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# Medicine information leaflets: Paper, digital or both?

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## Contents

.....

Green MEP advocates for keeping paper  
medicine leaflets 4

The mixed blessing of digitalising  
medical leaflets 6

Digital and Paper: Ensuring Universal Access to  
Pharmaceutical Information 8

The European Commission's proposed pharmaceutical strategy leaves it to the countries to decide whether the medicine information leaflet is in paper format electronic, or both. However, moving exclusively towards the electronic version could risk leaving behind those lacking digital skills.

Currently, medication instructions including dosage, storage or potential side effects are provided through a written, standardised leaflet enclosed in each package of medicines. But the revamp of the bloc's regulatory framework for pharmaceuticals, presented by the European Commission on 26 April, gives an option for having only an electronic format of the leaflet.

With only half of Europeans having basic overall digital skills, according to Eurostat data, having only digitally available information on medicines could put some patients at risk and reduce medicines' safety and efficiency. To address this Commission is proposing that "the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge". But this could add additional work to pharmacists.

In a series of articles, EURACTIV looks at the benefits and obstacles of digitalising medical information.

## INTERVIEW

# Green MEP advocates for keeping paper medicine leaflets

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By Giedre Peseckyte | euractiv.com



Tilly METZ in the EP in Brussels. [Philippe BUISSIN/EP]

The European Commission's proposed pharmaceutical strategy leaves it to the countries to decide whether drugs' package leaflet is in paper format electronic, or both. However, having only electronic leaflets might put patients' safety at risk, Luxembourgish MEP Tilly Metz has warned.

The revamp of the bloc's regulatory framework for pharmaceuticals, presented by the Commission on 26 April,

aims to unlock timely and equitable access to safe and effective medicines for all EU citizens while at the same time boosting the attractiveness of the EU pharmaceutical industry.

The proposal for a new directive and regulation that replace the 20-year-old pharmaceutical legislation deals with competitiveness, innovation, availability, and accessibility of medicines. But it also touches on package leaflets that provide medication instructions, including dosage, storage or potential side

effects.

Currently, information is provided on a standardised leaflet enclosed in each package of medicines but [Article 63](#) in the directive says that "member states may decide that the package leaflet shall be made available in paper format or electronically, or both".

As the proposed directive "has a general objective to guarantee a high level of public health by ensuring the quality, safety and efficacy of medicinal

products for EU patients," MEP Tilly Metz from the Greens, one of the six shadow rapporteurs for the new regulation, warned that having only electronic leaflets would put some patients at risk.

"There is a risk, a safety risk. It reduces the safety of medicine if we introduce that," she told Euractiv in an interview, listing connection issues, digital access, and digital literacy as some of the reasons.

According to [Eurostat](#), in 2021, only a bit more than 50% of people in the EU aged 16 to 74 had at least basic digital skills. The share of people with those skills was the highest in the Netherlands and Finland, nearly reaching 80% in both, while on the other side of the scale, in Romania it stood at under 30%, and around 31% in Bulgaria.

That lack of digital skills might make the information provided only electronically inaccessible for some, according to a [survey](#) conducted by consumer cluster Euroconsumers in Belgium, Italy, Portugal, and Spain.

The majority, nearly 80% of over 4,000 participants who responded to a paper questionnaire, disagreed with the suggestion of replacing paper leaflets inside drug packages with QR codes.

Respondents felt that having only electronic access to information would disadvantage older people (81%) and would make society too dependent on the Internet (70%).

Metz already voiced her concerns in a [debate](#) on 20 September in Parliament's Public Health Committee (ENVI) on behalf of Danish Green MEP Margrete Auken, who is a shadow rapporteur for a new directive.

"We are not keen on the idea of digital leaflets, especially when it comes to antimicrobials. Here, all info should be written on the immediate packaging of the drug," Metz told the meeting.

Asked by EURACTIV what is the optional solution, Metz said: "For us, it's very clear that the digital leaflet should only be a complement and not a substitute."

"As a complement – yes. But not to replace the paper leaflet.

Based on the proposal, she said, the countries can pick either or both formats for providing the information. "There should be a harmonised approach in the EU. [...] It's not really in the interest of the of the patient here," Metz said.

### Not buying the Commission's proposed solution

The Commission's proposal states that if the package leaflet is only made available electronically, "the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients".

This risks putting an additional burden on the pharmacists, which is why Metz called the solution "quite unrealistic".

"We know that pharmacists have a high workload, often they are confronted with medicine shortages and have to find a substitute for that," Metz said. Her comment touches on the drug shortages that hampered access to medicines across the EU last autumn.

Adding additional tasks to pharmacists would also affect customer satisfaction as it would "increase the people's waiting [time] in the pharmacy".

She added that this would also mean requiring pharmacies to invest in printers.

Another concern voiced by Metz is the possible misuse of digital leaflets for commercial purposes.

"We have to make safeguards that it is not used for commercial purposes so that it really only contains the needed information," she stressed, adding that this could also confuse patients.

"First of all, you get some advertisement [online] and then they look at what you were looking at. And later on, you get an advertisement saying: 'Oh, you have high blood pressure. We can suggest these vitamins,'" Metz gave a scenario, calling for this to be prevented.

Having the digital version of the leaflet is seen as useful by 35% of respondents to the Euroconsumers survey, going up to 43% in Italy and Spain.

One of the reasons for that is the environmental impact. Around 61% agree that QR codes are better for the environment than paper leaflets.

But Metz is not convinced as servers for storing information and smartphones for scanning QR codes would need energy. Additionally, pharmacies would still be using paper for printing information for those who request it on paper.

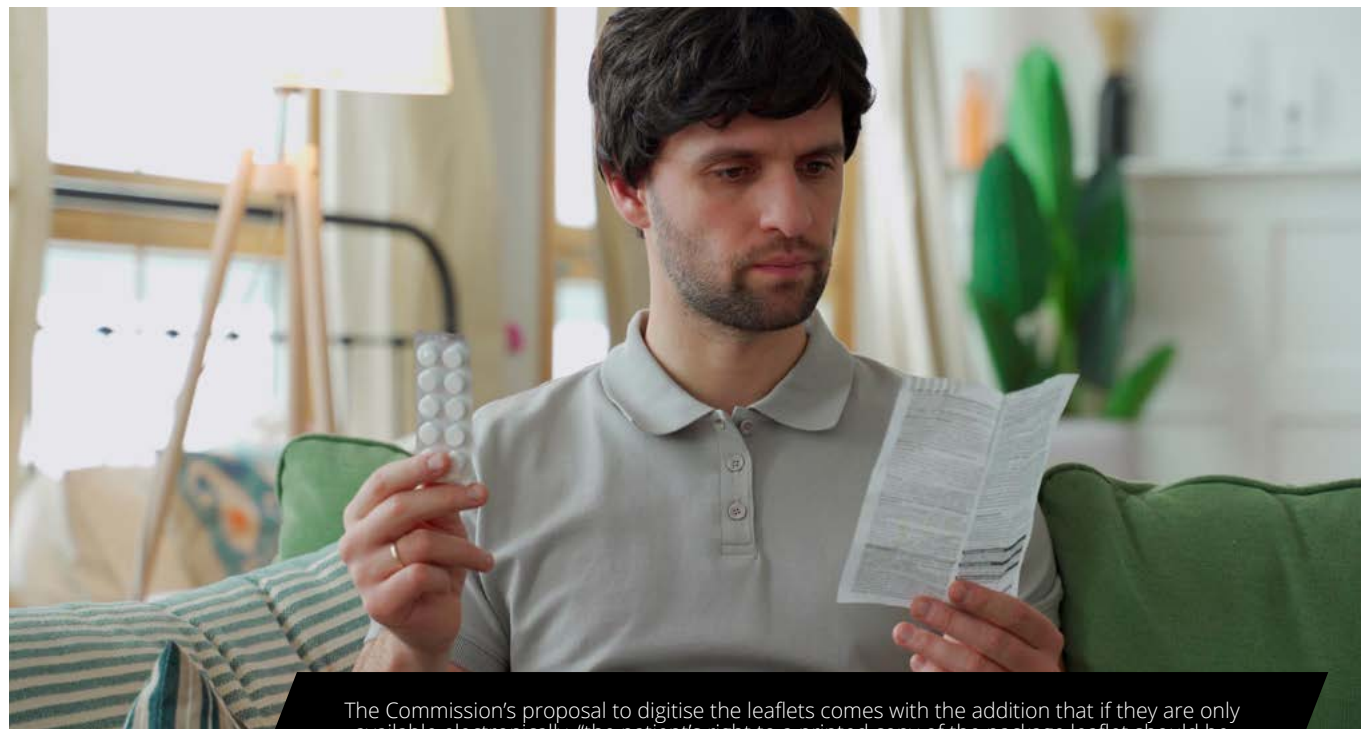
"It is a kind of greenwashing," she said. "We have really to look at the whole picture."



# The mixed blessing of digitalising medical leaflets

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By Amalie Holmgaard Mersh and Giedre Peseckyte | euractiv.com



The Commission's proposal to digitise the leaflets comes with the addition that if they are only available electronically, "the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge". [Grustock/SHUTTERSTOCK]

The proposal to revamp the EU regulatory framework for pharmaceuticals leaves it up to individual countries to decide whether drugs' package leaflets come in a paper or electronic format, or both – prompting concerns over digitisation and accessibility.

In the EU, every medicine package must contain a patient information leaflet (PIL), which contains regulated and scientifically approved information, such as its intended purpose, how it should be used or what side effects may occur when taking it, to ensure the proper use of the medicine.

As the digital transformation of healthcare across the EU picks up, the revamp of the bloc's regulatory framework for pharmaceuticals, presented by the Commission on 26 April, [proposed](#) that "member states may decide that the package leaflet shall be made available in paper format or electronically, or both".

This proposal has met mixed reactions from stakeholders, with some arguing that this will hamper access to medical information for some, and others stating the opposite. Both sides agree that no one should feel left behind in the digitalisation process.

## The benefits of electronic leaflets

Digital leaflets have their benefits, such as ensuring fast access for patients to updated information about the medicine.

According to the European Medicines Agency (EMA), digital platforms open additional possibilities to disseminate [product information](#) (PI) electronically.

In their [news release](#), EMA argued that digitalising information could address limitations of paper versions, such as making information interoperable with other electronic health

systems such as e-prescription and electronic health records.

Additionally, digital platforms can "better meet patients' and healthcare professionals' needs for accessible, trustworthy and up-to-date information on medicines available at the right time," EMA said.

Sophie Dagens, Regulatory Policy Officer at Medicines for Europe, shared similar thoughts: "Electronic product information could enhance health literacy, through search functions, and videos".

"It will also fill a gap: currently, surveys have revealed that patients in hospitals or for products administered by healthcare professionals, such as vaccines, do not receive the paper leaflet," she told Euractiv.

Public Health Advisors at pharma, be Marie Vande Ginste and Nathalie Lambot in a joint comment listed benefits for patients of digital leaflets such as: "an immediate access to the last up-to-date information, access to information tailored to their needs, and that the healthcare professionals remain with a key role in accompanying the patient when reading the product information".

Moreover, in their paper "Electronic leaflet pilot in Belgium and Luxembourg hospitals" they both argued that having electronic leaflets could have a positive impact on medicine shortages.

"This is because it would make it unnecessary to recall products to update the product information in the paper PIL," they explained adding that this could also facilitate imports between countries in Europe.

## Taking the right approach

However, the move towards

digitised leaflets without having paper versions has stirred worries that it could also harm patient safety, as only 54% of Europeans in 2021 had at least basic digital skills according to [Eurostat](#).

Ancel·la Santos Quintano, Senior Health Policy Officer at the European Consumer Organisation (BEUC), is worried that "the Commission could decide in a few years' time to get rid of paper package leaflets altogether which would be a mistake".

"Digital information should not replace paper leaflets but complement them," Quintano added, referring to article 63 paragraph 5, stating that the Commission can later amend the legislation and make electronic package leaflets mandatory.

"Consumers need to access crucial information about the medicine inside the box, and not only through some QR code, which we know will lead to fewer people consulting this information," Quintano said.

BEUC has also previously [warned](#) that certain people could be left behind, as has the European Patients Forum, which [calls](#) "access to high-quality information is an important aspect of health equity" and states that "electronic product information (ePI) should not be seen as a substitute for the paper leaflet, but rather as an opportunity to expand available formats."

## Ensuring access to printed information

So far the Commission's proposal to digitise the leaflets comes with the addition that if they are only available electronically, "the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all

patients."

Dagens from Medicines for Europe, assured that the industry is willing to look for solutions: "We are committed to finding solutions for all patients to ensure that no one is left behind. This includes the right to printed information."

"We are open to dialogues with other stakeholders to find solutions for patients who will not be able to access – in countries like New Zealand and Australia, the leaflet is printed out by healthcare professionals and pharmacists for patients who request it," Dagens said.

But Pharmaceutical Group of the European Union (PGEU) does not seem too optimistic about this. "In addition to causing serious workflow disruptions and delays in the delivery of medicines to patients, it would also place an unsensible financial burden on pharmacies and a responsibility that is today a key regulatory obligation for pharmaceutical companies," the group [write](#) in their position paper.

Therefore Ginste and Lambot are in favour of "a gradual implementation depending on the setting, hence starting in the hospital setting and for products administered by the healthcare professionals".

Ginste and Lambot added the importance of educating citizens about the existence and benefits of digital leaflets "to support a future smooth transition also outside the hospital setting, which takes on board all citizens".

"Only when citizens are well aware of the existence of the digital leaflet and how to access the digital leaflet, an implementation in ambulant care can be envisaged," they said adding that "it remains the patients' right to have access to a printed leaflet".



PROMOTED CONTENT

DISCLAIMER: All opinions in this column reflect the views of the author(s), not of EURACTIV Media network.

# Digital and Paper: Ensuring Universal Access to Pharmaceutical Information

By MLPS | MLPS



[Ingo Bartussek/Shutterstock]

The European Commission's recent proposal to review pharmaceutical legislation has sparked a significant debate. The directive's suggestion to allow Member States to opt between electronic and traditional paper medical leaflets raises valid concerns about the potential marginalization of older and vulnerable demographics.

MLPS, Medical Leaflet = Patient Safety,

is a subgroup of ECMA (TR: 948591610750-02), the European Carton Makers Association, and represents the printers of regulated pharmaceutical information, including Package Inserts (PIs), Medication Guides (MedGuides), and Patient Package Inserts (PPIs).

As MLPS (Medical Leaflet = Patient Safety), a branch of the European Carton Manufacturers Association, we echo these apprehensions. We advocate for

a complementary approach that seamlessly merges the advantages of both electronic and paper mediums.

Recent surveys underscore the importance of this complementarity. A [study](#) by the European Consumer Organisation (BEUC) spanning Belgium, Italy, Portugal, and Spain revealed a telling statistic: 79% of consumers believe that paper leaflets should accompany medications, even if a QR code alternative exists. The primary concerns? The

potential sidelining of the elderly (81%) and an over-reliance on the internet (70%).

While electronic leaflets offer numerous benefits, an outright replacement of paper leaflets could inadvertently deprive many Europeans of essential medical information. Such a move risks medication errors and compromises patient safety. The digital divide is real: Eurostat data shows that only 57% of those aged 55-74 use the internet regularly. Even in tech-savvy nations like Denmark, a significant 23% [lack smartphones](#). Furthermore, digital access remains elusive for many, especially in countries with higher poverty rates.

The proposed 'Print on Demand' (POD) policy, which would allow pharmacists to print leaflets upon request, is fraught with challenges. Beyond the added burden on pharmacists, there's the undeniable risk of inaccuracies when using standard printers, which could jeopardize patient safety.

Smaller nations with unique languages face their own set of challenges. However, the solution isn't to eliminate paper leaflets. A dual approach, offering digital translations while ensuring paper leaflets for those less tech-savvy, is the way forward. The printing industry is poised to support this, offering tailored solutions for these nations.

Electronic leaflets also bring up concerns about data privacy. With cyber threats on the rise, the safety of online health data is under scrutiny. It's essential to provide patients with offline access to critical information, ensuring their privacy remains uncompromised.

The proposed five-year transition to electronic leaflets seems rushed. Given the digital challenges many Europeans face, a more extended ten-year transition period would be more prudent, ensuring patient safety isn't compromised.

In essence, the path forward requires a harmonious blend of the digital and traditional. By leveraging the strengths of both electronic and paper leaflets, we can guarantee safe, accessible, and private information for every patient. It's time to prioritize patient well-being and craft a pharmaceutical legislation revision that leaves no one behind.

[IMotortion Films/Shutterstock]



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