

Fact bank ECMA – POD & Paper sustainability

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Contents

1. General.....	1
2. Print on demand	2
3. Sustainability	2
4. Digital	3

1. General

1.1. Will moving to ePI actually threaten the health and safety of patients?

Currently, printed pharmaceutical leaflets represent the only failsafe method of ensuring the right information reaches the patient, regardless of the patient's digital literacy or access to the internet. Without maintaining a complementarity approach, where paper leaflets continue to remain the primary source of information, a large part of the population risks no longer having access to vital information. Thus, we support ePI complementing printed pharmaceutical leaflets without fully replacing them.

1.2. Are patients better protected through paper leaflets?

Printed pharmaceutical leaflets are highly regulated – they are produced through a robust process with embedded automation and checks. This controlled environment allows any risks to be minimized throughout the production process. These paper leaflets are directly inserted in the medicines packaging and thus reach the patient along with the medication. This further minimizes the risk of confusion regarding the medication and the respective product information.

While electronic product information provides certain advantages to users, online product information is nonetheless subject to certain safety threats such as cyberattacks and safety breaches. Furthermore, ePI relies on patients of disposing of both electronic devices and a stable internet connection to access the information, whereas printed pharmaceutical leaflets arrive directly in the hands of the end users.

1.3. How many people still rely on printed pharmaceutical leaflets?

Within the EU, there is both a geographical¹ and age divide when it comes to the use of online tools. In particular, low income and senior citizens are negatively affected when it comes to accessing information online. For instance in Greece, only 78% of the general population access the internet regularly. Among citizens aged 65-74, in 2020 only 61%² reported using the internet in the past three months. While internet use and accessing information online is becoming more widespread across Europe and all age groups, a large part of the European

¹ Eurostat 2022.

[https://ec.europa.eu/eurostat/databrowser/view/isoc_ci_ifp_iu\\$DV_632/default/map?lang=en](https://ec.europa.eu/eurostat/databrowser/view/isoc_ci_ifp_iu$DV_632/default/map?lang=en)

² Eurostat 2022b. <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/edn-20210517-1>

population still heavily relies on other forms of information, such as printed pharmaceutical information.

2. Print on demand

2.1. *Why isn't POD a good option for replacing pharmaceutical leaflets with ePI?*

Print on demand (POD) raises multiple challenges, in particular from a safety perspective. Currently, printed pharmaceutical information is the only failsafe method to ensure vital information reaches the patient at all times. Printing product information on demand poses challenges in ensuring that the right and complete product information reaches the home of the patient and is not lost along the way. POD is subject to higher technical failure such as printers failing, skipping lines or not printing the full set of information – which can result in serious health threats to medicine users. It can also be subject to human error as the pharmacist needs to ensure that the right leaflet is printed in the right languages. POD also increases the chances of the leaflet getting separated from the product or being associated with the wrong medicine, potentially leading to serious health threats for the consumers.

2.2. *What risks does POD entail?*

POD is subject to higher risks of human and technical error. Common printers that could be subject to technical failures and problems cannot be expected to provide the same level of accuracy and safety as the highly regulated industrial printers. This is crucial, as misprinting or skipping a line containing vital information for the patient could translate into severe consequences for the safety and health. For instance, it could lead to the wrong dosage of the product leading to serious health issues.

2.3. *Do models of POD already exist in certain countries?*

In Italy, a certain model of POD exists called the 'Farmastampati' project. It seeks to provide the most recent pharmaceutical leaflet to patients by notifying pharmacists if updated leaflets are available and enabling them to either print it for the patient or send it via email. In such a system, the medical leaflet remains in the pack of all pharmaceutical products.

2.4. *How can we ensure that the patient always gets the latest and most accurate information about a pharmaceutical product? Won't digital solutions help getting the latest information possible?*

It is true that constantly updated information, accessible online, can offer additional benefits in the provision of care. As such, the industry sees a complementarity of online and offline tools to provide better care. Such step forward would need to be however carefully assessed. It should go through the same strict assessment on the information to be shared on leaflets.

3. Sustainability

3.1. *Are paper pharmaceutical leaflets really sustainable?*

In order to make pharmaceutical leaflets, no trees are cut down – the fibre required comes from recycled paper, trees rejected from other end-uses with a higher economic value as well as forest thinnings. Currently, the paper and paper leaflet industry functions as a circular economy in which recycled paper is re-inserted into the material loop. As such, 81.3% of the

fibres used in European fibre-based packaging come from recycling and industrial residues. Furthermore, European forests are growing by 2% net per year (equates to 1500 football pitches per day or an area the size of Switzerland since 1950).

3.2. *Where do the resources for the paper leaflets come from?*

No trees are cut down specifically to make paper or paperboard - 81.3% of the fibres used in European fibre-based packaging come from recycling and industrial residues. To make the leaflets, 6.2% of fibres were sourced from logs rejected by sawmills, 6.2% came from residue of timber production, 12.5% comes from forest thinnings and 75.1% from recycled paper and board.

3.3. *What is the share of recycled paper?*

The paper industry at large, and the specific branch of activity of printed pharmaceutical literature has for years invested in the circularity of its products. Paper is the most recycled packaging material in the EU. In 2020, 82.3% of paper and cardboard packaging was recycled in the EU³.

3.4. *What happens to all the paper leaflets?*

Paper leaflets are collected and recycled, closing the loop in the paper production. These resources get fed back into the production of new paper and cardboard and contribute to the 81.3% of recycled content. In 2020, 56.1 million tonnes of paper and board were collected and recycled in Europe. Paper and cardboard can be recycled 25+ times.

3.5. *How does the paper recycling work ?*

After paper is put in the recycling bin, it's taken to a recycling centre where contaminants such as plastic or glass are removed. Next, the paper is sorted into different grades and fed into a mill for processing. Here, large machines (pulpers) shred the paper into small pieces. This mixture of paper, water, and chemicals is heated and the pieces of paper break down into fibres. The mixture is pressed through a screen to remove adhesives and other remaining contaminants. Next, the paper will be spun in a cone-shaped cylinder to clean it, and sometimes ink will also be removed. At this point, the pulp is sent through a machine that sprays it onto a conveyor belt. Water will drip through the belt's screen, and the paper fibres will start bonding together. Heated metal rollers will dry the paper, and the paper will be put onto large rolls, which can be made into new paper products.

4. Digital

4.1. *Would a complete digital transition be more sustainable and guarantee the saving or precious resources (e.g. deforestation; use of chemicals, etc.)*

³ Eurostat 2022c. https://ec.europa.eu/eurostat/databrowser/view/cei_wm020/default/table?lang=en

The paper industry already ensures a high level of sustainability of its products and has invested heavily in the past years to increase its recycling levels which now reach 84.9% in 2018 (Eurostat).

The industry relies on sustainable raw materials. With regards to forests, EU's forests have grown by 10% between 1990 and 2020, according to Eurostat. In addition, 90% of the forests owned and/or managed by the paper and pulp industry are forest management certified.

Digital solutions have the opportunity to decarbonize many sectors. However, this needs to be carefully assessed bearing in mind how sustainable the industry currently is, if digital solutions can lower the overall environmental footprint of medical information and understand what adverse effects such measure could endanger on patient safety.

4.2. Don't you think that using digital solutions will help to keep costs down for pharmaceutical products?

This is the general assumption when introducing digital solutions. However, we must paint a more accurate picture around this claim. An in-depth cost-benefit analysis must be carried on the adverse effects caused by such measure, including the costs linked to the rise of emergency room visit due to the wrong intake of a medicine. While a direct saving will be felt by pharmaceutical company, removing the paper information would raise costs otherwise avoided with printed leaflets, which would be borne by national health systems.

4.3. How big is the carbon footprint of datacentres?

The International Agency for Energy (IAE) has estimated that data centres and data networks together use about 2% to 2.5% of global electricity consumption⁴. Digital infrastructures thus "burn" 200 to 250 terawatt hours (TWh) per year, equivalent to half of France's annual nuclear production. The global digital ecosystem is responsible for 2 – 4% of the planet's greenhouse gas emissions – twice as much as air travel.

4.4. Is cyber security really a big threat? If so, is it realistic to expect possible cyber threat to data and information such as the one reported on pharma leaflet?

Cyber attacks are growing across the globe. It is a threat simply because a 100% protection of the data linked to leaflets cannot be guaranteed. However, a certainty of this level is necessary for healthcare provision including a complete understanding of the medicine that is being sold and/or prescribed. This is an area where complementarity of information on medicine (online and paper) can be useful to reduce the level of risks.

There are many (recent) examples where cyber attacks have led to a loss of information, which often were very secured. As examples, we could name the following:

- Colonial Pipeline ransomware attack May 2021;

⁴ LeMonde 2022. https://www.lemonde.fr/economie/article/2022/01/09/le-numerique-dans-le-piege-climatique_6108779_3234.html

- 2020 cyber-attack on the USA government which also affected NATO, UK government and EU parliament;
- Covid 19 – Vaccine booking platform cyber attack to Lazio Region 2021;
- Covid 19 – Irish vaccine certification platform data leak caused the platform to shut.