



Re: Gift declaration of 2 August [SEC=UNCLASSIFIED]

Robert Prestridge to: Tara Condon

Cc: Bill Turner

28/09/2011 04:39 PM

History: This message has been forwarded.

Hi Tara,

I am very happy for you to organise the return of the medallions. I am sure that your research with input from Cheng and DFAT would put you in a much better position to return it tactfully.

I do thank you for your efforts in seeking as much information as possible in order to ensure that any embarrassment to Shineway will be as minimal as possible. I am also grateful for the information you have provided to me so that I can avoid this from happening to me personally ever again.

I attempted to review the attachment to your email (as per your advice), but unfortunately could only decipher about 50% of Stephen Dellar's comments.

I do understand from what I could read that it would be acceptable if a regulator gave the medallions to TGA rather than a manufacturer. Unfortunately GMP auditors only interact with manufacturers.

I think it would be useful for Bill Turner to develop and distribute a document for all auditors which gives a clear understanding of this entire process. Until this situation arose, I thought there actually was a gift register with entries on it and that low value gifts (even beyond \$100) could be accepted by auditors on behalf of TGA.

Thanks again for all of your assistance in this matter, it is very much appreciated.

Kindest regards

Robert

Robert Prestridge | GMP Auditor | Office of Manufacturing Quality | Therapeutic Goods Administration
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Tara Condon

Good afternoon Robert, Further to your disc...

28/09/2011 03:30:04 PM

From: Tara Condon/TGA/Health
To: Robert Prestridge/TGA/Health@TTRA
Date: 28/09/2011 03:30 PM
Subject: Re: Gift declaration of 2 August [SEC=UNCLASSIFIED]

Good afternoon Robert,

Further to your discussions with Emma I have undertaken the following steps to ensure we take the most appropriate approach regarding the return of our gift.

1. Sought Stephen's recommendation, following consideration of your concerns (please find his comments in the attachment)
2. Spoke with Dr Cheng Bai (who previously worked in the international relations area) for advice. He suggested that *you* may wish to prepare and sign the letter that will accompany the gift instead of using the attached letter? This is because Shineway may feel that our signing the letter is impersonal (as they haven't met us) and may also interpret this to mean you are 'in trouble' and we are taking over the return of the gift.
3. Spoke with a contact within the Cultural Diplomacy' branch in DFAT for advice on their protocols. They mentioned that due to the nature of their work, they would only accept gifts from international governments and believed that if gifts of high value were provided by *stakeholders*, there may be

some level of digression required (hence Stephen's comments).

Considering this advice, would you like to return the gift yourself? If you would, may I also please ask you if you are happy for the attached letter to be sent or alternatively wish to provide your own?

Given your suggestion to contact your liaison officer within the company, considering the advice outlined above, do you wish to contact them prior to returning the gift? or prior to OPSS returning the gift?

Many thanks Robert.
Tara.

[attachment "Stephen's comments.pdf" deleted by Robert Prestridge/TGA/Health]

[attachment "Letter to Shineway Pharmaceuticals.docx" deleted by Robert Prestridge/TGA/Health]

Tara Condon

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----- Forwarded by Tara Condon/TGA/Health on 28/09/2011 03:28 PM -----

From: Emma Wood/TGA/Health
To: Robert Prestridge/TGA/Health@TTRA
Cc: Tara Condon/TGA/Health@TTRA, Bill Turner/TGA/Health@TTRA, Pio Cesarin/TGA/Health@TTRA
Date: 12/09/2011 02:26 PM
Subject: Re: Gift declaration of 2 August [SEC=UNCLASSIFIED]

Hi Robert,

Further to our discussion this morning, we will pass on to Stephen Dellar your concerns regarding the sensitivities around returning the gift, including your suggestion that you make contact with the liaison officer who provided support to you in the audit of Shineway prior to the gift being returned. This may be a way of ensuring the messages are delivered in the appropriate manner to the appropriate person.

We will make contact again with you again, prior to returning the coins.

Kind regards,
Emma

Emma Wood

A/Director
Parliamentary and External Relations
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Therapeutic Goods Administration

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Robert Prestridge Hi Tara, I have been thinking about the retur...

12/09/2011 10:20:25 AM

From: Robert Prestridge/TGA/Health
To: Tara Condon/TGA/Health@TTRA
Cc: Bill Turner/TGA/Health@TTRA, Emma Wood/TGA/Health@TTRA, Pio Cesarin/TGA/Health@TTRA
Date: 12/09/2011 10:20 AM
Subject: Re: Gift declaration of 2 August [SEC=UNCLASSIFIED]

Hi Tara,

I have been thinking about the return of the gift to Shineway over the weekend, and given the amount of embarrassment it will cause the company, I was just seeking your assistance in finding out what TGA's rationale was for the decision to return it.


I do understand that TGA only includes gifts on the register with a value exceeding \$100 but there appears to be a very limited value ceiling after which gifts are returned to the giver.

I would estimate that the medallions would be worth around \$200-\$250 (based on their silver content), which to me does not appear excessive given that gifts are only considered for inclusion once they exceed \$100.

Further, the company was requested to pay approximately \$50 000 for my 4 day visit to the company, making the gift about 0.4% of the price paid by the company to TGA for the audit.

Could you please advise what the upper limit is for gifts included on the register so that I am aware of this in the future. This will enable me to have a quite word with key company representatives in private and give me an opportunity to receive information on the way in which I would be able to return the gift to the company. This information could then be provided to you and the company would be aware that the gift would be coming back to them via their preferred channel.

As you are no doubt aware, TGA auditors spend a great deal of time explaining to company's that they are unable to receive any gifts, but from time to time these types of things are presented by high status company officials at the conclusion of the audit closure and it is impossible to reject such a presented gift in front of the mass of employees attending the closing meeting.

If the final TGA decision is to return the gift, could I please ask that it is done in an extremely culturally sensitive way in order to ensure there is no embarrassment to 

Thank you for your assistance in providing the requested information.

Kind regards

Robert
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Tara Condon

Good afternoon Robert, Thank you for your...

09/09/2011 04:00:47 PM

From: Tara Condon/TGA/Health
To: Robert Prestridge/TGA/Health@TTRA
Cc: Bill Turner/TGA/Health@TTRA, Emma Wood/TGA/Health@TTRA, Pio Cesarin/TGA/Health@TTRA
Date: 09/09/2011 04:00 PM
Subject: Gift declaration of 2 August [SEC=UNCLASSIFIED]

Good afternoon Robert,

Thank you for your gift declaration of 2 August 2011 - (5 x 1oz silver (99.9%) medallions with a Chinese scene /image enamelled onto it presented in a wooden box).

On a monthly basis, OPSS assesses each gift and makes a recommendation to the Principal Adviser (Operations) regarding its inclusion in the TGA Gift Register.

In making this assessment, we take into account TGA's policy on the acceptance of gifts and benefits, the requirement to include gifts of more than \$100 in value in the register and we consider the cultural sensitivities involved where staff have received gifts so as not to cause offence. In this instance, the advice given to us by the Principal Adviser was to return the coins and their original packaging.

We are more than happy to send the gift back on your behalf with an appropriately worded letter to accompany.

We would be very grateful if you could provide us with the following information which we will use in the letter that will accompany the gift:

Contact person (of which the gift will be addressed to)
Company name and address
Date of audit

Please don't hesitate to contact OPSS if you would like to discuss further.

Kind regards,

Tara Condon
Office of Parliamentary & Strategic Support
Therapeutic Goods Administration

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