



WHY LEAFLETS WITH MEDICINE MATTER

AN OVERVIEW

April 2021

WHY PRINTED MEDICINE INFORMATION MATTERS


Healthcare professionals receive critical information through Package Inserts (PIs) which helps keep patients safe. Making sure that prescribing physicians are fully informed with PIs can help prevent potentially fatal drug interactions.

+1 Million People




Adverse drug events send more than 1 million people to hospital emergency rooms each year according to the CDC.

3x More Likely



People age 65 and older, are three times more likely to visit ERs due to adverse drug events and seven times more likely to be hospitalized.

Half a Billion €



PIs saves our healthcare system money. According to the FDA, almost half a billion dollars are saved from avoiding adverse drug events.

For those with chronic conditions, requiring and managing multiple prescriptions can be complicated. With the help of PMI documents, patients and their caregivers can digest critical information to avoid preventable medical errors and increase compliance with prescribing instructions.

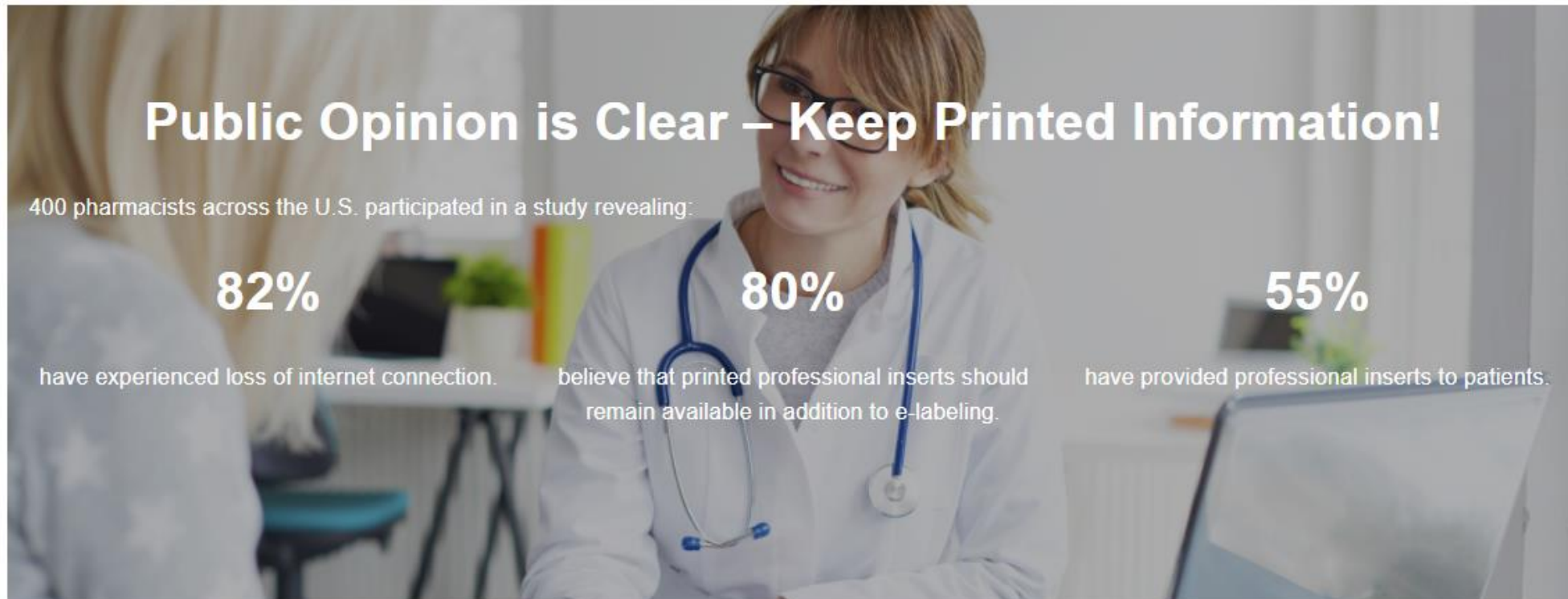
WHY I NEED INFORMATION ON PAPER?

“Medication information on paper is what I want because it’s always there when I need it. I’m one of the **33% of Americans** who doesn’t have access to the Internet. For me, it’s because of where my family lives.”

John

“My daughter helps me with my medication and it’s just easier if the information’s on paper and attached right to the bottle. Besides, I don’t know how to use a computer!”

Michelle



FACT CHECK

PACKAGE INSERTS (PI), MEDICATION GUIDES AND PATIENT PACKAGE INSERTS

Health care providers want or prefer electronic labeling and are sometimes “confused” by paper format PI.

Fact **93%**

Time and time again, health care professionals have made it clear their preference for paper format PI clear. Approximately 93% of health care providers opposed a previously proposed transition to electronic labeling.

Electronic labeling in lieu of paper improves patient safety.

Fact **\$671 billion**

There is no data that backs this claim. It is estimated that adverse drug events associated with ER visits and hospital admissions cost the health care system **\$671.6 billion in 2017**.

Only 6% of pharmacists reported using exclusively paper resources to retrieve prescribing information.

Fact **88%**

According to a 2014 NERA study, 88% of pharmacists indicated that they had utilised the printed package insert, with 73% having used the printed package insert at least monthly.

A transition to an electronic only PI labeling system will save money.

Fact **\$31.9 million**

FDA cost benefit analysis monetises the time lost by pharmacists using the proposed system at between **\$31.9 million and \$39.8 million annually**.

Electronic labeling, which patients prefer, ensures patients have the most up-to-date information.

Fact **24hrs**

It is unlikely that PI would need a major revision and updated materials can be printed and delivered to manufacturers within 24 hours if needed.

FDA has the authority to eliminate paper format PI.

Fact **NO**

FDA does not have the authority to eliminate paper format PI and has said as much. The requirement that paper format PI be provided to pharmacists by manufacturers was codified into law by an act of Congress.



WHO WE ARE

The European Leaflet Makers Association (ELMA) is a specialist interest group representing printers of regulated pharmaceutical information, including Package Inserts (PIs), Medication Guides (MedGuides), and Patient Package Inserts (PPIs). It operates within the European Carton Manufacturers Association (ECMA). Material and technology suppliers are also part of the ELMA.

ELMA serves as the voice for our members, advocating for patient safety and risk communication by fighting to keep information on paper and readily accessible for patients and caregivers. This information helps drive the patient involvement model of health care, helping patients get the maximum benefits from the powerful drugs they take while minimizing risk.

We are committed to keeping medication information on paper – for patient health and safety

Medication information is critical for patients, caregivers, and health care providers to understand prescription drug dosage, administration, side effects, adverse reactions, and interactions with other drugs. Providing printed information helps patients achieve higher compliance.

ELMA supports availability of medication information in electronic form as a compliment to information on paper. However, we strongly oppose efforts to make electronic media the ONLY source of medication information for healthcare providers or patients.

THE PURPOSE OF THE ELMA

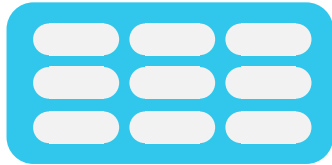
ELMA is committed to keeping medicine information on paper to ensure the safety and health of all patients.

- Promoting and improving patient safety, through the use of accessible, relevant and understandable printed medical information that accompanies drug products.
- Providing an informed voice for printed literature, as research has proven that people prefer and better comprehend technical information when it is printed.
- Increasing the body of knowledge and provide education regarding the importance of printed literature.
- Advocating for good preparation and manufacturing practices that ensure that delivers patient safety and encourages use and engagement

The European Leaflet Makers Association (ELMA) will serve as the voice of pharmaceutical printed package information manufacturers, providing a forum for members to promote and improve the delivery of information for the protection of patients and to support health care professionals, to advocate our interests to legislative and regulatory agencies, to support our member's economic well-being, and to provide industry education to promote our mission.

OUR PRIORITIES

ELMA IS FOCUSED ON THREE PRIORITIES



To promote and improve patient safety, through the use of accessible, relevant and understandable printed medical information that accompanies drug products.



To advocate for printed literature, since research proves people desire printed information for technically complicated communications.



To increase the body of knowledge and educate regarding the importance of printed literature.

MEMBER BENEFITS

By pooling resources and the cooperative investment of our time & effort, members enjoy the benefits of a more effective larger scale effort towards the mission of the ELMA, including:

- Support to lead and manage legislative and agency meetings and communications and coordinate member efforts internally and with other like-minded organisations.
- Pooled resources enabling us to support research to promote and improve patient safety through the use of relevant and understandable printed medical information that accompanies drug products.
- Coordination with regulatory, European Commission and government agencies regarding printed medicine information.
- The opportunity to network with member companies, including potential suppliers, partners, and agencies.
- Up-to-date information regarding legislative and rule-making activities affecting our industry.

d'akujem Tak Dankie kiitos
Спасибо תודה धन्यवाद terima kasih
Asante Gracias شكرا mulțumesc hvala
salamat 謝謝 Thank you Danke Hvala
ありがとう Obrigado Merci Grazie 谢谢
dank u ευχαριστώ Благодаря Děkuji
ačiū Tack хвала Sağol تشکر از شما
Дзякуй 감사합니다 dziękuję Спасибі
paldies teşekkür ederim তোমাকে ধন্যবাদ

MEMBER COMPANIES

