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Insights from global key opinion leaders on optimizing patient care in genitourinary malignancies

**Announcer:**
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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**Dr. Duran**
Hello, this is CME on ReachMD, and I'm Dr. Ignacio Duran.

**Dr. Xu:**
And I'm Dr. Vincent Xu.

Dr. Duran, the management strategies for different GU cancers vary among geographic regions due to changes in guidelines from different regions. Dr. Duran, what insights can you share from a European perspective, and what are some of the regulatory guidelines and nuances that you use to optimize patient care?

**Dr. Duran:**
Well, thank you, Dr. Xu, for this interesting question. I mean, I think — it's a reality that treatment strategies may change among different world regions. And I think there are a number of reasons to explain that, and it's probably of value that we can discuss those. So, let me summarize briefly, and I'm going to start by the regulatory situation.

Europe, where I work, aims to incorporate the new knowledge into clinical practice as soon as possible and I firmly believe that European oncologists are quite aware of the last developments in the field. And in fact, as we all know, many of key participants in the pivotal trials are Europeans. But nevertheless, it is very true that from a regulatory perspective, we tend to be slightly behind. And actually, data from 2022 revealed a median delay of about 8 months, compared with FDA approvals. So, we need first to get the European Medicines Agency, EMA, approval to get a drug incorporated into the European Union. But the next step is reimbursement, and this is not less important. You've got to understand, the European Union comprises 27 different countries with 27 different reimbursement policies. Just to give you an idea, we range from the case of Germany, where after EMA approval, they can prescribe the drug almost immediately. It's actually 2-3 days. And they get reimbursement very quickly. And there are other countries where sometimes the time elapsed from EMA approval to reimbursement may be close to 2 years. So, as you can see the situation changes a lot across– across Europe in terms of regulatory approaches.

Regarding the guidelines, there is no doubt that NCCN guidelines are usually broadly and worldwide. And actually, I can share an anecdote. A few years ago, I ran a survey among Spanish oncologists that ended up being a poster in ASCO-GU, trying to figure out what were the most used guidelines. What were the guidelines from the Spanish Medical Oncology Society, what're the guidelines from the European Society, what are the local guidelines, what was the answer? NCCN guidelines were number one. So, it means NCCN guidelines are very well received worldwide. It's true. And I'm biased because I'm part of it, that ESMO was making a big effort to be

there on time. And this is one of the problems.

NCCN works in a very timely fashion, and probably, ESMO guidelines run a little bit behind. It's also true that we have incorporated what we call the electronic updates, so there is no publication, but there is an update online. But there is still work to do, and I believe some big progress has been made. But we need to keep on working.

So, having said that, I'm going to pass it back to you, Dr. Xu.

**Dr. Xu:**
Thank you, Dr. Duran. That's really fascinating to hear about the regulatory situation in Europe. In the United States, after a drug is FDA approved, it tends to be covered almost immediately by Medicare and private insurances usually follow soon after that. Here, in terms of drug access, there is some ability to access non-FDA-approved medications, but it tends to be quite difficult and requires individual discussion with insurance companies to try to get their approval. And certainly, in the few cases where NCCN guidelines recommended treatment that's not yet FDA approved, the fact that they're on NCCN guidelines can be helpful.

When we're looking at the NCCN guidelines, the medications that are included in the NCCN guidelines are all medications that have an FDA approval. However, there are certain situations where the NCCN guidelines include off-label use of approved FDA drugs, and in those situations, the evidence that backs up the NCCN guidelines, and the fact that they're in the guidelines, can really help us when speaking to insurance companies about off-label use of drugs to help our patients.

Looking at the NCCN guidelines, there have been adjustments made and adaptations to the guidelines to help clinicians in different parts of the world. And I want to point out that NCCN has global guidelines adapted to certain regions. This reflects different availability of drugs and different practice patterns in different regions. For example, there are certain IO TKI combinations available in other parts of the world that are not actually available in the United States.

Dr. Duran, based on your experience both in Spain and actually, in Canada as a Canadian myself, are any of these guidelinesdifferent between countries?

**Dr. Duran:**
Well, they could beslightly different, but I would like to highlight a couple of things that you mentioned. One is the relevant of a treatment option being included in a guideline. There is no doubt that that's very helpful in terms of drug reimbursement, in terms ofsupport by regulatory authorities. And this is critical. And for you guys, NCCN is critical. For us, NCCN helps, there is no doubt. And we use it as an argument that other guidelines are quite relevant. And I think overall, I'd say the guidelines tend to be more or less homogeneous.It's true that in some countries they're more flexible and more open, and I think that's in partaffected by the healthcare system and the policy of reimbursement that you need to adapt to it.

In terms of what you mentioned about NCCN being adapted to other countries, I think that's a great initiative. I was part of it years ago with the translation of the NCCN guidelines to Spanish, and I have to say, that was really helpful. And I thinkpeople, clinicians, really welcome those kinds of initiatives that NCCN should keep on promoting.

**Dr. Xu:**
Thank you for that excellent discussion on global guideline recommendations and thank you for your attention.

**Announcer:**
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