

From: Smith, James JM SC-CSP
Sent: Tuesday, November 26, 2002 4:47 PM
To: Briggs, Barnaby D SC-CSEA; Tholstrup, Susan C SCC; Clegg, Patsy M SCC-CHSE-PC; Sullivan, Nancy E SCC-CBAR; Walls, Chuck G SCC-CHSE; Dammann, Angelika A SC-CSEA
Cc: Ho, Cheng-Kwee CK SC-CFC; Mecca, Rosemarie R SCC
Subject: FW: Benzene Health Study in China
Folks

Attached is a copy of the note I have sent to Malcolm Brinded re the Benzene study in China.

Barnaby and I have discussed. We need to tighten our procedures on issues management so that Country organisations get the chance to consider issues and we can demonstrably close with them on actions and issues management. This includes the annual letters process where we need to ensure Country Chairs have the chance to consider local impacts of our issues

Barnaby is documenting an updated procedure covering our ongoing issues management, the annual process, the Country chairs and the MACPs. Hoping to see this very soon because we need to get it into this year's letters process and because I expect follow up questions from Malcolm. An overall flow diagram would be good. Copying Chaeng Kwee so he can connect Barnaby into the letters process

James

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-----Original Message-----

From: Smith, James JM SC-CSP
Sent: 26 November 2002 22:20
To: Brinded, Malcolm A SI-MGDMB
Cc: Tan, EkKia EK SCHINA-CH; Henkes, Evert E SC-CS; Willems, Rein R SC-CX
Subject: Benzene Health Study in China

Malcolm

With regrets for the delay, set out below are the answers to the questions you raised on the benzene study in Shanghai:

Ethics

We did consider your question, among others, before committing to the study.

The study covers individuals who had already been identified by Shanghai medical authorities as having a potentially benzene exposure related condition. Each has agreed that their case be included as data in the study, on the basis of explanations provided to them. Consent forms signify agreement. The study itself is of course not creating new benzene exposures and medical treatment is not compromised.

The study is being conducted in Shanghai because the medical records and exposure data are

extensive and reasonably well organised. In addition it is known that there are exposures from which valid findings can be derived. Thus the basis exists for a sound scientific study which the authorities support both in principle and with technical capability. There is no reason from an ethical point of view that the study could not have been conducted in Europe or the USA. However it is known that occupational exposures had been higher in China and therefore a broader range of data is available. We considered the possibility that the individuals in China might have had less real freedom of choice about use of their records. However we believe that due process can be demonstrated.

We considered if the study could provoke discussion about poor practice on exposure management for benzene in China. We believe that a study of this kind is consistent with our continuing efforts to ensure high and consistent risk management practices globally.

More generally, before committing to the study, we considered its issues management aspects. We are satisfied that, both from the points of view of the product itself and from the point of view of developing country workers, the study can stand scrutiny. We began consideration of this study in November 2000. In addition to our own HSE, product stewardship and issues management people, the discussion included Xaiowei Liu, Jeremy Frearson and others in PX and OP. I need to add though that we were not properly thorough in our involvement of the Country organisation. We did raise the proposal with Nick Wood before committing to the study. He raised a number of concerns. We felt we answered these in the course of our review. However we did not communicate the answers clearly to Nick nor get proper agreement from the Country organisation before proceeding. This is taken up in the next answer.

The study is not on our top level issues management matrix. However it is listed second on our next level HSE list as a 'Potential Global Issue'.

Country organisation/ Issues system

As indicated above, I regret to say, we did not explicitly inform the country chair about this study and did not follow up in the letters process for 2001 to make sure he was notified. We will enhance our procedures on issues notification to countries to ensure this omission does not recur (this will involve the procedure itself, its communication and quality assurance for execution).

However as noted above, while we did not inform Ek Kia directly, the China country organisation was contacted before the study began as were PX and OP. But we clearly did not follow through and gain proper agreement with the Country organisation. This is a significant omission. We will take the learning from this too and ensure we achieve closure with Country organisations for a study of this kind -- and on any analogous issues.

Happy to try to respond to further questions.

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