From:
To:
Date: 08/04/2016 01:38 p.m.
Subject: RE: FW: Medsafe consultation on proposed changes to medicine data sheet format, review process and regulatory guideline

Dear

Thank you for the opportunity to provide feedback on this consultation. We consider that updating the data sheet format will be useful.

We note that the data sheet is a dual-purpose document, providing information to prescribers and operating as the product license, with the supplier legally responsible for the information. On this basis a name change could more accurately describe the document.

We consider that there is a question in relation to examples of efficacy on data sheets. Many current data sheets provide explicit evidence of efficacy. The EMA guidelines, which Medsafe bases its proposed datasheet template on, are silent on this. While we appreciate that it may not be practical or possible to include all trial data in data sheets, there need to be safeguards to ensure balanced and complete information. The issues of publication bias and post-publication peer review could be partially addressed via information requirements in data sheets.

Our suggestions are:

1. Data sheets be required to provide references and/or clinical trial numbers for the studies they refer to, so readers can find source publications/trial details. Where data are not yet published, the data sheet could state "data on file", and then be updated when published.
2. All datasheets to have a disclaimer at the beginning that "The studies cited are not all of the studies conducted. Prescribers are advised to undertake their research/literature searches on trial registries, eg clinicaltrials.gov. and note that results of all trials may not have been published."
3. Data sheets be required for medical devices.

Please do not hesitate to contact me if you have any questions about our feedback.

Regards

PHARMAC |