BEUC The European Consumer Organisation

The Consumer Voice in Europe

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Subject: EU key principles for electronic product information for medicines – a consumer perspective

Dear Professor Rasi,

Following our meeting in December 2018 where, among other issues, we discussed the EMA's work on electronic product information (ePI) for medicines, I would like to share with you our main reflections on the draft *'EU key principles for the use of ePI'.*

BEUC strongly supports consumers' right to access high quality information about medicines and treatments. We, therefore, welcome EMA-HMA's intention to improve information on medicines through electronic means. Electronic leaflets as a complement to the paper leaflet hold a potential to improve the readability and layout of leaflets, as well as provide an opportunity to ensure patients' access to the most updated version.

When implementing the key principles for the use of ePI, we however recommend that the EMA address the following aspects:

- **ePI must not come at the expense of EMA's work to improve the package information leaflets (PILs) which are still not user-friendly enough**. PILs remain crucial for consumers: in case of connectivity issues or for consumers with low digital literacy, PILs are the only accessible and reliable point of information on how the medicine should be taken. Therefore, both paper leaflet and e-leaflet must be well-integrated and provide safe, comprehensive, unbiased and timely information to patients and consumers.

- **All parties involved in the development of ePI must comply with the EU's data protection and security framework**. Compliance must be ensured not only by checking contract terms, but also by consistently monitoring the practical application of ePI. Beyond data protection, the security of ePI software and stored personal and non-personal data is moreover crucial. This is especially relevant in the context of ePI integration into a European cross-border exchange of electronic health records. Weak cybersecurity of ePI might thus offer a backdoor into the massive storage of personal sensitive data.

We further recommend that a single portal for ePI is managed by the medicines agencies to guarantee the transparency of information provided, as well as any apps developed to facilitate the provision of ePIs. Third parties should under no circumstances have access to any personal information to avoid potential misuse of data and targeted promotional information dissemination.

We thank you in advance for taking the above into consideration.

Yours sincerely,

Monique Goyens
Director General