



**MEDICAL LEAFLETS
= PATIENT SAFETY**

“Print on demand” is not a safe alternative to printed pharmaceutical information leaflets

- Print on demand as a way forward to complement ePIs does not represent a failsafe method to ensure patient safety.
- Medical leaflets are a sustainable way to convey the right and accurate safety information to patients.

MLPS do not support the use of 'print on demand' (POD) for pharmaceutical information leaflets as the only tool to complement electronic product information (ePI). The current forms of inserted printed pharmaceutical information leaflets made available together with drug packaging, play a fundamental role in ensuring the safety and health of all European citizens. They provide fail-safe access to accurate and available information, preventing the discriminatory effects linked to digital literacy or access to digital infrastructure. The introduction of POD information to complement ePI presents critical aspects for patient safety and the environment. POD could potentially trigger liability questions for pharmacists in case of wrong/incomplete on demand leaflets provided to the patients. We thus support the complementarity of digital and printed solutions, with regulated pharmaceutical leaflets remaining the main source of critical information.

MLPS does not support a “print on demand” model to replace paper information leaflets due to safety concerns for patients

MLPS supports measures that guarantees patient safety and do not lead to discrimination based on digital literacy and accessibility.

POD would require pharmacists to print the full product information leaflet for the patient. Printing the leaflet requires additional time and training for the pharmacist, whereas their role in administering medicine is vital in ensuring the patients health and wellbeing. Printing the individual leaflets in pharmacies is also subject to various technical hurdles and potential failure, which could lead to severe safety issues for patients.

The printing of crucial and highly regulated information concerning content and posology of drugs must meet specific need for 100% accuracy 100% of the time. Thus, common desktop printers used in pharmacies 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 crucial information for the patient could translate into severe consequences for the safety and health.

Additionally, whereas industrial level printers have been manufactured, calibrated and maintained precisely for printing , desktop printers are subject to a risk of character substitution, possibly altering the content and meaning of the pharmaceutical leaflets. This can lead to severe health risks for the patient.

Furthermore, pharmacists would always need to ensure that the printed information is not only correct but also complete (i.e., that all the pages have been printed and provided to the patient). The pharmacy would likely be held liable in case of printing the wrong product information, which in turn can lead to wrong dosage of medication and health consequences for the patient.

Finally, a leaflet printed on demand would be supplied separately from the drug packaging. This could trigger the risk of loss or in associating certain information to the wrong drugs. By printing the product information separately, this increases the chance of the product information getting lost or separated from the medicine during transport. In the case of printing multiple leaflets for different medicines, it would be hard to ensure the right leaflet accompanies its corresponding medicine. Traditional printed leaflets with the relevant, complete, and up-to-date information product information are supplied in the sealed drug box thus preventing the above-mentioned risks of loss or incorrect pairing.

Regulated pharmaceutical information leaflets are currently folded and inserted into the medicines carton – the complexity and cost of the equipment required to complete this function, adds an additional layer of security against the threat from counterfeit medicines

We thus do not consider POD to be a safe solution. While ePI can be complementary to printed pharmaceutical information leaflets, a full transition to ePI with complementary POD does not represent a safe option for patients. The chance of printing wrong or incomplete pharmaceutical information leaflets are increased due to technical and human error, and pose serious threats for patient health.

About MLPS

MLPS, Medical Leaflets = 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).