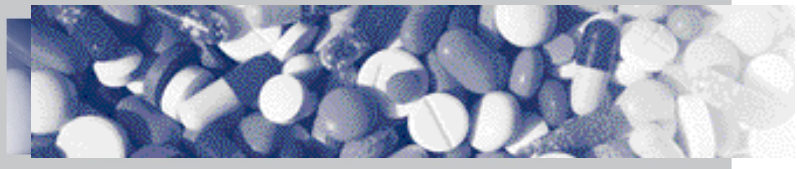
PAINT®
Package Insert Test



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Statement relating to the Report from the CMDh meeting held on 24-26 March 2020

COVID-19 outbreak and user testing of package leaflets

1 Introduction

The Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) held a meeting on 24 to 26 March of 2020, to discuss the COVID-19 outbreak and its impact on regulatory activities. This applies to user testing on package leaflets, also known as readability testing [1]. Firstly, we thank the CMDh for taking the time to discuss how best the pharmaceutical industry and their service providers should act in this situation, whereby social contacts between people should be reduced to the minimum possible. In the case of readability testing of package leaflets, for example, this applies to the contact between laypeople as test participants and interviewers, including other testers and test supervisors.

It is reassuring to note that the report points out “The CMDh is determined to work together with stakeholders to overcome these challenges.” [1].

2 User testing of the package leaflet during COVID-19 outbreak

2.1 General assessment

We at PAINT-Consult (service provider of readability tests) agree with the CMDh assessment “... that a user testing conducted solely on the electronic version of the PL would fail to address important aspects of the printed version, such as design and layout, navigation elements, quality of paper, contrast etc.” [1]. A clear layout/design, for example, has almost the same importance on locating and understanding information in a printed package leaflet as it is the case with user-friendly, comprehensible wording.

The interim solution provided by the CMDh in its report “... to send by post the printed versions to the interviewees and then organise the questionnaire electronically or by phone, thus avoiding any physical contact.” may be an option, as it avoids direct contact between people - a basic requirement to get the COVID-19 outbreak under control and save lives. However, we feel that the following concerns must be addressed:

- The suggested method carries the risk wherein the invited test participant might be supported by other person(s) while answering the questions via phone or completing the questionnaire electronically. This problem also cannot generally be excluded if a video conference is used, such as via Skype, Zoom. Even an affidavit could not exclude such a situation.
- Using a video conference, such as via Skype, Zoom, would not ensure the recommended selection of “... different types of people who are ... representative of the population to be treated” [2], as such way of testing would mostly limit the invited participants to those who

are technically competent and/or familiar with the internet and the aforementioned conference media.

- Non-approved package leaflets could become available in the public arena if the printed version is scanned, copied or not returned.

Furthermore, the CMDh states: “In the event such a scenario cannot be realised, user testing could be performed via an online platform or other suitable means. However, it needs to be clearly indicated, in the form of a disclaimer for the assessors, that certain aspects of the printed version have not been tested.”
An online platform does also not solve the concerns mentioned in the first two bullet points above.
What is meant by “disclaimer”? Can’t the readability test be used as reference for other package leaflets, such as in a bridging? Must the readability test be repeated after the COVID-19 outbreak? etc.

The CMDh report points out: “In case the submission of user testing results within a given procedure is delayed, the CMDh stresses the need to allow sufficient time for assessment. Delays in submission could be acceptable in principle, however, every effort should be made to avoid, as much as possible, to overload the later stages of the procedure.”

2.2 Suggestions from PAINT-Consult

Is it so important to push readability testing or any other testing through the approval procedures in a business-as-usual fashion?

We at PAINT-Consult must point out that the **quality of the package leaflet** must be the central focus – especially its improvements – rather than that authorities can state in the assessment report that a successful readability test was provided.

1: Testing alone does not significantly improve the quality! Most improvements can be achieved through a systematic optimisation of the entire package leaflet instead of testing only 12 to 15 pieces of key information [3, 4].

2. Many changes occur in package leaflets during most approval procedures after their successful readability test! Most of these changes demanded by authorities after a test are not content-related.

Two of many examples are: Moving the words “if you are/have” from the end of an opening sentence at the beginning of each bullet point in huge lists, as occur in contraindications and warnings/precautions sections. This increases the length of each bullet point and blocks the most important information from appearing at the beginning of the point. A layout/design example applies to “Increase the space after headings as this helps the user to easily locate the different sections.” This raises the question of the meaningfulness of readability tests, especially when the test illustrated no weakness in the presented examples and in the second case the package leaflet already contains a line spacing of more than 120% of the heading’s font size. Moreover, additional space between subheadings and text up to a full blank line should not be used in the typesetting as this reduces the optical connection between headings and subsequent texts.

3. Existing guidelines to create package leaflets contain many weaknesses. Most weaknesses remain unresolved even though these problems have been recognised for many years [5]. It is not acceptable if recommendations provided in official guidelines are not scientifically evidence-based or contrary to the current knowledge. One example is the explicit recommendation in the EU readability guideline to use landscape format in package leaflets, even though no evidence exists for this general favouritism and other formats, like portrait format, are also suitable [2, 6, 7]. Another example is the QRD template (the framework of headings and standard texts used in all EU package leaflets, current versions 10.1 and 4.1, which contain around 840 words), of which no version was evaluated before implementation [8, 9]. Two studies published in 2012 and 2014 show that a notably shorter version of 200 words has significant benefits compared to the official QRD template. Furthermore, this shorter template would significantly reduce the volume of text of each package leaflet used in the EU without loss of information [4, 10]. This significantly improves the usability of package leaflets, especially patients’ motivation to read and locate provided information [4, 10, 11].

PAINT-Consult recommends pausing readability testing during the COVID-19 outbreak as long as it cannot be performed in a way safe for participants and testers. If the health risks of the COVID-19 pandemic are significantly and acceptably reduced, then the readability test should be performed immediately once it is still at an acceptable stage of the procedure, or submitted within the next variation under provision of a commitment.

If the submission of readability test proofs is not possible at the usual stage, the applicant should guarantee that the best possible quality of the submitted package leaflet is ensured, which could be done in conjunction with the test provider. Sufficient quality can be ensured with using evidenced-based quality criteria [5].

Shortcomings in guidelines (e.g. the volume of text problem in the QRD template) must be solved immediately they become evident as this is not possible through readability testing. Furthermore, if a package leaflet has been successfully tested without showing weakness in the final version, in future authorities should accept the wording and layout used, unless it concerns substantial content-related issues.

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Date: Jena (Germany) 9 April 2020

Signature

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