From: [redacted]
To: [redacted] RMP Coordinator
Cc: [redacted]
Subject: RE: PM-2017-03103-1-5 [DLM=For-Official-Use-Only]
Date: Wednesday, 2 May 2018 2:44:22 PM

Hi [redacted]
Thanks for looping us in on this. I'm not convinced that requiring a full RMP will be necessary as I'm not sure there would be a requirement for any additional risk minimisation. Has one been requested yet?
In these circumstances we would seek the most pragmatic way to address the concern(s) – in the past this has taken the form of a 'single issue RMP' – which is basically a discussion of the risk of interest and strategies to mitigate it (in this case presumably its potential for medication error due to confusion?). For the current circumstance, if the issue can be addressed through labelling, and potentially a DHCP letter at launch to highlight the difference between capsule dose and dose delivered, then RMP involvement beyond informal advice may not be necessary.
Happy to discuss further if needed.
[redacted]

From: [redacted]
Sent: Wednesday, 2 May 2018 2:27 PM
To: [redacted] RMP Coordinator
Cc: [redacted]
Subject: PM-2017-03103-1-5 [DLM=For-Official-Use-Only]
Hi [redacted]
This is a generic application that will need an RMP.
It is a generic version of a dry powder inhaler. We are only up to milestone 4. It looks to be bioequivalent so far.
The issue is with the labelling. The TGO91 says that dry powder inhalers are doses with the capsule dose of drug. The problem is, the innovator has 18mcg tio and new generic 13mcg tio. But both deliver 10mcg and the systemic BE looks to be the same.
Thus – if we label according to the TGO it will be confusing.
I have spoken with the legal team and had a number of discussions with the chemistry team.
It may be we have an interim solution= ask the new generic to label as dose delivered
Then perhaps do condition of the sponsor of innovator to do also dose delivered (consistent with international labelling)
And in long term look at changing the therapeutic goods orders.
All still needs consideration and negotiation- but good to have you on board early.
Do you want any links for documents or will you be OK?

[redacted]
Prescription Medicines Authorisation Branch

[redacted]

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requirements