The Manager
Product Regulation
MEDSAFE
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10 July 2013

Attention: Sarah Reader

Consultation: International Harmonisation of Ingredient Names (IHIN)

Introduction

Mylan New Zealand is the largest supplier of generic pharmaceuticals in New Zealand and is part of the Mylan family of companies which also includes Alphapharm who are the largest supplier of generic pharmaceuticals in Australia.

Mylan New Zealand supplies a wide range of prescription and over the counter products, covering both those purchased directly by consumers or prescribed by doctors and funded via PHARMAC.

Mylan NZ is a full member of the NZ Self Medication Industry (NZSMI).

Feedback

Mylan New Zealand is overall supportive of the general principle of harmonisation proposed by TGA. However, we have some issues with specific ingredients which we will provide comments on under the relevant question.

Question 1:
Looking at all the lists of proposed ingredient name changes, do you foresee any specific concerns or benefits as a result of any of the proposed name changes?

Mylan New Zealand's main concern relates to the proposed name change for Adrenaline to Epinephrine (and Noradrenaline to Norepinephrine). We believe that there is a safety risk in renaming these ingredients as there is the possibility of epinephrine being confused with ephedrine.

An example of this occurring was published in Anaesthesia, Journal of the Associations of Anaesthetists of Great Britain and Ireland[1], following the European Commission's decision to require the UK to label drugs with their recommended International Non-proprietary Name. Labels reading 'epinephrine' had been ordered when the syringe labels for adrenaline ran out. Twice in one day, anaesthetists who used ephedrine for treating hypotension labelled their syringes 'epinephrine'. The error occurred despite anaesthetists being informed of the new nomenclature.

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It is uncertain whether dual labelling would be sufficient to avoid confusion of these ingredients, especially due to lack of space on some labels (see comments to Question 2). We would prefer that TGA followed Medsafe's practise with the two ingredients adrenaline and noradrenaline, and kept the BAN designation.

Some ingredient names are used in a wider sense on labels to alert consumers who may have allergies to particular ingredients e.g. "This product is lactose free", or "This product is sugar free". We would still want to be able to use these generic names and not the longer form of the name i.e. lactose monohydrate.

Question 2:
What do you think about the proposal to include both the current approved name and the proposed new name (dual labelling) for substances of high clinical significance?

Mylan New Zealand agrees with the proposal but highlights the space restrictions on some containers e.g. small vials. It would be problematic to include both "Noradrenaline acid tartrate" and "Norepinephrine acid tartrate monohydrate" on the same label due to limited space on the primary container.

Another example, as sponsor of EPIPEN® auto-injector and EPIPEN® JR auto-injector, both the 'Adrenaline' and 'Epinephrine' names are required to be listed on the container. This could be problematic as there is only limited space available on the primary and secondary containers.

Would there be an exemption in the event of space constraints on the label?

Question 3:
Is the proposed time period for using dual labelling appropriate?

The timeline proposed for dual labelling is appropriate with the concerns over specific ingredients highlighted earlier. Mylan NZ strongly supports the initiative to make these changes at the same time as the changes following the Packaging and Labelling review and to coincide with the ANZTPA project.

Question 4:
Do you agree that harmonising the names of ingredients with international practice will be beneficial?

Yes, we agree.

Question 5:
Will having international naming consistency assist in clinical practice?

Yes, we agree.

Question 6:
Do you agree that harmonising the names of ingredients with international practice will be beneficial?

Yes, with the exceptions of adrenaline and noradrenaline, as discussed earlier.

Question 7:
Specifically will the name changes make preparing labels and other documents for the Australian market easier in terms of international consistency?

Yes

Question 8:
Do you agree that the proposed transitional period is sufficient to ensure associated costs such as printing new labels could be met through business as usual activities?

We do not believe that the proposed transitional period is sufficient. We would suggest a minimum of three years and that the time frame for the label update is not be related to the next print run.

The transitional time would also need to coincide with other reviews to save on cost and time requirements.

Question 9:
Do you believe anything is missing from this document? If so, please specify.

It is unclear in the document if there is an allowance made for "stock-in-trade" to allow sell through and not require a recall of product from the market. Clarity on this point would be welcomed.

Question 10:
Do you agree that the updated document is more user-friendly?

Yes.

Question 11:
Will this update to the guidance assist you in proposing new ingredient names?

Yes, as supporting international journals and pharmacopoeial references will usually list the INN name.

Question 12:
Are there any general concerns with updates to the structure of TGA approved terminology for medicines?

No.

In summary, Mylan New Zealand supports the TGA initiatives for harmonisation of TGA ingredient names and hope the TGA will consider some of the points raised above in response to this consultation document prior to its finalisation.

Thank you for this opportunity to comment.

We look forward to the outcome of this consultation.

Yours sincerely
Mylan New Zealand Ltd

[redacted]

Reference:
1. James, Hugh R, Leicester Royal Infirmary, Leicester LE1 5WW, United Kingdom "Ephedrine/Epinephrine drug label confusion", Anaesthesia, 1998, Vol 53, Issue 5. http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2044.1998.04771.x/pdf
Accessed 10/07/2013