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Exemptions:

WATCH COMMITTEE

Alternatives to the use of glutaraldehyde in endoscopy sterilisation; and appropriate risk management for the use of Cidex-OPA in this context

Issue

1. Comments on a guidance document on the selection of alternatives to the use of glutaraldehyde in endoscopy sterilisation; and a recommendation for appropriate risk management for the use of Cidex-OPA in this context

Timing

2. The views of WATCH are requested now in order to facilitate the near-future publication of "An Evaluation of Chemical Disinfecting Agents Used in Endoscopy Suites in the NHS"

Recommendation

3. WATCH is asked to consider all of the information in this package, to listen to a presentation from the company Johnson & Johnson at the October WATCH meeting, and then to express its opinion in relation to the Action points in paragraph 18.

Background

4. Over a period of approximately 10 years (1992–2002) the previous WATCH committee received and took positions on a number of papers concerning glutaraldehyde and potential alternative chemicals to glutaraldehyde, primarily in the context of the sterilisation of endoscopy equipment in hospitals.

5. Attached at Annex 1 is the most recently considered package, debated by WATCH at its meeting in September 2002. The cover paper briefly reviews earlier positions taken on glutaraldehyde and leads on to a request for WATCH to consider the established and predictable toxicological hazards of two potential alternative chemicals for use in endoscopy sterilisation, succinic dialdehyde (SDA) and ortho-phthalaldehyde (OPA).

At its meeting in September 2002, WATCH reached the following position:

"WATCH noted that there was very little information on the toxicological properties of succinic dialdehyde and ortho-phthalaldehyde. On the basis of the information that is available, WATCH concluded that both substances may have the potential to cause occupational asthma. It recommended that control strategies for both substances should take account of this potential health hazard."

6. There have been subsequent developments. Most significantly, HSE commissioned Dr Karen Niven, Head of Health and Safety Services at OHSAS (Occupational Health and Safety Advisory Service), to develop guidance for users, which highlights the benefits and limitations of use of chemical disinfectants in endoscope decontamination. The document that emerged from this work is attached as Annex 2.

7. Also, in relation to the substance OPA and the sterilising formulation Cidex-OPA (containing 0.5% OPA), some additional toxicological information has appeared, which is summarised in Annex 3 and 4.

Argument

8. Karen Niven's report is seen by HSE as part of its initiative to reduce the incidence of occupational asthma – specifically by helping in the elimination of glutaraldehyde and/or the avoidance of asthma (or other health problems) arising from the use of alternatives to glutaraldehyde. This is a key Product within the asthma strand of the Respiratory Disease Project, within the Disease Reduction Programme.

9. The company Johnson & Johnson, which markets Cidex-OPA, has made a number of comments on the document (Annex 5). WATCH is the appropriate forum in which the technical quality and robustness of Karen Niven's document, and the impact that the Johnson & Johnson comments should have on the document, should be debated.

10. WATCH concluded in September 2002 that OPA may have the potential to cause occupational asthma. In HSE's opinion, the small amount of toxicological data that has emerged subsequently, captured in Annex 3 and 4, adds more weight in favour of this position.

11. HSE's view as a regulatory authority is that suppliers of the substance OPA should, within their responsibility to self-classify, consider classifying the substance with R42 (May cause sensitisation by inhalation) based on a prediction that OPA will possess this hazardous property. Cidex-OPA is a preparation, containing 0.5% OPA. The criteria for classification of preparations within the EU indicate that the "sensitising"/R42 classification **must** be applied to preparations containing 1% or more of an "R42" substance. The concentration of OPA in Cidex-OPA is lower than this threshold. Hence in HSE's view the appropriate classification status of Cidex-OPA, in respect of asthmagenicity, is less clear.

12. The nature of the toxicological properties of Cidex-OPA is important in itself, in terms of information provision and classification & labelling. However, it is also important in relation to determining the appropriate risk management measures to adopt in using Cidex-OPA. The choice of a risk management strategy within COSHH Essentials, for example, is driven by hazard classification, along with the quantity used and the propensity to become airborne.

13. Hence a crucial issue, now asked of WATCH, is what is the most appropriate risk management approach that should be adopted in the use of

Cidex-OPA in the sterilisation of endoscopy equipment? Such a view might be informed by considering initially the potential health hazards of Cidex-OPA and what this might mean for decision-making on self-classification and on allocation of Cidex-OPA to a COSHH Essentials Hazard Group.

14. Johnson & Johnson has commented on Karen Niven's review, has been invited to give comments on this WATCH paper and will make a presentation to WATCH at the beginning of this agenda item. Karen Niven will also be present for this item.

Link to HSC Strategy

15. This work falls under the Disease Reduction Programme (DRP) of HSE's "Fit3" Strategic Programme; it forms part of the Asthma strand of the Respiratory Disease Project within DRP.

Consultation

16. Johnson & Johnson, as manufacturers of Cidex-OPA, has also received and been invited to comment on this WATCH package.

European Context

17. None

Action

18. WATCH is asked to consider all of the information in this package, to listen to a presentation from the company Johnson & Johnson at the October WATCH meeting, and then to:

- i. Express its opinion on the report by Karen Niven "An Evaluation of Chemical Disinfecting Agents Used in Endoscopy Suites in the NHS"
- ii. Recommend the most appropriate risk management approach to employ in using Cidex-OPA in the sterilisation of endoscopy equipment

Contact:

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References / Attachments

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| Annex 1 | WATCH/20/2002, Chemical substitutes for glutaraldehyde in sterilisation of medical equipment |
| Annex 2 | An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS, Karen Niven, 2005 |
| Annex 3 | Cidex OPA – Episodes of anaphylaxis |
| Annex 4 | Ortho-Phthalaldehyde - The Local Lymph Node Assay in BALB/C Mice |
| Annex 5 | Comments from Johnson & Johnson to Dr Niven on draft report |