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MSD

21 May 2018

Product Regulation
Medsafe
PO Box 5013
Wellington 6140

Dear Sir/ Madam,

RE: Consultation on the revision of CMN Form B

I refer to the Medsafe consultation on the revision of the Changed Medicine Notification Form B published 08 May 2018. In general, MSD are supportive to the proposed amendments to the CMN form and welcome opportunities to provide feedback.

Consolidation of CMN form A and B

CMN form A and form B share a significant number of change types, and therefore could be combined into a single dual-purpose form. With reference to the below recommendations regarding change classification and grade/fee types, a more consistent approach to CMN could be realised.

Reduction of duplicate information

The first table in Section 6 contains duplicate information from Section 1 (i.e. File No., Product Name, Dose Form, and Strength) and could therefore be removed.

Clearer guidance on change types and risk categorisation

The relationship between Grade, Fee, and Change Type is unclear. Not all change types have a Grade associated with them. Likewise, some change types with different grades attract the same fee. Also, fee information is not useful when determining category of change, and hence, MSD recommend removing this information from the form and instead listing grade/fee information on the Medsafe website.

Integration with Medsafe guidelines

The relationship between the CMN forms and the New Zealand Guideline on the Regulation of Therapeutic Goods could be strengthened by integrating the change categories into the guideline. In turn, description of change requirements etc could be removed from the form altogether with a simple checklist to select the appropriate change category.

Clearer guidance on GMP requirements

With regard to changes to manufacturing sites, it would be useful for sponsors to know which sites require evidence of compliance with GMP to be provided as supporting evidence, and which of those sites in turn will be listed on the TPD. Including this information in the CMN form would be helpful.

In agreement with the above, MSD suggest updating the form such that:

1. Each category/description of change has a grade associated with it
2. Each Grade has a single fee associated with it
3. Each category clearly lists the requirements for that category
4. Each category clearly lists the supporting data to be provided and/or produced
5. Relocation of the 'tick box' to a separate list with change information tracked as-is, or alternatively integrated into the guideline as suggested above.

MSD would like to thank Medsafe for the opportunity to provide input into the CMN consultation. Please feel free to contact the undersigned should you wish to discuss any of the above further.

Kind Regards,
Merck Sharp & Dohme (Australia) Pty Limited on behalf of Merck Sharp & Dohme (New Zealand) Limited

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