

WHITE PAPER

Translation and Back Translation for Pharmaceutical Companies

The expanding global market for pharmaceuticals requires drug companies to translate their product information, labels, informed consent forms, and other printed material into various languages in order to be understood by end users. Translation is viewed as an art rather than a science; a subjective process in which there is no “right” answer. While there are exams and qualifications that can be taken and acquired, there is no “plug and play” at the end of the translation process in which the translation can be validated against its original source.

As a result, more pharmaceutical companies are turning to “back translation” as a secondary step. Back translation is the translation of an already-translated text back into its original language. It is performed, as with the forward translation, by a professional translator. The back-translator does not have access to the source text.

Clinical trial managers and other project and product managers use the completed back translation to validate original translation by comparing the back translation and source and looking for discrepancies in the text. While this would seem on a basic level to be a good way to judge the quality of the original translation, it is not always the case. Since translation is so subjective, those reviewing translations must be aware of the potential pitfalls in this process.

Reviewing Back Translations

The term “back” is somewhat misleading, as it implies that the text translated to exactly match the original. This is almost never the case. The primary objective of back translation is to identify problem areas in the original translation by providing a comparison to the original source. While this is certainly a valid quality assurance step, it also invites those comparing the texts to look at more than just the overall meaning of the

back translation. Understanding the importance of meaning in the back translation process will help.

Back translation hinges on the idea that the back translation and the source can be compared against one another. However, any translation that is done well will depart from the semantics and structure of the original source language in order to meet the requirements of good style in the translation. Grammar is inherently diverse across

different languages, and the translator will retain the meaning of the translation, rather than the original grammatical properties of the source text. A back-translation comparison should essentially ignore syntax and focus on the meanings of the two texts. As such, a back translator is usually able to translate more than one dialect (Mexican Spanish and Puerto Rican Spanish, for example) into English.

Meaning and Context

The concept of meaning has been thoroughly researched and documented by translation theorists and academics. For example, the noun "work" can be synonymous and equivalent in meaning both with "literary text" (e.g. "a work of Shakespeare") and "place of employment" (e.g. "workplace"). At a word-to-word level, equivalence in meaning can be useless; already we are beginning to see the importance of context.

Each translation segment, whether it be a sentence, heading or short paragraph, should be considered as a discrete entity. To break these segments down to the word level not only takes the words out of context, but results in the reviewer comparing word against word in a sentence that may be entirely equivalent in both languages, as is shown in the table below.

English source	Work	Work
Spanish translation	trabajo	obra
English back translation	work/job/paper	result/work/deed

With no context, the back translator has no way of knowing in which sense the original English word was used. It is important to remember that almost all translators are given reference material when they are working on a text. Whether this is a translation memory, past translated material, a glossary, or pictures, the translator knows definitively how their translation will be used. In back translation, on the other hand, it is impossible to provide the translator with as much reference material. Providing a brochure with pictures will let the back translator see the original text, which is not allowed as it could influence the translator's work 'back' into the original language.

Even at the highest textual level, equivalence of meaning relies not only on the context of the translation itself, but on other, similar materials, not all of which may be present at the time of back-translation review. Nevertheless, if the client is the end reviewer, s/he will almost certainly benefit from knowing the subject matter and having access to previous translations/ back translations so that cohesion across texts is maintained.

Identifying Discrepancies in Back Translations

In the pharmaceutical industry, such differences between the back translation and the original English as "dose" and "dosage" are common, as are the terms "adverse effect," "adverse event"

and “adverse reaction.” In these instances, it is the reviewer’s responsibility to research the terms and find out whether or not the meaning is different enough to warrant a change to the original translation.

When the source language is English (which is very common in the translation industry), there is often a discrepancy in the meanings between the source and the back translation. Spanish, for example, has a notably smaller vocabulary, and many words that are used in English simply do not exist. Below are some common examples of issues that arise in back translation (in this case, English into Spanish, and then Spanish into English). In each case, the meaning of the term in the back translation does equal the meaning of the original source.

English source	If you're experiencing joint aches and pains, and have skin lesions, you may have psoriatic arthritis (PsA).
Spanish translation	Si usted tiene dolor en las articulaciones y lesiones en la piel, puede tener artritis psoriásica (APs).
English back translation	If you have joint pain and skin lesions, you may have psoriatic arthritis (PsA).

Two separate nouns for “aches” and “pains” do not exist in Spanish, resigning the first translator to use only one noun: “dolor” (literally: “pain”). As such, the back translator, with no access to the source, is unaware that two nouns exist in this text, and translates simply “pain.” A comparison of the back translation and the source will reveal a missing noun, which will only become evident at the review stage. Writers of the English source text should be aware of these issues, wherever possible.

English source	Concomitant use of these agents impairs the compensatory increases in clotting factor synthesis.
Spanish translation	El uso concomitante de estos agentes afecta los aumentos compensadores de la síntesis de los factores de coagulación.
English back translation	Concomitant use of these agents affects the compensatory increase of the synthesis of clotting factors.

The Spanish “afectar” means not only “to affect”, but also “to harm, to influence unfavorably,” so the Spanish translation above is perfectly correct. The back translator, though, has translated as “affect”; also a correct translation. In this case, though, the difference between the two verbs is important, since we are referring to drug effects. This kind of example seems on first review of the back translation to be a mistranslation, and must be clarified with the translator during the review.

Should an actual mistake be made, we see where back translation is most valuable. In another example, if the original translator translated “decrease” as “aumenta”, the back translation would read “increase.” In these situations, back translation is of real value, since the words are antonyms, and there is a definite discrepancy in meaning.

Cost and Schedule

When a back translation is requested, it is built into a project schedule as any other step would be. Professional translators with subject-matter knowledge are assigned to work on the back translation, in the same way as professional translators are the ones translating the original text. Because the back translation cannot begin until the original translation is complete, it adds

a considerable amount of time to the schedule, sometimes almost doubling it. The cost of another round of translation is significant, too, and this should be accounted for in the budget.

Alternatives

Alternatives to back translation are usually employed when cost and schedule do not leave room for back translation. Since back translation is used as a linguistic quality assurance step, alternatives to this procedure must involve some level of linguistic knowledge (a formatting or other mechanical QA, for example, is not an alternative). In the translation industry, the main alternative to back translation is an in-country review of the original translation by an affiliate on site. The purpose of back translation is to determine whether there are any mistakes in the original translation, and an in-country reviewer is undoubtedly qualified to come to the same conclusion.

Conclusion

Back translation should be employed with caution. When comparing back translations against the source material, reviewers should be aware of the importance of meaning versus semantics. Syntactical or stylistic differences such as "November 12th, 2006" and "11/12/2006" should be viewed as having the same meaning. Back translation, a costly and time-consuming procedure, can only be successful if this concept is understood. Reviewers will find that this will help eliminate the back-and-forth to project managers and linguists, and aid in keeping costs and review cycle time to a minimum.

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