



Ministry of Health

Reykjavík 13 June 2019

Directorate-General for Health and Food Safety
Commissioner Vytenis Andriukaitis
European Commission,
1049 Brussels,
Belgium

Dear Commissioner Vytenis Andriukaitis,

The Ministers of Health in Denmark, Finland, Iceland, Norway and Sweden suggest that The Commission investigates if using only electronic leaflets should be an option for Member States. This would certainly help states with smaller language areas, which currently can be unattractive to marketing authorization holders. It should be up to each Member State to decide on whether to introduce electronic leaflets only, or not, depending on the specific circumstances in that state.

We are aware that this might call for changes to the appropriate Articles of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, allowing each Member State of the European Union and consequently the EEA Member States, to decide if they may allow the use of electronic package leaflets only. In this connection, we would like to refer to the recent Regulation concerning veterinary medicinal products that allows the use of electronic packages leaflets only and which Member States have agreed on. The following main arguments apply.

- *Patient safety*: Electronic leaflets will be available in the languages in which the medicinal products are approved in, so no one will have to deal with a language they are not familiar with. Electronic leaflets also allow updating of leaflet information to be done much faster.
- *Health literacy*: Electronic leaflets may make it possible to improve the readability of the content of the leaflet, thereby increasing the comprehension of the patient as well as addressing the needs of people with disabilities. Electronic dissemination of the leaflet also permits greater formatting flexibility (e.g. font sizes and line spacing) than paper-based systems.
- *Access to medicinal products and in particular to orphan medicines*: Smaller language areas fear that high printing and packaging cost, make their market less attractive for manufactures. This means that those markets run the risk of never receiving some medicinal products. This is particularly true in smaller markets where it is too expensive to put paper leaflets in the national language into medicine packages for a small number of patients with rare diseases.

- *Purchasing and joint tenders*: Electronic leaflets will make it easier to carry out joint tenders and purchasing of medicinal products for two or more countries and thus obtain lower price of medicines.

Yours sincerely,

On behalf of the Nordic Council of Ministers on Health and Social Affairs



Svandís Svavarsdóttir, Minister of Health in Iceland,

Chair of the Nordic Council of Ministers on Health and Social Affairs 2019