FTS-HHS FDA

Moderator: Theresa Toigo
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Coordinator: Good morning and thank you for standing by. At this time all participants are in a listen only mode until the question and answer portion of the conference. At that time if you would like to ask a question please press star, 1 on your phone.

I'd like to remind all parties this conference is being recorded. If you have any objections you may disconnect at this time. And I would now like to turn the call over to your host today, Ms. Terry Toigo. Ma'am, you may begin.

Theresa Toigo: Thank you (Stacey). This is Terry Toigo and I'm the director of FDA's Office of Special Health Issues. I want to start by apologizing for the late notice that you received for the phone call.

We wanted you to have the documents before the phone call. At the same time we have to maintain our responsibilities related to confidential information. So we started late and you got the announcement late but thank you very much for joining us.

The purpose of today's call is to tell you about the new safety program also known as the risk evaluation and mitigation strategy or REMS for a class of drugs known as erythropoiesis stimulating agents or ESAs. The email inviting your participation in the telephone call included a link to FDA's Web site where the pertinent documents are posted.

With us today from FDA's Center for Drug Evaluation and Research or CDER is Dr. Richard Pazdur, director of FDA's Office of Oncology Drug Products and Dr. Patricia Keegan, director of the Division of Biologic Oncology Products in CDER.

There are other CDER experts around the table who will join them to answer questions during the Q&A session. First Dr. Pazdur will give a brief overview of today's announcement and then we'll start with questions. And again, the experts will be joining in to help us with any questions. So with that, Dr. Pazdur, can you please get started?

Richard Pazdur: Thank you Terry. Good afternoon and thank you for joining us. We have arranged this teleconference today to tell you about a new risk management program for the class of drugs called erythropoiesis stimulating agents or ESAs.

This program requires the drug manufacturer to implement a program to ensure that healthcare professionals understand the appropriate use of these drugs and that they adequately inform their patients about the drugs' risks. ESAs are marketed under the names Epogen, Procrit and Aranesp and are approved for the treatment of anemia, which may occur as a result of kidney disease, treatment for HIV infection with AVT and cancer chemotherapy.

The risk management plan we are announcing today has two key elements, a medication guide informing all patients of the drugs' risks and a safe use program specifically intended for patients with cancer. The medication guide informs all patients receiving ESAs that using these drugs are associated with an increased risk of stroke, heart attack, heart failure, blood clot and death.

The safe use program, which has been created and will be monitored by the drug manufacturer Amgen, will ensure that all healthcare providers and their patients fully understand the risk of ESAs when used for the treatment of anemia in patients with cancer.

This new safety requirements is based on the findings in multiple studies that demonstrated that ESAs cause tumors to grow faster and/or resulted in earlier death in patients with cancer.

Under the program called APPRISE, A-P-P-R-I-S-E, which stands for Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs, Amgen will ensure that only APPRISE certified healthcare professionals may prescribe and dispense ESAs to patients with cancer and that all certified prescribers are trained to understand and communicate to patients the increased risk of tumor growth that these drugs present to patients with cancer.

The APPRISE program requires Amgen to ensure that prescribers do the following - register and maintain active enrollment in the APPRISE program, discuss with patients with cancer the risks, benefits, indications and dosing guidelines of ESAs and document the discussion by obtaining the patients' signatures;

Provide a medication guide detailing safety information to each patient at the initiation of treatment and whenever the treatment is dispensed. Amgen will be required to oversee and monitor prescribers of ESAs in hospitals treating patients with cancer to ensure they are fully compliant with all aspects of the program as a condition of receiving supplies of these drugs.

Healthcare providers not enrolled in the ESA APPRISE program will not be able to prescribe ESAs to patients with cancer. Healthcare providers must re-enroll in the ESA APPRISE oncology program every three years. What is the purpose of this action?

We understand that the requirements of this safe use program will create new responsibilities for busy healthcare providers. It will require additional time for training, record keeping and other tasks related to complying with the program's requirements.

However, we are not doing this to make things more difficult for healthcare providers. We are doing it to make absolutely certain that patients are fully informed of the risks related to the use of these drugs before they begin treatment and throughout the treatment regimen.

FDA's primary mission is to protect patients from undue harm from drugs and medical products and one important way the FDA does this is by ensuring that patients are given adequate information to make informed decisions about the risks and benefits of their drug therapy.

In this case the risk benefit balance is a delicate one and by requiring additional education on the part of the healthcare providers and ensuring that patients have all the important drug risk information we can help patients make the best possible choice given their individual situations.

This program uses the authority FDA has under our statute to ensure that patients have a full and comprehensive understanding of the risks and benefits of these drugs.

What is the background of this action? FDA's decision to require a risk management program was based on the cumulative evidence from multiple clinical trials and the advice of the FDA's oncologic drug advisory committee or ODAC.

While ESAs carry significant risk for all patients, the risks pertaining to patients with cancer is specific and the data underscoring that risk are strong. Eight different studies involving various types of cancer demonstrated a risk of stimulating the growth of tumors and/or decreasing the survival time in patients receiving cancer treatment.

For patents receiving cancer treatment that have the potential to be curative, ESAs risks may undermine this therapeutic goal. For patients whose cancer treatment is palliative, the risk benefit analysis may be different. Through this program FDA will be able to ensure that patients are receiving the safety information they need to make an informed decision with their healthcare provider regarding whether ESAs are appropriate for their individual care.

At the March 13, 2008 ODAC meeting committee members recommended that risk should be addressed through obtaining patient consent after a discussion of the specific risk in patients with cancer. On April 22, 2008 FDA issued a letter directing Amgen to develop a risk management program to reduce the risk of ESAs when given to patients with cancer.

At this point FDA staff who have worked on this project and myself will be happy to answer any of your questions.

Theresa Toigo: Thank you Dr. Pazdur. (Stacey), we'll open the lines for questions now.

Coordinator: Thank you. At this time if you would like to ask a question please press star, 1 on your phone. To withdraw your request press star, 2. Once again if you would like to ask a question please press star, 1.

Theresa Toigo: And while we're waiting for questions if there are any questions since today is a discussion on safety, I want to remind our listeners that you and your members are very important to us in helping FDA meet its responsibility for ensuring that marketed medical products are safe and effective.

Healthcare professionals can report serious adverse events or product quality problems with the use of FDA regulated products to FDA's Medwatch adverse event reporting program. And you can do that either online, by regular mail, by fax or phone, and addresses to do so are included in the press release. And we encourage you to share that with your members so that they know about these Medwatch reporting systems.

Coordinator: Once again to ask a question please press star, 1. We have a question from Mila Becker of American Society of Human Health.

Mila Becker: Hi. Thank you very much. We just would like clarification about when the program will begin to be implemented.

Richard Pazdur: Pat, would you like to address that?

Patricia Keegan: Yes. Amgen has committed to initiating the program within 45 days of the approval of the REMS, which is today, so within 45 days of today. And by initiating the program what we mean is that the Web site for enrollment into the program and for physicians and hospitals to undergo training and certification in the program is to begin within 45 days from today.

We have been informed by Amgen that they may be able to do it slightly sooner but 45 days from today is the day they have committed to meet.

Theresa Toigo: Does that answer your question?

Mila Becker: Yes thank you.

Patricia Keegan: Okay.

Theresa Toigo: Okay. Thank you.

Coordinator: Your next question comes from Tom Hostetter of American Sociology of Nephrology.

Tom Hostetter: Yes. American Society of Nephrology - I had two questions. One, the medication guide, which is for all patients receiving ESAs, could somebody expand on that a bit? And the second question I had was how will it be determined that the therapy is for patients with cancer?

I think for example of dialysis patients who may have a history of prostatic cancer or something like that and are really receiving it for the primary indication of chronic kidney disease. Would those patients because of their past history require their providers to go through the APPRISE?

Patricia Keegan: To answer your question regarding the medication guides first, you are correct. The medication guide is an important tool for safety for all patients and all indications.

And all patients should receive a copy of the medication guide and it's recommended that they read it and discuss and if they have any questions they have addressed with their doctor before beginning therapy. The difference is that the medication guide also becomes part of the informational tools for patients under the APPRISE program with cancer.

So they will also be asked to read that and review that specifically and to sign a form saying that has happened. That is unique to patients who are receiving an ESA for the treatment of anemia secondary to cancer chemotherapy. And I'm going to turn it over to Dr. Rieves for your second question.

But I think keeping in mind that the anemia/cancer chemotherapy is the specific area where we want patients to be sure that they have understood the risk/benefits of ESAs under these elements to ensure safe use in this risk program.

Dwaine Rieves: Okay. this is Dwaine Rieves from the Imaging and Hematology Division. As you're probably aware, the medication guides were approved last year actually, late last year.

Patricia Keegan: November 2008.

Dwaine Rieves: November of 2008 and for patients who are receiving the erythropoietins for the treatment of anemia, chronic renal failure, there is no substantive changes. The information about the dispensation of the medication guide, there is

information on our Web site about when that guide should be dispensed to the patients.

To a large extent the changes are predominantly for patients who are receiving the erythropoietin products in the oncologic setting. For patients receiving in the renal setting there are no notable changes We have updated the labels, the package information. Most recently we have added information about the (treat) study as I'm sure you're aware to the labeling for the products. But otherwise there is minimal change in the labeling as it applies to the renal use of the product.

Lynne Peterson: Ma'am.

Theresa Toigo: Yes.

Lynne Peterson: I misunderstood the time. I still have a half hour. I'm going to call back. I'm sorry. Go ahead.

Theresa Toigo: Tom, does that answer your question?

Tom Hostetter: Yeah, I think so. As I understand it then it's if the primary indication is end stage renal disease and patients are not on active chemotherapy, which would be reducing their hemoglobin or something then the provider certification by APPRISE would not be necessary it sounds to me.

Dwaine Rieves: You are correct in that understanding.

Tom Hostetter: Thanks.

Theresa Toigo: (Stacey), we'll take our next call.

Coordinator: Thank you. Your next question comes from (Elise Appol) of Oncology Nursing Society.

(Elise Appol): Yes. I have a clarification question regarding the definition of healthcare providers. The role of oncology nurses in supporting patients and providing informed consent and support throughout treatment, both active treatment and symptom management is quite significant as you all know.

What is the expectation of nurses with respect to the APPRISE program? And in particular, you are using the term healthcare providers, which is great. I just want a clarification also if it's only required of those who are actually doing the prescribing but what about those who are actually delivering the treatment?

Richard Pazdur: The healthcare provider basically is defined as an individual who can legally prescribe the medication, the drug ESA. So that may influence for example some of your membership such as oncology nurse practitioners.

(Elise Appol): That's right, advanced practice nurses.

Richard Pazdur: Advanced practice nurses but it does not necessarily entail or it does not entail the actual administration of the drug. It is - specifically the definition of a healthcare provider is an individual that is legally able to prescribe the drug.

(Elise Appol): Okay.

Patricia Keegan: Or prescribe and dispense, that's the purview under which hospitals may also enroll into the program.

Richard Pazdur: Okay.

(Elise Appol): Great. Thank you very much. I appreciate it.

Theresa Toigo: (Stacey), are there any more questions?

Coordinator: At this time I show no further questions from the phone.

Theresa Toigo: Okay. We'll give it one minute since recently we have done this and we have had questions come in later.

Coordinator: Once again if you would like to ask a question please press star, 1 on your phone.

Theresa Toigo: Okay. Well, I think we'll assume that anybody that has a question has asked it. We hope this information has been useful to the participants today. We appreciate you taking time from your busy schedules to participate in this call especially on such short notice.

If you do have questions after today's call you can direct them to me at Theresa.toigo@fda.hhs.gov or you can call 301-827-4460 and I or one of my colleagues will help try and get an answer to your question. As a reminder, a replay of today's call will be made available in approximately one hour.

To access the replay you can dial 866-501-7038 and we encourage you to share this number with your members so that they can listen to the briefing that Dr. Pazdur provided. Again, the information about today's announcement is available on FDA's home page.

And Dr. Pazdur mentioned the historical information rather than give you that Web site. The easiest way to find it is to just go on the FDA home page, type in historical ESA drug information and it will take you right to that page. If you just do drug information ESA you won't get there. So that's the easiest way to find all of the information on ESAs. (Stacey), are there any one last chance - are there any questions pending?

Coordinator: There is a question from Lynne Peterson of Trends in Medicine.

Lynn Peterson: Hi. (I'm sorry).

Theresa Toigo: Go ahead Lynne.

Lynne Peterson: I'm confused because my notes said this call started at 1:00 pm and I accidentally dialed in not looking at the clock and it was going on.

Theresa Toigo: You're on a different - there is a call at 1:00 for the media, Lynne and that's the one that you can participate in.

Lynne Peterson: Great. Thanks.

Theresa Toigo: Okay.

Lynne Peterson: (I don't know how I got in this one. Sorry). Bye.

Theresa Toigo: Okay. I think that's it then. And unless anyone here has any last comments they want to add - so thank you also to the FDA staff who took the time to present this information to our healthcare professional and patient advocacy groups today. And thank you (Stacey) and with that we'll end the call.

Coordinator: Thank you for joining today's conference. You may disconnect at this time.

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