Oral explanation – Your product's last stand

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What exactly is at stake when you're faced with an oral explanation? For a pharmaceutical company it is years, probably even decades of hard work, a fortune in investments, the chance of regulatory approval, and future sales. A high-stakes meeting unquestionably requires robust data, but to secure a successful outcome a well delivered, concise presentation, is equally crucial.

For a pharma company, there are 'make-or-break' regulatory events along the way to market. An oral explanation can be a tipping point for the success of a new drug hoping to achieve marketing authorisation in the EU. As it is a critically important step in the regulatory review process and presents an opportunity for the applicant to influence the outcome, preparation is essential. Backed by robust science, a high-quality presentation and well-prepared Q&A response strategy can resolve the issues and result in a positive opinion.

Preparing and presenting at an oral explanation to the Committee of Medicinal Products for Human Use (CHMP) is possibly one of the most stressful tasks that drug companies might face. These meetings are intended to give the applicant the opportunity to explain their position and arguments. This happens when there are still major objections at Day 180 of the assessment procedure, preventing the relevant EMA Committee* from adopting a positive opinion concerning the application. For applicants the aim is to get a positive majority vote for marketing authorisation. However, these meetings are not public but held behind closed doors, and the applicant is not present for most of the discussion. During the assigned one-hour meeting with the CHMP, you have 20 minutes to make your case.

One of the biggest differences between a scientist and a regulatory person is that in science you normally present your result starting with the data leading up to the conclusion, while presenting at an agency meeting you must do the opposite. Always start with your key point and build your supporting message. Dr Steffen Thirstrup, advisory board member at NDA, has attended more than 100 oral explanations during his time as CHMP member and has a firm understanding of the 'dos and don'ts' during this critical event.

"Stick to the science," he emphasises. "There is no room for speculation or emotion, you need to have your message perfectly packaged; what you show, what you say and how you say it, it must all come together in synergy."

The process of preparation

Start with the team. Provide structure to the team and clarity on team roles and responsibilities as early as possible. It's common for the team to consist of a planning committee and several sub-teams to address the individual topics, agree on key messages, and create supporting slides.

The key questions to address are:

- What are the key issues anticipated to remain unresolved?
- What are the main messages we wish to communicate to the Committee to resolve the issues?
- What are the key data supporting those main messages?

The oral explanation is often the final opportunity to resolve any concerns the regulators may have and to convince them that the benefit/risk of the product is positive. During the oral explanation, you must address the major concerns and objections with a robust and compelling strategy.

This can only be achieved by thorough preparation, key messaging, clear-cut slides, convincing script, and being ready to face any question.

It's vital to remember that although the rapporteurs know your dossier very well, other Committee members will be less familiar. Focus on answering the major objection but with enough background to make it understandable for everyone.

Providing your points with precision

Being well-prepared and performing professionally is the key to success. Having your process and timelines mapped out will help prepare your team and maximise the chances of success. Plan for rehearsal sessions where you can work on the presentation, back-up slides, and train comprehensively for questions and answers. If time allows, the team can be further coached by bringing in a 'challenge panel' of external experts who can act as a test panel for your presentation and Q&A performance.

Determining potential questions and being able to respond clearly will increase your chances of success. The team can prepare top-line responses, a more detailed explanation, and any supporting slides for these potential questions. However, stay away from introducing new data that the Committee has not had the opportunity to assess as this will not be favourably received.

The slide deck is intended to support the messaging, providing visual guidance, and highlighting the most important arguments. Therefore, reduce the complexity and information on slides to a minimum, as you do not want to lose the bridge you have built with your audience with inconsistency between the spoken word and the visuals.

"During the oral explanation, the opinions of your rapporteur and your co-rapporteur have already been made," Steffen explains. "The target for the hour should be the other members of the CHMP who each have a vote. It's important to focus on how you can persuade the majority into a positive opinion."

The resources to get it right first time

Having the possibility to engage with EU regulators is the ideal situation to help with the authorisation of your product. However, when it comes to an oral explanation you only get one chance to get it right.

Here's what you need in a nutshell:

1. Presentation coaching
You have a 20-minute window of opportunity and must make your message stick. Coaching will provide a sharpened message and increase the comfort of the main presenter and key Q&A responders

2. Well-crafted slides
Slide decks are a perfect way to guide people with data and context, but when confusing or boring, they have the opposite effect. Only begin working on the presentation once you have team alignment on the key content and messaging strategy

3. Challenge panels
A formal rehearsal in front of ex-regulators and other experts is invaluable when preparing for an oral explanation

4. Know your data
Knowing the strength and weaknesses of your data enables you to predict most questions you might receive from the Committee. Expect the unexpected and plan how to handle those questions you do not have the immediate answer to

5. Practice! Practice! Practice!
This goes for all of the above

If you are looking for support from the best in the field to help prepare you for your upcoming oral explanation, contact: **asktheexperts@ndareg.com**

*Oral explanations are used by the CHMP, Committee for Advanced Therapies (CAT), Scientific Advisory Groups (SAG), Committee for Orphan Medicinal Products (COMP), and the Pharmacovigilance and Risk Assessment Committee (PRAC).