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In light of the current review being undertaken regarding the pharmaceutical legislation, we kindly like to follow up on the meeting held October 28th and previous discussion we had on the need of allowing EEA Member States to have the option of solely using electronic leaflets instead of paper ones. We found it particularly useful to have the opportunity to introduce main elements for our reasoning in addition to providing you with a proposed text which we believe is essential in this regard.

We would like to reiterate our proposal presented at the meeting as an amendment (the bold text) to article 58 in the current law:

The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging. **“NCAs may omit inclusion of a package leaflet if other information systems are in place that give patients the same or better access to the information included in the package leaflet.”**

We also like to take this opportunity to inform on the proposal's background by enclosing questions and answers (Q&A) regarding electronic package leaflets, carried out by the Nordic Council's Committee for Growth and Development in the Nordic Region. Iceland initiated the questionnaire, and the proposal came from Norway.

And finally, we would like to remind that in June 2019, the Icelandic Minister of Health wrote a letter, to the Commission, on behalf of the Ministers of Health in Denmark, Finland, Iceland, Norway and Sweden, suggesting that the Commission would implement use of electronic leaflets into European regulations.

We look forward to following the progress on the review and are more than willing to further collaborate on the issue.

On behalf of the Minister of Health

Ásta Valdimarsdóttir
Permanent Secretary

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