From: [redacted]
To: [redacted]
Cc: Regulatory Impact Analysis
Subject: Up scheduling of Medicines [SEC=UNCLASSIFIED]
Date: Wednesday, 14 October 2015 2:30:29 PM

Good afternoon,

The OBPR has contacted the RIA team regarding the up scheduling of some Codeine medicines. They are very concerned about the TGA's intentions when it comes to best practice for up scheduling and wanted to know about the timing of a possible RIS. The matter has been brought to their attention by a concerned stakeholder.

I have advised them that the Delegate contacted me a number of weeks ago and the TGA has drafted a preliminary assessment but we did not want to seek a decision on whether a RIS was required until after the Delegate had made his decision and possible viable options had been agreed if a decision to up schedule was made. I also advised them that a RIS may not be required, as it hadn't been required when we recently proposed Advisory Label changes to NSAIDs (the numbers of affected stakeholders were more in comparison to codeine and the OBPR was considered change to be minor).

I have indicated to the OBPR that the TGA will provide a preliminary assessment early next week and that if required we will have a RIS completed before the Delegates final decision in November to ensure the Department is compliant. I advised that if a RIS is required we were not proposing to put the RIS out as a consultation document (as there has already been a number of opportunities for stakeholders to make submissions) and that we would work with the OBPR to produce a RIS for the two pass final assessment process only.

Given the tight timeframes, if a RIS is required, the TGA may want to consider using a consultant to produce the RIS and the associated quantifications for the options.

Kind regards, [redacted]

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