

Ref.: BEUC-X-2018-040

Brussels, 22 May 2018

Subject: Electronic product information will not benefit *all* patients

Dear Professor Rasi,

Many European citizens use medicines on a regular basis and information on why and how to use these medicines is crucial to promote a safe use of drugs. BEUC and its members strongly support and promote the consumer right to access high quality and non-promotional information about health, medicines and treatments. We therefore **welcome the action plan of the European Medicine Agency (EMA) to further improve product information¹**.

This action plan contains important recommendations **to improve the package leaflets** of medicines, including its readability and lay-out. In turn, this could facilitate outreach to the most disadvantaged groups, namely the elderly and people with low literate skills as highlighted by the 'Study on the Package Leaflets and the Summaries of Product Characteristics of Medicinal Products for Human use²'.

While these recommendations are welcome, we **highly regret the decision** of the Agency to primarily explore the electronic package leaflet format and invite you along with the Heads of Medicines Agency (HMA) to reconsider the priorities of your plan.

Package leaflets often provide the **very first information to patients**, particularly in the case of medicines that can be sold without prescriptions and hence do not require the interface with healthcare professionals. For this reason, it is a crucial tool to communicate medicines' risks and benefits, provides guidance for a correct use and ultimately gives confidence while increasing the compliance.

In our opinion, the decision to prioritize its electronic version poses several risks and may fail to address the main target population individualised by the study.

¹http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/11/WC500238305.pdf

²https://ec.europa.eu/health/sites/health/files/files/committee/75meeting/pil_s.pdf

Despite the improvements over the last years, **internet access and broadband connections** are still highly fragmented across Europe. In addition, when it comes to digital literacy, remarkable differences still exist between young people and the older population³. In general, **people with less digital skills** would be excluded *a priori* from this initiative, which in turn would further increase the existing inequalities among patients across Europe.

What is more, both the EMA-HMA task force⁴ and the industry-led group⁵ on eProduct information suggest the creation of a single portal to facilitate the dissemination of electronic product information. In principle BEUC supports a single access point as, for example, this could be used to provide the most updated version of the leaflet. However, this solution may ultimately pave the way for patients to be exposed to **biased information**. This would be the case especially if the information should come from the manufacturer, without appropriate supervision from the authorities.

In line with the recommendations of the above-mentioned study, we believe that EMA and HMA should prioritise and invest their resources to **improve the readability and the lay-out** of package leaflet, **strengthen the patient input** in their developing and promote the exchange of **best practices examples**. These actions would certainly make the package leaflet clearer and more legible, while meeting the expectations and needs of a higher number of patients.

Complementary electronic leaflets could be a tool to improve information, but it is imperative that stronger actions are implemented to provide high-quality information for *all* patient groups.

BEUC and its members are committed to continue supporting the agencies efforts to improve the information to patients and will be glad to provide further inputs in the future.

We would kindly ask you to share this letter with the Heads of Medicines Agency representatives that are expected to attend the "Support for better use of medicines' group" meeting on 3rd of July.

Please note that given the public interest in the matter BEUC will make this letter publicly available

Yours sincerely,

Monique Goyens
Director General

³http://ec.europa.eu/eurostat/statistics-explained/index.php/Internet_access_and_use_statistics_-_households_and_individuals

⁴ <http://www.hma.eu/531.html>

⁵https://www.efpia.eu/media/361697/annex1_eproduct-information-feb-2018-reduced.pdf