Dragon, Karen E. (CDC/NIOSH/EID)

From: de Lemos, Mario [mdelemos@bccancer.bc.ca]
Sent: Tuesday, August 02, 2011 5:34 PM
To: NIOSH Docket Office (CDC)
Subject: 190 - NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List

Comments on Proposed Additions and Deletions to the NIOSH Hazardous Drug List

The panel summary is a great improvement in providing more transparency on how decisions are made during the NIOSH review. However, I have a few more questions regarding this panel summary:

1. It would be very helpful for NIOSH to provide the complete list of the drugs that were reviewed, and not just the final 38 drugs that affect the hazardous drug list. This would allow us to more confidently designate drugs as non-hazardous if they are not on the NIOSH list, rather than guessing if these drugs have been reviewed by NIOSH or not.
2. It is not clear how the review methodology differs between the peer reviewers vs. the stakeholders. If the review methodology is the same, it is not clear why their recommendations need to be listed separately rather than combined.
3. It is not clear who the stakeholders were and whether they included representatives from staff personnel who handle the hazardous drugs.
4. It is not clear how the final NIOSH recommendations are made when the recommendations made by the groups of peer reviewers vs. stakeholders differ. For example:

Drugs	Peer Reviewer	Stakeholder	NIOSH
alemtuzumab	Hazardous-2/4 based on pancytopenia/marrow hypoplasia	Does not meet the criteria -4/5	Not hazardous
bevacizumab	Hazardous-3/4 based on adverse effect on fertility and teratogenicity	Does not meet the criteria -5/6	Not hazardous
cetuximab	Hazardous-2/4 based on fetal toxicity	Does not meet the criteria -5/6	Not hazardous
interferon alfa 2b	Hazardous-3/4 based on adverse reproductive effects	Does not meet the criteria -4/5	Not hazardous
nilotinib	Hazardous- 4/4 based on adverse developmental and reproductive effects at low doses	Does not meet the criteria -4/6	Hazardous based on adverse developmental and reproductive effects at low doses
pamidronate	Hazardous-2/4 based on adverse reproductive and fertility effects	Does not meet the criteria -4/6	Not hazardous
rituximab	Hazardous-2/4 based on fetal toxicity	Does not meet the criteria -5/6	Not hazardous

Regards,

Mario

Mario de Lemos, BSc(Pharm), MSc (Clin Pharm), PharmD, MSc (Oncol)
Provincial Drug Information Coordinator, Systemic Therapy, British Columbia Cancer Agency
Associate Clinical Professor, Faculty of Pharmaceutical Sciences, University of British Columbia
Expert Review Committee Member, Pan-Canadian Oncology Drug Review
600-750 West Broadway
Vancouver, BC, V5Z 1H1
Canada
Tel: 604-877-6000 local 676277
Fax: 604-708-2024

Email: mdelemos@bccancer.bc.ca