MAINE ADVISORY REGARDING FDA CONCERNS ABOUT POSTING OF DRUG TRIAL RESULTS AND PROMOTION

After consulting with FDA DDMAC, Maine understands that manufacturers can comply with the Maine rules requiring posting of clinical drug trial results without DDMAC considering the posting of this information to be promotion so long as the posting of results is accomplished in a non-promotional manner as follows:

Content must avoid promotional statements in order to avoid being regulated as promotion by DDMAC. Where it would be satisfactory to state that the subject drug reduced cholesterol (for example) by a given amount, a placebo by another amount and that the difference is statistically significant, our understanding is that DDMAC would consider a statement that the trial indicates the subject drug is safe and effective for lowering cholesterol, or that it looks more promising than other options, or that it may have a special benefit for a certain population to be promotional . Similarly, a factual statement of the incidence of a side effect seen with the drug as compared to placebo is distinguishable from a statement that the trial proves the drug isn't associated with the side effect or that doctors should consider using the drug as their first choice because of other drugs' association with the side effect ; the latter statements would be considered promotional. Similarly, a statement comparing the trial data to existing data for a competitor's drug and drawing conclusions about the comparative attributes of the two drugs would be considered promotional by DDMAC.

To the extent that the ICH E3 guideline allows or encourages such conclusive or summary statements that create DDMAC concerns about the material being promotional, they may be avoided by a manufacturer without being in violation of the Maine rules. Factual reporting of results for the endpoints studied and whether the results are statistically significant will satisfy the Maine rules.

Content also must avoid selective presentation of information. Selective presentation of information on endpoints favorable to the subject drug, in contrast to presentation of all endpoints studied, can render the information promotional.

Context also is significant. We understand that incorporation of a results website into a promotional setting, such as excerpting the information into promotional materials or distribution of the text with promotional materials or in detailing sessions with prescribers, would cause DDMAC to view such activity as promotion. Similarly, DDMAC would be likely to consider the activity as promotion if the results posting was part of or linked directly to a website that promotes the product, or if access to the website functioned so as to emphasize positive results over negative ones. DDMAC suggests that the website(s) with the clinical trial results be kept separate from promotional websites for the drug(s).

In short, Maine will not require conclusive or summary statements that put a manufacturer in conflict with the FDA DDMAC. Questions about the FDA DDMAC's positions should be directed to DDMAC.