

Pages 1-3 inclusive exempt in full under section 22(1) of the FOI Act

## Agenda Item 5.1 Pink-tinted Chlorhexidine

<b>Questions for the ACMD</b>	<p>The committee is requested to provide advice on the following specific issue:</p> <ol style="list-style-type: none"><li>1. Regarding the use of listed hard surface disinfectants as skin disinfectants, from instructions for use and labels that indicate the product is not to be used on 'broken skin' (thus implying that use on skin is intended), which of the following options would be appropriate?<ol style="list-style-type: none"><li>(a) The use of the products on skin is not implied; therefore all labels are compliant with the legislation. (The TGA review of these products will be closed without further action).</li><li>(b) Use on skin is implied; therefore sponsors should be requested to place additional warnings and advice on labels and instructions for use to advise users that the products are not intended to be used as skin disinfectants.</li><li>(c) Provide additional advice to users through a web statement and/or medical device safety update that the use of hard surface disinfectants as skin disinfectants is outside their intended purpose and they have not been assessed, and are not approved, by the TGA for this use.</li></ol></li></ol>
<b>Committee Advice:</b>	<p>The committee believes :</p> <ol style="list-style-type: none"><li>1. use on skin is not necessarily implied through the instruction not to use on broken skin; however, it is well known that all of these products are used for skin prep; therefore, the labelling should clearly and prominently state that a product is not to be used as a skin disinfectant if it has not been assessed for this use.</li><li>2. additional advice should be provided to users through a web statement and/or medical device safety update that the use of hard surface disinfectants as skin disinfectants is outside their intended purpose and they have not been assessed, and are not approved, by the TGA for this use.</li></ol> <p>In addition the committee believes that pink tint may be acceptable for use in dispensers for hand sanitising but poses unnecessary risk for surgical prep; and red tint should be used for this purpose.</p>

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