OPINION PIECE - 100% ePI

The switch to all-digital medical information leaflets would be a health mistake and an environmental nonsense

From the beginning of 2025, the French government is planning to test digital patient information leaflets (ePI) as a replacement for paper leaflets. This initiative raises serious concerns about patient safety, particularly for those affected by the digital divide, as well as major medico-social, economic and environmental issues. In view of these issues, representatives of the paper industry are calling for the project to be abandoned altogether.

The great forgotten of the digital divide

The elimination of paper medical information leaflets poses significant risks to patient safety, particularly for the elderly and those excluded from digital technology. These populations rely on paper leaflets for vital information about their medicines. Without them, they risk misuse of medicines and health complications.
In France, 62% of people aged 75 and over are digitally illiterate, and only 36% have a smartphone. More generally, 8 million people lack basic digital skills. What's more, 12% of the French population lives in areas with no Internet access or cannot afford a smartphone. It is hard to see how digitising medical records would not widen this gap even further, to the detriment of patients' health.

Increasing social isolation and discrimination among the elderly

The digital divide also increases the social isolation of the elderly, limiting their access to information and social activities. The 2021 *Défenseur des droits report entitled Difficultés d'accès aux droits et discriminations liées à l'âge avancé* (*Difficulties of access to rights and discrimination linked to advanced age*) stresses that older people face greater difficulties with online administrative tasks.

Nearly 50% of people aged over 70 are worried about e-government, and the COVID-19 crisis has exacerbated this phenomenon: 25% of this population feel isolated and 10% feel discriminated against. The abolition of paper records could exacerbate these feelings of exclusion and loneliness, especially as people who are seriously dependent are 7 times more likely to abandon digital procedures.

Digital technology pollutes more than global aviation as a whole

Furthermore, while the spearhead of this initiative seems to be ecological considerations, we are entitled to wonder about digital practices and their real environmental impact. The energy consumption of digital devices and data centres poses major environmental problems. Especially when compared with paper leaflets, which are highly recyclable, made in France and come from European forests that have grown by 9% over the last 30 years. The symbol of industrial excellence, led in particular by French, family-owned and long-established companies, with a recycling rate of over 79% by 2023.

By contrast, the carbon footprint of digital solutions is highly opaque and its data rarely accessible. The Shift Project's study entitled 'Lean ICT: Towards Digital Sobriety' (2019) makes it clear that current assessments of the digital sector's carbon footprint are based on partial data or on assumptions that vary considerably from one study to another. One figure often cited is the range of estimates of the sector's carbon footprint, which varies from 2% to 4% of global greenhouse gas emissions (compared with 2.5% for all global aviation). What about QR codes? Once again, this is a black box issue. While some people believe that ignorance brings peace of mind, we would ask that the price of this peace of mind should not be the health of patients and the elderly.

Growing vulnerability to cyber attacks

Finally, the confidentiality of patient data accessible via the ePI is not clearly guaranteed, and it is particularly vulnerable to the growing threat of cyber-attacks. These attacks have increased by 400% in France since 2020. As well as patient data and the need to safeguard it, access to information - i.e. the package leaflet - could also be put at risk. How can we ensure that, in the event of an attack, the package leaflet remains available? How can we check that it has not been modified? These are just some of the questions that raise questions about the risks that this measure poses for French citizens.

We consider it imperative to ensure that all citizens, especially the most vulnerable, have access to vital and reliable medical information. The transition to a 100% digital approach poses considerable risks to their safety, exacerbates social disparities, and threatens an ecologically virtuous industry that has been a source of French excellence for generations. And all this for a supposed added environmental value whose impact tends to demonstrate the exact opposite. MLPS therefore calls for the abandonment of this pilot project introducing digital drug information leaflets and the preservation of paper leaflets as an essential tool for safety, equity and sovereignty in public health.

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About MLPS

MLPS, Medical Leaflet = Patient Safety, is a sub-member of ECMA (TR: 948591610750-02), the European Carton Makers Association, and represents printers of regulated pharmaceutical information, including package inserts, medication guides and patient package inserts.