



FARMASIALIITTO

## **Pohjoismaisten farmasialiittojen lausunto lääkkeiden elektronista tuoteinformaatiota koskevan lainsäädäntötyön jatkamisesta**

24.9.2022

### **JOINT NORDIC RECOMMENDATION ON ELECTRONIC PACKAGE INFORMATION**

The Nordic Pharmaceutical Union (NFU) recommends Nordic countries to work on Electronic Package Information (ePI) for medicines. It is NFU's understanding that gradual and controlled transformation from paper to electronic form will be beneficial for the general patient safety and medicine shortages, and potentially lead to a reduction in medicine waste.

Electronic Package Information includes the Summary of Product Characteristics (SmPC) and the labelling and Package Leaflet (PL). The Package Leaflet is for patients/consumers and normally included as a printed copy in the medicines package.

#### Why ePI has a positive effect on patient safety:

- The information on the ePI can be updated continuously and rapidly in accordance with the latest authorized information available for the specific product. This would give both patients/consumers and healthcare professionals reliable and updated information and the latest information of benefits and risks of medicine.
- The information on the ePI can be made more accessible for disabled people; for visually impaired people, the texts can be presented with larger fonts, for blind people or people with dyslexia, spoken content can be made available.
- It will be easier to integrate with upcoming electronic systems where healthcare professionals retrieve information.

It must be stated that the transformation from paper to ePI needs to be gradual. Not all elderly patients are confident with electronic package information why it should be a requirement that pharmacies offer to hand out package leaflets in printed form to patients that are not confident with the electronic format. When handing out the printed form, the patient will also be able to get it in a readable font.

#### Why ePI has a positive effect on medicine shortage:

- Medicine packages or parts thereof can be shared by several countries, the most common version being the Nordic package.
- Studies show that one of the main reasons for medicine shortages is that the considered markets for distribution of medicine are too small; ePI will make it possible to reach a larger market of medicine in the Nordics.

It needs to be noted that medicine shortages are complex and global problem and ePI will not solve the problem but would help on some issues with medicine shortages



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Why ePI has a positive effect on medicine waste:

- The industry discards medicines due to errors on the package leaflet. There is no data on how much medicine that is discarded on the basis of errors, but it is known to be one of the causes; with ePI, such errors can be eliminated.
- Unnecessary destruction of medicine with the right quality due to lack of information.

The Nordic Pharmaceutical Union recommends that legislative work for ePI is continued. As more and more pharmaceuticals have central marketing authorization, the work would need to be continued at EU level and the Nordic countries should endorse this. The European Medicine Agency has already started the work on ePI and there is a clear need to continue this work. European countries have different starting points for using ePI, but it is the Nordic Pharmaceutical Union's understanding that the Nordic countries could act as testing ground for ePI.

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