

How To Win Over The EU CHMP At Virtual Meetings



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► By Ian Schofield

SPEAKERS AT A RECENT RAPS MEETING explained how companies should go about preparing for remote oral explanation meetings at the EMA, and why hybrid meetings with a mix of face-to-face and virtual presentations are likely to become the norm.



Pharmaceutical companies seeking new product approvals in the EU need to prepare for a change in the way that they present their oral arguments to the European Medicines Agency during the final stages of the drug evaluation process.

During the pandemic the EMA has been holding remote meetings of its human drugs committee (CHMP) and working parties, and although the regulators prefer face to face meetings, “future remote participation in some capacity is inevitable,” according to Michelle Zucatti of PR company 3D Communications.

Even after COVID-19 vaccines have been deployed, the infection will persist for years to come, and it will force the EMA to accept virtual attendance by those coming from coronavirus hotspots, those with COVID-19 symptoms and those potentially exposed to the virus, Zucatti told a session of the Euro Convergence virtual conference last month, organized by the Regulatory Affairs Professionals Society (RAPS).

This is particularly significant in the case of oral explanations, which are typically held when the CHMP still has major objections to recommending approval,



and which represent the final chance for the applicant to persuade the committee that their drug has a positive benefit-risk profile.

At a previous RAPS conference event in 2019, 3D's Kate Dion explained the reasons for calling an oral explanation (OE) meeting and the challenges companies face in explaining their case for approval. (Also see “The Stakes Are High So Get It Right: CHMP Oral Explanations & FDA AdComs” - Pink Sheet, 5 Aug, 2019.) Nearly two years on, the May event explored the additional hurdles thrown up by virtual and hybrid meetings.

“Having to deliver the oral explanation in a virtual environment adds another layer of challenge” - Michelle Zucatti, 3D Communications

One problem for companies attending OEs is that they may believe they have given the CHMP all the information they have to offer, but the committee is still not convinced, and this can be “confusing and frustrating,”

said Zucatti, who is 3D's communications lead. "All rides on the oral explanation and it feels very late in the day to resolve the issues."

The OE "is not a typical regulatory teleconference," she noted. "There are rules, and the meeting is not very interactive and is much more formal." Following the OE, the company is asked to leave while the CHMP conducts its deliberations. "Not being in the room for the deliberation means you can't correct misunderstandings or lead the discussion in a different direction."

She said it was hard enough for clients to get their message across in a face-to-face meeting. Having to deliver the oral explanation in a virtual environment "adds another layer of challenge. But the good news is that there are ways to overcome these challenges."

One area where the applicant can help to put over its point in a virtual OE is the supporting slides, which "take on extra importance now that we're virtual," Zucatti observed. "The only thing that the members are looking at is our slides and each slide should pass what we call the glance test."

If someone gets distracted, "which happens a lot in these virtual meetings, they can immediately see your headline message in the title of the slide and pick that up at a glance," Zucatti said. "And the same rule applies to the visuals that you use. They need to be clear, with one main idea per slide. The graphs need to be bold, and easy to understand. And the text slides need to be simple so that the messages don't get lost. The slides need to reinforce what the speaker is saying, because this is just another way to make sure that your messages stick."

Tame The Technology

Zucatti said that technology training was vital in today's virtual environment, particularly because "we don't expect that the CHMP will be going back to full in-person meetings anytime soon."

"Companies may need to prepare for a hybrid approach, where some people are in person and others are

virtual. And since some of the determining variables are unpredictable, companies will need to be ready to adapt without losing the impact in their presentation," she said.

In some recent CHMP meetings, the committee has used Adobe Connect, so Zucatti recommended practising with that same platform to "learn the lay of the land," while using Zoom for behind-the-scenes team communications. Whether the applicant is dealing with the technology on its own or bringing in a third party, they need to practise using the technology "because it can really make or break the day."

"We've all been having virtual meetings for a while now and in just about every meeting someone is still struggling with their internet or to unmute themselves or they have other tech issues," she continued. "You don't want your expert clinician getting distracted by that when it's time for them to answer a critical question."

Some Of The Benefits

Zucatti said there were also some very practical benefits to being virtual. "For example, clients have the chance to conduct real-time analyses when the CHMP is asking questions, or suggesting a post-approval activity, for example."

A back-channel Zoom meeting could help the company decide whether to offer a solution to a major objection. "This can't be done in a face-to-face world where the team is being fully observed," she noted.

A further practical advantage is that the speakers do not have to travel, meaning the team can spend more time practising its presentation and preparing for the Q&A. "So the bottom line is while being remote may seem daunting, with the right preparation you can be and will be successful."

From a practical point of view, Kell Cannon, scientific lead at 3D, agreed that working remotely might seem complicated and nerve-wracking, and the technology daunting.

“Clients know they’re talking to a large group of people dialing in from various locations in different countries. Remember, we have to reach each single person in the group remotely as they ultimately contribute to the final recommendation and vote. And in the virtual world, clients struggle with not being able to see people’s reactions to what they’re presenting or how they’re responding to questions. It can be very disconcerting to clients to feel like they’re talking to a black hole.”

“If you’re going to be pursuing a hybrid model, and that’s the way the CHMP is going, it’s not as easy as it sounds” – Kell Cannon, 3D Communications

One way to address these concerns, Cannon said, was to ensure the audio connections are clear and to practise using them before the meeting.

“If you’re going to be pursuing a hybrid model, and that’s the way the CHMP is going, it’s not as easy as it sounds. And it does require a lot of practice, because having your team together, whether it’s in Amsterdam [where the EMA is based], or even if you have your entire team together and you present from your headquarters, it still requires the technology, the setup, the cameras, the audio. It’s all got to be able to function perfectly on the day of the meeting.”

Zucatti agreed, saying it was “absolutely critical that presenters break through the technology and deliver an executive presence.” They should “maximize their voice tone and still use body language even though they can’t be seen. All you have is your voice to command attention to try to build trust.”

She emphasized the importance of holding mock meetings before the day of the OE because “they’re a simulator of sorts, so that when you’re in front of the committee that day, you’re familiar with how to work all the controls.”

Mock meetings also help to throw new light on issues that might crop up. “It’s incredibly important to prepare for those tough questions, and having a fresh set of eyes and opinions can sometimes be surprising. It’s always best to prepare for those unexpected positions before the meeting.”

One delegate at the May event asked whether the number of questions asked by CHMP members at oral explanations had declined since the meetings became virtual, the assumption being that some members might “struggle or be unwilling to put additional questions.”

Zucatti said that in her experience with attending fully remote meetings, the questions had been “abundant.” In fact, she said, “the last meeting that Kell and I participated in just in the past month or two we went well over the time with the questions.”

Cannon also noted that one issue with the remote environment was “knowing the voices of who is asking the questions... it becomes hard to identify the country that is asking that question. So you need to be very diligent and have your team continue to monitor as the chair will then call on the various countries after the rapporteur and co-rapporteur ask their questions.”

Convincing The CHMP

Looking more generally at how companies can maximize their chances of winning over the CHMP at oral explanation meetings, Cannon noted that major objections were “product-specific issues” that could range from “detailed statistical challenges to hypothetical safety concerns to issues of thresholds of clinical meaningfulness.”

He said former CHMP members “told us you can’t just regurgitate what you have already sent in your application. They really expect you to conduct alternative analyses, provide new arguments and offer arguments to lessen risks. You need to show you understand and can address objections.”

The OE was the “last chance to overcome a negative opinion and resolve major objections before the vote, so just repeating the same things you’ve said before but louder does not work.” And “let’s face it, we know the questions are going to be tough.”

He said applicants had to “anticipate what the questions will be and then have the data and information ready so that you can share and resolve the panel’s concerns.”

Zucatti added that even though the focus of the discussion might be the major objections, “the final vote will actually be on the benefit risk profile. So it’s really important that applicants constantly address the major objections in the context of the broader benefit risk profile. With only 20 minutes for the presentation, and 40 minutes for the discussion, every word counts.”

When the company is presenting at an oral explanation, “it’s really your responsibility to be clear and communicate the positive benefit risk to the CHMP. It’s not the committee’s responsibility to try to figure it out.”

She also pointed out that following the OE, the applicant is out of the room when the CHMP discussion happens and the final vote is taking place, so the applicant “can’t answer questions or set the record straight.”

And having spoken with former CHMP members, she said, “I can tell you that this is a very practical obstacle. They’ve reinforced how important it is for applicants to be very focused and clear with the information and data so that they can remember it during the discussion and vote. Because if there’s confusion, once you’re out of the room, you’ve missed your chance.”