EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

<Date of submission>

# Submission of comments on Reflection paper on patient experience data (EMA/CHMP/PRAC/148869/2025)

*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*
*When completed, this form should be sent to the European Medicines Agency electronically, in Excel format (not PDF), to the following address:*
PED_RP@ema.europa.eu

*All the cells with an asterisk (*) should be filled in prior to completing the columns "Comment and rationale" and/or "Proposed changes / recommendation".*
*For more details on how to use this template please refer to the tab "Manual for commenter".*

| Name of organisation or individual* | Line from* (line Nr or 0 for general comment) | Line to* (line Nr or 0 for general comment) | Section number | Comment and rationale (to go to next line within the same cell use Alt + Enter) | Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes) |
|---|---|---|---|---|---|
| Clare Bradley, CEO of Health Psychology Research Ltd and Emerita Professor at Royal Holloway, University of London | 0 | 0 | | I read the Reflection paper with interest and thank you for your attention to the importance of patient experience in assessing outcomes of treatment. One important omission from the document is any mention of copyright of patient experience questionnaires and the need to ensure that only versions of questionnaires authorised by the copyright holder are used.<br><br>I write as the developer of a substantial number of patient experience questionnaries, and as the CEO of the copyright owner, Health Psychology Research Ltd (HPR, see www.healthpsychologyresearch.com). These questionnaires include the widely used DTSQ (Diabetes Treatment Satisfaction Questionnaire) linguistically validated in >120 languages, the ADDQoL (Audit of Diabetes-Dependent Quality of Life) linguistically validated in >80 languages, and similar measures for other conditions including chronic kidney disease, eye conditions, HIV, hypothyroidism, aneurysm, cancer, and varicose veins. My company and I have made a very considerable investment in developing the questionnaires, establishing their psychometric properties and providing language versions for use world wide using gold standard linguistic validation procedures. We provide questionnaires, scoring guidelines and licence agreements free of charge to non-commercial researchers and clinicians, only charging licence fees for commercial use. Although in my experience commercial companies are now mostly well informed and scrupulous about ensuring they obtain authorised questionnaires and a licence to use them from the copyright holder, it is, sadly, the case that non-commercial users may use questionnaires they find online, translate them (poorly and unnecessarily when they could have obtained high quality translations from the copyright holder free of charge), and sometimes modify them in ways that undermine the validity of the instrument used. In worst-case scenarios, unauthorised translations of my questionnaires or modified versions have been posted on a website or published in a journal in full, leading others to use these unauthorised versions, sometimes retranslating and/or further modifying the instrument, thereby perpetuating copyright infringement and generating data of dubious scientific value whcih can cause confusion in the literature.<br><br>The EMA is currently contributing to the problem by inviting those submitting details of their clinical trial/research study to post the trial documents on the EMA's website. When our questionnaires are posted, this is a breach of licence conditions and we write to the authors to ask them to remove the questionnaires. When we are unable to get a response from the authors we need to approach the EMA to have the questionnaires removed but this is not straightforward. To contact the EMA we have had to register as if we were about to register a clinical trial and we are told that it is not possible to remove the questionnaires without redacting the entire submission which then becomes necessary. It would be helpful in preventing copyright infringement, if the EMA would make it clear in their instructions to those submitting information about their clinical trial/study that posting copyrighted questionnaires should only happen with the permission of the copyright holder and redacted versions of the questionnaire, approved by the copyright holder, may be needed. Authors of submissions might be encouraged to provide contact details for the copyright owner of the questionnaires they plan to use so that others may contact the copyright owner to view the questionnaires and to obtain permission for their own use without resorting to copyright infringement that may result in them being unable to publish their research. | I ask the EMA to discourage posting of questionnaires on the EMA website unless these are redacted with the approval of the copyright owner. This will be important for the prevention of copyright infringement and for the scientific value of patient experience data obtained. I will be glad to advise further if needed.<br><br>You may also wish, in due course, to cite guidelines regarding copyright of COAs (Clinical Outcome Assessments) currently in preparation by the COA Copyright Working Group of ISOQOL (International Society for Quality of Life research) which I co-chair along with Caroline Anfray who is first author of the following reflection paper:<br>Anfray C, Arnold B, Martin M, Eremenco S, Patrick DL, Conway K, Acquadro C – on behalf of the ISOQOL Translation and Cultural Special Interest Group (TCA SIG). Reflection paper on copyright, patient reported outcome instruments and their translations. *Health Qual Life Outcomes* 16, 224 (2018).<br>https://doi.org/10.1186/s12955-018-1050-4 |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

© European Medicines Agency, 2020. Reproduction is authorised provided the source is acknowledged.

| Name of organisation or individual* | Line from* (line Nr or 0 for general comment) | Line to* (line Nr or 0 for general comment) | Section number | Comment and rationale (to go to next line within the same cell use Alt + Enter) | Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |