

Dr. Jorg Fuchs,
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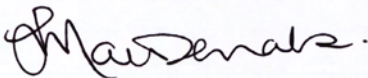
Dear Dr Fuchs,

[REDACTED]

In response to your points in relation to written readability tests I can confirm that marketing authorisation holders may submit any data which they consider demonstrate that their patient information leaflet meets the requirements of article 59(3). Indeed some applicants have chosen to support their application with data generated by your company on their behalf and leaflets supported by such data have been subject to approval.

[REDACTED]

Yours sincerely,



Jan MacDonald
B.Sc. M.Sc. M.R.Pharm.S.
Group Manager Information for Public Health.

cc. Dr J. Raine