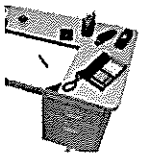
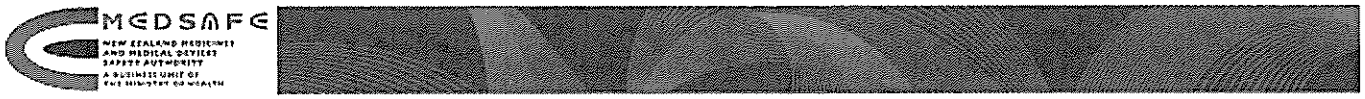


03/06/2015 11:53 a.m.

cc:
bcc:

Subject: Fw: Further feedback re: Pharmacovigilance guidelines consultation (MNZ)

FYI - to consider as part of feeback on Phv guidelines



From: Drug Safety Mylan NZ/NZI <drugsafety-nz@mylan.co.nz>
To: >,
Date: 02/06/2015 03:39 p.m.
Subject: Further feedback re: Pharmacovigilance guidelines consultation (MNZ)

Dear

Mylan New Zealand is aware that the consultation deadline has passed for the revision of the Pharmacovigilance guidelines, however we would like to add further comment on the matter.

We have just become aware of Adverse Drug Reaction reporting requirements from CARM and when they will or will not process the ADR cases into the CARM database. We would like to see clear guidance in the revised PV guidelines documenting what CARM considers a report and if this will be processed.

Please refer to the below email chain for reference. It is recent correspondence between myself and CARM about a recent case we have reported and the fact this will not be processed, as only the gender of the patient is available.

We believe that the guidance we have received from CARM is inconsistent to international guidelines, of what is considered a valid case. ICH guidance for good case management practices states, "One or more of the following should automatically qualify a patient as identifiable: age (or age category, e.g., adolescent, adult, elderly), gender, initials, date of birth, name, or patient identification number" - However, CARM require two patient identifiers (age and gender) to process an ADR. We would like to see this communicated in the revised Medsafe guidelines, if these are now the requirements of ADR reporting to CARM.

I hope you find our comments acceptable and we request that you please acknowledge receipt of this email.

Many thanks and kind regards,