INSIDE PMB (EARLY) NOVEMBER 2003

Time flies. Welcome to the second issue of the NCI CTEP Pharmaceutical Management Branch's "Inside PMB." We are publishing this issue early for three reasons:

- The requirements for ordering agents from PMB will change beginning November 10th *(see the article below)* and we wanted to warn you.
- The holidays are approaching.
- We wanted to update information on the bevacizumab Treatment Referral Center protocol *(See "NUMBERS" on the flip side)*.

We hope you find this information useful. Please send questions, comments and suggestions to pmbafterhours@mail.nih.gov.

Can John Hancock Order?

Beginning November 10th, Mr. Hancock can sign an NCI Clinical Drug Request (CDR; NIH-986) only if he is the investigator, or if the investigator for whom the agent is ordered has made him a shipping or ordering designee on the Supplemental Investigator Data Form (IDF).

Why?
(1) Investigators are ultimately responsible for all agents ordered in their names.
(2) Software upgrades happen here, too (big sigh). PMB's upgraded computer software will indicate specifically who is authorized to order for each investigator starting November 10th, 2003.
The advantages: Right now this closes the loop; investigators know who's using their names to order. Later, this will simplify linking investigators with shipping and ordering designees when we offer web-based ordering!

How is PMB preparing?
We are reviewing every CDR we receive. If the investigator hasn't designated the individual signing the CDR as a shipping or ordering designee, PMB will do two things:
(1) Fax a memo to the fax number provided on the CDR, explaining the new policy and providing instructions for necessary changes.
(2) Include the first two pages of the investigator's current Supplemental IDF.

What should you do?
If you receive a fax, have the investigator (1) complete section 10 (shipping designee) indicating the person who will receive all shipments of PMB-distributed agents and section 11 (ordering designees) indicating who can order PMB-distributed agents; (2) sign and date the form, and (3) fax it to PMB at 301-402-4870 before November 10th.

If you don't receive a fax, relax!

If you have questions, please contact the PMB by phone at 301-496-5725 Monday through Friday from 8:30 AM to 4:30 PM Eastern Time or by E-mail at pmbafterhours@mail.nih.gov.

Look for INSIDE PMB quarterly! Next issue: February, 2004

WHAT IS CARBOXYPEPTIDASE?

Carboxypeptidase ($CPDG_2$; NSC 641273) is used as a rescue agent for renal toxicity secondary to methotrexate. The NCI currently has the nation's only supply of this agent. Only one lot was made: lot 004 in 1991. As stated on the label, please store this agent in the freezer. It continues to pass bi-annual potency tests.

Watch this space for breaking news about carboxypeptidase in the future!

THAT's HISTORY:

BMS-247550 is no longer available as a 20 mg vial. All orders for BMS-247550 now include only one vial of vehicle with each 30 mg drug vial.

REMINDER!

All remaining **CCI-779** ampules will expire on October 31, 2003. We will stock only **vials** once the remaining 25 mg ampules are depleted. Only 125 mg vials are available. In 2004 Wyeth plans to manufacture a 25 mg Vial.

COMPETING WITH SANTA

Here come the Holidays! Please remember:

- "Next Day Delivery" is almost impossible from December 23 through January 5.
- If at all possible, consider doing the bulk of your agent ordering the week of December 15 (or before if you plan much better than I do!).

PMB AFTER HOURS

We close at 4:30, just as our west coast customers are finishing lunch. (We are not sure what the Australians are doing, but we know you're there, mates!) So.....Need to reach us? Try our new after hours E-mail address:

pmbafterhours@mail.nih.gov

Expect a response on the next business day!

Question of the Month

"I hate it when that happens!".....What do I do when the IV room pharmacist uses Velcade™ from the pharmacy's stock for an NCI CTEP-sponsored trial participant instead of using NCI-supplied investigational PS-341?

Using commercial drug instead of investigational supply for a CTEP-sponsored trial is an audit compliance concern. What should you do?

- On the drug accountability log, clearly document that commercial Velcade™ was dispensed in error.

What about the opposite "oops"? You used a CTEP-supplied investigational agent on a patient not enrolled on a CTEP-sponsored trial.

- Clearly document on the drug accountability log, that an investigational agent was dispensed to a non-study patient.
- Notify PMB of the error by E-mail or snail mail. The letter should contain the agent name, NSC number, amount used, a short explanation of the error, and corrective action implemented to prevent future occurrences.

In both cases, certain actions are forbidden:

- Do not replace the pharmacy's supply of Velcade™ with the NCI-supplied, investigationally labeled PS-341 or vice versa.
- Do not charge the patient.

As you can see, these compliance violation are costly for your pharmacy. The folks here at the PMB suggest these preventive measures:

- Use pre-printed or computer generated, protocol-specific order sets.
- Educate your oncologists and/or cancer center clinical trials office to alert you of newly enrolled protocol patients and to include the protocol number on all orders.
- Generate a list of all patients enrolled in CTEP-sponsored trials using investigational agents and commit it to memory. (

Have you have successfully implemented policies and procedures to prevent this problem? We want to hear from you. Please share your procedures with us. Send us an email at pmbafterhours@nih.gov. Please label the email "Question of the Month – Inside PMB October Special Edition." Look for responses in January 2004's "Inside PMB."

NUMBERS

Number of patients on the TRC-0301 (the Treatment's Referral Center's study for patients with locally advanced or metastatic colorectal cancer who are no longer benefitting from standard treatments) after one month (August 1):

1

Number patients enrolled on TRC-0301 as of October 1:

85

Number patients enrolled on TRC-0301 as of October 7:

102

***WHAT THIS MEANS:** This is brisk accrual! TRC-0301 will close to accrual on October 31, 2003, and patients will be monitored. If a response rate of 5% is confirmed, it will reopen in 2004 and continue enrolling until Avastin® (which is under priority review) is approved by the FDA.*

More information is available at:
http://www.cancer.gov/clinicaltrials/digestpage/bevacizumab

WHO ARE WE?
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Can we "biggie-size" that bevacizumab?

Bevacizumab (Avastin™, NSC 704865) is PMB's fastest moving agent, with 6300 4 mL vials distributed monthly. Until now....

Most bevacizumab protocols have been amended to include a new, bigger vial. We hope you'll find the new **1000 mg vial (25 mg/mL, 40 mL fill)** more convenient for patients who are on 10 mg/kg or 15 mg/kg doses.

PSD....PSD?....Hmmmm

What is a PSD and what can it do for you?

A PSD (Primary Shipping Designee) is an individual at an institution who is on file with the PMB as responsible for receiving ALL medications sent from the PMB to that institution. The PSD may order agents, but other individuals may also be named as Ordering Designees to help with this task.

The advantage of a PSD is that all shipments go to the exact same address and it is easier to coordinate those shipments both at your end and at ours. It also reduces costs.

Interested in creating a new PSD for your site? Call the PSD Coordinator at 301-496-5725 for more information!

New Transfer Request Form!

We have a new Transfer Investigational Agent Form! Some changes include an additional reason for transfer (other) and our Transfer Request Fax Number in the bottom right-hand corner. Please destroy old versions and replace them with the new one!

All CTEP forms are available on CTEP's web page (http://ctep.cancer.gov).

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