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Head of Unit

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Subject: Copy of article on package insert user tests

Dear Dr. Fuchs,

Commissioner Dalli would like to thank you for the copy of your article titled "the way forward in package insert user tests from CRO's perspective" published in the Drug Information Journal that you sent and that he passed to me. I have read it with great interest.

You refer in your article, inter alia, to the pharmacovigilance proposals and their proposed modifications regarding package leaflets. I am taking the occasion to inform you that in the legislative procedure the text has been modified. The Commission has committed in this process to issue an assessment report on the current shortcomings of the package leaflet and how it could be improved in order to better meet the needs of patients and healthcare professionals. On that basis, the Commission will consider a proposal aiming at improving the readability, layout and content of the package leaflet.

The ideas highlighted in your article are of great relevance and will be considered in the preparation of the report.

Yours sincerely,

Martin Terberger

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