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

From: Badry, Nadine [nbadry@bccancer.bc.ca]
Sent: Monday, August 15, 2011 2:56 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 for 2012

I am happy to see that NIOSH is beginning a process whereby the HD list will be reviewed with greater frequency. Many new drugs reach the market every year, and it is important to review these new drugs in a timely manner. I believe also that including the panel summary outcomes in your documentation is a great improvement in identifying your process for drug review.

I do have a few additional comments:
1. There appears to be some inconsistency in how NIOSH applies the 6 NIOSH characteristics to a given drug on the NIOSH list. For instance, when applying the principle that "drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals", I sometimes arrive at different conclusions from those published. I think that there needs to be further clarification of how these characteristics are applied, including whether some characteristics are more important than others or if there is a hierarchy to be followed in the assessment. An explanation may be necessary to define what constitutes a positive result for a particular characteristic.

2. What is the role of the stakeholder in the decision-making process? How is this group different from the peer reviewer? To achieve greater transparency and better guide decision-making about safe handling, further details about the stakeholder conclusions should be made available, especially in those situations where the stakeholder conclusion differs from that of the peer reviewer.

3. As an end-user, I have also found it difficult to interpret the status of a drug NOT appearing on the NIOSH list. For instance, it is clear to me that a drug appearing on the list has been assessed as hazardous by NIOSH, but I do not have the same confidence if a drug does not appear on the list. Will NIOSH make available a list of drugs that have been assessed but are considered to be non-hazardous?

4. Although I understand that your organization is American, many professionals consider your documents to be applicable internationally. In the absence of any other organizations such as yours, Canadian health care professionals are looking to your documents for guidance in this area. I was disturbed, therefore, to see in Proposed Additions and Deletions to the NIOSH Hazardous Drug List for 2012 that one of your criteria for deleting a number of items from the list was because these items are not currently available in the United States. Having taken the steps to include these drugs on the list in the past (i.e., NIOSH presumably having assessed these drugs), it would seem like a backwards approach to now remove these drugs from the list. I can understand that you may not have the resources or interest to assess new drugs that are only available elsewhere, but I cannot comprehend why you would delete drugs that have already been assessed.

5. I would also disagree with the decision to remove radiopharmaceuticals from the NIOSH list, on the basis of their regulation by the Nuclear Regulatory Commission. Having a different overseer does not change the hazardous nature of a drug, nor does it preclude some overlap between organizations. One of the advantages of a list such as the NIOSH list is the ability to collectively report on drugs meeting the established criteria. If professionals within an organization have to consult different lists to determine the status of a drug, operationalizing a policy for the safe handling of hazardous drugs becomes very difficult. Footnotes or other devices can be used to indicate drugs that may be governed by other standards.

6. A principle of transparency should also be applied for drugs that are reclassified as not meeting the criteria for a hazardous drug. Further details must be made available to explain how the drug no longer meets the NIOSH criteria.

Thank you for the opportunity to comment on the proposed additions and deletions to the NIOSH Hazardous Drug List.

Regards,
Nadine

Nadine Badry
BC Cancer Agency
Pharmacist, *BCCA Vancouver Island Centre*
Acting Editor, *BCCA Cancer Drug Manual*
(250) 519-5500 Ext.69-3742
nbadry@bccancer.bc.ca