EUROPEAN CARTON MAKERS ASSOCIATION

**Feedback to the Medical devices – online manuals replacing paper instructions**

**Commission Implementing Regulation Ares(2021)2803762**

We represent manufacturers of pharmaceutical paper information leaflets who are focussed on advancing patient safety through the use of printed medical information.

We are concerned with the Implementing regulation proposing online manuals (so called ePI) replace paper information leaflets for some medical devices and respectfully challenge the assertion that ePI can "reduce the environmental burden" and "reduce costs for the medical devices industry whilst maintaining safety"

- Research has proven that people desire printed information for technically complicated communications*
- Paper information leaflets are the only truly reliable and therefore safe means of the distribution of information with medical devices – the risk of hardware or software failure, that the Commission's document alludes to, are entirely negated with paper information leaflets
- Common templates can be used with paper information leaflets to facilitate cost control and increase patient comprehension
- Environmental claims regarding a reduction in the environmental burden by moving to ePI, need to be substantiated and include the carbon cost, which consider the power requirements of the server farms required to store and facilitate access to the ePI
- Whilst we note this regulation covers devices used by professional users and that use by other persons is not reasonably foreseen, this is nevertheless a possibility and we would accordingly draw your attention to a study by Lancaster University, UK, titled "**Why some older people are rejecting digital technology"**

We note the Commission's Implementing Regulation document states "for **some** medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial" which means by implication, for others, that electronic information is **not beneficial**, the obvious conclusion being that safety maybe compromised. We would hence robustly challenge how ePI can be considered, as the sole source of product information, when the safety performance is not guaranteed.

In conclusion, we request that the Commission supports the continuous and ongoing use of paper information leaflets for medical devices, because of the simple fact that it is **always** there when needed.

The Hague, 13 May 2021

*Patients' views on electronic patient information leaflets - Hammar, Nilsson, Hovstadius - Linnaeus University. Kalmar (Sweden)