



Sent by: I  
24/02/2016 09:58 a.m.

To:  
cc:  
bcc:

Subject: Re: Consultation on proposed changes to medicine data sheet format, review process and regulatory guideline

These suggests all look sensible to me and I have no further comment to make

<http://www.health.govt.nz>

Hi everyone This is to advise you th... 12/02/2016 11:21:31 a.m.

From:  
To:

Date: 12/02/2016 11:21 a.m.  
Subject: Consultation on proposed changes to medicine data sheet format, review process and regulatory guideline

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Hi everyone

This is to advise you that Medsafe has started consultation on proposed changes to the data sheet format, review process and regulatory guideline.

The consultation documents can be found at <http://www.medsafe.govt.nz/consultations/current.asp>.

We propose to standardise the data sheet format to the European Summary of Product Characteristics (SPC) format, as this is a well-known format used in many countries. This will result in medicine information set in a standard order, with the prescribing information and warnings usefully near the beginning of the data sheet. We believe this will help to improve medicine safety.

We are also seeking comments on terminology, how prescribing information can best be promulgated and whether some form of data sheet could apply to high-risk medical devices, in order to inform the new Therapeutic Products Bill.

Kind regards