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Moving to ePI: Reductions in energy, carbon emissions and paper use

Introduction

Data from the US and UK indicates that many people who take medicine don't read the patient information leaflets (PILs) that come with medication. Others find it hard to understand or want more information.

With 40% of those who take medicine never reading the leaflet and over half of those who do having difficulties reading them[1], it can reasonably be argued that paper PILs are not meeting the needs of today's society. In a digital economy, there is an opportunity to refresh and rethink this essential part of providing medicines. Transitioning from paper PILs to **electronic Product Information (ePI)** is an opportunity to support an industry-wide shift that will bring benefits for not only to patients and healthcare systems, but also to the planet through energy and greenhouse gas savings.

While ePI is gaining traction as a movement within the pharmaceutical industry, with industry leaders and regulators across the globe engaging in discussions to understand its impact and benefits, there is a gap in the understanding of specific energy and carbon savings via a reliable dataset. We aim to address this gap and test the hypothesis that ePI will provide environmental benefits through undertaking an assessment, based on **Life-cycle Assessment (LCA)** methodologies, with support from experts in the pharmaceutical industry. This publication outlines our findings.

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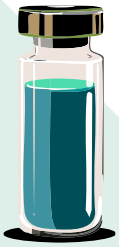
1: REV BRAS EPIDEMIOL 2019 'Medicine package inserts from the users' perspective: are they read and understood?'

The assessment focused on three environmental factors: **Energy Consumption**, **Global Warming Potential (GWP)**, and **Resources** used.

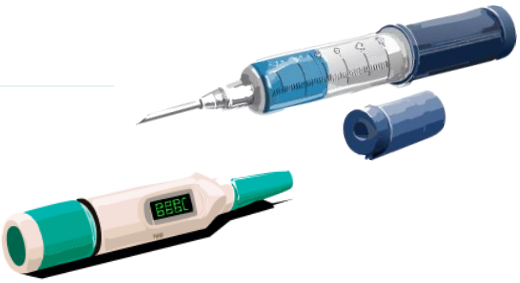
Our assessment makes use of **three pharmaceutical packaging archetypes** (vials, autoinjectors and blister packs) sold in the European market, including Norway, the UK and Switzerland. These archetypes were used as broadly representative of the range of different medicinal products typically used in these markets in hospital settings.



Vials

Sealed containers used to store liquid medicinal products.

Key assumptions:
Transported in refrigerated trucks.
1u of product per vial.



Autoinjectors

Single-use, pre-filled devices designed for self-administration of a specific drug dosage.

Key assumptions:
Transported in non-refrigerated trucks.
1u of product per auto-injector.

Blister packs

Plastic trays that separate individual tablets, capsules or other solid dosage forms, sealed with a foil.

Key assumptions:
Transported in non-refrigerated trucks.
6u of product per blister pack.

Please refer to the Annex for the full list of assumptions.

Analysis Method

Modelling was initially conducted at the packaging level, across the three archetypes. Drawing on real world data from the pharmaceutical industry it was possible to create an estimate of the impact that moving from a physical leaflet to an electronic leaflet would have. To provide an indication of the impact this would have across the whole sector this was extrapolated out across the market as a whole.

For complete set of assumptions for data collection and baseline calculations, please refer to the assumptions section in the Annex.

Archetype-level analysis according to ISO 14040 and ISO 14044

The LCA model was created using the data provided by pharmaceutical companies (for a total of 5 products across 3 packaging archetypes – vials, autoinjectors and blister packs), supplemented with data available from the Ecoinvent database where primary data was unavailable. The two methods used for the calculations were:

1) **Cumulative Energy Demand;** and

2) **IPCC 2021 GWP100**

We conducted the LCA in alignment with ISO 14040 and ISO 14044 methodologies, evaluating the cradle-to-grave life-cycle assessment for each packaging archetype in two scenarios: with PIL and with ePI. The specific life-cycle stages considered include production of the PIL and the packaging carton, packaging of the product, distribution of the product, use of the PI, and end-of-life disposal of the PI and carton. The assessment compares the energy usage, GWP, and paper/cardboard use of the paper-based leaflet system with the energy usage, GWP and paper/cardboard use of the proposed electronic format.

Please see the Annex for further details on the life-cycle stages considered.

For the ePI scenario specifically, this included the energy required and carbon footprint produced to use the ePI on a smartphone or computer, including the energy required to download and during smartphone/computer use to read the ePI. For the PIL scenario, this included the production of the paper and printing of the PIL, noting that usage of the PIL does not require energy usage or product emissions.

The functional unit used to measure and compare the paper and electronic product information scenarios for this study is defined as the provision of essential information about the medication to end-users, including usage instructions, precautions, and relevant details, while meeting regulatory requirements and ensuring user safety and comprehension.

Market-level extrapolation

To gain an indicative view of the broader impact of ePI adoption across the EU, Norway, Switzerland and the UK, the outputs from the archetype-level analysis were extrapolated using market sales data for the relevant products to cover all products used in hospitals. We then further extrapolated to include, in addition, products sold outside of hospitals (including over-the-counter (OTC) products).

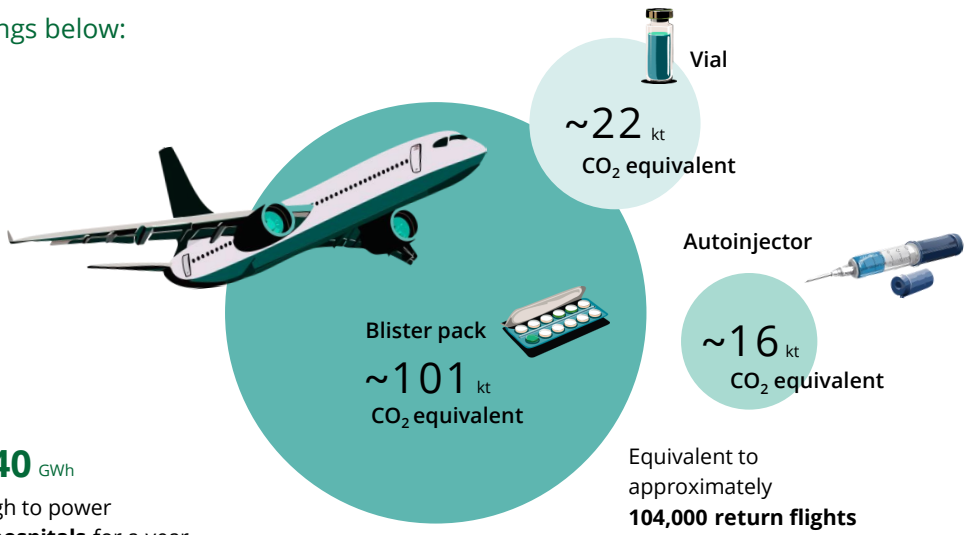
Hospital data for Cyprus, Malta, Denmark, Estonia, Greece, Luxembourg and Slovenia was unavailable, however these markets likely represent a small share of total volumes so could be viewed as negligible in the total calculation.

Market sales numbers were taken from a secondary source for extrapolation purposes i.e., IMS IQVIA Q2 MAT 2023 for Hospital Sales and IMS IQVIA Q4 MAT 2022 for Retail + Hospital Sales dataset.

Results

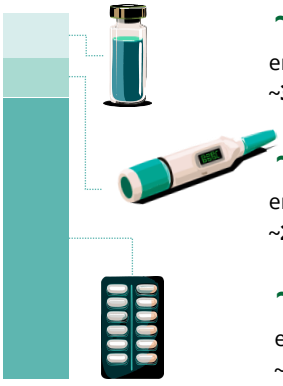
The results of our study demonstrate the positive environmental impact of transitioning to ePI, even if only vials, autoinjectors, and blister packs sold in hospitals are converted (equivalent to 30% of all medicinal products, including those sold outside hospitals), as shown by the projected energy, carbon and resource savings below:

Global-warming potential (GWP)



Equivalent to approximately **104,000 return flights** between Paris and New York

Energy savings



~140 GWh
enough to power
~**3-4 hospitals** for a year

~110 GWh
enough to power
~**2-3 hospitals** for a year

~730 GWh
enough to power
~**15-18 hospitals** for a year

Resource savings are enough to cover the surface of Paris in paper approximately

x1.2 **~115km²** for Vials

x1.0 **~100km²** for Autoinjectors

x7.7 **~750km²** for Blister packs

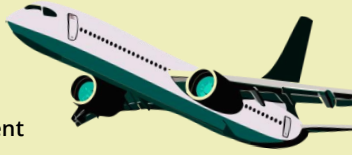
Our model, which assumes complete replacement of paper PILs with ePI for all vials, autoinjectors, and blister packs sold in the European market, demonstrates the significant positive environmental impact achievable through this strategic shift. While these three packaging archetypes represent only 30% of all pharmaceutical products sold in Europe (including OTC products), the findings highlight the substantial environmental benefits possible through wider ePI adoption across the industry. This is further demonstrated in the following two subsections which show extrapolations across further market segments. These extrapolations are given for estimation purposes only, to support high-level directional assumptions. They should not be relied upon for decision-making without further analysis.

Market-Level Savings

For hospital products only

The product assessed represented ~33% of all products used in hospitals. Hospital products are considered likely to be where ePI is first widely adopted, as they are usually administered by healthcare professionals. By extrapolating the LCA results from the assessment of vials, autoinjectors and blister packs to all products administered in hospitals, we see a range of potential savings that could be achieved as follows:

Global-warming potential (GWP)



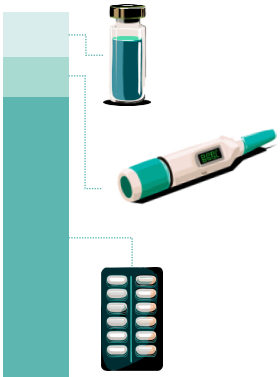
~370 kt **CO_2 equivalent**

Equivalent to approximately **245,000 return flights** between Paris and New York

Energy savings

~2,520 GWh

enough to power **~57 hospitals** for a year



~2,235km² Resource savings enough to cover the surface of Paris in paper approximately

x22

Market-Level Savings

For total market (hospital and pharmacy products, including over-the-counter (OTC) products)

As products used in hospitals represent approximately 45% of the total European market, further extrapolating the findings for hospital products to cover the whole European hospital and pharmacy market (including OTC products) reveals the significant positive environmental impact achievable through complete ePI adoption. Our projections, shown below, highlight the potential benefits of this transition and highlight the compelling case for transitioning to ePI.

Energy savings

More than 5 TWh

enough to power
~125 hospitals for a year

GWP reduction

More than 700 kt

CO_2 equivalent

Equivalent to approximately
600,000 return flights
between Paris
and New York

Resource savings

5200 km²

enough to cover the entire
surface of Paris in paper

52 times

Conclusion

The potential greenhouse gas and energy savings of up to 41% and 47% respectively, across the life-cycle stages considered, that can be gained by moving to ePI present a compelling sustainability case. Achieving the three saving types indicated in this report (greenhouse gas, energy and resources) will contribute to a more sustainable region, supporting the EU's progress towards delivering the Green Deal.

However, the case for adopting ePI extends beyond sustainability to encompass cost savings, enhanced patient experience, and innovative approaches to insights, metrics, and ways of working. While we have focused primarily on the sustainability benefits in this report, it's anticipated that advantages will be realised across all these areas.

The benefits case is clear: embracing ePI within the life sciences industry offers a compelling opportunity to significantly reduce environmental impact along with numerous other benefits. While challenges such as digital inclusion need to be addressed, the potential for a more sustainable, efficient, and patient-centric future makes the case for embracing ePI strong.

ePI Implementation

Deloitte can support you transition to ePI, wherever you are on your journey. We have a proven track record across all stages of ePI design and implementation, and have our own ePI platform and accelerators to fast-track your transition.

Strategy and Business Case

Building ***the case for change*** and identifying benefits of moving to ePI.

Strategy Definition

clarifying what ePI means to your organization and how you want to reach the future state.

Business Case Development

quantifying the benefits and costs of implementation: and defining the roadmap to realization.

Prototype and Pilot Development

Bringing the ePI vision to life and gaining insight on how this can work in your operation.

Prototype development

demonstrating the art of the possible.

Business Case Development

simulating how ePI can drive success in your organization both internally and externally.

Operating Model Design

Imagine and design new or updated structures, capabilities and operational ***processes to make ePI a reality.***

Operating Model Design

bringing the ePI strategy to life, leveraging our first-hand experience in successful design.

Process Redesign

defining the core processes for you to successfully drive your ePI operation.

Scale, Implement & Run

Enterprise-wide roll-out of the ePI transformation programme, developing necessary assets, solution architecture and other implementation activities.

ePI as a Service

we can provide ready made assets for you to manage ePI across the organisation.

Scaled Implementation

partnering with you to drive successful adoption.

To learn more about how Deloitte can partner with you in your journey to ePI, visit www.deloitte.com/uk/ePI

Authors & Acknowledgements

To learn more about how Deloitte can partner with you in your journey to ePI or eIFU, reach out to one of our ESG or Industry Leads listed below or visit our website

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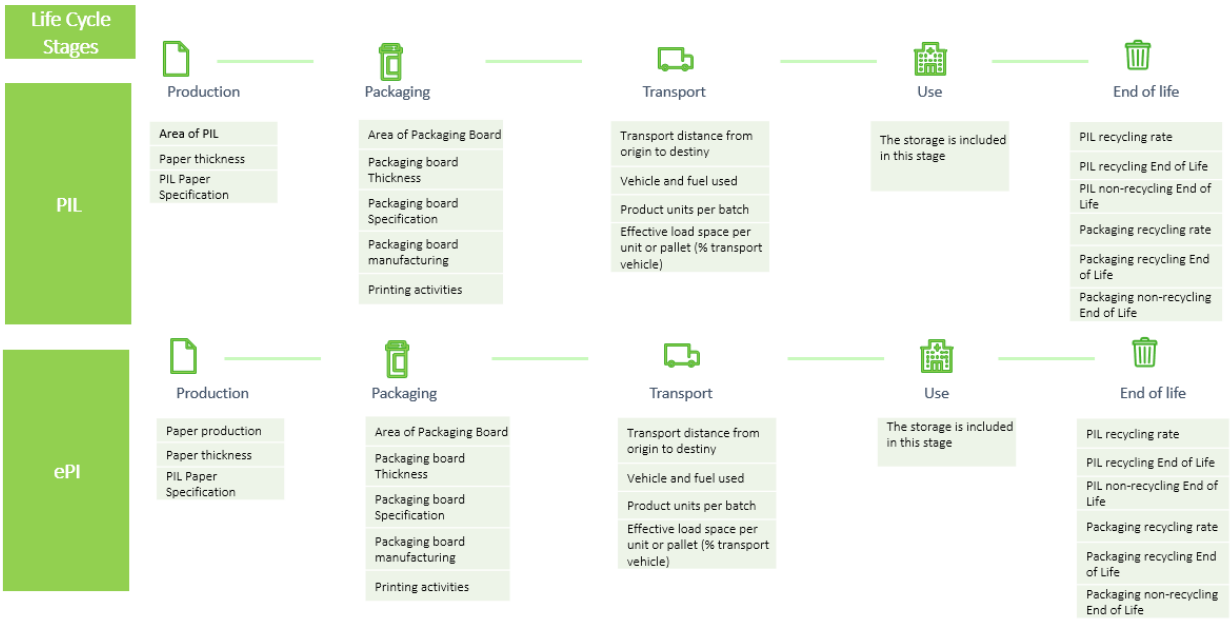
Further information

For further information about ePI please visit www.deloitte.com/uk/ePI

For further information about electronic Instructions for Use (eIFUs) please visit www.deloitte.com/uk/en/eIFU

Annexes

Life-cycle Stages Considered



Detailed Methodology

A cradle-to-grave LCA was conducted following the methodology outlined in ISO 14040-14044. Data collection and calculations were performed in the following way:

1. **Definition of scope**: The economical and geographic scope and limitations were determined.

2. **Archetype definition:** The characteristics of the study archetypes were defined to ensure they were representative.

3. **Data collection**: Primary and secondary data was gathered to establish the model's foundations and assumptions. Data was validated with industry experts.

4. **Definition of assumptions**: Where specific data was unavailable, assumptions were made based on industry averages. These were validated by the companies involved. Please see Appendix section Energy Consumption Assumptions by Archetype for data assumptions used.

5. **Modelling:**

5.1. The model was structured to account for all life-cycle phases. See Appendix section Life-cycle Stages Considered for further details.

5.2. Data was inputted into the Simapro tool, including:

5.2.1. Material composition and quantities for the PILs and packaging.

5.2.2. Energy consumption data for production, printing and transport processes.

5.2.3. Emission factors from the Ecoinvent database for specific materials and processes.

5.3. Simapro calculated the energy consumption, greenhouse gas emissions and resource usage for each life-cycle phase.

6. **Extrapolation and final analysis:**

6.1. Outputs from the LCA model were extrapolated to cover all vials, autoinjectors and blister packs sold in hospitals, using product sales volume data.

6.2. These were then extrapolated further to include hospital products from other packaging archetypes (i.e. not vials, autoinjectors or blister packs) using product sales volume data.

6.3. Results covering all hospital products were then extrapolated to give an indicative view of potential savings of across all hospital and pharmacy products.

Overarching Assumptions

Data Limitations:

- Original data set represents only five pharmaceutical product packages and the energy/resource usage across the leaflet life-cycle.
- Original data is standardised for analytical purposes and extrapolated to represent the total packs sold in the European market (incl. UK & Switzerland).
- Data represents 20 EU markets, UK & Switzerland.
- The percentage of savings is an estimated range and does not consider the infrastructure costs in the industry.

Leaflet Product & Packaging:

- These include the creation and packing of a paper-based leaflet in secondary pharmaceutical packaging (cardboard).
- Calculations consider costs for paper production, leaflet printing and transportation to packaging site, leaflet folding and packaging.
- It does not take into account costs from other sources such as physical human effort in folding and packing a leaflet, quality checks or packaging write-offs due to label changes or excess production or stock recalls.

Transport:

- We looked at two modes of transport – Upstream (journey from paper production to print and packaging site) and Downstream (journey from packaging site to storage facilities and pharmacies through to its point of use/ sale) and assumed that all transportation was conducted by road.
- We assume that there will be little to no impact on the Downstream mode of transport for pharmaceutical products, however the main cost savings will be realised from the Upstream mode of transportation.
- Data was collected from various touch points in the transportation supply chain. Original data had missing information with regards to unit sales per pack for autoinjectors, the data for vials and blister packs was used as an average indicator for autoinjector calculations.

Other:

- Storage costs: These will not change significantly with transition to ePI because the impact is only on the secondary packaging. We assume that the outer packaging size will not change as the actual pharmaceutical product will not change.
- Usage costs: These do not take in to account the set up (infrastructure) manufacturers will need to adapt to enable ePI use. They do take in to account the fact that PILs do not entail emissions or energy consumption during their use. In contrast, ePIs require an electronic device and access to the network, and hence do exhibit emissions and energy consumption during the usage phase.
- End of life: Only PIL weight (paper) and packaging weight (cardboard) will be considered as waste, as these are the only materials that undergo modification or elimination based on the scenario, and thus, may result in differences in waste generation.

Energy Consumption Assumptions by Archetype

Life-cycle Stage		Vial	Autoinjector	Blister
Packaging	Amount of Product per packaging	1 u	1 u	6 u
	PIL folding	The energy consumed regarding PIL folding is being considered in the product packaging process		
Transport	Upstream transport	Provided	Average between Vial and Blister	Provided
	Downstream transport	Refrigerated trucks*	Standard trucks*	
	Unit sales pack per shipper	Provided	Average between Vial and Blister	Provided
	Upstream and downstream transport	Road transport		
Storage	Product storage	Not significantly different from PIL*		
Use	ePI parameters	Estimated from current products: medicines.org.uk*		
	Device used to access the ePI	Smartphone / Computer*		
	time spent reading ePI	12 min*	12 min*	13 min*
	ePI views	10% view rate		
End of Life	Waste generated	PIL weight (paper) and packaging weight (cardboard) will be considered as waste*		
		ePI waste will be the same as the PIL but considered the absence of paper and the cardboard size reduction*		

* Research and estimated values due to lack of information received in data collection phase.

Archetype Inventory

Data		Unit	Archetype					
			Vial		Autoinjector		Blister	
			PIL	ePI	PIL	ePI	PIL	ePI
Pharma product	Weight per pharma product	g	33	33	100	100	19	19
PIL	PIL material	type of material	Primabrite Ultra	-	Primabrite Ultra	-	Primabrite Ultra	-
	PIL weight	g	9	-	15	-	6	-
	ePI size	kB	-	216	-	364	-	195
		nº of words	-	2.819	-	2.937	-	3.172
Packaging	Packaging board material	type of material	GC1, 100% virgin fibre	GC1, 100% virgin fibre	GC1, 100% virgin fibre	GC1, 100% virgin fibre	GC1, 100% virgin fibre	GC1, 100% virgin fibre
	Packaging board weight	g	11.0	7.7	12.3	11.0	7.0	6.6
	Change in packaging size	%	30%		10%		5%	
Transport	Upstream transport	type of transport	Road (standard)	Road (standard)	Road (standard)	Road (standard)	Road (standard)	Road (standard)
	Downstream transport	type of transport	Road (refrigerated)	Road (refrigerated)	Road (standard)	Road (standard)	Road (standard)	Road (standard)
Unit sales pack	Weight per unit sales pack	g	53	40	127	111	32	26
	Is it a cold chain product?	y/n	Yes	Yes	No	No	No	No
	Shipping packaging	unit/ shipping	40	53	30	34	150	187
	Weight per shipping packaging	g	2.125	2.125	3.823	3.823	4.815	4.815

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