



Australian Government
Department of Health

DEPUTY SECRETARY

15 March 2017

Ms Jeanette Radcliffe
Secretary
Senate Standing Committee on Community Affairs
Parliament House
CANBERRA ACT 2600

Dear Ms Radcliffe

**Correction of evidence to 2016 – 17 Additional Estimates Hearing,
1 March 2017**

I am writing to correct two statements that I made to the Committee during its examination of the Department of Health in the 2016 – 17 Additional Estimates hearing on 1 March 2017 (Hansard pages 10, 133, 134, 135 and 138).

In answering a question from Senator Singh, I said (page 10):

"It has taken some consumers up to 18 months because their doctor has not provided the required information. For example, they may have written on a form 'cancer' or they may have written on a form 'medicinal cannabis' without saying, 'This particular medicinal cannabis at this dose,' which is what is required under our act and regulations."

It has been brought to my notice that the response should have been (change is underlined):

"It has taken some consumers up to 18 months because their doctor has not provided the required information. For example, they may have written on the form 'cancer' or they may have written on the form 'medicinal cannabis' without saying, 'This particular medicinal cannabis product at this dose,' which is what is required under our act and regulations."

In answering a question from Senator Singh, I said (page 10):

"If I may answer, the majority of applications are under special access scheme. Special access scheme can be a suitable doctor in any state or territory. They obviously have to get the approval from the state and territory and from us. As I said, before—"

It has been brought to my notice that the response should have been (change is underlined):

If I may answer, the majority of applications are under special access scheme. Special access scheme approvals can be for a suitable doctor in any state or territory. They obviously have to get the approval from the state and territory and from us. As I said, before—

In answering a question from Senator Kakoschke-Moore, I said (page 133):

“Thank you for your question. Doctors have prescribed, and Special Access Scheme Category B approval has been given for, medicinal cannabis in every state of Australia. There have been no complete approved requests in the ACT and Northern Territory, but in every other state and territory, including Tasmania—”

It has been brought to my notice that the response should have been (change is underlined):

“Thank you for your question. Doctors have prescribed, and Special Access Scheme Category B approval has been given for, medicinal cannabis in every state of Australia. There have been no complete and approved requests in the ACT and Northern Territory, but in every other state and territory, including Tasmania—”

In answering a question from Senator Kakoschke-Moore, I said (page 133):

“It is possible for a doctor to request it in every part of Australia, including the territories. We react to requests. For example, I think there are only one or two from Tasmania who have done it, because that is how many requests we have had. We have granted every completely filled out application. We have not rejected one. Completely filled out applications have been answered. Some have been withdrawn when we asked questions like, 'Tell us more about the condition or what the product is,' but, when complete, applications have been granted.”

It has been brought to my notice that the response should have been (change is underlined):

“It is possible for a doctor to request it in every part of Australia, including the territories. We react to requests. For example, I think there are only one or two from Tasmania who have done it, because that is how many requests we have had. We have granted every completely filled out application. We have not rejected one. Completely filled out applications have been granted. Some have been withdrawn when we asked questions like, 'Tell us more about the condition or what the product is,' but, when complete, applications have been granted.”

In answering a question from Senator Kakoschke-Moore, I said (page 133):

“As a consequence of federation, doctors have to apply to the state or territory that they are in. The requirements differ by state and territory, and that is something the Commonwealth cannot control, much as we would sometimes like to. They also have to apply to the Therapeutic Goods Administration. That is in the case of individual patients who have the Special Access Scheme. An Authorised Prescriber can apply for a whole group of patients, even 100 or more. That is a much more streamlined scheme. I should read a correction in: I think I said this morning we had 23 Authorised Prescribers, and I think we are now up to 24. We would very much like more doctors to use that pathway, because it then enables that clinician to provide the medicine to a wider group of patients under their care without having to request on a patient-by-patient basis.”

It has been brought to my notice that the response should have been (change is underlined):

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In answering a question from Senator Kakoschke-Moore, I said (page 133):

“We are working closely with a lot of the clinical colleges, and also some patient groups, to improve education and information about the knowledge base on medicinal cannabis. It is fair to say that the knowledge base is mixed compared with a lot of other medicines, and that is because research has not been possible for many years in countries like the US, because of federal bans. But we have also commissioned a major piece of work from three universities in Australia to look at the evidence base, both here in Australia and overseas. For example, two weeks ago in Sydney we had a meeting of almost 50 people—largely clinicians, patient groups and state and territory reps—looking at the evidence and talking about the next steps that are to be carried out to make sure the knowledge base is broader.”

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In answering a question from Senator Kakoschke-Moore, I said (page 134):

“We are playing a coordination role, but it is always important for the Commonwealth, in any Commonwealth-state thing, not to be Big Brother. It is better for us to bring the states and territories together to allow them to reach a view that it is important to iron out wrinkles in a system. I understand that a number of state ministers are going to talk about this at the next COAG ministerial council.”

It has been brought to my notice that the response should have been (change is underlined):

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In answering a question from Senator Di Natale, I said (page 134):

"I would have to check the list of specialties. I know they are not only paediatric neurologists, but that is the overwhelming bulk of them."

It has been brought to my notice that the response should have been (change is underlined):

"I would have to check the list of specialties. I know there are not only paediatric neurologists, but that is the overwhelming bulk of them."

In answering a question from Senator Di Natale, I said (page 134):

"Coming down to two to three for complete applications."

It has been brought to my notice that the response should have been (change is underlined):

"Coming down to two to three days for complete applications."

In answering a question from Senator Di Natale, I said (page 134):

"The time lines that the states take are obviously set to the time lines. I should correct you by also saying that some states require the prescriber to be a specialist physician; others do not have that stipulation."

It has been brought to my notice that the response should have been (change is underlined):

"The time lines that the states take are obviously set by the states. I should correct you by also saying that some states require the prescriber to be a specialist physician; others do not have that stipulation."

In answering a question from Senator Di Natale, I said (page 135):

"They have been harder to access because of medicine scheduling in any of the states."

It has been brought to my notice that the response should have been (change is underlined):

"They have been harder to access because of medicine scheduling in some of the states."

In answering a question from Senator Di Natale, I said (page 135):

"The decision by government when the medicinal cannabis framework was introduced was that it would be treated like a medicine and new medicine in the context that little was known about its effects; little was known about its adverse effects. It was to be available at a high quality and with a degree of clinical oversight. There was a unanimous view from the states and territories and their health departments, who were consulted in this process, and more broadly, that it was appropriate to have a degree of clinical oversight over and above one individual prescriber, whether they be a specialist or a GP. For that reason, category A is not available."

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and territories and their health departments, who were consulted in this process, and more broadly, that it was appropriate to have a degree of clinical oversight over and above one individual prescriber, whether they be a specialist or a GP. For that reason, category A is not available.

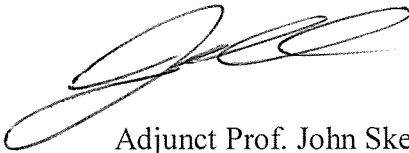
In answering a question from Senator Singh, I said (page 138):

“We were informed originally of this in October. It is good to hear that there may be more supply available. I reiterate my earlier comment that there is only so much vaccine globally, and it does not meet global demand. The medicine plants that are producing this vaccine are working 24/7 rosters, according to Andrew Witty, the CEO of GSK—.”

The response should be clarified to give a proper record of the timeline of notifications made to TGA (change is underlined):

“We were informed originally of this in October and that supply would become available in January 2017. We were then informed on 24 January 2017 that supply could not be guaranteed until July 2017. It is good to hear that there may be more supply available. I reiterate my earlier comment that there is only so much vaccine globally, and it does not meet global demand. The medicine plants that are producing this vaccine are working 24/7 rosters, according to Andrew Witty, the CEO of GSK—.”

Yours sincerely



Adjunct Prof. John Skerritt
Deputy Secretary
Health Products Regulation Group