



**RE: Up and coming ASMI conference [SEC=UNCLASSIFIED]**

Filomena Maiese to: John.Skerritt@tga.gov.au

Cc: "andrea.sadow@tga.gov.au", Deon Schoombie, Claire Johnston

04/11/2013 03:17 PM

Many thanks John (and Andrea)!

The structure of your regulatory plenary session is as follows:

1:05 – 1:35 pm (30 minutes)	<p><b><i>Plenary 4: Designing a Regulatory Framework for the 21<sup>st</sup> Century Consumer</i></b></p> <p><b><i>PRESENTATION: Reform Status Update – Pf John Skerritt</i></b></p> <p>Objective: John will overview the current regulatory reform projects (listed below), their current status and next steps:</p> <ol style="list-style-type: none"><li>1. ANZTPA</li><li>2. TGA's Business Process Review (BPR)</li><li>3. Labeling &amp; Packaging</li><li>4. Advertising Reforms</li><li>5. Complementary Medicines Reform</li><li>6. Scheduling Reforms</li></ol>
1:35 pm	<p><b>Virginia to thank Pf John Skerritt.</b></p> <p>Pf Skerritt to remain on stage and move to sofa area on stage left.</p> <p>Virginia to introduce Deon to stage. Deon to join Pf Skerritt on opposite sofa.</p>
1:35 – 1:50 pm (15 minutes)	<p><b><i>Q&amp;A SESSION – Pf John Skerritt &amp; Dr Deon Schoombie</i></b></p> <p>Q&amp;A facilitated by Virginia Trioli with Pf John Skerritt, National Manager of Therapeutic Goods Administration (TGA) &amp; Dr Deon Schoombie (ASMI).</p> <p>Objective: John &amp; Deon to cover questions in the following areas as per speaker brief:</p> <ol style="list-style-type: none"><li>1. ANZTPA</li><li>2. TGA's Business Process Review (BPR)</li><li>3. Labeling &amp; Packaging</li><li>4. Advertising Reforms</li></ol>

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|  | <p>5. Complementary Medicines Reform<br/>     6. Scheduling Reforms<br/> <b>Virginia to ask listed questions and facilitate question time from audience (including questions from conference App)</b></p> |
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| <p>1:50 – 1:55 pm<br/>     (5 minutes)</p> | <p><b>Virginia to summarise presentation and Q&amp;A</b><br/> <b>Virginia to thank Pf John Skerritt &amp; Dr Deon Schoombie (depart from stage)</b><br/> <b>Move to next plenary speaker</b></p> |
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In just reviewing the attached slide deck you sent through, it covers ANZTPA and labelling reforms in quite a lot of detail, but doesn't directly touch on BPR, advertising, complementary medicine and scheduling reforms, which also impact our industry. Is it possible to just provide a quick 'status' update and next steps on these reforms also in your presentation?

The balancing act will be covering these topics and still managing the presentation time limit of ~30 minutes!

FYI, The complementary medicines panel which you will also be participating in has not changed since the last time we spoke.

We have a teleconference scheduled to finalised details planned for this Thursday at 10am. Thought I would send the above in advance of the call.

Best Regards,

Filomena

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**From:** John.Skerritt@tga.gov.au [mailto:John.Skerritt@tga.gov.au]  
**Sent:** Friday, 1 November 2013 12:10 PM  
**To:** Filomena Maiese  
**Cc:** andrea.sadow@tga.gov.au; Deon Schoombie  
**Subject:** RE: Up and coming ASMI conference [SEC=UNCLASSIFIED]

Filomena

here is the presentation in standards screen - courtesy of Andrea

John

**Prof John Skerritt FTSE FIPAA (Vic)**  
**National Manager**  
**Therapeutic Goods Administration**

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Date: 31/10/2013 03:17 PM  
Subject: RE: Up and coming ASMI conference [SEC=UNCLASSIFIED]

Hi John,

That is great. Thanks for the flexibility!

The screen is a standard format, not wide screen. So the slides would need to be formatted accordingly so we don't lose the sides/edges.

Regards,

Filomena

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**Subject:** Re: Up and coming ASMI conference [SEC=UNCLASSIFIED]

Filomena

OK, happy to go with the different approach.

I have updated the talk - taking a couple of slides out and adding one on the advertising consultation etc.

Have attached my proposed talk, Just one question - its in a widescreen format and this sometimes causes us projection problems - should I have the talk edited to a standard format ?

John

**Prof John Skerritt FTSE FIPAA (Vic)**  
**National Manager**  
**Therapeutic Goods Administration**

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Date: 31/10/2013 01:17 PM  
Subject: Up and coming ASMI conference

Dear John,

Congratulations on a great session at the NZSMI conference last week! I think the marriage analogy is a very befitting one to describe the journey of the ANZTPA project thus far.

Deon and I were chatting after you presented and wanted to suggest an alteration to your plenary session based on this at our up and coming ASMI conference in 2 weeks.

If you are comfortable with this idea, the thought was to have you reproduce the same presentation as that talked through at the NZSMI conference for 1/2hr, and then both Deon and yourself be available for a 'Q&A session' with our MC Virginia Trioli for a further 1/2hr following this (1 hour in total). The thought was to have you both in armchairs on stage (similar to NZSMI stage set up) answering questions from the MC and audience.

I just wanted to check you are comfortable with this suggested alteration before we proceed.

Would love your thoughts!

Kind Regards,

Filomena

**Filomena Maiese**

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