



# Translation and the EMA Centralized Procedure

Working through a submission for the European Medicines Agency's centralized procedure to gain marketing authorization for a medicinal product? As you organize responses to the agency's LoQ and LoOI, don't forget to plan for translations.

Your product's summary of product characteristics and package leaflet comprise some 6000 words in English, and after a positive opinion on Day 210, you only get five calendar days to get each of those words translated into the required 24 languages. We could not agree more with the agency when they note, in their 2017 [guidance document](#):

**"In view of the short timeframe for finalisation of the translations and in order to optimise the quality of the translations, MAHs are strongly advised to initiate the translation process well in advance in the Pre-Opinion stage (e.g. after Day 180)."**

This executive brief outlines three tips for ensuring that you are prepared to submit all 24 translations on time and, even better, that you don't lose any sleep in the process!

## The Nuts and Bolts

During a centralized procedure process, you will submit several iterations of the English version of your product's SmPC and package leaflet over the course of your interactions with EMA; these include:

- the initial submission (Day 1)
- the response to the LoQ, which includes incorporating feedback from the Technical Labeling Review (Day 121)
- the response to the LoOI (Day 181\*)
- the post-opinion Eudralink package (Day 215)
- the final Eudralink package (Day 235)

Both Eudralink packages must contain the translated versions of the SmPC and package leaflet in all EU languages, including Norwegian and Icelandic. This means that you need to source translations in these 24 languages:

BG (Bulgarian)	EL (Greek)	FR (French)	IT (Italian)	NL (Dutch)	RO (Romanian)
CS (Czech)	ES (Spanish)	HR (Croatian)	LT (Lithuanian)	NO (Norwegian)	SK (Slovak)
DA (Danish)	ET (Estonian)	HU (Hungarian)	LV (Latvian)	PL (Polish)	SL (Slovenian)
DE (German)	FI (Finnish)	IS (Icelandic)	MT (Maltese)	PT (Portuguese)	SV (Swedish)

Effectively, you get only five calendar days (Day 210 to 215) to complete the translations on the basis of the final English version. Let's do some math:

- The average SmPC + package leaflet clocks in around 6000 words.
- A professional translator typically handles 2000-2500 words each working day.
- The international standard for translation services, ISO 17100, requires that translations be independently reviewed by a second translator (often called an editor or a revisor), who cannot begin their work until the draft translation is complete.
- Any translation agency worth their salt will also have a quality control step over and above the linguistic work undertaken by the translator and editor.

### \*A Day 180 Opinion

If, based on the EMA feedback on Day 120, you believe that you may receive a final, positive opinion from EMA on Day 180, we would recommend moving our suggested timeline up to begin the translation process based on the Day 121 version of the English documents.

So while it is conceivable that you could wait until Day 210 to start translating and still get your final English documents through the translation process before Day 215, it is very likely that you would pay a hefty surcharge for the privilege of running 24 translators, 24 editors, plus project managers and quality control over a weekend, particularly if you've surprised these 50-odd professionals with a last-minute project. What's more, EMA can reject translations for being of unacceptable quality, and quality is likely to degrade when you have the linguists rushing against the clock with little time to research and zero opportunities to ask any clarifying questions of your team.

But never fear! There is a better way!

## Tip #1: Build a Plan (and stay on top of it)

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You don't have to push the translations into a five day window...so don't! Around Day 150, begin a dialogue with your translation provider to plan your timeline from Day 181 until the final Eudralink packages are submitted. Begin by establishing a budgetary quotation for the translations. In order to make certain that you don't get bogged down in purchase order approvals, consider asking your translation provider to give you a quote that includes:

- a. translation of the current version of the documents + 10% (to account for any possible additions before Day 181),
- b. translation update of 50% of the text (to account for the potential, substantial changes that can arise from EMA review and queries between Day 180 and Day 210), and
- c. review and integration of final Member State comments to the translations.

Next, plan a firm timeline for when you will send information to your translation provider and when you will receive their deliverables. Here is a suggested schedule:

**Day 181:** Launch of the translations based on the current English version.

**Day 191:** Delivery of translations that match the Day 181 version of the English.

**Day 192-209:** Handling of any translation review process (see Tip #2).

**Day 210:** Launch of the translation update based on the final English version.

**Day 215:** Delivery of translations that match the Day 210 version of the English.

**Day 229:** Launch of review of any Member State comments on the translations.

**Day 235:** Delivery of final translations, incorporating any Member State comments.

The key is to establish a very specific schedule with your translation provider so that each party knows who is responsible for what and when it must be provided to the other. This timeline requires you to collaborate closely in order to meet the EMA's mandated Day 215 deadline and there is literally no room for anyone to run a day late.

## Tip #2: Internal Review? Review Early.

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You may have an internal or in-country review process that you want to run on the translations before you submit them to EMA at Day 215. This is easily accomplished, provided that you build it into your timeline between Day 192 and Day 209. It is imperative, however, that the review process be complete before Day 210; this includes giving your translation provider time to verify any comments from your team and integrate them into the translations before the new English version hits them on Day 210. A few suggestions to ensure that such a review runs smoothly:

- Inform your translation provider that you intend to have your team review internally and build this into your joint timeline.

- Train your internal/in-country reviewers on expectations: both yours (the scope and timeline of the review) and your translation provider’s (for instance, any technical requirements for how feedback is communicated).
- Ensure that your reviewers have already seen the English documents and understand that they are reviewing the translations for accuracy against the English (as opposed to offering their feedback on the actual content of the SmPC and/or package leaflet).
- Keep your reviewers on schedule.

You will want to work actively to avoid several common pitfalls in this process:

Review Runs Late	Technical Failure in Communication	Mismatched Review
<p>When a review runs late, it crashes into the Day 210 update. This is highly problematic as the Day 210 update is already extremely tight, with your professional translators working over the weekend to get the translations to match the new English. We have seen 20-50% changes in the English text between Days 181 and 210, so this is no minor update! If your team’s internal review comments arrive at the same time as the revised English, your translators will be under even greater time pressure as they attempt to integrate these comments while they simultaneously update the translation. Worse yet, they may be forced to simply ignore your team’s comments in order to get the document updated by the Day 215 deadline.</p>	<p>Depending upon the translation tools that your translation provider (and all their translators) are using, suggested changes must be handled in a particular way. These specifications should be established at the beginning of the project so that you have adequate time to train your team.</p> <p>On the basic level, you will want to instruct your reviewers to provide specific suggestions (for instance, as tracked changes) rather than questions or comments. This helps limit your team’s feedback to specific changes they would like to see implemented and it circumvents the need for any ongoing “dialogue” (i.e. comments and responses) between your reviewer and your translation provider.</p>	<p>By the time your team reviews the translations (around Day 192), your reviewers may already be aware of planned changes that are being implemented into the English documents. It is therefore vital that they understand the order of operations established with your translation provider: namely, that the translations were locked at Day 181 and will be updated with all remaining modifications at Day 210.</p> <p>Make sure that your reviewers receive the English version from Day 181 and use it as their baseline for the review. Any changes or comments pertaining to a later version of the English will only serve to confuse your translators, who haven’t yet seen the updated version!</p>

## Tip #3: Commit to a Locked Version

This is the simplest of our suggestions, but one that is difficult to achieve without the full dedication of your team.

When you release an English version to your translation provider, your project manager goes through a preparation process to get the document ready for all linguists involved in the project. (If you are curious about some of the technical details, check out [this brief](#) on how Translation Memory works.) They launch the project with a “kit” (which includes, for example, the current English version, the prepared version for the linguist to actually translate into, and the translation history for your product) to all 24 linguists. It is only at this launch and then again at the delivery back to you that all 24 languages are

at the exact same stage of the workflow at the exact same time. This is because each individual translator will work at a slightly different speed and may have slightly different office hours. So it is safe to assume that, within an hour of the official launch, each of the 24 languages is at a slightly different stage of the process.

So what happens when you make a minor tweak and submit a second version to your provider? Well, in short, your project manager has to make some calculations based on the various risks involved. Should she have all teams discard the work they already started and start afresh on a new, updated “kit”? This is a clean option, but it is frustrating for the translators and means that the hours between the initial launch and the revised launch are essentially lost time. Or should she hold the change until the translations are complete and then run it as another, iterative update? This prevents time from being “lost” on the front-end of the project, but pushing a new version through each translation stage (24 translator, 24 editors) will eat up a lot of time on the back-end of the project.

The truth is, in some cases, a last minute change will simply make it impossible to meet the Day 215 deadline. So commit to each revision. Once you release a version to your translation provider, consider it locked until the next round of EMA feedback. By eliminating wasted time where you project manager must communicate subsequent source document changes with each independent linguist, you actually maximize the time that the linguists can spend on the translation itself.

#### What About Labelling?

What we haven't mentioned here is the labelling artwork. The actual translation of the labels is the easy part! More difficult is establishing the country-specific (and potentially multilingual) label configurations, especially if you have multiple dosage strengths involved. Changes from Day 120 to Day 210 are less likely for the labels, so you would be wise to get them translated, formatted, and off your plate early in the process, even before you hit Day 181!

## Summary

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Translations are a big component of your final package to the EMA for a centralized procedure submission. By planning in advance and working in lockstep with your translation provider, you should be able to wake up on Day 210 with:

- translations of your SmPC/package leaflet that match the English version of Day 181 and which have already been reviewed by your team (with their comments fully verified and integrated by your translation provider)
- labelling artwork that is complete in all languages
- a translation provider standing by with a blanket approval to launch the five-day rush to update all SmPCs to match the final English version.

And then you're only five days from the finish line!

## About Idem Translations

Founded in 1983, Idem Translations, Inc. is a full-service provider of translation and localization services. Idem specializes in certified translations for medical device, biomedical, and pharmaceutical companies, as well as other organizations and entities working in the life sciences sector, such as contract research organizations, healthcare research centers, and institutional review boards. The company is a WBENC-certified woman-owned business and holds certifications to ISO 9001:2015, ISO 13485:2016, and ISO 17100:2015.

## Get Help

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