- Support early cross-sector engagement (vendors, suppliers, regulators) to prepare for sustainability requirements during product development.

Conclusion

The healthcare sector is committed to advancing circular economy principles while ensuring patient safety and global product availability. To succeed, the Circular Economy Act must offer realistic, coherent, and supportive frameworks that incentivize sustainable innovation and remove disruptive hurdles. Alignment, simplification, and pragmatic transition pathways, combined with early and sustained sector engagement are essential to fostering a thriving circular economy for a unified Europe and beyond, without disrupting vital healthcare solutions and supply chains.

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[13] FDA Pilot Program for streamlined/prioritized review for companies pursuing alternate and optimized sterilization methods. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices#MasterFile

[14] The Clean Industrial Deal: A joint roadmap for competitiveness and decarbonisation. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025DC0085

[15] United Nations' Global Treaty on Plastic Pollution. https://www.unep.org/inc-plastic-pollution

[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-use-recycled-plastics-food-packaging-chemistry-considerations

Part 2: Specific technical recommendations to the upcoming circular economy act

Design for circularity to comply with product quality

Data sharing along the supply chain

Design for recycling and ultimately circularity must start with the obligation of material suppliers to share information on material composition and circularity with downstream supply chain actors. Relevant information includes recycled and bio-based content and relevant certifications and traceability to source of origin, additives (identity and weight), material recyclability (including guidance assessed against) or biodegradability (including degradation time and conditions assessed) and carbon footprint. A relevant format could be digital product passports.

Creating standards for pharma-approved recyclates

Inspired by the new EU regulation for food-contact materials[17], similar **guidance for conditions under which mechanically recycled post-consumer material in pharma packaging** can be considered safe could help foster increased use of recycled content in the pharma sector.

Given current trends in newly enforced legislation such as the PPWR, derogations for the use of post-consumer recycled content in pharmaceutical applications for immediate packaging are timebound, and this may pose conflicts with pharmaceutical legislation[18]. This seems to be an appropriate position, given that there are limited controls currently on the collection and treatment of recyclates. As such, there is seen to be a much greater potential risk for impurity carryover in using mechanically recycled material than there is of environmental impact from using virgin plastics.

Processes involved in chemical recycling break down the polymers into their individual parts for clean up and reassembly into high quality resins/polymers where it is assumed that there is little risk for carryover compared to virgin material. In addition, the use of the material may also play a significant part in the overall risk to the patient from the use of recycled materials. An **appropriate science and risk-based guideline framework** for the introduction of recycled plastics is necessary to ensure predictability for industry. It's clear that there are different risk cases for plastic materials used in the sector.

Low risk materials would be those where there is a limited contact between the plastic materials and either the product or the patient. Examples of these could pen injector bodies or inhaler casings, where these have no interaction with the product. Voluntary takeback schemes where pen injectors can be returned to the manufacturer already exist; examples of which can be found in the White Paper on Circular Economy. Given the low-risk nature of the use of the plastic, it would seem simple to envisage a truly circular closed-loop system, perhaps benefitting from a more sustainable design. As the use of pen injectors increases, this will become a more pressing issue.

A second example, yet with a higher risk profile, would be **the single-use systems** used in the **manufacturing of biological products**. Advantages of using these single use systems are related to energy and Green House Gas emissions, especially when this is coupled with other process intensification initiatives; however, there are limited opportunities to recycle these plastics, and, generally, when this is done it is in the open-loop model. Instead, most materials must be

[17] Regulation on recycled plastic materials and articles intended to come into contact with foods (EU 2022/1616). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.243.01.0003.01.ENG&toc=OJ%3AL%3A2022%3A243%3ATOC

[18] More described in https://www.efpia.eu/media/5oif3bm4/efpia-white-paper-on-pharmaceutical-packaging.pdf

decontaminated and disposed of by incineration. The vision for single use systems is to recycle through pyrolysis, which would remove any biohazard contamination through heat. The resulting product from this would be indistinguishable from virgin material and could be used in the manufacture of further manufacturing systems. Recent studies has shown the potential for the use of recycled material in the production of one aspect of single use process train[19]. Notwithstanding this, there are still legal and regulatory issues with this. Firstly, there's the designation of the material as hazardous waste. Without agreement on a decontamination and recycling process the recycling of single use systems remains challenging. Secondly there would need to be clearly defined expectations around comparability which would be applicable globally. Without this, the other complexities of collection, recovering and recycling are moot.

Thirdly, it has been shown that a major part of the overall carbon footprint of a synthetic drug substance is linked to the use and disposal of solvents (est. 80%) during the synthesis. Studies conducted to date have shown that using effective recovery techniques and reusing these solvents can reduce this by 40%. There is some support for solvent reuse in the current Good Manufacturing Practices guidance, specifically ICH Q7 Ch.14.4:

- Solvents can be recovered and reused in the same processes or in different processes, provided that the recovery procedures are controlled and monitored to ensure that solvents meet appropriate standards before reuse or commingling with other approved materials
- Fresh and recovered solvents and reagents can be combined if adequate testing has shown their suitability for all manufacturing processes in which they may be used
- The use of recovered solvents, mother liquors, and other recovered materials should be adequately documented

However, this is vague and experience shows that this is not always interpreted in the same way globally. Often this is viewed in a "case-by-case" way, which leads to a lack of predictability for industry and a consequent reticence to move forward. Specific guidance to address this area would enable increased opportunity for solvent recovery using third party toll facilities or shared platform technology facilities where common solvents are used across multiple processes, e.g. for manufacture of oligonucleotides.

It should be acknowledged that there are sensitivities around the arising from the origin of the nitrosamine contamination issue. Here, poor practices and controls led to contamination of active substance with a potent carcinogen. However, recent explorations of the link between recovery processes and carryover or production of nitrosamine impurities have illustrated that this is not to be expected in most cases. In reality, this case illustrates the need for harmonised guidance and expectations around the recovery and reuse of solvents to move forward predictably in the future.
With the prudent guidance, encapsulating a science and risk-based approach, it should be possible to further the recovery and reuse of solvents during the manufacture of drug substances. This could provide a **global standard for reuse and lead to adoption of this practice as standard within the industry**

Harmonisation across EU Members States

Recyclability assessment & collection

During the design process, a **harmonized recyclability assessment methodology fit for healthcare** must be in place. Current guidelines (e.g. RecyClass in the EU, but also APR in the US) are tailored towards fast moving consumer goods and consequently do not provide guidance on specific packaging

[19] https://doi.org/10.1016/j.jclepro.2024.143436

formats used in the pharmaceutical sector. While a harmonized approach is expected under the PPWR, it is critical that this considers the specifics of pharmaceutical packaging formats.

Even though immediate packaging is exempted from the recyclability assessment under PPWR, for the specific case of multi laminate PVC-based blisters, recycling has consistently posed a challenge due to the hazards of chlorine emissions and potential to contaminate other waste streams. Current initiatives have been limited to examples of pharmacy-led schemes or pharmaceutical company-initiated take-back programs. These schemes typically utilize non-circular 'one-off recycling' pilots using specialist recyclers. However, these efforts often lead to higher costs, low take-back rates, and difficulties in scaling. In parallel, several pharmaceutical companies are actively assessing a switch to recyclable-ready mono-material alternatives, i.e. mono-polymer blisters made from plastics that can take advantage of established recycling streams. However, in that case blister design is critical to ensure compatibility with sorting and recycling infrastructure.

Achieving technical recyclability does not guarantee that the components will be recycled at scale, which is essential for true circularity. A divergence in collection of pharmaceutical packaging is noticed between EU Member States, where e.g. some countries refer the medicinal packaging to kerbside recycling (e.g. Sweden), whilst other member states highlight that even outer packaging should go to the pharmacy (Spain, Portugal), and still others are not giving clear guidance. **Clear guidance on whether empty pharmaceutical packaging is acceptable as part of kerbside recycling** is therefore needed for all layers of pharmaceutical packaging, especially for the immediate packaging.

EU-approval of cross-border shipment for specialised low volume waste

Because of the need to ensure patient safety, quality and efficacy of medicines, many types of pharmaceutical waste contain high quality materials which, if they could be efficiently recovered, could be used as high quality secondary raw materials to displace virgin material use in other sectors or ultimately be re-incorporated into the pharmaceutical supply chain. These materials occur across the value chain, from manufacturing (postindustrial) waste over clinical trials materials to used devices and packaging of medicines. Volumes at the member state level may be too low for efficient domestic recycling of these specialised high-quality materials. Allowing transboundary shipment within Europe to specialized treatment hubs could facilitate technology advancement and achieve the necessary economy of scale.

For example, several members have set up voluntary patient takeback schemes where the same type of waste is collected in several EU countries and transported for recycling within EU. Current processes are administratively heavy with long lead times for approval e.g. 6-9 months, with re-approval required yearly on a country-by-country basis. For these programs, a more practical way of working would be to **obtain approval and/or registration at the EU level**. Similarly, clear guidelines and templates that are the same in all EU countries must be designed, preferably in one language that can be shared across all member states. The guideline should refer to templates that need to be filled out as a part of the notification, this should include table for R12 and R13 treatment, contract between notifier and waste treatment facility, how to calculate financial guarantee and so on. Finally, harmonised waste classification interpretation is key to facilitate transboundary shipment.

Shift towards Incentivizing Systems

Creating a **functioning market for high-quality chemical and mechanical recycled materials, especially plastics** is key as the abatement cost when using high-quality recycled plastic is much higher compared to investing in decarbonizing processes. If EU seeks to exploit recycled materials as decarbonization lever, recycled materials must be made available at high quality and more reasonable prices.

To guarantee the quality needed for pharma, introducing incentives for voluntary take-back schemes can be a way to stimulate the sector. Examples of incentives could be:

- Make an **exemption for paying extended producer responsibility fee if a take-back scheme and recycling of the products can be documented**, as it is going to be the case in Denmark. The company should still pay a fee for products that they do not collect in the scheme.
- **Funding to cross-industry schemes for takeback and recycling activities**. Setting up a takeback scheme is costly, so financial support can be necessary for companies to establish takeback. The financial support could be given through the Trans-Regional Circularity Hub that is described in The Clean Industrial Deal but it could also be through other initiatives, such as healthcare systems.

At the same time, also recycling infrastructure must be further advanced. The incentives can e.g. be through access to funding for startups, governmental grants, regulatory support including fast-tracking permits and tax incentives.

Other

Align Pharma regulation with "reduce" mindset

Pharma regulation requires extensive regulatory text on leaflets and packaging which leads to larger sizes and typically results in higher materials use and increased emissions from larger and heavier items being shipped to patients. Implementing provisions that allow to reduce material use for pharma packaging without compromising patient safety (e.g. digital information) should be a top priority. One example is the provision of electronic patient information leaflets[20].

Sector specific standard for product life cycle assessment.

Incorporate global industry standard for product lifecycle assessment (LCA) for a circular product design by (a) using Product Category Rules (PCR) to identify life cycle impact hotspots; (b) evaluating a comprehensive set of environmental impacts to prevent burden-shifting; and (c) supporting the development PCR for high-volume products that currently don't have a PCR. PCRs should also enable the use of LCA to calculate lifecycle-based circularity metrics and thus to quantify the circularity of a certain product or service.

[20] https://www.efpia.eu/news-events/the-efpia-view/blog-articles/environmental-footprint-of-patient-information-leaflets-pil-how-a-paper-pil-compares-to-an-electronic-pil-epi-guest-blog/