NFTHD #40: Comparing clinical trials – is it possible?

In this Note from the Help Desk, we answer a question about comparing one clinical trial of a medicinal product against a clinical trial of another medicinal product.

By talking clinical trials, we mean research and development for a yet-to-be registered product or a yet-to-be-approved indication. It would be difficult to present late-stage clinical trial results for a particular product in a non-promotional manner. As you will know, any communication about products or indications still under development (or not yet approved in Australia) must not breach the Therapeutic Goods Act, which prohibits a company from promoting an unapproved product or indication to healthcare professionals or consumers. The Code is underpinned by the Act.

The concern in this case is that the act of comparing one clinical trial to another is likely to highlight a preference of one product's performance over another, because a comparison has been made. Context is key - it will depend on whether the comparison is between trials or between the results of those trials, or both. Either way, we need to avoid the no-go area of promotional exchange, which is defined to include statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product, and comparative information.

So, what is possible? A factual presentation on the company pipeline may be provided to healthcare professionals.

Medical department personnel could provide a presentation to healthcare professionals giving an overview of products/indications in development without making any claims in relation to the results of trials. The information on a clinical trial should be provided as a factual statement of the study design, number of patients, location of trial centres, primary purpose and progress to date as long as this is communicated in a non-promotional manner.

The relevant bit in the Code is Scientific Exchange – Section 7. And the conclusion is that it would not be appropriate to compare clinical trials of one medicine versus another, given the above rationale, but context remains key.

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