Re: grateful for some assistance with answers [SEC=UNCLASSIFIED]

Peter Bird to: John Skerritt 03/09/2013 03:18 PM
Cc: Lisa Studdert

History: This message has been forwarded.

Hi John,
Here are some answers to the questions you passed on for the ASMI conference. I ran these past Sarah Reader as an ANZTPA check and she is comfortable with them.

In NZ they have a mutual recognition agreement with the UK, which streamlines the application process in NZ if the product is already registered in the UK. Will we adopt a similar model with ANZTPA with 'like countries' (eg: UK, Canada, etc.)?

- The TGA and Medsafe will explore whether an abbreviated review process for OTC medicines approved for marketing in other jurisdictions is feasible under ANZTPA and, if so, what is an appropriate model. It is too early to provide any feedback.

TGA's Business Process Review (BPR)
What have been the key improvements with the Business Process Review?

- The new process started on 15 April 2013, so it has been in operation for around 6 months and it is a bit early to have enough data to have an effective evaluation.
- Still, early signs are that the requirements for acceptable submissions are much clearer. This, combined with a more rigorous pre-evaluation screening process, has meant that applications received so far are moving through the process much more swiftly and reliably than previously - with all applications meeting the target times.
- The OTC section started putting in practice some of the features of the new process late last year, such as separating applications according to the new types of classifications and applying a more rigorous pre-evaluation screening process. This resulted in a significant reduction in the number of old applications on hand.
- There were more than 500 applications in process at the beginning of 2012. There are now less than 40 applications remaining from all those submitted before 15 April this year.

Why has the TGA not mandated fixed timeframes for OTC product applications like they have with the prescription medicines market? Won't this drive more predictability and accountability?

- Before commencing the reforms, the TGA posted target times based on what it was reasonably confident of achieving in the short term. As the new processes bed in and the operational effectiveness is assessed, it is hoped that these target times can be reduced. By the time ANZTPA commences, the aim is to have achieved the 'aspirational' target times set out in the consultation paper about the OTC BPR.
- Had the TGA decided to adopt 'fixed' or 'statutory' times, it would have had to include sufficient margin of safety to be reasonably sure that these could be met 100% of the

time.

- The view adopted and discussed with the industry working group was that industry would benefit more from target times and a policy of continuous improvement, than it would from fixed timeframes.

BPR refers to a 'guidance document for umbrella branding decisions'. Who is developing this guideline and what evidence is it based on? Where will the 'onus of proof' lie – with the TGA or the applicant?

Who is developing this guideline

- Work on the guidance document for umbrella branding decisions will be carried out by the OTC sections from both TGA and Medsafe in consultation with the OTC industry working group. This work has been waiting for the initial outcomes of the Labelling & Packaging Review.

What evidence is it based on

- Current TGA and Medsafe guidelines, together with those from relevant overseas jurisdictions, such as the UK and Canada, will form a basis to go forward on. Working with the OTC industry working group will provide opportunities to explore whether there is other appropriate evidence.

Some general thoughts

- The decision maker has to have regard as to whether the presentation of the goods is acceptable and will use the test of whether the goods are capable of being confusing. Furthermore, the decision maker has to have regard as to whether the safety of the goods have been satisfactorily established and, in this case, any confusion about ingredients could lead to serious health outcomes.
- It seems that there will always be a tension between the use of brand extensions and the possibility of confusion. Appropriate and effective differentiation is the key.
- At times, individual sponsors will test how far they can go with a particular brand and this causes difficulties when guidelines are not sufficiently prescriptive and tends to lead to differences of view about adequacy of evidence and subjectivity.

Where will the 'onus of proof' lie – with the TGA or the applicant?

- It is not a question of where the 'onus of proof' will lie, it is a matter of meeting the requirements of the legislation in that the safety of the goods have been satisfactorily established and the presentation is acceptable. It is for the applicant to provide the evidence and for the Regulator to assess that evidence.
- There will always be comments about subjectivity and adequacy of data and this is why it is important that the guideline provides sufficient clarity for both the industry and the regulator. This is also why the TGA seeks independent advice from its committees.

Thanks,
Pete

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John Skerritt Peter For my sins I'm speaking at a Q&A S... 20/08/2013 06:34:38 PM

From: John Skerritt/TGA/Health
To: peter.bird@tga.gov.au,
Cc: Lisa Studdert/TGA/Health@TTRA
Date: 20/08/2013 06:34 PM
Subject: grateful for some assistance with answers [SEC=UNCLASSIFIED]

Peter

For my sins I'm speaking at a Q&A Session at the ASMI annual conference - getting grilled for 35 minutes in total with a list of about 30 questions.

Im keen to get some advice on the following, please:

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PETER B - JS - GRATEFUL FOR ADVICE - THIS MUST RELATE TO AN OTC MRA?

f) **TGA's Business Process Review (BPR)**

- What have been the key improvements with the Business Process Review?
- Why has the TGA not mandated fixed timeframes for OTC product applications like they have with the prescription medicines market? Won't this drive more predictability and accountability?
- BPR refers to a 'guidance document for umbrella branding decisions'. Who is developing this guideline and what evidence is it based on? Where will the 'onus of proof' lie – with the TGA or the applicant?

thanks

John

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